PURSUANT TO A.R.S. SECTION 38-431.01, THE GILA COUNTY BOARD OF SUPERVISORS WILL HOLD AN OPEN MEETING IN THE SUPERVISORS' AUDITORIUM, 1400 EAST ASH STREET, GLOBE, ARIZONA. ONE OR MORE BOARD MEMBERS MAY PARTICIPATE IN THE MEETING BY TELEPHONE CONFERENCE CALL OR BY INTERACTIVE TELEVISION VIDEO (ITV). **ANY MEMBER OF THE PUBLIC IS WELCOME TO ATTEND THE MEETING VIA ITV WHICH IS HELD AT 610 E. HIGHWAY 260, BOARD OF SUPERVISORS' CONFERENCE ROOM, PAYSON, ARIZONA.** THE AGENDA IS AS FOLLOWS:

GILA COUNTY BOARD OF SUPERVISORS
REGULAR MEETING - TUESDAY, OCTOBER 21, 2014 - 10:00 A.M.

1. **CALL TO ORDER - PLEDGE OF ALLEGIANCE - INVOCATION**

2. **PRESENTATIONS:**

   A. Public recognition of three employees for September's "Spotlight on Employees" Program, as follows: Rachel Abou Saleh, Deborah Bradway and Carol Branch. **(Erica Raymond)**

3. **REGULAR AGENDA ITEMS:**

   A. Information/Discussion/Action to approve Funding Agreement No. 103-15 between Gila County and the Arizona Department of Housing for Community Development Block Grant funds in the amount of $112,009 for the period of October 21, 2014, to November 15, 2015. **(Malissa Buzan)**

   B. Information/Discussion/Action to adopt the 2013 Food Code as recommended by the U.S. Public Health Service Food & Drug Administration (FDA) with an additional amendment that addresses the use of latex-free gloves, and discontinue using the FDA 1999 Food Code. **(Lauren Savaglio)**

   C. Information/Discussion/Action to approve Intergovernmental Agreement No. 062014 between Gila County and the City of Globe to establish services and fees provided by Gila County to the City of Globe for animal control services commencing on October 21, 2014, for a one-year term, with automatic renewals at the end of each term, at a cost of $40,000 per year, and either party may terminate the Agreement by giving the other party thirty days' prior written notice. **(Jeff Hessenius)**

   D. **(Motion to adjourn as the Board of Supervisors and convene as the Gila County Library District Board of Directors.)**
   Information/Discussion/Action to approve Library Service Agreements between the Gila County Library District and the following three libraries to cooperate in the provision of library services to the citizens of the District for the period July 1, 2014, through June 30, 2015: Globe Public Library - $107,920; San Carlos Public Library - $31,920; and Young Public Library - $52,820. **(Jacque Griffin) (Motion to adjourn as the Library District Board of Directors and reconvene as the Board of Supervisors.)**

E. **(Motion to adjourn as the Gila County Board of Supervisors and convene as the Gila County Board of Equalization.)** Information/Discussion/Action to approve the September 30, 2014, Board of Equalization's meeting minutes. **(Motion to adjourn as the Gila County Board of Equalization and reconvene as the Gila County Board of Supervisors.)**

4. **CONSENT AGENDA ACTION ITEMS: (Any matter on the Consent Agenda will be removed from the Consent Agenda and discussed and voted upon as a regular agenda item upon the request of any member of the Board of Supervisors.)**

A. Approval of Amendment No. 2 to Professional Services Contract No. 062813-Medical Examiner Services between Gila County and Mark A. Fischione, M.D., PLC to increase the contract amount from $70,000 to $100,000 to cover the remainder of the original contract term which expires on January 6, 2015.

B. Approval of Amendment No. 2 to a Lease Agreement between Arizona Public Service Company and Gila County to extend the term of the lease for an additional four years, from April 27, 2014, to April 26, 2018, in the amount of one dollar per month; and replace all parking lot asphalt on leased property by July 1, 2015, and seal coat parking lot by July 1, 2016.

C. Approval of Intergovernmental Agreement No. 061014-1 between Gila County and the Town of Hayden whereby upon request from the Town of Hayden, the County will provide various types of equipment and/or services on occasion and when available for safety needs and/or efforts by the Town of Hayden beginning July 1, 2014, through June 30, 2015.

D. Approval of the corrected Amendment No. 1 to Request for Qualified Vendor Agreement No. DDD 710000 between the Arizona Department of Economic Security, Division of Developmental Disabilities (DDD), and the Gila County Board of Supervisors d/b/a Gila County Employment and Special Training Department to allow for the continued provision of DDD services to eligible residents of Gila County, and remain in compliance with federal and state regulations and provisions of the Qualified Vendor Agreement.

E. Approval of an Intergovernmental Agreement renewal between Gila County and the City of Coolidge, whereby the City of Coolidge Library will continue to be a designated "Access Point" under the Workforce Investment Act for the period of July 1, 2014, through June 30, 2015.

F. Approval of Amendment No. 1 to an Intergovernmental Agreement (Contract No. ADHS14-063025) with the Arizona Department of Health Services in the amount of $47,968 to provide work force development infrastructure to the Health and Emergency Services Division to prepare for national accreditation for the period of October 1, 2014, through September 30, 2015.

G. Approval of a Grant Renewal Amendment to an Intergovernmental Agreement (Contract No. GRA-RC004-13-0556-01-Y3) between Gila County and First Things First to receive the 2015 Grant Award in the amount of $190,000, which allows the Gila County Health Department to continue to provide Healthy Steps Program services for the period of July 1, 2014, through June 30, 2015.

H. Approval of a fee-waiver request submitted by the Cobre Valley Regional Medical Center Foundation for use of the Fairgrounds Exhibit Hall from November 10, 2014, through November 15, 2014, for the November 15th Art and Wine Auction.

I. Acknowledgment of the resignation of James Hagen from the Christopher Kohl's Fire District Board of Directors and the appointment of Sharon L. Marksbury to complete Mr. Hagen's unexpired term of office which expires on December 31, 2016.

J. Acknowledgment of the resignation of Teri L. Peterson from the Round Valley/Oxbow Estates Fire District Board of Directors and the appointment of Charlene Hall to complete Ms. Peterson's unexpired term of office through December 31, 2016.

K. Adoption of an Order to cancel the November 4, 2014, governing board elections for the fire districts, water and waste water improvement districts, sanitary districts, technology school districts, provisional college districts, and school districts; and to appoint governing board members to those districts as listed on Attachments A through E of this Order.

L. Acknowledgment of the July and August 2014 monthly activity reports submitted by the Recorder's Office.

M. Approval of the September 30, 2014, Board of Supervisors' Special meeting minutes and the September 30, 2014, Work Session meeting minutes.

N. Acknowledgment of contracts under $50,000 which have been approved by the County Manager for the weeks of September 22, 2014, to September 26, 2014; and September 29, 2014, to October 3, 2014.

O. Approval of finance reports/demands/transfers for the weeks of October 14, 2014, and October 21, 2014.

5. **CALL TO THE PUBLIC:** Call to the Public is held for public benefit to allow individuals to address the Board of Supervisors on any issue within the jurisdiction of the Board of Supervisors. Board members may not discuss items that are not specifically identified on the agenda. Therefore, pursuant to Arizona Revised Statute §38-431.01(H), at the conclusion of an open call to the public, individual members of the Board of Supervisors may respond to criticism made by those who have addressed the Board, may ask staff to review a matter or may ask that a matter be put on a future agenda for further discussion and decision at a future date.

6. At any time during this meeting pursuant to A.R.S. §38-431.02(K), members of the Board of Supervisors and the County Manager may present a brief summary of current events. No action may be taken on issues presented.

IF SPECIAL ACCOMMODATIONS ARE NEEDED, PLEASE CONTACT THE RECEPTIONIST AT (928) 425-3231 AS EARLY AS POSSIBLE TO ARRANGE THE ACCOMMODATIONS. FOR TTY, PLEASE DIAL 7-1-1 TO REACH THE ARIZONA RELAY SERVICE AND ASK THE OPERATOR TO CONNECT YOU TO (928) 425-3231.

THE BOARD MAY VOTE TO HOLD AN EXECUTIVE SESSION FOR THE PURPOSE OF OBTAINING LEGAL ADVICE FROM THE BOARD'S ATTORNEY ON ANY MATTER LISTED ON THE AGENDA PURSUANT TO A.R.S. SECTION 38-431.03(A)((3)

THE ORDER OR DELETION OF ANY ITEM ON THIS AGENDA IS SUBJECT TO MODIFICATION AT THE MEETING

ARF-2782 **Presentation Agenda Item 2. A.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For: Shelley McPherson, HR and Risk Management Director

Submitted By: Erica Raymond, Human Resources Assistant, Human Resources Department

Department: Human Resources Department

Information

Request/Subject

September 2014 "Spotlight on Employees" Program

Background Information

The purpose of this program is to provide recognition to employees for the following qualities: teamwork, quality, morale building, integrity, customer service and initiative.

Evaluation

n/a

Conclusion

n/a

Recommendation

To allow the Human Resources Department to publicly recognize three employees for September 2014 through the County's Spotlight on Employees Program.

Suggested Motion

Public recognition of three employees for September's "Spotlight on Employees" Program, as follows: Rachel Abou Saleh, Deborah Bradway and Carol Branch. **(Erica Raymond)**

ARF-2802 **Regular Agenda Item 3. A.**

Regular BOS Meeting

Meeting Date:	10/21/2014		
Submitted For:	Malissa Buzan, Director	Submitted By:	Christine Lopez, Administrative Clerk Specialist, Community Services Division
Department:	Community Services Division	Division:	Comm. Action Program/Housing Servs.
Fiscal Year:	FY 2014	Budgeted?:	Yes
Contract Dates Begin & End:	10/21/2014 - 08/03/2015	Grant?:	Yes
Matching Requirement?:	No	Fund?:	Renewal

Information

Request/Subject

Funding Agreement No. 103-15 for Community Development Block Grant (CDBG) Regional Account Funds with Designation of Deposit of Grant Funds and Authorized Signature Card Documents.

Background Information

Arizona Department of Housing (ADOH) receives approximately $13 million in CDBG entitlement funds annually from the U.S. Department of Housing and Urban Development (HUD) to fund eligible programs and projects in communities located in the 13 rural counties in the state.

Funding is accessed through a process that is described in the Five-Year Consolidated Plan and annual updates to the Plan, a document required by HUD to describe such processes. The rural Councils of Government (COGs) partner with ADOH to assist communities with project administration and technical assistance.

CDBG funds may be utilized to address a wide variety of community needs, some of which include various affordable housing projects, including home reconstruction, rehabilitation and repair programs.

The Gila County Board of Supervisors authorized the submission of the CDBG Application for funding on July 16, 2013.

Funding Agreement No. 103-15 will provide $112,009 in CDBG funds for the period of October 21, 2014, through November 15, 2015. A Designation of Deposit of Grant Funds and Authorized Signature Card for Requests for Payment on CDBG Account and Authorized Signature Card For All Administrative Actions Pertaining to CDBG Funding Agreements are required to be completed and submitted with this funding agreement.

Evaluation

Funding Agreement No. 103-15 between Gila County and the Arizona Department of Housing for $112,009 of CDBG funds will allow owner-occupied housing rehabilitation for two eligible homeowners in Gila County. This funding agreement will be for the period of October 21, 2014, through November 15, 2015. The Designation of Deposit of Grant Funds (F-1), Authorized Signature Card For Request for Payment on CDBG Account (F-2), and Authorized Signature Card for All Administrative Actions Pertaining to CDBG Funding Agreements forms will allow for payments to be mailed to Gila County, and allow employees to perform payment requests and/or other actions in relation to this Funding Agreement.

Conclusion

Funding Agreement No. 103-15 will provide $112,009 in CDBG owner-occupied housing rehabilitation funding to Gila County, which will be used to rehabilitate two homes. The Designation of Deposit of Grant Funds (F-1), Authorized Signature Card For Request for Payment on CDBG Account (F-2), and Authorized Signature Card for All Administrative Actions Pertaining to CDBG Funding Agreements forms will allow for payments to be mailed to Gila County, and allow employees to perform payment requests and/or other actions in relation to this Funding Agreement.

Recommendation

The Community Services Division Director recommends that the Board of Supervisors approve Funding Agreement No. 103-15 and the supporting documents (F-1, F-2 and the Authorized Signature Card For All Administrative Actions Pertaining to CDBG Funding Agreements).

Suggested Motion

Information/Discussion/Action to approve Funding Agreement No. 103-15 between Gila County and the Arizona Department of Housing for Community Development Block Grant funds in the amount of $112,009 for the period of October 21, 2014, to November 15, 2015. **(Malissa Buzan)**

Attachments

Funding Agreement No. 103-15

F-1, F-2 Forms

CDBG 2013 Application

Legal Explanation

FUNDING AGREEMENT
with
ARIZONA DEPARTMENT OF HOUSING

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FUNDING AGREEMENT
with
ARIZONA DEPARTMENT OF HOUSING

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ATTACHMENTS

AGREEMENT NO. 103-15
TERMINATION DATE November 15, 2015

FUNDING AGREEMENT
BETWEEN THE ARIZONA DEPARTMENT OF HOUSING
AND
GILA COUNTY
FOR
OWNER OCCUPIED HOUSING REHABILITATION

This Funding Agreement is made by and between:

The **Arizona Department of Housing ("ADOH"),** located at, 1110 West Washington, Suite 310, Phoenix, Arizona 85007, acting pursuant to A.R.S. § 41-3953 and (please select applicable funding source):

☒ Title I of the Housing and Community Development Act of 1974, as amended ("CDBG")

☐ Title II of the National Affordable Housing Act of 1990, as amended (HOME Investments Partnerships Act) ("HOME")

☐ A.R.S. § 41-3955 (State Housing Trust Fund) ("HTF")

☐ Title 24 Part 574 and 42 U.S.C. Section 12902 of the AIDS Housing Opportunity Act of (Housing Opportunities for Persons With HIV/AIDS) ("HOPWA")

☐ Title IV Part 587 of the McKinney-Vento Homeless Assistance Act 42 USC. 11301 et seq. and the Continuum of Care Program regulations as amended by the Homeless Emergency Assistance and Rapid Transition to Housing (HEARTH) Act of 2009.

and

GILA COUNTY
(Entity)

An Arizona County **("Recipient"**) DUNS #02407139, located at

5515 South Apache Ave.
Street
Globe, AZ 85501-4430
City State Zip

In consideration of the mutual representations and obligations hereunder, ADOH and Recipient agree as follows:

Section 1. FUNDS PROVIDED

ADOH agrees to provide $112,009.00 in the following type of funds to Recipient in accordance with this Agreement.

☒ **CDBG**, CFDA # 14.228
Federal Fiscal Year 2013
$112,009.00

☐ **HOME**, CFDA # 14.239
Federal Fiscal Year _____
$_____

☐ **HTF**
State Fiscal Year _____
$_____

☐ **HOPWA**, CFDA # 14.241
Federal Fiscal Year _____
$_____

☐ **COC**, CFDA # 14.267
Federal Fiscal Year _____
$_____

Section 2. OTHER FUNDS

If applicable, Recipient agrees to secure funding other than that listed in **Section 1** for the completion of this Agreement as indicated in the ***Budget*** attached hereto as **Attachment C**. ADOH reserves the right to rescind some or all of the funding committed through this Agreement if other funding sources become unavailable.

Section 3. ACCEPTANCE OF FUNDS

Recipient hereby accepts the award of funds under the terms of this Agreement and agrees to execute and return this Agreement to ADOH within 30 days of receipt unless Recipient receives a written waiver of this requirement by ADOH.

Section 4. DURATION

This Agreement shall be effective beginning on the date of execution by ADOH and shall remain in effect until 11/15/2015 unless sooner terminated, extended or otherwise amended in accordance with the terms of this Agreement.

Section 5. INCORPORATION OF TERMS FOR COMPLIANCE WITH PROGRAM REQUIREMENTS AND APPLICABLE STATE AND FEDERAL LAW

Recipient shall carry out each activity in compliance with all applicable State and Federal laws, Federal regulations and other requirements including, but not limited to the provisions indicated as marked below and hereby incorporated into this Agreement, as if fully set forth herein. Also incorporated into this Agreement as applicable, are the terms of any resolution authorizing Recipient's application for funds, which is attached hereto as **Attachment G,** ***Authorizing Resolution(s)*** and any ***Special Conditions of the Agreement*** attached hereto as **Attachment E.**

☒ **CDBG** funds require adherence to the following additional provisions: (1) the provisions of 24 CFR, Part 570 as revised; (2) ***Certification and Other Requirements Relating to Title I Assistance*** attached hereto as **Attachment F**; (3) the provisions contained in the ***State of Arizona Consolidated Plan***; (4) ***ADOH ERR Handbook***; (5) ***ADOH Labor Standards Handbook*** (6) ***CDBG Application Handbook***; (7) ***CDBG Grant Administration Handbook;*** and (8) ***CDBG Procurement, Contracts and Acquisition Handbook*** (collectively "the Incorporated Documents") as each may be amended from time to time. In the event of a conflict between the terms of this Agreement and the terms of the Incorporated Documents, the terms of this Agreement shall govern.

☐ **HOME** funds require adherence to the following additional provisions: (1) the provisions contained in 24 CFR Part 92 Home Investment Partnerships Program as revised, (2) ***Certification and Other Requirements Relating to Title II Assistance*** attached hereto as **Attachment F;** (3) the provisions contained in the ***State of Arizona Consolidated Plan***; (4) ***ADOH ERR Handbook***; (5) ***ADOH Labor Standards Handboo***k (6) the ***State Housing Fund Program Summary and Application Guide*** and any revisions thereto.

☐ **The use of Housing Trust Funds (HTF)** requires adherence to the following additional provisions: (1) the ***State Housing Fund Program Summary and Application Guide*** as revised.

☐ **Special Needs Housing "homeless" funding from COC requires** adherence to 24 CFR Part 587 as revised.

☐ **Special Needs Housing "homeless" funding from HOPWA requires** adherence to 24 CFR Part 574 as revised.

Section 6. SCOPE OF WORK

Recipient agrees to utilize all funds made available under this Agreement only for the purpose of implementing the ***Scope of Work*** hereby incorporated into this Agreement and described in **Attachment A.**

Revisions to Scope of Work. Recipient agrees to follow the procedures indicated as marked below regarding changes to the ***Scope of Work***.

Revisions to the ***Scope of Work*** that change the manner in which an activity is to be executed or that change final outcome such as number of units, feet of utility line, number of households served, square footage of building, etc. require written approval from ADOH. The following substantial revisions to the ***Scope of Work*** require written amendment to this Agreement:

(a) The purpose of the project changes;
(b) The location of the project changes;
(c) A project activity is added, deleted or altered such that it becomes a different activity;
(d) The beneficiary of any activity changes;
(e) Recipient is requesting a change to the loan or grant terms. Recipient must submit a written request for an Agreement amendment to ADOH, with a revised ***Scope of Work*** attached;
(f) The ownership entity changes; and
(g) Any other changes that involve program requirements.

ADOH will respond to the written request within 14 business days. Amendments may not be implemented until ADOH consents in writing and an amendment to the Agreement has been executed.

Section 7. REPORTS

Recipient shall be responsible for providing various reports of all activities related to this Agreement both as identified below and as requested by ADOH or HUD. Recipient shall also provide to ADOH any additional written information requested by ADOH in a timely manner and within reasonable deadlines as shall be set by ADOH.

7.1 Performance Report. Recipient agrees to submit the ADOH *Performance Report* respective of the funding source indicated below and attached as Attachment B.

☐ **RENTAL Projects funded with HOME or HTF**. Recipient must submit a ***Bimonthly Performance Report*** attached hereto as **Attachment B.** The Bimonthly Progress Report must be submitted to ADOH on the 20th of January, March, May, July, September and November and address activities of the preceding two months, i.e., the January report covers the months of November and December.

☒ **All OTHER projects funded with HOME, HTF and CDBG**. Recipient must submit a ***Quarterly Progress Report*** attached hereto as **Attachment B.** The Quarterly Progress Report must be submitted to ADOH on the 15th of July, October, January and April and address activities of the preceding three months, i.e., the July report covers the months of April, May and June. Failure to submit timely Quarterly Progress Reports will result in suspension of payment reimbursement requests until such reports are brought current.

☐ **Special Needs Housing "homeless" funding from COC.** ADOH is required to administer the program during the contract term, which is synonymous with the HUD grant term and as set forth in **Section 4.** Recipient shall submit ***Annual Progress Report (APR)*** data from HMIS to ADOH, no later than 60 days following the contract termination date listed on Page 1 of the Agreement.

☐ **Special Needs Housing "homeless" funding HOPWA.** A Recipient of HOPWA awarded funding shall administer said program in the contract term as set forth in **Section 4** and submit one (1) ***HUD Annual Progress Report (APR) document No. 40110-C*** attached hereto as **Attachment B** no later than 60 days following the contract termination date listed on Page 1 of the Agreement.

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7.2 Contract Closeout—Completion Reports and Post-Funding Audits. Recipient's obligation to ADOH under this Agreement shall not end until all closeout requirements described in this paragraph are completed. ADOH will notify Recipient in writing that a **Completion Report** is due to ADOH within Sixty (60) days of one of the following occurrences:

(a) The funds have been expended;
(b) The Scope of Work has been completed;
(c) The contract period set forth in this Agreement has expired; or
(d) The Agreement has been otherwise terminated.

The Completion Report shall contain the information identified in the notice.

Following the receipt and approval of the Completion Report, ADOH will notify Recipient in writing that the Agreement is Administratively Closed.

After the project is administratively closed, Recipient must submit all required audits to ADOH. All audits for fiscal years in which Recipient received funds from ADOH must be received, reviewed and found to be satisfactory by ADOH. In the event that ADOH determines that any project costs described in a post funding audit are unjustified or

describe ineligible activities, Recipient will be required to refund such monies back to ADOH.

Section 8. SCHEDULE OF COMPLETION

Recipient agrees to make progress with the ***Scope of Work*** in accordance with the ***Schedule of Completion*** hereby incorporated into this Agreement and described in **Attachment B.**
Revisions to the Schedule of Completion. Recipient agrees to follow the procedures indicated as marked below regarding changes to the Schedule of Completion.

☐ **RENTAL Projects funded with HOME or HTF**. Recipient must notify ADOH of revisions to the ***Schedule of Completion*** using the ***Bimonthly Performance Report,*** attached hereto as **Attachment B.** To the extent that the changes cause the schedule timeline to be extended, Recipient must submit a written request for a contract amendment to ADOH with a revised ***Schedule of Completion*** attached. Contract amendment requests must be received by ADOH a minimum of 30 days prior to the contract expiration date. ADOH will respond to the written request within 14 business days. Amendments may not be implemented until ADOH consents in writing and an amendment to the Agreement has been executed.

☒ **All OTHER projects funded with HOME, HTF and CDBG**. Recipient must notify ADOH of revisions to the ***Schedule of Completion*** using the ***Quarterly Performance Report,*** attached hereto as **Attachment B.** To the extent that the changes cause the schedule timeline to be extended, Recipient must submit a written request for a contract amendment to ADOH with a revised ***Schedule of Completion*** attached. Contract amendment requests must be received by ADOH a minimum of 30 days prior to the contract expiration date. ADOH will respond to the written request within 14 business days. Amendments may not be implemented until ADOH consents in writing and an amendment to the Agreement has been executed.

☐ **Special Needs Housing "homeless" funding from COC.** To the extent that the changes cause the schedule timeline to be extended, Recipient must submit a written request for a contract amendment to ADOH with a revised ***Schedule of Completion and Performance Report*** attached. Contract amendment requests must be received by ADOH a minimum of 30 days prior to the contract expiration date. ADOH will respond to the written request within 14 business days. Amendments may not be implemented until ADOH consents in writing and an amendment to the Agreement has been executed.

Section 9. BUDGET

Recipient agrees to use the funds provided pursuant to this Agreement in accordance with the **Budget** that is attached as **Attachment C.** Recipient further agrees that

any project costs, unless otherwise specified, exceeding the Budget shall be the sole responsibility of Recipient.

Availability of funding under this Agreement is contingent on final review and approval of the Budget. Budgetary considerations for specific programs are described below:

☒ **CDBG Revisions to the Budget.** Recipient must obtain written approval from ADOH to move funds from one Budget Activity Line Item to another. The following substantial revisions to the **Budget** require a contract amendment:

(a) Funds are moved from one Budget Activity Line Item to another and the change in the Budget Activity Line from which it is moved or to which it is being moved exceeds 50%, unless the move is from administration to a non-administration activity, in which case only written notice without a contract amendment is required;
(b) Additional funding sources are added to the Project;
(c) Recipient is requesting a change to the grant terms.

☐ **HOME and HTF Revisions to the Budget.** Recipient must obtain prior written approval from ADOH to move funds from one Budget Activity Line Item to another. ADOH will only approve changes to the Budget for eligible costs as outlined in the State Housing Fund program. The following substantial revisions to the **Budget** require a contract amendment:

(a) Additional funding sources are added to the project which require a project to be re-underwritten to determine gap;
(b) Recipient is requesting a change to the loan terms.

See Section 10 for changes that affect the Budget.

Recipient shall not retain any funds that are drawn down in excess of immediate cash needs (to be utilized within 15 days of draw down) to cover subsequent requests for reimbursement, and must return them to ADOH within 30 days of receipt. Recipient must also return to ADOH any interest that is earned on these funds that are drawn down and not expended for eligible costs within 15 days of draw down.

Section 10. AMENDMENTS AND MODIFICATIONS

ADOH may consent to amendment or modification of this Agreement upon written request of Recipient. All amendments or modifications to this Agreement shall be by mutual consent of the parties in writing.

Requests for amendments or modifications that result in changes to the Budget must be supported by a revised Budget that is otherwise consistent with Section 9.

ADOH will respond to the request for amendment or modification to this Agreement within 14 business days.

Section 11. ENVIRONMENTAL REVIEW CONDITIONS

In accordance with 24 CFR 50 and 24 CFR 58 ("Environmental Review"), the environmental effects of each activity carried out with federal funds must be assessed. Local government entities are responsible for environmental reviews and requesting a release of funds from ADOH. Non-profits and other non-governmental entities are responsible for assisting ADOH with Environmental Review and ADOH then requests a release of funds from HUD. Completion of the Environmental Review Record ("ERR") is mandatory before taking any physical action on a site or entering into contracts. Only exempt activities such as architecture, engineering and administration may be undertaken and reimbursed by ADOH prior to receiving a written release of funds. Exempt activities described in 24 CFR 58.34(a)(1)-(11) are activities that generally have no physical impact on the environment. If federal funds are involved in a project, neither federal nor non-federal funds may be expended or committed by contract (conditional or not) for property acquisition, rehabilitation, conversion, lease, repair or construction activities, until HUD or ADOH has provided written authorization based on approval of an ERR.

An option agreement (to purchase land) on a proposed site or property is allowable prior to the completion of the Environmental Review if the option agreement is contingent upon an ADOH or HUD authorization to use funds based on a completed ERR. The cost of the option must be a nominal portion of the purchase price.

Projects funded solely with Housing Trust Funds do not require an ERR but are required to meet the requirements of the State Historic Preservation Act by consulting with the State Historic Preservation Office (SHPO). For State Housing Funded projects, Phase I Environmental Assessments are required to be completed on properties for which new construction/change in use is proposed, regardless of whether Federal or State funds are the source of funding. Expenditures incurred or obligated by construction contract prior to ADOH's release of funds or consultation with SHPO will not be reimbursed by ADOH.

Recipients who had committed or expended non-Federal funds to begin a project before receiving the authorization from ADOH or HUD may still be eligible to use federal funds on the project under the following circumstances:

(a) Recipients started the project without the intention of using Federal assistance (e.g., as evidenced by other anticipated funding, the original project budget, etc.);

(b) All work on the project ceases once an application for federal funds is made and an ERR is begun on all activities, i.e., acquisition, construction, etc. ADOH or HUD provides authorization to proceed based on the completed ERR.

Section 12. APPLICATION AND OTHER PRE-AWARD COSTS

Recipient may use a portion of the funds provided hereunder to reimburse itself for exempt activities pursuant to 24 CFR 58.34(a)(1)-(11) such as architecture, engineering, testing and sampling of asbestos and capital needs assessments and environmental reviews.

☒ **CDBG.** If Recipient is receiving funding under this Agreement from the CDBG program, in accordance with federal procedures, Recipient may use funds provided hereunder to reimburse it or to pay for costs incurred in preparing the application. In no event shall such compensation exceed 18 percent of the total funding provided to Recipient by ADOH.

Section 13. COMPENSATION AND METHOD OF PAYMENT

Subject to availability of and receipt of funds from the State's Unclaimed Property Fund (for state HTF funds) and/or the United States Treasury (for HOME, CDBG, COC and HOPWA funds) and the commitment of other required funding as indicated in Recipient's application, ADOH agrees to reimburse or advance Recipient for authorized expenditures according to the ***Budget*** in **Attachment C.** Recipient must maintain invoices and other similar documentation to support payment expenses under those generally accepted accounting principles and procedures approved by ADOH and outlined in OMB Circulars A-87, A-122, and A-133, as applicable, and 24 CFR Parts 44, 84, 85, 92 and 570 as applicable.

Recipient may request funds only after the date of the executed Agreement and other legal documents as applicable, provided Recipient has satisfied ADOH funding contingencies and federal Environmental Review conditions. Requests for reimbursement must be made using the ADOH ***Request for Payment*** form hereby incorporated into this Agreement and attached as **Attachment D**. For construction projects, Release of Lien documents must be attached to the Request for Payment in amounts proportionate to contractor reimbursement requests.

Recipient must maintain proof of said expenditures including checks, payrolls, time records, invoices, contracts, vouchers, orders and other accounting documents evidencing in proper detail the nature and propriety of the respective charges as may be required by applicable federal rules and regulations, including requirements by the Federal Office of Management and Budget, and as may be otherwise reasonably required to permit ADOH to determine or confirm that any such expenditures are prudent and within the Scope of Work.

Recipient's right to incur expenses under this Agreement shall cease upon expiration of this Agreement. All requests for reimbursement on expenditures made prior to expiration of this Agreement must be requested within 60-days after expiration. Unless expressly authorized by ADOH in writing, expenditures not requested within the 60-day period after expiration of this Agreement shall be disallowed and all funds shall be reclaimed by ADOH.

Section 14. FUNDS RECOUPED BY RECIPIENT, INTEREST AND PROGRAM INCOME

14.1 Definitions. For purposes of this section, the following definitions shall apply:

"Funds Recouped by Recipient" means funds initially provided by ADOH to Recipient under this Agreement and any matching contributions that are recouped by Recipient when: (1) the funds provided by ADOH under this Agreement or matching contributions or the proceeds of funds provided by ADOH (including, but not limited to, equipment or housing) do not continue to be used for an approved purpose or eligible activity, as described in applicable law or regulations, for the full period of affordability required by this Agreement, or (2) when a State-assisted homeownership housing does not continue to be the principal residence of the assisted homebuyer for the full affordability period required by this Agreement. Funds Recouped by Recipient are subject to all the requirements of Program Income described below with the exception that Recipient shall not use Funds Recouped by Recipient for administrative purposes. For this reason, Recipient must separately account for all Funds Recouped by Recipient.

"Interest" means any compensation paid or to be paid for the use or deposit of the funds provided by ADOH to Recipient under this Agreement.

"Program Income" means gross income received by Recipient directly generated from the use of funds provided by ADOH under this Agreement. When Program Income is generated by housing that is only partially assisted with funds provided by ADOH under this Agreement or matching contributions, the income shall be prorated to reflect the percentage of funds provided by ADOH under this Agreement. Program Income includes, but is not limited to, the following: (1) proceeds from the disposition by sale or long-term lease of real property purchased or improved with funds provided by ADOH under this Agreement; (2) gross income from the use or rental of real or personal property acquired by Recipient with funds provided by ADOH under this Agreement, less costs incidental to generation of the income; (3) payments of principal and interest on loans made using funds provided by ADOH under this Agreement or matching contributions; (4) proceeds from the sale of loans made with funds provided by ADOH under this Agreement or matching contributions; (5) proceeds from sale of obligations secured by loans made with funds provided by ADOH under this Agreement or matching contributions; (6) Interest earned on Program Income pending its disposition; (7) proceeds from the disposition of equipment purchased with CDBG funds; (8) gross income from the use or rental of real property, owned by Recipient, that was constructed or improved with funds provided by ADOH under this Agreement, less costs incidental to generation of the income; (9) if the funds provided by ADOH under this Agreement are from the CDBG Program, funds collected through special assessments made against properties owned and occupied by households not of low and moderate income, where the assessments are used to recover all or part of the CDBG portion of a public improvement; and (10) if the funds provided by ADOH under this Agreement are from the HOME Program, any other interest or return on the investment permitted under 24 C.F.R. Part 92.205(b) of HOME funds or matching contributions.

14.2 Use of Program Income and Funds Recouped by Recipient.

Recipient is not authorized by ADOH to retain and reuse Program Income, Funds Recouped by Recipient or accrued Interest as described in the following paragraph(s) except as authorized by ADOH through a written agreement.

Recipient must return all Program Income, Funds Recouped by Recipient, and Interest to ADOH within 30 days of receipt.

Recipient must remit to ADOH any Program Income, Funds Recouped by Recipient or Interest on hand at the time of expiration, cancellation, or termination of this Agreement or subsequently received by Recipient within **30 days** of receipt by Recipient.

Section 15. DE-OBLIGATION, RECAPTURE AND REPAYMENT OF FUNDS

15.1 De-obligation. ADOH may reduce funds from the funding award evidenced by this Agreement without regard to the source of funding, under the following circumstances: (1) Recipient has completed performance under the ***Scope of Work* (Attachment A)** without using all of the funds provided by ADOH under this Agreement; (2) this Agreement expires and not all funds have been expended; (3) ADOH's original allocation was a loan and Recipient or Sub-recipient paid the loan; (4) Recipient, with the consent of ADOH, cancelled or changed an activity required under the ***Scope of Work*** for reasons other than non-performance; or (5) Recipient receives Program Income that has not been included in the budget or set forth in the ***Scope of Work;*** and (6) this Agreement has otherwise been terminated. ADOH may de-obligate funds under this Agreement under the foregoing circumstances upon written notice to Recipient.

15.2 Reallocation of De-obligated HOME or State HTF Funds. If the funds provided by ADOH under this Agreement are from the State HTF or the HOME Program, ADOH may reallocate funds that it has de-obligated under this Agreement as it determines in its sole discretion.

15.3 Reallocation of De-obligated CDBG Funds. If the funds provided by ADOH under this Agreement are from the CDBG Program, ADOH may reallocate funds that it has de-obligated under this Agreement to Recipient from which the funds were de-obligated for use under an existing or new funding contract of the same funding year if Recipient can immediately commit the reallocated funds to a project and execute a new or amended funding contract within sixty (60) calendar days of the reallocation. If ADOH is not able to reallocate funds that it has de-obligated under this Agreement in accordance with the foregoing sentence of this subsection, ADOH may reallocate those funds as it determines in its sole discretion.

15.4 Recapture. ADOH may reduce funds from the amount of the funding award evidenced by this Agreement, without regard to the source of funding, under the following circumstances: (1) ADOH determines that Recipient has failed to use the funds provided by

ADOH under this Agreement in compliance with the terms of this Agreement or the requirements of applicable laws and regulations (non-compliance); or (2) Recipient fails to perform in accordance with the performance obligations set forth in the ***Scope of Work*** (**Attachment A**) and the ***Schedule of Completion*** (**Attachment B**) or the terms of this Agreement. ADOH may recapture funds under this Agreement under the foregoing circumstances upon written notice to Recipient.

15.5 Reallocation of Recaptured Funds. **ADOH** may reallocate funds that it has recaptured under this Agreement, without regard to the source of funding, as it determines in its sole discretion.

15.6 Repayment of Funds. Recipient agrees to repay funds provided under this contract if ADOH determines that Recipient has failed to use the funds provided by ADOH under this Agreement in compliance with the terms of this Agreement or the requirements of applicable laws and regulations. ADOH may specify in writing the terms of the repayment or alternative terms in lieu of repayment, however, in no case shall repayment or alternative terms be accomplished later than one hundred eighty (180) days following the written determination of non-compliance by ADOH.

Section 16. REVERSION OF ASSETS

16.1 Funds Remaining at Expiration. Upon expiration of this Agreement, Recipient shall transfer to ADOH any unexpended funds advanced to Recipient by ADOH under this Agreement.

16.2 Real Property Acquired or Improved with CDBG Funds. Upon expiration of this Agreement, any real property under Recipient's control that was acquired or improved in whole or in part with CDBG funds, for non-owner occupied use, provided to Recipient by ADOH under this Agreement (including CDBG funds provided to Recipient in the form of a loan) in excess of $25,000, shall either: (1) be used to meet one of the national objectives in 24 CFR Part 570.208 until five years after expiration of this Agreement, or for such longer period of time as determined to be appropriate by Recipient; or (2) not be used in accordance with 24 CFR Part 570.503(b)(8)(i), in which event Recipient shall pay to ADOH an amount equal to the current market value of the property less any portion of the value attributable to expenditures of non-CDBG funds for the acquisition of, or improvement to, the property. No payment is required after the period of time specified in 24 CFR Part 570.503 (b)(8)(i).

16.3 Real Property Acquired or Improved with HOME Funds. Upon expiration of this Agreement, any real property under Recipient's control that was acquired or improved in whole or in part with HOME funds, for non-owner occupied uses, provided to Recipient by ADOH under this Agreement (including funds provided to Recipient in the form of a loan), must be occupied only by households that are eligible as low-income families and must meet the requirements to qualify as affordable housing and is subject to encumbrances and obligations described in any applicable Declaration of Conditions,

Covenants, and Restrictions ("CC&Rs") for the period of affordability set forth in 24 CFR Part 92.252.

16.4 Real Property Acquired or Improved With State Housing Trust Funds. Upon expiration of this Agreement, any real property under Recipient's control that was acquired or improved in whole or in part with state HTF funds, for non-owner occupied uses, provided to Recipient by ADOH under this Agreement (including funds provided to Recipient in the form of a loan), must be occupied only by households that are eligible as low-income families and must meet the requirements to qualify as affordable housing and is subject to encumbrances and obligations described in any applicable Declaration of CC&Rs for the period of affordability set forth in the CC&Rs.

Section 17. DEPARTMENT OF HOUSING RESPONSIBILITIES

ADOH shall monitor and evaluate Recipient to determine compliance with and performance under this Agreement. A summary of discrepancies noted by ADOH during monitoring visits will be specified in writing. Appropriate time for correction of discrepancies will be specified in the written report to Recipient. ADOH shall follow up on discrepancies to ensure that they have been corrected in a timely manner. The failure of ADOH to require timely performance of any provision of this Agreement shall in no way affect the right of ADOH thereafter to enforce such provision nor shall the waiver of any succeeding breach of such provision act as waiver of the provision itself.

ADOH shall provide reasonable technical assistance to assist Recipient to comply with program requirements for the provision of services under this Agreement. However, this in no way relieves Recipient of full responsibility for its acts or omissions in the performance of activities required by this Agreement.

Section 18. SUBCONTRACTING

Recipient shall not disburse any funds received under this Agreement without fully completed written agreements with subcontractors requiring they follow all provisions of this Agreement and a completed Environmental Review pursuant to **Section 11** of this Agreement.

The use of subcontractors does not relieve Recipient of responsibility for ensuring the administration of the provided funds in accordance with all applicable program requirements. Recipient is responsible for determining the adequacy of performance under subcontractor agreements and procurement contracts and for taking appropriate action when performance issues arise.

Section 19. FAILURE TO MAKE PROGRESS

Failure of Recipient to make progress according to the **Schedule of Completion**, attached hereto as **Attachment B** may result in contract termination, de-obligation of funds or recapture of funds. Recipient agrees to meet with ADOH at the site in which the funded activity is taking place to discuss progress and allow ADOH to provide technical assistance if:

(a) Recipient fails to begin work on its Environmental Review pursuant to **Section 11** within the sixty (60) calendar days from the date ADOH executes this Agreement;

(b) Recipient fails to expend any funds in performance of and in accordance with the terms of this Agreement within ninety (90) calendar days from the inception date of this Agreement.

ADOH will terminate any Agreement and recapture funds from the same Agreement in which Recipient does not commence any of the activities described in the ***Scope of Work*** (**Attachment A**) or fails to expend any funds in accordance with the ***Budget*** **(Attachment C)** within one hundred eighty (180) calendar days from the full execution date of this Agreement. ADOH may in its sole discretion, forgo providing technical assistance and recapture funds as outlined in this Agreement under **Section 15.4** hereof and/or terminate this Agreement for cause pursuant to **Section 20** of this Agreement.

Section 20. TERMINATION FOR CAUSE

ADOH may terminate this Agreement in whole or in part at any time whenever it determines that Recipient has failed to comply with the conditions hereof including, but not limited to the **Scope of Work** set forth in **Attachment A**, **Schedule of Completion** set forth in **Attachment B** and **Budget** set forth in **Attachment C** to this Agreement. If ADOH so determines, it shall notify Recipient in writing by certified mail, return receipt requested, of such termination for cause with such notification to include the reason(s) for the termination and the effective date of termination. If ADOH terminates this Agreement pursuant to this Section, ADOH shall recapture all funds allocated to Recipient under this Agreement pursuant to **Section 15.4** hereof and obtain repayment of funds expended pursuant to **Section 15.6,** hereof.

Section 21. TERMINATION FOR CONVENIENCE

ADOH or Recipient may terminate this Agreement in whole or part (one or more activities) if either party believes that continuation will not produce beneficial results. If ADOH so determines, it shall notify Recipient in writing by certified mail, return receipt requested, of such termination for convenience and the effective date of termination. If Recipient so determines, it shall notify ADOH in writing by certified mail, return receipt requested, of such termination for convenience and the effective date of termination. If ADOH terminates this Agreement pursuant to this Section, ADOH shall de-obligate, recapture or receive repayment, as applicable, all funds allocated to Recipient under this Agreement pursuant to **Section 15** hereof.

Section 22. ENFORCEMENT

22.1 Remedies for Noncompliance. If Recipient materially fails to comply with any term of this Agreement or applicable law, ADOH may take one or more of the following actions, as appropriate in the circumstances:

(a) Temporarily withhold cash payments pending correction of the deficiency by Recipient or more severe enforcement action by the awarding agency;

(b) Disallow (that is, deny both use of funds and matching credit for) all or part of the cost of the activity or action not in compliance;

(c) Wholly or partly suspend or terminate the award evidenced by this Agreement;

(d) Withhold further awards to Recipient's project funded by the award evidenced by this Agreement;

(e) Recapture funds and terminate contract;

(f) Withhold future ADOH grant awards from all sources; or

(g) Take other remedies that may be legally available.

22.2 Appealable Agency Action. Enforcement action taken under this section is an appealable agency action pursuant to A.R.S., Title 41, Chapter 6, Article 10.

22.3 Effects of suspension and termination. Costs incurred by Recipient resulting from obligations incurred by Recipient during a suspension or after termination of an award are not allowable unless ADOH expressly authorizes them in the notice of suspension or termination or subsequently.

22.4 Relationship to debarment and suspension. The enforcement remedies identified in this section, including suspension and termination, do not preclude Recipient from being subject to "Debarment and Suspension" under the United States President's Executive Order 12549.

Section 23. CANCELLATION

Pursuant to A.R.S. § 38-511, ADOH may, within three years after its execution, cancel this Agreement, without penalty or further obligation, if any person significantly involved in initiating, negotiating, securing, drafting or creating this Agreement on behalf of ADOH, at any time while this Agreement or any extension of this Agreement is in effect, is or becomes an employee or agent of any other party to this Agreement in any capacity or a consultant to any party of this Agreement with respect to the subject matter of the contract. A cancellation notice made pursuant to this provision shall be effective when Recipient receives written notice of the cancellation unless the notice specifies a later time.

Section 24. RECORDS RETENTION

Pursuant to A.R.S. § 35-214, Recipient shall retain and require that its subcontractors retain for inspection and audit by ADOH, all books, accounts, reports, files, including information regarding actual beneficiaries of the fund, and other records relating to the bidding and performance of this Agreement for a period of five (5) years following the date of the letter informing Recipient of the Administrative Closeout or termination.

Upon request by ADOH, Recipient shall produce a legible copy of all such records at the Administrative Office of ADOH or at the Office of the Auditor General. The original records shall be available and produced for inspection and audit when required by ADOH or the Auditor General.

Recipient shall maintain records that adequately identify the source and application of the funds provided under this Agreement (including Program Income and Recaptured Funds) as part of the financial transactions of their funding program, consistent with generally accepted accounting principles and the requirements of 24 CFR Part 85.20. Recipient will provide reports regarding the capture and reuse of Program Income and Recaptured Funds as requested by ADOH from time to time.

In addition, in the event that the project resulted in Recipient holding any liens or notes as a result of this funding, Recipient must retain all pertinent records for five (5) years beyond the expiration or release of such liens or notes.

Section 25. NO OBLIGATION OF STATE GENERAL APPROPRIATIONS FUNDS

Nothing herein shall be construed as obligating state general appropriation funds, excepting HTF funds, for payment of any debt or liability of any nature arising hereunder. The parties expressly recognize that all payments to be made by ADOH are from federal funds and HTF funds made available to ADOH for this purpose.

Section 26. AVAILABILITY OF FUNDS

Payments under this Agreement are subject to the availability of the federal funds provided to the ADOH for the HOME and CDBG programs and the availability of state funds provided for the state HTF Program. Every payment obligation of ADOH under this Agreement is conditioned upon the availability of funds appropriated or allocated for the payment of such obligation. If funds are not allocated and available for the continuance of this Agreement, this Agreement may be terminated by ADOH at the end of the period for which funds are available. No liability shall accrue to ADOH in the event this provision is exercised, and ADOH shall not be obligated or liable for any future payments or for any damages as a result of termination under this paragraph.

Section 27. APPLICABLE LAW AND ARBITRATION

This Agreement shall be governed and interpreted by the laws of the State of Arizona. The parties to this Agreement agree to resolve all disputes arising out of or relating to this Agreement through arbitration, after exhausting applicable administrative review, to the extent required by A.R.S. § 12-1518 except as may be required by other applicable statutes.

Section 28. INDEMNIFICATION

Recipient shall indemnify, defend, and save harmless ADOH, the State of Arizona and its agents, officials, and employees from any and all claims, demands, suits, actions, proceedings, loss, costs, and damages of every kind and description, including any attorney's fees and litigation expenses, which may be brought or made against or incurred by the State on account of loss of or damage to any property or for injuries to or death of any person, caused by, arising out of or contributed to, in whole or in part, by reason of any alleged act, omission, professional error, fault, mistake, or negligence of Recipient, its employees, agents, representatives, or subcontractors, their employees, agents, or representatives in connection with or incidental to the performance of this Agreement, or arising out of Workmen's Compensation claims, Unemployment Compensation claims, or Unemployment Disability Compensation claims of employees of Recipient or its subcontractors or claims under similar such laws or obligations. Recipient's obligation under this section shall not extend to any liability caused by the sole negligence of ADOH, the State of Arizona, or its employees.

Section 29. FEDERAL GOVERNMENT LIABILITY

It is agreed by all parties that the Federal Government and particularly the U.S. Department of Housing and Urban Development ("HUD") is not a party to this Agreement, and that no legal liability on the part of the Federal Government is inferred or implied under the terms of this Agreement.

Section 30. AUDIT

If federal funds are paid to Recipient through this Agreement, Recipient shall comply with the audit requirements set forth in 24 CFR Part 84. Recipient shall comply with A.R.S. § 35-181.03 if any state funds are paid through this Agreement. Recipient agrees to rectify issues identified in audits within ADOH prescribed time periods. Failure to comply shall result in withholding of all present and future ADOH provided funds.

Section 31. AUDIT EXCEPTIONS

If federal or state audit exceptions are made relating to this Agreement, Recipient shall reimburse all costs incurred by the State of Arizona and ADOH associated with defending against the audit exception or performing an audit or follow-up audit including but not limited to: audit fees, court costs, attorney's fees based upon a reasonable hourly

amount for attorneys in the community, travel costs, penalty assessments, and all other costs of whatever nature.

Immediately upon notification from ADOH, Recipient shall reimburse the amount of the audit exception and any other related costs directly to ADOH as specified by ADOH in the notification.

Section 32. UNALLOWABLE USE OF FUNDS

Recipient, its officers, employees and agents, shall not utilize any of the federal funds or HTF provided under this Agreement to solicit or influence, or attempt to solicit or influence, directly or indirectly, any member of Congress regarding pending or prospective legislation.

Section 33. INTEREST OF MEMBERS OF DEPARTMENT OF HOUSING AND OTHERS

No officer or employee of ADOH and no public official, employee or member of the governing body of Recipient who exercises any functions or responsibilities in review or approval of the undertaking or carrying out of this Agreement shall participate in any decision relating to this Agreement which affects their personal interest or the interest of any corporation, partnership, or association in which they are directly or indirectly interested, or have any interest, direct or indirect, in this Agreement or its proceeds.

Section 34. ACCESS TO RECORDS, PARTICIPANTS AND STAFF

Recipient agrees to provide ADOH and its representatives access at any reasonable time to all participants and staff involved in this Agreement and to all records and reports involving this Agreement.

Section 35. IDENTIFICATION OF DOCUMENTS

All materials used for public outreach and for informational purposes as a part of this Agreement, other than documents exclusively for internal use by ADOH, shall identify the source of federal (CDBG, HOME, COC, HOPWA) or state (HTF) funds used as part of this Agreement as well as acknowledgement of support from ADOH.

Section 36. COPYRIGHT

Reports, maps or other documents produced in whole or in part under this Agreement are works for hire and shall not be the subject of any application for copyright by or on behalf of Recipient, by any employee or subcontractor of Recipient. Recipient shall advise ADOH or its designee at the time of delivery of any copyrighted or copyrightable work furnished under this Agreement, or any adversely held copyrighted or copyrightable material incorporated in any such work and of any invasion of the right of privacy therein contained.

Section 37. RIGHTS IN DATA

ADOH may duplicate, use and disclose in any manner and for any purpose whatsoever, within the limits established by federal and state laws and regulations, all information relating to this Agreement.

Section 38. FUNDING CONDITIONS

ADOH will make the funding assistance available to Recipient upon execution of this Agreement by the parties. The obligation and utilization of the funding assistance provided through this Agreement are subject to the proper observation of the requirements incorporated by reference. Recipient shall require any subcontracting entities to observe and follow all provisions of this Agreement.

Section 39. NON-DISCRIMINATION

(a) Recipient shall comply with A.R.S. § 41-1463 and Executive Orders 99-4 and 2009-09, which prohibit Recipient from discriminating against persons, or depriving or tending to deprive any individual of employment opportunities or otherwise adversely affecting the individual's status as an employee on the basis of race, color, religion, sex, age, national origin, disability or political affiliation and require Recipient to take action to ensure that applicants are employed and that employees are treated during employment without regard to race, color, religion, sex, age, national origin, disability, or political affiliation. Recipient shall comply with all of the other requirements of Executive Order 2009-09.

(b) Recipient agrees to comply with Title VII of the Civil Rights Act of 1964, as amended. Recipient shall also comply with applicable federal regulations that prohibit discrimination in the employment or advancement in employment of qualified persons because of physical or mental handicap. Recipient shall comply with all applicable federal regulations regarding equal employment opportunity and relevant orders issued by the U.S. Secretary of Labor. Recipient agrees to comply, and will require any subcontractor(s) to comply with applicable federal nondiscrimination requirements, which may include: Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. §3789(d)); the Victims of Crime Act (42 U.S.C. §10604(e)); the Juvenile Justice and Delinquency Prevention Act of 2002 (42 U.S.C. §5672(b)); the Civil Rights Act of 1964 (42 U.S.C. §2000(d)); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. §794); Title II of the Americans with Disabilities Act of 1990 (42 U.S.C. §§12132); Title IX of the Education Amendments of 1972 (20 U.S.C. §1681); the Age Discrimination Act of 1975 (42 U.S.C. §6102); 28 C.F.R. pt. 35 (DOJ Regulations- Nondiscrimination on the Basis of Disability in State and Local Government Services); 28 C.F.R. pt. 42 (DOJ Regulations- Nondiscrimination; Equal Employment Opportunity;

Policies and Procedures); Executive Order 13279 (equal protection of the laws for faith-based and community organizations); and 28 C.F.R. pt. 38 (DOJ Regulations- Equal Treatment for Faith-Based Organizations).

Section 40. THIRD PARTY ANTITRUST VIOLATIONS

Recipient assigns to the State of Arizona any claim for overcharges resulting from antitrust violations to the extent that such violations concern materials or services supplied by third parties to Recipient toward fulfillment of this Agreement.

Section 41. COMPLIANCE REQUIREMENTS FOR A.R.S. § 41-4401—IMMIGRATION LAWS AND E-VERIFY REQUIREMENT

(a) Recipient warrants compliance with all Federal immigration laws and regulations relating to employees and warrants its compliance with Section A.R.S. § 23-214, Subsection A. (That subsection reads: "After December 31, 2007, every employer, after hiring an employee, shall verify the employment eligibility of the employee through the E-Verify program.)

(b) A breach of a warranty regarding compliance with immigration laws and regulations shall be deemed a material breach of the contract and Recipient may be subject to penalties up to and including termination of this Agreement.

(c) The ADOH retains the legal right to inspect the papers of any employee who works on this Agreement to ensure that Recipient or Recipient's subcontractor is complying with the warranty under paragraph (a).

Section 42. INSURANCE

During the contract period, Recipient shall purchase and maintain in full force the following insurance. All certifications of insurance must provide for a thirty (30) day notice to ADOH of cancellation, non-renewal, or material change. Proof of insurance from Recipient shall be provided to ADOH prior to execution of this contract and periodic certifications must be furnished at the request of the Program Specialist.
Recipient and its Subcontractors, at Recipient's and Subcontractors' own expense, shall purchase and maintain the herein stipulated minimum insurance with companies duly licensed, possessing a current A.M. Best, Inc. Rating of A-, 7, local government insurance pools formed pursuant to ARS 11-952.01 or other as approved by ADOH, and licensed in the State of Arizona with policies and forms satisfactory to ADOH.

All insurance required herein shall be maintained in full force and effect until all work or service required to be performed under the terms of this Agreement is completed

satisfactorily and formally accepted; failure to do so may, at the sole discretion of ADOH, constitute a material breach of this Agreement.

Recipient's insurance shall be primary insurance as respects ADOH, and any insurance or self-insurance maintained by ADOH shall not contribute to it.

Recipient shall not fail to comply with the claim reporting provisions of the insurance policies or cause any breach of an insurance policy warranty, which would affect coverage afforded under insurance policies to protect ADOH.

The insurance policies, except Worker's Compensation, shall contain a waiver of transfer of rights of recovery (subrogation) against ADOH, its agents, representatives, directors, officers, and employees for any claims arising out of Recipient's acts, errors, mistakes, omissions, work or service.

The insurance policies may provide coverage, which contain deductibles or self-insured retentions. Such deductible and/or self-insured retentions shall not be applicable with respect to the coverage provided to ADOH under such policies. Recipient shall be solely responsible for the deductible and/or self-insured retention, and ADOH, at its option, may require Recipient to secure payment of such deductibles or self-insured retentions by a Surety Bond listing ADOH as the Obligee or Co-Obligee or an irrevocable and unconditional letter of credit.

ADOH reserves the right to request and to receive, within 10 working days, certified copies of any or all of the herein required insurance policies and/or endorsements. ADOH shall not be obligated, however, to review same or to advise Recipient of any deficiencies in such policies and endorsements, and such receipt shall not relieve Recipient from, or be deemed a waiver of ADOH's right to insist on, strict fulfillment of Recipient's obligations under this Agreement.

The insurance policies, except Worker's Compensation and Professional Liability, required by this Agreement, shall name ADOH, its agents, representatives, officers, directors, officials and employees as additionally insured.

43.1 Required Coverage

Commercial General Liability. Recipient shall maintain Commercial General Liability insurance with a limit of not less than $1,000,000 for each occurrence with a $2,000,000 Products/Completed Operations Aggregate and a $2,000,000 General Aggregate Limit. The policy shall include coverage for bodily injury, broad form property damage, personal injury, products and completed operations and blanket contractual coverage. Coverage will be at least as broad as Insurance Service Office, Inc. Policy Form CG 00011093 or any replacements thereof.

Such policy shall contain a severability of interest provision and shall not contain a sunset provision or commutation clause, nor any provision that would serve to limit third party action over claims. The Commercial General Liability additional insured endorsement shall be at least as broad as the Insurance Service Office, Inc. Additional Insured, Form B, CG 20101185, and shall include coverage for Recipient's operations and products and completed operations.

Automobile Liability. Recipient shall maintain Commercial/Business Automobile Liability insurance with a combined single limit for bodily injury and property damage of not less than $1,000,000 each occurrence with respect to Recipient's any auto, all owned autos, scheduled autos, hired autos, non-owned autos assigned to or used in performance of Recipient's work. Coverage will be at least as broad as coverage code 1, "any auto", (Insurance Service Office, Inc. Policy Form CA 00011293, or any replacements thereof).

Worker's Compensation. Recipient shall carry Worker's Compensation insurance to cover obligations imposed by federal and state statutes having jurisdiction of Recipient's employees engaged in the performance of the work or services; and Employer's Liability insurance of not less than $100,000 for each accident, $100,000 disease for each employee, and $500,000 disease policy limit.

In case any work is subcontracted, Recipient will require the Subcontractor to provide Worker's Compensation and Employer's Liability to at least the same extent as required of Recipient.

43.2 Certificates of Insurance

Prior to commencing work or services under this Agreement, Recipient shall furnish ADOH with Certificates of Insurance, or formal endorsements as required by this Agreement, issued by Recipient's insurer(s), as evidence that policies providing the required coverage, conditions and limits required by this Agreement are in full force and effect.

In the event any insurance policy(s) required by this contract is (are) written on a "claims made" basis, coverage shall extend for two years past completion and acceptance of Recipient's work or services and as evidenced by annual Certificates of Insurance.
If a policy does expire during the life of this Agreement, a renewal certificate must be sent to ADOH fifteen (15) days prior to the expiration date.

43.3 Cancellation and Expiration Notice

Insurance required herein shall not expire, be canceled, or materially changed without thirty (30) days written notice to ADOH.

Section 43. PRIVACY CONSIDERATIONS

Recipients of federal funds (for the purpose of this section "federal funds" means funding from the CDBG, HOME, HOPWA, and COC programs; *see* Section 1, above) from ADOH warrant and represent that commencing from the effective date of this Agreement and until the latest expiration or termination date of any promissory note, deed of trust, declaration, or other agreement that secures the federal funds that are the subject of this Agreement, Recipient and Recipient's contractors shall comply with the requirements of the federal Privacy Act, 5 U.S.C. § 552a. Recipient warrants and represents that it has read and understands the requirements of the Federal Privacy Act and requires the same of its contractors and subcontractors.

Section 44. NOTICES

When routine reports or correspondence is required to be sent to ADOH, it shall be addressed to Arizona Department of Housing, to the attention of the assigned Program Specialist at 1110 West Washington Street, Suite 310, Phoenix, AZ 85007. Notices or correspondence regarding material changes to the contract or requests for amendment shall be addressed to the same. All correspondence regarding this Agreement must be identified by its ADOH Agreement number (which is located on the top left hand corner of the first page of this Agreement).

When notice or correspondence is required to be sent to Recipient, it shall be addressed to:

GILA COUNTY COMMUNITY SERVICES
Entity
MALISSA BUZAN
Attention (if applicable)
5515 SOUTH APACHE AVE.
Mailing Address
GLOBE, AZ 85501-4430
City State Zip

Section 45. REGISTRATION WITH SOCIAL SERVE

For new construction or rehabilitation of rental projects, Recipient agrees to register the project with socialserve.com and keep the project listed with socialserve.com for the duration of the period of affordability as indicated in the Conditions, Covenants and Restrictions.

Section 46. ADOH SIGNAGE

For new construction and rehabilitation projects, Recipient must erect a sign at the project site indicating that the project is funded through the Arizona Department of Housing and indicate the sources of funds. The sign must be a minimum size of 24 inches

high by 36 inches wide, include a minimum 5-inch high ADOH logo and text printed at a minimum 72 point font. An individual ADOH sign does not have to be provided if Recipient incorporates ADOH information into a larger group sign.

Section 47. PHOTOGRAPHS

For new construction and rehabilitation projects, Recipient is required to provide to ADOH before and after photographs of the project in digital or film format.

AGREED, effective as of the later date of the signatures of the duly authorized representatives subscribed below:

THE STATE OF ARIZONA, **ARIZONA DEPARTMENT OF HOUSING**	Gila County **RECIPIENT**
BY: _____	BY: _____
Michael Trailor	Michael Pastor
TITLE: Director	TITLE: Chairman, Gila County Board of Supervisors
DATE: _____	DATE: _____

Attachment A
SCOPE OF WORK

Gila County #103-15– Owner Occupied Housing Rehabilitation

Activity #1 - Administration **$20,161 CDBG**

To carry out all required actions to administer activities funded from the **FY 2013 CAG Regional Account for Gila County.** Actions are to include requisite record keeping, reporting, monitoring and all other actions necessary to ensure compliance with CDBG Program requirements as identified in the 24 CFR 570.500 –570.614 and current Arizona Department of Housing Handbooks.

Activity #2 – OOHR **$91,848 CDBG**

To use CDBG funds for the rehabilitation of owner occupied housing units located within Gila County limits, with the exclusion of Reservation land and units located in floodplains.

- This program will assist 2 low-to-moderate income households.
- Financial assistance will consist of forgivable non-interest bearing deferred payment loans.
- This activity will meet the Low Moderate Income Benefit National Objective (LMH) and will benefit approximately 3 people, of whom 100% are considered low and moderate income at or below 80% of the Area Median Income.

HUD Performance Measures

Objective: Decent Housing

Outcome: Accessibility for the purpose of providing decent affordable housing

Indicator(s): Number of units brought to standard condition.

Data Collection Methodology: Document the number of housing units brought to standard conditions.

Arizona Department of Housing

CDBG

ATTACHMENT B

ADOH PERFORMANCE REPORT/SCHEDULE OF COMPLETION

Recipient	Gila County	Date	
Contract No	103-15 Contract Period: from November 2014 to 11/15/2015	Revision #	
Activity	OOHR	Jan April	July October
Recipient Address	5515 S. Apache Ave., Suite #200	Project City	Globe
Contact Person	Malissa Buzan	Zip Code	85501-4430
Phone	928-425-7631 Email mbuzan@co.gila.az.us	Fax	928-425-9468
Program Specialist	LaJerald Jackson Email lajerald.jackson@azhousing.gov	Project County	Gila

Indicate adherence to contract or schedule changes. Due by the 15th of January, April, July, October

Contract Schedule	Contract Date	Complete Yes/No	Modification Date
Environmental Review Clearance	7/30/2014	Yes	
Contract Execution	11/10/2014		
Unit #1			
Intitial inspection/work write-up	2/15/2015		
Contractor procurment complete	3/15/2015		
Begin construction	4/1/2015		
Construction complete	5/15/2015		
Unit #2			
Intitial inspection/work write-up	3/15/2015		
Contractor procurment complete	4/15/2015		
Begin construction	5/1/2015		
Construction complete	7/30/2015		
Project Complete-Contract Close Out	11/15/2015		

Please provide a brief description of activities performed this three month period. Include occurrences that caused variation from schedule changes to plans, unforeseen circumstances, etc. Please be specific.

Recipient Authorized Signature Date	Title

Arizona Department of Housing

CDBG

Attachment C

Budget

Recipient	Gila County			Date	
Contract No	103-15 Contract Period: from November 2014 to 11/15/2015			Revision No.	
Activity	OOHR				
Recipient Address	5515 S. Apache Ave., Suite #200			Project City	Globe
Contact Person	Malissa Buzan			Zip Code	85501-4430
Phone	928-425-7631	Email	mbuzan@co.gila.az.us	Fax	928-425-9468
Program Specialist	LaJerald Jackson	Email	lajerald.jackson@azhousing.gov	Project County	Gila

a	c	d	e	f	g	h
Budget Line Item or Activity No.	CDBG 2013	CDBG 2013	Source Program Year	Source Program Year	Source Program Year	Source Program Year
Activity No. - Project	$20,161.00					
Activity No. #2 - Project		$91,848.00				
Total						$112,009.00

REV. 8-2013

Arizona Department of Housing

CDBG (F-3)

Attachment D

ARIZONA DEPARTMENT OF HOUSING REQUEST FOR PAYMENT SUMMARY SHEET PAGE 1 OF 2

Recipient	Gila County	Date	
Contract No	103-15 Contract Period: from November 2014 to 11/15/2015	Pay Req. No/Mo	
Activity	OOHR	Direct Wire Dep	Yes No
Recipient Address	5515 S. Apache Ave., Suite #200	Project City	Globe
Contact Person	Malissa Buzan	Zip Code	85501-4430
Phone	928-425-7631 Email mbuzan@co.gila.az.us	Fax	928-425-9468
Program Specialist	LaJerald Jackson Email lajerald.jackson@azhousing.gov	Project County	Gila

Itemized Payment Statement (Sheet 2 of 2) must accompany this form. Include copies of invoices, cashed checks, and other backup documentation. ORIGINAL SIGNATURES are required for processing.

a	b	c	d	e	f	g	h
Budget Line Item or Activity No.	IDIS Act No.	CDBG 2013	CDBG 2013	Total Amount Req. to Date	Balance in Account	Amount of this Request	New Balance
Act. 1 Administration		$20,161.00			$ 20,161.00		$ 20,161.00
Act. 2 Project Specific			$91,848.00		$ 91,848.00		$ 91,848.00
					$ -		$ -
					$ -		$ -
					$ -		$ -
					$ -		$ -
					$ -		$ -
					$ -		$ -
					$ -		$ -
					$ -		$ -
					$ -		$ -
					$ -		$ -
Total		$ 20,161.00	$ 91,848.00	$ -	$ 112,009.00	$ -	$ 112,009.00

Recipient Authorized Signature Date Title

Recipient Authorized Signatory certifies that all activities undertaken by the contractor with funds provided under this contract have been carried out in accordance with the contract. Attach wiring information if not previously submitted. Attach alternate mailing address if necessary.

Performance Reports		Current ☐	Not Current ☐	For ADOH Use Only		
ADOH Program Specialist Approval			Date		ADOH Program Administrator Approval	Date

Arizona Department of Housing

F-4

ARIZONA DEPARTMENT OF HOUSING REQUEST FOR PAYMENT -ITEMIZED PAYMENT STATEMENT PAGE 2 OF 2

Recipient	Gila County	Date	
Contract No	2013 RA	Contract Period: fromNovember 2014 to 8/3/2015	Pay Req. No/Mo

Budget Line Item or Activity No	Description of Expense (List in according to funding source)	Paid (or Payable) to	Date Paid	Check # Invoice PO	Invoice Amount Charged to CDBG	Balance paid by other source	Name of other source
Totals							

ATTACHMENT F

CERTIFICATION AND OTHER REQUIREMENTS RELATING TO TITLE I ASSISTANCE

The applicant hereby assures and certifies that:

1. It possesses legal authority to apply for Community Development Block Grant funds, and to execute the proposed program.
2. Prior to the submission of the application, the applicant's governing body has duly adopted or passed as an official act a resolution authorizing the submission of the application, including all understandings, assurances, statutes, regulations and orders contained therein, and directing and authorizing the person identified as the official representative of the applicant to act in connection with the application and to provide such additional information as may be required.
3. Its chief executive officer or other officer of the applicant approved by the State:
   a. Consents to assume the status of a responsible Federal official under the National Environmental Policy Act of 1969 (NEPA) and other provisions of Federal law, as specified at 24 CFR 58.1(a) (3) and (a)(4), which further the purposes of NEPA insofar as the provisions of such Federal law apply to this program.
   b. Is authorized and consents on behalf of the applicant and him(her)self to accept the jurisdiction of the federal and State courts for the purpose of enforcement of his/her responsibilities as such an official.
4. It will comply with the provisions of Executive Order 11990, relating to evaluation of flood hazards and Executive Order 11288 relating to the prevention, control and abatement of water pollution.
5. It will, in connection with its performance of environmental assessments under the National Environmental Policy Act of 1969, comply with Section 106 of the National Historic Preservation Act of 1966 (16 U.S.C. 470), Executive Order 11593, and the Preservation of Archeological and Historical Data Act of 1966, P.L. 93-291 (16 U.S.C. 469a-1, et.seq.).
6. It will administer and enforce the labor standard requirements of the Davis Bacon Act, as amended at 40 U.S.C. 276a-276a-5, and the Contract Work Hours and Safety Standards Act at 40 U.S.C. 327-333.
7. It will comply with the provisions of 24 CFR Part 24 relating to the employment, engagement of services, awarding of contracts or funding of any contractors or subcontractors during any period of debarment, suspension or placement in ineligibility status.
8. It shall comply with the requirements of the 1992 Lead Based Paint Poisoning Prevention Act of 42 U.S.C. 4821-4846 (also Title X of the Housing and Community Development Act of 1992) and implementing regulations at 24 CFR Part 35.
9. It will comply with the provisions of 24 CFR part 58 "Uniform Grant Administrative Requirements" and OMB Circular A-87.
10. It will comply with the American Disabilities Act and Section 504 of the Rehabilitation Act, as amended.
11. It will comply with
    a. Title VI of the Civil Rights Act of 1964 (Pub. L. 88- 352), and the regulations issued pursuant thereto (24 CFR Part 1).
    b. Title VIII of the Civil Rights Act of 1968 (Pub. L. 90- 284), as amended.

c. Section 109 of the Housing and Community Development Act of 1974.
d. Executive Order 11063 pertaining to equal opportunity in housing and nondiscrimination in the sale or rental of housing built with Federal assistance.
e. Executive Order 11246, and the regulations issued pursuant thereto (24 CFR Part 130 and 41 CFR Chapter 60).
f. Section 3 of the Housing and Urban Development Act of 1968, as amended.
g. Federal Fair Housing Act of 1988, P.L. 100-430.
h. The prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1973, 42. U.S.C. 6101-07, and the prohibitions against discrimination against persons with handicaps under Section 504 of the Rehabilitation Act of 1973, (P.L. 93-112), as amended, and the regulations at 24 CFR Part 8.
i. The requirements of the Architectural Barriers Act of 1966 at 42 U.S.C. 4151-415.

12. It will comply with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 and implementing regulations.
13. It will comply with applicable conflict of interest provisions, incorporate such in all contracts and establish safeguards to prohibit employees from using positions for a purpose that is or gives the appearance of being motivated by a desire for private gain for themselves or others, particularly those with whom they have family, business, or other ties.
14. It will comply with the provisions of the Hatch Act which limit the political activity of employees.
15. It will give representatives of the State, the Secretary of HUD, the Inspector General, and the General Accounting Office access to all books, accounts, records, reports, files and other papers, things, or property belonging to it or in use by it pertaining to the administration of State CDBG assistance.
16. It will ensure that the facilities under its ownership, lease or supervision which shall be utilized in the accomplishment of the program are not listed on the Environmental Protection Agency's (EPA) list of violating facilities and that it will notify the State of the receipt of any communication from the Director of the EPA Office of Federal Activities indicating that a facility to be used in the project is under consideration for listing by the EPA.
17. It will comply with the flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973, Pub.L. 93-234, 87 Stat., 975, approved December 31, 1973. Section 103 (a) required, on and after March 2, 1974.
18. It has AND WILL COMPLY WITH THE PROVISIONS OF THE STATE OF ARIZONA CITIZEN AND PUBLIC PARTICIPATION PLAN FOR THE STATE OF ARIZONA CDBG PROGRAM.
19. It has developed plans to minimize displacement of persons as a result of activities assisted in whole or in part with CDBG funds and to assist persons actually displaced as a result of such activities, and has provided information about such plans to the public.
20. It will not recover any capital costs of public improvements assisted in whole or in part with CDBG funds by assessing any amount against properties owned and occupied by persons of low and moderate income, including any fee charged or assessment made as a condition of obtaining access to such public improvements **unless**:
    a. the CDBG funds are used to pay the proportion of the fee or assessment that is financed from other revenue sources, or:
    b. it will certify to the State in writing that it lacks sufficient CDBG funds to comply with (a) but that it will not assess properties owned by very low income persons.

21. It will provide all other funds/resources identified in the application, or any additional funds/resources necessary to complete the project as described in the application as submitted, or as may be later amended.
22. It will comply with the requirements of the Single Audit Act of 1996 and OMB Circular A-133; and if the grant is closed out prior to all funds having been audited, it shall refund to Commerce any costs disallowed as a result of any audit conducted after the date of grant closeout.
23. It hereby adopts and will enforce a policy prohibiting the use of excessive force by law enforcement agencies within its jurisdiction against any individuals engaged in nonviolent civil rights demonstrations; and will enforce applicable State and local laws against physically barring entrance to or exit from a facility or location which is the subject of such nonviolent civil rights demonstrations within its jurisdiction.
24. It will ensure that, to the best of the knowledge and belief of the undersigned:
    a. no Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in the connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement;
    b. if any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, and officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form - LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
    c. the undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

    "This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by Section 1352, Title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure."

25. It shall comply with the provisions of Section 102 of the HUD Reform Act of 1989.
26. It shall ensure that efforts are made to recruit minority, disabled and woman owned businesses for its vendor/supplier lists.

RESOLUTION NO. 13-07-02

A RESOLUTION OF THE GILA COUNTY BOARD OF SUPERVISORS AUTHORIZING THE SUBMISSION OF AN APPLICATION FOR FY 2013-2014 STATE COMMUNITY DEVELOPMENT BLOCK GRANT (CDBG) REGIONAL ACCOUNT AND STATE SPECIAL PROJECTS FUNDS, CERTIFYING THAT SAID APPLICATION MEETS THE COMMUNITY'S PREVIOUSLY IDENTIFIED HOUSING AND COMMUNITY DEVELOPMENT NEEDS AND THE REQUIREMENTS OF THE STATE CDBG PROGRAM, AND AUTHORIZING ALL ACTIONS NECESSARY TO IMPLEMENT AND COMPLETE THE ACTIVITIES OUTLINED IN SAID APPLICATION.

WHEREAS, the Gila County Board of Supervisors is desirous of undertaking community development activities; and

WHEREAS, the State of Arizona is administering the Community Development Block Grant (CDBG) Program; and

WHEREAS, the State CDBG Program requires that CDBG funds requested address one of the three Congressional mandated National Objectives; and

WHEREAS, the activities within this application address the community's identified housing and community development needs, including the needs of low- and moderate-income persons; and

WHEREAS, an applicant of State CDBG funds is required to comply with the program guidelines and federal statutes and regulations.

THEREFORE, BE IT RESOLVED that the full body of the Gila County Board of Supervisors authorizes an application to be made to the State of Arizona, Department of Housing for FY 2013-2014 CDBG funds; authorizes its Chairman to sign the application and contract or grant documents for receipt and use of these funds for housing rehabilitation; and authorizes its Chairman to take all actions necessary to implement and complete the activities submitted in said application; and

BE IF FURTHER RESOLVED that this application for State CDBG funds meets the requirements of low- and moderate-income benefit for activities justified as benefiting low- and

moderate-income persons, aids in the prevention or elimination of slum and blight or addresses an urgent need which poses a threat to health; and that the County of Gila will comply with all State CDBG Program guidelines, federal statutes and regulations applicable to the State CDBG Program and the certifications contained in this application.

PASSED AND ADOPTED this 16th day of July 2013, at Globe, Gila County, Arizona

Attest:

Marian Sheppard
Clerk of the Board

GILA COUNTY BOARD OF SUPERVISORS

Michael A. Pastor, Chairman

Approved as to form:

Bryan Chambers
Deputy Attorney Principal

Arizona Department of Housing

Community Development Block Grant (CDBG) Program

DESIGNATION OF DEPOSIT OF GRANT FUNDS (F-1)

Funding Agreement Number(s): 103-15

(Complete the name and address of Recipient Unit of Local Government [UGLG])

UGLG: Gila County Community Services

Address: 5515 S. Apache Avenue, Suite 200

City: Globe

State: Arizona

Zip: 85501

has been designated as the recipient for all funds to be received from ADOH resulting from CDBG Funding Agreement Number(s) shown above.

Funds shall be deposited by the recipient UGLG to:

Name of Financial Institution: _____ Account Name/#: _____

A. ☐ Check this box if payment to be mailed to grantee

B. ☒ Check this box if payment to be sent electronically (direct deposit).

Note: If Box B is checked, GA0-618 Automated Clearinghouse (ACH) Vendor Authorization must be sent to ADOH.

Account number by which CDBG funds will be recorded in grantee financial records: _____

Leverage account number, if applicable: _____

I certify that CDBG funds shall be deposited as specified above; shall not be deposited in an interest bearing account (unless all requests for payment shall be on a reimbursement basis); and shall be deposited in an FDIC-insured financial institution.

Michael A. Pastor
Typed Name of Chief Elected Official

_____
Signature of Chief Elected Official

Chairman, Gila County Board of Supervisors
Title

October 21, 2014
Date

Arizona Department of Housing

Community Development Block Grant (CDBG) Program

AUTHORIZED SIGNATURE CARD FOR REQUESTS FOR PAYMENT ON CDBG ACCOUNT (F-2)

UGLG: Gila County Community Services	Funding Agreement Number(s): 103-15

SIGNATURES OF INDIVIDUALS AUTHORIZED TO REQUEST FUNDS ON THE CITED CDBG FUNDING AGREEMENTS(s).:

❶

Nicholas Montague	9/30/14
Signature	Date
Nicholas Montague	Community Services Fiscal Manager
Typed Name	Title

❷

Malissa Buzan	9/30/14
Signature	Date
Malissa Buzan	Community Services Director
Typed Name	Title

❸

Dana True	9/29/14
Signature	Date
Dana True	Community Services Accounting Clerk Senior
Typed Name	Title

❹

Signature	Date
Typed Name	Title

I certify that the signatures above are of the individuals authorized to request payments for the cited contract and that I, as the Chief Elected Official (Mayor/County Board Chairperson), have the authority to designate these individuals to take such action.

Signature of Chief Elected Official	Date
Michael A. Pastor	Chairman, Gila County Board of Supervisors
Typed Name	Title

Arizona Department of Housing

Community Development Block Grant (CDBG) Program
AUTHORIZED SIGNATURE CARD FOR ALL ADMINISTRATIVE ACTIONS PERTAINING TO CDBG FUNDING AGREEMENTS

UGLG: Gila County Community Services	FUNDING AGREEMENT NUMBER(S): 103-15

ONLY ONE SIGNATURE REQUIRED (additional recommended to ensure signatory availability)

SIGNATURE(S) OF AUTHORIZED INDIVIDUAL(S)

Typed Name Nicholas Montague Title Community Services Fiscal Manager

Signature Nicholas Montague Date 9/30/14

Typed Name Malissa Buzan Title Community Services Director

Signature Malissa Buzan Date 9/30/14

Typed Name _____ Title _____

Signature _____ Date _____

Typed Name _____ Title _____

Signature _____ Date _____

I certify that the signatures above are those of the individuals who may authorize administrative actions for the cited contract and that I, as the Chief Elected Official, have the authority to designate these individuals to take such action.

Chief Elected Official Michael A. Pastor (Typed Name) Title Chairman, Gila County Board of Supervisors

Signature _____ Date _____

Arizona Department of Housing

FORM 1

FY 13/14 COMMUNITY DEVELOPMENT BLOCK GRANT APPLICATION COVER SHEET

☒	A. Regional Account (RA) COG: CAAG	☐	B. State Special Project (SSP)
☐	C. Colonias	☐	D. NRS: Date approved: / / Approval on page:

1. Applicant and DUNS Number: Gila County 02407139	**2. Legislative/ Congressional Districts:** 1 / 5
3. Address (with 9-digit zip code): 5515 S. Apache Avenue, Suite 200, Globe, Arizona 85501-4430 **Name of County Applicant Located In:** Gila	
4. Contact Person/Title (Grantee) Malissa Buzan/Director	**5. Contact Person/Title (COG/Other):** Malissa Buzan/Director
Phone/Fax/Email: 928-425-7631/928-425-9468/mbuzan@co.gila.az.us	**Phone/Fax/Email:** 928-425-7631/928-425-9468/mbuzan@co.gila.az.us

6. Complete the following information for the activities for which you are requesting funds in a single contract (maximum of 2 including Administration). Complete an additional Form 1 for each additional activity included in the application. Item d: Fund types are (1) Leverage, (2) Program Income, or (3) Other.

a. Activity Name	b. CDBG Funds	c. Non-CDBG Funds	d. Fund Type	e. Total Funds
1. Administration	20,161.00		CDBG	20,161.00
2. OOHR	91,846.00		CDBG	91,846.00

Total CDBG Funds Requested for this Project (Activities #1 and #2): $ 112,007.00

8. List **all other** activities applied for this fiscal year. Indicate by ☒ which application includes the required general information (Certifications, Disclosure Report, etc.) and administration funds. Note that there will be a separate contract for each activity except Administration.

Activity Name	Amount (CDBG $ only)	CDBG USE ONLY - Contract No.
☐ a.		
☐ b.		
☐ c.		
☐ d.		

9. Total CDBG Funds Requested (all activities applied for this fiscal year, including administration): $

10. Certification: To the best of my knowledge and belief, data in this application are true and correct, the document has been duly authorized by the governing body of the applicant and the applicant will comply with the attached Certifications if the assistance is approved.

Signature of the Chief Elected Official →	Date: 7-16-13 Michael A. Pastor
Name (typed): Michael A. Pastor	Title: Chairman,Gila County Board of Supervisors

Arizona Department of Housing

FORM 2
COMMUNITY DEVELOPMENT BLOCK GRANT
GENERAL ADMINISTRATIN SUMMARY

1. **Applicant: Gila County**

ITEM		a. CDBG $	b. Non-CDBG $*	c. Total
2. TAAP. Total costs for COG Technical Assistance and Application Preparation, as per local government/ COG Agreement		500.00		500.00
3. Salaries, Wages, Fringe Benefits	% or Hours			
3.1 Position #1 Title:Director	5%	4,021.00		4,021.00
3.2 Position #2 Title: Admin. Assistant	5%	3187.00		3,187.00
3.3 Position #3 Title: Accountant	6%	3405.00		3,405.00
3.4 Position #4 Title: Fiscal Manager	6%	4,815.00		4,815.00
4. Professional Services (Contractual)				
4.1 For:				
4.2 For:				
4.3 For:				
5. Travel		200.00		200.00
6. Office Supplies and Equipment		430.00		430.00
7. Advertising/Publications		101.00		101.00
8. Indirect Costs (% documented by cost allocation plan)		3,202.00		3,202.00
9. Other Operating Expenses *(specify)*				
9.1 Item 1:				
9.2 Item 2:				
9.3 Item 3:				
9.4 Other (Fair Housing, Section 504, etc.)		300.00		300.00
10. **TOTALS**		20,161.00		20,161.00

* **Indicate in parentheses if the amount is Leverage (L), Program Income (PI), or Other (O). If the amount is a mixture of different types of funds, indicate the amount for each type.**

11. a. Indicate who will be in charge of the financial record keeping (give name and title):
Bree'na York, Fiscal Manager

b. Provide the street address for the location of the financial records:
5515 S. Apache Ave., Suite 200, Globe, Arizona 85501- 4430

Arizona Department of Housing

FORM 3
COMMUNITY DEVELOPMENT BLOCK GRANT
ACTIVITY BUDGET

1. Applicant: Gila County	2. Activity Name: OOHR		
	a. CDBG $	b. Non-CDBG $	c. TOTAL $
3. Environmental Review Record Check box if included in Administration ☒	$200.00		$200.00
4. Design/Engineering/Inspection (or other Professional Services related to project) Previously Procured ☐ Procure ☐ In-House ☐			
5. Construction Contract Work (include materials and DB wage rates)	$75,379.00		75,379.00
6. Fixed Asset Equipment			
7. Land Acquisition (includes easements) *(must comply with the Uniform Relocation Act)*			
8. Rehabilitation Services (if this exceeds 20% of total activity costs, attach a rationale) Procure ☐ In-House ☒	$16,267.00		$16,267.00
9. Other (specify or attached as page):			
10. For City/Town, County or Other Construction			
10.1 Purchase of materials			
10.2.a Employees (documentation attached as page regarding number of employees, wages, number of hours, etc.)			
10.2.b Offenders			
10.2.c Volunteers			
10.3 Equipment (Use vs. Purchase) (documentation attached regarding rental rates, number of hours to be used, type of equipment, etc.)			
10.4 Other (attached as page)			
11. **TOTALS**	$91,846.00		$91,846.00

Arizona Department of Housing

FORM 8

COMMUNITY DEVELOPMENT BLOCK GRANT
ACTIVITY DESCRIPTION: HOUSING ACTIVITIES

1. **Applicant: Gila County**

2. **Activity Name: Owner-Occupied Housing Rehab**

3. **Map(s) attached as page(s)** 17

Examples of eligible housing activities include: private housing rehabilitation, public housing rehabilitation and modernization, infrastructure in support of new housing, new construction by eligible sub-recipients, housing services, property acquisition or conversion.

4. Type of Housing Activity (check all which apply):

a. ☒ Single family unit, owner-occupied residential rehabilitation (Housing Rehab Guidelines required)

b. ☐ Residential rental rehabilitation, one or two units (one of which must be occupied by low and moderate income persons) (Guidelines required)

c. ☐ Residential rental rehabilitation, more than two units (51% low and moderate income persons)

d. ☐ New housing construction (only eligible if executed by a sub-recipient)
Proforma attached as page

e. ☐ Acquisition or conversion of property for housing
Proforma attached as page

f. ☐ Housing services

g. ☐ Lead-based paint hazard evaluation and reduction

h. ☐ Infrastructure related to a proposed housing project
Proforma attached as page

i. ☐ Home Ownership Assistance (Home Ownership Assistance Guidelines required)

j. ☐ NRS Area (If the activity will take place in an approved NRS area, persons do not need to be income qualified. However, the applicant must also complete Form 13 and attach to application as page .)

k. ☐ Commercial Rehabilitation

l. ☐ Other (describe):

5. **WHAT ARE YOU GOING TO DO?**

Describe the activity and what is intended to be accomplished. See instructions.
We propose to provide Owner-Occupied Housing Rehabilitation assistance to two homes. This activity will be conducted with in Gila County boundaries except reservation land. OOHR will complete 2 projects @ 40,500.00 (each participant will meet the low/mod income qualifications) in the form of a forgivable non-interest bearing deferred payment loan. The option of replacement may be performed as per our Housing Rehab Guidelines. Each participant will be selected on a first come, first served basis from Gila County's housing rehabilitation waiting list. All rehabilitation services will be done by in house staff and all construction services will be done by licensed and insured general contractors that meet the Gila County and State criteria.

6. For construction or acquisition or conversion of property, complete the following:

a. Is the site properly zoned? Yes ☐ No ☐ If no, when will the zoning issue be resolved?
n /a

b. Are all utilities presently available to the site? ☐ Yes ☐ No If no, which utilities must be brought to the site? **n/a**
Who has the responsibility for bringing utilities to the site? **n/a**

c. Provide copy of deed of ownership as page **n/a**

7. **WHY ARE YOU GOING TO DO IT?**

Describe the problems and conditions or other factors that indicate a need for the activity.
Gila County has an area fo 4,768 square miles. With a high percentage of homes built before 1939. Our housing stock is in a very poor condition, especially in the southern part of Gila County, with a high percentage of elderly population. We would like to continue to preserve our housing stock allowing our elderly and low-income population to remain in their homes as long as possible. Our economic outloook has remained dismal, with above average unemployment rates hovering around 10%, and waves of foreclosure emergencies and ressession, that the rest of the State of Arizona is experiencing, our housing stock continues to be wholly inadequate and our waiting list for OOHR runs at the 100 applicants range. That is why we propose to rehabilitate 2 owner occupied single family residences.

8. Indicate:

a. Total Number of People to be Served: 3	d. Total Number of Units: 2
b. Total Low Moderate People: 3	e. Total Low Moderate Units: 2
c. LM Percentage: 100%	f. Source of Information as page:

9. Will there be program income generated from the activity? ☐ Yes ☒ No

If yes, describe the program income source and estimated amount. If a DPL is required, this must be completed and RLF procedures developed and submitted for approval to CDBG.

10. Describe the income qualification process to be used. Include the name, title, and phone number of the persons responsible for the process and indicate the date the information was obtained.

Income will be verified during the Pre-Application Process, Estelle Belarde, Housing Assistant will review documentation of all household income during this time. Project #1 income was verified on 5/3/13, and Project #2 Income was verified on 6/19/13.

11. If applicable, it is assumed that the activity will use federal Housing Quality Standards (HQS) as the housing rehabilitation standard. If HQS or a more stringent state or local code will not be adhered to, describe the code or standard that will be used and provide a rationale for the proposed standard. This cannot be "NA." ***Please specify the specific code that will be followed in your rehab program, which at a minimum must be HQS.***

Arizona State Weatherization Standards as well as Federal Housing Quality Standards will be used for all OOHR projects in this contract.

12. **For housing acquisition, conversion, or new construction projects and programs**, indicate the entities that will act as the owner, developer, and manager, including a name, title, address and phone number of a responsible official for each entity (if available).

n/a

13. a. For **housing acquisition, construction, or conversion projects**, attach documentation verifying a commitment to finance the project and make the dwellings available to low and moderate income households as page **n/a**.

    b. Proforma attached as page

14. For all **rental housing projects and programs**:

    a. attach a listing of the rents to be charged after rehabilitation (which must be affordable);

    b. a definition of affordable;

    c. a method whereby such were made public; and

    d. if available, submit a copy of the draft agreement with the landlord that includes the process to be used to solicit tenants (see page)

15. For homeownership assistance, include the following:

a. Indicate if potential homeowners will seek their own financing. If a particular financing entity has been identified, provide the name, address and contact person for that entity.
n/a

b. Name, address, and phone number of the entity that will provide housing support services:

16. Ensure that any permanent relocation or displacement impacts of the project have been considered. This could potentially occur with the removal of low income housing stock from the market through demolition, acquisition, or conversion of dwellings. Contact the Council of Governments or CDBG Program staff for details.

Permanent Relocation/displacement anticipated? ☐ Yes (Describe plans or see page) ☒ No

17. If assistance to an eligible non-profit organization is proposed, supplemental information must be provided with your application. This information must include: N/A

a. Copy of articles of incorporation attached as page

b. By-laws attached as page

c. Tax exempt status attached as page

d. Current board of directors attached as page

b. Most recent audit and financial report attached as page

c. Civil Rights Certification attached as page

d. Financial Management Certification attached as page

h. Statement from the Corporation Commission that the corporation has not been dissolved and is currently in good standing, attached as page

Arizona Department of Housing

FORM 12
COMMUNITY DEVELOPMENT BLOCK GRANT
NATIONAL OBJECTIVE COMPLIANCE
DEMOGRAPHIC/RACIAL DATA

1. Applicant Name	Gila County	2. Project Name	Owner Occupied Housing Rehabilitation

This form should be used to capture demographic/racial data for CDBG-funded projects.

3. **Demographic/Ethnicity Data**

a) Source of Racial/Demographic Data: Waiting List

b) See page(s): 9+10

Demographic Category	Number/ # 4a)	Percentage/ % 4b)	Hispanic/Latino Ethnicity/# 5a)	Percentage/ % 5b)
Single Race Categories				
White	2	100%	0	0
Black/African American				
Asian				
American Indian/Alaskan Native				
Native Hawaiian/Other Pacific Islander				
Multi-Race Categories:				
American Indian/Alaskan Native & White				
Asian & White				
Black/African American & White				
American Indian/Alaskan Native & Black/African American				
Other Multi-Racial				
Non-Hispanic/Latino Ethnicity				
TOTAL 6)	2	100%	0	0

Total Hispanic/Latino Ethnicity 7)			0	

For reporting purposes, Hispanic is no longer classified as a race, but as an ethnic category. Thus, those collecting data on race must also ask the individual if he/she considers his/herself to be of Hispanic ethnicity. The Hispanic ethnicity has the potential to span across all races. Those who are White, Black, Asian, Pacific Islanders, American Indian, or Other Multi-Racial may also be counted as being Hispanic.

Arizona Department of Housing

FORM 16 - HR
CDBG - MILESTONES FOR PROJECT PLANNING
HOUSING REHABILITATION

1. Applicant Gila County Housing Services

2. Activity Owner Occupied Housing Rehab

Indicate below the initiation and completion dates for activity milestones (i.e. major events that must be accomplished to initiate and implement the CDBG funded activity). Month one is the first month after the effective date of the contract. If a milestone has already been achieved on an item pre-approved by the CDBG program, please note it.

Milestones ↓ Months →	1 Jan '14	2 Feb '14	3 Mar '14	4 Apr '14	5 May 2014	6 June '14	7 Jul '14	8 Aug '14	9 Sept "14	10 Oct '14	11 Nov '14	12 Dec '14
General ERR	11-1-13	x	x	4-1-14								
Marketing	1-1-14	x	x									
Quarterly Progress Reports	x	x	x	4-15-14	x	x	7-15-14	x	x	10-15-14	x	x
Request for Payment (at least quarterly)				4-15-14	x	x	7-15-14	x	x	10-15-14	x	x
House(s) #1												
ERR (Appendix A)			3-15-14									
Initial Inspection & Work write-ups			3-15-14	x	5-1-14							
Procurement					5-10-14							
Construction & Final Inspection							7-10-14	x	x	10-10-14		
House(s) #2												
ERR (Appendix A)			3-15-14									
Initial Inspection & Work write-ups			3-15-14	x	5-1-14							
Procurement					5-10-14							
Construction & Final Inspection							7-10-14	x	x	10-10-14		

REV. 3-2013

House(s) #												
ERR (Appendix A)												
Initial Inspection & Work write-ups												
Procurement												
Construction & Final Inspection												
House(s) #												
ERR (Appendix A)												
Initial Inspection & Work write-ups												
Procurement												
Construction & Final Inspection												
Milestones ↓ Months →	**13 Jan '15**	**14 Feb '15**	**15 Mar '15**	**16 Apr '15**	**17 May '15**	**18 Jun '15**	**19**	**20**	**21**	**22**	**23**	**24**
Marketing												
Quarterly Progress Reports	1-15-15											
Request for Payment (at least quarterly)	1-15-15											
House(s) #												
ERR (Appendix A)												
Initial Inspection & Work write-ups												
Procurement												
Construction & Final Inspection												

House(s) #												
ERR (Appendix A)												
Initial Inspection & Work write-ups												
Procurement												
Construction & Final Inspection												
House(s) #												
ERR (Appendix A)												
Initial Inspection & Work write-ups												
Procurement												
Construction & Final Inspection												
House(s) #												
ERR (Appendix A)												
Initial Inspection & Work write-ups												
Procurement												
Construction & Final Inspection												
CLOSEOUT												
Milestones↓ **Months** →	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**
Marketing												
Quarterly Progress Reports												
Request for Payment (at least quarterly)												

House(s) #												
ERR (Appendix A)												
Initial Inspection & Work write-ups												
Procurement												
Construction & Final Inspection												
House(s) #												
ERR (Appendix A)												
Initial Inspection & Work write-ups												
Procurement												
Construction & Final Inspection												
House(s) #												
ERR (Appendix A)												
Initial Inspection & Work write-ups												
Procurement												
Construction & Final Inspection												
CLOSEOUT		2-28-15										

Arizona Department of Housing

CERTIFICATIONS

APPLICANT CERTIFICATIONS FOR FY13/14

The applicant hereby assures and certifies that:

1. It possesses legal authority to apply for Community Development Block Grant funds, and to execute the proposed program.
2. Prior to the submission of the application, the applicant's governing body has duly adopted or passed as an official act a resolution authorizing the submission of the application, including all understandings, assurances, statutes, regulations and orders contained therein, and directing and authorizing the person identified as the official representative of the applicant to act in connection with the application and to provide such additional information as may be required.
3. Its chief executive officer or other officer of the applicant approved by the State:
   a. Consents to assume the status of a responsible Federal official under the National Environmental Policy Act of 1969 (NEPA) and other provisions of Federal law, as specified at 24 CFR 58.1(a) (3) and (a)(4), which further the purposes of NEPA insofar as the provisions of such Federal law apply to this program.
   b. Is authorized and consents on behalf of the applicant and him(her)self to accept the jurisdiction of the federal and State courts for the purpose of enforcement of his/her responsibilities as such an official.
4. It will comply with the provisions of Executive Order 11990, relating to evaluation of flood hazards and Executive Order 11288 relating to the prevention, control and abatement of water pollution.
5. It will, in connection with its performance of environmental assessments under the National Environmental Policy Act of 1969, comply with Section 106 of the National Historic Preservation Act of 1966 (16 U.S.C. 470), Executive Order 11593, and the Preservation of Archeological and Historical Data Act of 1966, P.L. 93-291 (16 U.S.C. 469a-1, et.seq.).
6. It will administer and enforce the labor standard requirements of the Davis Bacon Act, as amended at 40 U.S.C. 276a-276a-5, and the Contract Work Hours and Safety Standards Act at 40 U.S.C. 327-333.
7. It will comply with the provisions of 24 CFR Part 24 relating to the employment, engagement of services, awarding of contracts or funding of any contractors or subcontractors during any period of debarment, suspension or placement in ineligibility status.
8. It shall comply with the requirements of the 1992 Lead Based Paint Poisoning Prevention Act of 42 U.S.C. 4821-4846 (also Title X of the Housing and Community Development Act of 1992) and implementing regulations at 24 CFR Part 35.
9. It will comply with the provisions of 24 CFR part 58 "Uniform Grant Administrative Requirements" and OMB Circular A-87.
10. It will comply with the American Disabilities Act and Section 504 of the Rehabilitation Act, as amended.

11. It will comply with
    a. Title VI of the Civil Rights Act of 1964 (Pub. L. 88- 352), and the regulations issued pursuant thereto (24 CFR Part 1).
    b. Title VIII of the Civil Rights Act of 1968 (Pub. L. 90- 284), as amended.
    c. Section 109 of the Housing and Community Development Act of 1974.
    d. Executive Order 11063 pertaining to equal opportunity in housing and nondiscrimination in the sale or rental of housing built with Federal assistance.
    e. Executive Order 11246, and the regulations issued pursuant thereto (24 CFR Part 130 and 41 CFR Chapter 60).
    f. Section 3 of the Housing and Urban Development Act of 1968, as amended.
    g. Federal Fair Housing Act of 1988, P.L. 100-430.
    h. The prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1973, 42. U.S.C. 6101-07, and the prohibitions against discrimination against persons with handicaps under Section 504 of the Rehabilitation Act of 1973, (P.L. 93-112), as amended, and the regulations at 24 CFR Part 8.
    i. The requirements of the Architectural Barriers Act of 1966 at 42 U.S.C. 4151-415.

12. It will comply with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 and implementing regulations.
13. The Applicant certifies that there was no participation in any aspect or manner of the due diligence, compilation, preparation, or submission process relating to this Application, or the project that is the subject of this Application, by any person(s) or entity(ies) in violation of applicable State of Arizona (such as those found at A.R.S. §§ 38-501 - 38-511) or federal (such as those found at 24 CFR 92.365 relating to the administration of HOME funds or 24 CFR 570.611 relating to the administration of CDBG funds) conflict of interest laws . Should ADOH determine that such a conflict exists; the Application will be discontinued from consideration of the award at issue. Further, violations of any other applicable state or federal law will similarly result in disqualification of the Application from consideration of said award. Applicant further certifies It will comply with applicable conflict of interest provisions, incorporate such in all contracts and establish safeguards to prohibit employees from using positions for a purpose that is or gives the appearance of being motivated by a desire for private gain for themselves or others, particularly those with whom they have family, business, or other ties.
14. It will comply with the provisions of the Hatch Act that limits the political activity of employees.
15. It will give representatives of the State, the Secretary of HUD, the Inspector General, and the General Accounting Office access to all books, accounts, records, reports, files and other papers, things, or property belonging to it or in use by it pertaining to the administration of State CDBG assistance.
16. It will ensure that the facilities under its ownership, lease or supervision which shall be utilized in the accomplishment of the program are not listed on the Environmental Protection Agency's (EPA) list of violating facilities and that it will notify the State of the receipt of any communication from the Director of the EPA Office of Federal Activities indicating that a facility to be used in the project is under consideration for listing by the EPA.
17. It will comply with the flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973, Pub.L. 93-234, 87 Stat., 975, approved December 31, 1973. Section 103 (a) required, on and after March 2, 1974.

18. It has AND WILL COMPLY WITH THE PROVISIONS OF THE STATE OF ARIZONA CITIZEN AND PUBLIC PARTICIPATION PLAN FOR THE STATE OF ARIZONA CDBG PROGRAM.
19. It has developed plans to minimize displacement of persons as a result of activities assisted in whole or in part with CDBG funds and to assist persons actually displaced as a result of such activities, and has provided information about such plans to the public.
20. It will not recover any capital costs of public improvements assisted in whole or in part with CDBG funds by assessing any amount against properties owned and occupied by persons of low and moderate income, including any fee charged or assessment made as a condition of obtaining access to such public improvements **unless**:
    a. the CDBG funds are used to pay the proportion of the fee or assessment that is financed from other revenue sources, or:
    b. it will certify to the State in writing that it lacks sufficient CDBG funds to comply with (a) but that it will not assess properties owned by very low-income persons.

21. It will provide all other funds/resources identified in the application, or any additional funds/resources necessary to complete the project as described in the application as submitted, or as may be later amended.
22. It will comply with the requirements of the Single Audit Act of 1996 and OMB Circular A-133; and if the grant is closed out prior to all funds having been audited, it shall refund to ADOH any costs disallowed as a result of any audit conducted after the date of grant closeout.
23. It hereby adopts and will enforce a policy prohibiting the use of excessive force by law enforcement agencies within its jurisdiction against any individuals engaged in nonviolent civil rights demonstrations; and will enforce applicable State and local laws against physically barring entrance to or exit from a facility or location which is the subject of such nonviolent civil rights demonstrations within its jurisdiction.
24. It will ensure that, to the best of the knowledge and belief of the undersigned:
    a. no Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in the connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement;
    b. if any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, and officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form - LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
    c. the undersigned shall require that the language of this certification be included in the award documents for all sub-awards at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly.

"This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by Section 1352, Title 31, U.S. Code. Any person who fails to file the required

certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure."

25. It shall comply with the provisions of Section 102 of the HUD Reform Act of 1989.
26. It shall ensure that efforts are made to recruit minority, disabled and woman owned businesses for its vendor/supplier lists.

CERTIFIED BY:

Michael A. Pastor

Signature of Mayor or Chair of County Board

7-16-13
Date

Michael A. Pastor, Chairman, Gila County Board of Supervisors
Typed Name of Mayor or Chair of County Board

NOTE: The Attorney General has ruled that these Certifications must have an original signature when submitted to the CDBG Program. If an applicant submits more than one application, the Certifications should be included in the application that includes administration funds and other general items such as public participation, resolutions, etc.

Arizona Department of Housing

Applicant: Gila County

CDBG Contract No.(if known):_____ ☒ RA for FFY 13/14 ☐ SSP for FFY _____

CDBG DISCLOSURE REPORT
FEDERAL FISCAL YEAR
10/1/2013- 9/30/2014

This form must be completed and submitted with each application for CDBG funds.

PART I - APPLICANT INFORMATION

1. Applicant, Complete Address with 9-digit zip code, Phone Number:

Gila County Community Services Division

5515 S. Apache Avenue, Suite 200

Globe, Arizona 85501-4430 Telephone: 928-425-7631

2. Federal Employer Identification Number: 86-60000444

3. Indicate whether this is: ☒ Initial Report ☐ Update Report #_____

4. Amount of this CDBG Grant Applied for: $98,853.00

PART II - THRESHOLD DETERMINATION

1. Is the amount listed in 4(above) more than $500,000? ☐ Yes ☒ No

2. Have you received, can reasonably expect to receive, or applied for other HUD assistance (through programs listed in Appendix A of the Instructions) during the current federal fiscal year, which when added to 4. (above) amounts to more than $500,000? ☒ Yes ☐ No

PART III - OTHER GOVERNMENT ASSISTANCE PROVIDED/APPLIED FOR

Provide the requested information for any other Federal, State and/or local governmental assistance ***either awarded or applied for, which will be used in conjunction with this CDBG grant.***

Name and Address of Agency Providing or Applied to for Assistance	Program	Type of Assistance	Amount Requested or Awarded
Arizona Dep't. of Housing	HOME	OOHR	440,000.00
Phoenix AZ			$
			$
			$
AZCAA	DOE, LIHEAP	Weatherization	$
Phoenix, AZ	SWG/APS	Weatherization	$206,000.00
	URRD		7,000.00
			$
			$
			$

PART IV - INTERESTED PARTIES

Identify any person or entity that has a pecuniary interest in this project that exceeds $50,000 or 10% of the CDBG assistance (whichever is lower). All consultants, developers or contractors involved in the CDBG application or in the planning, development or implementation of the project must be identified as an interested party unless procured through a competitive process.

List of all Persons with a Reportable Financial Interest in the Project	Social Security No. or Employer ID No.	Type of Participation in the Project	Financial Interest in the Project ($ and %)
			$ / %
			$ / %
			$ / %
			$ / %
			$ / %
			$ / %
			$ / %
			$ / %
			$ / %
			$ / %
			$ / %

PART V - EXPECTED SOURCES AND USES OF FUNDS

Identify the *source and use of all assistance* (include this CDBG grant and all other governmental and non-governmental sources) that has been or may be used in this contract.

Activity No. and Source	Use
HOME Partnership Program Fund	Housing Rehabilitation
URRD	Minor Repair
DOE/SWG/APS/LIHEAP WAP	Weatherization

PART VI - CERTIFICATION

I hereby certify that the information provided in this disclosure is true and correct and I am aware that any false information or lack of information knowingly made or omitted may subject me to civil or criminal penalties under Section 1001 of Title 18 of the United States Code. In addition, I am aware that if I knowingly and materially violate any required disclosure of information, including intentional non-disclosure, I am subject to a civil money penalty not to exceed $10,000 for each violation.

Michael A. Pastor 7-16-13

Michael A. Pastor, Chairman

DISCLOSURE REPORT INSTRUCTIONS

All communities receiving CDBG grants must complete and submit the Disclosure Report either with the application or after receipt of the CDBG award letter. ***Note that no contract will be issued until the CDBG Program receives a completed Disclosure Report.***

PART I - GRANTEE INFORMATION

Complete information requested.
Updated reports are required if:

- Information was omitted from the initial report;
- Additional interested parties are identified (unless such are identified through other documents such as those relating to the procurement process);
- A person or entity's pecuniary interest has increased;
- Government assistance has increased by $250,000 or 10% (whichever is lower);
- There is a change in the source and/or use of funds that exceeds the amount of all previously disclosed sources and/or uses of funds by $250,000 or 10% (whichever is lower).

PART II - THRESHOLD DETERMINATION

Complete information requested.

PART III - OTHER GOVERNMENT ASSISTANCE PROVIDED/APPLIED FOR

Complete information requested.

PART IV - INTERESTED PARTIES

Interested parties are those persons and entities with a reportable pecuniary interest in the project. A *pecuniary interest means **any** financial involvement* in the project, including such situations in which a person or entity:

- Has an equity interest in the project,
- Shares in any profit or resale;
- Shares in any distribution of cash surplus or other assets of the project;
- Receives compensation for any goods or services provided in connection with the project. (Exception: if compensated as a result of a competitive procurement process.)

(The following are not considered interested parties: local CDBG administrative staff, recipients of housing rehab assistance, and rehab contractors as long as the rehab agreement is between the property owner and the contractor.)

If an entity is disclosed, the information provided in Part IV must include the identification of each officer, director, principal stockholder or other official of the entity.

Applicants/grantees may not be aware of all interested parties when completing this report. If, as the project is implemented, the grantee becomes aware of other interested parties, it should submit an updated Disclosure Report.

PART V - EXPECTED SOURCES AND USES OF FUNDS

Note that this section must include all other assistance identified in Part III as well as the CDBG funds.

Describe the "Uses of Funds" in general terms - do not provide line item budget information.

PART VI - CERTIFICATION

Have Chief Elected Official sign and date form.

Original must be included with application.

APPENDIX A

The following HUD programs are considered "covered assistance" for purposes of the Disclosure Report. All applicants for CDBG funds must review this list to determine if they are receiving or can reasonably expect to receive assistance from any of these covered sources in determining whether they reach the threshold (Part II). Applicants must consider: a) ALL CDBG funds for which they will apply, both RA and all SSPs; b) ALL other "covered assistance" whether received directly from HUD or through the State, e.g., ADOH or DES.

NOTE: **This list does NOT include the HOME program.**

1. Section 312 Rehab Loans under 24 CFR Part 510 except loans for single-family properties
2. Rental Rehabilitation Grant Programs
3. Specific projects or activities under Title I of the Housing and Community Development Act of 1974 to:

   a) HUD for a Special Purpose Grant
   b) HUD for a loan under 24 CFR Part 470, Subpart M
   c) HUD for a grant to an Indian tribe under Title I
   d) HUD for a grant under the HUD administered Small Cities program; and
   e) a state or unit of general local government for CDBG
4. Emergency Shelter Grants (specific project or activity), under 24 CFR part 576
5. Transitional Housing under 24 CFR part 577
6. Permanent Housing for Handicapped Homeless Persons under 24 CFR part 578
7. Section 8 Housing Assistance Payments (only project-based housing under the Existing Housing and Moderate Rehab Programs under 224 CFR part 88 but including the Moderate Rehabilitation Program for Single Room Occupancy Dwellings for the Homeless under Subpart H)
8. Section 9 Housing Assistance Payments for Housing for the elderly or handicapped under 24 CFR part 855
9. Loans for Housing for the Elderly or Handicapped including operating assistance for Housing for the Handicapped under Section 162 of the Housing and Community Development Act of 1987 and Seed Money Loans under Section 106(b) of the Housing and Urban Development Act of 1968
10. Section 8 Housing Assistance Payments, Special Allocations under 24 CFR part 886
11. Flexible Subsidy under 25 CFR part 219, both Operating Assistance under Subpart B and Capital Improvement Loans under Subpart C
12. Low Rent Housing Opportunities under 24 CFR part 904
13. Indian Housing under 24 CFR part 905
14. Public Housing Development under 24 CFR art 942
15. Comprehensive Improvement Assistance under 24 CFR part 968
16. Resident Management under 24 CFR part 964, Subpart C
17. Neighborhood Development Demonstration under Section 123 of the Housing and Urban Rural Recovery Act of 1983

18. Nehemiah Grants under 24 CFR part 280

19. Research and Technology Grants under Title V of the Housing and Urban Development Act of 1970

20. Congregate Services under the Congregate Housing Services Act of 1978

21. Counseling Under Section 106 of the Housing and Urban Development Act of 1968

22. Fair Housing Initiates under 24 CFR part 125

23. Public Housing Drug Elimination Grants under Section 5129 of the Anti Drug Abuse Act of 1988

24. Fair Housing Assistance under 24 CFR part 111

25. Public Housing Early Childhood Development Grants under Section 222 of the Housing and urban Rural Recovery Act of 1983

26. Mortgage Insurance under 24 CFR Subtitle B, chapter II (only multifamily and non residential)

27. Supplemental Assistance for Facilities to Assist the Homeless under 24 CFR part 57928. Shelter Plus Care Assistance under Section 837 of the Cranston Gonzales National Affordable Housing Act

29. Planning and Implementation Grants for HOPE for Public and Indian Housing Homeownership under Title IV, Subtitle A of the Cranston-Gonzales National Affordable Housing Act

30. Planning and Implementation Grants for HOPE for Homeownership of Multifamily Units under Title IV, Subtitle B of the Cranston-Gonzales National Affordable Housing Act

31. HOPE for Elderly Independence Demonstration under section 803 of the Cranston-Gonzales National Affordable Housing Act.

GILA COUNTY ATTORNEY

Bradley D. Beauchamp

Re: County Attorney's Office approval of IGA pursuant to A.R.S. § 11-952(D).

To whom it may concern:

The County Attorney's Office has reviewed the Intergovernmental Agreement attached to this agenda item and has determined that it is in its "proper form" and "is within the powers and authority granted under the laws of this state to such public agency or public procurement unit" pursuant to A.R.S. § 11-952(D).

Explanation of the Gila County Attorney's Office Intergovernmental Agreement (IGA) Review

A.R.S. § 11-952(D) requires that

> every agreement or contract involving any public agency or public procurement unit of this state . . . before its execution, shall be submitted to the attorney for each such public agency or public procurement unit, who shall determine whether the agreement is in proper form and is within the powers and authority granted under the laws of this state to such public agency or public procurement unit.

In performing this review, the County Attorney's Office reviews IGAs to see that they are in "proper form" prior to their execution. "Proper form" means that the contract conforms to fundamental contract law, conforms to specific legislative requirements, and is within the powers and authority granted to the public agency. It does not mean that the County Attorney's Office approves of or supports the policy objectives contained in the IGA. That approval is solely the province of the public agency through its elected body.

Likewise, this approval is not a certification that the IGA has been properly executed. Proper execution can only be determined after all the entities entering into the IGA have taken legal action to approve the IGA. There is no statutory requirement for the County Attorney's Office to certify that IGAs are properly executed.

Nonetheless, it is imperative for each public agency to ensure that each IGA is properly executed because A.R.S. § 11-952(F) requires that "[a]ppropriate action … applicable to the governing bodies of the participating agencies approving or extending the duration of the … contract shall be necessary before any such agreement, contract or extension may be filed or become effective." This can be done by ensuring that the governing body gives the public proper notice of the meeting wherein action will be taken to approve the IGA, that the item is adequately described in the agenda accompanying the notice, and that the governing body takes such action. Any questions regarding whether the IGA has been properly executed may be directed to the County Attorney's Office.

Proper execution of IGAs is important because A.R.S. § 11-952(H) provides that "[p]ayment for services under this section shall not be made unless pursuant to a fully approved written contract." Additionally, A.R.S. § 11-952(I) provides that "[a] person who authorizes payment of any monies in violation of this section is liable for the monies paid plus twenty per cent of such amount and legal interest from the date of payment."

The public agency or department submitting the IGA for review has the responsibility to read and understand the IGA in order to completely understand its obligations under the IGA if it is ultimately approved by the public entity's board. This is because while the County Attorney's Office can approve the IGA as to form, the office may not have any idea whether the public agency has the capacity to actually comply with its contractual obligations. Also, the County Attorney's Office does not monitor IGA compliance. Hence the public entity or submitting department will need to be prepared to monitor their own compliance. A thorough knowledge of the provisions of the IGA will be necessary to monitor compliance.

Before determining whether an IGA contract "is in proper form," the County Attorney's Office will answer any questions or concerns the public agency has about the contract. It is the responsibility of the public agency or department submitting the IGA for review to ask any specific questions or address any concerns it has about the IGA to the County Attorney's Office at the same time they submit the IGA for review. Making such an inquiry also helps improve the County Attorney's Office review of the IGA because it will help focus the review on specific issues that are of greatest concern to the public agency. Failing to make such an inquiry when the agency does have issues or concerns will decrease the ability of the County Attorney's Office to meaningfully review the IGA.

ARF-2800 **Regular Agenda Item 3. B.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For:	Michael O'Driscoll, Director	Submitted By:	Lauren Savaglio Environmental Health Manager Health & Emergency Services Division
Department:	Health & Emergency Services Division	Division:	Health Services

Information

Request/Subject

Adoption of the U.S. Public Health Service Food & Drug Administration (FDA) 2013 Food Code.

Background Information

Currently, Gila County Division of Health & Emergency Services (GCDHES) operates under the 1999 Food & Drug Administration (FDA) Food Code. The latest Food Code was released November 13, 2013. This updated Food Code provides all levels of government and industry with practical, science-based guidance and manageable provisions for mitigation known risks of food-borne illness. The 2013 Food Code reflects the input of the regulatory officials (FDA, U.S. Department of Agriculture, Centers for Disease Control and Prevention, and U.S. Department of Health & Human Services), industry, academia, and consumers that participated in the 2012 meeting of the Conference for Food Protection. Such collaboration helps ensure the Food Code establishes sound requirements that prevent food-borne illness and injury and eliminates the most important food safety hazards in retail and food service facilities. Adopting the current 2013 FDA Food Code would put Gila County in line with the most up-to-date science-based recommendations to reduce the risk of food-borne illness, create uniform standards for retail food safety, and establish a more standardized approach to inspections.

GCDHES is also enrolled in the FDA Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards). The Retail Program Standards provide a foundation and system upon which regulatory programs can build through a continuous improvement process in order to improve food safety. They are intended to reinforce proper sanitation (good retail practices) and operational and environmental prerequisite programs while encouraging regulatory agencies and industry to focus on the factors that cause and contribute to food-borne illness, with the ultimate goal of reducing the occurrence of those factors. As part of these Retail Program Standards, jurisdictions need to adopt the most recent Food Code.

Arizona Department of Health Services (ADHS) amended the Food Code to include the restriction of latex gloves in order to meet minimum standards set forth by ADHS; adoption of the FDA 2013 Food Code will include an amendment that restricts the use of latex gloves in food establishments.

On July 19, 2014, GCDHES first presented adopting the 2013 FDA Food Code to the Board of Supervisors during a work session. Materials from that work session are attached.

On August 25, 2014, and August 26, 2014, 50 representatives from Gila County food establishments participated in meetings held by GCDHES to discuss and receive feedback regarding adoption of the 2013 FDA Food Code and other changes to food inspections.

Evaluation

Without the changes proposed, GCDHES would be at greater risk for food-borne illness and this will create undue stress and burden on Gila County food establishments and residents.

Conclusion

Due to newly released best practices, it would be in the best interest of the County for the Board of Supervisors to adopt the 2013 Food Code, replacing the 1999 FDA Food Code, with a latex-free glove amendment.

Recommendation

Based on the information provided, the Health & Emergency Services Division Director recommends that the Board of Supervisors adopt the FDA 2013 Food Code with a latex-free glove amendment.

Suggested Motion

Information/Discussion/Action to adopt the 2013 Food Code as recommended by the U.S. Public Health Service Food & Drug Administration (FDA) with an additional amendment that addresses the use of latex-free gloves, and discontinue using the FDA 1999 Food Code. **(Lauren Savaglio)**

Attachments

FDA 2013 Food Code
FDA 1999 Food Code
Food Code Powerpoint
Food Code Summary of Changes
Major Changes in 2013 Food Code

Food Code

U.S. Public Health Service

2013

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service • Food and Drug Administration

College Park, MD 20740

Food Code

2013 Recommendations of the
United States Public Health Service
Food and Drug Administration

The Food Code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service.

This model is offered for adoption by local, state, and federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction that have been delegated compliance responsibilities for food service, retail food stores, or food vending operations. Alternatives that offer an equivalent level of public health protection to ensure that food at retail and foodservice is safe are recognized in this model.

For public sale by:

U.S. Department of Commerce
National Technical Information Service
5301 Shawnee Road, Alexandria, VA 22312
Phone: 1-800-553-6847
refer to report number **PB2013-110462**

ISBN 978-1-935239-02-4

Previous Editions of Codes
Recommended by The
United States Public Health Service
for
Regulating Operations Providing Food Directly to the Consumer

1934 - *Restaurant Sanitation Regulations,*
Proposed by the U.S. Public Health Service in cooperation with the Conference of State and Territorial Health Officers and the National Restaurant Code Authority

1935 - *An Ordinance Regulating Food and Drink Establishments*
(Recommended by U.S. Public Health Service), December 1935, Mimeographed

1938 - *Ordinance and Code Regulating Eating and Drinking Establishments, Recommended by the U.S. Public Health Service,* March 1938, Mimeographed

1940 - *Ordinance and Code Regulating Eating and Drinking Establishments, Recommended* by the U.S. Public *Health Service,* June 1940, Mimeographed

1943 - *Ordinance and Code Regulating Eating and Drinking Establishments, Recommended by the United States Public Health Service,* 1943, FSA, Public Health Bulletin No. 280 (Republished in 1955, DHEW, PHS Publication No. 37)

1957 - *The Vending of Foods and Beverages - A Sanitation Ordinance and Code, 1957 Recommendations of the Public Health Service,* DHEW, PHS Publication No. 546

1962 - *Food Service Sanitation Manual Including A Model Food Service Sanitation Ordinance and Code, 1962 Recommendations of the Public Health Service,* DHEW, PHS Publication No. 934

1965 - *The Vending of Food and Beverages - A Sanitation Ordinance and Code, 1965 Recommendations of the Public Health Service,* DHEW, PHS Publication No. 546

1976 - *Food Service Sanitation Manual Including A Model Food Service Sanitation Ordinance, 1976 Recommendations of the Food and Drug Administration,* DHEW/PHS/FDA, DHEW Publication No. (FDA) 78-2091

1978 - *The Vending of Food and Beverages Including A Model Sanitation Ordinance, 1978 Recommendations of the Food and Drug Administration,* DHEW/PHS/FDA, DHEW Publication No. (FDA) 78-2091

1982 - *Retail Food Store Sanitation Code, 1982 Recommendations of the Association of Food and Drug Officials and U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration,* AFDO/HHS Publication

1993 - *Food Code, 1993 Recommendations of the United States Public Health Service, Food and Drug Administration,* National Technical Information Service Publication PB94-113941

1995 - *Food Code, 1995 Recommendations of the United States Public Health Service, Food and Drug Administration,* National Technical Information Service Publication PB95-265492

1997 - *Food Code, 1997 Recommendations of the United States Public Health Service, Food and Drug Administration,* National Technical Information Service Publication PB97-133656

1999 - *Food Code, 1999 Recommendations of the United States Public Health Service, Food and Drug Administration,* National Technical Information Service Publication PB99-115925

2001 - *Food Code, 2001Recommendations of the United States Public Health Service, Food and Drug Administration,* National Technical Information Service Publication PB2002-100819

2003 - *Supplement to the 2001 Food Code,* National Technical Information Service Publication PB2003-106843

2005 - *Food Code, 2005 Recommendations of the United States Public Health Service, Food and Drug Administration,* National Technical Information Service Publication PB2005-102200

2007 - *Supplement to the 2005 Food Code,* National Technical Information Service Publication PB2007-112622

2009 - *Food Code, 2009 Recommendations of the United States Public Health Service, Food and Drug Administration,* National Technical Information Service Publication PB2009-112613

2011 - *Supplement to the 2009 Food Code,* National Technical Information Service Publication PB2011-114303

INTRODUCTION to the 2013 FOOD CODE

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) and the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA) are pleased to announce the release of the 2013 and eighth edition of the Food Code. The Food Code is a model code and reference document for state, city, county and tribal agencies that regulate operations such as restaurants, retail food stores, food vendors, and foodservice operations in institutions such as schools, hospitals, assisted living, nursing homes and child care centers. Food safety practices at these facilities play a critical role in preventing foodborne illness. The Food Code establishes practical, science-based guidance for mitigating risk factors that are known to cause or contribute to foodborne illness outbreaks associated with retail and foodservice establishments and is an important part of strengthening our nation's food protection system.

As of 2012, all 50 states and 3 of 6 territories report having retail codes patterned after previous editions of the Food Code. We strongly encourage the adoption and implementation of the 2013 Food Code at all levels of government.

This edition of the Food Code reflects our current understanding of evidenced-based practices for the effective control of microbiological, chemical and physical hazards in food facilities that can cause foodborne illness. Many of the changes to this edition reflect recommendations made at the 2012 biennial meeting of the Conference for Food Protection, a national organization that affords scientists and policy makers from all levels of government, industry, academia and consumers the opportunity to propose and deliberate on improvements to the Food Code.

The federal government is committed to enhanced coordination with state, local, and tribal agencies, and the food industry to protect our food supply, and the Food Code is one important element in this strategy. HHS and USDA will continue to take progressive steps to partner with all who have a stake in food safety, and are committed to reducing the incidence of foodborne illness in the United States.

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services

Alfred V. Almanza
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture

Thomas R. Frieden, M.D., M.P.H
Director
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

Preface

1. FOODBORNE ILLNESS ESTIMATES, RISK FACTORS, AND INTERVENTIONS

Foodborne illness in the United States is a major cause of personal distress, preventable illness and death, and avoidable economic burden. Scallan et al. (2011a,b) estimated that foodborne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths in the United States each year. The occurrence of approximately 1,000 reported disease outbreaks (local, regional, and national) each year highlights the challenges of preventing these infections.

Most foodborne illnesses occur in persons who are not part of recognized outbreaks. For many victims, foodborne illness results only in discomfort or lost time from the job. For some, especially preschool age children, older adults in health care facilities, and those with impaired immune systems, foodborne illness is more serious and may be life threatening.

The annual cost of foodborne illness in terms of pain and suffering, reduced productivity, and medical costs are estimated to be $10 - $83 billion. As stated by Meade et. al., the nature of food and foodborne illness has changed dramatically in the United States over the last century. While technological advances such as pasteurization and proper canning have all but eliminated some disease, new causes of foodborne illness have been identified. Surveillance of foodborne illness is complicated by several factors. The first is underreporting. Although foodborne illnesses can be severe or even fatal, milder cases are often not detected through routine surveillance. Second, many pathogens transmitted through food are also spread through water or from person to person, thus obscuring the role of foodborne transmission. Finally, pathogens or agents that have not yet been identified and thus cannot be diagnosed cause some proportion of foodborne illness.

Epidemiological outbreak data repeatedly identify five major risk factors related to employee behaviors and preparation practices in retail and food service establishments as contributing to foodborne illness:

- Improper holding temperatures,
- Inadequate cooking, such as undercooking raw shell eggs,
- Contaminated equipment,
- Food from unsafe sources, and
- Poor personal hygiene

The Food Code addresses controls for risk factors and further establishes 5 key public health interventions to protect consumer health. Specifically, these interventions are: demonstration of knowledge, employee health controls, controlling hands as a vehicle of contamination, time and temperature parameters for controlling pathogens, and the consumer advisory. The first two interventions are found in Chapter 2 and the last three in Chapter 3.

The Food and Drug Administration (FDA) endeavors to assist the approximately 75 state and territorial agencies and more than 3,000 local departments that assume primary responsibility for preventing foodborne illness and for licensing and inspecting establishments within the retail segment of the food industry. This industry segment consists of more than one million establishments and employs a work force of over 16 million.

2. PHS MODEL CODES HISTORY, PURPOSE, AND AUTHORITY

(A) History and Purpose

U.S. Public Health Service (PHS) activities in the area of food protection began at the turn of the 20th century with studies on the role of milk in the spread of disease. These studies led to the conclusion that effective disease prevention requires the application of comprehensive food sanitation measures from production to consumption. Additional studies identified and evaluated measures which would most effectively control disease, including work which led to improved processes for pasteurization.

Next, model codes were developed to assist state and local governments in initiating and maintaining effective programs for prevention of foodborne illness. The first of these, which is now titled *Grade A Pasteurized Milk Ordinance – Recommendations of the PHS/FDA,* was initially published in 1924. Subsequently, the PHS published recommended model food codes that address the various components of the retail segment of the food industry. These code editions are listed chronologically on pp. iii and iv. Through the years all states, hundreds of local jurisdictions, and many federal agencies have adopted some edition of model food codes recommended by the PHS.

Today, FDA's purpose in maintaining an updated model food code is to assist food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail segment of the food industry. The retail segment includes those establishments or locations in the food distribution chain where the consumer takes possession of the food.

The model Food Code is neither federal law nor federal regulation and is not preemptive. Rather, it represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. Although not federal requirements (until adopted by federal bodies for use within federal jurisdictions), the model Food Code provisions are designed to be consistent with federal food laws and regulations, and are written for ease of legal adoption at all levels of government. A list of jurisdictions that have reported to FDA their status in adopting the Food Code is available on the FDA CFSAN Web Page at: http://www.fda.gov/RetailFoodProtection. The list is self-reported and FDA has not yet evaluated whether all the adopted codes are equivalent to the model Food Code.

Providing model food codes and model code interpretations and opinions is the mechanism through which FDA, as a lead federal food control agency, promotes uniform implementation of national food regulatory policy among the several thousand federal, state, and local agencies and tribes that have primary responsibility for the regulation or oversight of retail level food operations.

(B) Authority

PHS authority for providing assistance to state and local governments is derived from the Public Health Service Act [42 USC 243]. Section 311(a) states in part:
"... The Secretary shall ... assist states and their political subdivisions in the prevention and suppression of communicable diseases, and with respect to other public health matters, shall cooperate with and aid state and local authorities in the enforcement of their ... health regulations and shall advise the several states on matters relating to the preservation and improvement of the public health." Responsibility for carrying out the provisions of the Act relative to food protection was delegated within the PHS to the Commissioner of Food and Drugs in 1968 [21 CFR 5.10(a)(2) and (3)].

Under authority of the Economy Act, June 30, 1932 as amended [31 USC 1535], FDA provides assistance to federal agencies.
Assistance provided to local, state, and federal governmental bodies is also based on FDA's authorities and responsibilities under the Federal Food, Drug, and Cosmetic Act [21 USC 301].

3. PUBLIC HEALTH AND CONSUMER EXPECTATIONS

It is a shared responsibility of the food industry and the government to ensure that food provided to the consumer is safe and does not become a vehicle in a disease outbreak or in the transmission of communicable disease. This shared responsibility extends to ensuring that consumer expectations are met and that food is unadulterated, prepared in a clean environment, and honestly presented.

Under FDA's 2012 Mission Statement the agency is responsible for:

Protecting the public health by assuring the safety of our nation's food supply…and for advancing the public health by helping the public get accurate, science-based information they need about foods to maintain and improve their health.

Accordingly, the provisions of the Food Code provide a system of prevention and overlapping safeguards designed to minimize foodborne illness; ensure employee health, industry manager knowledge, safe food, nontoxic and cleanable equipment, and acceptable levels of sanitation on food establishment premises; and promote fair dealings with the consumer.

4. ADVANTAGE OF UNIFORM STANDARDS

The advantages of well-written, scientifically sound, and up-to-date model codes have long been recognized by industry and government officials.

Industry conformance with acceptable procedures and practices is far more likely where regulatory officials "speak with one voice" about what is required to protect the public health, why it is important, and which alternatives for compliance may be accepted.

Model codes provide a guide for use in establishing what is required. They are useful to business in that they provide accepted standards that can be applied in training and quality assurance programs. They are helpful to local, state, and federal governmental bodies that are developing or updating their own codes.

The model Food Code provides guidance on food safety, sanitation, and fair dealing that can be uniformly adopted for the retail segment of the food industry. The document is the cumulative result of the efforts and recommendations of many contributing individuals, agencies, and organizations with years of experience using earlier model code editions. It embraces the concept that our quality of life, state of health, and the public welfare are directly affected by how we collectively provide and protect our food.

The model Food Code provisions are consistent with, and where appropriate incorporate, federal performance standards for the same products and processes. Federal performance standards in effect define public food safety expectations for the

product, usually in terms of lethality to a pathogenic microorganism of particular concern. Use of performance standards as the measure of regulatory compliance means establishments are free to use innovative approaches in producing safe products, in lieu of adherence to traditional processing approaches, such as specified cooking times and temperatures, that achieve the same end. Federally inspected establishments demonstrate compliance with performance standards by showing that their process adheres to an appropriately designed, validated HACCP plan.

Retail processors may be given the same opportunity as federally-regulated establishments to use innovative techniques in the production of safe foods. Retail establishments may apply to the regulatory authority for a variance to use a specific federal food safety performance standard for a product or a process in lieu of compliance with otherwise applicable specifications in the Food Code. However, to show compliance with the federal performance standard, the retail processor must, like a federally inspected establishment, show that processing controls are in place to ensure that the standard is being met. Thus, a request for a variance based on a federal performance standard must be supported by a validated HACCP plan with record keeping and documented verification being made available to the regulatory authority.

5. MODIFICATIONS AND IMPROVEMENTS IN THIS EDITION

The revisions contained in this edition reflect changes, additions, deletions, and format modifications listed in the Supplement to the 2009 FDA Food Code and recommendations developed during the 2012 Biennial meeting of the Conference for Food Protection. The revisions also reflect input provided by those who have been intimately involved with studying, teaching, and using the earlier editions. Most of these enhancements involve added clarification or new information. Some reflect evolving regulatory policy contained in new or revised federal regulations.

Several of the Tables, Charts, and images were converted throughout the Code to meet web accessibility requirements under Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d). Section 508 mandates that all federal agencies eliminate the barriers in accessing electronic and information technology. The law helps to ensure that members of the public with disabilities have the ability to access government information and services.

The needed clarifications and missing Code provisions were identified by FDA and others during standardization and certification activities, State Training Team courses, regional food protection seminars, the deliberations of food equipment standards organizations, and the verbal and written requests for clarification received by FDA field and headquarters components.

Changes in provisions related to federal laws and regulations administered by other federal agencies such as the United States Department of Agriculture were jointly developed with those agencies.

In the 2009 FDA Food Code a revised designation system for Code provisions was introduced. In the 2013 edition of the FDA Food Code, Annex 7 Form 3-A Food Establishment Inspection Report and Guide 3-B Instructions for Marking the Food Establishment Inspection Report were updated to reflect the revised designation system.

A Summary of Changes is provided at the end of the Food Code. General enhancements include:

(1) Added and improved definitions that are more precise and more consistent with terminology and definitions found in related laws and regulations;

(2) Modified provisions to make them more consistent with national requirements and standards administered by other federal agencies and international bodies; more flexible without compromising public health; and more internally consistent with other Food Code provisions;

(3) Clarified other provisions regarding their intent, thereby reducing confusion and the potential for inconsistent application;

(4) Improved user aids contained in the Annexes such as added references and updated public health reasons, model forms, guides, and lists; and

(5) Expanded the Index with additional terms to assist a broader base of users in finding topics of interest.

6. DISCUSSION OF THE CODE AS A HACCP MODEL AND THE INTENTION TO INCORPORATE OTHER MODELS

It is important to note that preapproval of HACCP plans for food establishments operating pursuant to a variance is provided for under the Food Code, but such a plan preapproval is not a part of another HACCP regulatory model, the Fish and Fishery Products regulation 21 CFR 123, effective December 18, 1997. FDA published the Fish and Fisheries Hazards and Controls Guidance Fourth Edition April 2011. Additionally, there are differences between the two models in the required content of the HACCP plan. For example, the HACCP plans requested by the Food Code must include flow diagrams, product formulations, training plans, and a corrective action plan. Flow diagrams and product formulations are suggested but not mandated components of the Fish and Fishery Products regulation.

These differences are necessitated by differences in the nature of the regulations and the regulatory structure set up to enforce them. HACCP plans developed under the Food Code variance process are provided to the regulatory authority to enable the regulatory authority to assess whether the establishment has designed a system of controls sufficient to ensure the safety of the product. The plans will be reviewed outside the food establishment and, in most cases, in the absence of any historical performance information for the product at that establishment. Therefore, the plan must contain sufficient detail to allow the regulator to fully understand the operations and the intended controls. Products requiring a variance are those which are deemed to be time/temperature control for safety food and for which retail production would otherwise be prohibited.

To assist food establishments in applying HACCP principles at retail, FDA has issued a document entitled: Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level. This document is available from FDA and can be found on the FDA Web Page at: http://www.fda.gov/RetailFoodProtection.

Under the Fish and Fishery Products regulation, every seafood processor is required to perform a hazard analysis, and must have and implement a written HACCP Plan whenever a hazard analysis reveals a food safety hazard that is reasonably likely to occur. HACCP plans developed pursuant to the Fish and Fishery Products regulation are for all products in the class and are not for products for which production is presently prohibited. Plans will be reviewed on site, with records available to judge, among other things, the adequacy of past corrective actions.

It is intended that the Food Code will be amended to incorporate federal HACCP regulations and guidelines by inclusion in the text of the Food Code, by reference, or through the issuance of interpretations. This will provide alternatives to the preapproval of HACCP plans, such as simplified HACCP plans in line with the Fish and Fishery Products model, if the product is produced under a HACCP plan developed in conformance with such regulation or guideline. In so doing, the need for preapproved plans under the more intensive regimen of the Food Code will be significantly reduced.

HACCP plans are key to the use of performance standards as measures of regulatory compliance. Performance standards issued by the Food Safety and Inspection Service are applicable to a broad range of meat, poultry, and egg products. Federal performance standards are acceptable, equivalent alternatives to the command-and-control provisions that now provide specific times and temperatures for processing various products. Federal performance standards may be used to determine the safety of a product or process under the Food Code if authorized under a variance granted in accord with the Code's variance provisions, and demonstrated by adherence to a validated HACCP plan, consistent with the Code's HACCP provisions.

7. CODE ADOPTION/CERTIFIED COPIES

The model Food Code is provided for use by food regulatory jurisdictions at all levels of government. At the state and local levels the model may be:

(A) Enacted into statute as an act of the state legislative body;

(B) Promulgated as a regulation, if the state legislative body has delegated rule-making authority to a governmental administrative agency; or

(C) Adopted as an ordinance, if the local legislative body has been delegated rule-making authority or regulatory powers.

Typically, code adoption bodies publish a notice of their intent to adopt a code, make copies available for public inspection, and provide an opportunity for public input prior to adoption. This is usually done in one of two ways.

The recommended method is the "short form" or "adoption by reference" approach where a simple statement is published stating that certified copies of the proposed code are on file for public review. This approach may be used by governmental bodies located in states that have enabling laws authorizing the adoption of codes by reference. An advantage to this approach is a substantial reduction in the cost of publishing and printing.

Certified copies of the Food Code for use in adopting the model by reference are available through the FDA Retail Food Protection Team, HFS-320, 5100 Paint Branch Parkway, College Park, MD 20740-3835. Refer to item 2. *(A)* of this Preface to access a listing of jurisdictions' adoptions.

The alternative method is the "long form" or "section-by-section" approach where the proposed code is published in its entirety.

Both methods of adoption allow for the modification of specific provisions to accommodate existing law, administrative procedure, or regulatory policy. Annex 7 contains model adoption forms for use by governmental bodies who wish to use either of these methods.

8. INFORMATION TO ASSIST THE USER

Many of the improvements contained in the model Food Code, as listed under item 5 of this Preface, are provided to make the document easier to use. Other characteristics of the new edition, if they are understood by the user, make it easier to follow and apply. These include structure, nomenclature, and methodology.

Food Code provisions address essentially four areas: personnel (Chapter 2), food (Chapter 3), equipment/facilities/supplies (Chapters 4, 5, 6, 7), and compliance and enforcement (Chapter 8). A new user will find it helpful to review the Table of Contents together with the Code Reference Sheet (Annex 7, Guide 3-B) in order to quickly gain an understanding of the scope and sequence of subjects included within these four areas. The structural nomenclature of the document is as follows:

Chapter	9
Part	9-1
Subpart	9-101
Section (§)	9-101.11
Paragraph (¶)	9-101.11(A)
Subparagraph	9-101.11(A)(1)

Code provisions are either appropriate for citing and debiting on an inspection report or they are not. Those not intended for citing/debiting are identified by the digits following the decimal point in the numbering system. These "nondebitable" provisions fall into two categories, those that end with two digits after the decimal point and the last digit is a zero, e.g., § 1-201.10; and those that end with three digits after the decimal point and the last 2 digits are zeros, e.g., § 8-805.100.

Two types of internal cross referencing are widely used throughout the Code to eliminate the need for restating provisions.

A. The first type of cross reference uses phrases that contain the word "under", e.g., "as specified **under** … (followed by the relevant portion of the Code)."

   The purpose of this type of cross reference is to:

   1) Alert the reader to relevant information, and

   2) Provide a system by which each violation is recorded under the one most appropriate provision. This type of cross reference signals to the reader the provision of the Code under which a certain violation is properly cited/debited.

B. The second type of cross reference uses phrases that contain the word "in," e.g., "as specified **in**... (followed by the relevant portion of the Code)."

   The purpose of this type of cross reference is to:

   1) Indicate the specific provisions of a separate document such as a federal regulation that are being incorporated by reference in the requirement of the Code, e.g., ¶ 3-201.11(C); or

2) Refer the reader to a nondebitable provision of the Code which provides further information for consideration, such as provision for an exception or for an allowance to comply via an alternative method.

   For example, ¶ 3-201.16 (A) begins with "Except as specified in ¶ (B)…" and ¶ (B) states the relevant exceptions to ¶ (A). Paragraph 3-201.11(E) states in part, "… as specified *in* ¶ 3-401.11(C)" and ¶ 3-401.11(C) provides for an allowance to serve or sell raw or undercooked, whole-meat, intact beef steaks in a ready-to-eat form.

   If you review the exception in ¶ 3-201.16(B) and the allowance in ¶ 3-401.11(C), you will see that exceptions and allowances often contain conditions of compliance, i.e., conditions that must be met in order for the exception or allowance to convey.

Based on the violation being cited, the substance of the text being referred to, and the context in which the reference is made, users of the Code must infer the intent of the cross reference. That is, the user must determine if the cross reference simply alerts the user to additional information about the requirement or if the cross reference:

- sends (via the word "under") the citing/debiting to another Code provision;
  or
- incorporates (via the word "in") the referenced requirements into the Code provision.

The Food Code presents requirements by principle rather than by subject. For example, equipment requirements are presented under headings such as Materials, Design and Construction, Numbers and Capacities, Location and Installation, and Maintenance and Operation rather than by refrigerators, sinks, and thermometers. In this way provisions need be stated only once rather than repeated for each piece or category of equipment. Where there are special requirements for certain equipment, the requirement is delineated under the appropriate principle (e.g., Design and Construction) and listed separately in the index.

Portions of some sections are written in *italics.* These provisions are not requirements, but are provided to convey relevant information about specific exceptions and alternative means for compliance. Italics are pursuant to a preceding provision that states a requirement, to which the italics offer an exception or another possibility. Italicized sections usually involve the words "except for," "may", "need not" or "does not apply." See ¶ 3-202.18(D).

The former use of "critical" or "non-critical" has been changed in recognition of the need to better identify risk-based controls within the Code's provisions. Requirements contained in the Food Code are presented as being in one of three categories of importance: PRIORITY ITEM (i.e. a provision in this Code whose application

contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard); PRIORITY FOUNDATION ITEM (i.e., a provision in this Code whose application supports, facilitates or enables one or more PRIORITY ITEMS); and, CORE ITEM (i.e., a provision in this Code that is not designated as a PRIORITY ITEM or a PRIORITY FOUNDATION ITEM and that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

A "P" or "Pf" designation after a paragraph or subparagraph indicates that the provision within that section is a PRIORITY ITEM or PRIORITY FOUNDATION ITEM. Any unmarked provisions within a section are CORE ITEMS.

The following conventions are used in the Food Code. "Shall" means the act is imperative, i.e., "shall" constitutes a command. "May not" means absolute prohibition. "May" is permissive and means the act is allowed. The term "means" is followed by a declared fact.

Defined words and terms are in "small caps" in the text of the Food Code chapters to alert the reader to the fact that there is a specific meaning assigned to those words and terms and that the meaning of a provision is to be interpreted in the defined context. A concerted effort was also made to place in "small caps" all forms and combinations of those defined words and terms that were intended to carry the weight of the definition.

The annexes located at the back of the document can provide tremendous assistance to those charged with applying Food Code provisions. No reference is made in the text of a provision to the annexes which support its requirements. This is necessary in order to keep future laws or other requirements based on the model Food Code "clean." However, the annexes are provided specifically to assist the regulatory authority apply the provisions uniformly and effectively.

It is, therefore, important for users to preview the subject and essence of each of the annexes before using the document. Some of the annexes (e.g., References, Public Health Reasons) are structured to present the information by the specific Food Code item number to which they apply. Other annexes provide information and materials intended to be helpful to the user such as model forms that can be used, a delineation of the principles of HACCP, guidelines for establishment inspection, and criteria for certain food processes for use in evaluating proposed HACCP plans.

9. THE CODE REVISION PROCESS

(A) Food Code Revision and Publication Cycles

FDA is issuing a new edition of the Food Code every 4 years. During the 4-year span of time between editions, FDA may issue supplements to an existing edition. Each new edition will incorporate the changes made in the supplement as well as any new revisions.

(B) Submission of Food Code Change Suggestions

FDA will continue to receive concerns and recommendations for modification of the Food Code from any individual or organization.

Given the purpose of the document as discussed in item 2 of this Preface, the Agency will be especially interested in addressing problems identified by those in government and industry who are responsible for implementing the Food Code. FDA will also be especially responsive to those needed policy and technical changes raised by an organization that uses a democratic process for addressing problems and concerns.

Included are organizations that provide a process that encourages representative participation in deliberations by government, industry, and academic and consumer interests, followed by public health ratification such as a state-by-state vote by officially designated delegates. The Conference for Food Protection (retail food issues), the National Conference on Interstate Milk Shipments (milk and dairy products issues), and the Interstate Shellfish Sanitation Conference (molluscan shellfish issues) are examples of such organizations. These organizations receive problems submitted by any interested individual, but specify the forms on which the issues must be detailed and provide specific time frames during which they may be submitted.

FDA encourages interested individuals to consider raising issues and suggesting solutions involving the federal-state cooperative programs based on FDA's model codes through these organizations.

10. ACKNOWLEDGMENTS

Many individuals devoted considerable time and effort in addressing concerns and developing recommendations that are now reflected in the Food Code. These individuals represent a wide diversity of regulators, educators, industry leaders, and consumer representatives acting through their agencies, companies, professional groups, or trade organizations. It is only through the dedicated efforts and contributions of experienced professionals that a scientifically sound, well focused, and up-to-date model code is possible. FDA acknowledges with gratitude the substantial assistance of those who contributed to public health and food safety in the development of the Food Code.

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Chapter

1 Purpose and Definitions

Parts

1-1 TITLE, INTENT, SCOPE

Subparts

Title

1-101.10 Food Code.

These provisions shall be known as the Food Code, hereinafter referred to as "this Code."

Intent

1-102.10 Food Safety, Illness Prevention, and Honest Presentation.

The purpose of this Code is to safeguard public health and provide to CONSUMERS FOOD that is safe, unADULTERATED, and honestly presented.

Scope

1-103.10 Statement.

This Code establishes definitions; sets standards for management and personnel, FOOD operations, and EQUIPMENT and facilities; and provides for FOOD ESTABLISHMENT plan review, PERMIT issuance, inspection, EMPLOYEE RESTRICTION, and PERMIT suspension.

1-2 DEFINITIONS

Subpart

1-201 Applicability and Terms Defined

Applicability and Terms Defined 1-201.10 Statement of Application and Listing of Terms.

(A) The following definitions shall apply in the interpretation and application of this Code.

(B) Terms Defined. As used in this Code, each of the terms listed in ¶ 1-201.10(B) shall have the meaning stated below.

Accredited Program.

(1) **"Accredited program"** means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals.

(2) **"Accredited program"** refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, re-certification, discipline and grievance procedures; and test development and administration.

(3) ***"Accredited program"*** *does not refer to training functions or educational programs*.

Additive.

(1) **"Food additive"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR 170.3(e)(1).

(2) **"Color additive"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR 70.3(f).

"Adulterated" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 402.

"Approved" means acceptable to the REGULATORY AUTHORITY based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

Asymptomatic.

(1) **"Asymptomatic"** means without obvious symptoms; not showing or producing indications of a disease or other medical condition, such as an individual infected with a pathogen but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice.

(2) **"Asymptomatic"** includes not showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.

"a_w" means water activity which is a measure of the free moisture in a FOOD, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol A_W.

"Balut" means an embryo inside a fertile EGG that has been incubated for a period sufficient for the embryo to reach a specific stage of development after which it is removed from incubation before hatching.

"Beverage" means a liquid for drinking, including water.

"Bottled drinking water" means water that is SEALED in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

"Casing" means a tubular container for sausage products made of either natural or artificial (synthetic) material.

"Certification number" means a unique combination of letters and numbers assigned by a SHELLFISH CONTROL AUTHORITY to a MOLLUSCAN SHELLFISH DEALER according to the provisions of the National Shellfish Sanitation Program.

"CFR" means CODE OF FEDERAL REGULATIONS. Citations in this Code to the CFR refer sequentially to the Title, Part, and Section numbers, such as 40 CFR 180.194 refers to Title 40, Part 180, Section 194.

CIP.

(1) **"CIP"** means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and SANITIZING solution onto or over EQUIPMENT surfaces that require cleaning, such as the method used, in part, to clean and SANITIZE a frozen dessert machine.

(2) ***"CIP"*** *does not include the cleaning of EQUIPMENT such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system.*

"Commingle" means:

(1) To combine SHELLSTOCK harvested on different days or from different growing areas as identified on the tag or label, or

(2) To combine SHUCKED SHELLFISH from containers with different container codes or different shucking dates.

Comminuted.

(1) **"Comminuted"** means reduced in size by methods including chopping, flaking, grinding, or mincing.

(2) **"Comminuted"** includes FISH or MEAT products that are reduced in size and restructured or reformulated such as gefilte FISH, gyros, ground beef, and sausage; and a mixture of 2 or more types of MEAT that have been reduced in size and combined, such as sausages made from 2 or more MEATS.

"Conditional employee" means a potential FOOD EMPLOYEE to whom a job offer is made, conditional on responses to subsequent medical questions or examinations designed to identify potential FOOD EMPLOYEES who may be suffering from a disease that can be transmitted through FOOD and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.

"Confirmed disease outbreak" means a FOODBORNE DISEASE OUTBREAK in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the FOOD as the source of the illness.

"Consumer" means a PERSON who is a member of the public, takes possession of FOOD, is not functioning in the capacity of an operator of a FOOD ESTABLISHMENT or FOOD PROCESSING PLANT, and does not offer the FOOD for resale.

Core Item.

(1) **"Core item"** means a provision in this Code that is not designated as a PRIORITY ITEM or a PRIORITY FOUNDATION ITEM.

(2) **"Core item"** includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

"Corrosion-resistant material" means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the FOOD to be contacted, the normal use of cleaning compounds and SANITIZING solutions, and other conditions of the use environment.

"Counter-mounted equipment" means EQUIPMENT that is not portable and is designed to be mounted off the floor on a table, counter, or shelf.

"Critical control point" means a point or procedure in a specific FOOD system where loss of control may result in an unacceptable health RISK.

"Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a CRITICAL CONTROL POINT to minimize the RISK that the identified FOOD safety HAZARD may occur.

"Cut leafy greens" means fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. The term "leafy greens" includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard. The term "leafy greens" does not include herbs such as cilantro or parsley.

"Dealer" means a PERSON who is authorized by a SHELLFISH CONTROL AUTHORITY for the activities of SHELLSTOCK shipper, shucker-packer, repacker, reshipper, or depuration processor of MOLLUSCAN SHELLFISH according to the provisions of the National Shellfish Sanitation Program.

"Disclosure" means a written statement that clearly identifies the animal-derived FOODS which are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.

Drinking Water.

(1) **"Drinking water"** means water that meets criteria as specified in 40 CFR 141 National Primary Drinking Water Regulations.

(2) **"Drinking water"** is traditionally known as "potable water."

(3) **"Drinking water"** includes the term "water" *except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water*.

"Dry storage area" means a room or area designated for the storage of PACKAGED or containerized bulk FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and dry goods such as SINGLE-SERVICE items.

Easily Cleanable.

(1) **"Easily cleanable"** means a characteristic of a surface that:

(a) Allows effective removal of soil by normal cleaning methods;

(b) Is dependent on the material, design, construction, and installation of the surface; and

(c) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into FOOD based on the surface's APPROVED placement, purpose, and use.

(2) **"Easily cleanable"** includes a tiered application of the criteria that qualify the surface as EASILY CLEANABLE as specified in Subparagraph (1) of this definition to different situations in which varying degrees of cleanability are required such as:

(a) The appropriateness of stainless steel for a FOOD preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for CONSUMER dining; or

(b) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the CONSUMER dining area.

"Easily movable" means:

(1) Portable; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of EQUIPMENT for cleaning; and

(2) Having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the EQUIPMENT to be moved for cleaning of the EQUIPMENT and adjacent area.

Egg.

(1) **"Egg"** means the shell EGG of avian species such as chicken, duck, goose, guinea, quail, RATITES or turkey.

(2) ***"Egg"*** *does not include*:

(a) *A BALUT;*

(b) *The egg of reptile species such as alligator; or*

(c) *An EGG PRODUCT*.

Egg Product.

(1) **"Egg Product"** means all, or a portion of, the contents found inside EGGS separated from the shell and pasteurized in a FOOD PROCESSING PLANT, with or without added ingredients, intended for human consumption, such as dried, frozen or liquid eggs.

(2) ***"Egg Product"*** *does not include FOOD which contains EGGS only in a relatively small proportion such as cake mixes*.

"Employee" means the PERMIT HOLDER, PERSON IN CHARGE, FOOD EMPLOYEE, PERSON having supervisory or management duties, PERSON on the payroll, family member, volunteer, PERSON performing work under contractual agreement, or other PERSON working in a FOOD ESTABLISHMENT.

"EPA" means the U.S. Environmental Protection Agency.

Equipment.

(1) **"Equipment"** means an article that is used in the operation of a FOOD ESTABLISHMENT such as a freezer, grinder, hood, ice maker, MEAT block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, TEMPERATURE MEASURING DEVICE for ambient air, VENDING MACHINE, or WAREWASHING machine.

(2) ***"Equipment"*** *does not include apparatuses used for handling or storing large quantities of PACKAGED FOODS that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.*

"Exclude" means to prevent a PERSON from working as an EMPLOYEE in a FOOD ESTABLISHMENT or entering a FOOD ESTABLISHMENT as an EMPLOYEE.

"FDA" means the U.S. Food and Drug Administration.

Fish.

(1) **"Fish"** means fresh or saltwater finfish, crustaceans and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption.

(2) **"Fish"** includes an edible human FOOD product derived in whole or in part from FISH, including FISH that have been processed in any manner.

"Food" means a raw, cooked, or processed edible substance, ice, BEVERAGE, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

"Foodborne disease outbreak" means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common FOOD.

"Food-contact surface" means:

(1) A surface of EQUIPMENT or a UTENSIL with which FOOD normally comes into contact; or

(2) A surface of EQUIPMENT or a UTENSIL from which FOOD may drain, drip, or splash:

(a) Into a FOOD, or

(b) Onto a surface normally in contact with FOOD.

"Food employee" means an individual working with unPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES.

Food Establishment.

(1) **"Food establishment"** means an operation that:

(a) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides FOOD for human consumption such as a restaurant; satellite or catered feeding location; catering operation if the operation provides FOOD directly to a CONSUMER or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or FOOD bank; and

(b) relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(2) **"Food establishment"** includes:

(a) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location *unless the vending or feeding location is permitted by the* REGULATORY AUTHORITY; and

(b) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD.

(3) **"*Food establishment*"** *does not include:*

(a) *An establishment that offers only pre*PACKAGED FOODS *that are not* TIME/TEMPERATURE CONTROL FOR SAFETY FOODS;

(b) *A produce stand that only offers whole, uncut fresh fruits and vegetables*;

(c) *A* FOOD PROCESSING PLANT*; including those that are located on the PREMISES of a FOOD ESTABLISHMENT*

(d) *A kitchen in a private home if only* FOOD *that is not* TIME/TEMPERATURE CONTROL FOR SAFETY FOOD*, is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by* LAW *and if the* CONSUMER *is informed by a clearly visible placard at the sales or service location that the* FOOD *is prepared in a kitchen that is not subject to regulation and inspection by the* REGULATORY AUTHORITY*;*

(e) *An area where* FOOD *that is prepared as specified in Subparagraph (3)(d) of this definition is sold or offered for human consumption*;

(f) *A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers* FOOD *to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the* CONSUMER *is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the* FOOD *is prepared in a kitchen that is not regulated and inspected by the* REGULATORY AUTHORITY*; or*

(g) *A private home that receives catered or home-delivered* FOOD.

Food Processing Plant.

(1) **"Food processing plant"** means a commercial operation that manufactures, packages, labels, or stores FOOD for human consumption, and provides FOOD for sale or distribution to other business entities such as FOOD PROCESSING PLANTS or FOOD ESTABLISHMENTS.

(2) ***"Food processing plant"*** *does not include a FOOD ESTABLISHMENT.*

Game Animal.

(1) **"Game animal"** means an animal, the products of which are FOOD, that is not classified as livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2 Definitions, or as Poultry, or FISH.

(2) **"Game animal"** includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.

(3) **"*Game animal*"** *does not include RATITES*.

"General use pesticide" means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175 Pesticides classified for restricted use.

"Grade A standards" means the requirements of the United States Public Health Service/FDA "Grade A Pasteurized Milk Ordinance" with which certain fluid and dry milk and milk products comply.

"HACCP plan" means a written document that delineates the formal procedures for following the HAZARD Analysis and CRITICAL CONTROL POINT principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

Handwashing Sink.

(1) **"Handwashing sink"** means a lavatory, a basin or vessel for washing, a wash basin, or a PLUMBING FIXTURE especially placed for use in personal hygiene and designed for the washing of the hands.

(2) **"Handwashing sink"** includes an automatic handwashing facility.

"Hazard" means a biological, chemical, or physical property that may cause an unacceptable CONSUMER health RISK.

"Health practitioner" means a physician licensed to practice medicine, or if allowed by LAW, a nurse practitioner, physician assistant, or similar medical professional.

"Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned FOODS, to maintain the commercial sterility of its contents after processing.

"Highly susceptible population" means PERSONS who are more likely than other people in the general population to experience foodborne disease because they are:

(1) Immunocompromised; preschool age children, or older adults; and

(2) Obtaining FOOD at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

"Imminent health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:

(1) The number of potential injuries, and

(2) The nature, severity, and duration of the anticipated injury.

"Injected" means manipulating MEAT to which a solution has been introduced into its interior by processes that are referred to as "injecting," “pump marinating,” or "stitch pumping”.

Juice.

(1) **"Juice"** means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or purée.

(2) ***"Juice"*** *does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as* BEVERAGES *or ingredients of* BEVERAGES.

"Kitchenware" means FOOD preparation and storage UTENSILS.

"Law" means applicable local, state, and federal statutes, regulations, and ordinances.

"Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.

Major Food Allergen.

(1) **"Major food allergen"** means:

(a) Milk, EGG, FISH (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

(b) A FOOD ingredient that contains protein derived from a FOOD, as specified in Subparagraph (1)(a) of this definition.

(2) ***"Major food allergen"*** *does not include:*

(a) *Any highly refined oil derived from a* FOOD *specified in Subparagraph (1)(a) of this definition and any ingredient derived from such highly refined oil; or*

(b) *Any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282)*.

"Meat" means the flesh of animals used as FOOD including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, *except* FISH, POULTRY, *and wild* GAME ANIMALS *as specified under Subparagraphs 3-201.17(A)(3) and (4).*

Mechanically Tenderized.

(1) **"Mechanically tenderized"** means manipulating meat with deep penetration by processes which may be referred to as “blade tenderizing,” “jaccarding,” “pinning,” “needling,” or using blades, pins, needles or any mechanical device.

(2) **"Mechanically tenderized"** does not include processes by which solutions are INJECTED into meat.

"mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

"Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, *except when the scallop product consists only of the shucked adductor muscle*.

Non-Continuous Cooking.

(1) **"Non-continuous cooking"** means the cooking of FOOD in a FOOD ESTABLISHMENT using a process in which the initial heating of the FOOD is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service.

(2) **"Non-continuous cooking"** does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

Packaged.

(1) **"Packaged"** means bottled, canned, cartoned, bagged, or wrapped, whether PACKAGED in a FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT.

(2) ***"Packaged"*** *does not include wrapped or placed in a carry-out container to protect the FOOD during service or delivery to the CONSUMER, by a FOOD EMPLOYEE, upon CONSUMER request.*

"Permit" means the document issued by the REGULATORY AUTHORITY that authorizes a PERSON to operate a FOOD ESTABLISHMENT.

"Permit holder" means the entity that:

(1) Is legally responsible for the operation of the FOOD ESTABLISHMENT such as the owner, the owner's agent, or other PERSON; and

(2) Possesses a valid PERMIT to operate a FOOD ESTABLISHMENT.

"Person" means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

"Person in charge" means the individual present at a FOOD ESTABLISHMENT who is responsible for the operation at the time of inspection.

Personal Care Items.

(1) **"Personal care items"** means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a PERSON'S health, hygiene, or appearance.

(2) **"Personal care items"** include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

"pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.

"Physical facilities" means the structure and interior surfaces of a FOOD ESTABLISHMENT including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

"Plumbing fixture" means a receptacle or device that:

(1) Is permanently or temporarily connected to the water distribution system of the PREMISES and demands a supply of water from the system; or

(2) Discharges used water, waste materials, or SEWAGE directly or indirectly to the drainage system of the PREMISES.

"Plumbing system" means the water supply and distribution pipes; PLUMBING FIXTURES and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the PREMISES; and water-treating EQUIPMENT.

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in 4 categories:

(1) Cleaners and SANITIZERS, which include cleaning and SANITIZING agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

(2) Pesticides, *except SANITIZERS*, which include substances such as insecticides and rodenticides;

(3) Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and PERSONAL CARE ITEMS that may be deleterious to health; and

(4) Substances that are not necessary for the operation and maintenance of the establishment and are on the PREMISES for retail sale, such as petroleum products and paints.

"Poultry" means:

(1) Any domesticated bird (chickens, turkeys, ducks, geese, guineas, RATITES, or squabs), whether live or dead, as defined in 9 CFR 381.1 Poultry Products Inspection Regulations Definitions, Poultry; and

(2) Any migratory waterfowl or game bird, pheasant, partridge, quail, grouse, or pigeon, whether live or dead, as defined in 9 CFR 362.1 Voluntary Poultry Inspection Regulations, Definitions.

"Premises" means:

(1) The PHYSICAL FACILITY, its contents, and the contiguous land or property under the control of the PERMIT HOLDER; or

(2) The PHYSICAL FACILITY, its contents, and the land or property not described in Subparagraph (1) of this definition if its facilities and contents are under the control of the PERMIT HOLDER and may impact FOOD ESTABLISHMENT personnel, facilities, or operations, and a FOOD ESTABLISHMENT is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

"Primal cut" means a basic major cut into which carcasses and sides of MEAT are separated, such as a beef round, pork loin, lamb flank, or veal breast.

Priority Item.

(1) **"Priority item"** means a provision in this Code whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard.

(2) **"Priority item"** includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and

(3) **"Priority item"** is an item that is denoted in this Code with a superscript P-^{P}.

Priority Foundation Item.

(1) **"Priority foundation item"** means a provision in this Code whose application supports, facilitates or enables one or more PRIORITY ITEMS.

(2) **"Priority foundation item"** includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and

(3) **"Priority foundation item"** is an item that is denoted in this Code with a superscript Pf - ^{Pf}.

"Public water system" has the meaning stated in 40 CFR 141 National Primary Drinking Water Regulations.

"Ratite" means a flightless bird such as an emu, ostrich, or rhea.

Ready-to-Eat Food.

(1) **"Ready-to-eat food"** means FOOD that:

(a) Is in a form that is edible without additional preparation to achieve FOOD safety, as specified under one of the following: ¶ 3-401.11(A) or (B), § 3-401.12, or § 3-402.11, or as specified in ¶ 3-401.11(C); or

(b) Is a raw or partially cooked animal FOOD and the consumer is advised as specified in Subparagraphs 3-401.11(D)(1) and (3); or

(c) Is prepared in accordance with a variance that is granted as specified in Subparagraph 3-401.11(D) (4); and

(d) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

(2) **"Ready-to-eat food"** includes:

(a) Raw animal FOOD that is cooked as specified under § 3-401.11 or 3-401.12, or frozen as specified under § 3-402.11;

(b) Raw fruits and vegetables that are washed as specified under § 3-302.15;

(c) Fruits and vegetables that are cooked for hot holding, as specified under § 3-401.13;

(d) All TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is cooked to the temperature and time required for the specific FOOD under Subpart 3-401 and cooled as specified under § 3-501.14;

(e) Plant FOOD for which further washing, cooking, or other processing is not required for FOOD safety, and from which rinds, peels, husks, or shells, if naturally present are removed;

(f) Substances derived from plants such as spices, seasonings, and sugar;

(g) A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for FOOD safety;

(h) The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured MEAT and POULTRY products, such as prosciutto ham, country cured ham, and Parma ham; and dried MEAT and POULTRY products, such as jerky or beef sticks; and

(i) FOODS manufactured as specified in 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers.

Reduced Oxygen Packaging.

(1) **"Reduced oxygen packaging"** means:

(a) The reduction of the amount of oxygen in a PACKAGE by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and

(b) A process as specified in Subparagraph (1)(a) of this definition that involves a FOOD for which the HAZARDS ***Clostridium botulinum*** or ***Listeria monocytogenes*** require control in the final PACKAGED form.

(2) **"Reduced oxygen packaging"** includes:

(a) Vacuum PACKAGING, in which air is removed from a PACKAGE of FOOD and the PACKAGE is HERMETICALLY SEALED so that a vacuum remains inside the PACKAGE;

(b) Modified atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the PACKAGING material or the respiration of the FOOD. Modified atmosphere PACKAGING includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen;

(c) Controlled atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that until the PACKAGE is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring FOOD, and impermeable PACKAGING material;

(d) Cook chill PACKAGING, in which cooked FOOD is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

(e) Sous vide PACKAGING, in which raw or partially cooked FOOD is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

"Refuse" means solid waste not carried by water through the SEWAGE system.

"Regulatory authority" means the local, state, or federal enforcement body or authorized representative having jurisdiction over the FOOD ESTABLISHMENT.

"Reminder" means a written statement concerning the health RISK of consuming animal FOODS raw, undercooked, or without otherwise being processed to eliminate pathogens.

"Re-service" means the transfer of FOOD that is unused and returned by a CONSUMER after being served or sold and in the possession of the CONSUMER, to another PERSON.

"Restrict" means to limit the activities of a FOOD EMPLOYEE so that there is no RISK of transmitting a disease that is transmissible through FOOD and the FOOD EMPLOYEE does not work with exposed FOOD, clean EQUIPMENT, UTENSILS, LINENS, or unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES.

"Restricted egg" means any check, dirty EGG, incubator reject, inedible, leaker, or loss as defined in 9 CFR 590.

"Restricted use pesticide" means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 Pesticides classified for restricted use, and that is limited to use by or under the direct supervision of a certified applicator.

"Risk" means the likelihood that an adverse health effect will occur within a population as a result of a HAZARD in a FOOD.

"Safe material" means:

(1) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any FOOD;

(2) An additive that is used as specified in § 409 of the Federal Food, Drug, and Cosmetic Act; or

(3) Other materials that are not ADDITIVES and that are used in conformity with applicable regulations of the Food and Drug Administration.

"Sanitization" means the application of cumulative heat or chemicals on cleaned FOOD-CONTACT SURFACES that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

"Sealed" means free of cracks or other openings that allow the entry or passage of moisture.

"Service animal" means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to an individual with a disability.

"Servicing area" means an operating base location to which a mobile FOOD ESTABLISHMENT or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding FOOD.

"Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

"Shellfish control authority" means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of MOLLUSCAN SHELLFISH harvesters and DEALERs for interstate commerce.

"Shellstock" means raw, in-shell MOLLUSCAN SHELLFISH.

"Shiga toxin-producing *Escherichia coli*" (STEC) means any ***E. coli*** capable of producing Shiga toxins (also called verocytotoxins). STEC infections can be asymptomatic or may result in a spectrum of illness ranging from mild non-bloody diarrhea, to hemorrhagic colitis (i.e., bloody diarrhea), to hemolytic uremic syndrome (HUS - a type of kidney failure). Examples of serotypes of STEC include: *E. coli* O157:H7; *E. coli* O157:NM; *E. coli* O26:H11; *E. coli* O145:NM; *E. coli* O103:H2; and *E. coli* O111:NM. STEC are sometimes referred to as VTEC (verocytotoxigenic *E. coli*) or as EHEC (Enterohemorrhagic *E. coli*). EHEC are a subset of STEC which can cause hemorrhagic colitis or HUS.

"Shucked shellfish" means MOLLUSCAN SHELLFISH that have one or both shells removed.

"Single-service articles" means TABLEWARE, carry-out UTENSILS, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one PERSON use after which they are intended for discard.

Single-Use Articles.

(1) **"Single-use articles"** means UTENSILS and bulk FOOD containers designed and constructed to be used once and discarded.

(2) **"Single-use articles"** includes items such as wax paper, butcher paper, plastic wrap, formed aluminum FOOD containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength, and cleanability specifications under §§ 4-101.11, 4-201.11, and 4-202.11 for multiuse UTENSILS.

"Slacking" means the process of moderating the temperature of a FOOD such as allowing a FOOD to gradually increase from a temperature of -23°C (-10°F) to -4°C (25°F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen FOOD such as shrimp.

"Smooth" means:

(1) A FOOD-CONTACT SURFACE having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number 3 stainless steel;

(2) A nonFOOD-CONTACT SURFACE of EQUIPMENT having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and

(3) A floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

"Tableware" means eating, drinking, and serving UTENSILS for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, and tumblers; and plates.

"Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of FOOD, air, or water.

"Temporary food establishment" means a FOOD ESTABLISHMENT that operates for a period of no more than 14 consecutive days in conjunction with a single event or celebration.

Time/Temperature Control for Safety Food (formerly “potentially hazardous food” (PHF)).

(1) **"Time/temperature control for safety food"** means a FOOD that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

(2) **"Time/temperature control for safety food"** includes:

(a) An animal FOOD that is raw or heat-treated; a plant FOOD that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and

(b) Except as specified in Subparagraph (3)(d) of this definition, a FOOD that because of the interaction of its A_W and pH values is designated as Product Assessment Required (PA) in Table A or B of this definition:

Table A. Interaction of pH and A_W for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

A_W values	pH: 4.6 or less	pH: > 4.6 - 5.6	pH: > 5.6
≤0.92	non-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 - 0.95	non-TCS FOOD	non-TCS FOOD	PA**
> 0.95	non-TCS FOOD	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD
** PA means Product Assessment required

Table B. Interaction of pH and A_W for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

A_W values	pH: < 4.2	pH: 4.2 - 4.6	pH: > 4.6 - 5.0	pH: > 5.0
< 0.88	non-TCS food*	Non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD
** PA means Product Assessment required

(3) "***Time/temperature control for safety food***" *does not include:*

(a) *An air-cooled hard-boiled EGG with shell intact, or an EGG with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable* ***salmonellae****;*

(b) *A FOOD in an unopened* HERMETICALLY SEALED CONTAINER *that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;*

(c) *A FOOD that because of its pH or A_W value, or interaction of A_W and pH values, is designated as a non-TCS FOOD in Table A or B of this definition;*

(d) *A FOOD that is designated as Product Assessment Required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that FOOD is precluded due to:*

(i) *Intrinsic factors including added or natural characteristics of the FOOD such as preservatives, antimicrobials, humectants, acidulants, or nutrients,*

(ii) *Extrinsic factors including environmental or operational factors that affect the FOOD such as packaging, modified atmosphere such as REDUCED OXYGEN PACKAGING, shelf life and use, or temperature range of storage and use, or*

(iii) *A combination of intrinsic and extrinsic factors; or*

(e) *A* FOOD *that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the Subparagraphs (3)(a) - (3)(d) of this definition even though the* FOOD *may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.*

"USDA" means the U.S. Department of Agriculture.

"Utensil" means a FOOD-CONTACT implement or container used in the storage, preparation, transportation, dispensing, sale, or service of FOOD, such as KITCHENWARE or TABLEWARE that is multiuse, SINGLE-SERVICE, or SINGLE-USE; gloves used in contact with FOOD; temperature sensing probes of FOOD TEMPERATURE MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD.

"Variance" means a written document issued by the REGULATORY AUTHORITY that authorizes a modification or waiver of one or more requirements of this Code if, in the opinion of the REGULATORY AUTHORITY, a health HAZARD or nuisance will not result from the modification or waiver.

"Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of FOOD in bulk or in packages without the necessity of replenishing the device between each vending operation.

"Vending machine location" means the room, enclosure, space, or area where one or more VENDING MACHINES are installed and operated and includes the storage areas and areas on the PREMISES that are used to service and maintain the VENDING MACHINES.

"Warewashing" means the cleaning and SANITIZING of UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT.

"Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

Chapter

2 Management and Personnel

Parts

2-1 SUPERVISION

Subparts

Responsibility

2-101.11 Assignment.

(A) Except as specified in ¶ (B) of this section, the PERMIT HOLDER shall be the PERSON IN CHARGE or shall designate a PERSON IN CHARGE and shall ensure that a PERSON IN CHARGE is present at the FOOD ESTABLISHMENT during all hours of operation.[Pf]

(B) In a FOOD ESTABLISHMENT with two or more separately PERMITTED departments that are the legal responsibility of the same PERMIT HOLDER and that are located on the same PREMISES, the PERMIT HOLDER may, during specific time periods when food is not being prepared, packaged, or served, designate a single PERSON IN CHARGE who is present on the PREMISES during all hours of operation, and who is responsible for each separately PERMITTED FOOD ESTABLISHMENT on the PREMISES.[Pf]

Knowledge

2-102.11 Demonstration.

Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by:

(A) Complying with this Code by having no violations of PRIORITY ITEMS during the current inspection; [Pf]

(B) Being a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM;[Pf] or

(C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation. The areas of knowledge include:

(1) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a FOOD EMPLOYEE; [Pf]

(2) Explaining the responsibility of the PERSON IN CHARGE for preventing the transmission of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne disease; [Pf]

(3) Describing the symptoms associated with the diseases that are transmissible through FOOD; [Pf]

(4) Explaining the significance of the relationship between maintaining the time and temperature of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and the prevention of foodborne illness; [Pf]

(5) Explaining the HAZARDS involved in the consumption of raw or undercooked MEAT, POULTRY, EGGS, and FISH; [Pf]

(6) Stating the required FOOD temperatures and times for safe cooking of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD including MEAT, POULTRY, EGGS, and FISH; [Pf]

(7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD; Pf

(8) Describing the relationship between the prevention of foodborne illness and the management and control of the following:

(a) Cross contamination, Pf

(b) Hand contact with READY-TO-EAT FOODS, Pf

(c) Handwashing, Pf and

(d) Maintaining the FOOD ESTABLISHMENT in a clean condition and in good repair; Pf

(9) Describing FOODS identified as MAJOR FOOD ALLERGENS and the symptoms that a MAJOR FOOD ALLERGEN could cause in a sensitive individual who has an allergic reaction. Pf

(10) Explaining the relationship between FOOD safety and providing EQUIPMENT that is:

(a) Sufficient in number and capacity, Pf and

(b) Properly designed, constructed, located, installed, operated, maintained, and cleaned; Pf

(11) Explaining correct procedures for cleaning and SANITIZING UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT; Pf

(12) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections; Pf

(13) Identifying POISONOUS OR TOXIC MATERIALS in the FOOD ESTABLISHMENT and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to LAW; Pf

(14) Identifying CRITICAL CONTROL POINTS in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code; Pf

(15) Explaining the details of how the PERSON IN CHARGE and FOOD EMPLOYEES comply with the HACCP PLAN if a plan is required by the LAW, this Code, or an agreement between the REGULATORY AUTHORITY and the FOOD ESTABLISHMENT; Pf

(16) Explaining the responsibilities, rights, and authorities assigned by this Code to the:

(a) FOOD EMPLOYEE, Pf

(b) CONDITIONAL EMPLOYEE, Pf

(c) PERSON IN CHARGE, Pf

(d) REGULATORY AUTHORITY; Pf and

(17) Explaining how the PERSON IN CHARGE, FOOD EMPLOYEES, and CONDITIONAL EMPLOYEES comply with reporting responsibilities and EXCLUSION or RESTRICTION of FOOD EMPLOYEES. Pf

2-102.12 Certified Food Protection Manager

(A) At least one EMPLOYEE that has supervisory and management responsibility and the authority to direct and control FOOD preparation and service shall be a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM.

(B) This section does not apply to certain types of FOOD ESTABLISHMENTS deemed by the REGULATORY AUTHORITY to pose minimal risk of causing, or contributing to, foodborne illness based on the nature of the operation and extent of FOOD preparation.

2-102.20 Food Protection Manager Certification.

(A) A PERSON IN CHARGE who demonstrates knowledge by being a FOOD protection manager that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of FOOD Protection Manager Certification Programs is deemed to comply with ¶2-102.11(B).

(B) A FOOD ESTABLISHMENT that has an EMPLOYEE that is certified by a FOOD protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of FOOD Protection Manager Certification Programs is deemed to comply with §2-102.12.

Duties

2-103.11 Person in Charge.

The PERSON IN CHARGE shall ensure that:

(A) FOOD ESTABLISHMENT operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under § 6-202.111; [Pf]

(B) PERSONS unnecessary to the FOOD ESTABLISHMENT operation are not allowed in the FOOD preparation, FOOD storage, or WAREWASHING areas, except that brief visits and tours may be authorized by the PERSON IN CHARGE if steps are taken to ensure that exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES are protected from contamination; [Pf]

(C) EMPLOYEES and other PERSONS such as delivery and maintenance PERSONS and pesticide applicators entering the FOOD preparation, FOOD storage, and WAREWASHING areas comply with this Code; [Pf]

(D) EMPLOYEES are effectively cleaning their hands, by routinely monitoring the EMPLOYEES' handwashing; [Pf]

(E) EMPLOYEES are visibly observing FOODS as they are received to determine that they are from APPROVED sources, delivered at the required temperatures, protected from contamination, UNADULTERED, and accurately presented, by routinely monitoring the EMPLOYEES' observations and periodically evaluating FOODS upon their receipt; [Pf]

(F) EMPLOYEES are verifying that FOODS delivered to the FOOD ESTABLISHMENT during non-operating hours are from APPROVED sources and are placed into appropriate storage locations such that they are maintained at the required temperatures, protected from contamination, unADULTERATED, and accurately presented;[Pf]

(G) EMPLOYEES are properly cooking TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, being particularly careful in cooking those FOODS known to cause severe foodborne illness and death, such as EGGS and COMMINUTED MEATS, through daily oversight of the EMPLOYEES' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under § 4-203.11 and ¶ 4-502.11(B); [Pf]

(H) EMPLOYEES are using proper methods to rapidly cool TIME/TEMPERATURE CONTROL FOR SAFETY FOODS that are not held hot or are not for consumption within 4 hours, through daily oversight of the EMPLOYEES' routine monitoring of FOOD temperatures during cooling; [Pf]

(I) CONSUMERS who order raw; or partially cooked READY-TO-EAT FOODS of animal origin are informed as specified under § 3-603.11 that the FOOD is not cooked sufficiently to ensure its safety; [Pf]

(J) EMPLOYEES are properly SANITIZING cleaned multiuse EQUIPMENT and UTENSILS before they are reused, through routine monitoring of solution temperature and exposure time for hot water SANITIZING, and chemical concentration, pH, temperature, and exposure time for chemical SANITIZING; [Pf]

(K) CONSUMERS are notified that clean TABLEWARE is to be used when they return to self-service areas such as salad bars and buffets as specified under § 3-304.16; [Pf]

(L) Except when APPROVAL is obtained from the REGULATORY

AUTHORITY as specified in ¶ 3-301.11(E), EMPLOYEES are preventing cross-contamination of READY-TO-EAT FOOD with bare hands by properly using suitable UTENSILS such as deli tissue, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT; [Pf]

(M) EMPLOYEES are properly trained in FOOD safety, including FOOD allergy awareness, as it relates to their assigned duties;[Pf]

(N) FOOD EMPLOYEES and CONDITIONAL EMPLOYEES are informed in a verifiable manner of their responsibility to report in accordance with LAW, to the PERSON IN CHARGE, information about their health and activities as they relate to diseases that are transmissible through FOOD, as specified under ¶ 2-201.11(A); [Pf] and

(O) Written procedures and plans, where specified by this Code and as developed by the FOOD ESTABLISHMENT, are maintained and implemented as required. [Pf]

2-2 EMPLOYEE HEALTH

Subpart

2-201 Responsibilities of Permit Holder, Person in Employees

Responsibilities and Reporting Symptoms and Diagnosis

2-201.11 Responsibility of Permit Holder, Person in Charge, and Conditional Employees.

(A) The PERMIT HOLDER shall require FOOD EMPLOYEES and CONDITIONAL EMPLOYEES to report to the PERSON IN CHARGE information about their health and activities as they relate to diseases that are transmissible through FOOD. A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report the information in a manner that allows the PERSON IN CHARGE to reduce the RISK of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms, if the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE:

reportable symptoms

(1) Has any of the following symptoms:

(a) Vomiting,[P]

(b) Diarrhea,[P]

(c) Jaundice,[P]

(d) Sore throat with fever,[P] or

(e) A lesion containing pus such as a boil or infected wound that is open or draining and is:

(i) On the hands or wrists, *unless an impermeable cover such as a finger cot or stall protects the lesion and a SINGLE-USE glove is worn over the impermeable cover,*[P]

(ii) On exposed portions of the arms, *unless the lesion is protected by an impermeable cover,*[P] or

(iii) On other parts of the body, *unless the lesion is covered by a dry, durable, tight-fitting bandage;*[P]

reportable diagnosis

(2) Has an illness diagnosed by a HEALTH PRACTITIONER due to:

(a) Norovirus,[P]

(b) Hepatitis A virus,[P]

(c) *Shigella* spp., [P]

(d) SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI,*[P]

(e) *Salmonella* Typhi;[P] or

(f) nontyphoidal *Salmonella*;[P]

reportable past illness

(3) Had a previous illness, diagnosed by a HEALTH PRACTITIONER, within the past 3 months due to *Salmonella* Typhi, without having received antibiotic therapy, as determined by a HEALTH PRACTITIONER;[P]

reportable history of exposure

(4) Has been exposed to, or is the suspected source of, a CONFIRMED DISEASE OUTBREAK, because the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE consumed or prepared FOOD implicated in the outbreak, or consumed FOOD at an event prepared by a PERSON who is infected or ill with:

(a) Norovirus within the past 48 hours of the last exposure,[P]

(b) SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI or Shigella* spp. within the past 3 days of the last exposure,[P]

(c) *Salmonella* Typhi within the past 14 days of the last exposure,[P] or

(d) Hepatitis A virus within the past 30 days of the last exposure;[P] or

reportable history of exposure

(5) Has been exposed by attending or working in a setting where there is a CONFIRMED DISEASE OUTBREAK, or living in the same household as, and has knowledge about, an individual who works or attends a setting where there is a CONFIRMED

DISEASE OUTBREAK, or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:

(a) Norovirus within the past 48 hours of the last exposure,[P]

(b) SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* or *Shigella* spp. within the past 3 days of the last exposure,[P]

(c) *Salmonella* Typhi within the past 14 days of the last exposure,[P] or

(d) Hepatitis A virus within the past 30 days of the last exposure.[P]

responsibility of person in charge to notify the regulatory authority

(B) The PERSON IN CHARGE shall notify the REGULATORY AUTHORITY when a FOOD EMPLOYEE is:

(1) Jaundiced,[Pf] or

(2) Diagnosed with an illness due to a pathogen as specified under Subparagraphs (A)(2)(a) - (f) of this section.[Pf]

responsibility of the person in charge to prohibit a conditional employee from becoming a food employee

(C) The PERSON IN CHARGE shall ensure that a CONDITIONAL EMPLOYEE:

(1) Who exhibits or reports a symptom, or who reports a diagnosed illness as specified under Subparagraphs (A)(1) - (3) of this section, is prohibited from becoming a FOOD EMPLOYEE until the CONDITIONAL EMPLOYEE meets the criteria for the specific symptoms or diagnosed illness as specified under § 2-201.13;[P] and

(2) Who will work as a FOOD EMPLOYEE in a FOOD ESTABLISHMENT that serves as a HIGHLY SUSCEPTIBLE POPULATION and reports a history of exposure as specified under Subparagraphs (A)(4) – (5), is prohibited from becoming a FOOD EMPLOYEE until the CONDITIONAL EMPLOYEE meets the criteria as specified under ¶ 2-201.13(I).[P]

responsibility of the person in charge to exclude or restrict

(D) The PERSON IN CHARGE shall ensure that a FOOD EMPLOYEE who exhibits or reports a symptom, or who reports a diagnosed illness or a history of exposure as specified under Subparagraphs (A)(1) - (5) of this section is:

(1) EXCLUDED as specified under ¶¶ 2-201.12 (A) - (C), and Subparagraphs (D)(1), (E)(1), (F)(1), (G) or (H)(1) and in compliance with the provisions specified under ¶¶ 2-201.13(A) - (H);[P] or

(2) RESTRICTED as specified under Subparagraphs 2-201.12 (D)(2), (E)(2), (F)(2), (H)(2), or ¶¶ 2-201.12(I) or (J) and in compliance with the provisions specified under ¶¶ 2-201.13(D) - (J).[P]

responsibility of food employees and conditional employees to report

(E) A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report to the PERSON IN CHARGE the information as specified under ¶ (A) of this section.[Pf]

responsibility of food employees to comply

(F) A FOOD EMPLOYEE shall:

(1) Comply with an EXCLUSION as specified under ¶¶ 2-201.12(A) - (C) and Subparagraphs 2-201.12(D)(1), (E)(1), (F)(1), (G), or (H)(1) and with the provisions specified under ¶¶ 2-201.13(A) - (H);[P] or

(2) Comply with a RESTRICTION as specified under Subparagraphs 2-201.12(D)(2), (E)(2), (F)(2), (G), (H)(2), or ¶¶ 2-201.12 (H), (I), or (J) and comply with the provisions specified under ¶¶ 2-201.13(D) - (J).[P]

conditions of exclusion and restriction

2-201.12 Exclusions and Restrictions.

The PERSON IN CHARGE shall EXCLUDE or RESTRICT a FOOD EMPLOYEE from a FOOD ESTABLISHMENT in accordance with the following:

symptomatic with vomiting or diarrhea

(A) *Except when the symptom is from a noninfectious condition,* EXCLUDE a FOOD EMPLOYEE if the FOOD EMPLOYEE is:

(1) Symptomatic with vomiting or diarrhea;[P] or

(2) Symptomatic with vomiting or diarrhea and diagnosed with an infection from Norovirus, *Shigella* spp., nontyphoidal *Salmonella,* or SHIGA TOXIN-PRODUCING *E. COLI.*[P]

jaundiced or diagnosed with ***hepatitis A infection***

(B) EXCLUDE a FOOD EMPLOYEE who is:

(1) Jaundiced and the onset of jaundice occurred within the last 7 calendar days, *unless the FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER specifying that the jaundice is not caused by hepatitis A virus or other fecal-orally transmitted infection;*[P]

(2) Diagnosed with an infection from hepatitis A virus within 14 calendar days from the onset of any illness symptoms, or within 7 calendar days of the onset of jaundice;[P] or

(3) Diagnosed with an infection from hepatitis A virus without developing symptoms.[P]

diagnosed or reported previous infection due to ***S. Typhi***

(C) EXCLUDE a FOOD EMPLOYEE who is diagnosed with an infection from *Salmonella* Typhi, or reports a previous infection with *Salmonella* Typhi within the past 3 months as specified under Subparagraph 2-201.11(A)(3).[P]

diagnosed with an asymptomatic infection from ***Norovirus***

(D) If a FOOD EMPLOYEE is diagnosed with an infection from Norovirus and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION;[P] or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.[P]

diagnosed with ***Shigella spp.*** *infection and asymptomatic*

(E) If a FOOD EMPLOYEE is diagnosed with an infection from *Shigella* spp. and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION;[P] or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.[P]

*diagnosed with **STEC** and asymptomatic*

(F) If a FOOD EMPLOYEE is diagnosed with an infection from SHIGA TOXIN-PRODUCING *E. COLI*, and is ASYMPTOMATIC:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION;[P] or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.[P]

*diagnosed with **nontyphoidal Salmonella** and asymptomatic*

(G) If a FOOD EMPLOYEE is diagnosed with an infection from nontyphoidal *Salmonella* and is ASYMPTOMATIC, RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION or in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.[P]

*symptomatic with **sore throat with fever***

(H) If a FOOD EMPLOYEE is ill with symptoms of acute onset of sore throat with fever:

(1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION;[P] or

(2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.[P]

*symptomatic with **uncovered infected wound or pustular boil***

(I) If a FOOD EMPLOYEE is infected with a skin lesion containing pus such as a boil or infected wound that is open or draining and not properly covered as specified under Subparagraph 2-201.11(A)(1)(e), RESTRICT the FOOD EMPLOYEE.[P]

***exposed** to foodborne pathogen and works in food establishment serving HSP*

(J) If a FOOD EMPLOYEE is exposed to a foodborne pathogen as specified under Subparagraphs 2-201.11(A)(4)(a-d) or 2-201.11(A)(5)(a-d), RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION.[P]

Managing Exclusions and Restrictions

2-201.13 Removal, Adjustment, or Retention of Exclusions and Restrictions.

The PERSON IN CHARGE shall adhere to the following conditions when removing, adjusting, or retaining the EXCLUSION or RESTRICTION of a FOOD EMPLOYEE:

(A) *Except when a FOOD EMPLOYEE is diagnosed with an infection from hepatitis A virus or Salmonella* Typhi:

removing exclusion for food employee who was symptomatic and not diagnosed

(1) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraph 2-201.12(A)(1) if the FOOD EMPLOYEE:

(a) Is ASYMPTOMATIC for at least 24 hours;[P] or

(b) Provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER that states the symptom is from a noninfectious condition.[P]

Norovirus diagnosis

(2) If a FOOD EMPLOYEE was diagnosed with an infection from Norovirus and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (D)(1) or (2) of this section are met;[P] or

retaining exclusion for food employee who was asymptomatic and is now asymptomatic and works in food establishment serving HSP

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (D)(1) or (2) of this section are met.[P]

Shigella spp. diagnosis

(3) If a FOOD EMPLOYEE was diagnosed with an infection from *Shigella* spp. and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (E)(1) or (2) of this section are met;[P] or

retaining exclusion for food employee who was asymptomatic and is now asymptomatic

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (E)(1) or (2) , or (E)(1) and (3)(a) of this section are met.[P]

STEC diagnosis

(4) If a FOOD EMPLOYEE was diagnosed with an infection from SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (F)(1) or (2) of this section are met;[P] or

retaining exclusion for food employee who was symptomatic and is now asymptomatic and works in food establishment serving HSP

(b) Retain the EXCLUSION for the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 24 hours and works in a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, until the conditions for reinstatement as specified under Subparagraphs (F)(1) or (2) are met.[P]

Nontyphoidal Salmonella diagnosis

(5) If a FOOD EMPLOYEE was diagnosed with an infection from nontyphoidal *Salmonella* and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):

Adjusting exclusion for food employee who was symptomatic and is now asymptomatic

(a) RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 30 days until conditions for reinstatement as specified under Subparagraphs (G)(1) or (2) of this section are met;[P] or

Retaining exclusion for food employee that remains symptomatic

(b) Retain the EXCLUSION for the FOOD EMPLOYEE who is SYMPTOMATIC, until conditions for reinstatement as specified under Paragraphs (G)(1) or (G)(2) of this section are met.[P]

hepatitis A virus or jaundice diagnosis *- removing exclusions*

(B) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under ¶ 2-201.12(B) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met;

(1) The FOOD EMPLOYEE has been jaundiced for more than 7 calendar days;[P]

(2) The anicteric FOOD EMPLOYEE has been symptomatic with symptoms other than jaundice for more than 14 calendar days;[P] or

(3) The FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a hepatitis A virus infection.[P]

S. Typhi diagnosis - removing exclusions

(C) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under ¶ 2-201.12(C) if:

(1) The PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY;[P] and

(2) The FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER that states the FOOD EMPLOYEE is free from *S.* Typhi infection.[P]

Norovirus diagnosis - removing exclusion or restriction

(D) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraphs 2-201.12(A)(2) or (D)(1) who was RESTRICTED under Subparagraph 2-201.12(D)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a Norovirus infection;[P]

(2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 48 hours have passed since the FOOD EMPLOYEE became ASYMPTOMATIC;[P] or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 48 hours have passed since the FOOD EMPLOYEE was diagnosed.[P]

Shigella spp. diagnosis - removing exclusion or restriction

(E) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraphs 2-201.12(A)(2) or (E)(1) or who was RESTRICTED under Subparagraph 2-201.12(E)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a *Shigella* spp. infection based on test results showing 2 consecutive negative stool specimen cultures that are taken:

(a) Not earlier than 48 hours after discontinuance of antibiotics,[P] and

(b) At least 24 hours apart;[P]

(2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 7 calendar days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC;[P] or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 7 calendar days have passed since the FOOD EMPLOYEE was diagnosed.[P]

STEC diagnosis - removing exclusion or restriction

(F) Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraphs 2-201.12(A)(2) or (F)(1) or who was RESTRICTED under Subparagraph 2-201.12(F)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of an infection from SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* based on test results that show 2 consecutive negative stool specimen cultures that are taken:

(a) Not earlier than 48 hours after discontinuance of antibiotics;[P] and

(b) At least 24 hours apart;[P]

(2) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED after symptoms of vomiting or diarrhea resolved and more than 7 calendar days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC;[P] or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 7 days have passed since the FOOD EMPLOYEE was diagnosed.[P]

nontyphoidal Salmonella -removing exclusion or restriction

(G) Reinstate a food employee who was EXCLUDED as specified under Subpargraph 2-201.12(A)(2) or who was RESTRICTED as specified under ¶ 2-201.12(G) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY [P] and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a nontyphoidal *Salmonella* infection based on test results showing 2 consecutive negative stool specimen cultures that are taken;

(a) Not earlier than 48 hours after discontinuance of antibiotics,[P] and

(b) At least 24 hours apart;[P]

(2) The FOOD EMPLOYEE was RESTRICTED after symptoms of vomiting or diarrhea resolved, and more than 30 days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC;[P] or

(3) The FOOD EMPLOYEE was EXCLUDED or RESTRICTED and did not develop symptoms and more than 30 days have passed since the FOOD EMPLOYEE was diagnosed.[P]

sore throat with fever - removing exclusion or restriction

(H) Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraphs 2-201.12(H)(1) or (2) if the FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE meets one of the following conditions:

(1) Has received antibiotic therapy for *Streptococcus pyogenes* infection for more than 24 hours;[P]

(2) Has at least one negative throat specimen culture for *Streptococcus pyogenes* infection;[P] or

(3) Is otherwise determined by a HEALTH PRACTITIONER to be free of a *Streptococcus pyogenes* infection.[P]

uncovered infected wound or pustular boil - removing restriction

(I) Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under ¶ 2-201.12(I) if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:

(1) An impermeable cover such as a finger cot or stall and a single-use glove over the impermeable cover if the infected wound or pustular boil is on the hand, finger, or wrist;[P]

(2) An impermeable cover on the arm if the infected wound or pustular boil is on the arm;[P]or

(3) A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body.[P]

exposure to foodborne pathogen and works in food establishment serving HSP – removing restriction

(J) Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under ¶ 2-201.12(J) and was exposed to one of the following pathogens as specified under Subparagraph 2-201.11(A)(4)(a-d) or 2-201.11(A)(5)(a-d):

Norovirus

(1) Norovirus and one of the following conditions is met:

(a) More than 48 hours have passed since the last day the FOOD EMPLOYEE was potentially exposed;[P] or

(b) More than 48 hours have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.[P]

Shigella spp. or STEC

(2) *Shigella* spp. or SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* and one of the following conditions is met:

(a) More than 3 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed;[P] or

(b) More than 3 calendar days have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.[P]

***S.* Typhi**

(3) *S.* Typhi and one of the following conditions is met:

(a) More than 14 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed;[P] or

(b) More than 14 calendar days have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.[P]

hepatitis A

(4) Hepatitis A virus and one of the following conditions is met:

(a) The FOOD EMPLOYEE is immune to hepatitis A virus infection because of a prior illness from hepatitis A;[P]

(b) The FOOD EMPLOYEE is immune to hepatitis A virus

infection because of vaccination against hepatitis A;[P]

(c) The FOOD EMPLOYEE is immune to hepatitis A virus infection because of IgG administration;[P]

(d) More than 30 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed;[P]

(e) More than 30 calendar days have passed since the FOOD EMPLOYEE'S household contact became jaundiced;[P] or

(f) The FOOD EMPLOYEE does not use an alternative procedure that allows bare hand contact with READY-TO-EAT FOOD until at least 30 days after the potential exposure, as specified in Subparagraphs (I)(4)(d) and (e) of this section, and the FOOD EMPLOYEE receives additional training about:

(i)Hepatitis A symptoms and preventing the transmission of infection,[P]

(ii) Proper handwashing procedures,[P] and

(iii) Protecting READY-TO-EAT FOOD from contamination introduced by bare hand contact.[P]

2-3 PERSONAL CLEANLINESS

Subparts

Hands and Arms

2-301.11 Clean Condition.

FOOD EMPLOYEES shall keep their hands and exposed portions of their arms clean.[P]

2-301.12 Cleaning Procedure.

(A) Except as specified in ¶ (D) of this section, FOOD EMPLOYEES shall clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands or arms for at least 20 seconds, using a cleaning compound in a HANDWASHING SINK that is equipped as specified under § 5-202.12 and Subpart 6-301. [P]

(B) FOOD EMPLOYEES shall use the following cleaning procedure in the order stated to clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands and arms:

(1) Rinse under clean, running warm water; [P]

(2) Apply an amount of cleaning compound recommended by the cleaning compound manufacturer; [P]

(3) Rub together vigorously for at least 10 to 15 seconds while:

(a) Paying particular attention to removing soil from underneath the fingernails during the cleaning procedure, [P] and

(b) Creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, finger tips, and areas between the fingers; P

(4) Thoroughly rinse under clean, running warm water; P and

(5) Immediately follow the cleaning procedure with thorough drying using a method as specified under § 6-301.12. P

(C) *To avoid recontaminating their hands or surrogate prosthetic devices, FOOD EMPLOYEES may use disposable paper towels or similar clean barriers when touching surfaces such as manually operated faucet handles on a HANDWASHING SINK or the handle of a restroom door*.

(D) *If APPROVED and capable of removing the types of soils encountered in the FOOD operations involved, an automatic handwashing facility may be used by FOOD EMPLOYEES to clean their hands or surrogate prosthetic devices.*

2-301.13 Special Handwash Procedures.

Reserved.

2-301.14 When to Wash.

FOOD EMPLOYEES shall clean their hands and exposed portions of their arms as specified under § 2-301.12 immediately before engaging in FOOD preparation including working with exposed FOOD, clean EQUIPMENT and UTENSILS, and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES P and:

(A) After touching bare human body parts other than clean hands and clean, exposed portions of arms; P

(B) After using the toilet room; P

(C) After caring for or handling SERVICE ANIMALS or aquatic animals as specified in ¶ 2-403.11(B); P

(D) Except as specified in ¶ 2-401.11(B), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking; P

(E) After handling soiled EQUIPMENT or UTENSILS; [P]

(F) During FOOD preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks; [P]

(G) When switching between working with raw FOOD and working with READY-TO-EAT FOOD; [P]

(H) Before donning gloves to initiate a task that involves working with FOOD; [P] and

(I) After engaging in other activities that contaminate the hands.[P]

2-301.15 Where to Wash.

FOOD EMPLOYEES shall clean their hands in a HANDWASHING SINK or APPROVED automatic handwashing facility and may not clean their hands in a sink used for FOOD preparation or WAREWASHING, or in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste. [Pf]

2-301.16 Hand Antiseptics.

(A) A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:

(1) Comply with one of the following:

(a) Be an APPROVED drug that is listed in the FDA publication **Approved Drug Products with Therapeutic Equivalence Evaluations** as an APPROVED drug based on safety and effectiveness; [Pf] or

(b) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, [Pf] and

(2) Consist only of components which the intended use of each complies with one of the following:

(a) A threshold of regulation exemption under 21 CFR 170.39 - Threshold of regulation for substances used in FOOD-contact articles;[Pf] or

(b) 21 CFR 178 - Indirect FOOD Additives: Adjuvants, Production Aids, and Sanitizers as regulated for use as a FOOD ADDITIVE with conditions of safe use, [Pf] or

(c) A determination of generally recognized as safe (GRAS). Partial listings of substances with FOOD uses that are GRAS may be found in 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct FOOD Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 – Indirect FOOD Substances Affirmed as Generally Recognized as Safe for use in contact with FOOD, and in FDA's Inventory of GRAS Notices, [Pf] or

(d) A prior sanction listed under 21 CFR 181 – Prior Sanctioned FOOD Ingredients,[Pf] or

(e) a FOOD Contact Notification that is effective,[PF] and

(3) Be applied only to hands that are cleaned as specified under § 2-301.12. [Pf]

(B) If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified under Subparagraph (A)(2) of this section, use shall be:

(1) Followed by thorough hand rinsing in clean water before hand contact with FOOD or by the use of gloves; [Pf] or

(2) Limited to situations that involve no direct contact with FOOD by the bare hands. [Pf]

(C) A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 MG/L chlorine. [Pf]

Fingernails

2-302.11 Maintenance.

(A) FOOD EMPLOYEES shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough. [Pf]

(B) *Unless wearing intact gloves in good repair*, a FOOD EMPLOYEE may not wear fingernail polish or artificial fingernails when working with exposed FOOD. [Pf]

Jewelry

2-303.11 Prohibition.

Except for *a plain ring such as a wedding band,* while preparing FOOD, FOOD EMPLOYEES may not wear jewelry including medical information jewelry on their arms and hands.

Outer Clothing

2-304.11 Clean Condition.

FOOD EMPLOYEES shall wear clean outer clothing to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

2-4 HYGIENIC PRACTICES

Subparts

Food Contamination Prevention

2-401.11 Eating, Drinking, or Using Tobacco.

(A) Except as specified in ¶ (B) of this section, an EMPLOYEE shall eat, drink, or use any form of tobacco only in designated areas where the contamination of exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES; or other items needing protection can not result.

(B) *A FOOD EMPLOYEE may drink from a closed BEVERAGE container if the container is handled to prevent contamination of:*

(1) *The EMPLOYEE'S hands;*

(2) *The container; and*

(3) *Exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.*

2-401.12 Discharges from the Eyes, Nose, and Mouth.

FOOD EMPLOYEES experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth may not work with exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; or unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES.

Hair Restraints

2-402.11 Effectiveness.

(A) Except as provided in ¶ (B) of this section, FOOD EMPLOYEES shall wear hair restraints such as hats, hair coverings or nets, beard restraints, and clothing that covers body hair, that are designed and worn to effectively keep their hair from contacting exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

(B) *This section does not apply to FOOD EMPLOYEES such as counter staff who only serve BEVERAGES and wrapped or PACKAGED FOODS, hostesses, and wait staff if they present a minimal RISK of contaminating exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES*.

Animals

2-403.11 Handling Prohibition.

(A) Except as specified in ¶ (B) of this section, FOOD EMPLOYEES may not care for or handle animals that may be present such as patrol dogs, SERVICE ANIMALS, or pets that are allowed as specified in Subparagraphs 6-501.115(B)(2)-(5). [Pf]

(B) *FOOD EMPLOYEES with SERVICE ANIMALS may handle or care for their SERVICE ANIMALS and FOOD EMPLOYEES may handle or care for FISH in aquariums or MOLLUSCAN SHELLFISH or crustacea in display tanks if they wash their hands as specified under § 2-301.12 and ¶ 2-301.14(C).*

2-5 RESPONDING TO CONTAMINATION EVENTS

Subpart

2-501 Procedures for Responding

2-501.11 Clean-up of Vomiting and Diarrheal Events.

A FOOD ESTABLISHMENT shall have procedures for EMPLOYEES to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the FOOD ESTABLISHMENT. The procedures shall address the specific actions EMPLOYEES must take to minimize the spread of contamination and the exposure of EMPLOYEES, consumers, FOOD, and surfaces to vomitus or fecal matter. [Pf]

Chapter

3 Food

Parts

3-1 CHARACTERISTICS

Subparts

Condition

3-101.11 Safe, Unadulterated, and Honestly Presented.

FOOD shall be safe, UNADULTERATED, and, as specified under § 3-601.12, honestly presented.[P]

3-2 SOURCES, SPECIFICATIONS, AND ORIGINAL CONTAINERS AND RECORDS

Subparts

Sources

3-201.11 Compliance with Food Law.

(A) FOOD shall be obtained from sources that comply with LAW.[P]

(B) FOOD prepared in a private home may not be used or offered for human consumption in a FOOD ESTABLISHMENT.[P]

(C) PACKAGED FOOD shall be labeled as specified in LAW, including 21 CFR 101 FOOD Labeling, 9 CFR 317 Labeling, Marking Devices, and Containers, and 9 CFR 381 Subpart N Labeling and Containers, and as specified under §§ 3-202.17 and 3-202.18.[Pf]

(D) FISH, *other than those specified in paragraph 3-402.11(B), that are intended for consumption in raw or undercooked form and allowed as specified in paragraph 3-401.11(D), may be offered for sale or service if they are obtained from a supplier that freezes the FISH as specified under § 3-402.11; or if they are frozen on the PREMISES as specified under § 3-402.11 and records are retained as specified under § 3-402.12.*

(E) WHOLE-MUSCLE, INTACT BEEF steaks that are intended for consumption in an undercooked form without a CONSUMER adv1isory as specified in ¶ 3-401.11(C) shall be:

(1) Obtained from a FOOD PROCESSING PLANT that, upon request by the purchaser, packages the steaks and labels them, to indicate that the steaks meet the definition of WHOLE-MUSCLE, INTACT BEEF,[Pf] or

(2) Deemed acceptable by the REGULATORY AUTHORITY based on other evidence, such as written buyer specifications or invoices, that indicates that the steaks meet the definition of WHOLE-MUSCLE, INTACT BEEF,[Pf] and

(3) If individually cut in a FOOD ESTABLISHMENT:

(a) Cut from WHOLE-MUSCLE INTACT BEEF that is labeled by a FOOD PROCESSING PLANT as specified in Subparagraph (E)(1) of this section or identified as specified in Subparagraph (E)(2) of this section, [Pf]

(b) Prepared so they remain intact, [Pf] and

(c) If PACKAGED for undercooking in a FOOD ESTABLISHMENT, labeled as specified in Subparagraph (E)(1) of this section or identified as specified in (E)(2) of this section. [Pf]

(F) MEAT and POULTRY that is not a READY-TO-EAT FOOD and is in a PACKAGED form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in LAW, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

(G) EGGS that have not been specifically treated to destroy all viable ***Salmonellae*** shall be labeled to include safe handling instructions as specified in LAW, including 21 CFR 101.17(h).

3-201.12 Food in a Hermetically Sealed Container.

FOOD in a HERMETICALLY SEALED CONTAINER shall be obtained from a FOOD PROCESSING PLANT that is regulated by the FOOD regulatory agency that has jurisdiction over the plant. [P]

3-201.13 Fluid Milk and Milk Products.

Fluid milk and milk products shall be obtained from sources that comply with GRADE A STANDARDS as specified in LAW. [P]

3-201.14 Fish.

(A) FISH that are received for sale or service shall be:

(1) Commercially and legally caught or harvested; [P] or

(2) APPROVED for sale or service. [P]

(B) MOLLUSCAN SHELLFISH that are recreationally caught may not be received for sale or service. [P]

3-201.15 Molluscan Shellfish.

(A) MOLLUSCAN SHELLFISH shall be obtained from sources according to LAW and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. [P]

(B) MOLLUSCAN SHELLFISH received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List. [P]

3-201.16 Wild Mushrooms.

(A) Except as specified in ¶ (B) of this section, mushroom species picked in the wild shall not be offered for sale or service by a FOOD ESTABLISHMENT unless the FOOD ESTABLISHMENT has been APPROVED to do so. [P]

(B) *This section does not apply to:*

(1) *Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the FOOD regulatory agency that has jurisdiction over the operation; or*

(2) *Wild mushroom species if they are in packaged form and are the product of a FOOD PROCESSING PLANT that is regulated by the FOOD regulatory agency that has jurisdiction over the plant.*

3-201.17 Game Animals.

(A) If GAME ANIMALS are received for sale or service they shall be:

(1) Commercially raised for FOOD [P] and:

(a) Raised, slaughtered, and processed under a voluntary inspection program that is conducted by the agency that has animal health jurisdiction, [P] or

(b) Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction, [P] and

(c) Raised, slaughtered, and processed according to:

(i) LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, [P] and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an APPROVED veterinarian or veterinarian's designee; [P]

(2) Under a voluntary inspection program administered by the USDA for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and APPROVED" in accordance with 9 CFR 352 Exotic animals; voluntary inspection or rabbits that are "inspected and certified" in accordance with 9 CFR 354 voluntary inspection of rabbits and edible products thereof; [P]

(3) As allowed by LAW, for wild GAME ANIMALS that are live-caught:

(a) Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction, [P] and

(b) Slaughtered and processed according to:

(i) LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, [P] and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an APPROVED veterinarian or veterinarian's designee; [P] or

(4) As allowed by LAW, for field-dressed wild GAME ANIMALS under a routine inspection program that ensures the animals:

(a) Receive a postmortem examination by an APPROVED veterinarian or veterinarian's designee, [P] or

(b) Are field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program, [P] and

(c) Are processed according to LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program. [P]

(B) A GAME ANIMAL may not be received for sale or service if it is a species of wildlife that is listed in 50 CFR 17 Endangered and threatened wildlife and plants.

Specifications for Receiving

3-202.11 Temperature.

(A) Except as specified in ¶ (B) of this section, refrigerated, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be at a temperature of 5°C (41°F) or below when received. [P]

(B) *If a temperature other than 5°C (41°F) for a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD is specified in LAW governing its distribution, such as LAWS governing milk and MOLLUSCAN SHELLFISH, the FOOD may be received at the specified temperature.*

(C) Raw EGGS shall be received in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F) or less. [P]

(D) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is cooked to a temperature and for a time specified under §§ 3-401.11 - 3-401.13 and received hot shall be at a temperature of 57°C (135°F) or above. [P]

(E) A FOOD that is labeled frozen and shipped frozen by a FOOD PROCESSING PLANT shall be received frozen. [Pf]

(F) Upon receipt, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be free of evidence of previous temperature abuse. [Pf]

3-202.12 Additives.

FOOD may not contain unAPPROVED FOOD ADDITIVES or ADDITIVES that exceed amounts specified in 21 CFR 170-180 relating to FOOD ADDITIVES, generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181-186, substances that exceed amounts specified in 9 CFR Subpart C Section 424.21(b) Food ingredients and sources of radiation, or pesticide residues that exceed provisions specified in 40 CFR 180 Tolerances for pesticides chemicals in food, and exceptions. [P]

3-202.13 Eggs.

EGGS shall be received clean and sound and may not exceed the restricted EGG tolerances for U.S. Consumer Grade B as specified in United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56.200 *et seq*., administered by the Agricultural Marketing Service of USDA. [P]

3-202.14 Eggs and Milk Products, Pasteurized.

(A) EGG PRODUCTS shall be obtained pasteurized. [P]

(B) Fluid and dry milk and milk products shall:

(1) Be obtained pasteurized; [P] and

(2) Comply with GRADE A STANDARDS as specified in LAW. [P]

(C) Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in 21 CFR 135 - Frozen desserts. [P]

(D) Cheese shall be obtained pasteurized *unless alternative procedures to pasteurization are specified in the CFR, such as 21 CFR 133 - Cheeses and related cheese products, for curing certain cheese varieties.* [P]

3-202.15 Package Integrity.

FOOD packages shall be in good condition and protect the integrity of the contents so that the FOOD is not exposed to ADULTERATION or potential contaminants. [Pf]

3-202.16 Ice.

Ice for use as a FOOD or a cooling medium shall be made from DRINKING WATER. [P]

3-202.17 Shucked Shellfish, Packaging and Identification.

(A) Raw SHUCKED SHELLFISH shall be obtained in nonreturnable packages which bear a legible label that identifies the: [Pf]

(1) Name, address, and CERTIFICATION NUMBER of the shucker, packer or repacker of the MOLLUSCAN SHELLFISH; [Pf] and

(2) The "sell by" or "best if used by" date for packages with a capacity of less than 1.89 L (one-half gallon) or the date shucked for packages with a capacity of 1.89 L (one-half gallon) or more. [Pf]

(B) A package of raw SHUCKED SHELLFISH that does not bear a label or which bears a label which does not contain all the information as specified under ¶ (A) of this section shall be subject to a hold order, as allowed by LAW, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d) Molluscan shellfish.

3-202.18 Shellstock Identification.

(A) SHELLSTOCK shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester or DEALER that depurates, ships, or reships the SHELLSTOCK, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that list: [Pf]

(1) Except as specified under ¶ (C) of this section, on the harvester's tag or label, the following information in the following order: [Pf]

(a) The harvester's identification number that is assigned by the SHELLFISH CONTROL AUTHORITY, [Pf]

(b) The date of harvesting, [Pf]

(c) The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the SHELLFISH CONTROL AUTHORITY and including the abbreviation of the name of the state or country in which the shellfish are harvested, [Pf]

(d) The type and quantity of shellfish, [Pf] and

(e) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days"; [Pf] and

(2) Except as specified in ¶ (D) of this section, on each DEALER'S tag or label, the following information in the following order: [Pf]

(a) The DEALER'S name and address, and the CERTIFICATION NUMBER assigned by the SHELLFISH CONTROL AUTHORITY, [Pf]

(b) The original shipper's CERTIFICATION NUMBER including the abbreviation of the name of the state or country in which the shellfish are harvested, [Pf]

(c) The same information as specified for a harvester's tag under Subparagraphs (A)(1)(b)-(d) of this section, [Pf] and

(d) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for 90 days." [Pf]

(B) A container of SHELLSTOCK that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified under ¶ (A) of this section shall be subject to a hold order, as allowed by LAW, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

(C) If a place is provided on the harvester's tag or label for a DEALER's name, address, and CERTIFICATION NUMBER, the DEALER's information shall be listed first.

(D) *If the harvester's tag or label is designed to accommodate each DEALER's identification as specified under Subparagraphs (A)(2)(a) and (b) of this section, individual DEALER tags or labels need not be provided.*

3-202.19 Shellstock, Condition.

When received by a FOOD ESTABLISHMENT, SHELLSTOCK shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or SHELLSTOCK with badly broken shells shall be discarded.

3-202.110 Juice Treated.

Commercially Processed

Pre-PACKAGED JUICE shall:

(A) Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120 Hazard Analysis and Critical Control (HACCP) Systems; [Pf] and

(B) Be obtained pasteurized or otherwise treated to attain a 5-log reduction of the most resistant microorganism of public health significance as specified in 21 CFR Part 120.24 Process Controls. [P]

Original Containers and Records

3-203.11 Molluscan Shellfish, Original Container.

(A) Except as specified in ¶¶ (B) - (D) of this section, MOLLUSCAN SHELLFISH may not be removed from the container in which they are received other than immediately before sale or preparation for service.

(B) *For display purposes,* SHELLSTOCK *may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a* CONSUMER *may be removed from the display or display container and provided to the* CONSUMER *if:*

(1) *The source of the* SHELLSTOCK *on display is identified as specified under § 3-202.18 and recorded as specified under § 3-203.12; and*

(2) *The* SHELLSTOCK *are protected from contamination.*

(C) *S*HUCKED SHELLFISH *may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a* CONSUMER'S *request if:*

(1) *The labeling information for the shellfish on display as specified under § 3-202.17 is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and*

(2) *The shellfish are protected from contamination.*

(D) *S*HUCKED SHELLFISH *may be removed from the container in which they were received and repacked in* CONSUMER *self service containers where allowed by* LAW *if:*

(1) *The labeling information for the shellfish is on each* CONSUMER *self service container as specified under § 3-202.17 and ¶¶ 3-602.11(A) and (B)(1) - (5);*

(2) *The labeling information as specified under § 3-202.17 is retained and correlated with the date when, or dates during which, the shellfish are sold or served;*

(3) *The labeling information and dates specified under Subparagraph (D)(2) of this section are maintained for 90 days; and*

(4) *The shellfish are protected from contamination.*

3-203.12 Shellstock, Maintaining Identification.

(A) Except as specified under Subparagraph (C) (2) of this section, SHELLSTOCK tags or labels shall remain attached to the container in which the SHELLSTOCK are received until the container is empty. [Pf]

(B) The date when the last SHELLSTOCK from the container is sold or served shall be recorded on the tag or label. [Pf]

(C) The identity of the source of SHELLSTOCK that are sold or served shall be maintained by retaining SHELLSTOCK tags or labels for 90 calendar days from the date that is recorded on the tag or label, as specified under ¶ B of this section, by: [Pf]

(1) Using an APPROVED record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under ¶ B of this section; [Pf] and

(2) If SHELLSTOCK are removed from its tagged or labeled container:

(a) Preserving source identification by using a record keeping system as specified under Subparagraph (C)(1) of this section, [Pf] and

(b) Ensuring that SHELLSTOCK from one tagged or labeled container are not COMMINGLED with SHELLSTOCK from another container with different CERTIFICATION NUMBERS; different harvest dates; or different growing areas as identified on the tag or label before being ordered by the CONSUMER. [Pf]

3-3 PROTECTION FROM CONTAMINATION AFTER RECEIVING

Subparts

Preventing Contamination by Employees

3-301.11 Preventing Contamination from Hands.

(A) FOOD EMPLOYEES shall wash their hands as specified under § 2-301.12.

(B) *Except when washing fruits and vegetables as specified under §3-302.15 or as specified in ¶¶ (D) and (E) of this section,* FOOD EMPLOYEES may not contact exposed, READY-TO-EAT FOOD with their bare hands and shall use suitable UTENSILS such as deli tissue, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT. [P]

(C) FOOD EMPLOYEES shall minimize bare hand and arm contact with exposed FOOD that is not in a READY-TO-EAT form. [Pf]

(D) *Paragraph (B) of this section does not apply to a FOOD EMPLOYEE that contacts exposed, READY-TO-EAT FOOD with bare hands at the time the READY-TO-EAT FOOD is being added as an ingredient to a FOOD that:*

(1) contains a raw animal FOOD and is to be cooked in the FOOD ESTABLISHMENT to heat all parts of the FOOD to the minimum temperatures specified in ¶¶3-401.11(A)-(B) or §3-401.12; or

(2) does not contain a raw animal FOOD but is to be cooked in the FOOD ESTABLISHMENT to heat all parts of the FOOD to a temperature of at least 63°C (145°F).

(E) *FOOD EMPLOYEES not serving a HIGHLY SUSCEPTIBLE POPULATION may contact exposed, READY-TO-EAT FOOD with their bare hands if:*

(1) *The PERMIT HOLDER obtains prior APPROVAL from the REGULATORY AUTHORITY;*

(2) *Written procedures are maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request that include:*

(a) *For each bare hand contact procedure, a listing of the specific READY-TO-EAT FOODS that are touched by bare hands,*

(b) *Diagrams and other information showing that handwashing facilities, installed, located, equipped, and maintained as specified under §§ 5-203.11, 5-204.11, 5-205.11, 6-301.11, 6-301.12, and 6-301.14, are in an easily accessible location and in close proximity to the work station where the bare hand contact procedure is conducted;*

(3) *A written EMPLOYEE health policy that details how the FOOD ESTABLISHMENT complies with §§ 2-201.11, 2-201.12, and 2-201.13 including*:

(a) *Documentation that FOOD EMPLOYEES and CONDITIONAL EMPLOYEES acknowledge that they are informed to report information about their health and activities as they relate to gastrointestinal symptoms and diseases that are transmittable through FOOD as specified under ¶ 2-201.11(A)*,

(b) *Documentation that FOOD EMPLOYEES and CONDITIONAL EMPLOYEES acknowledge their responsibilities as specified under ¶ 2-201.11(E) and (F), and*

(c) *Documentation that the PERSON IN CHARGE acknowledges the responsibilities as specified under ¶¶ 2-201.11(B), (C) and (D), and §§ 2-201.12 and 2-201.13*;

(4) *Documentation that FOOD EMPLOYEES acknowledge that they have received training in*:

(a) *The* RISKS *of contacting the specific* READY-TO-EAT FOODS *with bare hands*,

(b) *Proper handwashing as specified under § 2-301.12*,

(c) *When to wash their hands as specified under § 2-301.14*,

(d) *Where to wash their hands as specified under § 2-301.15*,

(e) *Proper fingernail maintenance as specified under § 2-302.11*,

(f) *Prohibition of jewelry as specified under § 2-303.11, and*

(g) *Good hygienic practices as specified under §§2-401.11 and 2-401.12;*

(5) *Documentation that hands are washed before* FOOD *preparation and as necessary to prevent cross contamination by* FOOD EMPLOYEES *as specified under §§ 2-301.11, 2-301.12, 2-301.14, and 2-301.15 during all hours of operation when the specific* READY-TO-EAT FOODS *are prepared*;

(6) *Documentation that* FOOD EMPLOYEES *contacting* READY-TO-EAT FOOD *with bare hands use two or more of the following control measures to provide additional safeguards to* HAZARDS *associated with bare hand contact*:

(a) *Double handwashing,*

(b) *Nail brushes,*

(c) *A hand antiseptic after handwashing as specified under § 2-301.16,*

(d) *Incentive programs such as paid sick leave that assist or encourage* FOOD EMPLOYEES *not to work when they are ill, or*

(e) *Other control measures* APPROVED *by the* REGULATORY AUTHORITY*; and*

(7) *Documentation that corrective action is taken when Subparagraphs (E)(1) - (6) of this section are not followed*.

3-301.12 Preventing Contamination When Tasting.

A FOOD EMPLOYEE may not use a UTENSIL more than once to taste FOOD that is to be sold or served. [P]

Preventing Food and Ingredient Contamination

3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.

(A) FOOD shall be protected from cross contamination by:

(1) Except as specified in (1)(c) below, separating raw animal FOODS during storage, preparation, holding, and display from:

(a) Raw READY-TO-EAT FOOD including other raw animal FOOD such as FISH for sushi or MOLLUSCAN SHELLFISH, or other raw READY-TO-EAT FOOD such as fruits and vegetables, [P] and

(b) Cooked READY-TO-EAT FOOD; [P]

(c) *Frozen, commercially processed and packaged raw animal FOOD may be stored or displayed with or above frozen, commercially processed and packaged, ready-to-eat food.*

(2) *Except when combined as ingredients*, separating types of raw animal FOODS from each other such as beef, FISH, lamb, pork, and POULTRY during storage, preparation, holding, and display by:

(a) Using separate EQUIPMENT for each type, [P] or

(b) Arranging each type of FOOD in EQUIPMENT so that cross contamination of one type with another is prevented, [P] and

(c) Preparing each type of FOOD at different times or in separate areas; [P]

(3) Cleaning EQUIPMENT and UTENSILS as specified under

¶ 4-602.11(A) and SANITIZING as specified under § 4-703.11;

(4) Except as specified under Subparagraph 3-501.15(B)(2) and in ¶ (B) of this section, storing the FOOD in packages, covered containers, or wrappings;

(5) Cleaning HERMETICALLY SEALED CONTAINERS of FOOD of visible soil before opening;

(6) Protecting FOOD containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;

(7) Storing damaged, spoiled, or recalled FOOD being held in the FOOD ESTABLISHMENT as specified under § 6-404.11; and

(8) Separating fruits and vegetables, before they are washed as specified under § 3-302.15 from READY-TO-EAT FOOD.

(B) *Subparagraph (A)(4) of this section does not apply to:*

(1) Whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;

(2) *PRIMAL CUTS, quarters, or sides of raw MEAT or slab bacon that are hung on clean, SANITIZED hooks or placed on clean, SANITIZED racks;*

(3) *Whole, uncut, processed MEATS such as country hams, and smoked or cured sausages that are placed on clean, SANITIZED racks;*

(4) *FOOD being cooled as specified under Subparagraph 3-501.15(B)(2); or*

(5) *SHELLSTOCK*.

3-302.12 Food Storage Containers, Identified with Common Name of Food.

Except for containers holding FOOD *that can be readily and unmistakably recognized such as dry pasta,* working containers holding FOOD or FOOD ingredients that are removed from their original packages for use in the FOOD ESTABLISHMENT, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar shall be identified with the common name of the FOOD.

3-302.13 Pasteurized Eggs, Substitute for Raw Eggs for Certain Recipes.

Pasteurized EGGS or EGG PRODUCTS shall be substituted for raw EGGS in the preparation of FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and EGG-fortified BEVERAGES that are not: [P]

(A) Cooked as specified under Subparagraphs 3-401.11(A)(1) or (2); [P] or

(B) Included in ¶ 3-401.11(D). [P]

3-302.14 Protection from Unapproved Additives.

(A) FOOD shall be protected from contamination that may result from the addition of, as specified in § 3-202.12:

(1) Unsafe or unAPPROVED FOOD or COLOR ADDITIVES; [P] and

(2) Unsafe or unAPPROVED levels of APPROVED FOOD and COLOR ADDITIVES. [P]

(B) A FOOD EMPLOYEE may not:

(1) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a FOOD considered to be a good source of vitamin B_1; [P] or

(2) *Except for grapes,* serve or sell FOOD specified under Subparagraph (B)(1) of this section that is treated with sulfiting agents before receipt by the FOOD ESTABLISHMENT. [P]

3-302.15 Washing Fruits and Vegetables.

(A) *Except as specified in ¶ (B) of this section and except for whole,* raw *fruits and vegetables that are intended for washing by the* CONSUMER *before consumption,* raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in READY-TO-EAT form.

(B) *Fruits and vegetables may be washed by using chemicals as specified under § 7-204.12.*

(C) Devices used for on-site generation of chemicals meeting the requirements specified in 21 CFR 173.315, Chemicals used in the washing or to assist in the peeling of fruits and vegetables, for the washing of raw, whole fruits and vegetables shall be used in accordance with the manufacturer's instructions. [Pf]

Preventing Contamination from Ice Used as a Coolant

3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient.

After use as a medium for cooling the exterior surfaces of FOOD such as melons or FISH, PACKAGED FOODS such as canned BEVERAGES, or cooling coils and tubes of EQUIPMENT, ice may not be used as FOOD. [P]

3-303.12 Storage or Display of Food in Contact with Water or Ice.

(A) PACKAGED FOOD may not be stored in direct contact with ice or water if the FOOD is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water

(B) Except as specified in ¶¶ (C) and (D) of this section, unPACKAGED FOOD may not be stored in direct contact with undrained ice.

(C) *Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.*

(D) *Raw poultry and raw FISH that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale.*

Preventing Contamination from Equipment, Utensils, and Linens

3-304.11 Food Contact with Equipment and Utensils.

FOOD shall only contact surfaces of:

(A) EQUIPMENT and UTENSILS that are cleaned as specified under Part 4-6 of this Code and SANITIZED as specified under Part 4-7 of this Code; [P]

(B) SINGLE-SERVICE and SINGLE-USE ARTICLES; [P] or

(C) LINENS, such as cloth napkins, as specified under § 3-304.13 that are laundered as specified under Part 4-8 of this Code. [P]

3-304.12 In-Use Utensils, Between-Use Storage.

During pauses in FOOD preparation or dispensing, FOOD preparation and dispensing UTENSILS shall be stored:

(A) Except as specified under ¶ (B) of this section, in the FOOD with their handles above the top of the FOOD and the container;

(B) In FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD with their handles above the top of the FOOD within containers or EQUIPMENT that can be closed, such as bins of sugar, flour, or cinnamon;

(C) On a clean portion of the FOOD preparation table or cooking EQUIPMENT only if the in-use UTENSIL and the FOOD-CONTACT surface of the FOOD preparation table or cooking EQUIPMENT are cleaned and SANITIZED at a frequency specified under §§ 4-602.11 and 4-702.11;

(D) In running water of sufficient velocity to flush particulates to the drain, if used with moist FOOD such as ice cream or mashed potatoes;

(E) In a clean, protected location if the UTENSILS, such as ice scoops, are used only with a FOOD that is not

TIME/TEMPERATURE CONTROL FOR SAFETY FOOD; or

(F) In a container of water if the water is maintained at a temperature of at least 57°C (135°F) and the container is cleaned at a frequency specified under Subparagraph 4-602.11(D)(7).

3-304.13 Linens and Napkins, Use Limitation.

LINENS, such as cloth napkins, may not be used in contact with FOOD *unless they are used to line a container for the service of FOODS and the LINENS and napkins are replaced each time the container is refilled for a new CONSUMER*.

3-304.14 Wiping Cloths, Use Limitation.

(A) Cloths in-use for wiping FOOD spills from TABLEWARE and carry-out containers that occur as FOOD is being served shall be:

(1) Maintained dry; and

(2) Used for no other purpose.

(B) Cloths in-use for wiping counters and other EQUIPMENT surfaces shall be:

(1) Held between uses in a chemical sanitizer solution at a concentration specified under § 4-501.114; and

(2) Laundered daily as specified under ¶ 4-802.11(D).

(C) Cloths in-use for wiping surfaces in contact with raw animal FOODS shall be kept separate from cloths used for other purposes.

(D) Dry wiping cloths and the chemical sanitizing solutions specified in Subparagraph (B)(1) of this section in which wet wiping cloths are held between uses shall be free of FOOD debris and visible soil.

(E) Containers of chemical sanitizing solutions specified in Subparagraph (B)(1) of this section in which wet wiping cloths are held between uses shall be stored off the floor and used in a manner that prevents contamination of FOOD, EQUIPMENT,

UTENSILS, LINENS, SINGLE-SERVICE, or SINGLE-USE ARTICLES.

(F) SINGLE-USE disposable sanitizer wipes shall be used in accordance with EPA-approved manufacturer's label use instructions.

3-304.15 Gloves, Use Limitation.

(A) If used, SINGLE-USE gloves shall be used for only one task such as working with READY-TO-EAT FOOD or with raw animal FOOD, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation. P

(B) Except as specified in ¶ (C) of this section, slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with FOOD that is subsequently cooked as specified under Part 3-4 such as frozen FOOD or a PRIMAL CUT of MEAT.

(C) *Slash-resistant gloves may be used with READY-TO-EAT FOOD that will not be subsequently cooked if the slash-resistant gloves have a SMOOTH, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a SMOOTH, durable, nonabsorbent glove, or a SINGLE-USE glove*.

(D) Cloth gloves may not be used in direct contact with FOOD *unless the FOOD is subsequently cooked as required under Part 3-4 such as frozen FOOD or a PRIMAL CUT of MEAT*.

3-304.16 Using Clean Tableware for Second Portions and Refills.

(A) Except for refilling a CONSUMER'S drinking cup or container without contact between the pouring UTENSIL and the lip-contact area of the drinking cup or container, FOOD EMPLOYEES may not use TABLEWARE, including SINGLE-SERVICE ARTICLES, soiled by the CONSUMER, to provide second portions or refills.

(B) Except as specified in ¶ (C) of this section, self-service CONSUMERS may not be allowed to use soiled TABLEWARE, including SINGLE-SERVICE ARTICLES, to obtain additional FOOD from the display and serving EQUIPMENT.

(C) *Drinking cups and containers may be reused by self-service*

CONSUMERS if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D).

3-304.17 Refilling Returnables.

(A) Except as specified in ¶¶ (B) - (E) of this section, empty containers returned to a FOOD ESTABLISHMENT for cleaning and refilling with FOOD shall be cleaned and refilled in a regulated FOOD PROCESSING PLANT. [P]

(B) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with FOOD if the FOOD container is:

(1) Designed and constructed for reuse and in accordance with the requirements specified under Part 4-1 and 4-2; [P]

(2) One that was initially provided by the FOOD ESTABLISHMENT to the CONSUMER, either empty or filled with FOOD by the FOOD ESTABLISHMENT, for the purpose of being returned for reuse;

(3) Returned to the FOOD ESTABLISHMENT by the CONSUMER after use;

(4) Subject to the following steps before being refilled with FOOD:

(a) Cleaned as specified under Part 4-6 of this Code,

(b) Sanitized as specified under Part 4-7 of this Code; [P]

(c) Visually inspected by a FOOD EMPLOYEE to verify that the container, as returned, meets the requirements specified under Part 4-1 and 4-2; [P] *and*

(C) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with BEVERAGE if:

(1) *The BEVERAGE is not a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD;*

(2) *The design of the container and of the rinsing EQUIPMENT and the nature of the BEVERAGE, when considered together,*

allow effective cleaning at home or in the FOOD ESTABLISHMENT*;*

(3) *Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;*

(4) *The* CONSUMER*-owned container returned to the* FOOD ESTABLISHMENT *for refilling is refilled for sale or service only to the same* CONSUMER*; and*

(5) The container is refilled by:

(a) An EMPLOYEE *of the* FOOD ESTABLISHMENT*, or*

(b) *The owner of the container if the* BEVERAGE *system includes a contamination-free transfer process as specified under ¶¶ 4-204.13(A), (B), and (D).that cannot be bypassed by the container owner.*

(D) Consumer-owned, personal take-out BEVERAGE *containers, such as thermally insulated bottles, nonspill coffee cups, and promotional* BEVERAGE *glasses, may be refilled by* EMPLOYEES *or the* CONSUMER *if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D)*.

(E) CONSUMER*-owned containers that are not* FOOD*-specific may be filled at a water* VENDING MACHINE *or system.*

Preventing Contamination from the Premises

3-305.11 Food Storage.

(A) Except as specified in ¶¶ (B) and (C) of this section, FOOD shall be protected from contamination by storing the FOOD:

(1) In a clean, dry location;

(2) Where it is not exposed to splash, dust, or other contamination; and

(3) At least 15 cm (6 inches) above the floor.

(B) *FOOD in packages and working containers may be stored less than 15 cm (6 inches) above the floor on case lot handling* EQUIPMENT *as specified under § 4-204.122*.

(C) *Pressurized* BEVERAGE *containers, cased* FOOD *in waterproof containers such as bottles or cans, and milk containers in plastic crates may be stored on a floor that is clean and not exposed to floor moisture*.

3-305.12 Food Storage, Prohibited Areas.

FOOD may not be stored:

(A) In locker rooms;

(B) In toilet rooms;

(C) In dressing rooms;

(D) In garbage rooms;

(E) In mechanical rooms;

(F) Under sewer lines that are not shielded to intercept potential drips;

(G) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;

(H) Under open stairwells; or

(I) Under other sources of contamination.

3-305.13 Vended Time/Temperature Control for Safety Food, Original Container.

TIME/TEMPERATURE CONTROL FOR SAFETY FOOD dispensed through a VENDING MACHINE shall be in the PACKAGE in which it was placed at the FOOD ESTABLISHMENT or FOOD PROCESSING PLANT at which it was prepared.

3-305.14 Food Preparation.

During preparation, unPACKAGED FOOD shall be protected from environmental sources of contamination.

Preventing Contamination by Consumers

3-306.11 Food Display.

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the CONSUMER *before consumption*, FOOD on display shall be protected from contamination by the use of PACKAGING; counter, service line, or salad bar FOOD guards; display cases; or other effective means.[P]

3-306.12 Condiments, Protection.

(A) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected FOOD displays provided with the proper UTENSILS, original containers designed for dispensing, or individual PACKAGES or portions.

(B) Condiments at a VENDING MACHINE LOCATION shall be in individual PACKAGES or provided in dispensers that are filled at an APPROVED location, such as the FOOD ESTABLISHMENT that provides FOOD to the VENDING MACHINE LOCATION, a FOOD PROCESSING PLANT that is regulated by the agency that has jurisdiction over the operation, or a properly equipped facility that is located on the site of the VENDING MACHINE LOCATION.

3-306.13 Consumer Self-Service Operations.

(A) Raw, unPACKAGED animal FOOD, such as beef, lamb, pork, POULTRY, and FISH may not be offered for CONSUMER self-service.[P] *This paragraph does not apply to:*

(1) CONSUMER *self-service of* READY-TO-EAT FOODS *at buffets or salad bars that serve* FOODS *such as sushi or raw shellfish;*

(2) *Ready-to-cook individual portions for immediate cooking and consumption on the* PREMISES *such as* CONSUMER*-cooked* MEATS *or* CONSUMER*-selected ingredients for Mongolian barbecue; or*

(3) *Raw, frozen, shell-on shrimp, or lobster*.

(B) CONSUMER self-service operations for READY-TO-EAT FOODS shall be provided with suitable UTENSILS or effective dispensing

methods that protect the FOOD from contamination. [Pf]

(C) CONSUMER self-service operations such as buffets and salad bars shall be monitored by FOOD EMPLOYEES trained in safe operating procedures. [Pf]

3-306.14 Returned Food and Re-Service of Food.

(A) Except as specified in ¶ (B) of this section, after being served or sold and in the possession of a CONSUMER, FOOD that is unused or returned by the CONSUMER may not be offered as FOOD for human consumption. [P]

(B) Except as specified under ¶ 3-801.11(G), *a container of FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD may be RE-SERVED from one CONSUMER to another if:*

(1) *The FOOD is dispensed so that it is protected from contamination and the container is closed between uses, such as a narrow-neck bottle containing catsup, steak sauce, or wine; or*

(2) *The FOOD, such as crackers, salt, or pepper, is in an unopened original PACKAGE and is maintained in sound condition*.

Preventing Contamination from Other Sources

3-307.11 Miscellaneous Sources of Contamination.

FOOD shall be protected from contamination that may result from a factor or source not specified under Subparts 3-301 - 3-306.

3-4 DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN

Subparts

Cooking

3-401.11 Raw Animal Foods.

(A) Except as specified under ¶ (B) and in ¶¶ (C) and (D) of this section, raw animal FOODS such as EGGS, FISH, MEAT, POULTRY, and FOODS containing these raw animal FOODS, shall be cooked to heat all parts of the FOOD to a temperature and for a time that complies with one of the following methods based on the FOOD that is being cooked:

(1) 63°C (145°F) or above for 15 seconds for: [P]

(a) Raw EGGS that are broken and prepared in response to a CONSUMER'S order and for immediate service, [P] and

(b) Except as specified under Subparagraphs (A)(2) and (A)(3) and ¶ (B), and in ¶ (C) of this section, FISH and MEAT including GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1) and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2); [P]

(2) 68°C (155°F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for RATITES, MECHANICALLY TENDERIZED, and INJECTED MEATS; the following if they are COMMINUTED: FISH, MEAT, GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1), and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2); and raw EGGS that are not prepared as specified under Subparagraph (A)(1)(a) of this section: [P]

Minimum Temperature °C (°F)	Minimum Time
63 (145)	3 minutes
66 (150)	1 minute
70 (158)	< 1 second (instantaneous)

;or

(3) 74°C (165°F) or above for 15 seconds for POULTRY, BALUTS, wild GAME ANIMALS as specified under Subparagraphs 3-201.17(A)(3) and (4), stuffed FISH, stuffed MEAT, stuffed pasta, stuffed POULTRY, stuffed RATITES, or stuffing containing FISH, MEAT, POULTRY, or RATITES. [P]

(B) Whole MEAT roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham shall be cooked:

(1) In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature: [Pf]

Oven Temperature Based on Roast Weight

Oven Type	Less than 4.5 kg (10 lbs)	4.5 kg (10 lbs) or More
Still Dry	177°C (350°F) or more	121°C (250°F) or more
Convection	163°C (325°F) or more	121°C (250°F) or more
High Humidity[1]	121°C (250°F) or less	121°C (250°F) or less

[1]Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.

; and

(2) As specified in the following chart, to heat all parts of the FOOD to a temperature and for the holding time that corresponds to that temperature: P

Temperature °C (°F)	Time[1] in Minutes
54.4 (130)	112
55.0 (131)	89
56.1 (133)	56
57.2 (135)	36
57.8 (136)	28
58.9 (138)	18
60.0 (140)	12
61.1 (142)	8
62.2 (144)	5
62.8 (145)	4

Temperature °C (°F)	Time[1] in Seconds
63.9 (147)	134
65.0 (149)	85
66.1 (151)	54
67.2 (153)	34
68.3 (155)	22
69.4 (157)	14
70.0 (158)	0

[1]*Holding time may include postoven heat rise.*

(C) *A raw or undercooked WHOLE-MUSCLE, INTACT BEEF steak may be served or offered for sale in a READY-TO-EAT form if:*

(1) *The FOOD ESTABLISHMENT serves a population that is not a HIGHLY SUSCEPTIBLE POPULATION,*

(2) *The steak is labeled to indicate that it meets the definition of "WHOLE-MUSCLE, INTACT BEEF" as specified under ¶ 3-201.11(E), and*

(3) *The steak is cooked on both the top and bottom to a surface temperature of 63°C (145°F) or above and a cooked color change is achieved on all external surfaces.*

(D) *A raw animal* FOOD *such as raw* EGG, *raw* FISH, *raw-marinated* FISH, *raw* MOLLUSCAN SHELLFISH, *or steak tartare; or a partially cooked* FOOD *such as lightly cooked* FISH, *soft cooked* EGGS, *or rare* MEAT *other than* WHOLE-MUSCLE, INTACT BEEF *steaks as specified in ¶ (C) of this section, may be served or offered for sale upon* CONSUMER *request or selection in a* READY-TO-EAT *form if:*

(1) *As specified under ¶¶ 3-801.11(C)(1) and (2), the* FOOD ESTABLISHMENT *serves a population that is not a* HIGHLY SUSCEPTIBLE POPULATION;

(2) *The* FOOD, *if served or offered for service by* CONSUMER *selection from a children's menu, does not contain* COMMINUTED MEAT;[Pf] *and*

(3) *The* CONSUMER *is informed as specified under § 3-603.11 that to ensure its safety, the* FOOD *should be cooked as specified under ¶ (A) or (B) of this section; or*

(4) *The* REGULATORY AUTHORITY *grants a* VARIANCE *from ¶ (A) or (B) of this section as specified in § 8-103.10 based on a HACCP* PLAN *that:*

(a) *Is submitted by the* PERMIT HOLDER *and* APPROVED *as specified under § 8-103.11,*

(b) *Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe* FOOD, *and*

(c) *Verifies that* EQUIPMENT *and procedures for* FOOD *preparation and training of* FOOD EMPLOYEES *at the* FOOD ESTABLISHMENT *meet the conditions of the* VARIANCE.

3-401.12 Microwave Cooking.

Raw animal FOODS cooked in a microwave oven shall be:

(A) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;

(B) Covered to retain surface moisture;

(C) Heated to a temperature of at least 74°C (165°F) in all parts of the FOOD;[P] and

(D) Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 57°C (135°F). [Pf]

3-401.14 Non-Continuous Cooking of Raw Animal Foods.

Raw animal FOODS that are cooked using a NON-CONTINUOUS COOKING process shall be:

(A) Subject to an initial heating process that is no longer than sixty minutes in duration; [P]

(B) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked TIME/TEMPERATURE CONTROL FOR SAFETY FOOD under ¶ 3-501.14(A); [P]

(C) After cooling, held frozen or cold, as specified for TIME/TEMPERATURE CONTROL FOR SAFETY FOOD under ¶ 3-501.16(A)(2); [P]

(D) Prior to sale or service, cooked using a process that heats all parts of the FOOD to a temperature and for a time as specified under ¶¶3-401.11 (A)-(C); [P]

(E) Cooled according to the time and temperature parameters specified for cooked TIME /TEMPERATURE CONTROL FOR SAFETY FOOD under ¶ 3-501.14(A) if not either hot held as specified under ¶3-501.16(A), served immediately, or held using time as a public health control as specified under §3-501.19 after complete cooking; [P] and

(F) Prepared and stored according to written procedures that:

(1) Have obtained prior APPROVAL from the REGULATORY AUTHORITY; [Pf]

(2) Are maintained in the FOOD ESTABLISHMENT and are available to the REGULATORY AUTHORITY upon request; [Pf]

(3) Describe how the requirements specified under ¶ (A)-(E) of this Section are to be monitored and documented by the PERMIT HOLDER and the corrective actions to be taken if the requirements are not met; [Pf]

(4) Describe how the FOODS, after initial heating, but prior to complete cooking, are to be marked or otherwise identified as FOODS that must be cooked as specified under ¶ (D) of this section prior to being offered for sale or service; [Pf] and

(5) Describe how the FOODS, after initial heating but prior to cooking as specified under ¶(D) of this section, are to be separated from READY-TO-EAT FOODS as specified under ¶3-302.11 (A). [Pf]

Freezing

3-402.11 Parasite Destruction.

(A) Except as specified in ¶ (B) of this section, before service or sale in READY-TO-EAT form, raw, raw-marinated, partially cooked, or marinated-partially cooked FISH shall be:

(1) Frozen and stored at a temperature of -20°C (-4°F) or below for a minimum of 168 hours (7 days) in a freezer; [P]

(2) Frozen at -35°C (-31°F) or below until solid and stored at -35°C (-31°F) or below for a minimum of 15 hours; [P] or

(3) Frozen at -35°C (-31°F) or below until solid and stored at -20°C (-4°F) or below for a minimum of 24 hours. [P]

(B) *Paragraph (A) of this section does not apply to*:

(1) *MOLLUSCAN SHELLFISH*;

(2) *A scallop product consisting only of the shucked adductor muscle*;

(3) *Tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna), Thunnus atlanticus, Thunnus maccoyii (Bluefin tuna, Southern), Thunnus obesus (Bigeye tuna), or Thunnus thynnus (Bluefin tuna, Northern); or*

(4) *Aquacultured FISH, such as salmon, that*:

(a) *If raised in open water, are raised in net-pens, or*

(b) *Are raised in land-based operations such as ponds or tanks, and*

(c) *Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured FISH*.

(5) FISH eggs that have been removed from the skein and rinsed.

3-402.12 Records, Creation and Retention.

(A) Except as specified in ¶ 3-402.11(B) and ¶ (B) of this section, if raw, raw-marinated, partially cooked, or marinated-partially cooked FISH are served or sold in READY-TO-EAT form, the PERSON IN CHARGE shall record the freezing temperature and time to which the FISH are subjected and shall retain the records of the FOOD ESTABLISHMENT for 90 calendar days beyond the time of service or sale of the FISH. [Pf]

(B) *If the FISH are frozen by a supplier, a written agreement or statement from the supplier stipulating that the FISH supplied are frozen to a temperature and for a time specified under § 3-402.11 may substitute for the records specified under ¶ (A) of this section.*

(C) If raw, raw-marinated, partially cooked, or marinated-partially cooked FISH are served or sold in READY-TO-EAT form, and the FISH are raised and fed as specified in Subparagraph

3-402.11(B)(3), a written agreement or statement from the supplier or aquaculturist stipulating that the FISH were raised and fed as specified in Subparagraph 3-402.11(B)(3) shall be obtained by the PERSON IN CHARGE and retained in the records of the FOOD ESTABLISHMENT for 90 calendar days beyond the time of service or sale of the FISH. [Pf]

3-403.10 Preparation for Immediate Service.

Cooked and refrigerated FOOD that is prepared for immediate service in response to an individual CONSUMER order, such as a roast beef sandwich au jus, may be served at any temperature.

Reheating

3-403.11 Reheating for Hot Holding.

(A) Except as specified under ¶¶ (B) and (C) and in ¶ (E) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) for 15 seconds. [P]

(B) Except as specified under ¶ (C) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD reheated in a microwave oven for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) and the FOOD is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating. [P]

(C) READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that has been commercially processed and PACKAGED in a FOOD PROCESSING PLANT that is inspected by the REGULATORY AUTHORITY that has jurisdiction over the plant, shall be heated to a temperature of at least 57°C (135°F) when being reheated for hot holding. [P]

(D) Reheating for hot holding as specified under ¶¶ (A) - (C) of this section shall be done rapidly and the time the FOOD is between 5ºC (41ºF) and the temperatures specified under ¶¶ (A) - (C) of this section may not exceed 2 hours. [P]

(E) *Remaining unsliced portions of MEAT roasts that are cooked as specified under ¶ 3-401.11(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under ¶ 3-401.11(B).*

Other Methods

3-404.11 Treating Juice.

JUICE PACKAGED in a FOOD ESTABLISHMENT shall be:

(A) Treated under a HACCP PLAN as specified in ¶¶ 8-201.14(B) - (E) to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; [P] or

(B) Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance: [Pf]

(1) As specified under § 3-602.11, [Pf] and

(2) As specified in 21 CFR 101.17(g) Food labeling, warning, notice, and safe handling statements, JUICES that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens with the following, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." [Pf]

3-5 LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

Subparts

Temperature and Time Control

3-501.11 Frozen Food.

Stored frozen FOODS shall be maintained frozen.

3-501.12 Time/Temperature Control for Safety Food, Slacking.

Frozen TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is slacked to moderate the temperature shall be held:

(A) Under refrigeration that maintains the FOOD temperature at 5°C (41°F) or less; or

(B) At any temperature if the FOOD remains frozen.

3-501.13 Thawing.

Except as specified in ¶ (D) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be thawed:

(A) Under refrigeration that maintains the FOOD temperature at 5°C (41°F) or less; or

(B) Completely submerged under running water:

(1) At a water temperature of 21°C (70°F) or below,

(2) With sufficient water velocity to agitate and float off loose particles in an overflow, and

(3) For a period of time that does not allow thawed portions of READY-TO-EAT FOOD to rise above 5°C (41°F), or

(4) For a period of time that does not allow thawed portions of a raw animal FOOD requiring cooking as specified under ¶ 3-401.11(A) or (B) to be above 5°C (41°F), for more than 4 hours including:

(a) The time the FOOD is exposed to the running water and the time needed for preparation for cooking, or

(b) The time it takes under refrigeration to lower the FOOD temperature to 5°C (41°F);

(C) As part of a cooking process if the FOOD that is frozen is:

(1) Cooked as specified under ¶¶3-401.11(A) or (B) or § 3-401.12, or

(2) Thawed in a microwave oven and immediately transferred to conventional cooking EQUIPMENT, with no interruption in the process; or

(D) *Using any procedure if a portion of frozen READY-TO-EAT*

FOOD is thawed and prepared for immediate service in response to an individual CONSUMER'S order.

(E) REDUCED OXYGEN PACKAGED FISH that bears a label indicating that it is to be kept frozen until time of use shall be removed from the reduced oxygen environment:

(1) Prior to its thawing under refrigeration as specified in ¶(A) of this section; or

(2) Prior to, or Immediately upon completion of, its thawing using procedures specified in ¶ (B) of this section.

3-501.14 Cooling.

(A) Cooked TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled:

(1) Within 2 hours from 57ºC (135ºF) to 21ºC (70°F); [P] and

(2) Within a total of 6 hours from 57ºC (135ºF) to 5ºC (41°F) or less. [P]

(B) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled within 4 hours to 5°C (41°F) or less if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna. [P]

(C) Except as specified under ¶ (D) of this section, a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in ¶ 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less. [P]

(D) Raw EGGS shall be received as specified under ¶ 3-202.11(C) and immediately placed in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less. [P]

3-501.15 Cooling Methods.

(A) Cooling shall be accomplished in accordance with the time and temperature criteria specified under § 3-501.14 by using one or more of the following methods based on the type of FOOD being cooled:

(1) Placing the FOOD in shallow pans; [Pf]

(2) Separating the FOOD into smaller or thinner portions; [Pf]

(3) Using rapid cooling EQUIPMENT; [Pf]

(4) Stirring the FOOD in a container placed in an ice water bath; [Pf]

(5) Using containers that facilitate heat transfer; [Pf]

(6) Adding ice as an ingredient; [Pf] or

(7) Other effective methods. [Pf]

(B) When placed in cooling or cold holding EQUIPMENT, FOOD containers in which FOOD is being cooled shall be:

(1) Arranged in the EQUIPMENT to provide maximum heat transfer through the container walls; and

(2) Loosely covered, or uncovered if protected from overhead contamination as specified under Subparagraph 3-305.11(A)(2), during the cooling period to facilitate heat transfer from the surface of the FOOD.

3-501.16 Time/Temperature Control for Safety Food, Hot and Cold Holding.

(A) *Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under §3-501.19,* and except as specified under ¶ (B) and in ¶ (C) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be maintained:

(1) At 57°C (135°F) or above, *except that roasts cooked to a temperature and for a time specified in ¶ 3-401.11(B) or reheated as specified in ¶ 3-403.11(E) may be held at a temperature of 54°C (130°F) or above*; [P] or

(2) At 5ºC (41ºF) or less. [P]

(B) EGGS that have not been treated to destroy all viable ***Salmonellae*** shall be stored in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less. [P]

(C) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD in a homogenous liquid form *may be maintained outside of the temperature control requirements, as specified under ¶ (A) of this section, whil e contained within specially designed* EQUIPMENT *that complies with the design and construction requirements as specified under ¶ 4-204.13(E).*

on-premises preparation
• prepare and hold cold

3-501.17 Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking.

(A) Except when PACKAGING FOOD using a REDUCED OXYGEN PACKAGING method as specified under § 3-502.12, and except as specified in ¶¶ (E) and (F) of this section, refrigerated, READY-TO-EAT, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD prepared and held in a FOOD ESTABLISHMENT for more than 24 hours shall be clearly marked to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded when held at a temperature of 5ºC (41ºF) or less for a maximum of 7 days. The day of preparation shall be counted as Day 1. [Pf]

commercially processed food
• open and hold cold

(B) Except as specified in ¶¶ (E) - (G) of this section, refrigerated, READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD prepared and PACKAGED by a FOOD PROCESSING PLANT shall be clearly marked, at the time the original container is opened in a FOOD ESTABLISHMENT and if the FOOD is held for more than 24 hours, to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded, based on the temperature and time combinations specified in ¶ (A) of this section and: [Pf]

(1) The day the original container is opened in the FOOD ESTABLISHMENT shall be counted as Day 1; [Pf] and

(2) The day or date marked by the FOOD ESTABLISHMENT may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on FOOD safety. [Pf]

(C) A refrigerated, READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD ingredient or a portion of a refrigerated, READY-TO-EAT, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is subsequently combined with additional ingredients or portions of FOOD shall retain the date marking of the earliest-prepared or first-prepared ingredient. [Pf]

(D) *A date marking system that meets the criteria stated in ¶¶ (A) and (B) of this section may include*:

(1) *Using a method* APPROVED *by the* REGULATORY AUTHORITY *for refrigerated,* READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD *that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft serve mix or milk in a dispensing machine;*

(2) *Marking the date or day of preparation, with a procedure to discard the* FOOD *on or before the last date or day by which the* FOOD *must be consumed on the premises, sold, or discarded as specified under ¶ (A) of this section;*

(3) *Marking the date or day the original container is opened in a* FOOD ESTABLISHMENT, *with a procedure to discard the* FOOD *on or before the last date or day by which the* FOOD *must be consumed on the premises, sold, or discarded as specified under ¶ (B) of this section; or*

(4) *Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the* REGULATORY AUTHORITY *upon request.*

(E) *Paragraphs (A) and (B) of this section do not apply to individual meal portions served or re*PACKAGED *for sale from a bulk container upon a consumer's request*.

(F) *Paragraphs (A) and (B) of this section do not apply to* SHELLSTOCK.

(G) *Paragraph (B) of this section does not apply to the following* FOODS *prepared and* PACKAGED *by a* FOOD PROCESSING PLANT *inspected by a* REGULATORY AUTHORITY:

(1) *Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR 110 Current good manufacturing practice in manufacturing, packing, or holding human food;*

(2) *Hard cheeses containing not more than 39% moisture as defined in 21 CFR 133 Cheeses and related cheese products, such as cheddar, gruyere, parmesan and reggiano, and romano;*

(3) *Semi-soft cheeses containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR 133 Cheeses and related cheese products, such as blue, edam, gorgonzola, gouda, and monterey jack;*

(4) *Cultured dairy products as defined in 21 CFR 131 Milk and cream, such as yogurt, sour cream, and buttermilk;*

(5) *Preserved* FISH *products, such as pickled herring and dried or salted cod, and other acidified* FISH *products defined in 21 CFR 114 Acidified foods;*

(6) *Shelf stable, dry fermented sausages, such as pepperoni and Genoa; and*

(7) *Shelf stable salt-cured products such as prosciutto and Parma (ham).*

3-501.18 Ready-to-Eat, Time/Temperature Control for Safety Food, Disposition.

(A) A FOOD specified in ¶ 3-501.17(A) or (B) shall be discarded if it:

(1) Exceeds the temperature and time combination specified in ¶ 3-501.17(A), except time that the product is frozen; P

(2) Is in a container or PACKAGE that does not bear a date or day; P or

(3) Is appropriately marked with a date or day that exceeds a temperature and time combination as specified in ¶ 3-501.17(A). P

(B) Refrigerated, READY-TO-EAT, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD prepared in a FOOD ESTABLISHMENT and dispensed through a VENDING MACHINE with an automatic shutoff control shall be discarded if it exceeds a temperature and time combination as specified in ¶ 3-501.17(A). P

3-501.19 Time as a Public Health Control.

(A) Except as specified under ¶ (D) of this section, if time without

temperature control is used as the public health control for a working supply of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD before cooking, or for READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is displayed or held for sale or service:

(1) Written procedures shall be prepared in advance, maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request that specify: [Pf]

(a) Methods of compliance with Subparagraphs (B)(1)-(3) or C)(1)-(5) of this section; [Pf] and

(b) Methods of compliance with § 3-501.14 for FOOD that is prepared, cooked, and refrigerated before time is used as a public health control. [Pf]

Time – maximum up to 4 hours

(B) If time without temperature control is used as the public health control up to a maximum of 4 hours:

(1) The FOOD shall have an initial temperature of 5ºC (41ºF) or less when removed from cold holding temperature control, or 57°C (135°F) or greater when removed from hot holding temperature control; [P]

(2) The FOOD shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the FOOD is removed from temperature control; [Pf]

(3) The FOOD shall be cooked and served, served at any temperature if READY-TO-EAT, or discarded, within 4 hours from the point in time when the FOOD is removed from temperature control; [P] and

(4) The FOOD in unmarked containers or PACKAGES, or marked to exceed a 4-hour limit shall be discarded. [P]

Time – maximum up to 6 hours

(C) If time without temperature control is used as the public health control up to a maximum of 6 hours:

(1) The FOOD shall have an initial temperature of 5ºC (41ºF) or less when removed from temperature control and the FOOD temperature may not exceed 21ºC (70ºF) within a maximum time period of 6 hours; [P]

(2) The FOOD shall be monitored to ensure the warmest portion of the FOOD does not exceed 21ºC (70ºF) during the 6-hour period, *unless an ambient air temperature is maintained that ensures the FOOD does not exceed 21ºC (70ºF) during the 6-hour holding period*; [Pf]

(3) The FOOD shall be marked or otherwise identified to indicate: [Pf]

(a) The time when the FOOD is removed from 5ºC (41ºF) or less cold holding temperature control, [Pf] and

(b) The time that is 6 hours past the point in time when the FOOD is removed from cold holding temperature control; [Pf]

(4) The FOOD shall be:

(a) Discarded if the temperature of the FOOD exceeds 21°C (70°F), [P] or

(b) Cooked and served, served at any temperature if READY-TO-EAT, or discarded within a maximum of 6 hours from the point in time when the FOOD is removed from 5ºC (41ºF) or less cold holding temperature control; [P] and

(5) The FOOD in unmarked containers or PACKAGES, or marked with a time that exceeds the 6-hour limit shall be discarded. [P]

(D) A FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION may not use time as specified under ¶¶ (A), (B) or (C) of this section as the public health control for raw EGGS.

Specialized Processing Methods

3-502.11 Variance Requirement.

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before: [Pf]

(A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement; [Pf]

(B) Curing FOOD; [Pf]

(C) Using FOOD ADDITIVES or adding components such as

vinegar: Pf

(1) As a method of FOOD preservation rather than as a method of flavor enhancement, Pf or

(2) To render a FOOD so that it is not TIME/TEMPERATURE CONTROL OF SAFETY FOOD; Pf

(D) Packaging TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method *except where the growth of and toxin formation by* ***Clostridium botulinum*** *and the growth of* ***Listeria monocytogenes*** *are controlled as specified under § 3-502.12*; Pf

(E) Operating a MOLLUSCAN SHELLFISH life-support system display tank used to store or display shellfish that are offered for human consumption;Pf

(F) Custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT; Pf

(G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE; Pf or

(H) Sprouting seeds or beans. Pf

Clostridium botulinum and Listeria monocytogenes Controls

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method shall control the growth and toxin formation of ***Clostridium botulinum*** and the growth of ***Listeria monocytogenes***. P

(B) Except as specified under ¶ (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a REDUCED OXYGEN PACKAGING method shall implement a HACCP PLAN that contains the information specified under ¶¶ 8-201.14 (B) and (D) and that: Pf

(1) Identifies the FOOD to be PACKAGED; Pf

(2) Except as specified under ¶¶ (C) - (E) of this section, requires that the PACKAGED FOOD shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria: [Pf]

(a) Has an A_W of 0.91 or less, [Pf]

(b) Has a pH of 4.6 or less, [Pf]

(c) Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact PACKAGE, [Pf] or

(d) Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables; [Pf]

(3) Describes how the PACKAGE shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to: [Pf]

(a) Maintain the FOOD at 5°C (41°F) or below, [Pf] and

(b) Discard the FOOD if within 30 calendar days of its PACKAGING if it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption; [Pf]

(4) Limits the refrigerated shelf life to no more than 30 calendar days from PACKAGING to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first; [P]

(5) Includes operational procedures that:

(a) Prohibit contacting READY-TO-EAT FOOD with bare hands as specified under ¶ 3-301.11(B), [Pf]

(b) Identify a designated work area and the method by which: [Pf]

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, [Pf] and

(ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, [Pf] and

(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; [Pf] and

(6) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the: [Pf]

(a) Concepts required for a safe operation, [Pf]

(b) EQUIPMENT and facilities, [Pf] and

(c) Procedures specified under Subparagraph (B)(5) of this section and ¶¶ 8-201.14 (B) and (D). [Pf]

(7) Is provided to the REGULATORY AUTHORITY prior to implementation as specified under ¶ 8-201.13(B).

Fish

(C) *Except for FISH that is frozen before, during, and after PACKAGING*, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method. [P]

Cook-Chill or Sous Vide

(D) Except as specified under ¶ (C) and ¶ (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TIME/TEMPERATURE CONTROL FOR SAFETY FOOD using a cook-chill or sous vide process shall:

(1) Provide to the REGULATORY AUTHORITY prior to implementation, a HACCP PLAN that contains the information as specified under ¶¶ 8-201.14 (B) and (D); [Pf]

(2) Ensure the FOOD is:

(a) Prepared and consumed on the PREMISES, or prepared and consumed off the PREMISES but within the same business entity with no distribution or sale of the PACKAGED product to another business entity or the CONSUMER, [Pf]

(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under ¶¶ 3-401.11 (A), (B), and (C), [P]

(c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4, [P]

(d) Placed in a PACKAGE with an oxygen barrier and sealed before cooking, or placed in a PACKAGE and sealed immediately after cooking and before reaching a temperature below 57°C (135°F), [P]

(e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3-501.14 and: [P]

(i) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of PACKAGING;[P]

(ii) Held at 5°C (41°F) or less for no more than 7 days, at which time the FOOD must be consumed or discarded; [P] or

(iii) Held frozen with no shelf life restriction while frozen until consumed or used. [P]

(f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily, [Pf]

(g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, [Pf] and

(h) Labeled with the product name and the date PACKAGED;[Pf] and

(3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP PLAN and:

(a) Make such records available to the REGULATORY AUTHORITY upon request, [Pf] and

(b) Hold such records for at least 6 months; [Pf] and

(4) Implement written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section.[Pf]

Cheese

(E) Except as specified under ¶ (F) of this section, a FOOD ESTABLISHMENT that PACKAGES cheese using a REDUCED OXYGEN PACKAGING method shall:

(1) Limit the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses; [P]

(2) Have a HACCP PLAN that contains the information specified under ¶¶ 8-201.14 (B) and (D) and as specified under ¶¶ (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section; [Pf]

(3) Labels the PACKAGE on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first; [Pf] and

(4) Discards the REDUCED OYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING. [Pf]

(F) A HACCP Plan is not required when a FOOD ESTABLISHMENT uses a REDUCED OXYGEN PACKAGING method to PACKAGE TIME/TEMPERATURE CONTROL FOR SAFETY FOOD *that is always:*

(1) Labeled with the production time and date,

(2) Held at 5°C (41°F) or less during refrigerated storage, and

(3) Removed from its PACKAGE in the FOOD ESTABLISHMENT within 48 hours after PACKAGING.

3-6 FOOD IDENTITY, PRESENTATION, AND ON-PREMISES LABELING

Subparts

Accurate Representation

3-601.11 Standards of Identity.

PACKAGED FOOD shall comply with standard of identity requirements in 21 CFR 131-169 and 9 CFR 319 Definitions and standards of identity or composition, and the general requirements in 21 CFR 130 – Food Standards: General and 9 CFR 319 Subpart A – General.

3-601.12 Honestly Presented.

(A) FOOD shall be offered for human consumption in a way that does not mislead or misinform the CONSUMER.

(B) FOOD or COLOR ADDITIVES, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a FOOD.

Labeling

3-602.11 Food Labels.

(A) FOOD PACKAGED in a FOOD ESTABLISHMENT, shall be labeled as specified in LAW, including 21 CFR 101 - Food labeling, and 9 CFR 317 Labeling, marking devices, and containers.

(B) Label information shall include:

(1) The common name of the FOOD, or absent a common name, an adequately descriptive identity statement;

(2) If made from two or more ingredients, a list of ingredients and sub-ingredients in descending order of predominance by weight, including a declaration of artificial colors, artificial flavors and chemical preservatives, if contained in the FOOD;

(3) An accurate declaration of the net quantity of contents;

(4) The name and place of business of the manufacturer, packer, or distributor; and

(5) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient. [Pf]

(6) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(g)(3) - (5), nutrition labeling as specified in 21 CFR 101 - Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling.

(7) For any salmonid FISH containing canthaxanthin or astaxanthin as a COLOR ADDITIVE, the labeling of the bulk FISH container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin or astaxanthin.

(C) Bulk FOOD that is available for CONSUMER self-dispensing shall be prominently labeled with the following information in plain view of the CONSUMER:

(1) The manufacturer's or processor's label that was provided with the FOOD; or

(2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), and (6) of this section.

(D) *Bulk, unPACKAGED FOODS such as bakery products and unPACKAGED FOODS that are portioned to CONSUMER specification need not be labeled if:*

(1) *A health, nutrient content, or other claim is not made;*

(2) *There are no state or local LAWS requiring labeling; and*

(3) *The FOOD is manufactured or prepared on the PREMISES of the FOOD ESTABLISHMENT or at another FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT that is owned by the same PERSON and is regulated by the FOOD regulatory agency that has jurisdiction.*

3-602.12 Other Forms of Information.

(A) If required by LAW, CONSUMER warnings shall be provided.

(B) FOOD ESTABLISHMENT or manufacturers' dating information on FOODS may not be concealed or altered.

Consumer Advisory

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.

(A) Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(4) and under ¶ 3-801.11(C), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased RISK of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in ¶¶ (B) and (C) of this section using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means. [Pf]

(B) DISCLOSURE shall include:

(1) A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)," "raw-EGG Caesar salad," and "hamburgers (can be cooked to order)"; [Pf] or

(2) Identification of the animal-derived FOODS by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients. [Pf]

(C) REMINDER shall include asterisking the animal-derived FOODS requiring DISCLOSURE to a footnote that states:

(1) Regarding the safety of these items, written information is available upon request; [Pf]

(2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; [Pf] or

(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions. [Pf]

3-7 CONTAMINATED FOOD

Subpart

3-701 Disposition

Disposition

3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.

(A) A FOOD that is unsafe, ADULTERATED, or not honestly presented as specified under § 3-101.11 shall be discarded or reconditioned according to an APPROVED procedure. [P]

(B) FOOD that is not from an APPROVED source as specified under §§ 3-201.11 - .17 shall be discarded. [P]

(C) READY-TO-EAT FOOD that may have been contaminated by an EMPLOYEE who has been RESTRICTED or EXCLUDED as specified under § 2-201.12 shall be discarded. [P]

(D) FOOD that is contaminated by FOOD EMPLOYEES, CONSUMERS, or other PERSONS through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded. [P]

3-8 SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS

Subpart

3-801 Additional Safeguards

Additional Safeguards

3-801.11 Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

(A) The following criteria apply to JUICE:

(1) For the purposes of this paragraph only, children who are age 9 or less and receive FOOD in a school, day care setting, or similar facility that provides custodial care are included as HIGHLY SUSCEPTIBLE POPULATIONS;

(2) PrePACKAGED JUICE or a prePACKAGED BEVERAGE containing JUICE, that bears a warning label as specified in 21 CFR, 101.17(g) Food labeling, warning, notice, and safe handling statements, Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens, or a PACKAGED JUICE or BEVERAGE containing JUICE, that bears a warning label as specified under ¶ 3-404.11(B) may not be served or offered for sale; [P] and

(3) UnPACKAGED JUICE that is prepared on the premises for service or sale in a READY-TO-EAT form shall be processed under a HACCP PLAN that contains the information specified under ¶¶ 8-201.14(B) - (E) and as specified in 21 CFR Part 120 – Hazard Analysis and Critical Control Point (HACCP) Systems, Subpart B Pathogen Reduction, 120.24 Process controls. [P]

(B) Pasteurized EGGS or EGG PRODUCTS shall be substituted for raw EGGS in the preparation of: [P]

(1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, EGGnog, ice cream, and EGG-fortified BEVERAGES, [P] and

(2) Except as specified in ¶ (F) of this section, recipes in which more than one EGG is broken and the EGGS are combined; P

(C) The following FOODS may not be served or offered for sale in a READY-TO-EAT form: P

(1) Raw animal FOODS such as raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH, and steak tartare, P

(2) A partially cooked animal FOOD such as lightly cooked FISH, rare MEAT, soft-cooked EGGS that are made from raw EGGS, and meringue; P and

(3) Raw seed sprouts. P

(D) FOOD EMPLOYEES may not contact READY-TO-EAT FOOD as specified under ¶¶ 3-301.11(B) and (E). P

(E) Time only, as the public health control as specified under ¶ 3-501.19(D), may not be used for raw EGGS. P

(F) *Subparagraph (B)(2) of this section does not apply if:*

(1) *The raw EGGS are combined immediately before cooking for one CONSUMER'S serving at a single meal, cooked as specified under Subparagraph 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled EGGS;*

(2) *The raw EGGS are combined as an ingredient immediately before baking and the EGGS are thoroughly cooked to a READY-TO-EAT form, such as a cake, muffin, or bread; or*

(3) *The preparation of the food is conducted under a HACCP PLAN that:*

(a) *Identifies the FOOD to be prepared,*

(b) *Prohibits contacting READY-TO-EAT FOOD with bare hands,*

(c) *Includes specifications and practices that ensure*:

(i) ***Salmonella* Enteritidis** *growth is controlled before and after cooking, and*

(ii) ***Salmonella* Enteritidis** *is destroyed by cooking the* EGGS *according to the temperature and time specified in Subparagraph 3-401.11(A)(2),*

(d) *Contains the information specified under ¶ 8-201.14(D) including procedures that:*

(i) *Control cross contamination of* READY-TO-EAT FOOD *with raw* EGGS, *and*

(ii) *Delineate cleaning and* SANITIZATION *procedures for* FOOD-CONTACT SURFACES, and

(e) *Describes the training program that ensures that the* FOOD EMPLOYEE *responsible for the preparation of the* FOOD *understands the procedures to be used*.

Re-service of Food

(G) Except as specified in paragraph (H) of this section, FOOD may be re-served as specified under Subparagraph 3-306.14(B)(1) and (2).

Prohibited Re-service of Food

(H) *FOOD may not be re-served under the following conditions:*

(1) *Any* FOOD *served to patients or clients who are under contact precautions in medical isolation or quarantine, or protective environment isolation may not be re-served to others outside*.

(2) *Packages of* FOOD *from any patients, clients, or other* CONSUMERS *should not be re-served to* PERSONS *in protective environment isolation*.

Chapter

4 Equipment, Utensils, and Linens

Parts

4-1 MATERIALS FOR CONSTRUCTION AND REPAIR

Subparts

Multiuse

4-101.11 Characteristics.

Materials that are used in the construction of UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT may not allow the migration of deleterious substances or impart colors, odors, or tastes to FOOD and under normal use conditions shall be: [P]

(A) Safe; [P]

(B) Durable, CORROSION-RESISTANT, and nonabsorbent;

(C) Sufficient in weight and thickness to withstand repeated WAREWASHING;

(D) Finished to have a SMOOTH, EASILY CLEANABLE surface; and

(E) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.

4-101.12 Cast Iron, Use Limitation.

(A) Except as specified in ¶¶ (B) and (C) of this section, cast iron may not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT.

(B) *Cast iron may be used as a surface for cooking.*

(C) *Cast iron may be used in UTENSILS for serving FOOD if the UTENSILS are used only as part of an uninterrupted process from cooking through service.*

4-101.13 Lead, Use Limitation.

(A) Ceramic, china, and crystal UTENSILS, and decorative UTENSILS such as hand painted ceramic or china that are used in contact with FOOD shall be lead-free or contain levels of lead not exceeding the limits of the following UTENSIL categories: P

UTENSIL Category	Ceramic Article Description	Maximum Lead MG/L
Beverage Mugs, Cups, Pitchers	Coffee Mugs	0.5
Large Hollowware (excluding pitchers)	Bowls ≥ 1.1 Liter (1.16 Quart)	1
Small Hollowware (excluding cups & mugs)	Bowls < 1.1 Liter (1.16 Quart)	2.0
Flat TABLEWARE	Plates, Saucers	3.0

(B) Pewter alloys containing lead in excess of 0.05% may not be used as a FOOD-CONTACT SURFACE. P

(C) Solder and flux containing lead in excess of 0.2% may not be used as a FOOD-CONTACT SURFACE.

4-101.14 Copper, Use Limitation.

(A) Except as specified in ¶ (B) of this section, copper and copper alloys such as brass may not be used in contact with a FOOD that has a pH below 6 such as vinegar, fruit JUICE, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator. P

(B) *Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.*

4-101.15 Galvanized Metal, Use Limitation.

Galvanized metal may not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT that are used in contact with acidic FOOD. P

4-101.16 Sponges, Use Limitation.

Sponges may not be used in contact with cleaned and SANITIZED or in-use FOOD-CONTACT SURFACES.

4-101.17 Wood, Use Limitation.

(A) Except as specified in ¶¶ (B), (C), and (D) of this section, wood and wood wicker may not be used as a FOOD-CONTACT SURFACE.

(B) *Hard maple or an equivalently hard, close-grained wood may be used for:*

(1) *Cutting boards; cutting blocks; bakers' tables; and UTENSILS such as rolling pins, doughnut dowels, salad bowls, and chopsticks; and*

(2) *Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110°C (230°F) or above.*

(C) *Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping containers in which they were received, until the fruits, vegetables, or nuts are used.*

(D) *If the nature of the* FOOD *requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw* FOOD *may be kept in:*

(1) *Untreated wood containers; or*

(2) *Treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800 Preservatives for wood.*

4-101.18 Nonstick Coatings, Use Limitation.

Multiuse KITCHENWARE such as frying pans, griddles, sauce pans, cookie sheets, and waffle bakers that have a perfluorocarbon resin coating shall be used with nonscoring or nonscratching UTENSILS and cleaning aids.

4-101.19 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES of EQUIPMENT that are exposed to splash, spillage, or other FOOD soiling or that require frequent cleaning shall be constructed of a CORROSION-RESISTANT, nonabsorbent, and SMOOTH material.

Single-Service and Single-Use

4-102.11 Characteristics.

Materials that are used to make SINGLE-SERVICE and SINGLE-USE ARTICLES:

(A) May not:

(1) Allow the migration of deleterious substances, [P] or

(2) Impart colors, odors, or tastes to FOOD; and

(B) Shall be:

(1) Safe, [P] and

(2) Clean.

4-2 DESIGN AND CONSTRUCTION

Subparts

Durability and Strength

4-201.11 Equipment and Utensils.

EQUIPMENT and UTENSILS shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

4-201.12 Food Temperature Measuring Devices.

FOOD TEMPERATURE MEASURING DEVICES may not have sensors or stems constructed of glass, *except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used*. [P]

Cleanability

4-202.11 Food-Contact Surfaces.

(A) Multiuse FOOD-CONTACT SURFACES shall be:

(1) SMOOTH; [Pf]

(2) Free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections; [Pf]

(3) Free of sharp internal angles, corners, and crevices; [Pf]

(4) Finished to have SMOOTH welds and joints; [Pf] and

(5) Except as specified in ¶ (B) of this section, accessible for cleaning and inspection by one of the following methods:

(a) Without being disassembled, [Pf]

(b) By disassembling without the use of tools, [Pf] or

(c) By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches. [Pf]

(B) *Subparagraph (A)(5) of this section does not apply to cooking oil storage tanks, distribution lines for cooking oils, or* BEVERAGE *syrup lines or tubes*.

4-202.12 CIP Equipment.

(A) CIP EQUIPMENT shall meet the characteristics specified under § 4-202.11 and shall be designed and constructed so that:

(1) Cleaning and SANITIZING solutions circulate throughout a fixed system and contact all interior FOOD-CONTACT SURFACES, [Pf] and

(2) The system is self-draining or capable of being completely drained of cleaning and SANITIZING solutions; and

(B) CIP EQUIPMENT that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior FOOD-CONTACT SURFACES throughout the fixed system are being effectively cleaned.

4-202.13 "V" Threads, Use Limitation.

Except for hot oil cooking or filtering EQUIPMENT, "V" type threads may not be used on FOOD-CONTACT SURFACES.

4-202.14 Hot Oil Filtering Equipment.

Hot oil filtering EQUIPMENT shall meet the characteristics specified under § 4-202.11 or § 4-202.12 and shall be readily accessible for filter replacement and cleaning of the filter.

4-202.15 Can Openers.

Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement.

4-202.16 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES shall be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance.

4-202.17 Kick Plates, Removable.

Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being:

(A) Removable by one of the methods specified under Subparagraph 4-202.11(A)(5) or capable of being rotated open; and

(B) Removable or capable of being rotated open without unlocking EQUIPMENT doors.

4-202.18 Ventilation Hood Systems, Filters.

Filters or other grease extracting EQUIPMENT shall be designed to be readily removable for cleaning and replacement if not designed to be cleaned in place.

Accuracy

4-203.11 Temperature Measuring Devices, Food.

(A) FOOD TEMPERATURE MEASURING DEVICES that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to ±1°C in the intended range of use. [Pf]

(B) FOOD TEMPERATURE MEASURING DEVICES that are scaled only in Fahrenheit shall be accurate to ±2°F in the intended range of use. [Pf]

4-203.12 Temperature Measuring Devices, Ambient Air and Water.

(A) Ambient air and water TEMPERATURE MEASURING DEVICES that are scaled in Celsius or dually scaled in Celsius and Fahrenheit shall be designed to be easily readable and accurate to ±1.5°C in the intended range of use. [Pf]

(B) Ambient air and water TEMPERATURE MEASURING DEVICES that are scaled only in Fahrenheit shall be accurate to ±3°F in the intended range of use. [Pf]

4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment.

Pressure measuring devices that display the pressures in the water supply line for the fresh hot water SANITIZING rinse shall have increments of 7 kilopascals (1 pound per square inch) or smaller and shall be accurate to ±14 kilopascals (±2 pounds per square inch) in the range indicated on the manufacturer's data plate.

Functionality

4-204.11 Ventilation Hood Systems, Drip Prevention.

Exhaust ventilation hood systems in FOOD preparation and WAREWASHING areas including components such as hoods, fans, guards, and ducting shall be designed to prevent grease or condensation from draining or dripping onto FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

4-204.12 Equipment Openings, Closures and Deflectors.

(A) A cover or lid for EQUIPMENT shall overlap the opening and be sloped to drain.

(B) An opening located within the top of a unit of EQUIPMENT that is designed for use with a cover or lid shall be flanged upward at least 5 millimeters (two-tenths of an inch).

(C) Except as specified under ¶ (D) of this section, fixed piping, TEMPERATURE MEASURING DEVICES, rotary shafts, and other parts extending into EQUIPMENT shall be provided with a watertight joint at the point where the item enters the EQUIPMENT.

(D) If a watertight joint is not provided:

(1) The piping, TEMPERATURE MEASURING DEVICES, rotary shafts, and other parts extending through the openings shall be equipped with an apron designed to deflect condensation, drips, and dust from openings into the FOOD; and

(2) The opening shall be flanged as specified under ¶ (B) of this section.

4-204.13 Dispensing Equipment, Protection of Equipment and Food.

In EQUIPMENT that dispenses or vends liquid FOOD or ice in unPACKAGED form:

(A) The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the FOOD shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the FOOD;

(B) The delivery tube, chute, and orifice shall be protected from manual contact such as by being recessed;

(C) The delivery tube or chute and orifice of EQUIPMENT used to vend liquid FOOD or ice in unPACKAGED form to self-service CONSUMERS shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self-closing door if the EQUIPMENT is:

(1) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain,

windblown debris, insects, rodents, and other contaminants that are present in the environment, or

(2) Available for self-service during hours when it is not under the full-time supervision of a FOOD EMPLOYEE; and

(D) The dispensing EQUIPMENT actuating lever or mechanism and filling device of CONSUMER self-service BEVERAGE dispensing EQUIPMENT shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

(E) Dispensing EQUIPMENT in which TIME/TEMPERATURE CONTROL FOR SAFETY FOOD in a homogenous liquid form is maintained outside of the temperature control requirements as specified under §3-501.16(A) shall:

(1) be specifically designed and equipped to maintain the commercial sterility of aseptically PACKAGED FOOD in a homogenous liquid form for a specified duration from the time of opening the PACKAGING within the EQUIPMENT;[P] and

(2) conform to the requirements for this EQUIPMENT as specified in *NSF/ANSI 18-2006- Manual Food and Beverage Dispensing Equipment.*[P]

4-204.14 Vending Machine, Vending Stage Closure.

The dispensing compartment of a VENDING MACHINE including a machine that is designed to vend prePACKAGED snack FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD such as chips, party mixes, and pretzels shall be equipped with a self-closing door or cover if the machine is:

(A) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

(B) Available for self-service during hours when it is not under the full-time supervision of a FOOD EMPLOYEE.

4-204.15 Bearings and Gear Boxes, Leakproof.

EQUIPMENT containing bearings and gears that require lubricants shall be designed and constructed so that the lubricant cannot leak, drip, or be forced into FOOD or onto FOOD-CONTACT SURFACES.

4-204.16 Beverage Tubing, Separation.

Except for cold plates that are constructed integrally with an ice storage bin, BEVERAGE tubing and cold-plate BEVERAGE cooling devices may not be installed in contact with stored ice.

4-204.17 Ice Units, Separation of Drains.

Liquid waste drain lines may not pass through an ice machine or ice storage bin.

4-204.18 Condenser Unit, Separation.

If a condenser unit is an integral component of EQUIPMENT, the condenser unit shall be separated from the FOOD and FOOD storage space by a dustproof barrier.

4-204.19 Can Openers on Vending Machines.

Cutting or piercing parts of can openers on VENDING MACHINES shall be protected from manual contact, dust, insects, rodents, and other contamination.

4-204.110 Molluscan Shellfish Tanks.

(A) Except as specified under ¶ (B) of this section, MOLLUSCAN SHELLFISH life support system display tanks may not be used to store or display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the CONSUMER that the shellfish are for display only.[P]

(B) MOLLUSCAN SHELLFISH life-support system display tanks that are used to store or display shellfish that are offered for human

consumption shall be operated and maintained in accordance with a VARIANCE granted by the REGULATORY AUTHORITY as specified in § 8-103.10 and a HACCP PLAN that: [Pf]

(1) Is submitted by the PERMIT HOLDER and APPROVED as specified under § 8-103.11; [Pf] and

(2) Ensures that:

(a) Water used with FISH other than MOLLUSCAN SHELLFISH does not flow into the molluscan tank, [Pf]

(b) The safety and quality of the shellfish as they were received are not compromised by the use of the tank, [Pf] and

(c) The identity of the source of the SHELLSTOCK is retained as specified under § 3-203.12. [Pf]

4-204.111 Vending Machines, Automatic Shutoff.

(A) A machine vending TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall have an automatic control that prevents the machine from vending FOOD:

(1) If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that cannot maintain FOOD temperatures as specified under Chapter 3; [P] and

(2) If a condition specified under Subparagraph (A)(1) of this section occurs, until the machine is serviced and restocked with FOOD that has been maintained at temperatures specified under Chapter 3. [P]

(B) When the automatic shutoff within a machine vending TIME/TEMPERATURE CONTROL FOR SAFETY FOOD is activated:

(1) In a refrigerated vending machine, the ambient air temperature may not exceed 5°C (41°F) for more than 30 minutes immediately after the machine is filled, serviced, or restocked; [P] or

(2) In a hot holding vending machine, the ambient air temperature may not be less than 57 °C (135 °F) for more than 120 minutes immediately after the machine is filled, serviced, or restocked. [P]

4-204.112 Temperature Measuring Devices.

(A) In a mechanically refrigerated or hot FOOD storage unit, the sensor of a TEMPERATURE MEASURING DEVICE shall be located to measure the air temperature or a simulated product temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot FOOD storage unit.

(B) Except as specified in ¶ (C) of this section, cold or hot holding EQUIPMENT used for TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be designed to include and shall be equipped with at least one integral or permanently affixed TEMPERATURE MEASURING DEVICE that is located to allow easy viewing of the device's temperature display.

(C) *Paragraph (B) of this section does not apply to EQUIPMENT for which the placement of a TEMPERATURE MEASURING DEVICE is not a practical means for measuring the ambient air surrounding the FOOD because of the design, type, and use of the EQUIPMENT, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated FOOD transport containers, and salad bars*.

(D) TEMPERATURE MEASURING DEVICES shall be designed to be easily readable.

(E) FOOD TEMPERATURE MEASURING DEVICES and water TEMPERATURE MEASURING DEVICES on WAREWASHING machines shall have a numerical scale, printed record, or digital readout in increments no greater than 1°C or 2°F in the intended range of use. [Pf]

4-204.113 Warewashing Machine, Data Plate Operating Specifications.

A WAREWASHING machine shall be provided with an easily accessible and readable data plate affixed to the machine by the manufacturer that indicates the machine's design and operation specifications including the:

(A) Temperatures required for washing, rinsing, and SANITIZING;

(B) Pressure required for the fresh water SANITIZING rinse *unless the machine is designed to use only a pumped SANITIZING rinse;* and

(C) Conveyor speed for conveyor machines or cycle time for stationary rack machines.

4-204.114 Warewashing Machines, Internal Baffles.

WAREWASHING machine wash and rinse tanks shall be equipped with baffles, curtains, or other means to minimize internal cross contamination of the solutions in wash and rinse tanks.

4-204.115 Warewashing Machines, Temperature Measuring Devices.

A WAREWASHING machine shall be equipped with a TEMPERATURE MEASURING DEVICE that indicates the temperature of the water:

(A) In each wash and rinse tank; [Pf] and

(B) As the water enters the hot water SANITIZING final rinse manifold or in the chemical SANITIZING solution tank. [Pf]

4-204.116 Manual Warewashing Equipment, Heaters and Baskets.

If hot water is used for SANITIZATION in manual WAREWASHING operations, the SANITIZING compartment of the sink shall be:

(A) Designed with an integral heating device that is capable of maintaining water at a temperature not less than 77°C (171°F); [Pf] and

(B) Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water. [Pf]

4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers.

A WAREWASHING machine that is installed after adoption of this Code by the REGULATORY AUTHORITY, shall be equipped to:

(A) Automatically dispense detergents and SANITIZERS; [Pf] and

(B) Incorporate a visual means to verify that detergents and SANITIZERS are delivered or a visual or audible alarm to signal if the detergents and SANITIZERS are not delivered to the respective washing and SANITIZING cycles. [Pf]

4-204.118 Warewashing Machines, Flow Pressure Device.

(A) WAREWASHING machines that provide a fresh hot water SANITIZING rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the WAREWASHING machine; and

(B) If the flow pressure measuring device is upstream of the fresh hot water SANITIZING rinse control valve, the device shall be mounted in a 6.4 millimeter or one-fourth inch Iron Pipe Size (IPS) valve.

(C) *Paragraphs (A) and (B) of this section do not apply to a machine that uses only a pumped or recirculated SANITIZING rinse.*

4-204.119 Warewashing Sinks and Drainboards, Self-Draining.

Sinks and drainboards of WAREWASHING sinks and machines shall be self-draining.

4-204.120 Equipment Compartments, Drainage.

EQUIPMENT compartments that are subject to accumulation of moisture due to conditions such as condensation, FOOD or BEVERAGE drip, or water from melting ice shall be sloped to an outlet that allows complete draining.

4-204.121 Vending Machines, Liquid Waste Products.

(A) VENDING MACHINES designed to store BEVERAGES that are PACKAGED in containers made from paper products shall be equipped with diversion devices and retention pans or drains for container leakage.

(B) VENDING MACHINES that dispense liquid FOOD in bulk shall be:

(1) Provided with an internally mounted waste receptacle for the collection of drip, spillage, overflow, or other internal wastes; and

(2) Equipped with an automatic shutoff device that will place the machine out of operation before the waste receptacle overflows.

(C) Shutoff devices specified under Subparagraph (B)(2) of this section shall prevent water or liquid FOOD from continuously running if there is a failure of a flow control device in the water or liquid FOOD system or waste accumulation that could lead to overflow of the waste receptacle.

4-204.122 Case Lot Handling Apparatuses, Moveability.

Apparatuses, such as dollies, pallets, racks, and skids used to store and transport large quantities of PACKAGED FOODS received from a supplier in a cased or overwrapped lot, shall be designed to be moved by hand or by conveniently available

apparatuses such as hand trucks and forklifts.

4-204.123 Vending Machine Doors and Openings.

(A) VENDING MACHINE doors and access opening covers to FOOD and container storage spaces shall be tight-fitting so that the space along the entire interface between the doors or covers and the cabinet of the machine, if the doors or covers are in a closed position, is no greater than 1.5 millimeters or one-sixteenth inch by:

(1) Being covered with louvers, screens, or materials that provide an equivalent opening of not greater than 1.5 millimeters or one-sixteenth inch. Screening of 12 or more mesh to 2.5 centimeters (12 mesh to 1 inch) meets this requirement;

(2) Being effectively gasketed;

(3) Having interface surfaces that are at least 13 millimeters or one-half inch wide; or

(4) Jambs or surfaces used to form an L-shaped entry path to the interface.

(B) VENDING MACHINE service connection openings through an exterior wall of a machine shall be closed by sealants, clamps, or grommets so that the openings are no larger than 1.5 millimeters or one-sixteenth inch.

Acceptability

4-205.10 Food Equipment, Certification and Classification.

FOOD EQUIPMENT that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with Parts 4-1 and 4-2 of this chapter.

4-3 NUMBERS AND CAPACITIES

Subparts

Equipment

4-301.11 Cooling, Heating, and Holding Capacities.

EQUIPMENT for cooling and heating FOOD, and holding cold and hot FOOD, shall be sufficient in number and capacity to provide FOOD temperatures as specified under Chapter 3. [Pf]

4-301.12 Manual Warewashing, Sink Compartment Requirements.

(A) Except as specified in ¶ (C) of this section, a sink with at least 3 compartments shall be provided for manually washing, rinsing, and SANITIZING EQUIPMENT and UTENSILS. [Pf]

(B) Sink compartments shall be large enough to accommodate immersion of the largest EQUIPMENT and UTENSILS. If EQUIPMENT or UTENSILS are too large for the WAREWASHING sink, a WAREWASHING machine or alternative EQUIPMENT as specified in ¶ (C) of this section shall be used. [Pf]

(C) *Alternative manual WAREWASHING EQUIPMENT may be used when there are special cleaning needs or constraints and its use is APPROVED. Alternative manual WAREWASHING EQUIPMENT may include:*

(1) *High-pressure detergent sprayers;*

(2) *Low- or line-pressure spray detergent foamers;*

(3) *Other task-specific cleaning EQUIPMENT;*

(4) *Brushes or other implements;*

(5) *2-compartment sinks as specified under ¶¶ (D) and (E) of this section; or*

(6) *Receptacles that substitute for the compartments of a multicompartment sink.*

(D) Before a 2-compartment sink is used:

(1) The PERMIT HOLDER shall have its use APPROVED; and

(2) The PERMIT HOLDER shall limit the number of KITCHENWARE items cleaned and SANITIZED in the 2-compartment sink, and shall limit WAREWASHING to batch operations for cleaning KITCHENWARE such as between cutting one type of raw MEAT and another or cleanup at the end of a shift, and shall:

(a) Make up the cleaning and SANITIZING solutions immediately before use and drain them immediately after use, and

(b) Use a detergent-SANITIZER to SANITIZE and apply the detergent-SANITIZER in accordance with the manufacturer's label instructions and as specified under § 4-501.115, or

(c) Use a hot water SANITIZATION immersion step as specified under ¶ 4-603.16(C).

(E) A 2-compartment sink may not be used for WAREWASHING operations where cleaning and SANITIZING solutions are used for a continuous or intermittent flow of KITCHENWARE or TABLEWARE in an ongoing WAREWASHING process.

4-301.13 Drainboards.

Drainboards, UTENSIL racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation shall be provided for necessary UTENSIL holding before cleaning and after SANITIZING.

4-301.14 Ventilation Hood Systems, Adequacy.

Ventilation hood systems and devices shall be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceilings.

4-301.15 Clothes Washers and Dryers.

(A) Except as specified in ¶ (B) of this section, if work clothes or LINENS are laundered on the PREMISES, a mechanical clothes washer and dryer shall be provided and used.

(B) *If on-PREMISES laundering is limited to wiping cloths intended to be used moist, or wiping cloths are air-dried as specified under § 4-901.12, a mechanical clothes washer and dryer need not be provided.*

Utensils, Temperature Measuring Devices, and Testing Devices

4-302.11 Utensils, Consumer Self-Service.

A FOOD dispensing UTENSIL shall be available for each container displayed at a CONSUMER self-service unit such as a buffet or salad bar. [Pf]

4-302.12 Food Temperature Measuring Devices.

(A) FOOD TEMPERATURE MEASURING DEVICES shall be provided and readily accessible for use in ensuring attainment and maintenance of FOOD temperatures as specified under Chapter 3. [Pf]

(B) A TEMPERATURE MEASURING DEVICE with a suitable small-diameter probe that is designed to measure the temperature of thin masses shall be provided and readily accessible to accurately measure the temperature in thin FOODS such as MEAT patties and FISH filets. [Pf]

4-302.13 Temperature Measuring Devices, Manual and Mechanical Warewashing.

(A) In manual WAREWASHING operations, a TEMPERATURE MEASURING DEVICE shall be provided and readily accessible for frequently measuring the washing and SANITIZING temperatures. [Pf]

(B) In hot water mechanical WAREWASHING operations, an irreversible registering temperature indicator shall be provided and readily accessible for measuring the UTENSIL surface temperature.[Pf]

4-302.14 Sanitizing Solutions, Testing Devices.

A test kit or other device that accurately measures the concentration in MG/L of SANITIZING solutions shall be provided.[Pf]

4-4 LOCATION AND INSTALLATION

Subparts

Location

4-401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.

(A) Except as specified in ¶ (B) of this section, EQUIPMENT, a cabinet used for the storage of FOOD, or a cabinet that is used to store cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be located:

(1) In locker rooms;

(2) In toilet rooms;

(3) In garbage rooms;

(4) In mechanical rooms;

(5) Under sewer lines that are not shielded to intercept potential drips;

(6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(7) Under open stairwells; or

(8) Under other sources of contamination.

(B) *A storage cabinet used for* LINENS *or* SINGLE-SERVICE *or* SINGLE-USE ARTICLES *may be stored in a locker room.*

(C) If a mechanical clothes washer or dryer is provided, it shall be located so that the washer or dryer is protected from contamination and only where there is no exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

Installation

4-402.11 Fixed Equipment, Spacing or Sealing.

(A) EQUIPMENT that is fixed because it is not EASILY MOVABLE shall be installed so that it is:

(1) Spaced to allow access for cleaning along the sides, behind, and above the EQUIPMENT;

(2) Spaced from adjoining EQUIPMENT, walls, and ceilings a distance of not more than 1 millimeter or one thirty-second inch; or

(3) SEALED to adjoining EQUIPMENT or walls, if the EQUIPMENT is exposed to spillage or seepage.

(B) COUNTER-MOUNTED EQUIPMENT that is not EASILY MOVABLE shall be installed to allow cleaning of the EQUIPMENT and areas underneath and around the EQUIPMENT by being:

(1) SEALED; or

(2) Elevated on legs as specified under ¶ 4-402.12(D).

4-402.12 Fixed Equipment, Elevation or Sealing.

(A) Except as specified in ¶¶ (B) and (C) of this section, floor-mounted EQUIPMENT that is not EASILY MOVABLE shall be SEALED to the floor or elevated on legs that provide at least a 15 centimeter (6 inch) clearance between the floor and the EQUIPMENT.

(B) *If no part of the floor under the floor-mounted* EQUIPMENT *is more than 15 centimeters (6 inches) from the point of cleaning access, the clearance space may be only 10 centimeters (4 inches)*.

(C) *This section does not apply to display shelving units, display refrigeration units, and display freezer units located in the* CONSUMER *shopping areas of a retail* FOOD *store, if the floor under the units is maintained clean*.

(D) Except as specified in ¶ (E) of this section, COUNTER-MOUNTED EQUIPMENT that is not EASILY MOVABLE shall be elevated on legs that provide at least a 10 centimeter (4 inch) clearance between the table and the EQUIPMENT.

(E) *The clearance space between the table and* COUNTER-MOUNTED EQUIPMENT *may be*:

(1) *7.5 centimeters (3 inches) if the horizontal distance of the table top under the* EQUIPMENT *is no more than 50 centimeters (20 inches) from the point of access for cleaning; or*

(2) *5 centimeters (2 inches) if the horizontal distance of the table top under the* EQUIPMENT *is no more than 7.5 centimeters (3 inches) from the point of access for cleaning*

4-5 MAINTENANCE AND OPERATION

Subparts

Equipment

4-501.11 Good Repair and Proper Adjustment.

(A) EQUIPMENT shall be maintained in a state of repair and condition that meets the requirements specified under Parts 4-1 and 4-2.

(B) EQUIPMENT components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with manufacturer's specifications.

(C) Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate FOOD when the container is opened.

4-501.12 Cutting Surfaces.

Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and SANITIZED, or discarded if they are not capable of being resurfaced.

4-501.13 Microwave Ovens.

Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10 Microwave ovens.

4-501.14 Warewashing Equipment, Cleaning Frequency.

A WAREWASHING machine; the compartments of sinks, basins, or other receptacles used for washing and rinsing EQUIPMENT, UTENSILS, or raw FOODS, or laundering wiping cloths; and drainboards or other EQUIPMENT used to substitute for drainboards as specified under § 4-301.13 shall be cleaned:

(A) Before use;

(B) Throughout the day at a frequency necessary to prevent recontamination of EQUIPMENT and UTENSILS and to ensure that the EQUIPMENT performs its intended function; and

(C) If used, at least every 24 hours.

4-501.15 Warewashing Machines, Manufacturers' Operating Instructions.

(A) A WAREWASHING machine and its auxiliary components shall be operated in accordance with the machine's data plate and other manufacturer's instructions.

(B) A WAREWASHING machine's conveyor speed or automatic cycle times shall be maintained accurately timed in accordance with manufacturer's specifications.

4-501.16 Warewashing Sinks, Use Limitation.

(A) A WAREWASHING sink may not be used for handwashing as specified under § 2-301.15.

(B) If a WAREWASHING sink is used to wash wiping cloths, wash produce, or thaw FOOD, the sink shall be cleaned as specified under § 4-501.14 before and after each time it is used to wash wiping cloths or wash produce or thaw FOOD. Sinks used to wash or thaw FOOD shall be SANITIZED as specified under Part 4-7 before and after using the sink to wash produce or thaw FOOD.

4-501.17 Warewashing Equipment, Cleaning Agents.

When used for WAREWASHING, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C), shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions. Pf

4-501.18 Warewashing Equipment, Clean Solutions.

The wash, rinse, and SANITIZE solutions shall be maintained clean.

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The temperature of the wash solution in manual WAREWASHING EQUIPMENT shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions. [Pf]

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

(A) The temperature of the wash solution in spray type warewashers that use hot water to SANITIZE may not be less than:

(1) For a stationary rack, single temperature machine, 74°C (165°F); [Pf]

(2) For a stationary rack, dual temperature machine, 66°C (150°F); [Pf]

(3) For a single tank, conveyor, dual temperature machine, 71°C (160°F); [Pf] or

(4) For a multitank, conveyor, multitemperature machine, 66°C (150°F). [Pf]

(B) The temperature of the wash solution in spray-type warewashers that use chemicals to SANITIZE may not be less than 49°C (120°F). [Pf]

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures.

If immersion in hot water is used for SANITIZING in a manual operation, the temperature of the water shall be maintained at 77°C (171°F) or above. [P]

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

(A) Except as specified in ¶ (B) of this section, in a mechanical operation, the temperature of the fresh hot water SANITIZING rinse as it enters the manifold may not be more than 90°C (194°F), or less than: [Pf]

(1) For a stationary rack, single temperature machine, 74°C (165°F); [Pf] or

(2) For all other machines, 82°C (180°F). [Pf]

(B) *The maximum temperature specified under ¶ (A) of this section, does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and SANITIZING of EQUIPMENT such as meat saws.*

4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure.

The flow pressure of the fresh hot water SANITIZING rinse in a WAREWASHING machine, as measured in the water line immediately downstream or upstream from the fresh hot water SANITIZING rinse control value, shall be within the range specified on the machine manufacturer's data plate and may not be less than 35 kilopascals (5 pounds per square inch) or more than 200 kilopascals (30 pounds per square inch).

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at contact times specified under ¶4-703.11(C) shall meet the criteria specified under §7-204.11 Sanitizers, Criteria, shall be used in accordance with the EPA-registered label use instructions, [P] and shall be used as follows:

(A) A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart; P

Concentration Range (MG/L)	**Minimum Temperature** pH 10 or less **°C (°F)**	**Minimum Temperature** pH 8 or less **°C (°F)**
25 – 49	49 (120)	49 (120)
50 – 99	38 (100)	24 (75)
100	13 (55)	13 (55)

(B) An iodine solution shall have a:

(1) Minimum temperature of 20°C (68°F), P

(2) pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective, P and

(3) Concentration between 12.5 MG/L and 25 MG/L; P

(C) A quaternary ammonium compound solution shall:

(1) Have a minimum temperature of 24°C (75°F), P

(2) Have a concentration as specified under § 7-204.11 and as indicated by the manufacturer's use directions included in the labeling, P and

(3) Be used only in water with 500 MG/L hardness or less or in water having a hardness no greater than specified by the EPA-registered label use instructions; P

(D) If another solution of a chemical specified under ¶¶ (A) - (C) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANITIZATION and the use of the solution shall be APPROVED;P

(E) If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the EPA-registered label use instructions; [P] and

(F) If a chemical SANITIZER is generated by a device located on-site at the FOOD ESTABLISHMENT it shall be used as specified in ¶¶(A) - (D) of this section and shall be produced by a device that:

(1) Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[P]

(2) Complies with 40 CFR 152.500 Requirement for Devices and 40 CFR 156.10 Labeling Requirements, [P]

(3) Displays the EPA device manufacturing facility registration number on the device, [Pf] and

(4) Is operated and maintained in accordance with manufacturer's instructions [Pf].

4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers.

If a detergent-SANITIZER is used to SANITIZE in a cleaning and SANITIZING procedure where there is no distinct water rinse between the washing and SANITIZING steps, the agent applied in the SANITIZING step shall be the same detergent-SANITIZER that is used in the washing step.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device. [Pf]

Utensils and Temperature and Pressure Measuring Devices

4-502.11 Good Repair and Calibration.

(A) UTENSILS shall be maintained in a state of repair or condition that complies with the requirements specified under Parts 4-1 and 4-2 or shall be discarded.

(B) FOOD TEMPERATURE MEASURING DEVICES shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy. [Pf]

(C) Ambient air temperature, water pressure, and water TEMPERATURE MEASURING DEVICES shall be maintained in good repair and be accurate within the intended range of use.

4-502.12 Single-Service and Single-Use Articles, Required Use.

A FOOD ESTABLISHMENT without facilities specified under Parts 4-6 and 4-7 for cleaning and SANITIZING KITCHENWARE and TABLEWARE shall provide only SINGLE-USE KITCHENWARE, SINGLE-SERVICE ARTICLES, and SINGLE-USE ARTICLES for use by FOOD EMPLOYEES AND SINGLE-SERVICE ARTICLES for use by CONSUMERS. [P]

4-502.13 Single-Service and Single-Use Articles, Use Limitation.

(A) SINGLE-SERVICE and SINGLE-USE ARTICLES may not be reused.

(B) The bulk milk container dispensing tube shall be cut on the diagonal leaving no more than one inch protruding from the chilled dispensing head.

4-502.14 Shells, Use Limitation.

Mollusk and crustacea shells may not be used more than once as serving containers.

4-6 CLEANING OF EQUIPMENT AND UTENSILS

Subparts

Objective

4-601.11 Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be clean to sight and touch. [Pf]

(B) The FOOD-CONTACT SURFACES of cooking EQUIPMENT and pans shall be kept free of encrusted grease deposits and other soil accumulations.

(C) NonFOOD-CONTACT SURFACES of EQUIPMENT shall be kept free of an accumulation of dust, dirt, FOOD residue, and other debris.

Frequency

4-602.11 Equipment Food-Contact Surfaces and Utensils.

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be cleaned:

(1) Except as specified in ¶ (B) of this section, before each use with a different type of raw animal FOOD such as beef, FISH, lamb, pork, or POULTRY; [P]

(2) Each time there is a change from working with raw FOODS to working with READY-TO-EAT FOODS; [P]

(3) Between uses with raw fruits and vegetables and with TIME/TEMPERATURE CONTROL FOR SAFETY FOOD; [P]

(4) Before using or storing a FOOD TEMPERATURE MEASURING DEVICE; [P] and

(5) At any time during the operation when contamination may have occurred. [P]

(B) *Subparagraph (A)(1) of this section does not apply if the* FOOD-CONTACT SURFACE *or* UTENSIL *is in contact with a succession of different types of raw* MEAT *and* POULTRY *each requiring a higher cooking temperature as specified under § 3-401.11 than the previous type*.

(C) Except as specified in ¶ (D) of this section, if used with TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be cleaned throughout the day at least every 4 hours.[P]

(D) *Surfaces of* UTENSILS *and* EQUIPMENT *contacting* TIME/TEMPERATURE CONTROL FOR SAFETY FOOD *may be cleaned less frequently than every 4 hours if:*

(1) *In storage, containers of* TIME/TEMPERATURE CONTROL FOR SAFETY FOOD *and their contents are maintained at temperatures specified under Chapter 3 and the containers are cleaned when they are empty;*

(2) *UTENSILS and* EQUIPMENT *are used to prepare* FOOD *in a refrigerated room or area that is maintained at one of the temperatures in the following chart and:*

(a) *The* UTENSILS *and* EQUIPMENT *are cleaned at the frequency in the following chart that corresponds to the temperature; and*

Temperature	Cleaning Frequency
5.0°C (41°F) or less	24 hours
>5.0°C - 7.2°C (>41°F - 45°F)	20 hours
>7.2°C - 10.0°C (>45°F - 50°F)	16 hours
>10.0°C - 12.8°C (>50°F - 55°F)	10 hours

(b) *The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the* FOOD ESTABLISHMENT.

(3) *Containers in serving situations such as salad bars, delis,*

and cafeteria lines hold READY-TO-EAT TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is maintained at the temperatures specified under Chapter 3, are intermittently combined with additional supplies of the same FOOD that is at the required temperature, and the containers are cleaned at least every 24 hours;

(4) *TEMPERATURE MEASURING DEVICES are maintained in contact with FOOD, such as when left in a container of deli FOOD or in a roast, held at temperatures specified under Chapter 3;*

(5) *EQUIPMENT is used for storage of PACKAGED or unPACKAGED FOOD such as a reach-in refrigerator and the EQUIPMENT is cleaned at a frequency necessary to preclude accumulation of soil residues;*

(6) *The cleaning schedule is APPROVED based on consideration of:*

(a) *Characteristics of the EQUIPMENT and its use,*

(b) *The type of FOOD involved,*

(c) *The amount of FOOD residue accumulation, and*

(d) *The temperature at which the FOOD is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or*

(7) In-use UTENSILS are intermittently stored in a container of water in which the water is maintained at 57°C (135°F) or more and the UTENSILS and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.

(E) *Except when dry cleaning methods are used as specified under § 4-603.11*, surfaces of UTENSILS and EQUIPMENT contacting FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cleaned:

(1) At any time when contamination may have occurred;

(2) At least every 24 hours for iced tea dispensers and

CONSUMER self-service UTENSILS such as tongs, scoops, or ladles;

(3) Before restocking CONSUMER self-service EQUIPMENT and UTENSILS such as condiment dispensers and display containers; and

(4) In EQUIPMENT such as ice bins and BEVERAGE dispensing nozzles and enclosed components of EQUIPMENT such as ice makers, cooking oil storage tanks and distribution lines, BEVERAGE and syrup dispensing lines or tubes, coffee bean grinders, and water vending EQUIPMENT:

(a) At a frequency specified by the manufacturer, or

(b) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

4-602.12 Cooking and Baking Equipment.

(A) The FOOD-CONTACT SURFACES of cooking and baking EQUIPMENT shall be cleaned at least every 24 hours. *This section does not apply to hot oil cooking and filtering EQUIPMENT if it is cleaned as specified in Subparagraph 4-602.11(D)(6)*.

(B) The cavities and door seals of microwave ovens shall be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.

4-602.13 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES of EQUIPMENT shall be cleaned at a frequency necessary to preclude accumulation of soil residues.

Methods

4-603.11 Dry Cleaning.

(A) If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only SURFACES that are soiled with dry FOOD residues that are not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD.

(B) Cleaning EQUIPMENT used in dry cleaning FOOD-CONTACT SURFACES may not be used for any other purpose.

4-603.12 Precleaning.

(A) FOOD debris on EQUIPMENT and UTENSILS shall be scraped over a waste disposal unit or garbage receptacle or shall be removed in a WAREWASHING machine with a prewash cycle.

(B) If necessary for effective cleaning, UTENSILS and EQUIPMENT shall be preflushed, presoaked, or scrubbed with abrasives.

4-603.13 Loading of Soiled Items, Warewashing Machines.

Soiled items to be cleaned in a WAREWASHING machine shall be loaded into racks, trays, or baskets or onto conveyors in a position that:

(A) Exposes the items to the unobstructed spray from all cycles; and

(B) Allows the items to drain.

4-603.14 Wet Cleaning.

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary such as the application of detergents containing wetting agents and emulsifiers; acid, alkaline, or abrasive cleaners; hot water; brushes; scouring pads; high-pressure sprays; or ultrasonic devices.

(B) The washing procedures selected shall be based on the type and purpose of the EQUIPMENT or UTENSIL, and on the type of soil to be removed.

4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment.

If washing in sink compartments or a WAREWASHING machine is impractical such as when the EQUIPMENT is fixed or the UTENSILS are too large, washing shall be done by using alternative

manual WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C) in accordance with the following procedures:

(A) EQUIPMENT shall be disassembled as necessary to allow access of the detergent solution to all parts;

(B) EQUIPMENT components and UTENSILS shall be scrapped or rough cleaned to remove FOOD particle accumulation; and

(C) EQUIPMENT and UTENSILS shall be washed as specified under ¶ 4-603.14(A).

4-603.16 Rinsing Procedures.

Washed UTENSILS and EQUIPMENT shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent-sanitizer solution by using one of the following procedures:

(A) Use of a distinct, separate water rinse after washing and before SANITIZING if using:

(1) A 3-compartment sink,

(2) Alternative manual WAREWASHING EQUIPMENT equivalent to a 3-compartment sink as specified in ¶ 4-301.12(C), or

(3) A 3-step washing, rinsing, and SANITIZING procedure in a WAREWASHING system for CIP EQUIPMENT;

(B) Use of a detergent-SANITIZER as specified under § 4-501.115 if using:

(1) Alternative WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C) that is APPROVED for use with a detergent-SANITIZER, or

(2) A WAREWASHING system for CIP EQUIPMENT;

(C) Use of a nondistinct water rinse that is integrated in the hot water SANITIZATION immersion step of a 2-compartment sink operation;

(D) If using a WAREWASHING machine that does not recycle the SANITIZING solution as specified under ¶ (E) of this section, or alternative manual WAREWASHING EQUIPMENT such as sprayers, use of a nondistinct water rinse that is:

(1) Integrated in the application of the SANITIZING solution, and

(2) Wasted immediately after each application; or

(E) If using a WAREWASHING machine that recycles the SANITIZING solution for use in the next wash cycle, use of a nondistinct water rinse that is integrated in the application of the SANITIZING solution.

4-7 SANITIZATION OF EQUIPMENT AND UTENSILS

Subparts

Objective

4-701.10 Food-Contact Surfaces and Utensils.

EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED.

Frequency

4-702.11 Before Use After Cleaning.

UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT shall be SANITIZED before use after cleaning.[P]

Methods

4-703.11 Hot Water and Chemical.

After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in:

(A) Hot water manual operations by immersion for at least 30 seconds and as specified under § 4-501.111;[P]

(B) Hot water mechanical operations by being cycled through EQUIPMENT that is set up as specified under §§ 4-501.15, 4-501.112, and 4-501.113 and achieving a UTENSIL surface temperature of 71°C (160°F) as measured by an irreversible registering temperature indicator;[P] or

(C) Chemical manual or mechanical operations, including the application of SANITIZING chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under § 4-501.114. Contact times shall be consistent with those on EPA-registered label use instructions by providing:

(1) Except as specified under Subparagraph (C)(2) of this section, a contact time of at least 10 seconds for a chlorine solution specified under ¶ 4-501.114(A),[P]

(2) A contact time of at least 7 seconds for a chlorine solution of 50 MG/L that has a PH of 10 or less and a temperature of at least 38°C (100°F) or a PH of 8 or less and a temperature of at least 24°C (75°F),[P]

(3) A contact time of at least 30 seconds for other chemical SANITIZING solutions,[P] or

(4) A contact time used in relationship with a combination of temperature, concentration, and PH that, when evaluated for efficacy, yields SANITIZATION as defined in ¶ 1-201.10(B).[P]

4-8 LAUNDERING

Subparts

Objective **4-801.11 Clean Linens.**

Clean LINENS shall be free from FOOD residues and other soiling matter.

Frequency

4-802.11 Specifications.

(A) LINENS that do not come in direct contact with FOOD shall be laundered between operations if they become wet, sticky, or visibly soiled.

(B) Cloth gloves used as specified in ¶ 3-304.15(D) shall be laundered before being used with a different type of raw animal FOOD such as beef, FISH, lamb, pork or POULTRY.

(C) LINENS that are used as specified under § 3-304.13 and cloth napkins shall be laundered between each use.

(D) Wet wiping cloths shall be laundered daily.

(E) Dry wiping cloths shall be laundered as necessary to prevent contamination of FOOD and clean serving UTENSILS.

Methods

4-803.11 Storage of Soiled Linens.

Soiled LINENS shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of FOOD, clean EQUIPMENT, clean UTENSILS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

4-803.12 Mechanical Washing.

(A) Except as specified in ¶ (B) of this section, LINENS shall be mechanically washed.

(B) *In FOOD ESTABLISHMENTS in which only wiping cloths are laundered as specified in ¶ 4-301.15(B), the wiping cloths may be laundered in a mechanical washer, sink designated only for laundering wiping cloths, or a WAREWASHING or FOOD preparation sink that is cleaned as specified under § 4-501.14.*

4-803.13 Use of Laundry Facilities.

(A) Except as specified in ¶ (B) of this section, laundry facilities on the PREMISES of a FOOD ESTABLISHMENT shall be used only for the washing and drying of items used in the operation of the establishment.

(B) *Separate laundry facilities located on the* PREMISES *for the purpose of general laundering such as for institutions providing boarding and lodging may also be used for laundering* FOOD ESTABLISHMENT *items.*

4-9 PROTECTION OF CLEAN ITEMS

Subparts

Drying

4-901.11 Equipment and Utensils, Air-Drying Required.

After cleaning and SANITIZING, EQUIPMENT and UTENSILS:

(A) Shall be air-dried or used after adequate draining as specified in the first paragraph of 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface SANITIZING solutions), before contact with FOOD; and

(B) May not be cloth dried *except that* UTENSILS *that have been air-dried may be polished with cloths that are maintained clean and dry*.

4-901.12 Wiping Cloths, Air-Drying Locations.

Wiping cloths laundered in a FOOD ESTABLISHMENT that does not have a mechanical clothes dryer as specified in ¶ 4-301.15(B) shall be air-dried in a location and in a manner that prevents contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES and the wiping cloths. *This section does not apply if wiping cloths are stored after laundering in a* SANITIZING *solution as specified under § 4-501.114.*

Lubricating and Reassembling

4-902.11 Food-Contact Surfaces.

Lubricants as specified under § 7-205.11 shall be applied to FOOD-CONTACT SURFACES that require lubrication in a manner that does not contaminate FOOD-CONTACT SURFACES.

4-902.12 Equipment.

EQUIPMENT shall be reassembled so that FOOD-CONTACT SURFACES are not contaminated.

Storing

4-903.11 Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.

(A) Except as specified in ¶ (D) of this section, cleaned EQUIPMENT and UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES shall be stored:

(1) In a clean, dry location;

(2) Where they are not exposed to splash, dust, or other contamination; and

(3) At least 15 cm (6 inches) above the floor.

(B) Clean EQUIPMENT and UTENSILS shall be stored as specified under ¶ (A) of this section and shall be stored:

(1) In a self-draining position that allows air drying; and

(2) Covered or inverted.

(C) SINGLE-SERVICE and SINGLE-USE ARTICLES shall be stored as specified under ¶ (A) of this section and shall be kept in the original protective PACKAGE or stored by using other means that afford protection from contamination until used.

(D) *Items that are kept in closed PACKAGES may be stored less than 15 cm (6 inches) above the floor on dollies, pallets, racks, and skids that are designed as specified under § 4-204.122.*

4-903.12 Prohibitions.

(A) Except as specified in ¶ (B) of this section, cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be stored:

(1) In locker rooms;

(2) In toilet rooms;

(3) In garbage rooms;

(4) In mechanical rooms;

(5) Under sewer lines that are not shielded to intercept potential drips;

(6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(7) Under open stairwells; or

(8) Under other sources of contamination.

(B) *Laundered LINENS and SINGLE-SERVICE and SINGLE-USE ARTICLES that are PACKAGED or in a facility such as a cabinet may be stored in a locker room.*

Preventing Contamination

4-904.11 Kitchenware and Tableware.

(A) SINGLE-SERVICE and SINGLE-USE ARTICLES and cleaned and SANITIZED UTENSILS shall be handled, displayed, and dispensed so that contamination of FOOD- and lip-contact surfaces is prevented.

(B) Knives, forks, and spoons that are not prewrapped shall be presented so that only the handles are touched by EMPLOYEES and by CONSUMERS if CONSUMER self-service is provided.

(C) Except as specified under ¶ (B) of this section, SINGLE-SERVICE ARTICLES that are intended for FOOD- or lip-contact shall be furnished for CONSUMER self-service with the original individual wrapper intact or from an APPROVED dispenser.

4-904.12 Soiled and Clean Tableware.

Soiled TABLEWARE shall be removed from CONSUMER eating and drinking areas and handled so that clean TABLEWARE is not contaminated.

4-904.13 Preset Tableware.

(A) Except as specified in ¶ (B) of this section, TABLEWARE that is preset shall be protected from contamination by being wrapped, covered, or inverted.

(B) *Preset TABLEWARE may be exposed if:*

(1) Unused settings are removed when a CONSUMER is seated; or

(2) Settings not removed when a CONSUMER is seated are cleaned and SANITIZED before further use.

4-904.14 Rinsing Equipment and Utensils after Cleaning and Sanitizing.

After being cleaned and SANITIZED, EQUIPMENT and UTENSILS shall not be rinsed before air drying or use unless:

(A) The rinse is applied directly from a potable water supply by a warewashing machine that is maintained and operated as specified under Subparts 4-204 and 4-501; and

(B) The rinse is applied only after the EQUIPMENT and UTENSILS have been SANITIZED by the application of hot water or by the application of a chemical SANITIZER solution whose EPA-registered label use instructions call for rinsing off the SANITIZER after it is applied in a commercial WAREWASHING machine.

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Chapter

5 Water, Plumbing, and Waste

Parts

5-1 WATER

Subparts

Source

5-101.11 Approved System.

DRINKING WATER shall be obtained from an APPROVED source that is:

(A) A PUBLIC WATER SYSTEM;[P] or

(B) A nonPUBLIC WATER SYSTEM that is constructed, maintained, and operated according to LAW.[P]

5-101.12 System Flushing and Disinfection.

A DRINKING WATER system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system. [P]

5-101.13 Bottled Drinking Water.

BOTTLED DRINKING WATER used or sold in a FOOD ESTABLISHMENT shall be obtained from APPROVED sources in accordance with 21 CFR 129 - Processing and Bottling of Bottled DRINKING WATER. [P]

Quality

5-102.11 Standards.

Except as specified under § 5-102.12:

(A) Water from a PUBLIC WATER SYSTEM shall meet 40 CFR 141 - National Primary Drinking Water Regulations and state DRINKING WATER quality standards; [P] and

(B) Water from a nonPUBLIC WATER SYSTEM shall meet state DRINKING WATER quality standards. [P]

5-102.12 Nondrinking Water.

(A) A nonDRINKING WATER supply shall be used only if its use is APPROVED. [P]

(B) NonDRINKING WATER shall be used only for nonculinary purposes such as air conditioning, nonFOOD EQUIPMENT cooling, and fire protection. [P]

5-102.13 Sampling.

Except when used as specified under § 5-102.12, water from a nonPUBLIC WATER SYSTEM shall be sampled and tested at least annually and as required by state water quality regulations. [Pf]

5-102.14 Sample Report.

The most recent sample report for the nonPUBLIC WATER SYSTEM shall be retained on file in the FOOD ESTABLISHMENT or the report shall be maintained as specified by state water quality regulations.

Quantity and Availability

5-103.11 Capacity.

(A) The water source and system shall be of sufficient capacity to meet the peak water demands of the FOOD ESTABLISHMENT. Pf

(B) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the FOOD ESTABLISHMENT. Pf

5-103.12 Pressure.

Water under pressure shall be provided to all fixtures, EQUIPMENT, and nonFOOD EQUIPMENT that are required to use water *except that water supplied as specified under ¶¶ 5-104.12(A) and (B) to a TEMPORARY FOOD ESTABLISHMENT or in response to a temporary interruption of a water supply need not be under pressure*. Pf

Distribution, Delivery, and Retention

5-104.11 System.

Water shall be received from the source through the use of:

(A) An APPROVED public water main; Pf or

(B) One or more of the following that shall be constructed, maintained, and operated according to LAW: Pf

(1) Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances, Pf

(2) Water transport vehicles, Pf or

(3) Water containers. Pf

5-104.12 Alternative Water Supply.

Water meeting the requirements specified under Subparts 5-101, 5-102, and 5-103 shall be made available for a mobile facility, for a TEMPORARY FOOD ESTABLISHMENT without a permanent water supply, and for a FOOD ESTABLISHMENT with a temporary interruption of its water supply through:

(A) A supply of containers of commercially BOTTLED DRINKING WATER; [Pf]

(B) One or more closed portable water containers; [Pf]

(C) An enclosed vehicular water tank; [Pf]

(D) An on-PREMISES water storage tank; [Pf] or

(E) Piping, tubing, or hoses connected to an adjacent APPROVED source. [Pf]

5-2 PLUMBING SYSTEM

Subparts

Materials

5-201.11 Approved.

(A) A PLUMBING SYSTEM and hoses conveying water shall be constructed and repaired with APPROVED materials according to LAW. [P]

(B) A water filter shall be made of SAFE MATERIALS. [P]

Design, Construction, and Installation

5-202.11 Approved System and Cleanable Fixtures.

(A) A PLUMBING SYSTEM shall be designed, constructed, and installed according to LAW. [P]

(B) A PLUMBING FIXTURE such as a HANDWASHING SINK, toilet, or urinal shall be EASILY CLEANABLE.

5-202.12 Handwashing Sink, Installation.

(A) A HANDWASHING SINK shall be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet. [Pf]

(B) A steam mixing valve may not be used at a HANDWASHING SINK.

(C) A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

(D) An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.

5-202.13 Backflow Prevention, Air Gap.

An air gap between the water supply inlet and the flood level rim of the PLUMBING FIXTURE, EQUIPMENT, or nonFOOD EQUIPMENT shall be at least twice the diameter of the water supply inlet and may not be less than 25 mm (1 inch). [P]

5-202.14 Backflow Prevention Device, Design Standard.

A backflow or backsiphonage prevention device installed on a water supply system shall meet American Society of Sanitary Engineering (A.S.S.E.) standards for construction, installation, maintenance, inspection, and testing for that specific application and type of device. [P]

5-202.15 Conditioning Device, Design.

A water filter, screen, and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.

Numbers and Capacities

5-203.11 Handwashing Sinks.

(A) Except as specified in ¶¶ (B) and (C) of this section, at least 1 HANDWASHING SINK, a number of HANDWASHING SINKS necessary for their convenient use by EMPLOYEES in areas specified under § 5-204.11, and not fewer than the number of HANDWASHING SINKS required by LAW shall be provided. [Pf]

(B) *If APPROVED and capable of removing the types of soils encountered in the FOOD operations involved, automatic handwashing facilities may be substituted for HANDWASHING SINKS in a FOOD ESTABLISHMENT that has at least 1 HANDWASHING SINK.*

(C) *If APPROVED, when FOOD exposure is limited and HANDWASHING SINKS are not conveniently available, such as in some mobile or TEMPORARY FOOD ESTABLISHMENTS or at some VENDING MACHINE LOCATIONS, EMPLOYEES may use chemically treated towelettes for handwashing.*

5-203.12 Toilets and Urinals.

At least 1 toilet and not fewer than the toilets required by LAW shall be provided. If authorized by LAW and urinals are substituted for toilets, the substitution shall be done as specified in LAW.

5-203.13 Service Sink.

(A) At least 1 service sink or 1 curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

(B) Toilets and urinals may not be used as a service sink for the disposal of mop water and similar liquid waste.

5-203.14 Backflow Prevention Device, When Required.

A PLUMBING SYSTEM shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the FOOD ESTABLISHMENT, including on a hose bibb if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by LAW, by:

(A) Providing an air gap as specified under § 5-202.13 [P]; or

(B) Installing an APPROVED backflow prevention device as specified under § 5-202.14. [P]

5-203.15 Backflow Prevention Device, Carbonator.

(A) If not provided with an air gap as specified under §5-202.13, a dual check valve with an intermediate vent preceded by a screen of not less than 100 mesh to 25.4 mm (100 mesh to 1 inch) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.[P]

(B) *A dual check valve attached to the carbonator need not be of the vented type if an air gap or vented backflow prevention device has been otherwise provided as specified under ¶ (A) of this section.*

Location and Placement

5-204.11 Handwashing Sinks.

A HANDWASHING SINK shall be located:

(A) To allow convenient use by EMPLOYEES in FOOD preparation, FOOD dispensing, and WAREWASHING areas; [Pf] and

(B) In, or immediately adjacent to, toilet rooms. [Pf]

5-204.12 Backflow Prevention Device, Location.

A backflow prevention device shall be located so that it may be serviced and maintained.

5-204.13 Conditioning Device, Location.

A water filter, screen, and other water conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning.

Operation and Maintenance

5-205.11 Using a Handwashing Sink.

(A) A HANDWASHING SINK shall be maintained so that it is accessible at all times for EMPLOYEE use. [Pf]

(B) A HANDWASHING SINK may not be used for purposes other than handwashing. [Pf]

(C) An automatic handwashing facility shall be used in accordance with manufacturer's instructions. [Pf]

5-205.12 Prohibiting a Cross Connection.

(A) A PERSON may not create a cross connection by connecting a pipe or conduit between the DRINKING WATER system and a nonDRINKING WATER system or a water system of unknown quality. [P]

(B) The piping of a nonDRINKING WATER system shall be durably identified so that it is readily distinguishable from piping that carries DRINKING WATER. [Pf]

5-205.13 Scheduling Inspection and Service for a Water System Device.

A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the PERSON IN CHARGE. [Pf]

5-205.14 Water Reservoir of Fogging Devices, Cleaning.

(A) A reservoir that is used to supply water to a device such as a produce fogger shall be:

(1) Maintained in accordance with manufacturer's specifications; [P] and

(2) Cleaned in accordance with manufacturer's specifications or according to the procedures specified under ¶ (B) of this section, whichever is more stringent. [P]

(B) Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

(1) Draining and complete disassembly of the water and aerosol contact parts; [P]

(2) Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution; [P]

(3) Flushing the complete system with water to remove the detergent solution and particulate accumulation; [P] and

(4) Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 MG/L hypochlorite solution. [P]

5-205.15 System Maintained in Good Repair.

A PLUMBING SYSTEM shall be:

(A) Repaired according to LAW; [P] and

(B) Maintained in good repair.

5-3 MOBILE WATER TANK AND MOBILE FOOD ESTABLISHMENT WATER TANK

Subparts

Materials

5-301.11 Approved.

Materials that are used in the construction of a mobile water tank, mobile FOOD ESTABLISHMENT water tank, and appurtenances shall be:

(A) Safe; [P]

(B) Durable, CORROSION-RESISTANT, and nonabsorbent; and

(C) Finished to have a SMOOTH, EASILY CLEANABLE surface.

5-302.11 Enclosed System, Sloped to Drain.

A mobile water tank shall be:

(A) Enclosed from the filling inlet to the discharge outlet; and

(B) Sloped to an outlet that allows complete drainage of the tank.

5-302.12 Inspection and Cleaning Port, Protected and Secured.

If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank and:

(A) Flanged upward at least 13 mm (one-half inch); and

(B) Equipped with a port cover assembly that is:

(1) Provided with a gasket and a device for securing the cover in place, and

(2) Flanged to overlap the opening and sloped to drain.

5-302.13 "V" Type Threads, Use Limitation.

A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached.

5-302.14 Tank Vent, Protected.

If provided, a water tank vent shall terminate in a downward direction and shall be covered with:

(A) 16 mesh to 25.4 mm (16 mesh to 1 inch) screen or equivalent when the vent is in a protected area; or

(B) A protective filter when the vent is in an area that is not protected from windblown dirt and debris.

5-302.15 Inlet and Outlet, Sloped to Drain.

(A) A water tank and its inlet and outlet shall be sloped to drain.

(B) A water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil, or grease.

5-302.16 Hose, Construction and Identification.

A hose used for conveying DRINKING WATER from a water tank shall be:

(A) Safe; [P]

(B) Durable, CORROSION-RESISTANT, and nonabsorbent;

(C) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;

(D) Finished with a SMOOTH interior surface; and

(E) Clearly and durably identified as to its use if not permanently attached.

Numbers and Capacities

5-303.11 Filter, Compressed Air.

A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and DRINKING WATER system when compressed air is used to pressurize the water tank system. [P]

5-303.12 Protective Cover or Device.

A cap and keeper chain, closed cabinet, closed storage tube, or other APPROVED protective cover or device shall be provided for a water inlet, outlet, and hose.

5-303.13 Mobile Food Establishment Tank Inlet.

A mobile FOOD ESTABLISHMENT'S water tank inlet shall be:

(A) 19.1 mm (three-fourths inch) in inner diameter or less; and

(B) Provided with a hose connection of a size or type that will prevent its use for any other service.

Operation and Maintenance

5-304.11 System Flushing and Sanitization.

A water tank, pump, and hoses shall be flushed and SANITIZED before being placed in service after construction, repair, modification, and periods of nonuse.[P]

5-304.12 Using a Pump and Hoses, Backflow Prevention.

A PERSON shall operate a water tank, pump, and hoses so that backflow and other contamination of the water supply are prevented.

5-304.13 Protecting Inlet, Outlet, and Hose Fitting.

If not in use, a water tank and hose inlet and outlet fitting shall be protected using a cover or device as specified under § 5-303.12.

5-304.14 Tank, Pump, and Hoses, Dedication.

(A) Except as specified in ¶ (B) of this section, a water tank, pump, and hoses used for conveying DRINKING WATER shall be used for no other purpose.[P]

(B) *Water tanks, pumps, and hoses APPROVED for liquid FOODS may be used for conveying DRINKING WATER if they are cleaned and SANITIZED before they are used to convey water.*

5-4 SEWAGE, OTHER LIQUID WASTE, AND RAINWATER

Subparts

Mobile Holding Tank

5-401.11 Capacity and Drainage.

A SEWAGE holding tank in a mobile FOOD ESTABLISHMENT shall be:

(A) Sized 15 percent larger in capacity than the water supply tank; and

(B) Sloped to a drain that is 25 mm (1 inch) in inner diameter or greater, equipped with a shut-off valve.

Retention, Drainage, and Delivery

design, construction, and installation

5-402.10 Establishment Drainage System.

FOOD ESTABLISHMENT drainage systems, including grease traps, that convey SEWAGE shall be designed and installed as specified under ¶ 5-202.11(A).

5-402.11 Backflow Prevention.

(A) Except as specified in ¶¶ (B), (C), and (D) of this section, a direct connection may not exist between the SEWAGE system and a drain originating from EQUIPMENT in which FOOD, portable EQUIPMENT, or UTENSILS are placed. [P]

(B) *Paragraph (A) of this section does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building*.

(C) *If allowed by LAW, a WAREWASHING machine may have a direct connection between its waste outlet and a floor drain when the machine is located within 1.5 m (5 feet) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.*

(D) *If allowed by* LAW, *a* WAREWASHING *or culinary sink may have a direct connection*.

location and placement

5-402.12 Grease Trap.

If used, a grease trap shall be located to be easily accessible for cleaning.

operation and maintenance

5-402.13 Conveying Sewage.

SEWAGE shall be conveyed to the point of disposal through an APPROVED sanitary SEWAGE system or other system, including use of SEWAGE transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to LAW.[P]

5-402.14 Removing Mobile Food Establishment Wastes.

SEWAGE and other liquid wastes shall be removed from a mobile FOOD ESTABLISHMENT at an APPROVED waste SERVICING AREA or by a SEWAGE transport vehicle in such a way that a public health HAZARD or nuisance is not created.[Pf]

5-402.15 Flushing a Waste Retention Tank.

A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation.

Disposal Facility

5-403.11 Approved Sewage Disposal System.

design and construction

SEWAGE shall be disposed through an APPROVED facility that is:

(A) A public SEWAGE treatment plant;[P] or

(B) An individual SEWAGE disposal system that is sized, constructed, maintained, and operated according to LAW.[P]

5-403.12 Other Liquid Wastes and Rainwater.

Condensate drainage and other nonSEWAGE liquids and rainwater shall be drained from point of discharge to disposal according to LAW.

5-5 REFUSE, RECYCLABLES, AND RETURNABLES

Subparts

Facilities on the Premises
materials, design, construction, and installation

5-501.10 Indoor Storage Area.

If located within the FOOD ESTABLISHMENT, a storage area for REFUSE, recyclables, and returnables shall meet the requirements specified under §§ 6-101.11, 6-201.11 - 6-201.18, 6-202.15, and 6-202.16.

5-501.11 Outdoor Storage Surface.

An outdoor storage surface for REFUSE, recyclables, and returnables shall be constructed of nonabsorbent material such as concrete or asphalt and shall be SMOOTH, durable, and sloped to drain.

5-501.12 Outdoor Enclosure.

If used, an outdoor enclosure for REFUSE, recyclables, and returnables shall be constructed of durable and cleanable materials.

5-501.13 Receptacles.

(A) Except as specified in ¶ (B) of this section, receptacles and waste handling units for REFUSE, recyclables, and returnables and for use with materials containing FOOD residue shall be durable, cleanable, insect- and rodent-resistant, leakproof, and nonabsorbent.

(B) *Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the* FOOD ESTABLISHMENT, *or within closed outside receptacles.*

5-501.14 Receptacles in Vending Machines.

Except for a receptacle for BEVERAGE *bottle crown closures,* a REFUSE receptacle may not be located within a VENDING MACHINE.

5-501.15 Outside Receptacles.

(A) Receptacles and waste handling units for REFUSE, recyclables, and returnables used with materials containing FOOD residue and used outside the FOOD ESTABLISHMENT shall be designed and constructed to have tight-fitting lids, doors, or covers.

(B) Receptacles and waste handling units for REFUSE and recyclables such as an on-site compactor shall be installed so that accumulation of debris and insect and rodent attraction and harborage are minimized and effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit.

numbers and capacities

5-501.16 Storage Areas, Rooms, and Receptacles, Capacity and Availability.

(A) An inside storage room and area and outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold REFUSE, recyclables, and returnables that accumulate.

(B) A receptacle shall be provided in each area of the FOOD ESTABLISHMENT or PREMISES where REFUSE is generated or commonly discarded, or where recyclables or returnables are placed.

(C) If disposable towels are used at handwashing lavatories, a waste receptacle shall be located at each lavatory or group of adjacent lavatories.

5-501.17 Toilet Room Receptacle, Covered.

A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

5-501.18 Cleaning Implements and Supplies.

(A) Except as specified in ¶ (B) of this section, suitable cleaning implements and supplies such as high pressure pumps, hot water, steam, and detergent shall be provided as necessary for effective cleaning of receptacles and waste handling units for REFUSE, recyclables, and returnables.

(B) *If APPROVED, off-PREMISES-based cleaning services may be used if on-PREMISES cleaning implements and supplies are not provided.*

location and placement

5-501.19 Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.

(A) An area designated for REFUSE, recyclables, returnables, and, except as specified in ¶ (B) of this section, a redeeming machine for recyclables or returnables shall be located so that it is separate from FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES and a public health HAZARD or nuisance is not created.

(B) *A redeeming machine may be located in the PACKAGED FOOD storage area or CONSUMER area of a FOOD ESTABLISHMENT if FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES are not subject to contamination from the machines and a public health HAZARD or nuisance is not created.*

(C) The location of receptacles and waste handling units for REFUSE, recyclables, and returnables may not create a public health HAZARD or nuisance or interfere with the cleaning of adjacent space.

operation and maintenance

5-501.110 Storing Refuse, Recyclables, and Returnables.

REFUSE, recyclables, and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents.

5-501.111 Areas, Enclosures, and Receptacles, Good Repair.

Storage areas, enclosures, and receptacles for REFUSE, recyclables, and returnables shall be maintained in good repair.

5-501.112 Outside Storage Prohibitions.

(A) Except as specified in ¶ (B) of this section, REFUSE receptacles not meeting the requirements specified under ¶ 5-501.13(A) such as receptacles that are not rodent-resistant, unprotected plastic bags and paper bags, or baled units that contain materials with FOOD residue may not be stored outside.

(B) *Cardboard or other packaging material that does not contain FOOD residues and that is awaiting regularly scheduled delivery to a recycling or disposal site may be stored outside without being in a covered receptacle if it is stored so that it does not create a rodent harborage problem.*

5-501.113 Covering Receptacles.

Receptacles and waste handling units for REFUSE, recyclables, and returnables shall be kept covered:

(A) Inside the FOOD ESTABLISHMENT if the receptacles and units:

(1) Contain FOOD residue and are not in continuous use; or

(2) After they are filled; and

(B) With tight-fitting lids or doors if kept outside the FOOD ESTABLISHMENT.

5-501.114 Using Drain Plugs.

Drains in receptacles and waste handling units for REFUSE, recyclables, and returnables shall have drain plugs in place.

5-501.115 Maintaining Refuse Areas and Enclosures.

A storage area and enclosure for REFUSE, recyclables, or returnables shall be maintained free of unnecessary items, as specified under § 6-501.114, and clean.

5-501.116 Cleaning Receptacles.

(A) Receptacles and waste handling units for REFUSE, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, or SINGLE-SERVICE and SINGLE-USE ARTICLES, and waste water shall be disposed of as specified under § 5-402.13.

(B) Soiled receptacles and waste handling units for REFUSE, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a buildup of soil or becoming attractants for insects and rodents.

Removal

5-502.11 Frequency.

REFUSE, recyclables, and returnables shall be removed from the PREMISES at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents.

5-502.12 Receptacles or Vehicles.

REFUSE, recyclables, and returnables shall be removed from the PREMISES by way of:

(A) Portable receptacles that are constructed and maintained according to LAW; or

(B) A transport vehicle that is constructed, maintained, and operated according to LAW.

Facilities for Disposal and Recycling

5-503.11 Community or Individual Facility.

Solid waste not disposed of through the SEWAGE system such as through grinders and pulpers shall be recycled or disposed of in an APPROVED public or private community recycling or REFUSE facility; or solid waste shall be disposed of in an individual REFUSE facility such as a landfill or incinerator which is sized, constructed, maintained, and operated according to LAW.

Chapter

6 Physical Facilities

Parts

6-1 MATERIALS FOR CONSTRUCTION AND REPAIR

Subparts

Indoor Areas

6-101.11 Surface Characteristics.

(A) Except as specified in ¶ (B) of this section, materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be:

(1) SMOOTH, durable, and EASILY CLEANABLE for areas where FOOD ESTABLISHMENT operations are conducted;

(2) Closely woven and EASILY CLEANABLE carpet for carpeted areas; and

(3) Nonabsorbent for areas subject to moisture such as FOOD preparation areas, walk-in refrigerators, WAREWASHING areas, toilet rooms, mobile FOOD ESTABLISHMENT SERVICING AREAS, and areas subject to flushing or spray cleaning methods.

(B) *In a TEMPORARY FOOD ESTABLISHMENT:*

(1) *If graded to drain, a floor may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other APPROVED materials that are effectively treated to control dust and mud; and*

(2) *Walls and ceilings may be constructed of a material that protects the interior from the weather and windblown dust and debris.*

Outdoor Areas

6-102.11 Surface Characteristics.

(A) The outdoor walking and driving areas shall be surfaced with concrete, asphalt, or gravel or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.

(B) Exterior surfaces of buildings and mobile FOOD ESTABLISHMENTS shall be of weather-resistant materials and shall comply with LAW.

(C) Outdoor storage areas for REFUSE, recyclables, or returnables shall be of materials specified under §§ 5-501.11 and 5-501.12.

6-2 DESIGN, CONSTRUCTION, AND INSTALLATION

Subparts

Cleanability

6-201.11 Floors, Walls, and Ceilings.

Except as specified under § 6-201.14 and *except for antislip floor coverings or applications that may be used for safety reasons,* floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are SMOOTH and EASILY CLEANABLE.

6-201.12 Floors, Walls, and Ceilings, Utility Lines.

(A) Utility service lines and pipes may not be unnecessarily exposed.

(B) Exposed utility service lines and pipes shall be installed so they do not obstruct or prevent cleaning of the floors, walls, or ceilings.

(C) Exposed horizontal utility service lines and pipes may not be installed on the floor.

6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed.

(A) In FOOD ESTABLISHMENTS in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than 1 mm (one thirty-second inch).

(B) The floors in FOOD ESTABLISHMENTS in which water flush cleaning methods are used shall be provided with drains and be graded to drain, and the floor and wall junctures shall be coved and SEALED.

6-201.14 Floor Carpeting, Restrictions and Installation.

(A) A floor covering such as carpeting or similar material may not be installed as a floor covering in FOOD preparation areas, walk-in refrigerators, WAREWASHING areas, toilet room areas where handwashing lavatories, toilets, and urinals are located, REFUSE storage rooms, or other areas where the floor is subject to moisture, flushing, or spray cleaning methods.

(B) If carpeting is installed as a floor covering in areas other than those specified under ¶ (A) of this section, it shall be:

(1) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method; and

(2) Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.

6-201.15 Floor Covering, Mats and Duckboards.

Mats and duckboards shall be designed to be removable and EASILY CLEANABLE.

6-201.16 Wall and Ceiling Coverings and Coatings.

(A) Wall and ceiling covering materials shall be attached so that they are EASILY CLEANABLE.

(B) *Except in areas used only for dry storage*, concrete, porous blocks, or bricks used for indoor wall construction shall be finished and SEALED to provide a SMOOTH, nonabsorbent, EASILY CLEANABLE surface.

6-201.17 Walls and Ceilings, Attachments.

(A) Except as specified in ¶ (B) of this section, attachments to walls and ceilings such as light fixtures, mechanical room ventilation system components, vent covers, wall mounted fans, decorative items, and other attachments shall be EASILY CLEANABLE.

(B) *In a CONSUMER area, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean.*

6-201.18 Walls and Ceilings, Studs, Joists, and Rafters.

Except for TEMPORARY FOOD ESTABLISHMENTS, studs, joists, and rafters may not be exposed in areas subject to moisture.

Functionality

6-202.11 Light Bulbs, Protective Shielding.

(A) Except as specified in ¶ (B) of this section, light bulbs shall be shielded, coated, or otherwise shatter-resistant in areas where there is exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; or unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

(B) *Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing FOOD in unopened packages, if*:

(1) *The integrity of the packages cannot be affected by broken glass falling onto them; and*

(2) *The packages are capable of being cleaned of debris from broken bulbs before the packages are opened*.

(C) An infrared or other heat lamp shall be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed.

6-202.12 Heating, Ventilating, Air Conditioning System Vents.

Heating, ventilating, and air conditioning systems shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of FOOD, FOOD-CONTACT SURFACES, EQUIPMENT, or UTENSILS.

6-202.13 Insect Control Devices, Design and Installation.

(A) Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device.

(B) Insect control devices shall be installed so that:

(1) The devices are not located over a FOOD preparation area; and

(2) Dead insects and insect fragments are prevented from being impelled onto or falling on exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

6-202.14 Toilet Rooms, Enclosed.

Except where a toilet room is located outside a FOOD ESTABLISHMENT and does not open directly into the FOOD ESTABLISHMENT such as a toilet room that is provided by the management of a shopping mall, a toilet room located on the PREMISES shall be completely enclosed and provided with a tight-fitting and self-closing door.

6-202.15 Outer Openings, Protected.

(A) Except as specified in ¶¶ (B), (C), and (E) and under ¶ (D) of this section, outer openings of a FOOD ESTABLISHMENT shall be protected against the entry of insects and rodents by:

(1) Filling or closing holes and other gaps along floors, walls, and ceilings;

(2) Closed, tight-fitting windows; and

(3) Solid, self-closing, tight-fitting doors.

(B) *Paragraph (A) of this section does not apply if a FOOD ESTABLISHMENT opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.*

(C) *Exterior doors used as exits need not be self-closing if they are:*

(1*) Solid and tight-fitting;*

(2) *Designated for use only when an emergency exists, by the fire protection authority that has jurisdiction over the FOOD ESTABLISHMENT; and*

(3) *Limited-use so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.*

(D) Except as specified in ¶¶ (B) and (E) of this section, if the windows or doors of a FOOD ESTABLISHMENT, or of a larger structure within which a FOOD ESTABLISHMENT is located, are kept open for ventilation or other purposes or a TEMPORARY FOOD ESTABLISHMENT is not provided with windows and doors as specified under ¶ (A) of this section, the openings shall be protected against the entry of insects and rodents by:

(1) 16 mesh to 25.4 mm (16 mesh to 1 inch) screens;

(2) Properly designed and installed air curtains to control flying insects; or

(3) Other effective means.

(E) *Paragraph (D) of this section does not apply if flying insects and other pests are absent due to the location of the* ESTABLISHMENT, *the weather, or other limiting condition.*

6-202.16 Exterior Walls and Roofs, Protective Barrier.

Perimeter walls and roofs of a FOOD ESTABLISHMENT shall effectively protect the establishment from the weather and the entry of insects, rodents, and other animals.

6-202.17 Outdoor Food Vending Areas, Overhead Protection.

Except for machines that vend canned BEVERAGES, if located outside, a machine used to vend FOOD shall be provided with overhead protection.

6-202.18 Outdoor Servicing Areas, Overhead Protection.

Except for areas used only for the loading of water or the discharge of SEWAGE *and other liquid waste, through the use of a closed system of hoses,* SERVICING AREAS shall be provided with overhead protection.

6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.

Exterior walking and driving surfaces shall be graded to drain.

6-202.110 Outdoor Refuse Areas, Curbed and Graded to Drain.

Outdoor REFUSE areas shall be constructed in accordance with LAW and shall be curbed and graded to drain to collect and dispose of liquid waste that results from the REFUSE and from cleaning the area and waste receptacles.

6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibition.

A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for conducting FOOD ESTABLISHMENT operations.[P]

6-202.112 Living or Sleeping Quarters, Separation.

Living or sleeping quarters located on the PREMISES of a FOOD ESTABLISHMENT such as those provided for lodging registration clerks or resident managers shall be separated from rooms and areas used for FOOD ESTABLISHMENT operations by complete partitioning and solid self-closing doors.

6-3 NUMBERS AND CAPACITIES

Subparts

Handwashing Sinks

6-301.10 Minimum Number.

HANDWASHING SINKS shall be provided as specified under § 5-203.11.

6-301.11 Handwashing Cleanser, Availability.

Each HANDWASHING SINK or group of 2 adjacent HANDWASHING SINKS shall be provided with a supply of hand cleaning liquid, powder, or bar soap.[Pf]

6-301.12 Hand Drying Provision.

Each HANDWASHING SINK or group of adjacent HANDWASHING SINKS shall be provided with:

(A) Individual, disposable towels; [Pf]

(B) A continuous towel system that supplies the user with a clean towel; [Pf] or

(C) A heated-air hand drying device; [Pf] or

(D) A hand drying device that employs an air-knife system that delivers high velocity, pressurized air at ambient temperatures. [Pf]

6-301.13 Handwashing Aids and Devices, Use Restrictions.

A sink used for FOOD preparation or UTENSIL washing, or a service sink or curbed cleaning facility used for the disposal of mop water or similar wastes, may not be provided with the handwashing aids and devices required for a HANDWASHING SINK as specified under §§ 6-301.11 and 6-301.12 and ¶ 5-501.16(C).

6-301.14 Handwashing Signage.

A sign or poster that notifies FOOD EMPLOYEES to wash their hands shall be provided at all HANDWASHING SINKS used by FOOD EMPLOYEES and shall be clearly visible to FOOD EMPLOYEES.

6-301.20 Disposable Towels, Waste Receptacle.

A HANDWASHING SINK or group of adjacent HANDWASHING SINKS that is provided with disposable towels shall be provided with a waste receptacle as specified under ¶ 5-501.16(C).

Toilets and Urinals

6-302.10 Minimum Number.

Toilets and urinals shall be provided as specified under § 5-203.12.

6-302.11 Toilet Tissue, Availability.

A supply of toilet tissue shall be available at each toilet. [Pf]

Lighting

6-303.11 Intensity.

The light intensity shall be:

(A) At least 108 lux (10 foot candles) at a distance of 75 cm (30 inches) above the floor, in walk-in refrigeration units and dry FOOD storage areas and in other areas and rooms during periods of cleaning;

(B) At least 215 lux (20 foot candles):

(1) At a surface where FOOD is provided for CONSUMER self-service such as buffets and salad bars or where fresh produce or PACKAGED FOODS are sold or offered for consumption,

(2) Inside EQUIPMENT such as reach-in and under-counter refrigerators; and

(3) At a distance of 75 cm (30 inches) above the floor in areas used for handwashing, WAREWASHING, and EQUIPMENT and UTENSIL storage, and in toilet rooms; and

(C) At least 540 lux (50 foot candles) at a surface where a FOOD EMPLOYEE is working with FOOD or working with UTENSILS or EQUIPMENT such as knives, slicers, grinders, or saws where EMPLOYEE safety is a factor.

Ventilation

6-304.11 Mechanical.

If necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes, mechanical ventilation of sufficient capacity shall be provided.

Dressing Areas and Lockers

6-305.11 Designation.

(A) Dressing rooms or dressing areas shall be designated if EMPLOYEES routinely change their clothes in the establishment.

(B) Lockers or other suitable facilities shall be provided for the orderly storage of EMPLOYEES' clothing and other possessions.

Service Sinks

6-306.10 Availability.

A service sink or curbed cleaning facility shall be provided as specified under ¶ 5-203.13(A).

6-4 LOCATION AND PLACEMENT

Subparts

Handwashing Sinks

6-401.10 Conveniently Located.

HANDWASHING SINKS shall be conveniently located as specified under § 5-204.11.

Toilet Rooms

6-402.11 Convenience and Accessibility.

Toilet rooms shall be conveniently located and accessible to EMPLOYEES during all hours of operation.

Employee Accommodations

6-403.11 Designated Areas.

(A) Areas designated for EMPLOYEES to eat, drink, and use tobacco shall be located so that FOOD, EQUIPMENT, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES are protected from contamination.

(B) Lockers or other suitable facilities shall be located in a designated room or area where contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES can not occur.

Distressed Merchandise

6-404.11 Segregation and Location.

Products that are held by the PERMIT HOLDER for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.[Pf]

Refuse, Recyclables, and Returnables

6-405.10 Receptacles, Waste Handling Units, and Designated Storage Areas.

Units, receptacles, and areas designated for storage of REFUSE and recyclable and returnable containers shall be located as specified under § 5-501.19.

6-5 MAINTENANCE AND OPERATION

Subpart

6-501 Premises, Structures, Attachments, and Fixtures - Methods

Premises, Structures, Attachments, and Fixtures - Methods

6-501.11 Repairing.

PHYSICAL FACILITIES shall be maintained in good repair.

6-501.12 Cleaning, Frequency and Restrictions.

(A) PHYSICAL FACILITIES shall be cleaned as often as necessary to keep them clean.

(B) *Except for cleaning that is necessary due to a spill or other accident,* cleaning shall be done during periods when the least amount of FOOD is exposed such as after closing.

6-501.13 Cleaning Floors, Dustless Methods.

(A) Except as specified in ¶ (B) of this section, only dustless methods of cleaning shall be used, such as wet cleaning, vacuum cleaning, mopping with treated dust mops, or sweeping using a broom and dust-arresting compounds.

(B) *Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:*

(1) *Without the use of dust-arresting compounds; and*

(2) *In the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.*

6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

(A) Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.

(B) If vented to the outside, ventilation systems may not create a public health HAZARD or nuisance or unLAWful discharge.

6-501.15 Cleaning Maintenance Tools, Preventing Contamination.

FOOD preparation sinks, HANDWASHING SINKS, and WAREWASHING EQUIPMENT may not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes. [Pf]

6-501.16 Drying Mops.

After use, mops shall be placed in a position that allows them to air-dry without soiling walls, EQUIPMENT, or supplies.

6-501.17 Absorbent Materials on Floors, Use Limitation.

Except as specified in ¶ 6-501.13(B), sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials may not be used on floors.

6-501.18 Cleaning of Plumbing Fixtures.

PLUMBING FIXTURES such as HANDWASHING SINKS, toilets, and urinals shall be cleaned as often as necessary to keep them clean.

6-501.19 Closing Toilet Room Doors.

Except during cleaning and maintenance operations, toilet room doors as specified under § 6-202.14 shall be kept closed.

6-501.110 Using Dressing Rooms and Lockers.

(A) Dressing rooms shall be used by EMPLOYEES if the EMPLOYEES regularly change their clothes in the establishment.

(B) Lockers or other suitable facilities shall be used for the orderly storage of EMPLOYEE clothing and other possessions.

6-501.111 Controlling Pests.

The PREMISES shall be maintained free of insects, rodents, and other pests. The presence of insects, rodents, and other pests shall be controlled to eliminate their presence on the PREMISES by:

(A) Routinely inspecting incoming shipments of FOOD and supplies;

(B) Routinely inspecting the PREMISES for evidence of pests;

(C) Using methods, if pests are found, such as trapping devices or other means of pest control as specified under §§ 7-202.12, 7-206.12, and 7-206.13; [Pf] and

(D) Eliminating harborage conditions.

6-501.112 Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.

Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the PREMISES at a frequency that prevents their accumulation, decomposition, or the attraction of pests.

6-501.113 Storing Maintenance Tools.

Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be:

(A) Stored so they do not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES; and

(B) Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

6-501.114 Maintaining Premises, Unnecessary Items and Litter.

The PREMISES shall be free of:

(A) Items that are unnecessary to the operation or maintenance of the establishment such as EQUIPMENT that is nonfunctional or no longer used; and

(B) Litter.

6-501.115 Prohibiting Animals.

(A) Except as specified in ¶¶ (B) and (C) of this section, live animals may not be allowed on the PREMISES of a FOOD ESTABLISHMENT. [Pf]

(B) *Live animals may be allowed in the following situations if the contamination of FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES can not result:*

(1) *Edible* FISH *or decorative* FISH *in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;*

(2) *Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;*

(3) *In areas that are not used for* FOOD *preparation and that are usually open for customers, such as dining and sales areas,* SERVICE ANIMALS *that are controlled by the disabled* EMPLOYEE *or* PERSON, *if a health or safety* HAZARD *will not result from the presence or activities of the* SERVICE ANIMAL*;*

(4) *Pets in the common dining areas of institutional care facilities such as nursing homes, assisted living facilities, group homes, or residential care facilities at times other than during meals if:*

(a) *Effective partitioning and self-closing doors separate the common dining areas from* FOOD *storage or* FOOD *preparation areas,*

(b) *Condiments,* EQUIPMENT, *and* UTENSILS *are stored in enclosed cabinets or removed from the common dining areas when pets are present, and*

(c) *Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; and*

(5) *In areas that are not used for* FOOD *preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly confined, such as in a variety store that sells pets or a tourist park that displays animals.*

(C) *Live or dead* FISH *bait may be stored if contamination of* FOOD*; clean* EQUIPMENT, UTENSILS, *and* LINENS*; and unwrapped* SINGLE-SERVICE *and* SINGLE-USE ARTICLES *can not result.*

Chapter

7 Poisonous or Toxic Materials

Parts

7-1 LABELING AND IDENTIFICATION

Subparts

Original Containers

7-101.11 Identifying Information, Prominence.

Containers of POISONOUS OR TOXIC MATERIALS and PERSONAL CARE ITEMS shall bear a legible manufacturer's label. [Pf]

Working Containers

7-102.11 Common Name.

Working containers used for storing POISONOUS OR TOXIC MATERIALS such as cleaners and SANITIZERS taken from bulk supplies shall be clearly and individually identified with the common name of the material. [Pf]

7-2 OPERATIONAL SUPPLIES AND APPLICATIONS

Subparts

Storage

7-201.11 Separation.

POISONOUS OR TOXIC MATERIALS shall be stored so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES by:

(A) Separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning;[P] and

(B) Locating the POISONOUS OR TOXIC MATERIALS in an area that is not above FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE or SINGLE-USE ARTICLES. *This paragraph does not apply to EQUIPMENT and UTENSIL cleaners and SANITIZERS that are stored in WAREWASHING areas for availability and convenience if the materials are stored to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.*[P]

Presence and Use

7-202.11 Restriction.

(A) Only those POISONOUS OR TOXIC MATERIALS that are required for the operation and maintenance of a FOOD ESTABLISHMENT, such as for the cleaning and SANITIZING of EQUIPMENT and UTENSILS and the control of insects and rodents, shall be allowed in a FOOD ESTABLISHMENT.[Pf]

(B) *Paragraph (A) of this section does not apply to PACKAGED POISONOUS OR TOXIC MATERIALS that are for retail sale.*

7-202.12 Conditions of Use.

POISONOUS OR TOXIC MATERIALS shall be:

(A) Used according to:

(1) LAW and this Code,

(2) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a FOOD ESTABLISHMENT, [P]

(3) The conditions of certification, if certification is required, for use of the pest control materials, [P] and

(4) Additional conditions that may be established by the REGULATORY AUTHORITY; and

(B) Applied so that:

(1) A HAZARD to EMPLOYEES or other PERSONS is not constituted, [P] and

(2) Contamination including toxic residues due to drip, drain, fog, splash or spray on FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES is prevented, and for a RESTRICTED USE PESTICIDE, this is achieved by: [P]

(a) Removing the items, [P]

(b) Covering the items with impermeable covers, [P] or

(c) Taking other appropriate preventive actions, [P] and

(d) Cleaning and SANITIZING EQUIPMENT and UTENSILS after the application. [P]

(C) A RESTRICTED USE PESTICIDE shall be applied only by an applicator certified as defined in 7 USC 136 Definitions, (e) Certified Applicator, of the Federal Insecticide, Fungicide, and Rodenticide Act, or a PERSON under the direct supervision of a certified applicator. [Pf]

Container Prohibitions

7-203.11 Poisonous or Toxic Material Containers.

A container previously used to store POISONOUS OR TOXIC MATERIALS may not be used to store, transport, or dispense FOOD. [P]

Chemicals

7-204.11 Sanitizers, Criteria.

Chemical SANITIZERS, including chemical sanitizing solutions generated on-site, and other chemical antimicrobials applied to FOOD-CONTACT SURFACEs shall:

(A) Meet the requirements specified in 40 CFR 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions)[P], or

(B) Meet the requirements as specified in 40 CFR 180.2020 Pesticide Chemicals Not Requiring a Tolerance or Exemption from Tolerance-Non-food determinations.[P]

7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.

(A) Chemicals, including those generated on-site, used to wash or peel raw, whole fruits and vegetables shall:

(1) Be an approved food additive listed for this intended use in 21 CFR 173, [P] or

(2) Be generally recognized as safe (GRAS) for this intended use, [P] or

(3) Be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification), [P] and

(4) Meet the requirements in 40 CFR 156 Labeling Requirements for Pesticide and Devices. [P]

(B) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a FOOD ESTABLISHMENT shall meet the requirements specified in 21 CFR 173.368 Ozone.[P]

7-204.13 Boiler Water Additives, Criteria.

Chemicals used as boiler water ADDITIVES shall meet the requirements specified in 21 CFR 173.310 Boiler water additives.[P]

7-204.14 Drying Agents, Criteria.

Drying agents used in conjunction with SANITIZATION shall:

(A) Contain only components that are listed as one of the following:

(1) Generally recognized as safe for use in FOOD as specified in 21 CFR 182 - Substances Generally Recognized as Safe, or 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe,[P]

(2) Generally recognized as safe for the intended use as specified in 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe,[P]

(3) Generally recognized as safe for the intended use as determined by experts qualified in scientific training and experience to evaluate the safety of substances added, directly or indirectly, to FOOD as described in 21 CFR 170.30 Eligibility for classification as generally recognized as safe (GRAS),[P]

(4) Subject of an effective Food Contact Notification as described in the Federal Food Drug and Cosmetic Act (FFDCA) Section 409(h),[P]

(5) APPROVED for use as a drying agent under a prior sanction as described in the Federal Food Drug and Cosmetic Act (FFDCA) § 201(s)(4);[P]

(6) Specifically regulated as an indirect FOOD ADDITIVE for use as a drying agent as specified in 21 CFR Parts 174-178,[P] or

(7) APPROVED for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 Threshold of regulation for substances used in food-contact

articles;[P] and

(B) When SANITIZATION is with chemicals, the approval required under Subparagraph (A)(5) or (A)(7) of this section or the regulation as an indirect FOOD ADDITIVE required under Subparagraph (A)(6) of this section, shall be specifically for use with chemical SANITIZING solutions.[P]

Lubricants

7-205.11 Incidental Food Contact, Criteria.

Lubricants shall meet the requirements specified in 21 CFR 178.3570 Lubricants with incidental food contact, if they are used on FOOD-CONTACT SURFACES, on bearings and gears located on or within FOOD-CONTACT SURFACES, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into FOOD or onto FOOD-CONTACT SURFACES.[P]

Pesticides

7-206.11 Restricted Use Pesticides, Criteria.

RESTRICTED USE PESTICIDES specified under ¶ 7-202.12(C) shall meet the requirements specified in 40 CFR 152 Subpart I - Classification of Pesticides.[P]

7-206.12 Rodent Bait Stations.

Rodent bait shall be contained in a covered, tamper-resistant bait station.[P]

7-206.13 Tracking Powders, Pest Control and Monitoring.

(A) Except as specified in ¶ (B) of this section, a tracking powder pesticide may not be used in a FOOD ESTABLISHMENT.[P]

(B) If used, a nontoxic tracking powder such as talcum or flour may not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

Medicines

7-207.11 Restriction and Storage.

(A) *Except for medicines that are stored or displayed for retail*

sale, only those medicines that are necessary for the health of EMPLOYEES shall be allowed in a FOOD ESTABLISHMENT. [Pf]

(B) Medicines that are in a FOOD ESTABLISHMENT for the EMPLOYEES' use shall be labeled as specified under § 7-101.11 and located to prevent the contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES. [P]

7-207.12 Refrigerated Medicines, Storage.

Medicines belonging to EMPLOYEES or to children in a day care center that require refrigeration and are stored in a FOOD refrigerator shall be:

(A) Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines; [P] and

(B) Located so they are inaccessible to children. [P]

First Aid Supplies

7-208.11 Storage.

First aid supplies that are in a FOOD ESTABLISHMENT for the EMPLOYEES' use shall be:

(A) Labeled as specified under § 7-101.11; [Pf] and

(B) Stored in a kit or a container that is located to prevent the contamination of FOOD, EQUIPMENT, UTENSILS, and LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES. [P]

Other Personal Care Items

7-209.11 Storage.

Except as specified under §§ 7-207.12 and 7-208.11, EMPLOYEES shall store their PERSONAL CARE ITEMS in facilities as specified under ¶ 6-305.11(B).

7-3 STOCK AND RETAIL SALE

Subpart

7-301 Storage and Display

Storage and Display

7-301.11 Separation.

POISONOUS or TOXIC MATERIALS shall be stored and displayed for retail sale so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES by:

(A) Separating the POISONOUS or TOXIC MATERIALS by spacing or partitioning; [P] and

(B) Locating the POISONOUS OR TOXIC MATERIALS in an area that is not above FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE or SINGLE-USE ARTICLES. [P]

Chapter

8 Compliance and Enforcement

Parts

8-1 CODE APPLICABILITY

Subparts

Use for Intended Purpose

8-101.10 Public Health Protection.

(A) The REGULATORY AUTHORITY shall apply this Code to promote its underlying purpose, as specified in § 1-102.10, of safeguarding public health and ensuring that FOOD is safe, unADULTERATED, and honestly presented when offered to the CONSUMER.

(B) In enforcing the provisions of this Code, the REGULATORY AUTHORITY shall assess existing facilities or EQUIPMENT that were in use before the effective date of this Code based on the following considerations:

(1) Whether the facilities or EQUIPMENT are in good repair and capable of being maintained in a sanitary condition;

(2) Whether FOOD-CONTACT SURFACES comply with Subpart 4-101;

(3) Whether the capacities of cooling, heating, and holding EQUIPMENT are sufficient to comply with § 4-301.11; and

(4) The existence of a documented agreement with the PERMIT HOLDER that the facilities or EQUIPMENT will be replaced as specified under ¶ 8-304.11(G).

Additional Requirements

8-102.10 Preventing Health Hazards, Provision for Conditions Not Addressed.

(A) If necessary to protect against public health HAZARDS or nuisances, the REGULATORY AUTHORITY may impose specific requirements in addition to the requirements contained in this Code that are authorized by LAW.

(B) The REGULATORY AUTHORITY shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation shall be provided to the PERMIT applicant or PERMIT HOLDER and a copy shall be maintained in the REGULATORY AUTHORITY'S file for the FOOD ESTABLISHMENT.

Variances

8-103.10 Modifications and Waivers.

The REGULATORY AUTHORITY may grant a VARIANCE by modifying or waiving the requirements of this Code if in the opinion of the REGULATORY AUTHORITY a health HAZARD or nuisance will not result from the VARIANCE. If a VARIANCE is granted, the REGULATORY AUTHORITY shall retain the information specified under § 8-103.11 in its records for the FOOD ESTABLISHMENT.

8-103.11 Documentation of Proposed Variance and Justification.

Before a VARIANCE from a requirement of this Code is APPROVED, the information that shall be provided by the PERSON requesting the VARIANCE and retained in the REGULATORY AUTHORITY'S file on the FOOD ESTABLISHMENT includes:

(A) A statement of the proposed VARIANCE of the Code requirement citing relevant Code section numbers;[Pf]

(B) An analysis of the rationale for how the potential public health HAZARDS and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal; [Pf] and

(C) A HACCP PLAN if required as specified under ¶ 8-201.13(A) that includes the information specified under § 8-201.14 as it is relevant to the VARIANCE requested. [Pf]

8-103.12 Conformance with Approved Procedures.

If the REGULATORY AUTHORITY grants a VARIANCE as specified in § 8-103.10, or a HACCP PLAN is otherwise required as specified under § 8-201.13, the PERMIT HOLDER shall:

(A) Comply with the HACCP PLANs and procedures that are submitted as specified under § 8-201.14 and APPROVED as a basis for the modification or waiver; [P] and

(B) Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under ¶¶ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;

(1) Procedures for monitoring the CRITICAL CONTROL POINTS, [Pf]

(2) Monitoring of the CRITICAL CONTROL POINTS, [Pf]

(3) Verification of the effectiveness of the operation or process, [Pf] and

(4) Necessary corrective actions if there is failure at a CRITICAL CONTROL POINT. [Pf]

8-2 PLAN SUBMISSION AND APPROVAL

Subparts

Facility and Operating Plans

8-201.11 When Plans Are Required.

A PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY properly prepared plans and specifications for review and approval before:

(A) The construction of a FOOD ESTABLISHMENT; [Pf]

(B) The conversion of an existing structure for use as a FOOD ESTABLISHMENT; [Pf] or

(C) The remodeling of a FOOD ESTABLISHMENT or a change of type of FOOD ESTABLISHMENT or FOOD operation as specified under ¶ 8-302.14(C) if the REGULATORY AUTHORITY determines that plans and specifications are necessary to ensure compliance with this Code. [Pf]

8-201.12 Contents of the Plans and Specifications.

The plans and specifications for a FOOD ESTABLISHMENT, including a FOOD ESTABLISHMENT specified under § 8-201.13, shall include, as required by the REGULATORY AUTHORITY based on the type of operation, type of FOOD preparation, and FOODS prepared, the following information to demonstrate conformance with Code provisions:

(A) Intended menu;

(B) Anticipated volume of FOOD to be stored, prepared, and sold or served;

(C) Proposed layout, mechanical schematics, construction materials, and finish schedules;

(D) Proposed EQUIPMENT types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;

(E) Evidence that standard procedures that ensure compliance with the requirements of this Code are developed or are being developed; and

(F) Other information that may be required by the REGULATORY AUTHORITY for the proper review of the proposed construction, conversion or modification, and procedures for operating a FOOD ESTABLISHMENT.

8-201.13 When a HACCP Plan is Required.

(A) Before engaging in an activity that requires a HACCP PLAN, a PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY for approval a properly prepared HACCP PLAN as specified under § 8-201.14 and the relevant provisions of this Code if:

(1) Submission of a HACCP PLAN is required according to LAW;

(2) A VARIANCE is required as specified under Subparagraph 3-401.11(D)(4), § 3-502.11, or ¶ 4-204.110(B);

(3) The REGULATORY AUTHORITY determines that a FOOD preparation or processing method requires a VARIANCE based on a plan submittal specified under § 8-201.12, an inspectional finding, or a VARIANCE request.

(B) Before engaging in REDUCED OXYGEN PACKAGING without a VARIANCE as specified under § 3-502.12, a PERMIT applicant or PERMIT HOLDER shall submit a properly prepared HACCP PLAN to the REGULATORY AUTHORITY.

8-201.14 Contents of a HACCP Plan.

For a FOOD ESTABLISHMENT that is required under § 8-201.13 to have a HACCP PLAN, the plan and specifications shall indicate:

(A) A categorization of the types of TIME/TEMPERATURE CONTROL FOR SAFETY FOODS that are specified in the menu such as soups and sauces, salads, and bulk, solid FOODS such as MEAT roasts, or of other FOODS that are specified by the REGULATORY AUTHORITY; Pf

(B) A flow diagram by specific FOOD or category type identifying CRITICAL CONTROL POINTS and providing information on the following:

(1) Ingredients, materials, and EQUIPMENT used in the preparation of that FOOD, Pf and

(2) Formulations or recipes that delineate methods and procedural control measures that address the FOOD safety concerns involved; Pf

(C) FOOD EMPLOYEE and supervisory training plan that addresses the FOOD safety issues of concern; Pf

(D) A statement of standard operating procedures for the plan under consideration including clearly identifying:

(1) Each CRITICAL CONTROL POINT, Pf

(2) The CRITICAL LIMITS for each CRITICAL CONTROL POINT, Pf

(3) The method and frequency for monitoring and controlling each CRITICAL CONTROL POINT by the FOOD EMPLOYEE designated by the PERSON IN CHARGE, Pf

(4) The method and frequency for the PERSON IN CHARGE to routinely verify that the FOOD EMPLOYEE is following standard operating procedures and monitoring CRITICAL CONTROL POINTS, Pf

(5) Action to be taken by the PERSON IN CHARGE if the CRITICAL LIMITS for each CRITICAL CONTROL POINT are not met, Pf and

(6) Records to be maintained by the PERSON IN CHARGE to demonstrate that the HACCP PLAN is properly operated and managed; Pf and

(E) Additional scientific data or other information, as required by the REGULATORY AUTHORITY, supporting the determination that FOOD safety is not compromised by the proposal. [Pf]

Confidentiality

8-202.10 Trade Secrets.

The REGULATORY AUTHORITY shall treat as confidential in accordance with LAW, information that meets the criteria specified in LAW for a trade secret and is contained on inspection report forms and in the plans and specifications submitted as specified under §§ 8-201.12 and 8-201.14.

Construction Inspection and Approval

8-203.10 Preoperational Inspections.

The REGULATORY AUTHORITY shall conduct one or more preoperational inspections to verify that the FOOD ESTABLISHMENT is constructed and equipped in accordance with the APPROVED plans and APPROVED modifications of those plans, has established standard operating procedures as specified under ¶ 8-201.12(E), and is in compliance with LAW and this Code.

8-3 PERMIT TO OPERATE

Subparts

Requirement

8-301.11 Prerequisite for Operation.

A PERSON may not operate a FOOD ESTABLISHMENT without a valid PERMIT to operate issued by the REGULATORY AUTHORITY. [Pf]

Application Procedure

8-302.11 Submission 30 Calendar Days Before Proposed Opening.

An applicant shall submit an application for a PERMIT at least 30 calendar days before the date planned for opening a FOOD ESTABLISHMENT or the expiration date of the current PERMIT for an existing facility.

8-302.12 Form of Submission.

A PERSON desiring to operate a FOOD ESTABLISHMENT shall submit to the REGULATORY AUTHORITY a written application for a PERMIT on a form provided by the REGULATORY AUTHORITY.

8-302.13 Qualifications and Responsibilities of Applicants.

To qualify for a PERMIT, an applicant shall:

(A) Be an owner of the FOOD ESTABLISHMENT or an officer of the legal ownership;

(B) Comply with the requirements of this Code;

(C) As specified under § 8-402.11, agree to allow access to the FOOD ESTABLISHMENT and to provide required information; and

(D) Pay the applicable PERMIT fees at the time the application is submitted.

8-302.14 Contents of the Application.

The application shall include:

(A) The name, birth date, mailing address, telephone number, and signature of the PERSON applying for the PERMIT and the name, mailing address, and location of the FOOD ESTABLISHMENT;

(B) Information specifying whether the FOOD ESTABLISHMENT is owned by an association, corporation, individual, partnership, or other legal entity;

(C) A statement specifying whether the FOOD ESTABLISHMENT:

(1) Is mobile or stationary and temporary or permanent, and

(2) Is an operation that includes one or more of the following:

(a) Prepares, offers for sale, or serves TIME/TEMPERATURE CONTROL FOR SAFETY FOOD:

(i) Only to order upon a CONSUMER'S request,

(ii) In advance in quantities based on projected CONSUMER demand and discards FOOD that is not sold or served at an APPROVED frequency, or

(iii) Using time as the public health control as specified under § 3-501.19,

(b) Prepares TIME/TEMPERATURE CONTROL FOR SAFETY FOOD in advance using a FOOD preparation method that involves two or more steps which may include combining TIME/TEMPERATURE CONTROL FOR SAFETY FOOD ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing,

(c) Prepares FOOD as specified under Subparagraph (C)(2)(b) of this section for delivery to and consumption at a location off the PREMISES of the FOOD ESTABLISHMENT where it is prepared,

(d) Prepares FOOD as specified under Subparagraph (C)(2)(b) of this section for service to a HIGHLY SUSCEPTIBLE POPULATION,

(e) Prepares only FOOD that is not TIME/TEMPERATURE CONTROL OF SAFETY FOOD, or

(f) Does not prepare, but offers for sale only prePACKAGED FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD;

(D) The name, title, address, and telephone number of the PERSON directly responsible for the FOOD ESTABLISHMENT;

(E) The name, title, address, and telephone number of the PERSON who functions as the immediate supervisor of the PERSON specified under ¶ (D) of this section such as the zone, district, or regional supervisor;

(F) The names, titles, and addresses of:

(1) The PERSONS comprising the legal ownership as specified under ¶ (B) of this section including the owners and officers, and

(2) The local resident agent if one is required based on the type of legal ownership;

(G) A statement signed by the applicant that:

(1) Attests to the accuracy of the information provided in the application, and

(2) Affirms that the applicant will:

(a) Comply with this Code, and

(b) Allow the REGULATORY AUTHORITY access to the establishment as specified under § 8-402.11 and to the records specified under §§ 3-203.12 and 5-205.13 and Subparagraph 8-201.14(D)(6); and

(H) Other information required by the REGULATORY AUTHORITY.

Issuance

8-303.10 New, Converted, or Remodeled Establishments.

For FOOD ESTABLISHMENTS that are required to submit plans as specified under § 8-201.11 the REGULATORY AUTHORITY shall issue a PERMIT to the applicant after:

(A) A properly completed application is submitted;

(B) The required fee is submitted;

(C) The required plans, specifications, and information are reviewed and APPROVED; and

(D) A preoperational inspection as specified in § 8-203.10 shows that the establishment is built or remodeled in accordance with the APPROVED plans and specifications and that the establishment is in compliance with this Code.

8-303.20 Existing Establishments, Permit Renewal, and Change of Ownership.

The REGULATORY AUTHORITY may renew a PERMIT for an existing FOOD ESTABLISHMENT or may issue a PERMIT to a new owner of an existing FOOD ESTABLISHMENT after a properly completed application is submitted, reviewed, and APPROVED, the fees are paid, and an inspection shows that the establishment is in compliance with this Code.

8-303.30 Denial of Application for Permit, Notice.

If an application for a PERMIT to operate is denied, the REGULATORY AUTHORITY shall provide the applicant with a notice that includes:

(A) The specific reasons and Code citations for the PERMIT denial;

(B) The actions, if any, that the applicant must take to qualify for a PERMIT; and

(C) Advisement of the applicant's right of appeal and the process and time frames for appeal that are provided in LAW.

Conditions of Retention

8-304.10 Responsibilities of the Regulatory Authority.

(A) At the time a PERMIT is first issued, the REGULATORY AUTHORITY shall provide to the PERMIT HOLDER a copy of this Code so that the PERMIT HOLDER is notified of the compliance requirements and the conditions of retention, as specified under § 8-304.11, that are applicable to the PERMIT.

(B) *Failure to provide the information specified in ¶ (A) of this section does not prevent the* REGULATORY AUTHORITY *from taking authorized action or seeking remedies if the* PERMIT HOLDER *fails to comply with this Code or an order, warning, or directive of the* REGULATORY AUTHORITY.

8-304.11 Responsibilities of the Permit Holder.

Upon acceptance of the PERMIT issued by the REGULATORY AUTHORITY, the PERMIT HOLDER in order to retain the PERMIT shall:

(A) Post the PERMIT in a location in the FOOD ESTABLISHMENT that is conspicuous to CONSUMERS;

(B) Comply with the provisions of this Code including the conditions of a granted VARIANCE as specified under § 8-103.12, and APPROVED plans as specified under § 8-201.12;

(C) If a FOOD ESTABLISHMENT is required under § 8-201.13 to operate under a HACCP PLAN, comply with the plan as specified under § 8-103.12;

(D) Immediately contact the REGULATORY AUTHORITY to report an illness of a FOOD EMPLOYEE or CONDITIONAL EMPLOYEE as specified under ¶ 2-201.11(B);

(E) Immediately discontinue operations and notify the REGULATORY AUTHORITY if an IMMINENT HEALTH HAZARD may exist as specified under § 8-404.11;

(F) Allow representatives of the REGULATORY AUTHORITY access to the FOOD ESTABLISHMENT as specified under § 8-402.11;

(G) Replace existing facilities and EQUIPMENT specified in § 8-101.10 with facilities and EQUIPMENT that comply with this Code if:

(1) The REGULATORY AUTHORITY directs the replacement because the facilities and EQUIPMENT constitute a public health HAZARD or nuisance or no longer comply with the criteria upon which the facilities and EQUIPMENT were accepted,

(2) The REGULATORY AUTHORITY directs the replacement of the facilities and EQUIPMENT because of a change of ownership, or

(3) The facilities and EQUIPMENT are replaced in the normal course of operation;

(H) Comply with directives of the REGULATORY AUTHORITY including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the REGULATORY AUTHORITY in regard to the PERMIT HOLDER'S FOOD ESTABLISHMENT or in response to community emergencies;

(I) Accept notices issued and served by the REGULATORY AUTHORITY according to LAW; and

(J) Be subject to the administrative, civil, injunctive, and criminal remedies authorized in LAW for failure to comply with this Code or a directive of the REGULATORY AUTHORITY, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.

(K) Notify customers that a copy of the most recent establishment inspection report is available upon request by posting a sign or placard in a location in the food establishment that is conspicuous to customers or by another method acceptable to the REGULATORY AUTHORITY.

8-304.20 Permits Not Transferable.

A PERMIT may not be transferred from one PERSON to another PERSON, from one FOOD ESTABLISHMENT to another, or from one type of operation to another if the FOOD operation changes from the type of operation specified in the application as specified under ¶ 8-302.14(C) and the change in operation is not APPROVED.

8-4 INSPECTION AND CORRECTION OF VIOLATIONS

Subparts

Frequency

8-401.10 Establishing Inspection Interval.

(A) Except as specified in ¶¶ (B) and (C) of this section, the REGULATORY AUTHORITY shall inspect a FOOD ESTABLISHMENT at least once every 6 months.

(B) *The REGULATORY AUTHORITY may increase the interval between inspections beyond 6 months if:*

(1) *The FOOD ESTABLISHMENT is fully operating under an APPROVED and validated HACCP PLAN as specified under § 8-201.14 and ¶¶ 8-103.12(A) and (B);*

(2) *The FOOD ESTABLISHMENT is assigned a less frequent inspection frequency based on a written RISK-based inspection schedule that is being uniformly applied throughout the jurisdiction and at least once every 6 months the establishment is contacted by telephone or other means by the REGULATORY AUTHORITY to ensure that the establishment manager and the nature of FOOD operation are not changed; or*

(3) *The establishment's operation involves only coffee service and other unPACKAGED or prePACKAGED FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD such as carbonated BEVERAGES and snack FOOD such as chips, nuts, popcorn, and pretzels.*

(C) The REGULATORY AUTHORITY shall periodically inspect throughout its PERMIT period a TEMPORARY FOOD ESTABLISHMENT that prepares, sells, or serves unPACKAGED TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and that:

(1) Has improvised rather than permanent facilities or EQUIPMENT for accomplishing functions such as handwashing, FOOD preparation and protection, FOOD temperature control, WAREWASHING, providing DRINKING WATER, waste retention and disposal, and insect and rodent control; or

(2) Has inexperienced FOOD EMPLOYEES.

8-401.20 Performance- and Risk-Based.

Within the parameters specified in § 8-401.10, the REGULATORY AUTHORITY shall prioritize, and conduct more frequent inspections based upon its assessment of a FOOD ESTABLISHMENT'S history of compliance with this Code and the establishment's potential as a vector of foodborne illness by evaluating:

(A) Past performance, for nonconformance with Code or HACCP PLAN requirements that are PRIORITY ITEMS or PRIORITY FOUNDATION ITEMS;

(B) Past performance, for numerous or repeat violations of Code or HACCP PLAN requirements that are CORE ITEMS;

(C) Past performance, for complaints investigated and found to be valid;

(D) The HAZARDS associated with the particular FOODS that are prepared, stored, or served;

(E) The type of operation including the methods and extent of FOOD storage, preparation, and service;

(F) The number of people served; and

(G) Whether the population served is a HIGHLY SUSCEPTIBLE POPULATION.

Competency

8-402.10 Competency of Inspectors.

An authorized representative of the REGULATORY AUTHORITY who inspects a FOOD ESTABLISHMENT or conducts plan review for compliance with this Code shall have the knowledge, skills, and ability to adequately perform the required duties.

Access

8-402.11 Allowed at Reasonable Times after Due Notice.

After the REGULATORY AUTHORITY presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the PERSON IN CHARGE shall allow the REGULATORY AUTHORITY to determine if the FOOD ESTABLISHMENT is in compliance with this Code by allowing access to the establishment, allowing inspection, and providing information and records specified in this Code and to which the REGULATORY AUTHORITY is entitled according to LAW, during the FOOD ESTABLISHMENT'S hours of operation and other reasonable times.

8-402.20 Refusal, Notification of Right to Access, and Final Request for Access.

If a PERSON denies access to the REGULATORY AUTHORITY, the REGULATORY AUTHORITY shall:

(A) Inform the PERSON that:

(1) The PERMIT HOLDER is required to allow access to the REGULATORY AUTHORITY as specified under § 8-402.11 of this Code,

(2) Access is a condition of the acceptance and retention of a FOOD ESTABLISHMENT PERMIT to operate as specified under ¶ 8-304.11(F), and

(3) If access is denied, an order issued by the appropriate authority allowing access, hereinafter referred to as an inspection order, may be obtained according to LAW; and

(B) Make a final request for access.

8-402.30 Refusal, Reporting.

If after the REGULATORY AUTHORITY presents credentials and provides notice as specified under § 8-402.11, explains the authority upon which access is requested, and makes a final request for access as specified in § 8-402.20, the PERSON IN CHARGE continues to REFUSE access, the REGULATORY AUTHORITY shall provide details of the denial of access on an inspection report form.

8-402.40 Inspection Order to Gain Access.

If denied access to a FOOD ESTABLISHMENT for an authorized purpose and after complying with § 8-402.20, the REGULATORY AUTHORITY may issue, or apply for the issuance of, an inspection order to gain access as provided in LAW.

Report of Findings

8-403.10 Documenting Information and Observations.

The REGULATORY AUTHORITY shall document on an inspection report form:

(A) Administrative information about the FOOD ESTABLISHMENT'S legal identity, street and mailing addresses, type of establishment and operation as specified under ¶ 8-302.14(C), inspection date, and other information such as type of water supply and SEWAGE disposal, status of the PERMIT, and personnel certificates that may be required; and

(B) Specific factual observations of violative conditions or other deviations from this Code that require correction by the PERMIT HOLDER including:

(1) Failure of the PERSON IN CHARGE to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this Code as specified under § 2-102.11,

(2) Failure of FOOD EMPLOYEES, CONDITIONAL EMPLOYEES, and the PERSON IN CHARGE to report a disease or medical condition as specified under ¶¶ 2-201.11(B) and (D),

(3) Nonconformance with PRIORITY ITEMS OR PRIORITY FOUNDATION ITEMS of this Code,

(4) Failure of the appropriate FOOD EMPLOYEES to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the REGULATORY AUTHORITY as specified under § 8-103.12,

(5) Failure of the PERSON IN CHARGE to provide records required by the REGULATORY AUTHORITY for determining conformance with a HACCP PLAN as specified under Subparagraph 8-201.14(D)(6), and

(6) Nonconformance with CRITICAL LIMITS of a HACCP PLAN.

8-403.20 Specifying Time Frame for Corrections.

The REGULATORY AUTHORITY shall specify on the inspection report form the time frame for correction of the violations as specified under §§ 8-404.11, 8-405.11, and 8-406.11.

8-403.30 Issuing Report and Obtaining Acknowledgment of Receipt.

At the conclusion of the inspection and according to LAW, the REGULATORY AUTHORITY shall provide a copy of the completed inspection report and the notice to correct violations to the PERMIT HOLDER or to the PERSON IN CHARGE, and request a signed acknowledgment of receipt.

8-403.40 Refusal to Sign Acknowledgment.

The REGULATORY AUTHORITY shall:

(A) Inform a PERSON who declines to sign an acknowledgment of receipt of inspectional findings as specified in § 8-403.30 that:

(1) An acknowledgment of receipt is not an agreement with findings,

(2) Refusal to sign an acknowledgment of receipt will not affect the PERMIT HOLDER'S obligation to correct the violations noted in the inspection report within the time frames specified, and

(3) A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the REGULATORY AUTHORITY'S historical record for the FOOD ESTABLISHMENT; and

(B) Make a final request that the PERSON IN CHARGE sign an acknowledgment receipt of inspectional findings.

8-403.50 Public Information.

Except as specified in § 8-202.10, the REGULATORY AUTHORITY shall treat the inspection report as a public document and shall make it available for disclosure to a PERSON who requests it as provided in LAW.

Imminent Health Hazard

8-404.11 Ceasing Operations and Reporting.

(A) Except as specified in ¶ (B) of this section, a PERMIT HOLDER shall immediately discontinue operations and notify the REGULATORY AUTHORITY if an IMMINENT HEALTH HAZARD may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, SEWAGE backup, misuse of POISONOUS OR TOXIC MATERIALS, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health.[P]

(B) *A PERMIT HOLDER need not discontinue operations in an area of an establishment that is unaffected by the IMMINENT HEALTH HAZARD.*

8-404.12 Resumption of Operations.

If operations are discontinued as specified under § 8-404.11 or otherwise according to LAW, the PERMIT HOLDER shall obtain approval from the REGULATORY AUTHORITY before resuming operations.

Violation of Priority Item or Priority Foundation Item

8-405.11 Timely Correction.

(A) Except as specified in ¶ (B) of this section, a PERMIT HOLDER shall at the time of inspection correct a violation of a PRIORITY ITEM or PRIORITY FOUNDATION ITEM of this Code and implement corrective actions for a HACCP PLAN provision that is not in compliance with its CRITICAL LIMIT. [Pf]

(B) *Considering the nature of the potential HAZARD involved and the complexity of the corrective action needed, the REGULATORY AUTHORITY may agree to or specify a longer time frame, not to exceed:*

> *(1) 72 hours after the inspection, for the PERMIT HOLDER to correct violations of a PRIORITY ITEM*; or
>
> *(2) 10 calendar days after the inspection, for the PERMIT HOLDER to correct violations of a PRIORITY FOUNDATION ITEM or HACCP PLAN deviations.*

8-405.20 Verification and Documentation of Correction.

(A) After observing at the time of inspection a correction of a violation of a PRIORITY ITEM or PRIORITY FOUNDATION ITEM or a HACCP PLAN deviation, the REGULATORY AUTHORITY shall enter the violation and information about the corrective action on the inspection report.

(B) As specified under ¶ 8-405.11(B), after receiving notification that the PERMIT HOLDER has corrected a violation of a PRIORITY ITEM OR PRIORITY FOUNDATION ITEM or HACCP PLAN deviation, or at the end of the specified period of time, the REGULATORY AUTHORITY shall verify correction of the violation, document the information on an inspection report, and enter the report in the REGULATORY AUTHORITY'S records.

Core Item Violation

8-406.11 Time Frame for Correction.

(A) Except as specified in ¶ (B) of this section, the PERMIT HOLDER shall correct CORE ITEMS by a date and time agreed to or specified by the REGULATORY AUTHORITY but no later than 90 calendar days after the inspection.

(B) *The* REGULATORY AUTHORITY *may approve a compliance schedule that extends beyond the time limits specified under ¶ (A) of this section if a written schedule of compliance is submitted by the* PERMIT HOLDER *and no health* HAZARD *exists or will result from allowing an extended schedule for compliance.*

8-5 PREVENTION OF FOODBORNE DISEASE TRANSMISSION BY EMPLOYEES

Subpart

8-501 Investigation and Control

Investigation and Control

8-501.10 Obtaining Information: Personal History of Illness, Medical Examination, and Specimen Analysis.

The REGULATORY AUTHORITY shall act when it has reasonable cause to believe that a FOOD EMPLOYEE or CONDITIONAL EMPLOYEE has possibly transmitted disease; may be infected with a disease in a communicable form that is transmissible through FOOD; may be a carrier of infectious agents that cause a disease that is transmissible through FOOD; or is affected with a boil, an infected wound, or acute respiratory infection, by:

(A) Securing a confidential medical history of the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE suspected of transmitting disease or making other investigations as deemed appropriate; and

(B) Requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected FOOD EMPLOYEE or CONDITIONAL EMPLOYEE.

8-501.20 Restriction or Exclusion of Food Employee, or Summary Suspension of Permit.

Based on the findings of an investigation related to a FOOD EMPLOYEE or CONDITIONAL EMPLOYEE who is suspected of being infected or diseased, the REGULATORY AUTHORITY may issue an order to the suspected FOOD EMPLOYEE, CONDITIONAL EMPLOYEE or PERMIT HOLDER instituting one or more of the following control measures:

(A) RESTRICTING the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE;

(B) EXCLUDING the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE; or

(C) Closing the FOOD ESTABLISHMENT by summarily suspending a PERMIT to operate in accordance with LAW.

8-501.30 Restriction or Exclusion Order: Warning or Hearing Not Required, Information Required in Order.

Based on the findings of the investigation as specified in § 8-501.10 and to control disease transmission, the REGULATORY AUTHORITY may issue an order of RESTRICTION or EXCLUSION to a suspected FOOD EMPLOYEE or the PERMIT HOLDER without prior warning, notice of a hearing, or a hearing if the order:

(A) States the reasons for the RESTRICTION or EXCLUSION that is ordered;

(B) States the evidence that the FOOD EMPLOYEE or PERMIT HOLDER shall provide in order to demonstrate that the reasons for the RESTRICTION or EXCLUSION are eliminated;

(C) States that the suspected FOOD EMPLOYEE or the PERMIT HOLDER may request an appeal hearing by submitting a timely request as provided in LAW; and

(D) Provides the name and address of the REGULATORY AUTHORITY representative to whom a request for an appeal hearing may be made.

8-501.40 Removal of Exclusions and Restrictions.

The REGULATORY AUTHORITY shall release a FOOD EMPLOYEE, OR CONDITIONAL EMPLOYEE from RESTRICTION or EXCLUSION according to LAW and the conditions specified under § 2-201.13.

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Food Code

U.S. Public Health Service

ANNEXES
2013

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service • Food and Drug Administration

College Park, MD 20740

Annex

1 Compliance and Enforcement

1. PURPOSE

The purpose of this Annex is to set forth provisions, in codified form, that provide a full array of enforcement mechanisms while recognizing the diverse statutes and regulations that currently govern the operations of the thousands of State and local regulatory agencies.

2. EXPLANATION

State or local statutes, regulations, and ordinances vary in their design, specificity, and degree of comprehensiveness in that they may:

(A) Contain authorities that provide the basis for certain post-inspection compliance strategies but remain silent with respect to other enforcement mechanisms;

(B) Include specific requirements that are different from those provided in this Annex; and

(C) Be structured so that provisions such as administrative procedures are embodied in sections of the law that transcend and are separate from those governing food establishments.

Consequently, in this document a deliberate attempt is made to extract those provisions that could conceptually be adopted as an extension of Chapter 8 if they were compatible with existing, governing State and local statutes. The extracted provisions are numbered to sequentially follow Chapter 8 but are placed in this Annex so that regulatory agencies can revise them to be consistent with their statutes and their needs as discussed in the Recommendation, below.

It is anticipated that adoption of this Code will be facilitated by the fact that:

(A) The compliance provisions of Chapter 8 that should be an integral part of State or local food regulations are part of the text of the Code; and

(B) The administrative and judicial enforcement provisions that are critical to the framework of a food regulatory program, but that may be repetitive or discrepant when compared to State or local statutes, are separated in this Annex.

3. PRINCIPLE

Although the situations necessitating escalated enforcement actions comprise a small percentage of those encountered by the regulator, a full spectrum of enforcement tools must be available where immediate hazards exist, or where compliance is not obtained voluntarily. Thus, a jurisdiction must have in place both the necessary statutory framework that includes a broad-based, well-defined enforcement component and regulations that specify the requirements within those legal authorities. It is imperative that there be clearly stated and legally sound rules that include the criteria for compliance and enforcement, the responsibilities of all parties, sanctions for noncompliance, and due process guarantees.

4. RECOMMENDATION

FDA recommends that agencies assess their statutory provisions that pertain to food establishments in light of this Annex and consider proposing changes to their statutes and regulations where they determine that provisions contained within this Annex will strengthen their programs. Such an assessment may involve reviewing problems encountered in attempts to prosecute under existing State or local provisions; considering comments received by the regulatory authority about its enforcement process; consulting with staff and legal counsel to identify gaps or weaknesses in the provisions; comparing provisions with sister agencies for comprehensiveness, equity, and uniformity; and seeking input from outside sources that have experience in taking, or being the subject of, enforcement actions.

Appropriate wording and cross referencing changes to the provisions in this Annex may be necessary, based on whether they are adopted as statutes or regulations. Modifications to the adoption forms (Forms #2-A and #2-B in Annex 7) may also be necessary based on that decision.

Parts

8-6 CONSTITUTIONAL PROTECTION

Subparts

Procedural Safeguards

8-601.10 Preservation of Rights.

The REGULATORY AUTHORITY shall justly apply the remedies according to LAW and this Code, to preserve the rights to equal protection and due process of a PERSON to whom the remedies are applied.

Judicial Review

8-602.10 Rights of Recipients of Orders or Decisions.

A recipient of a REGULATORY AUTHORITY order or decision may file a petition for judicial review in a court of competent jurisdiction after available administrative appeal remedies are exhausted.

8-7 AUTHORITY

Subpart

8-701 Legal Authority

Legal Authority

8-701.10 Adoption of Regulations.

The REGULATORY AUTHORITY shall have the requisite legal authority from the appropriate statute/ordinance making authority to adopt and enforce regulations to carry out the administrative and judicial enforcement provisions of the Code that are critical to the framework of a Food Establishment regulatory program, to include the requirement for the issuance of a Permit.

8-701.11 Implementation of Regulations.

Appropriate modifications to the adoption forms (Form #2-A (Adoption by Reference short form) and #2-B (Adoption by Section-by-Section Reference)) in Annex 7, where used, shall be made consistent with said legal authority to enact regulations and enforce compliance of the Code, whether they are adopted as statutes or regulations.

8-701.20 Basis for Action.

The REGULATORY AUTHORITY shall clearly state and reference within the Code the legally sound basis for compliance and enforcement action, the responsibilities of the parties, sanctions for noncompliance and due process.

8-8 NOTICES

Subpart

8-801 Service of Notice

Service of Notice

8-801.10 Proper Methods.

(Note: Adoption of this section provides the basis for serving notice of inspectional findings as specified in § 8-403.30 and would be cited there.)

A notice issued in accordance with this Code shall be considered to be properly served if it is served by one of the following methods:

(A) The notice is personally served by the REGULATORY AUTHORITY, a LAW enforcement officer, or a PERSON authorized to serve a civil process to the PERMIT HOLDER, the PERSON IN CHARGE, or PERSON operating a FOOD ESTABLISHMENT without a PERMIT;

(B) The notice is sent by the REGULATORY AUTHORITY to the last known address of the PERMIT HOLDER or the PERSON operating a FOOD ESTABLISHMENT without a PERMIT, by registered or certified mail or by other public means so that a written acknowledgment of receipt may be acquired; or

(C) The notice is provided by the REGULATORY AUTHORITY in accordance with another manner of service authorized in LAW.

8-801.20 Restriction or Exclusion Order, Hold Order or Summary Suspension.

An EMPLOYEE RESTRICTION or EXCLUSION order, an order to hold and not distribute FOOD, such as a hold, detention, embargo, or seizure order which is hereinafter referred to as a hold order, or a summary suspension order shall be:

(A) Served as specified in ¶ 8-801.10(A); or

(B) Clearly posted by the REGULATORY AUTHORITY at a public entrance to the FOOD ESTABLISHMENT and a copy of the notice sent by first class mail to the PERMIT HOLDER or to the owner or custodian of the FOOD, as appropriate.

8-801.30 When Notice is Effective.

Service is effective at the time of the notice's receipt or if service is made as specified in ¶ 8-801.20(B), at the time of the notice's posting.

8-801.40 Proof of Proper Service.

Proof of proper service may be made by affidavit of the PERSON making service or by admission of the receipt signed by the PERMIT HOLDER, the PERSON operating a FOOD ESTABLISHMENT without a PERMIT to operate, or an authorized agent.

8-9 REMEDIES

Subparts

Criteria for Seeking Remedies

8-901.10 Conditions Warranting Remedy.

The REGULATORY AUTHORITY may seek an administrative or judicial remedy to achieve compliance with the provisions of this Code if a PERSON operating a FOOD ESTABLISHMENT or EMPLOYEE:

(A) Fails to have a valid PERMIT to operate a FOOD ESTABLISHMENT as specified under § 8-301.11;

(B) Violates any term or condition of a PERMIT as specified under § 8-304.11;

(C) Allows serious or repeated code violations to remain uncorrected beyond time frames for correction APPROVED, directed, or ordered by the REGULATORY AUTHORITY under ¶¶ 8-405.11(A) and (B), and ¶¶ 8-406.11(A) and (B);

(D) Fails to comply with a REGULATORY AUTHORITY order issued as specified in § 8-501.20 concerning an EMPLOYEE or CONDITIONAL EMPLOYEE suspected of having a disease transmissible through FOOD by infected PERSONS;

(E) Fails to comply with a hold order as specified in § 8-903.10;

(F) Fails to comply with an order issued as a result of a hearing for an administrative remedy as specified in § 8-906.40; or

(G) Fails to comply with a summary suspension order issued by the REGULATORY AUTHORITY as specified in §§ 8-801.20 and 8-904.10.

Administrative

Inspection Orders

8-902.10 Gaining Access to Premises and Records.

(Note: Adoption of this section provides the basis for Subparagraph 8-402.20(A)(3) and § 8-402.40 and would be cited there.)

The REGULATORY AUTHORITY may order access for one or more of the following purposes, subject to LAW for gaining access:

(A) If admission to the PREMISES of a FOOD ESTABLISHMENT is denied or other circumstances exist that would justify an inspection order under LAW, to make an inspection including taking photographs;

(B) To examine and sample the FOOD; and

(C) To examine the records on the PREMISES relating to FOOD purchased, received, or used by the FOOD ESTABLISHMENT.

8-902.20 Contents of Inspection Order.

The REGULATORY AUTHORITY'S inspection order shall:

(A) Stipulate that access be allowed on or to the described PREMISES, FOOD, or records under the order's provisions;

(B) Provide a description that specifies the PREMISES, FOOD, or records subject to the order; and

(C) Specify areas to be accessed and activities to be performed.

Holding, Examination, and Destruction of Food

8-903.10 Hold Order, Justifying Conditions and Removal of Food.

(Note: Adoption of this section provides the basis for ¶ 3-202.18(B) and would be cited there.)

(A) According to time limits imposed by LAW, the REGULATORY AUTHORITY may place a hold order on a FOOD that:

(1) Originated from an unAPPROVED source;

(2) May be unsafe, ADULTERATED, or not honestly presented;

(3) Is not labeled according to LAW, or, if raw MOLLUSCAN SHELLFISH, is not tagged or labeled according to LAW; or

(4) Is otherwise not in compliance with this Code.

(B) If the REGULATORY AUTHORITY has reasonable cause to believe that the hold order will be violated, or finds that the order is violated, the REGULATORY AUTHORITY may remove the FOOD that is subject to the order to a place of safekeeping.

8-903.20 Hold Order, Warning or Hearing Not Required.

The REGULATORY AUTHORITY may issue a hold order to a PERMIT HOLDER or to a PERSON who owns or controls the FOOD, as specified in § 8-903.10, without prior warning, notice of a hearing, or a hearing on the hold order.

8-903.30 Hold Order, Contents.

The hold order notice shall:

(A) State that FOOD subject to the order may not be used, sold, moved from the FOOD ESTABLISHMENT, or destroyed without a written release of the order from the REGULATORY AUTHORITY;

(B) State the specific reasons for placing the FOOD under the hold order with reference to the applicable provisions of this Code and the HAZARD or adverse effect created by the observed condition;

(C) Completely identify the FOOD subject to the hold order by the common name, the label information, a container description, the quantity, REGULATORY AUTHORITY'S tag or identification information, and location;

(D) State that the PERMIT HOLDER has the right to an appeal hearing and may request a hearing by submitting a timely request as specified in §§ 8-905.10 and 8-905.20;

(E) State that the REGULATORY AUTHORITY may order the destruction of the FOOD if a timely request for an appeal hearing is not received; and

(F) Provide the name and address of the REGULATORY AUTHORITY representative to whom a request for an appeal hearing may be made.

8-903.40 Hold Order, Official Tagging of Food.

(A) The REGULATORY AUTHORITY shall securely place an official tag or label on the FOOD or containers or otherwise conspicuously identify FOOD subject to the hold order.

(B) The tag or other method used to identify a FOOD that is the subject of a hold order shall include a summary of the provisions specified in § 8-903.30 and shall be signed and dated by the REGULATORY AUTHORITY.

8-903.51 Hold Order, Food May Not Be Used or Moved.

(A) Except as specified in ¶ (B) of this section, a FOOD placed under a hold order may not be used, sold, served, or moved from the establishment by any PERSON.

(B) *The REGULATORY AUTHORITY may allow the PERMIT HOLDER the opportunity to store the FOOD in an area of the FOOD ESTABLISHMENT if the FOOD is protected from subsequent deterioration and the storage does not restrict operations of the establishment.*

8-903.60 Examining, Sampling, and Testing Food.

The REGULATORY AUTHORITY may examine, sample, and test FOOD in order to determine its compliance with this Code.

8-903.70 Hold Order, Removing the Official Tag.

Only the REGULATORY AUTHORITY may remove hold order tags, labels, or other identification from FOOD subject to a hold order.

8-903.80 Destroying or Denaturing Food.

If a hold order is sustained upon appeal or if a timely request for an appeal hearing is not filed, the REGULATORY AUTHORITY may order the PERMIT HOLDER or other PERSON who owns or has custody of the FOOD to bring the FOOD into compliance with this Code or to destroy or denature the FOOD under the REGULATORY AUTHORITY'S supervision.

8-903.90 Releasing Food from Hold Order.

The REGULATORY AUTHORITY shall issue a notice of release from a hold order and shall remove hold tags, labels, or other identification from the FOOD if the hold order is vacated.

Summary Permit Suspension

8-904.10 Conditions Warranting Action.

The REGULATORY AUTHORITY may summarily suspend a PERMIT to operate a FOOD ESTABLISHMENT if it determines through inspection, or examination of EMPLOYEES, FOOD, records, or other means as specified in this Code, that an IMMINENT HEALTH HAZARD exists.

8-904.20 Summary Suspension, Warning or Hearing Not Required.

The REGULATORY AUTHORITY may summarily suspend a PERSON'S PERMIT as specified in § 8-904.10 by providing written notice as specified in § 8-801.20 of the summary suspension to the PERMIT HOLDER or PERSON IN CHARGE, without prior warning, notice of a hearing, or a hearing.

8-904.30 Contents of the Notice.

A summary suspension notice shall state:

(A) That the FOOD ESTABLISHMENT PERMIT is immediately suspended and that all FOOD operations shall immediately cease;

(B) The reasons for summary suspension with reference to the provisions of this Code that are in violation;

(C) The name and address of the REGULATORY AUTHORITY representative to whom a written request for reinspection may be made and who may certify that reasons for the suspension are eliminated; and

(D) That the PERMIT HOLDER may request an appeal hearing by submitting a timely request as specified in §§ 8-905.10 and 8-905.20.

8-904.40 Time Frame for Reinspection.

After receiving a written request from the PERMIT HOLDER stating that the conditions cited in the summary suspension order no longer exist, the REGULATORY AUTHORITY shall conduct a reinspection of the FOOD ESTABLISHMENT for which the PERMIT was summarily suspended within 2 business days, which means 2 days during which the REGULATORY AUTHORITY'S office is open to the public.

8-904.50 Term of Suspension, Reinstatement of Permit.

(A) A summary suspension shall remain in effect until the conditions cited in the notice of suspension no longer exist and their elimination has been confirmed by the REGULATORY AUTHORITY through reinspection and other means as appropriate.

(B) The suspended PERMIT shall be reinstated immediately if the REGULATORY AUTHORITY determines that the public health HAZARD or nuisance no longer exists. A notice of reinstatement shall be provided to the PERMIT HOLDER or PERSON IN CHARGE.

Hearings Administration

8-905.10 Response to Notice of Hearing or Request for Hearing, Basis and Time Frame.

(Note: Adoption of this section provides the basis for ¶¶ 8-303.30(C) and 8-501.30(C). ¶¶ 8-905.10(C) and (D) would be cited there.)

(A) A PERSON who receives a notice of hearing for an administrative remedy as specified in Part 8-8, § 8-901.10, or ¶ 8-905.30(A) and elects to respond to the notice shall file a response to notice as specified in § 8-905.20 within 7 calendar days after service.

(B) A PERMIT applicant may request a hearing regarding the disposition of an application for a new or revised PERMIT if the REGULATORY AUTHORITY does not issue or deny the PERMIT within the time frame specified in LAW.

(C) A PERMIT HOLDER may request a hearing to address concerns about the REGULATORY AUTHORITY'S denial of application for a PERMIT or request for a VARIANCE, or compliance actions, except that a hearing request does not stay the REGULATORY AUTHORITY'S restriction or exclusion of EMPLOYEES specified in §§ 8-501.10 - 8-501.40, a hold order specified in § 8-903.10, or the imposition of a summary suspension specified in § 8-904.10.

(D) A PERSON desiring a hearing in response to a denial of an application for PERMIT or an adverse administrative determination shall submit a hearing request to the REGULATORY AUTHORITY within 10 calendar days of the date of the denial, inspection, or compliance action, unless the REGULATORY AUTHORITY specifies in

certain situations that the request shall be submitted within a shorter period of time.

8-905.20 Response to a Notice of Hearing or Request for Hearing, Required Form and Contents.

A response to a hearing notice or a request for hearing as specified in § 8-905.10 shall be in written form and contain the following:

(A) If a response to notice of hearing,

(1) An admission or denial of each allegation of fact;

(2) A statement as to whether the respondent waives the right to a hearing; and may also contain

(3) A statement of defense, mitigation, or explanation concerning any allegation of fact; and

(4) A request to the REGULATORY AUTHORITY for a settlement of the proceeding by consent agreement, if the REGULATORY AUTHORITY will provide this opportunity.

(B) If a request for hearing,

(1) A statement of the issue of fact specified in ¶ 8-905.30(B) for which the hearing is requested; and

(2) A statement of defense, mitigation, denial, or explanation concerning each allegation of fact.

(C) If either a response to notice of hearing or a request for a hearing,

(1) A statement indicating whether the presence of witnesses for the REGULATORY AUTHORITY is required; and

(2) The name and address of the respondent's or requester's legal counsel, if any.

8-905.30 Provided Upon Request.

The REGULATORY AUTHORITY shall hold hearings according to LAW and the provisions of this Code:

(A) As determined necessary by LAW or the REGULATORY AUTHORITY to accomplish the purpose and intent of this Code specified in § 8-101.10; and

(B) As requested by a PERMIT applicant or a PERMIT HOLDER if:

(1) Requested as specified in § 8-905.10, and

(2) The request demonstrates that there is a genuine and material issue of fact that justifies that a hearing be held.

8-905.40 Provided in Accordance with Law.

Hearings shall be conducted according to LAW, administrative procedures, and this Code.

8-905.50 Timeliness, Appeal Proceeding Within 5 Business Days, Other Proceeding Within 30 Calendar Days.

(A) The REGULATORY AUTHORITY shall afford a hearing:

(1) Except as provided in ¶ (B) of this section, within 5 business days after receiving a written request for an appeal hearing from:

(a) A PERSON who is EXCLUDED by the REGULATORY AUTHORITY from working in a FOOD ESTABLISHMENT as specified in §§ 8-501.10 - 8-501.40,

(b) A PERMIT HOLDER or PERSON whose FOOD is subject to a hold order as specified in Subpart 8-903, or

(c) A PERMIT HOLDER whose PERMIT is summarily suspended as specified in Subpart 8-904; and

(2) Within 30 calendar days but no earlier than 7 calendar days after the service of a hearing notice to consider administrative remedies for other matters as specified in ¶ 8-905.10(C) or for matters as determined necessary by the REGULATORY AUTHORITY.

(B) A PERMIT HOLDER or PERSON who submits a request for a hearing as specified in Subparagraphs (A)(1)(a)-(c) of this section may waive the prompt hearing in the written request to the REGULATORY AUTHORITY.

8-905.60 Notice, Contents.

A notice of hearing shall contain the following information:

(A) Time, date, and place of the hearing;

(B) Purpose of the hearing;

(C) Facts that constitute the basis or reason for the hearing including specific details of violations or allegations;

(D) The rights of the respondent, including the right to be represented by counsel and to present witnesses and evidence on the respondent's behalf as specified in § 8-907.10;

(E) At the REGULATORY AUTHORITY'S discretion, the procedure for the respondent to request an offer from the REGULATORY AUTHORITY to settle the matter;

(F) The consequences of failing to appear at the hearing;

(G) The maximum sanctions or penalties as specified in ¶¶ 8-906.40(B) - (D) that may result from the hearing if the hearing concerns a proposed administrative remedy and if the facts are found to be as alleged;

(H) If the hearing concerns a proposed administrative remedy, a statement specifying the form and time frame for response as specified in § 8-905.10;

(I) Notification that the written response shall include the information specified in § 8-905.20; and

(J) The name and address of the PERSON to whom such written response shall be addressed.

8-905.70 Proceeding Commences Upon Notification.

A hearing proceeding commences at the time the REGULATORY AUTHORITY notifies the respondent of the hearing proceeding.

8-905.80 Procedure, Expeditious and Impartial.

Hearings shall be conducted in an expeditious and impartial manner.

8-905.90 Confidential.

(A) Hearings or portions of hearings may be closed to the public:

(1) If compelling circumstances, such as the need to discuss in the hearing a PERSON'S medical condition or a FOOD ESTABLISHMENT'S trade secrets, indicate that it would be prudent; and

(2) According to LAW, such as an open meetings LAW.

(B) A party to a hearing shall maintain confidentiality of discussions that warrant closing the hearing to the public.

8-905.100 Record of Proceeding.

A complete record of a hearing shall be prepared under the direction of the PERSON conducting the hearing and maintained as part of the REGULATORY AUTHORITY'S records for the FOOD ESTABLISHMENT. *Except as required by LAW, a verbatim transcript of the hearing need not be prepared*.

Hearing Officer, Purpose Qualifications, Appointment, and Powers

8-906.10 Appointment by Regulatory Authority and Purpose.

The REGULATORY AUTHORITY may appoint a PERSON such as an adjudicator, administrative LAW judge, or examiner, hereinafter referred to as a hearing officer, who presides over a proceeding initiated by the REGULATORY AUTHORITY or by a PERSON contesting an action of the REGULATORY AUTHORITY, to perform one or more of the following:

(A) Hear the facts presented by an applicant or a PERMIT HOLDER;

(B) Make a decision or recommendation concerning administrative remedies to achieve compliance with this Code; or

(C) Address other concerns or allegations appropriately raised according to LAW, in the matter before the hearing officer.

8-906.20 Qualifications.

A hearing officer shall be knowledgeable of the provisions of this chapter and the LAW as they relate to hearings, and be:

(A) A REGULATORY AUTHORITY representative other than the PERSON who inspects the FOOD ESTABLISHMENT or who has any other role in making the decision that is being contested; or

(B) An individual who is not employed by the REGULATORY AUTHORITY.

8-906.30 Powers, Administration of Hearings.

(A) A hearing officer shall have the following powers in a hearing in which the hearing officer presides:

(1) Setting and conducting the course of a hearing requested in accordance with or authorized by this Code,

(2) Issuing subpoenas in the name of the REGULATORY AUTHORITY at the request of a party to a hearing, administering oaths and affirmations, examining witnesses, receiving evidence,

(3) Approving a consent agreement on the issues involved in the hearing entered into by the REGULATORY AUTHORITY and the respondent after the respondent receives a hearing notice,

(4) Sustaining, modifying, rescinding, or vacating an order or directive of the REGULATORY AUTHORITY in an appeal hearing proceeding, and if the order or directive is sustained, ordering appropriate measures to execute the REGULATORY AUTHORITY'S order or directive; and

(B) *Unless a party appeals to the head of the REGULATORY AUTHORITY within 15 days of the hearing or a lesser number of days specified by the hearing officer:*

(1) Rendering a binding decision and final order in a proceeding after conducting a hearing, if the respondent has not waived the right to a hearing, and

(2) Then notifying the respondent of the decision and the order which contains the findings and conclusions of LAW.

8-906.40 Powers, Administrative Remedies.

The hearing officer shall have the following powers in a hearing proceeding concerning an administrative remedy specified in §§ 8-901.10 and 8-905.30:

(A) Issuing orders to abate or correct violations of this Code and establishing a schedule for the abatement or correction of violations;

(B) Making a finding of fact regarding the occurrence of each violation and assessing, levying, and ordering a reasonable civil penalty, according to LAW and not to exceed the amount specified in ¶ 8-913.10(B) for each violation of this Code that is alleged and found to be committed, and calculated based on each day a violation occurs as specified in ¶ 8-913.10(C);

(C) Suspending, revoking, modifying, or imposing reasonable restrictions or conditions on a PERMIT to operate a FOOD ESTABLISHMENT, or ordering the closure of a FOOD ESTABLISHMENT that is operated without a valid PERMIT as required under § 8-301.11;

(D) Making a finding of fact regarding the occurrence of each violation of the REGULATORY AUTHORITY'S or hearing officer's LAWful order issued in accordance with this Code and assessing, levying, and ordering a reasonable civil penalty, in accordance with LAW and not to exceed the amount specified in ¶ 8-913.10(B) for each violation of this Code that is alleged and found to be committed, and calculated based on each day a violation occurs as specified in ¶ 8-913.10(C);

(E) Deferring or suspending the imposition of a decision or execution of an order, and imposing a probationary period, upon the condition that the respondent comply with the hearing officer's reasonable terms and conditions;

(F) Dismissing the appeal if the matter is settled between the REGULATORY AUTHORITY and the respondent after a hearing notice is served;

(G) Ordering reinspection of a FOOD ESTABLISHMENT to determine compliance with a hearing officer's order;

(H) Suspending or ordering the payment of a fee established by the REGULATORY AUTHORITY for a reinspection that is required to determine compliance and for the reinstatement of a PERMIT after suspension;

(I) Retaining and exercising jurisdiction for a specific period of time not to exceed 90 calendar days after the hearing officer's decision and final order is issued, over a respondent who receives a hearing notice; and

(J) Modifying or setting aside an order by rehearing upon the hearing officer's own motion, the motion of the REGULATORY AUTHORITY, or the motion of the respondent.

Rights of Parties and Evidence

8-907.10 Rights of Parties.

Parties to a hearing may be represented by counsel, examine and cross examine witnesses, and present evidence in support of their position.

8-907.20 Evidence to be Presented by the Regulatory Authority.

The REGULATORY AUTHORITY shall present at the hearing its evidence, orders, directives, and reports related to the proposed or appealed administrative remedy.

8-907.30 Evidence to be Excluded.

Evidence shall be EXCLUDED:

(A) If it is irrelevant, immaterial, unduly repetitious, or excludable on constitutional or statutory grounds or on the basis of evidentiary privilege recognized by the state's courts; or

(B) Otherwise according to LAW.

8-907.40 Testimony under Oath.

Testimony of parties and witnesses shall be made under oath or affirmation administered by a duly authorized official.

8-907.50 Written Evidence.

Written evidence may be received if it will expedite the hearing without substantial prejudice to a party's interests.

8-907.60 Documentary Evidence.

Documentary evidence may be received in the form of a copy or excerpt.

Settlement

8-908.10 Authorization.

The REGULATORY AUTHORITY may settle a case after a notice of hearing is served by providing a respondent with an opportunity to request a settlement before a hearing commences on the matter and by entering into a consent agreement with the respondent.

8-908.20 Respondent Acceptance of Consent Agreement Is Waiver of Right to Appeal.

Respondents accepting a consent agreement waive their right to a hearing on the matter.

Judicial

Inspection Orders

8-909.10 Gaining Access to Premises and Records.

(Note: Adoption of this section provides the basis for Subparagraph 8-402.20(A)(3) and § 8-402.40 and would be cited there.)

The REGULATORY AUTHORITY may seek access for one or more of the following purposes, according to LAW for gaining access:

(A) If admission to the PREMISES of a FOOD ESTABLISHMENT is denied or other circumstances exist that would justify an inspection order under LAW, to make an inspection including taking photographs;

(B) To examine and sample the FOOD; and

(C) To examine the records on the PREMISES relating to FOOD purchased, received, or used by the FOOD ESTABLISHMENT.

8-909.20 Contents of Court Petition.

In the absence of a specific set of requirements established by LAW, in its petition to the court to compel access the REGULATORY AUTHORITY shall:

(A) Describe in detail the PREMISES, FOOD, or records on or to which access was denied;

(B) Detail the legal authority to regulate and to have access

for a specific purpose on or to the PREMISES, FOOD, or records where access was denied; and

(C) Provide information that the FOOD ESTABLISHMENT possesses a valid PERMIT from the REGULATORY AUTHORITY and that it applies to the PREMISES where access was denied; or

(D) Provide information that a PERSON is known to be or suspected of operating a FOOD ESTABLISHMENT without possessing a valid PERMIT as specified in LAW and under this Code.

8-909.30 Sworn Statement of Denied Access.

The REGULATORY AUTHORITY shall demonstrate to the court by affidavit, sworn testimony, or both that:

(A) Access on or to the PREMISES, FOOD, or records was denied after the REGULATORY AUTHORITY acted as specified in §§ 8-402.20 and 8-402.30; or

(B) There is reason to believe that a FOOD ESTABLISHMENT is being operated on the PREMISES and that access was denied or is sought under a REGULATORY AUTHORITY'S reasonable administrative plan to enforce the provisions of this Code.

8-909.40 Contents of an Order.

Upon petition of the REGULATORY AUTHORITY, the court may issue an inspection order that:

(A) Includes the information specified in ¶¶ 8-902.20(A) - (C); and

(B) Orders or authorizes any other identified agencies and persons including LAW enforcement agencies to execute, or assist with the execution of, the order.

8-909.50 Optional Contents of an Order.

Upon petition of the REGULATORY AUTHORITY, the court may further issue an inspection order that:

(A) Provides a maximum time limit for the order's execution;

(B) Authorizes LAW enforcement officers who assist in the order's execution to use necessary force against PERSONS or property to execute the order; and

(C) Requires that the agencies or PERSONS ordered or authorized to execute the order shall report to the court the date and time of the order's execution and the findings reached by the inspection, examination, or sampling conducted under the order.

Means of Instituting Judicial Enforcement Proceedings

8-910.10 Institution of Proceedings.

(A) Proceedings to enforce this Code may be instituted by the REGULATORY AUTHORITY according to LAW by issuing a citation or summons, by filing a misdemeanor complaint affidavit and request for a warrant of arrest with the court of competent jurisdiction, or by referring the complaint to a grand jury for indictment, as appropriate.

(B) The REGULATORY AUTHORITY may designate a representative to issue summons or citations or sign warrants on behalf of the agency.

Criminal Proceedings

8-911.10 Authorities, Methods, Fines, and Sentences.

(A) The REGULATORY AUTHORITY may seek to enforce the provisions of this Code and its orders by instituting criminal proceedings as provided in LAW against the PERMIT HOLDER or other PERSONS who violate its provisions.

(B) A PERSON who violates a provision of this Code shall be guilty of a misdemeanor, punishable by:

(1) A fine of not more than (designate amount) dollars, or by imprisonment not exceeding 1 year, or both the fine and imprisonment; or

(2) If the PERSON has been convicted once of violating this Code or if there is an intent to defraud or mislead, a fine not exceeding (designate amount) or imprisonment not exceeding (designate time) year(s) or both.

(C) Each day on which a violation occurs is a separate violation under this section.

Injunctive Proceeding

8-912.10 Petitions for Injunction.

The REGULATORY AUTHORITY may, according to LAW, petition a court of competent jurisdiction for temporary or permanent injunctive relief to achieve compliance with the provisions of this Code or its orders.

Civil Proceedings

8-913.10 Petitions, Penalties, and Continuing Violations.

(A) The REGULATORY AUTHORITY may petition a court of competent jurisdiction to enforce the provisions of this Code or its administrative orders and according to LAW collect penalties and fees for violations.

(B) In addition to any criminal fines and sentences imposed as specified in § 8-911.10, or to being enjoined as specified in § 8-912.10, a PERSON who violates a provision of this Code, any rule or regulation adopted in accordance with LAW related to FOOD ESTABLISHMENTS within the scope of this Code, or to any term, condition, or limitation of a PERMIT issued as specified in §§ 8-303.10 and 8-303.20 is subject to a civil penalty not exceeding (designate amount).

(C) Each day on which a violation occurs is a separate violation under this section.

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Annex

2 References

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS
2. BIBLIOGRAPHY
3. SUPPORTING DOCUMENTS
4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS

The *Food Code* makes frequent reference to federal statutes contained in the United States Code (USC) and the *Code of Federal Regulations* (CFR). Copies of the USC and CFR can be viewed and copied at government depository libraries or may be purchased as follows.

(A) Viewing and Copying the USC or CFR

(1) Federal Depository Library

The USC and CFR are widely available for reference and viewing in some 1300 "depository libraries" located throughout the United States. *A Directory of U.S. Government Depository Libraries* is published by the Joint Committee on Printing of the United States Congress and is available through the Superintendent of Documents, U.S. Government Printing Office. This publication lists all depository libraries by state, city, and congressional district.

Persons may also obtain information about the location of the depository library nearest to them by contacting:

GPO Customer Contact Center, Mail Stop: IDCC
U.S. Government Printing Office
732 North Capitol Street, NW
Washington, DC 20401-0001
(866) 512-1800, Fax (202) 512-2104
Email: ContactCenter@gpo.gov

(2) Internet World Wide Web Information System

The CFRs are available on-line in downloadable form through the Internet World Wide Web information system. The source is:

The National Archives and Records Administration
Copies of Federal Regulations - Retrieve CFR by Citation
Provided through the Government Printing Office Web Site - GPO Inet Services

http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1

(B) Purchasing Portions of the USC or CFR

Persons wishing to purchase relevant portions of the USC or CFR may do so

by writing:	or by calling:
Superintendent of Documents (New Orders) U.S. Government Printing Office P.O. Box 371954 Pittsburgh, PA 15250-7954;	(202) 512-1800 from 8:00 a.m. to 5:30 p.m. eastern time, Monday-Friday (except Federal holidays. Orders may be charged to American Express, Discover, MasterCard, or Visa

Or by emailing: gpo@custhelp.com or at http://www.gpo.gov/customers/print.htm .

(C) USC as it Relates to the Code Definition of "Adulterated"

This language has been retyped as accurately as possible and inserted in the Food Code Annex for informational purposes. For legal purposes, use only language taken directly from the United States Code (USC).

21 USC Sec. 342
Title 21 - Food and Drugs
Chapter 9 - Federal Food, Drug and Cosmetic Act
Subchapter IV - Food

ADULTERATED FOOD

Sec. 402 [342]

A food shall be deemed to be adulterated -

(a) Poisonous, insanitary, etc., ingredients

A food shall be deemed to be adulterated -

(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.[1]

(2)

(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or

(B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a (a) of this title; or

(C) if it is or if it bears or contains

(i) any food additive that is unsafe within the meaning of section 348 of this title; or

(ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

(b) Absence, substitution, or addition of constituents

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) if any substance has been substituted wholly or in part therefor; or

(3) if damage or inferiority has been concealed in any manner; or

(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) Color additives

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e (a) of this title.

(d) Confectionery containing alcohol or nonnutritive substance

If it is confectionery, and—

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale;

(3) bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) Oleomargarine containing filthy, putrid, etc., matter

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(f) Dietary supplement or ingredient: safety

(1) If it is a dietary supplement or contains a dietary ingredient that—

(A) presents a significant or unreasonable risk of illness or injury under—

(i) conditions of use recommended or suggested in labeling, or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5 to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is

adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph [2] (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

(g) Dietary supplement: manufacturing practices

(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5.

(h) Reoffer of food previously denied admission

If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 381 (a) of this title, unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this chapter, as determined by the Secretary.

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[1] So in or". original. The period probably should be ";

[2] So in original. Probably should be "subparagraph".

(As amended by Congress, 2002 – Subsec. (h). Pub. L. 107-188 added subsec. (h).)

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2-301.16 Hand Antiseptics.

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3. Code of Federal Regulations, Title 21, Part 182 Substances Generally Recognized as Safe.

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2-303.11 Prohibition. (Jewelry)
2-304.11 Clean Condition. (Outer Clothing)
2-401.11 Eating, Drinking, or Using Tobacco.
2-402.11 Effectiveness. (Hair Restraints)

1. Code of Federal Regulations, Title 21, Sections 110.10 Personnel. (b) (1) "Wearing outer garments suitable to the operation ...." (4) "Removing all unsecured jewelry ...." (6) "Wearing, where appropriate, in an effective manner, hair nets, head bands, caps, beard covers, or other effective hair restraints." (8) "Confining...eating food, chewing gum, drinking beverages or using tobacco...." and (9) "Taking other necessary precautions ...."

2-403.11 Handling Prohibition. (Animals)

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Chapter 3 Food

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3-201.17 Game Animals.

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Chapter 5 Water, Plumbing, and Waste

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2. FDA, Guide to Minimize Microbial Food Safety Hazards for Fresh-cut Fruits and Vegetables, posted 10/26/98, updated 08/19/03, 02/2008. Available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm

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7-204.11 Sanitizers, Criteria.

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2. Code of Federal Regulations, Title 40 Part 180.2020 Pesticide Chemicals Not Requiring a Tolerance or an Exemption From Tolerance-Non-Food determinations found at: http://edocket.access.gpo.gov/cfr_2010/julqtr/pdf/40cfr180.2020.pdf

3. Code of Federal Regulations, Title 29 Part 1910.1000 Occupational Safety and Health Standards found at:
http://edocket.access.gpo.gov/cfr_2010/julqtr/pdf/29cfr1910.1000.pdf

7-204.12 Chemicals for Washing Fruits and Vegetables, Criteria.

1. Code of Federal Regulations, Title 21, Part 173.315, Chemicals used in washing or to assist in the peeling of fruits and vegetables.

2. Code of Federal Regulations, Title 21, Part 173.405, Secondary Direct Food Additives Permitted in Food for Human Consumption; Sodium Dodecylbenzenesulfonate.

7-204.13 Boiler Water Additives, Criteria.

1. Code of Federal Regulations, Title 21, Part 173.310, Boiler water additives.

7-204.14 Drying Agents, Criteria.

1. Code of Federal Regulations, Title 21, Part 184, Direct Food Substances Affirmed as Generally Recognized as Safe.

2. Code of Federal Regulations, Title 21, Parts 175, Indirect Food Additives: Adhesives and Components of Coatings.

3. Code of Federal Regulations, Title 21, Parts 178, Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers.

4. Code of Federal Regulations, Title 21, Parts 176, Indirect Food Additives: Paper and Paperboard Components.

5. Code of Federal Regulations, Title 21, Parts 177, Indirect Food Additives: Polymers.

6. Code of Federal Regulations, Title 21, Part 186, Indirect Food Substances Affirmed as Generally Recognized as Safe.

7. Code of Federal Regulations, Title 21, Part 181, Prior-Sanctioned Food Ingredients.

8. Code of Federal Regulations, Title 21, Part 182, Substances Generally Recognized as Safe.

9. Code of Federal Regulations, Title 21, Part 170.39, Threshold of regulation for substances used in food-contact articles.

10. Code of Federal Regulations, Title 21, Part 170.30, Eligibility for classification as generally recognized as safe (GRAS)

11. Code of Federal Regulations, Title 21, Part 174, Indirect Food Additives: General.

12. Federal Food Drug and Cosmetic Act, Section, 409 (h), http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm

13. Federal Food Drug and Cosmetic Act, Section 201(s)(4)
http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm

14. Food Contact Notification, Ingredients and Packaging,
http://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm

7-205.11 Incidental Food Contact, Criteria.

1. Code of Federal Regulations, Title 21, Part 178.3570, Lubricants with incidental food contact.

7-206.11 Restricted use Pesticides, Criteria.

1. Code of Federal Regulations, Title 40, Part 152 Subpart I, Classification of Pesticides.

3. SUPPORTING DOCUMENTS

FDA is providing the following guidance documents for reference. A brief summary for each document is provided.

A. Voluntary National Retail Food Regulatory Program Standards
B. FDA Procedures for Standardization and Certification of Retail food Inspection/Training Officers
C. Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments
D. Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems
E. Food Establishment Plan Review Guide
F. FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)
G. Growing Sprouts in a Retail Food Establishment
H. Advisories for Retail Processing with Proper Controls and Variances for Product Safety
I. Evaluation and Definition of Potentially Hazardous Foods
J. The U.S. Equal Employment Opportunity Commission (EEOC) Guide, "How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers" October 28, 2004
K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information

L. Recommended Guidelines for Permanent Outdoor Cooking Establishments, 2003
M. Comprehensive Guidelines for Food Recovery Programs
N. Retail Food Protection Program Information Manual: Storage and Handling of Tomatoes, 2007.
O. Retail Food Protection Program Information Manual: Recommendations to Food Establishments for Serving or Selling Cut Leafy Greens
P. Employee Health and Personal Hygiene Handbook
Q. Risk Assessment Process and Spreadsheet to Redesignate Food Code Provisions
R. Parameters for Determining Inoculated Pack/Challenge Study Protocols
S. The Council to Improve Foodborne Outbreak Response (CIFOR) – Guidelines for Foodborne Outbreak Response
T. CIFOR Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments (CIFOR Industry Guidelines)

A. Voluntary National Retail Food Regulatory Program Standards

This document can be accessed at the following web site:

http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm and was formulated from ideas and input by Federal, State, and local regulatory officials, industry, trade and professional associations, academia, and consumers. The purposes of these standards are:

- To serve as a bench mark to retail food regulatory program managers in the design and management of a retail food program;
- To provide a means of recognition of programs meeting these standards;
- To promote uniformity in retail food programs to reduce the risk factors known to cause foodborne illness;
- To provide a foundation for the food regulatory program that is focused on the risk factors and other factors that may contribute to foodborne illness; and
- To promote, through the management of a retail food regulatory program, the active managerial control in the retail establishment of all the factors that may cause foodborne illness.

Further purposes of these standards are to serve as a guide to regulatory retail food program managers in the design and management of a retail food program and to provide a means of recognition for those programs that meet these standards.

The intent in the development of these standards is to establish a basic foundation in design and management of a retail food program. Program management may add additional requirements to meet individual program needs.

The standards apply to the operation and management of a regulatory retail food program focused on the reduction of risk factors known to cause foodborne illness as well as other factors that may contribute to foodborne illness and on the promotion of active managerial control of all factors that may cause foodborne illness.

B. FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officers

This document can be found by accessing the following web site: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/InspectionsQualityAssurance/ucm2006814.htm. This is a procedure that integrates the assessment of an individual's knowledge, skills, and abilities in a manageable number of inspections while preserving the quality and integrity of the process. At the same time, we continue to learn from our experiences in applying it and remain open to improving these Procedures based on your experiences and feedback.

As they are written, the Procedures address the situation wherein an FDA Standard is assessing a CANDIDATE who is not employed by FDA. For example, Paragraph 3-301(C) mentions but does not require recording citations (i.e., identifying the codified provision that relates to each observed violation). Since jurisdiction's codification systems (numeric or alphanumeric) are usually different from the system in the FDA Food Code, the utility of that practice would be minimal in an FDA-to-jurisdiction field exercise. However, within a jurisdiction where the same Code is in use, the practice could be useful in reinforcing diligence in ensuring that violations listed during inspections are, in fact, soundly based in regulation.

FDA invites and encourages jurisdictions to use these Procedures in their internal Standardization and Certifications and to add dimensions that promote uniformity such as citing codified provisions, as discussed above. With a few language changes, the document can be custom-tailored to fit individual jurisdictions and serve as their procedures. As with other documents provided as guidance for applying regulatory requirements in the retail sector, these Procedures are in the "public domain" and we encourage their duplication and use.

C. Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments

The Operator's Manual can be found by accessing the following web site: http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006811.htm. FDA has issued guidance to industry in voluntarily applying HACCP principles in food establishments. It recognizes that there are differences between using HACCP at retail and in food manufacturing. By incorporating the seven principles of HACCP, a good set of Standard Operating Procedures, and using a process approach, this Guide sets up a framework for the retail food industry to develop and implement a sound food safety management system.
This document is intended to serve as a guide in the writing of a simple plan based on HACCP principles that can be used to manage food safety. It is very important to understand that this Guide is intended to assist industry's voluntary implementation of HACCP principles. It is not meant to stand alone, but instead should be used together with advice from and in consultation with your Federal, State, local, or tribal food safety regulatory authority. The regulatory authority is an important resource for reviewing your food safety management system. Regulatory food safety professionals can provide important information for the public health rationale for controlling a particular hazard. Users of this document also need to consult and use the latest edition of the FDA Food Code since many of its requirements are not reproduced here but constitute a fundamental program that is prerequisite to implementing a HACCP program.

Hazard Analysis Critical Control Point (HACCP) is a common sense technique to control food safety hazards. It is a preventive system of hazard control rather than a reactive one. Food establishments can use it to ensure safer food products for consumers. It is not a zero risk system, but is designed to minimize the risk of food safety hazards. HACCP is not a stand alone program but is one part of a larger system of control procedures that must be in place in order for HACCP to function effectively. These control procedures are prerequisite programs and are discussed more in Annex 4.

The success of a HACCP program is dependent upon both people and facilities. Management and employees must be properly motivated and trained if a HACCP program is to successfully reduce the risk of foodborne illness. Education and training in the principles of food safety and management commitment to the implementation of a HACCP system are critical and must be continuously reinforced. Instilling food worker commitment and dealing with problems such as high employee turnover and communication barriers must be considered when designing a HACCP plan.

Successful implementation of a HACCP plan is also dependent upon the design and performance of facilities and equipment. The likelihood of the occurrence of a hazard in a finished product is definitely influenced by facility and equipment design, construction, and installation that play a key role in any preventive strategy.

The Agency recognizes that this document has areas that need to be further clarified and developed with broader input and based on industry's experiences with the practicalities of integrating the HACCP approach in their operations. This Guide will continue to evolve and improve.

D. Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems

The Regulator's Manual can be found by accessing the following website: http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006812.htm. This document provides State, local, and tribal regulatory authorities with a step-by-step scheme for conducting risk-based inspections based on HACCP principles to assist them with identifying and assessing control of foodborne illness risk factors. In addition, the manual details intervention strategies that can be developed with retail and food service operators to reduce the occurrence of foodborne illness risk factors. It also provides recommendations for evaluating voluntarily-implemented food safety management systems if invited to do so by industry.

The utilization of voluntary food safety management systems by industry and the incorporation of risk-based methodology into regulatory inspection programs are important elements in reaching the goals established by the Healthy People 2010 health improvement strategy and FDA retail program goals.

In 2004, the Conference for Food Protection (CFP) endorsed both documents with a recommendation that both industry and regulatory entities consider implementing the principles of the documents into their respective food safety programs. The CFP is composed of regulators, industry, academia, professional organizations, and consumers whose purpose is to identify problems, formulate recommendations, and develop and implement practices that relate to food safety.

A Federal Register notice announcing the availability of these documents was published July 21, 2005 (Docket No. 2005D-0274).

E. Food Establishment Plan Review Guide

This document can be found at: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm101639.htm. This Food Establishment Plan Review document has been developed for the purpose of assisting both regulatory and industry personnel in achieving greater uniformity in the plan review process. It is the result of a joint effort by FDA and the Conference for Food Protection.

Plan review of food service establishments, retail food stores, and all other food operations, must be maintained as a high priority by all regulatory food agencies for both new and existing facilities.

This document has been developed to serve as a guide in facilitating greater uniformity and ease in conducting plan review whether your position is a regulator or an industry person wishing to build or to expand. You need not be an expert to effectively complete this process.

A good review of plans helps to avoid future problems. By listing and locating equipment on floor plans and diagramming specifications for electrical, mechanical and plumbing systems, potential problems can be spotted while still on paper and modifications made BEFORE costly purchases, installation and construction.

Food establishment plan review is recognized as an important food program component that allows:

-- Regulatory agencies to ensure that food establishments are built or renovated according to current regulations or rules.
-- Industry to establish an organized and efficient flow of food.
-- Regulatory agencies to eliminate code violations prior to construction.

F. FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)

In 1998, FDA initiated a project designed to determine the incidence of foodborne illness risk factors in retail and food service establishments. Inspections focusing on the occurrence of foodborne illness risk factors were conducted in establishments throughout the United States. The results of this project are published in the 2000 *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors*, commonly referred to as the "FDA Baseline Report." The Baseline Report is available from FDA through the following website: http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf. The data collection project was repeated in 2003 and the results are published in the *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional*

Foodservice, Restaurant, and Retail Food Store Facility Types (2004). This second report is available from FDA through the following website: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm089696.htm. An additional data collection project is planned for 2008.

G. Growing Sprouts in a Retail Food Establishment

This document, Growing Sprouts in a Retail Food Establishment, can be found at the web site http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ucm078758.htm . There were 25 reported outbreaks associated with raw and lightly cooked seed sprouts in the United States between January 1996 and December 2003. No single treatment so far has been shown to completely eliminate pathogens on seeds or sprouts without affecting germination or yield; therefore a combination of factors is used to eliminate and control potential pathogens and assure a safe, ready-to-eat food product. Seeds or beans grown using Good Agricultural Practices (GAPs) and conditioned, transported, and stored according to GMPs reduce the potential for seed to serve as a source of contamination. Retail Sprouting Industry Best Practices help ensure that no further contamination occurs and precautionary measures are taken to prevent high levels of bacteria from growing on the seeds or sprouts. Seeds for sprouting or sprouts should receive a chemical disinfection treatment that has been approved by EPA for reduction of pathogens. Other treatments such as irradiation of seeds [21 CFR 179.26(b)(10)] have been approved. Because no treatments are known to completely eliminate pathogens without adversely affecting germination or yield, microbial testing of spent irrigation water from the sprouting process is also necessary to verify that no pathogens are present. Raw sprouts are considered time/temperature control for safety food (TCS) and therefore, require refrigeration.

H. Advisories for Retail Processing with Proper Controls and Variances for Product Safety

These documents are available for purchase at minimum cost from the Association of Food and Drug Officials (AFDO) at the website http://www.afdo.org/. These guides were funded by USDA through the University of Florida in cooperation with Florida A&M University and the Association of Food and Drug Officials and developed by experts from academic, regulatory, and industry areas. Nine guides help retailers and regulatory personnel understand the food safety controls to implement in retail food and food service operations in order to process and sell safe food products. They can also be used as a reference in applying for or reviewing a variance and HACCP Plan, where required, for retail processing of beef jerky, cured and hot smoked sausage, cured and smoked ham, fermented and dried sausage, fresh-cut produce, fresh juice, reduced oxygen packaging (ROP), smoked seafood, and sushi.

Each guide provides a definition of terms, a flow diagram, and a detailed check list for operations including receiving, food storage, preparation, and display. Information in the Appendices helps identify specific food safety hazards associated with that product, necessary equipment calibrations, product labeling, recommended record keeping with sample log sheets, and a daily SOP check list. Authoritative sources are also referenced such as FDA's "Fish and Fisheries Products Hazards & Controls Guidance" and 21 CFR 101 for labeling requirements.

These guides are not intended to replace or duplicate existing regulations within the jurisdictions of the regulatory authority or food establishment but they offer information and references for more uniform practices.

I. Evaluation and Definition of Potentially Hazardous Foods

This document can be found at the web site http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm094141.htm . The Institute of Food Technologists (IFT) prepared and submitted this report as part of a contract with FDA. It contains responses to various questions posed by FDA about time/temperature control for safety food (TCS food). The IFT reviewed the evolution of the term TCS and recommended a change to time/temperature control for safety (TCS) food as well as a science-based framework for determining the effectiveness of processing technologies that formulate a food so that it is non-TCS.

The IFT Science and Technology Expert Panel reviewed the two protocols used by NSF International and the American Baking Association for determining if a food is a TCS and proposed an alternate approach. The report examines intrinsic factors such as a_w, pH, redox potential, natural and added antimicrobials and competitive microorganisms, and extrinsic factors such as packaging, atmospheres, storage conditions, processing steps, and new preservation technologies that influence microbial growth. The report also analyzes microbial hazards related to time/temperature control of foods for safety.

The IFT developed a framework that could be used to determine whether a food is a TCS food or not. Part of the framework includes two tables that consider the interaction of pH and a_w in a food, whether the food is raw or heat-treated, and whether it is packaged. When further product assessment is required, the application of microbiological challenge testing (inoculation studies) is discussed along with pathogen modeling programs and reformulation of the food. An extensive reference list is included in the report.

J. The U.S. Equal Employment Opportunity Commission (EEOC) Guide, "How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers" October 28, 2004

The guide is designed to assist restaurants and other food service employers in complying with the employment provisions of the Americans with Disabilities Act (ADA). The EEOC worked extensively with the Food and Drug Administration in developing this new publication.

Available online at http://www.eeoc.gov/facts/restaurant_guide.html, http://www.eeoc.gov/facts/restaurant_guide_summary.html, and www.fda.gov, the guide covers such topics as how the FDA Food Code provisions about restricting and excluding sick employees interact with the ADA's requirements; types of reasonable accommodations, including the use of service animals; and what an employer should do if a charge of discrimination is filed against the employer's business.

Title I of the ADA, which prohibits employment discrimination against people with disabilities in the private sector and State and local governments, and the Rehabilitation Act's prohibitions against disability discrimination in the federal government. The EEOC enforces Title VII of the Civil Rights Act of 1964, which prohibits employment discrimination based on race, color, religion, sex, and national origin; the Age Discrimination in Employment Act, which prohibits discrimination against individuals 40 years of age or older; the Equal Pay Act; and sections of the Civil Rights Act of 1991.

K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information

This document may be found at the web site for "Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7" at http://www.fsis.usda.gov/wps/wcm/connect/f5001b3d-defa-4db8-a510-881ca90415ff/ecolio157h7dirguid4-13-04.pdf?MOD=AJPERES. On October 7, 2002, USDA/FSIS published a Federal Register Notice (67 FR 62332) entitled, *E. coli* O157:H7 Contamination of Beef Products, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf, in which the Agency discussed its views on the application of the Hazard Analysis and Critical Control Point (HACCP) system regulations with respect to *Escherichia coli (E. coli)* O157:H7 contamination.

USDA/FSIS announced in 2002 that there is sufficient new scientific data on the increased prevalence of *E. coli* O157:H7 in live cattle coming to slaughter and on its impact on public health to require that all establishments producing raw beef products reassess their HACCP plans, in light of these data.

Of particular concern to the USDA/FSIS is its ability to quickly and adequately traceback contaminated product that is in commerce to its source and to remove it from commerce. In the Spring of 2004, FSIS began conducting sampling and microbiological verification testing for *E. coli* O157:H7 in raw ground beef products at federally inspected establishments, retail facilities as well as at import facilities. Some of the products most likely to be sampled and tested at retail facilities are:

- Ground beef products produced from retail steaks and roasts.
- Manufacturing trimmings derived at retail.
- Ground beef that is formulated at retail by co-mingling in-store trim and trim from federally inspected establishments.
- Irradiated ground beef co-mingled with non-irradiated meat or poultry.

Additionally, ground beef products have been implicated as a transmission vehicle in foodborne outbreaks of infections with pathogens such as *Escherichia coli* O157:H7 and Salmonella. To facilitate product traceback and to meet regulatory requirements, USDA/FSIS expects retail facilities as well as federally inspected establishments to maintain and provide FSIS with access to all applicable records associated with the source material used for ground beef products. In cases where USDA/FSIS identifies adulterated ground beef, and a product recall is necessary, grinding logs will facilitate identifying the source of the product and narrowing the scope of the recall.

FSIS recently published "Sanitation Guidance for Beef Grinders" which contains an example of a fresh ground beef production log. The guidance is located at the following website: http://www.fsis.usda.gov/shared/PDF/Sanitation_Guidance_Beef_Grinders.pdf.

The following information would be used to facilitate traceback of contaminated ground beef products:

- The manufacturer name of source material used for product produced.
- The type of product or description of the purchased or received article(s).
- The establishment information from the label of source product used such as the name, address, and establishment number
- The supplier lot numbers, product code or production or pack date of source materials used.
- Any other information that would be useful in the quick removal of adulterated product from the market or commerce such as time of grind, grinder sanitation records and amount (in pounds) and lot/batch numbers, production codes, name and package size of the products produced.

In addition to the references cited above, the following references also provide information:

1. Federal Meat Inspection Act (21 USC Sec. 642).
2. Title 9 of the Code of Federal Regulations, section 320.1 Records required to be kept.
3. Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products.
4. Best Practices for Raw Ground Products.
5. FSIS Sanitation Performance Standards Compliance Guide.
6. U.S. Department of Agriculture, Food Safety and Inspection Service, April 13, 2004, Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 (http://www.fsis.usda.gov/wps/wcm/connect/f5001b3d-defa-4db8-a510-881ca90415ff/ecolio157h7dirguid4-13-04.pdf?MOD=AJPERES)

L. Recommended Guidelines for Permanent Outdoor Cooking Establishments, 2003

This document can be found at http://www.foodprotect.org/guides/ . Permanent Outdoor Cooking Establishments (POCE) include a wide range of facilities from barbecue pits at beach resorts to campfire meals at dude ranches, pig roasts and clam bakes, and multi-menu food service sites in amusement and theme parks. It is essential that the equipment and physical facility requirements be based upon a menu review of the items to be prepared, cooked, held, and served. Many of these POCEs are high risk operations engaging in extensive preparation of raw ingredients: processes that include the cooking, hot and cold holding, and reheating of time/temperature control for safety foods. These guidelines provide the basis on which regulatory authorities can evaluate and permit permanent outdoor cooking establishments.

M. Comprehensive Guidelines for Food Recovery Programs

Food recovery programs collect foods from commercial production and distribution channels and redistribute them to people in need. There are food recovery efforts carried out by public, private, and nonprofit organizations across the country. The primary goal of food recovery programs is to collect safe and wholesome food donated from commercial sources to meet the nutritional needs of the hungry.

With bipartisan support, Congress passed the Bill Emerson Good Samaritan Food Donation Act in 1996. The Act is designed to encourage the donation of food and grocery products to nonprofit organizations such as homeless shelters, soup kitchens, and churches for distribution to hungry individuals. The Bill Emerson Good Samaritan Food Donation Act promotes food recovery by limiting the liability of donors to instances of gross negligence or intentional misconduct.

The *Guidelines* are intended to provide guidance to those who want to participate in food recovery programs as donors and receiving operations as well as to those who oversee standards compliance as regulators or peer inspectors.

The *Guidelines* also give advice on implementing a food recovery program, various ways to contribute to food recovery programs, choosing suitable partners, and laying the foundation for a successful program. This includes food safety provisions in alignment with the FDA Food Code, guidelines for monitoring food recovery programs, and handling of donations of game animals. For simple recordkeeping, the *Guidelines* contain sample forms designed to facilitate the management of a variety of aspects of food recovery programs.

For in-depth information, see the *Comprehensive Guidelines for Food Recovery Programs* available via the Conference for Food Protection web page at http://www.foodprotect.org/guides/

N. Retail Food Protection Program Information Manual: Storage and Handling of Tomatoes, 2007.

This document can be found at the web site:

http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm

The Retail Food Protection Program Information Manual, Storage and Handling of Tomatoes provides safe storage and handling practices for cut tomatoes and additional rationale for including cut tomatoes in the definition of time/temperature control for safety food in the 2005 Food Code. Historically, uncooked fruits and vegetables have been considered non-TCS food unless they were epidemiologically implicated in foodborne illness outbreaks and are capable of supporting the growth of pathogenic bacteria in the absence of temperature control. Since 1990, at least 12 multi-state foodborne illness outbreaks have been associated with different varieties of tomatoes. From 1998 – 2006, outbreaks associated with tomatoes made up 17% of the produce-related outbreaks reported to FDA. *Salmonella* has been the pathogen of concern most often associated with tomato outbreaks. Recommendations are being offered to prevent contamination in food service facilities and retail food stores and to reduce the growth of pathogenic bacteria when contamination of fresh tomatoes may have already occurred (regardless of the location where the contamination occurred).

O. Retail Food Protection Program Information Manual: Recommendations to Food Establishments for Serving or Selling Cut Leafy Greens.

This document can be found at:
http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm.

Following 24 multi-state outbreaks between 1998 and 2008, cut leafy greens was added to the definition of time/temperature for safety food requiring time-temperature control for safety (TCS). The term used in the definition includes a variety of cut lettuces and leafy greens. Raw agricultural commodities (RACs) that are not processed or cut on-site are excluded from the definition of cut leafy greens. Herbs such as cilantro or parsley are also not considered cut leafy greens. The pH, water activity, available moisture and nutrients of cut leafy greens supports the growth of foodborne pathogens and refrigeration at 41ºF (5ºC) or less inhibits growth and promotes general die off in some pathogens such as *E. coli* O157:H7. *Salmonella, E. coli* O157:H7 and *Listeria monocytogenes*, once attached to the surface or internalized into cut surfaces of leafy greens, are only marginally affected by chemical sanitizers. Recommended handling instructions for leafy greens during purchasing and receiving, storage, food employee handling fresh produce, washing fresh produce, preparation for sale or service and display for sale or service are attached to the document.

P. Employee Health and Personal Hygiene Handbook

This document can be found at:

http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113827.htm.

The Employee Health and Personal Hygiene Handbook was developed to encourage practices and behaviors that can help prevent food employees from spreading foodborne pathogens to food. Information is provided in a question-and-answer format and includes easy references to forms and tables that food service and retail food establishments and the public health community may find useful when training staff and addressing employee health and hygiene matters. This handbook highlights a combination of three interventions that can be effective in prevention of the transmission of foodborne viruses and bacteria in food establishments. These interventions include: (a) restricting or excluding ill food employees from working with food; (b) using proper handwashing procedures; and (c) eliminating bare hand contact with foods that are ready-to-eat (RTE). Concurrent use of each intervention will help prevent the transmission of viruses, bacteria and protozoan oocysts from food employees to consumers through contaminated food. **Note that the recommendations provided are not to be construed as medical advice or directions to diagnose a medical condition.**

The person in charge and the food employee always have the option to seek professional medical attention as warranted by the situation at hand.

Q. Risk Assessment Process and Spreadsheet to Redesignate Food Code Provisions

These documents can be found at:
http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/default.htm.

FDA developed a set of definitions and a qualitative risk assessment process to redesignate the Food Code provisions and work with the CFP Critical Items Committee of stakeholders for feedback. It changed "critical" and "non-critical" to risk designations which include "priority item," " priority foundation item" and "core item" to link the provision to hazards associated with foodborne illness or injury. The method used is described in "**Risk Assessment Process to Redesignate Food Code Provisions**" and the decision-making process recorded in the Excel spreadsheet for transparency. The risk assessment decision-making process explained in the instructions provides a science-based rationale for each redesignation. It is internally consistent and consistent with peer-reviewed publications.

The process considered the general and specific hazards that each provision is intended to address. An initial risk designation was made based on the definitions for "priority item," " priority foundation item", and "core item", to show how directly the provision eliminated, prevented or reduced to an acceptable level, the hazards associated with foodborne illness or injury. To further refine the designation, the virulence or severity of the hazard in the absence of control by this Code provision was also examined. Contributing factors (contamination factors, proliferating/amplification factors, survival factors and method of preparation) identified for foodborne outbreaks reported to the Centers for Disease Control and Prevention were also considered. The risk designation was then re-evaluated in terms of meeting the definition, characteristics of the potential hazards, size and/or number of outbreaks caused by the hazard in conjunction with non-application of this Code provision and the contributing factors. The final determination was based on the term which most closely defined that provision, taking into account any weighting due to severity and infectivity of the hazard. Additional comments and references to explain or support this determination were included on the spreadsheet.

R. Parameters for Determining Inoculated Pack/Challenge Study Protocols

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), in response to questions posed by FDA, developed guidelines for conducting challenge studies on pathogen inhibition and inactivation studies in a variety of foods. The guidelines are available at:

http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/!ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOINAg3MDC2dDbz8LQ3dDDz9wgL9vZ2dDdz9TfQLsh0VAfb5Y5I!/?1dmy&current=true&urile=wcm%3Apath%3A%2Ffsis-content%2Finternet%2Fmain%2Ftopics%2Fdata-collection-and-reports%2Fnacmcf%2Fcurrent-subcommittees%2Fparameters-for-inoculated-pack-challenge-study-protocols%2Fct_index9

The document is intended for use by the food industry, including food processors, food service operators and food retailers; federal, state and local food safety regulators; public health officials; food testing laboratories; and process authorities. The document is focused on, and limited to, bacterial inactivation and growth inhibition and does not make specific recommendations with respect to public health. NACMCF concluded that challenge studies should be designed considering the most current advances in methodologies, current thinking on pathogens of concern, and an understanding of the product preparation, variability and storage conditions. Studies should be completed and evaluated under the guidance of an expert microbiologist in a qualified laboratory and should include appropriate statistical design and data analyses.

This document provides guidelines for choice of microorganisms for studies, inoculum preparation, inoculum level, methods of inoculation, incubation temperatures and times, sampling considerations, and interpreting test results. Examples of appropriately designed growth inhibition and inactivation studies are provided. The NACMCF report, through tables and appendices, also provides sources of accepted laboratory methods, considerations for selecting a laboratory, pathogens of concern with control methods for food product categories, relevant Food Code definitions and food product checklists that test the protocol. It also includes recommended minimum expertise for designing, conducting and evaluating microbiological studies; potential pathogens of concern for growth studies based on pH and a_w; examples of mathematical growth and inactivation models and their application to different foods; pathogen growth ranges used in CommBase and Pathogen Modeling Program models; and limits for growth when other conditions are near optimum.

S. The Council to Improve Foodborne Outbreak Response (CIFOR) – Guidelines for Foodborne Outbreak Response

This document can be found at: http://www.cifor.us/CIFORGuidelinesProjectMore.cfm

The Guidelines for Foodborne Outbreak Response describe the overall approach to foodborne disease outbreaks, including preparation, detection, investigation, control and follow-up. The Guidelines also describe the roles of all key organizations in foodborne disease outbreaks. The Guidelines are targeted at local, state and federal agencies that are responsible for preventing and managing foodborne disease.

T. CIFOR Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments (CIFOR Industry Guidelines)

In 2009, the Council to Improve Foodborne Outbreak Response (CIFOR) convened a workgroup comprised of representatives from the food industry and local, state and Federal government for the purpose of creating guidelines and tools specific for industry response to foodborne illness. The resulting document, called the CIFOR *Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments (CIFOR Industry Guidelines),* was developed as *voluntary* guidance for managers of Food Establishments ("Industry") to help outline, clarify, and explain Industry's recommended role in a foodborne illness outbreak investigation. These CIFOR Industry Guidelines:

- Provide a step-by-step approach including Preparation, Illness Complaints, Investigation, Control, and Follow-up
- Describe what to expect when first notified of potential illnesses or outbreak
- Provide Tools to guide Industry through the regulatory investigation process.

This document is available for download at: http://www.cifor.us/index.cfm

4. FOOD DEFENSE GUIDANCE FROM FARM TO TABLE

The following is a summary of available resources on food defense that is of interest to the retail and food service food community. This listing is provided below and is not all-inclusive. It contains links to publications from federal regulatory agencies (primarily FDA, CDC, and USDA) and industry groups with information of interest to regulators, industry, and consumers. Responsibility for updating the web pages lies with the listed organization and those listed are up-to-date as of the printing of the 2005 Food Code.

FDA Publications:

These guidance documents identify the kinds of preventive measures that food establishment and food processing operators may take to minimize risks to food under their control, from tampering or other malicious, criminal, or terrorist actions:

- **Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance** at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm082751.htm

- **Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance** at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083075.htm

- **Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors Food Security Preventive Measures Guidance** at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083049.htm.

- **Importers and Filers: Food Security Preventive Measures Guidance** at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm078978.htm.

- The **Bioterrorism Act of 2002** at: http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm.

USDA Publications:

- **Food Safety and Inspection Service (FSIS) Security Guidelines for Food Processors** at http://www.fsis.usda.gov/wps/portal/searchhelp/sitemap/!ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOINAg3MDC2dDbz8LQ3dDDz9wgL9vZ2dDdx9jfQLsh0VAcILpdM!/?1dmy&current=true&urile=wcm%3Apath%3A%2Ffsis-content%2Finternet%2Fmain%2Ftopics%2Ffood-defense-and-emergency-response%2Fpreparation-and-prevention%2Fguidance-documents%2Fguidance-documents

- **FSIS Guidelines "Keep America's Food Safe"** at http://www.fsis.usda.gov/wps/portal/frame-redirect?url=/wps/wcm/connect/FSIS-Content/fsis-questionable-content/security-guidelines/keep-americas-food-safe/CT_Index.

  This guidance is designed to assist transporters, warehouses, distributors, retailers, and restaurants with enhancing their security programs to further protect the food supply from contamination due to criminal or terrorist acts.

- **FSIS Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products** at: http://www.fsis.usda.gov/wps/portal/fsis/topics/food-defense-and-emergency-response/preparation-and-prevention/guidance-documents/guidance-documents.

This guidance contains recommendations to ensure the security of food products through all phases of the distribution process.

Additional information on FSIS food security guidance publications is available over the Internet at http://www.fsis.usda.gov.

Industry Publications:

- **National Restaurant Association**. Information for restaurants can be found on the National Restaurant Association's web page at http://www.restaurant.org.

- **Food Marketing Institute** (FMI) Security Information and Resources web page at http://www.fmi.org/foodsafety/ provides access to security information and guidelines targeted specifically to food retailers.

Guidance on Responding to Food Emergencies:

- Centers for Disease Control and Prevention (CDC) Emergency Preparedness and Response information can be found at http://www.bt.cdc.gov/.

- USDA – Food and Nutrition Service food emergency publication, **Responding to a Food Recall** at http://fsrio.nal.usda.gov/emergency-preparedness-and-management/response/foodservice-and-retail.

  FDA's Office of Emergency Operations at 301-443-1240 for FDA regulated products and FSIS Technical Service Center at 1-800-233-3935 for USDA regulated products.

Food Defense and Emergency Guidance of Interest to Schools:

- **A Biosecurity Checklist for School Foodservice: Developing a Biosecurity Management Plan**

  The document is from the USDA – Food and Nutrition Service and provides information for school food service managers. It can be found at http://fsrio.nal.usda.gov/emergency-preparedness-and-management/prevention-and-preparation/foodservice-and-retail. The exact link to the checklist is http://healthymeals.nal.usda.gov/hsmrs/biosecurity.pdf . Currently the checklist is only available in an electronic format.

- USDA – Food and Nutrition Service food emergency publication, **Emergency Readiness Plan: A Guide for the School Foodservice Operation** at: http://fsrio.nal.usda.gov/emergency-preparedness-and-management/prevention-and-preparation/foodservice-and-retail

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Defense Guidance of Interest to Consumers:

- **Food Safety and Security: What Consumers Need to Know**, at http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/emergency-preparedness/food-safety-and-security-what-consumers-need-to-know .

- **Food Tampering: An Extra Ounce of Caution**, at http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079137.htm

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Annex

3 Public Health Reasons/ Administrative Guidelines

Chapter 1 Purpose and Definitions

Applicability and Terms Defined **1-201.10** **Statement of Application and Listing of Terms.**

(B) ***Terms Defined***

The individual definitions in Chapter 1 are not numbered, consistent with current conventions regarding the use of plain language in drafting rules, and with use in national and international standards and some Federal regulations. This facilitates making changes to the definitions as they become necessary in subsequent editions of the Food Code. The intent of the definitions to be binding in terms of the application and interpretation of the Code is clearly stated in Chapter 1.

Accredited Program.

Refer to the definition for Accredited Program in ¶1-201.10 (B)(3).

Food protection manager *certification* occurs when *individuals* demonstrate through a certification program that they have met specified food safety knowledge standards.

Food protection certification program *accreditation* occurs when *certification organizations* demonstrate through an accreditation program that they have met specified program standards.

Accreditation is a conformity assessment process through which organizations that certify individuals may voluntarily seek independent evaluation and listing by an

accrediting agency based upon the certifying organization=s meeting program accreditation standards. Such accreditation standards typically relate to such factors as the certifying organization's structure, mission, policies, procedures, and the defensibility of its examination processes. These standards are intended to affirm or enhance the quality and credibility of the certification process, minimize the potential for conflicts of interest, ensure fairness to candidates for certification and others, and thereby increase public health protection.

Program accreditation standards known to be relevant to food protection manager certification programs include those contained in the *Standards for Accreditation of Food Protection Manager Certification Programs* available from the Conference for Food Protection, 2792 Miramar Lane, Lincoln, CA 95648 and found at http://www.foodprotect.org/

Allowing food protection managers to demonstrate their required food safety knowledge "through passing a test that is part of an accredited program" is predicated on the fact that their credentials have been issued by certifying organizations that have demonstrated conformance with rigorous and nationally recognized program standards.

Egg.

The definition of egg includes avian species' shell eggs known to be commercially marketed in the United States. Also included are the eggs of quail and ratites such as ostrich.

Not included are baluts. Baluts are considered a delicacy among Philippine and Vietnamese populations. They are derived from fertile eggs, typically duck eggs, subjected to incubation temperatures for a period of time less than necessary for the embryo to hatch resulting in a partially formed embryo within the shell. Under the Egg Products Inspection Act (EPIA), an egg is typically considered adulterated if it has been subjected to incubation. However, in 9 CFR 590.5, baluts are specifically exempted from inspection as eggs under the EPIA.

In producing baluts, fertile duck eggs are incubated for approximately 18 days at a temperature of 42.5°C (108.5°F) in incubators with a relatively high humidity. (Complete development and hatching would take place in 28 days.) Under these conditions, the potential for growth of transovarian *Salmonella* organisms such as *S.* Enteritidis within the shell, and the potential for an increase in pathogenic microflora on the shell itself, are increased. Where chicken eggs are used in preparing baluts, the incubation period may only be 14 days at an incubation temperature of 37°C (99°F). A balut is a time/temperature control for safety food subject to time/temperature management including proper cooking and hot and cold holding. Baluts are typically boiled and packed in salt before sale or service.

Also, not included in this definition are the eggs of reptile species such as alligators and turtles. Alligator eggs are available for sale in some parts of the southern United States. In restaurants, the menu item “Alligator Eggs” is sometimes made of alligator egg, but other times is simply a fanciful name for a menu item that may include seafood items such as shrimp, but contains no alligator egg.

Sea turtle eggs have been consumed in Asian and Latin American Countries. However, turtle eggs are not mentioned in the definitions section because sea turtles (Loggerhead, East Pacific Green, Leatherback, Hawksbill, Kemp’s Ridley, and Olive Ridley) are protected by The Endangered Species Act of 1973 and therefore may not be sold or consumed. This Act, with respect to turtle eggs, is enforced by the United States Department of Interior, U.S. Fish and Wildlife Service, Washington, DC.

Food establishment and food processing plant.

Food Establishment and a food processing plant located within the same premises of a food establishment

Some food businesses perform operations that provide food directly to consumers as a “Food Establishment,” and also supply food to other business entities as a “Food Processing Plant.” Within such a business, those operations that provide food directly to consumers only should be considered part of a “Food Establishment” for the purposes of applying the Food Code while those operations that supply food to other business entities may be subject to other rules and regulations that apply to “Food Processing Plants”. It is essential that the permit holder and persons in charge be aware that regulatory requirements and the appropriate operational practices for “Food Establishments” may differ from those for “Food Processing Plants.”

Some facilities and functions may be subject to different regulatory requirements depending on whether that facility or function is regulated as a “Food Establishment” or as a “Food Processing Plant”, or both. Those facilities and functions within a business that are shared by both the “Food Establishment” and “Food Processing Plant” operations, e.g., refrigeration units, dressing room and toilet facilities, food equipment, water and waste systems, pest control, might be subject to similar regulatory requirements. The Food Code is intended to apply to “food establishments”.

Packaged.

The definition of “packaged” was revised in (2) to clarify when foods packaged at retail need not be labeled.

Refer to Public Health Reasons for Food Labels §3-602.11.

Time/Temperature Control for Safety Food

Time Temperature Control for Safety Food (TCS) is defined in terms of whether or not it requires time/temperature control for safety to limit pathogen growth or toxin formation. The term does not include foods that do not support growth but may contain a pathogenic microorganism or chemical or physical food safety hazard at a level sufficient to cause foodborne illness or injury. The progressive growth of all foodborne pathogens is considered whether slow or rapid.

The definition of TCS food takes into consideration pH, a_w, pH and a_w interaction, heat treatment, and packaging for a relatively simple determination of whether the food requires time/temperature control for safety. If the food is heat-treated to eliminate vegetative cells, it needs to be addressed differently than a raw product with no, or inadequate, heat treatment. In addition, if the food is packaged after heat treatment to destroy vegetative cells and subsequently packaged to prevent re-contamination, higher ranges of pH and/or a_w can be tolerated because remaining spore-forming bacteria are the only microbial hazards of concern. While foods will need to be cooled slightly to prevent condensation inside the package, they must be protected from contamination in an area with limited access and packaged before temperatures drop below 57°C (135°F). In some foods, it is possible that neither the pH value nor the a_w value is low enough by itself to control or eliminate pathogen growth; however, the interaction of pH and a_w may be able to accomplish it. This is an example of a hurdle technology. Hurdle technology involves several inhibitory factors being used together to control or eliminate pathogen growth, when they would otherwise be ineffective if used alone. When no other inhibitory factors are present and the pH and/or a_w values are unable to control or eliminate bacterial pathogens which may be present, growth may occur and foodborne outbreaks result. Cut melons, cut tomatoes, and cut leafy greens are examples where intrinsic factors are unable to control bacterial growth once pathogens are exposed to the cellular fluids and nutrients after cutting.

In determining if time/temperature control is required, combination products present their own challenge. A combination product is one in which there are two or more distinct food components and an interface between the two components may have a different property than either of the individual components. A determination must be made about whether the food has distinct components such as pie with meringue topping, focaccia bread, meat salads, or fettuccine alfredo with chicken or whether it has a uniform consistency such as gravies, puddings, or sauces. In these products, the pH at the interface is important in determining if the item is a TCS food.

A well designed inoculation study or other published scientific research should be used to determine whether a food can be held without time/temperature control when:

- process technologies other than heat are applied to destroy foodborne pathogens (e.g., irradiation, high pressure processing, pulsed light, ozonation);
- combination products are prepared; or

- other extrinsic factors (e.g., packaging/atmospheres) or intrinsic factors (e.g., redox potential, salt content, antimicrobials) are used to control or eliminate pathogen growth.

Before using Tables A and B in paragraph 1-201.10(B) of the definition for "time/temperature control for safety food" in determining whether a food requires time/temperature control for safety (TCS), answers to the following questions should be considered:

- Is the intent to hold the food without using time or temperature control?
    - If the answer is No, no further action is required. The decision tree later in this Annex is not needed to determine if the item is a TCS food.
- Is the food raw, or is the food heat-treated?
- Does the food already require time/temperature control for safety by definition in paragraph 1-201.10(B)?
- Does a product history with sound scientific rationale exist indicating a safe history of use?
- Is the food processed and packaged so that it no longer requires TCS such as ultra high temperature (UHT) creamers or shelf-stable canned goods?
- What is the pH and a_w of the food in question using an independent laboratory and Association of Official Analytical Chemists (AOAC) methods of analysis?

A food designated as product assessment required (PA), in either table should be considered TCS Food until further study proves otherwise. The PA means that based on the food's pH and a_w and whether it was raw or heat-treated or packaged, it has to be considered TCS until inoculation studies or some other acceptable evidence shows that the food is a TCS food or not. The Food Code requires a variance request to the regulatory authority with the evidence that the food does not require time/temperature control for safety.

The Food Code definition designates certain raw plant foods as TCS food because they have been shown to support the growth of foodborne pathogens in the absence of temperature control and to lack intrinsic factors that would inhibit pathogen growth. Unless product assessment shows otherwise, these designations are supported by Tables A and B. For example:

For cut cantaloupe (pH 6.2-7.1, $a_w > 0.99$, not heat-treated),. fresh sprouts (pH > 6.5, $a_w > 0.99$, not heat-treated), and cut tomatoes (pH 4.23 – 5.04, $a_w > 0.99$, not heat-treated), Table B indicates that they are considered TCS Foods unless a product assessment shows otherwise. Maintaining these products under the temperature control requirements prescribed in this code for TCS food will limit the growth of pathogens that may be present in or on the food and may help prevent foodborne illness.

If a facility adjusts the pH of a food using vinegar, lemon juice, or citric acid for purposes other than flavor enhancement, a variance is required under ¶ 3-502.11(C). A HACCP plan is required whether the food is a TCS food as in subparagraph 3-502.11 (C)(1) or not a TCS food, as in subparagraph 3-502.11(C)(2). A standardized recipe validated by lab testing for pH and a_w would be an appropriate part of the variance request with annual (or other frequency as specified by the regulatory authority) samples tested to verify compliance with the conditions of the variance.

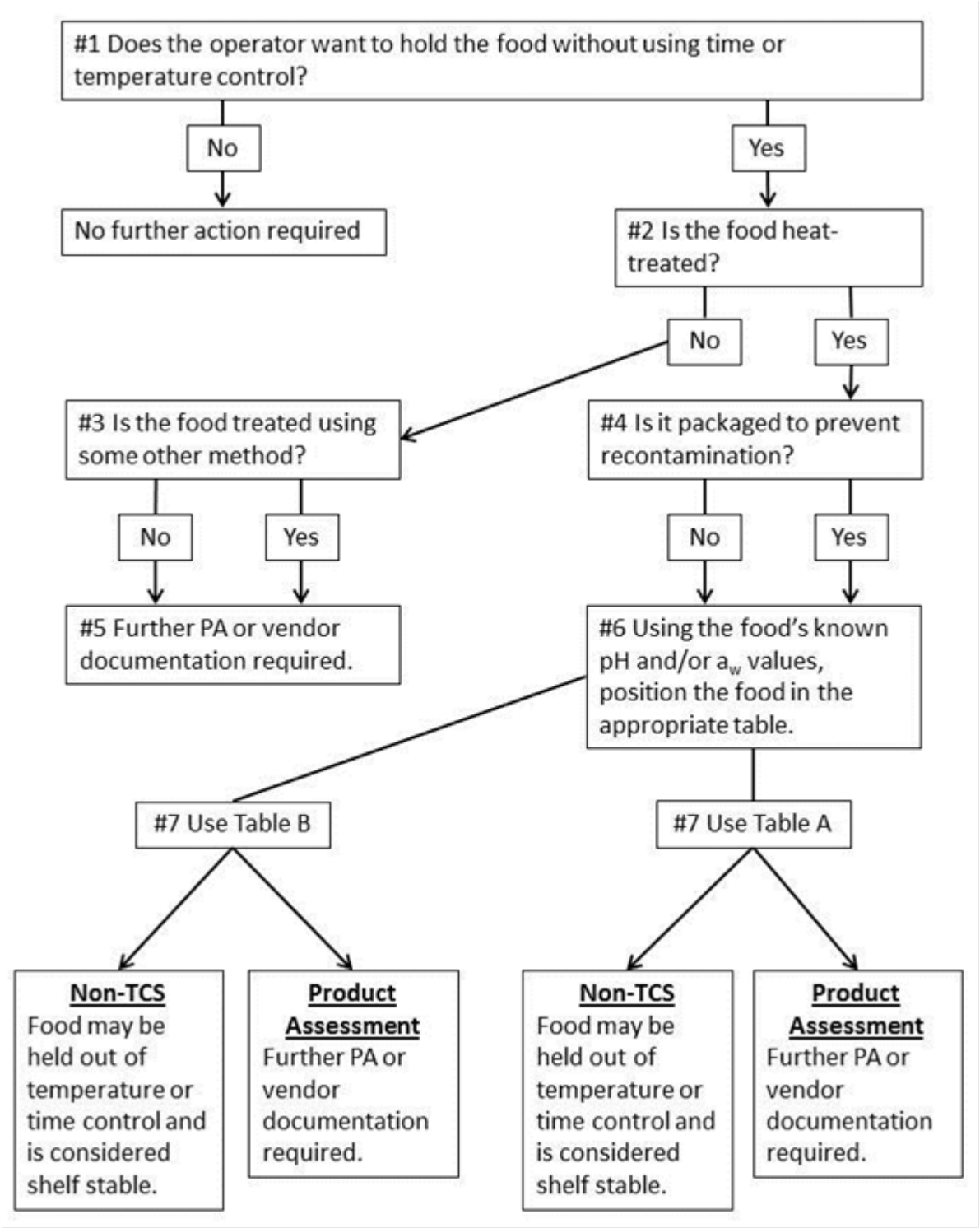
More information can be found in the Institute of Food Technologists (IFT) Report, "Evaluation and Definition of Potentially Hazardous Foods" at http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm094141.htm

Instructions for using the following Decision Tree and Table A and Table B:

1. Does the operator want to hold the food without using time or temperature control?
    a. No – Continue holding the food at ≤5°C(41°F) or ≥57°C(135°F) for safety and/or quality.
    b. Yes – Continue using the decision tree to identify which table to use to determine whether time/temperature control for safety (TCS) is required.
2. Is the food heat-treated?
    a. No – The food is either raw, partially cooked (not cooked to the temperature specified in section 3-401.11 of the Food Code) or treated with some other method other than heat. Proceed to step #3.
    b. Yes – If the food is heat-treated to the required temperature for that food as specified under section 3-401.11 of the Food Code, vegetative cells will be destroyed although spores will survive. Proceed to step #4.
3. Is the food treated using some other method?
    a. No –The food is raw or has only received a partial cook allowing vegetative cells and spores to survive. Proceed to step #6.
    b. Yes – If a method other than heat is used to destroy pathogens such as irradiation, high pressure processing, pulsed light, ultrasound, inductive heating, or ozonation, the effectiveness of the process needs to be validated by inoculation studies or other means. Proceed to step #5.
4. Is it packaged to prevent re-contamination?
    a. No – Re-contamination of the product can occur after heat treatment because it is not packaged. Proceed to step #6.
    b. Yes – If the food is packaged immediately after heat treatment to prevent re-contamination, higher ranges of pH and/or a_w can be tolerated because spore-forming bacteria are the only microbial hazard. Proceed to step #7.
5. Further product assessment or vendor documentation required.
    a. The vendor of this product may be able to supply documentation that inoculation studies indicate the food can be safely held without time/temperature control for safety.

   b. Food prepared or processed using new technologies may be held without time/temperature control provided the effectiveness of the use of such technologies is based on a validated inoculation study.
6. Using the food's known pH and/or a_w values, position the food in the appropriate table.
   a. Choose the column under "pH values" that contains the pH value of the food in question.
   b. Choose the row under "a_w values" that contains the a_w value of the food in question.
   c. Note where the row and column intersect to identify whether the food is "non-TCS food" and therefore does not require time/temperature control, or whether further product assessment (PA) is required. Other factors such as redox potential, competitive microorganisms, salt content, or processing methods may allow the product to be held without time/temperature control but an inoculation study is required.
7. Use **Table A** for foods that are heat-treated and packaged **OR** use **Table B** for foods that are not heat-treated or heat-treated but not packaged.
8. Determine if the item is non-TCS or needs further product assessment (PA).

1-201.10(B) Decision Tree #1 – Using pH, a_w, or the Interaction of pH and a_w to Determine if a Food Requires Time/Temperature Control for Safety



1-201.10(B) – Table A and Table B

Table A. Interaction of pH and A_W for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

a_w values	pH: 4.6 or less	pH: > 4.6 - 5.6	pH: > 5.6
≤0.92	non-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 - 0.95	non-TCS FOOD	non-TCS FOOD	PA**
> 0.95	non-TCS FOOD	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD
** PA means Product Assessment required

Table B. Interaction of pH and A_W for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

A_W values	pH: < 4.2	pH: 4.2 - 4.6	pH: > 4.6 - 5.0	pH: > 5.0
< 0.88	non-TCS food*	non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

Chapter 2 Management and Personnel

Responsibility **2-101.11 Assignment.**

Designation of a person in charge during all hours of operations ensures the continuous presence of someone who is responsible for monitoring and managing all food establishment operations and who is authorized to take actions to ensure that the Code's objectives are fulfilled. During the day-to-day operation of a food establishment, a person who is immediately available and knowledgeable in both operational and Code requirements is needed to respond to questions and concerns and to resolve problems.

In cases where a food establishment has several departments on the premises (e.g., a grocery store with deli, seafood, and produce departments) and the regulatory authority has permitted those departments individually as separate food establishments, it may be unnecessary from a food safety standpoint to staff each department with a separate Person in Charge during periods when food is not being prepared, packaged or served. While activities such as moving food products from a refrigerated display case to the walk-in refrigerator, cleaning the floors, or doing inventory when the department is not busy, do take place during these times, a designated Person in Charge for multiple departments or the entire facility can oversee these operations and be ready to take corrective actions if necessary.

Knowledge **2-102.11 Demonstration.**

The designated person in charge who is knowledgeable about foodborne disease prevention, Hazard Analysis and Critical Control Point (HACCP) principles, and Code requirements is prepared to recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with Code requirements, and to take appropriate preventive and corrective actions.

There are many ways in which the person in charge can demonstrate competency. Many aspects of the food operation itself will reflect the competency of that person. A dialogue with the person in charge during the inspection process will also reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.

The Food Code does not require reporting of uninfected cuts or reporting of covered, protected infected cuts/lesions/boils since no bare hand contact with ready-to-eat (RTE) food is a Code requirement.

2-102.12 Certified Food Protection Manager

The increasing complexity of the food industry, the improved ability to identify/trace foodborne outbreaks and other economic, staffing, cultural and behavioral challenges make it imperative that food protection managers know and control the risk factors that impact the safety of the food they sell or serve. Food protection managers have an important role in formulating policies, verifying food employees carry out these policies, and communicating with these same employees to give information about recommended practices to reduce the risk of foodborne illness. A Centers for Disease Control and Prevention Environmental Health Specialist-Network (EHS-Net) study suggests that the presence of a certified food protection manager reduces the risk for a foodborne outbreak for an establishment and was a distinguishing factor between restaurants that experienced a foodborne illness outbreak and those that had not.

FDA's Retail Food Risk Factor Studies suggest that the presence of a certified manager has a positive correlation with more effective control of certain risk factors, such as poor personal hygiene, in different facility types.

There are a number of state and local agencies that currently mandate food protection manager certification. It is appropriate for State and local agencies, by way of codes and ordinances or by policy to establish criteria for what types of permitted establishments could be exempt from the mandatory manager certification requirement and for determining the conditions under which the minimum number of certified food protection managers must be some number greater than one.

Factors to consider when establishing such criteria include:

- the size and scope of the operation;
- the hours of operation;,
- the types of foods sold or served;
- the extent to which food is prepared on site;
- the number of staff,
- type of population served, e.g. highly susceptible or not; and
- the number of meals served.

2-102.20 Food Protection Manager Certification.

Many food protection manager certification programs have shared a desire to have the food manager certificates they issue universally recognized and accepted by others – especially by the increasing number of regulatory authorities that require food manager certification.

Needed has been a mechanism for regulatory authorities to use in determining which certificates should be considered credible based on which certificate issuing programs meet sound organizational and certification procedures and use defensible processes in their test development and administration.

After a multi-year effort involving a diversity of stakeholder groups, the Conference for Food Protection (CFP) completed work on its ***Standards for Accreditation of Food Protection Manager Certification Programs*** found at: http://www.foodprotect.org/manager-certification/. In 2002 the Conference entered into a cooperative agreement with the American National Standards Institute (ANSI) to provide independent third-party evaluation and accreditation of certification bodies determined to be in conformance with these Conference standards. ANSI published its first listing of accredited certifiers in 2003.

The Acting Commissioner of the Food and Drug Administration, in his address before the 2004 biennial meeting of the Conference for Food Protection, commended this Conference achievement and encouraged universal acceptance based on the CFP/ANSI accreditation program.

Distributed at this meeting was the following letter addressed to the Conference Chair and signed by the Director of FDA's Center for Food Safety and Applied Nutrition. The letter puts forth the Agency's basis for its support of universal acceptance of food protection manager certifications.

> "The 2004 biennial meeting of the **Conference for Food Protection** is a fitting occasion for FDA's Center for Food Safety and Applied Nutrition to commend the Conference for its significant achievements in support of State and local food safety programs.
>
> The FDA in a Memorandum of Understanding recognizes the Conference for Food Protection as a voluntary national organization qualified to develop standards to promote food protection. Conference recommendations contribute to improvements in the model FDA Food Code and help jurisdictions justify, adopt and implement its provisions.
>
> Conference mechanisms involving active participation by representatives of diverse stakeholder groups produce consensus standards of the highest quality. An excellent example is the Conference's ***Standards for Accreditation of Food Protection Manager Certification Programs***, and its announcement of the new on-line listing of accredited certifiers of industry food protection managers. Many years in their development, these Conference standards identify the essential components necessary for a credible certification program. Components cover a wide range of requirements such as detailed criteria for exam development and administration, and responsibilities of the certification organization to candidates and the public.

FDA applauds the Conference for this significant achievement, and encourages agencies at all levels of government to accept certificates issued by listed certifiers as meeting their jurisdictions' food safety knowledge and certification requirements. The American National Standards Institute (ANSI) has independently evaluated these certification programs under an agreement with the Conference for Food Protection. Governments and industry widely recognize and respect ANSI as an accrediting organization. ANSI has found certifiers it lists as accredited (http://www.ansi.org/) under "conformity assessment" – "personnel certification accreditation" to conform to the Conference's ***Standards for Accreditation of Food Protection Manager Certification Programs***.*

The Food Code states the person in charge of a food establishment is accountable for developing, carrying out, and enforcing procedures aimed at preventing food-borne illness. Section 2-102.11 states that one means by which a person in charge may demonstrate required knowledge of food safety is through certification as a food protection manager by passing an examination that is part of an accredited program.**

FDA encourages food regulatory authorities and others evaluating credentials for food protection managers to recognize the Conference for Food Protection/ANSI means of accrediting certification programs. This procedure provides a means for universal acceptance of individuals who successfully demonstrate knowledge of food safety. The procedure provides officials assurance that food safety certification is based on valid, reliable, and legally defensible criteria. In addition, universal acceptance eliminates the inconvenience and unnecessary expense of repeating training and testing when managers work across jurisdictional boundaries.

FDA, along with State, local, tribal, and other Federal agencies and the food industry, share the responsibility for ensuring that our food supply is safe. It is anticipated that this new Conference for Food Protection/ANSI program will lead to enhanced consumer protection, improve the overall level of food safety, and be an important component of a seamless national food safety system."

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*The ANSI-CFP Accreditation Program list of accredited organizations utilizing the Conference for Food Protection (CFP) Standards may be viewed on-line by going to:
https://www.ansica.org/wwwversion2/outside/ALLdirectoryListing.asp?menuID=8&prgID=8&status=4

** Accredited program does not refer to training functions or educational programs.

Duties **2-103.11 Person in Charge.**

A primary responsibility of the person in charge is to ensure compliance with Code requirements. Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service personnel, and pest control operators, comply with the Code requirements, the person in charge establishes an important barrier to food contamination.

Tours of food preparation areas serve educational and promotional purposes; however, the timing of such visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for contamination are reduced.

When food and other purchased goods are delivered and placed into designated locations within the food establishment during non-operating hours, the Person in Charge must make sure food employees inspect such product and verify that it is from the appropriate supplier, is in the desired condition, and was delivered to a proper storage location. Distributors deliver and place food and other goods in refrigeration units, freezers, and dry storage areas for confirmation of receipt and inspection by employees immediately upon arrival to the food establishment. Distributors contracted by the food establishment are often given a key to allow access into the establishment outside of normal working hours. Upon delivery, all food must be appropriately stored in a safe and secure manner within the food establishment. For example, time/temperature control for safety foods must be stored within refrigeration units and held at temperatures of 41°F or below. Likewise, if the food product is frozen, it must be placed into the freezer.

To minimize the potential for access to the food establishment and the food by an unauthorized person, precautions should be applied overall to the food establishment and especially when access to the facility is made under key access deliveries. Additional information on food defense can be viewed at: http://www.fda.gov/Food/FoodDefense/default.htm

Food allergy is an increasing food safety and public health issue, affecting approximately 4% of the U.S. population, or twelve million Americans.

Restaurant and retail food service managers need to be aware of the serious nature of food allergies, including allergic reactions, anaphylaxis, and death; to know the eight major food allergens; to understand food allergen ingredient identities and labeling; and to avoid cross-contact during food preparation and service. The 2008 Conference of Food Protection (CFP) passed Issue 2008-III-006 which provided that food allergy awareness should be a food safety training duty of the Person in Charge. Accordingly, the Person in Charge's Duties under paragraph (M) were amended to assure the food safety training of employees includes food allergy awareness in order for them to safely perform duties related to food allergies.

Paragraph (M) "EMPLOYEES are properly trained in FOOD safety, including food allergy awareness, as it relates to their assigned duties" allows industry to develop and implement operational-specific training programs for food employees. It is not intended to require that all food employees pass a test that is part of an accredited program.

Paragraph (N) emphasizes the important role the Person in Charge (PIC) has in making sure employees properly report certain information about their health status as it relates to diseases that are transmitted by food. In an effort to reinforce dialogue between food employees and the PIC, there must be a way to verify that food employees and conditional employees are informed of their responsibility to report such information. Examples of ways to verify that employees have been appropriately informed include:

- The ability to provide documentation that all food employees and conditional employees are informed of their responsibility to report to management, such as completion of Form 1-B, "Conditional Employees or Food Employees Reporting Agreement" in Annex 7 or other similar state or local forms containing the same information;

- Presenting evidence such as curriculum and attendance rosters documenting that each employee has completed a training program which includes all the information required for reporting in Form 1-B;

- Implementation of an employee health policy that includes a system of employee notification using a combination of training, signs, pocket cards or other means to convey all the required information (Refer to Annex 3, 2-201 Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201, for further guidance);

- Other methods that satisfactorily demonstrate that all food employees and conditional employees are informed of their responsibility to report to the PIC information about their health and activities as it relates to diseases that are transmissible through food, as specified under ¶2-201.11 (A)

In various places throughout the Code, it is specified that either written operating procedures or operational plans be developed. The link between management responsibility for developing and implementing the procedures or plans is now established as a new duty for the Person in Charge (PIC). This new provision does not establish new requirements in the development of plans or procedures; rather it emphasizes the importance of the role the PIC plays in ensuring active managerial control of the food establishment with the development and implementation of plans and/or procedures as specified in this Code. Examples of Code provisions that call for the development of plans or procedures can be found in: §2-501.11, ¶¶3-301.11(D) and 3-401.14 (F), §§ 3-501.19, and 5-205.14. Ultimately, responsibility for food safety at the retail level lies with retail and food service operators and their ability to develop and maintain effective food safety management systems. There are many tools that industry can use to develop an effective system to achieve active managerial control of foodborne illness risk factors. An important tool in controlling risk factors inherent in a food establishment is the development and implementation of written procedures or plans.

(Also refer to Annex 4 – Management of Food Safety Practices (1) (D) for further information).

2-2 Employee Health

Overall goals

The purpose of this section of the Food Code is to reduce the likelihood that certain viral and bacterial agents will be transmitted from infected food employees into food. The agents of concern are known to be readily transmissible via food that has been contaminated by ill food employees, and so for that reason, are the primary focus of the Employee Health section of the Food Code. However, there are different levels of risk associated with different levels of clinical illness. The structure of the restrictions and exclusions has, therefore, been designed in a tiered fashion depending on the clinical situation to offer the maximum protection to public health with the minimal disruption to employees and employers.

Four levels of illness or potential illness have been identified with the first level being the highest potential risk to public health and the fourth level being the lowest. The first level relates to employees who have specific symptoms (e.g., vomiting, diarrhea, jaundice) while in the workplace. These symptoms are known to be associated commonly with the agents most likely to be transmitted from infected food employees through contamination of food. The first level also relates to employees who have been diagnosed with typhoid fever or an infection with hepatitis A virus (within 14 days of symptoms). The second level relates to employees who have been diagnosed with the specific agents that are of concern, but who are not exhibiting symptoms of disease because their symptoms have resolved. The third level relates to employees who are diagnosed with the specific agents, but never develop any gastrointestinal symptoms. The fourth level relates to those individuals who are clinically well but who may have been exposed to a listed pathogen and are within the normal incubation period of disease.

The most significant degree of restriction and exclusion applies to the first level of food employee illness. Infected food employees in the first level are likely to be excreting high levels of their infectious pathogen, increasing the chance of transmission to food products, and thus on to those consuming the food. The first level includes food employees who are:

- Experiencing active symptoms of diarrhea or vomiting – with no diagnosis,
- Experiencing jaundice within the last 7 days-- with no diagnosis,
- Diagnosed with typhoid fever,
- Diagnosed with hepatitis A within 7 days of jaundice or 14 days of any symptoms, or
- Experiencing active symptoms of diarrhea or vomiting, and diagnosed with Norovirus, ***E. coli*** O157:H7 or other Shiga toxin-producing ***Escherichia coli*** (STEC), ***Shigella*** spp. infection, or nontyphoidal *Salmonella*.

Diagnosis with typhoid fever or hepatitis A virus is included in level 1 because employees diagnosed with these pathogens are likely to be shedding high levels of the pathogen in their stool without exhibiting gastrointestinal symptoms. Peak levels of hepatitis A viral shedding in the feces typically occurs before symptoms appear. Diarrhea and vomiting are reliable indicators of infection with Norovirus, ***E. coli*** O157:H7 or other STEC, and ***Shigella*** spp., but are not typical symptoms of typhoid fever or hepatitis A. For example, employees diagnosed with typhoid fever are more likely to experience constipation, rather than diarrhea. Jaundice is also not always reliable as an indicator of a hepatitis A infection because employees can be infected with hepatitis A virus without experiencing jaundice (anicteric employees). Dark urine and light colored stool may be an indicator of a hepatitis A infection but may go unreported.

Maximum protection to public health requires excluding food employees suffering from typhoid fever, hepatitis A virus, or specific gastrointestinal symptoms associated with diseases identified as likely to be transmitted through contamination of food (See section 2-201.12, Tables 2-201.12 #1a and #1b in this Annex). This situation describes the highest level of risk in transmitting pathogens to food, or what we would find in the first level.

Food employees who have been diagnosed with one of the agents of concern, but are not symptomatic because their symptoms have resolved, are still likely to be carrying the infected agent in their intestinal tract. This makes such employees less likely to spread the agent into food than others who are actually symptomatic, but employees diagnosed with one of the agents of concern still pose an elevated threat to public health. For this reason, there are a series of exclusions (if the employees work in facilities serving highly susceptible populations (HSP)) and restrictions (for non-HSP facilities) depending on the agent involved (See section 2-201.12, Table #2). This situation describes the second level of risk in transmitting pathogens to food.

Diagnosed, asymptomatic food employees who never develop symptoms are typically identified during a foodborne illness outbreak investigation through microbiological testing. If infected and asymptomatic employees are not microbiologically tested, they will remain undetected and could therefore extend the duration of a foodborne illness outbreak through continued contamination of food. The Food Code provides restriction or exclusion guidelines for employees that are identified through microbiological testing with an infection from a listed foodborne pathogen, but are otherwise asymptomatic and clinically well (See section 2-201.12, Table #3). The exclusion or restriction guidelines are applied until the identified food employees no longer present a risk for foodborne pathogen transmission. This situation describes the third level of risk in transmitting pathogens to food.

Some food employees or conditional employees may report a possible exposure to an agent. For example, a food employee may have attended a function at which the food employee ate food that was associated with an outbreak of shigellosis, but the employee remains well. Such individuals fall into the category of having had a potential exposure and present a lower risk to public health than someone who is either symptomatic or who has a definitive diagnosis. They present a level of risk to public health that is greater than if they had not had the exposure. The approach taken in the Food Code to food employees who have had a potential exposure is based on the incubation times (time between exposure and the onset of symptoms) of the various agents. The times chosen for restriction are the upper end of the average incubation periods for the specific agents. The Food Code provides restriction guidelines for food employees working in facilities serving a HSP. The reasoning is that this will restrict food employees only up to the time when it is unlikely they will develop symptoms. As a further protection to public health, it is recommended that such exposed food employees working in facilities not serving a HSP pay particular attention to personal hygiene and report the onset of any symptoms (See section 2-201.12, Table #4). This situation describes the fourth level of risk in transmitting pathogens to food.

This structured approach has linked the degree of exclusion and restriction to the degree of risk that an infected food employee will transmit an agent of concern into food. The approach strikes a balance between protecting public health and the needs of the food employee and employer.

The Food Code provisions related to employee health are aimed at removing highly infectious food employees from the work place. They were developed with recognition of the characteristics of the six important pathogens, and of the risk of disease transmission associated with symptomatic and asymptomatic shedders. The provisions also account for the increased risk associated with serving food to HSP's and the need to provide extra protection to those populations.

The Employee Health section was developed and revised with assistance and input from the Centers for Disease Control and Prevention (CDC) and the U.S. Equal Employment Opportunity Commission (EEOC). The exclusion and restriction criteria are based on communicable disease information, as required by the Americans with Disabilities Act of 1990, in the list of Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens posted on CDC's website, and from the Control of Communicable Diseases Manual, 19th Ed., David L. Heymann, MD, Editor, by the American Public Health Association, Washington D.C., 2008.

2-201 Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201

The information provided in Subpart 2-201 is designed to assist food establishment managers and regulatory officials in removing infected food employees when they are at greatest risk of transmitting foodborne pathogens to food. Practical applications of the information in Subpart 2-201 by a food establishment manager may involve using Subpart 2-201 as a basis for obtaining information on the health status of food employees and can also be used as a basis in developing and implementing an effective Employee Health Policy. Regulatory officials can benefit by using the information provided below as a basis for determining compliance with Subpart 2-201 during a facility food safety inspection.

The development and effective implementation of an employee health policy based on the provisions in Subpart 2-201 may help to prevent foodborne illness associated with contamination of food by ill or infected food employees. The person in charge and food employees should be familiar with and able to provide the following information through direct dialogue or other means when interviewed by facility managers or regulatory officials. Compliance must be based, however, on first hand observations or information and cannot be based solely on responses from the person in charge to questions regarding hypothetical situations or knowledge of the Food Code. Also, when designing and implementing an employee health policy, the following information should be considered and addressed:

1. Does the establishment have an Employee Health Policy? If so, are the food employees aware of the employee health policy, and is it available in written format and readily available for food employees? (Note: A written Employee Health Policy is not a Food Code requirement unless the facility is operating under a pre-approved alternative procedure specified under ¶3-301.11(E)).
2. Does the establishment require conditional employees and food employees to report certain illnesses, conditions, symptoms, and exposures?
3. Are the reporting requirements explained to all employees?
4. What are the reporting requirements for conditional employees, food employees, and the food establishment manager?
5. Are conditional employees asked if they are experiencing certain symptoms or illnesses upon offer of employment? If so, which symptoms or illnesses?
6. If a food employee reports a diagnosis with one of the 6 listed pathogens in the Food Code, what questions are asked of the food employee? (The first question every food manager should ask a food employee who reports diagnosis with a listed pathogen is if the employee is currently having any symptoms.)
7. Who does the establishment notify when a food employee reports a diagnosis with one of the listed pathogens?
8. What gastrointestinal symptoms would require exclusion of a food employee from the food establishment?
9. What history of exposure is a conditional employee or food employee required to report?
10. If a food employee reports a gastrointestinal symptom, what criteria are used to allow the employee to return to work?

Responsibilities and Reporting Symptoms and Diagnosis	**2-201.11**	**Responsibility of the Person in Charge, Food Employees, and Conditional Employees.**

Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees. The person in charge is responsible for ensuring all food employees and conditional employees are knowledgeable and understand their responsibility to report listed symptoms, diagnosis with an illness from a listed pathogen, or exposure to a listed pathogen to the person in charge. The person in charge is also responsible for reporting to the regulatory official if a food employee reports a diagnosis with a listed pathogen.

This reporting requirement is an important component of any food safety program. A food employee who suffers from any of the illnesses or medical symptoms or has a history of exposure to a listed pathogen in this Code may transmit disease through the food being prepared. The person in charge must first be aware that a food employee or conditional employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

The person in charge may observe some of the symptoms that must be reported. However, food employees and conditional employees share a responsibility for preventing foodborne illness and are obligated to inform the person in charge if they are suffering from any of the listed symptoms, have a history of exposure to one of the listed pathogens, or have been diagnosed with an illness caused by a listed pathogen. Food employees must comply with restrictions or exclusions imposed upon them.

A conditional employee is a potential food employee to whom a job offer has been made, conditional on responses to subsequent medical questions or examinations. The questions or examinations are designed to identify potential food employees who may be suffering from a disease that can be transmitted through food and done in compliance with Title 1 of the Americans with Disabilities Act of 1990. A conditional employee becomes a food employee as soon as the employee begins working, even if only on a restricted basis. When a conditional employee reports a listed diagnosis or symptom, the person in charge is responsible for ensuring that the conditional employee is prohibited from becoming a food employee until the criteria for reinstatement of an exclusion are met (as specified under section 2-201.13 of the Food Code). When a symptomatic or diagnosed conditional employee has met the same criteria for reinstatement that apply to an excluded symptomatic or diagnosed food employee (as specified under section 2-201.13 of the Food Code), the conditional employee may then begin working as a food employee.

Reporting Symptoms:

In order to protect the health of consumers and employees, information concerning the health status of conditional employees and food employees must be disclosed to the person in charge. The symptoms listed in the Code cover the common symptoms experienced by persons suffering from the pathogens identified by CDC as transmissible through food by infected food employees. A food employee suffering from any of the symptoms listed presents an increased risk of transmitting foodborne illness.

<u>The symptoms of vomiting, diarrhea, or jaundice</u> serve as an indication that an individual may be infected with a fecal-oral route pathogen, and is likely to be excreting high levels of the infectious agent. When a food employee is shedding extremely high numbers of a pathogen through the stool or vomitus, there is greater chance of transmitting the pathogen to food products.

Sore throat with fever serves as an indication that the individual may be infected with *Streptococcus pyogenes. Streptococcus pyogenes* causes a common infection otherwise known as “streptococcal sore throat” or “strep throat.” Streptococcal sore throat can spread from contaminated hands to food, which has been the source of explosive streptococcal sore throat outbreaks. Previous foodborne episodes with streptococcus sore throat have occurred in contaminated milk and egg products. Food products can be contaminated by infected food employees hands or from nasal discharges. Untreated individuals in uncomplicated cases can be communicable for 10-21 days, and untreated individuals with purulent discharges may be communicable for weeks or months.

Lesions containing pus that may occur on a food employee’s hands, as opposed to such wounds on other parts of the body, represent a direct threat for introducing ***Staphylococcus aureus*** into food. Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other parts of the body need to be covered; but an impermeable bandage is not considered necessary for food safety purposes. Food employees should be aware that hands and fingers that contact pustular lesions on other parts of the body or with the mucous membrane of the nose also pose a direct threat for introducing ***Staphylococcus aureus*** into food.

If a food employee has an infected cut and bandages it and puts on a glove, the employee does not have to report the infected cut to the person in charge. However, if the employee does not bandage it, reporting is required.

Title I of the Americans with Disabilities Act of 1990 (ADA)

Title I of the Americans with Disabilities Act of 1990 (ADA) prohibits medical examinations and inquiries as to the existence, nature, or severity of a disability before extending a conditional offer of employment. In order for the permit holder and the person in charge to be in compliance with this particular aspect of the Code and the ADA, a conditional job offer must be made before making inquiries about the applicant’s health status.

The ADA also requires that employers provide reasonable accommodation to qualified applicants and employees with disabilities. A reasonable accommodation is a change in the application process, in the way a job is done, or to other parts of the job that enables a person with a disability to have equal employment opportunities. ADA disabilities are serious, long-term conditions. Most people with diseases resulting from the pathogens listed in the Food Code do not have ADA disabilities because these diseases are usually short-term in duration. In addition, the gastrointestinal symptoms listed in the Food Code usually are not long-term and severe enough, in themselves, to be ADA disabilities. Of course, these symptoms may be linked to other conditions that may be serious enough to be ADA disabilities, like Crohn's disease or cancer.

A food employer may exclude any employee under the Food Code upon initially learning that the employee has *Salmonella* Typhi, or has a gastrointestinal symptom listed in the Food Code. The excluded employee may then ask for an ADA reasonable accommodation instead of the exclusion. In response, the employer's first step should be to ask the employee to establish that the employee is disabled by the disease or symptom (or that the symptom is caused by another ADA disability). If the employee successfully proves that the employee has an ADA disability, then the employer may continue to exclude the employee under the Food Code if:

- there is no reasonable accommodation at work that would eliminate the risk of transmitting the disease while also allowing the employee to work in a food handling position, or

- all reasonable accommodations would pose an undue hardship on the employer's business; and

- there is no vacant position **not involving food handling** for which the employee is qualified and to which the employee can be reassigned.

Example 1: A food employee working in the café of a department store informs the employer that the employee has been diagnosed with a disease caused by *Salmonella* Typhi. The employer immediately excludes the employee under the requirements of the Food Code. The employee then establishes that the disease is an ADA disability because it is severe and long-term and the employee requests reasonable accommodation instead of an exclusion. The employer determines that no reasonable accommodation would eliminate the risk of transmitting *Salmonella* Typhi through food and refuses to remove the exclusion. However, there is a vacant clerical position in another part of the store for which the employee is qualified. Unless the employer can establish that reassigning the employee to this position would be an undue hardship, the employer's failure to make the reassignment instead of continuing the exclusion would be a violation of the ADA.[1]

[1] Whether or not the employee in question is an individual with an ADA disability, in those jurisdictions where the Code is adopted, Food Code exclusions or restrictions must be removed when requirements for removal under § 2-201.13 of the Code are met.

Example 2: A food employee has diarrhea and is excluded. The employee establishes that the diarrhea is caused by Crohn's disease. This employee also establishes a serious longstanding history of Crohn's disease and is an individual with an ADA disability. Crohn's disease is not a communicable disease and cannot be transmitted through food. No reasonable accommodation is needed to eliminate the risk of transmitting the disease through the food supply, so the Food Code exclusion should be removed. Of course, the Food Code's provisions on personal cleanliness for hands and arms apply as usual, requiring employees to clean hands and exposed portions of arms after using the toilet room and in other specified circumstances (Subpart 2-301).

Somewhat different rules apply to conditional employees. If a conditional employee reports a disease or symptom listed in the Food Code and shows that the disease or symptom makes the conditional employee an individual with an ADA disability, the employer may withdraw the job offer only if:

- The job involves food handling; and
- The employer determines that either there is no reasonable accommodation that would eliminate the risk of transmitting the disease through food, or any such accommodation would be an undue hardship to the business.
- There is no need to offer the conditional employee a vacant position not involving food handling as a reasonable accommodation.

It should be noted that the information provided here about the ADA is intended to alert employers to the existence of ADA and related CFR requirements. For a comprehensive understanding of the ADA and its implications, consult the references listed in Annex 2 that relate to this section of the Code or contact the U. S. Equal Employment Opportunity Commission. See the Equal Employment Opportunity Commission's *How to Comply with the Americans with Disabilities Act: A Guide for Restaurants and Other Food Service Employers*, found at http://www.eeoc.gov/facts/restaurant_guide.html or http://www.eeoc.gov/facts/restaurant_guide_summary.html for detailed information about the interaction between the FDA Food Code and the ADA.

The information required from applicants and food employees is designed to identify employees who may be suffering from a disease that can be transmitted through food. It is the responsibility of the permit holder to convey to applicants and employees the importance of notifying the person in charge of changes in their health status. Once notified, the person in charge can take action to prevent the likelihood of the transmission of foodborne illness. Applicants, to whom a conditional offer of employment is extended, and food employees are required to report their specific history of exposure, medical symptoms, and previous illnesses.

The symptoms listed may be indicative of a disease that is transmitted through the food supply by infected food employees.

Section 103 (d) of the Americans with Disabilities Act of 1990, Public Law 101–336, requires the Secretary to publish a list of infectious and communicable diseases that are transmitted through handling the food supply and to review and update the list annually. The CDC published on its website in November 2012 a list of Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens. See the list at http://www.cdc.gov/foodsafety/food-safety-office.html#food

The final list has been reviewed in light of new information and has been revised as set forth below.

Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens

Some pathogens are frequently transmitted by food contaminated by infected persons. The presence of any one of the following signs or symptoms in persons who handle food may indicate infection by a pathogen that could be transmitted to others through handling the food supply: diarrhea, vomiting, open skin sores, boils, fever, dark urine or jaundice. The failure of food-handlers to wash hands in certain situations (such as after using the toilet, handling raw meat, cleaning spills, or carrying garbage), wear clean gloves, or use clean utensils is responsible for the foodborne transmission of these pathogens. Non-foodborne routes of transmission, such as from one person to another, are also major contributors in the spread of these pathogens.

Some pathogens usually cause disease when food is intrinsically contaminated or cross-contaminated during production, processing or transportation, but may also be contaminated when prepared by infected persons. Bacterial pathogens in this category often cause disease after bacteria have multiplied in food after it has been kept at improper temperatures permitting their multiplication to an infectious dose. Preventing food contact by persons who have an acute diarrheal illness will decrease the risk of transmitting these pathogens.

The following represent both types of pathogens that may be transmitted by an infected food handler:

Astroviruses
Bacillus cereus
Campylobacter jejuni
Clostridium perfringens
Cryptosporidium species
Entamoeba histolytica
Enterohemorrhagic *E. coli*
Enterotoxigenic *E. coli*

Giardia intestinalis
Hepatitis A virus
Nontyphoidal *Salmonella*
Noroviruses
Rotaviruses
Salmonella Typhi*
Sapoviruses
Shigella species
Staphylococcus aureus
Streptococcus pyogenes
Taenia solium - cysticercosis
Vibrio cholera

Yersinia enterocolitica

* 1. Kauffmann-White scheme for designation of Salmonella serotypes

The 6 Listed Pathogens:

The CDC has designated the 6 organisms listed in the Food Code as having high infectivity via contamination of food by infected food employees. This designation is based on the number of confirmed cases reported that involved food employees infected with one of these organisms and/ or the severity of the medical consequences to those who become ill.

The following is taken from information provided in the 19th Edition of Control of Communicable Diseases Manual, the CDC website, and the FDA Bad Bug Book, 2nd Edition, and is provided as background information on pathogen virulence, infectivity, and common symptoms exhibited with infection of each of the 6 listed pathogens.

NOROVIRUS

Noroviruses (genus Norovirus, family Caliciviridae) are small (27-40 nm), round structured, single-stranded RNA, nonenveloped viruses. They are a genetically diverse group classified into at least five genogroups, designated GI-GV, which are further sub-divided into at least 35 genotypes. Noroviruses are recognized as the most common cause of epidemic and sporadic gastroenteritis across all age groups worldwide.

Transmission of norovirus occurs primarily through the fecal-oral route, including direct person-to-person contact and indirect transmission through contaminated food, water, or environmental surfaces. Vomitus-oral transmission can also occur through aerosolization followed by direct ingestion or environmental contamination.

Noroviruses are the leading cause of foodborne illness in the United States. Food handler contact with raw or other ready-to-eat foods is the most common scenario resulting in foodborne norovirus outbreaks. Norovirus contamination of produce and shellfish can also occur during production. Secondary household transmission is common.

Noroviruses are environmentally stable, able to survive both freezing and heating (although not thorough cooking), are resistant to many common chemical disinfectants, and can persist on surfaces for up to 2 weeks. Proper hand hygiene and exclusion of food employees exhibiting symptoms of norovirus disease (i.e., diarrhea or vomiting) are critical for norovirus control.

Incubation Period: In volunteer studies, the range is 10-50 hours. In foodborne norovirus outbreaks, the median incubation period is 33 hours.

Symptoms and Complications: Acute-onset of vomiting, watery non-bloody diarrhea, abdominal cramps, and nausea, or a combination of these symptoms. Low grade fever and body aches may also be associated. Symptoms typically last 24 to 72 hours. Norovirus disease is usually self-limited without any serious long-term sequelae. Among the young and the elderly, dehydration is a common complication. Volunteer studies have found that as many as 30% of individuals infected with norovirus are asymptomatic. There is no specific treatment for norovirus disease. Supportive therapy consists of oral or intravenous rehydration solutions to replace fluid loss and electrolytes. Previous exposure does not provide long-term immunity; thus, individuals may be repeatedly infected throughout their lifetimes.

Infectivity: Noroviruses are highly contagious, and it is thought that an inoculum of as few as 18 viral particles may be sufficient to infect an individual. Although pre-symptomatic shedding may occur, shedding usually begins with onset of symptoms, peaks 4 days after exposure, and may persist for 3 weeks after recovery. However the degree of infectivity of prolonged shedding has not been determined and peak contagiousness is during the acute stage of disease. Peak viral loads in both symptomatic and asymptomatic infections (may be as high as 100 billion viral particles/g feces).

NONTYPHOIDAL *SALMONELLA*

Caused by serotypes ***other than*** *S.* Typhi and *S.* Paratyphi A.

Unlike previous editions of the FDA Food Code, the 2013 edition requires food employees to report a diagnosis of nontyphoidal *Salmonella* (NTS), prompts the person in charge to exclude food employees with diagnosis of NTS, and provides conditions for reinstatement of a food employee who provides to the person in charge written medical documentation from a health practitioner that states the food employee is free from NTS, and where appropriate, approval from the regulatory authority

Nontyphoidal *Salmonella* (NTS) *enterica* serotypes are among the most common bacterial cause of foodborne illness. NTS are estimated to cause more than one million domestically acquired foodborne illnesses in the United States each year (Scallan et. al. 2011), and are the leading cause of hospitalizations and deaths due to foodborne illness in the United States (Barton-Behravesh et al. 2011, CDC 2011). Whereas reductions in incidence have been achieved for many other foodborne pathogens in recent years, no significant change in incidence of NTS infections has occurred since the start of FoodNet surveillance during 1996–1998 (CDC 2011). Therefore, further interventions are needed to reduce the incidence of NTS infections.

Commercial food establishments are an important setting for the transmission of NTS, both in the form of recognized foodborne disease outbreaks as well as sporadic infections. During 1998 to 2002, the 585 *Salmonella enterica* outbreaks reported to the Centers for Disease Control and Prevention accounted for 49% of all bacterial outbreaks (Lynch et al. 2006). Forty-six percent of *Salmonella* outbreaks occurred in restaurant/deli establishments, the most common setting for *Salmonella* outbreaks (Lynch et al. 2006). For the period of 2009-2010, the 243 *Salmonella* outbreaks reported to the CDC accounted for 51% of bacterial foodborne disease outbreaks. Outbreaks of salmonellosis at commercial food establishments frequently involve direct transmission to patrons from fresh produce or undercooked foods of animal origin, or cross contamination from these foods. However, numerous NTS outbreak investigations have implicated food workers as the source of the outbreak or strongly suggested transmission from food workers (Ethelberg et al. 2004; Greig et al. 2007; Hedberg et. al. 1991; Hedican et al. 2009; Hundy and Cameron 2002; Khuri-Bulos et al. 1994; Maguire et al. 2000; Medus et al. 2006; Todd et al 2007a, 2007b).

In a study of restaurant-associated salmonellosis outbreaks in Minnesota published by Medus et al. (2006), the importance of infected food workers as a source of contamination in the outbreaks was supported by several observations. First, a specific food vehicle was statistically implicated or suspected in a low proportion of the restaurant outbreaks (39%), which suggests that the specific food items or food handling errors were not the primary causes for these outbreaks. Second, food workers infected with NTS were identified in the majority (83%) of the outbreak investigations. Infected food workers who reported a history of illness shed NTS in the stool for a median of 1 month. The authors concluded that regardless of the original source of a *Salmonella* outbreak in a restaurant (e.g., raw meat or eggs), the initial source of a salmonellosis outbreak, food workers frequently serve as reservoirs for NTS and contribute to transmission to patrons. Thus, assessment of food worker history, i.e., symptoms and exposures, testing of stool samples and exclusion or restriction of infected food workers from the food establishment are essential for controlling restaurant-associated outbreaks of salmonellosis.

In a study of food workers with salmonellosis who were detected through routine surveillance (Medus et al. 2010), 2.2% of identified culture-confirmed *Salmonella* cases were food workers, and identification of these cases were critical to the identification of numerous outbreaks. The authors concluded that the rapid identification and follow-up of food workers among reported cases of salmonellosis is important to the early detection and control of outbreaks in restaurant settings. Importantly, even hostesses, servers, bartenders, and others who theoretically have limited food preparation duties can serve as sentinels of transmission within the restaurant. The authors also stated that food workers should be considered an important source of *Salmonella* transmission, and those identified through surveillance should raise a high index of suspicion of a possible outbreak at their place of work. Food service managers need to be alert to *Salmonella*-like illnesses among food workers to facilitate prevention and control efforts, including exclusion of infected food workers or restriction of their duties.

The biology of NTS and the epidemiology of salmonellosis are complex; food workers may be an underappreciated part of that complexity. In order to decrease the incidence of NTS infections in the United States, commercial food establishments should also be targets for more focused prevention measures, and prevention and control efforts should consider food workers as an important source of NTS transmission.

General Description:
Nontyphoidal *Salmonella* (NTS) *enterica* are bacteria that cause a diarrheal illness called salmonellosis. NTS are among the most common and important causes of enteric disease. An estimated 1.2 million cases occur annually in the United States; of these, approximately 42,000 are culture-confirmed cases reported to the Centers for Disease Control and Prevention.

Salmonella lives in the intestines of animals or humans. It can be found in water, food, soil, or surfaces that have been contaminated with the feces of infected animals or humans. People can become infected with *Salmonella* by:

- Eating foods contaminated with the bacteria. Contaminated foods are often of animal origin, such as beef, poultry, unpasteurized milk, or eggs. Fruits and vegetables may also be contaminated. Any food can be contaminated by an infected food handler.
- Contacting farm animals or pets (including reptiles, amphibians, chicks, and ducklings), animal feces, or animal environments.
- Touching contaminated surfaces or objects and then touching ones mouth or putting a contaminated object into ones mouth.
- Drinking contaminated water.

Most infections are thought to be acquired through consumption of contaminated food.

Incubation Period:
Symptoms often begin 12 to 72 hours after being exposed to the bacteria, although it can take up to a week or more for symptoms to develop in some people.

Symptoms and Complications:
Symptoms of salmonellosis include diarrhea, abdominal cramps, and fever. The illness usually lasts 4 to 7 days. Persons with NTS infections usually recover without treatment. However, in approximately 20% of persons, the illness is so severe that hospitalization is required. In these patients the NTS infection may spread from the intestine to the blood stream, and then to other body sites and can cause death unless the person is treated promptly with antibiotics. An estimated 400 fatal cases of salmonellosis occur each year. A small number of persons experience long-term consequences from NTS infections, such as arthritis that can last for months or years.

Antibiotic treatment for salmonellosis is generally not indicated for typical intestinal illness. Antibiotics typically do not shorten the duration of illness or eliminate the carrier state. However, antibiotic treatment is recommended for persons who develop invasive (extraintestinal) infections, infants under 2 months of age, the elderly, or those who have certain underlying medical conditions that predispose them to invasive infection.

Infectivity:
The minimum infectious dose of NTS for humans is generally described as 100 to 1,000 organisms. However, doses of fewer than 10 organisms have caused illness in multiple outbreaks. Persistence of NTS in the stool after the acute phase of illness is a well described consequence of NTS infections. This persistence is often referred to as a temporary carrier state, and the term “shedding” is used to describe the excretion of *Salmonella* in the stool.

Studies have consistently shown that the median duration of shedding in the stool to be 4 to 5 weeks after onset of acute gastroenteritis. Persons who have been exposed to NTS but who never develop symptoms can also be temporary carriers of NTS; these persons shed NTS for a shorter period of time than persons who experienced illness. Carriers of NTS are known to shed the bacteria in the stool intermittently. Treatment with antimicrobials does not eradicate NTS from stool and may actually prolong the duration of shedding.

SALMONELLA TYPHI

Salmonella enterica subspecies *enterica* serovar Typhi (commonly *S*. Typhi) causes a systemic bacterial disease, with humans as the only host. This disease is relatively rare in the United States, with fewer than 500 sporadic cases occurring annually in the U.S. Worldwide, the annual estimated incidence of typhoid fever is about 17 million cases with approximately 600,000 deaths. Currently, most cases of ***S.* Typhi** in industrialized nations are imported into the country from developing countries. Antibiotic-resistant strains have become prevalent in several areas of the world.

Incubation period: Generally 1 to 3 weeks, but may be as long as 2 months after exposure.

Symptoms and Complications: High fever, from 103° to 104°F; lethargy; gastrointestinal symptoms, including abdominal pains and diarrhea or constipation; headache; achiness; loss of appetite. A rash of flat, rose-colored spots sometimes occurs. Septicemia, with colonization of other tissues and organs; e.g., may lead to endocarditis. Septic arthritis may occur, in which the infection directly affects the joints and may be difficult to treat. Chronic infection of the gallbladder may occur, which may cause the infected person to become a carrier.

Infectivity: The minimal infectious dose is estimated to be less than 1000 bacterial cells. An individual infected with ***S.* Typhi** is infectious as long as the bacilli appear in the excreta, usually from the first week throughout the convalescence; variable thereafter. About 10% of untreated typhoid fever patients will discharge bacilli for 3 months after onset of symptoms, and 2%-5% become permanent carriers.

SHIGA TOXIN-PRODUCING ESCHERICHIA *COLI*

E. coli O157:H7 is the most commonly identified serotype of Shiga toxin-producing ***Escherichia coli*** (STEC) as a cause of foodborne illness in the United States. ***E. coli*** O157:H7 is a zoonotic disease derived from cattle and other ruminants. However, ***E. coli*** O157:H7 also readily transmits from person-to-person, so contaminated raw ingredients and ill food employees both can be sources of foodborne disease. Other STEC serotypes have been identified as a source of foodborne illness in the United States, however not as frequently as ***E. coli*** O157:H7. The other serogroups most commonly implicated as a cause of foodborne illness in the United States are O26, O111, O103, O45, and O121.

The Food Code definition of STEC covers all ***E. coli*** identified in clinical laboratories that produce Shiga toxins. Nearly 200 O:H combinations of ***E. coli*** have been shown to produce Shiga toxins. The Food Code definition includes all STEC, including those that have not been specifically implicated in human disease such as hemorrhagic colitis (i.e., bloody diarrhea) or hemolytic uremic syndrome (HUS). Infections with STEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). [Note: “enterohemorrhagic” (EHEC) is a subset of STEC that has the capacity to both produce Shiga toxin and cause “attaching and effacing” lesions in the intestine.]

Incubation period: Symptoms usually begin 3 to 4 days after exposure, but the time may range from 1 to 9 days.

Symptoms and Complications: Hemorrhagic colitis is characterized by severe cramping (abdominal pain), nausea or vomiting, and diarrhea that initially is watery, but becomes grossly bloody. In some cases, the diarrhea may be extreme, appearing to consist entirely of blood and occurring every 15 to 30 minutes. Fever typically is low-grade or absent. Infections from EHEC may range from asymptomatic to mild diarrhea to severe, life threatening complications (e.g., hemorrhagic colitis, hemolytic uremic syndrome)). About 3% to 7% STEC infections progress to HUS .

Infectivity: The infective dose of E. coli O157:H7 is estimated to be very low, in the range of 10 to 100 cells. Children under 5 years old are most frequently diagnosed with infection and are at greatest risk of developing HUS. The elderly also experience a greater risk of complications. The duration of excretion of STEC in the stool is typically 1 week or less in adults, but can be up to 3 weeks or longer in one-third of infected children.

SHIGELLA SPP.

Causes an acute bacterial disease, known as shigellosis, and primarily occurs in humans, but also occurs in other primates such as monkeys and chimpanzees. An estimated 300,000 cases of shigellosis occur annually in the U.S. ***Shigella*** spp. consist of 4 species or serogroups, including ***S. flexneri***, ***S. boydii***, ***S. sonnei***, and ***S. dysenteriae***; which all differ in geographical distribution and pathogenicity. ***Shigella*** spp. are highly infectious and highly virulent. Outbreaks occur in overcrowding conditions, where personal hygiene is poor, including in institutions, such as prisons, mental hospitals, day care centers, and refugee camps, and also among men who have sex with men. Water and RTE foods contaminated by feces, frequently from food employees' hands, are common causes of disease transmission. Multidrug-resistant ***Shigella*** (including ***S. dysenteriae*** **type** 1) have appeared worldwide. Concern over increasing antimicrobial resistance has led to reduced use of antimicrobial therapy in treating shigellosis.

Incubation period: Eight to 50 hours.

Symptoms and Complications: Abdominal pain, diarrhea, fever, nausea, and sometimes vomiting, tenesmus, toxaemia, and cramps. The stools typically contain blood, pus, or mucus resulting from mucosal ulcerations. The illness is usually self-limited, with an average duration of 5-7 days. Infections are also associated with rectal bleeding, drastic dehydration, and convulsions in young children. The fatality rate for ***Shigella dysenteriae*** 1 may be as high as 20% among hospitalized cases. Other complications can also occur, such as reactive arthritis, intestinal perforation, and hemolytic uremic syndrome.

Infectivity: The infectious dose for humans is low, with as few as 10 bacterial cells depending on age and condition of the host. Infectivity occurs during acute infection and until the infectious agent is no longer present in feces, usually within 4 weeks after illness. Asymptomatic carriers may transmit infection; rarely, the carrier state may persist for months or longer.

HEPATITIS A VIRUS

Hepatitis A virus (HAV) is a 27-nanometer picornavirus (positive strand RNA, non-enveloped virus). The hepatitis A virus has been classified as a member of the family *Picornaviridae*. The exact pathogenesis of HAV infection is not understood, but the virus appears to invade from the intestinal tract and is subsequently transported to the liver. The hepatocytes are the site of viral replication and the virus is thought to be shed via the bile.

HAV is most commonly spread by the fecal-oral route through person-to-person contact. Risk factors for reported cases of hepatitis A include personal or sexual contact with another case, illegal drug use, homosexual male sex contact, and travel to an endemic country. Common source outbreaks also can occur through ingestion of water or food that has fecal contamination. However, the source of infection is not identified for approximately 50% of reported cases.

HAV infection is endemic in developing countries, and less common in industrialized countries with good environmental sanitation and hygienic practices. In the developing world, nearly all HAV infections occur in childhood and are asymptomatic or cause a mild illness. As a result, hepatitis A (symptomatic infection with jaundice) is rarely seen in the developing world. More than 90% of adults born in many developing countries are seropositive.

Children play an important role in the transmission of HAV and serve as a source of infection for others, because most children have asymptomatic infections or mild, unrecognized HAV infections. In the United States, the disease is most common among school-aged children and young adults. After correction for under-reporting and undiagnosed infections, an estimated 61,000 HAV infections (includes cases of hepatitis A as well as asymptomatic infections) occurred in 2003.

HAV Immunization: Immune globulin (IG) can be used to provide passive pre-exposure immunoprophylaxis against hepatitis A. Protection is immediately conferred to an exposed individual following administration of IG, and immunity is provided for 3-5 months following inoculation. IG is effective in preventing HAV infection when given as post-exposure immunoprophylaxis, if given within 14 days of exposure. When a food employee with hepatitis A is identified, IG is often given to co-workers. Active immunoprophylaxis using hepatitis A vaccine (a formalin-inactivated, attenuated strain of HAV) has been shown to provide immunity in > 95% of those immunized, with minimal adverse reactions.

Hepatitis A vaccination of food employee has been advocated, but has not been shown to be cost-effective and generally is not recommended in the United States, although it may be appropriate in some communities.

Incubation period: Average 28-30 days (range 15-50 days).

Symptoms and Complications: Illness usually begins with symptoms such as nausea/ vomiting, diarrhea, abdominal pain, fever, headache, and/or fatigue. Jaundice, dark urine or light colored stools might be present at onset, or follow illness symptoms within a few days. HAV infection of older children and adults is more likely to cause clinical illness with jaundice (i.e., hepatitis A); onset of illness is usually abrupt. In young adults, 76-97% have symptoms and 40-70% are jaundiced. Jaundice generally occurs 5-7 days after the onset of gastrointestinal symptoms. For asymptomatic infections, evidence of hepatitis may be detectable only through laboratory tests of liver infections such as alanine aminotransferase (ALT) tests. The disease varies in severity from a mild illness to a fulminant hepatitis, ranging from 1-2 weeks to several months in duration. In up to 10-15% of the reported cases, prolonged, relapsing hepatitis for up to 6 months occurs. The degree of severity often increases with age; however, most cases result in complete recovery, without sequelae or recurrence. The reported case fatality rate is 0.1% - 0.3% and can reach 1.8% for adults over 50 years old.

Diagnosis: Diagnosis of HAV infection requires specific serological testing for IgM anti-HAV. IgM anti-HAV becomes undetectable within 6 months of illness onset for most persons; however, some persons can remain IgM anti-HAV positive for years after acute infection. Total anti-HAV (the only other licensed serologic test) can be detected during acute infection but remains positive after recovery and for the remainder of the person's life.

Infectivity: The infective dose of HAV is presumed to be low (10 to 100 viral particles), although the exact dose is unknown. The viral particles are excreted in the feces of ill people (symptomatic and asymptomatic) at high densities (10^6 to 10^8/gm) and have been demonstrated to be excreted at these levels for up to 36 days post-infection. Evidence indicates maximum infectivity during the latter half of the incubation period, continuing for a few days after onset of jaundice. Most cases are probably noninfectious after the first week of jaundice. Chronic shedding of HAV in feces has not been reported. HAV is shed at peak levels in the feces, one to two weeks before onset of symptoms, and shedding diminishes rapidly after liver dysfunction or symptoms appear. Liver dysfunction or symptoms occur at the same time circulating antibodies to HAV first appear. Immunity after infection probably lasts for life; immunity after vaccination is estimated to last for at least 20 years.

Reporting History of Exposure:

The reporting requirements for history of exposure are designed to identify employees who may be incubating an infection due to norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other STEC, typhoid fever, HAV.

Which employees who report exposure are restricted?

- Employees who work in a food establishment serving a highly susceptible population (HSP) facility, except those employees who are exposed to nontyphoidal *Salmonella* (NTS).

Why don't employees who are exposed to nontyphoidal *Salmonella* (NTS) need to be restricted?

- For those employees who are exposed to nontyphoidal *Salmonella,* exposure alone does not necessitate restriction of the employee based on epidemiologic evidence of no increased risk of employees with only a history of exposure versus employees who were infected and diagnosed.

What constitutes exposure?

- Consuming a food that caused illness in another consumer due to infection with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other STEC, typhoid fever, or HAV.
- Attending an event or working in a setting where there is a known disease outbreak.
- Close contact with a household member who is ill and is diagnosed with a listed pathogen.

Why are other guidelines provided, in addition to restriction for employees serving an HSP who report exposure to hepatitis A virus?

- Employees who have had a hepatitis A illness in the past are most likely protected from infection by life-time immunity to hepatitis A infection.
- Immunity developed through immunization or IgG inoculation prevents hepatitis A infection in exposed employees.
- Our standard definition of HSP doesn't apply very well to HAV. Children under 6 years old who become infected with HAV are generally asymptomatic, and while a higher proportion of susceptible elderly who become infected have serious illness, most institutionalized elderly are protected from HAV by prior infection.

What is the period of restriction?

- The period of restriction begins with the most recent time of foodborne or household member exposure and lasts for the usual incubation period of the pathogen as defined in the Control of Communicable Diseases Manual. This is the time that the employee is most likely to begin shedding the pathogen.

    - For norovirus, 48 hours after the most recent exposure
    - For ***Shigella*** spp., 3 days after the most recent exposure
    - For ***E. coli*** O157:H7 or other STEC, 3 days after the most recent exposure
    - For typhoid fever (***S.* Typhi**), 14 days after the most recent exposure
    - For HAV, 30 days after the most recent exposure

What is the period of restriction when exposed to a diagnosed, ill household member?

- While the household member is symptomatic with an infection due to Norovirus, ***Shigella*** spp., ***E coli*** O157:H7 or other STEC, typhoid fever (***S.* Typhi**) or HAV;
- Plus during the usual incubation period of the pathogen of concern:
    - For norovirus, symptomatic period plus 48 hours
    - For ***Shigella*** spp., symptomatic period plus 3 days
    - For ***E. coli*** O157:H7 or other STEC, symptomatic period plus 3 days
    - For typhoid fever (***S.* Typhi**), symptomatic period plus 14 days
    - For HAV, onset of jaundice plus 30 days

What is the appropriate response to a report of exposure to other food employees?

- Employees who report a history of exposure but who do not work in a HSP facility should be reminded of the requirements for reporting illness, avoidance of bare hand contact with RTE foods, and proper hand washing and personal hygiene.

2-201.12 Exclusions and Restrictions.[2]

Refer to public health reasons for § 2-201.11 for actions to take with conditional employees.

It is necessary to exclude food employees symptomatic with diarrhea, vomiting, or jaundice, or suffering from a disease likely to be transmitted through contamination of food, because of the increased risk that the food being prepared will be contaminated such as with a pathogenic microorganism. However, if the food employee is suffering from vomiting or diarrhea symptoms, and the condition is from a non-infectious condition, Crohn's disease or an illness during early stages of a pregnancy, the risk of transmitting a pathogenic microorganism is minimal. In this case, the food employee may remain working in a full capacity if they can substantiate that the symptom is from a noninfectious condition. The food employee can substantiate this through providing to the person in charge medical documentation or other documentation proving that the symptom is from a noninfectious condition.

Because of the high infectivity (ability to invade and multiply) and/ or virulence (ability to produce severe disease), of typhoid fever (***Salmonella* Typhi**) and hepatitis A virus, a food employee diagnosed with an active case of illness caused by either of these two pathogens, whether asymptomatic or symptomatic, must be excluded from food establishments. The exclusion is based on the high infectivity, and/or the severe medical consequences to individuals infected with these organisms. A food employee diagnosed with an active case of illness caused by norovirus, ***Shigella*** spp., STEC, or nontyphoidal *Salmonella* (NTS), is excluded if exhibiting symptoms of vomiting and diarrhea, and then allowed to work as the level of risk of pathogen transmission decreases (See section 2-201.12, Tables #1b, #2 and #3).

The degree of risk for a food employee or conditional employee who is diagnosed with an infection but asymptomatic with regard to symptoms, to transmit a foodborne pathogen decreases with the resolution of symptoms. This risk decreases even further for those employees that are diagnosed with a listed pathogen, but never developed symptoms. The decrease in risk is taken under consideration when excluding and restricting diagnosed food employees and results in a slight difference in the way food employees diagnosed with Norovirus, but asymptomatic with respect to gastrointestinal symptoms are handled (See section 2-201.12, Table #2).

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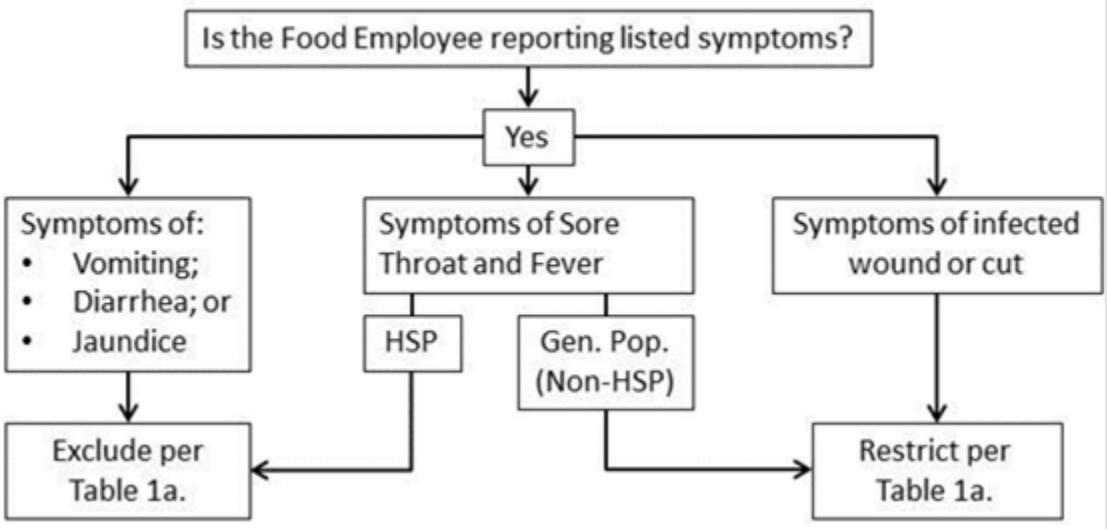
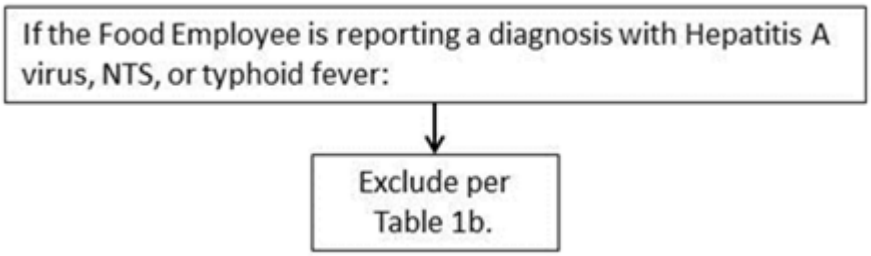
[2]In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

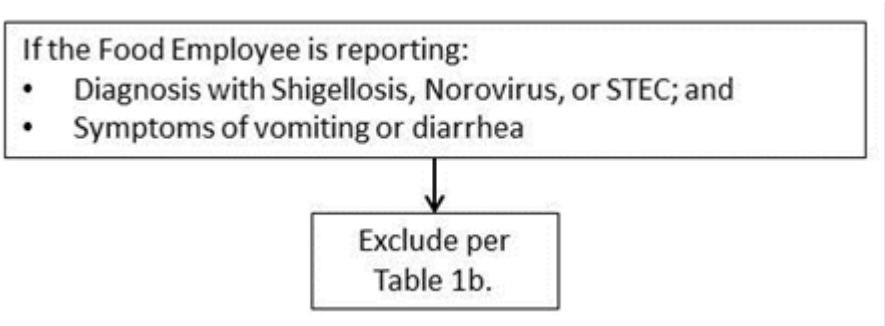
Restriction of food employees infected with NTS after resolution of symptoms has not been a national standard. However, because of the prolonged duration of shedding of NTS, evidence that food workers have been the source of foodborne outbreaks, evidence that food workers work while ill (Green et al. 2005), and evidence of inadequate hand hygiene practices (Green et al. 2006; US FDA 2004), exclusion or restriction of infected food worker duties is a reasonable public health measure. At a minimum, potential for transmission and how to prevent it should be discussed with the food employee and their manager.

There is no epidemiological evidence of an increased risk of NTS transmission from food employees in highly susceptible populations over the general population. Current evidence suggests that restriction is sufficient in food establishments that serve either highly susceptible populations or the non-highly susceptible populations to control transmission on NTS. Further, events where an infected food handler is involved in nontyphoidal salmonellosis outbreaks in establishments serving highly susceptible populations are much less frequent than those in establishments not serving highly susceptible populations. For example, from 1998-2011, only 41 nontyphoidal salmonellosis outbreaks were reported to CDC that occurred in nursing home facilities and 16 outbreaks in hospitals, compared with 731 outbreaks in restaurants or delis. There are many highly susceptible persons in the general population who eat in regular, non-institutionalized settings. A more restrictive exclusion criteria for establishments serving highly susceptible populations is not warranted at this time.

2-201.11 / 2-201.12 Decision Tree 1. When to Exclude or Restrict a Food Employee Who Reports a Symptom and When to Exclude a Food Employee Who Reports a Diagnosis with Symptoms Under the Food Code

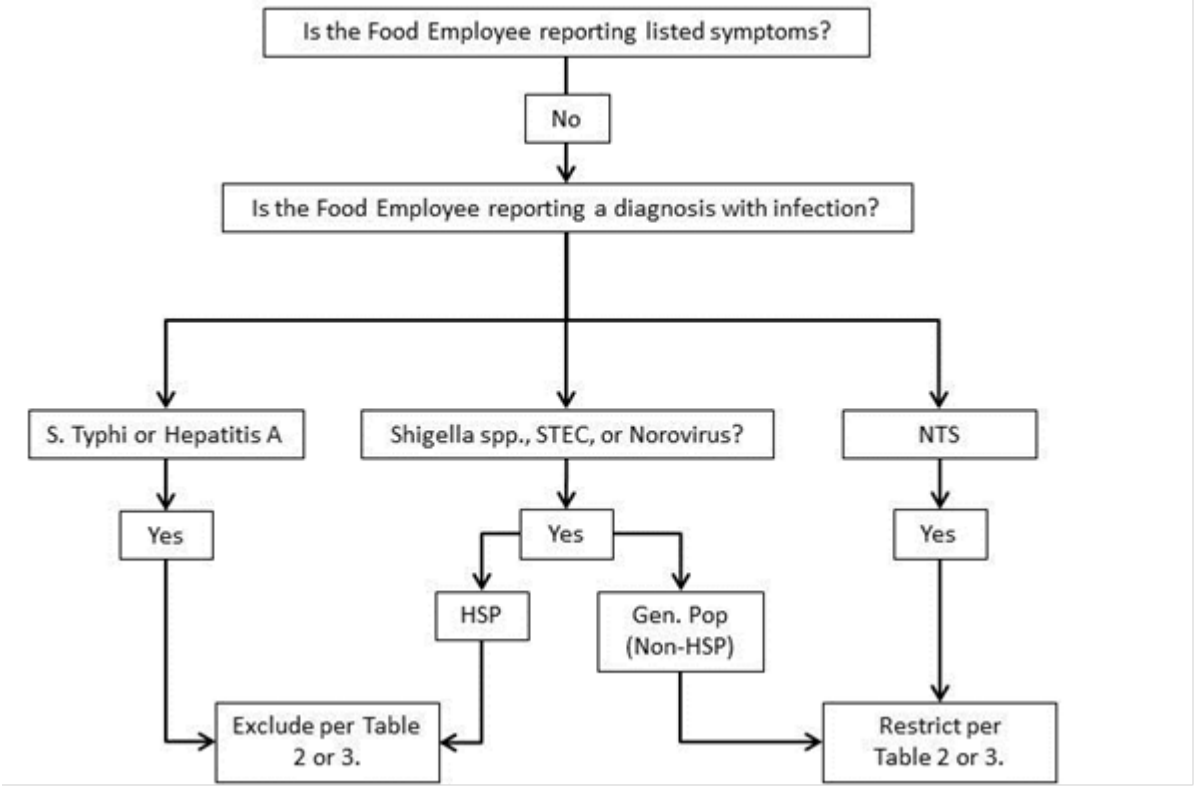






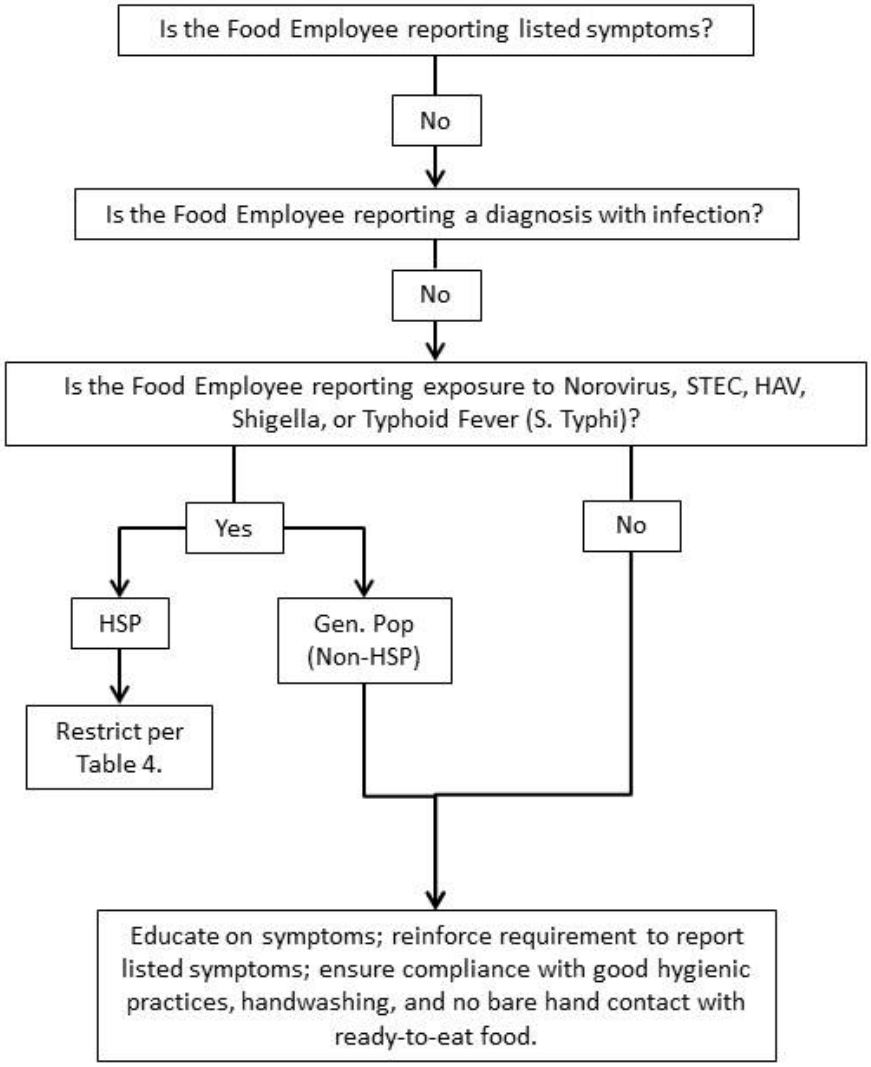
Key: Decision Tree 1
STEC = Shiga toxin-producing *Escherichia coli*
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*

2-201.11 / 2-201.12 Decision Tree 2a. When to Exclude or Restrict a Food Employee Who is Asymptomatic and Reports a Listed Diagnosis Under the Food Code



Key: Decision Tree 2a
STEC = Shiga toxin-producing *Escherichia coli*
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*

2-201.11 / 2-201.12 Decision Tree 2b. When to Restrict a Food Employee Who Reports a Listed Exposure Under the Food Code



Key: Decision Tree 2b
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population

2-201.12 Table 1a: Summary of Requirements for Symptomatic Food Employees

Food employees and conditional employees shall report symptoms immediately to the person in charge

The person in charge shall prohibit a conditional employee who reports a listed symptom from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a symptomatic food employee.

Symptom	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not serving an HSP)	Removing Symptomatic Food Employees from Exclusion or Restriction	RA Approval Needed to Return to Work?
Vomiting	**EXCLUDE** 2-201.12(A)(1)	**EXCLUDE** 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2-201.13(A)(1). ***Exceptions:*** If diagnosed with Norovirus, ***Shigella*** spp., STEC, HAV, or typhoid fever (***S.* Typhi**) (see Tables 1b & 2).	No if not diagnosed
Diarrhea	**EXCLUDE** 2-201.12(A)(1)	**EXCLUDE** 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2-201.13(A). ***Exceptions:*** If Diagnosed with Norovirus, STEC, HAV, or ***S.* Typhi** (see Tables 1b & 2).	No if not diagnosed
Jaundice	**EXCLUDE** 2-201.12(B)(1) if the onset occurred within the last 7 days	**EXCLUDE** 2-201.12(B)(1) if the onset occurred within the last 7 days	When approval is obtained from the RA 2-201.13 (B), and: • Food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • Food employee provides medical documentation 2-201.13(B)(3).	Yes
Sore Throat with Fever	**EXCLUDE** 2-201.12(G)(1)	**RESTRICT** 2-201.12(G)(2)	When food employee provides written medical documentation 201.13(G) (1)-(3).	No
Infected wound or pustular boil	**RESTRICT** 2-201.12(I)	**RESTRICT** 2-201.12(I)	When the infected wound or boil is properly covered 2-201.13(I)(1)-(3).	No

Key: Table 1a
RA = Regulatory Authority
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population

2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees

Food employees and conditional employees shall report a listed Diagnosis with symptoms immediately to the person in charge

- The person in charge shall notify the RA when a food employee is jaundiced or reports a listed diagnosis

- The person in charge shall prohibit a conditional employee who reports a listed diagnosis with symptoms from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed, symptomatic food employee.

Diagnosis	EXCLUSION (Facilities Serving an HSP or Not Serving an HSP)	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
Hepatitis A virus	**EXCLUDE** if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	When approval is obtained from the RA 2-201.13(B), and: • The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3) (also see Table 2).	Yes
Typhoid Fever (***S.* Typhi**)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: • Food employee provides medical documentation, that states the food employee is free of a ***S.* Typhi** infection 2-201.13(C)(2) (also see Table 2).	Yes **(continued)**

Diagnosis	EXCLUSION (Facilities Serving an HSP or Not Serving an HSP)	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
Nontyphoidal *Salmonella*	**EXCLUDE Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)**	When approval is obtained from the RA 2-201.13(G), and: • Food employee provides medical documentation, that states the food employee is free of a nontyphoidal *Salmonella* infection 2-201.13)(G)(1) or • Food employee symptoms of vomiting or diarrhea resolved and >30 days have passed since the food employee became asymptomatic (2-201.13(G)(2)).	Yes
STEC	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving a non-HSP facility: 2-201.13(A)(4)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from RA 2-201.13(F), and • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(F)(2) (also see Table 2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Norovirus	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving a non-HSP facility: 2-201.13 (A)(2)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility **(continued)**

Diagnosis	EXCLUSION (Facilities Serving an HSP or Not Serving an HSP)	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
Shigella spp.	**EXCLUDE Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)**	1. Serving a non-HSP facility: 2-201.13(A)(3)(a): Shall only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(3)(b): Remains excluded until meeting the requirements in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA 2-201.13(E), and • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(E)(2) (also see Table 2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

Key: Table 1b
RA = Regulatory Authority
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*

2-201.12 Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms

Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge

- The person in charge shall notify the RA when a food employee reports a listed diagnosis
- The person in charge shall prohibit a conditional employee who reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee.

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Typhoid fever (***S.* Typhi**) including previous illness with ***S.* Typhi** (see 2-201.11 (A)(3))	**EXCLUDE** 2-201.12(C)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: • Food employee provides medical documentation that states the food employee is free of an ***S.* Typhi** infection 2-201.13)(C)(2) (also see Table 1b).	Yes
Nontyphoidal *Salmonella*	**RESTRICT** 2-201.12(G)	**RESTRIC**T 2-201.12(G)	When approval is obtained from the RA 2-201.13(G), and: • Food employee provides medical documentation, that states the food employee is free of a nontyphoidal *Salmonella* infection 2-201.13)(G)(1) or • Food employee symptoms of vomiting or diarrhea resolved and >30 days have passed since the food employee became asymptomatic (2-201.13(G)(2)).	Yes **(continued)**

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Shigella spp.	**EXCLUDE** 2-201.12(E)(1)	**RESTRICT** 2-201.12(E)(2)	1. <u>Serving a non-HSP facility</u>: 2-201.13(A)(3)(a): Shall only work on a restricted basis 24 hours after symptoms resolve, and remains restricted until meeting the requirements listed in No. 3. 2. <u>Serving an HSP facility</u>: 2-201.13(A)(3)(b): Remains excluded until meeting the requirements listed in No. 3. 3. <u>Restriction or Exclusion remains until:</u> • Approval is obtained from the RA 2-201.13(E), and: • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 201.13(E)(3)(a) (also see Table 1b).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility **(continued)**

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Norovirus	**EXCLUDE 2-201.12(D)(1)**	**RESTRICT 2-201.12(D)(2)**	1. Serving a non-HSP facility: 2-201.13(A)(2)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 1b).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
STEC	**EXCLUDE 2-201.12(F)(1)**	**RESTRICT 2-201.12(F)(2)**	1. Serving a non-HSP facility: 2-201.13(A)(4)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed in No. 3. 2. Serving an HSP facility: 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed in No. 3. 3. Restriction or Exclusion remains until: • Approval is obtained from the RA 2-201.13(F), and • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(F)(2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility **(continued)**

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Hepatitis A virus	**EXCLUDE if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)**	**EXCLUDE if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)**	When approval is obtained from the RA 2-201.13(B), and: • The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3) (see also Table 1b).	Yes

Key: Table 2
RA = Regulatory Authority
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*

2-201.12 Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms

Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge

- The person in charge shall notify the RA when a food employee reports a listed diagnosis
- The person in charge shall prohibit a conditional employee who reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Typhoid Fever (***S.* Typhi**) including previous illness with ***S.* Typhi** (see 2-201.11 (A)(3))	**EXCLUDE** 2-201.12(C)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: Food employee provides medical documentation, specifying that the food employee is free of a ***S.* Typhi** infection 2-201.13(C)(2).	Yes
Shigella spp.	**EXCLUDE** 2-201.12(E)(1)	**RESTRICT** 2-201.12(E)(2)	Remains excluded or restricted until approval is obtained from the RA, and: • Medically cleared 2-201.13(E)(1), or • More than 7 calendar days have passed since the food employee was last diagnosed 2-201.13(E)(3).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Nontyphoidal *Salmonella*	**RESTRICT** 2-201.12(G)	**RESTRICT** 2-201.12(G)	When approval is obtained from the RA 2-201.13(G), and: • Food employee provides medical documentation, that states the food employee is free of a nontyphoidal *Salmonella* infection 2-201.13)(G)(1) or • Food employee did not develop symptoms and >30 days have passed since the food employee was diagnosed (2-201.13(G)(3)).	**(continued)**

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	EXCLUSION OR RESTRICTION (Facilities Not Serving an HSP)	Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Norovirus	**EXCLUDE** 2-201.12(D)(1)	**RESTRICT** 2-201.12(D)(2)	Remains excluded or restricted until approval is obtained from the RA 2-201.13(D), and • Medically cleared 2-201.13(D)(1), or • More than 48 hours have passed since the food employee was diagnosed 2-201.13(D)(3).	Yes to return to an HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
STEC	**EXCLUDE** 2-201.12(F)(1)	**RESTRICT** 2-201.12(F)(2)	Remains excluded or restricted until approval is obtained from the RA 2-201.13(F), and: • Medically cleared 2-201.13(F)(1), or • More than 7 calendar days have passed since the food employee was diagnosed 2-201.13(F)(3).	Yes to return to HSP or to return unrestricted; Not required to work on a restricted basis in a non-HSP facility
Hepatitis A virus	**EXCLUDE** 2-201.12(B)(3)	**EXCLUDE** 2-201.12(B)(3)	When approval is obtained from the RA 2-201.13(B), and • The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or • The food employee provides medical documentation 2-201.13(B)(3).	Yes

Key: Table 3
RA = Regulatory Authority
STEC = Shiga toxin-producing *Escherichia coli*
HAV = Hepatitis A virus
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella*

2-201.12 Table 4: History of Exposure, and Absent Symptoms or Diagnosis

Food employees and conditional employees shall report a listed exposure to the person in charge

- The person in charge shall prohibit a conditional employee who reports a listed exposure from becoming a food employee in a facility serving an HSP until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of an exposed food employee

- The person in charge shall reinforce and ensure compliance with good hygienic practices, symptom reporting requirements, proper handwashing and no BHC with RTE foods for all food employees that report a listed exposure

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	Facilities Not Serving an HSP	When Can the Restricted Food Employee Return to Work?	RA Approval Needed?
Typhoid Fever (***S.* Typhi**)	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(3) When 14 calendar days have passed since the last exposure, or more than 14 days has passed since the food employee's household contact became asymptomatic.	No
Shigella spp.	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(2) When more than 3 calendar days have passed since the last exposure, or more than 3 days have passed since the food employee's household contact became asymptomatic.	No
Norovirus	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(1) When more than 48 hours have passed since the last exposure, or more than 48 hours has passed since the food employee's household contact became asymptomatic.	No
STEC	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(2) When more than 3 calendar days have passed since the last exposure, or more than 3 calendar days has passed since the food employee's household contact became asymptomatic.	No

Pathogen Diagnosis	EXCLUSION OR RESTRICTION (Facilities Serving an HSP)	Facilities Not Serving an HSP	When Can the Restricted Food Employee Return to Work?	RA Approval Needed?
Hepatitis A virus	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing and no BHC with RTE foods.	2-201.13(I)(2) When any of the following conditions is met: • The food employee is immune to HAC infection because of a prior illness from HAV, vaccination against HAV, or IgG administration; or • More than 30 calendar days have passed since the last exposure, or since the food employee's household contact became jaundiced; or • The food employee does not use an alternative procedure that allows BHC with RTE food until at least 30 days after the potential exposure, and the employee receives additional training.	No

Key: Table 4
HSP = Highly Susceptible Population
BHC = Bare Hand Contact
RTE = Ready-To-Eat
GHP = Good Manufacturing Practices
STEC = Shiga toxin-producing *Escherichia coli*

2-201.12 Exclusion and Restrictions (continued)[3]

Restrictions and exclusions vary according to the population served because highly susceptible populations have increased vulnerability to foodborne illness. For example, foodborne illness in a healthy individual may be manifested by mild flu-like symptoms. The same foodborne illness may have serious medical consequences in immunocompromised individuals. This point is reinforced by statistics pertaining to deaths associated with foodborne illness caused by ***Salmonella* Enteritidis**. Over 70% of the deaths in outbreaks attributed to this organism occurred among individuals who for one reason or another were immunocompromised. This is why the restrictions and exclusions listed in the Code are especially stringent for food employees serving highly susceptible populations.

Periodic testing of food employees for the presence of diseases transmissible through food is not cost effective or reliable. Therefore, restriction and exclusion provisions are triggered by the active gastrointestinal symptoms, followed by diagnosis and history of exposure.

The history of exposure that must be reported applies to Norovirus, Hepatitis A, *Shigella* spp., STEC and *Salmonella* Typhi. It does not include nontyphoidal *Salmonella*.

Upon being notified of the history of exposure, the person in charge should immediately:

1. Discuss the traditional modes of transmission of fecal-oral route pathogens.

2. Advise the food employee to observe good hygienic practices both at home and at work. This includes a discussion of proper handwashing, as described in the Code, after going to the bathroom, changing diapers, or handling stool-soiled material.

3. Review the symptoms listed in the Code that require immediate exclusion from the food establishment.

4. Remind food employees of their responsibility as specified in the Code to inform the person in charge immediately upon the onset of any of the symptoms listed in the Code.

5. Ensure that the food employee stops work immediately if any of the symptoms described in the Code develop and reports to the person in charge.

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[3]In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

A restricted food employee may work in an area of the food establishment that houses packaged food, wrapped single-service or single-use articles, or soiled food equipment or utensils. Examples of activities that a restricted person might do include working at the cash register, seating patrons, bussing tables, stocking canned or other packaged foods, or working in a non-food cleaning or maintenance capacity consistent with the criteria in the definition of the term "restricted." A food employee who is restricted from working in one food establishment may not work in an unrestricted capacity in another food establishment, but could work unrestricted in another retail store that is not a food establishment. A restricted food employee may enter a food establishment as a consumer.

An excluded individual may not work as a food employee on the premises of any food establishment.

2-201.13 Removal of Exclusions and Restrictions.[4]

Food employees diagnosed with Norovirus, hepatitis A virus**, *Shigella*** spp., ***E. coli*** O157:H7 or other STEC, nontyphoidal *Salmonella* and symptomatic with diarrhea, vomiting, or jaundice, are excluded under subparagraph 2-201.12 (A)(2) or 2-201.12(B)(2). However these symptomatic, diagnosed food employees differ from symptomatic, undiagnosed food employees in the requirements that must be met before returning to work in a full capacity after symptoms resolve.

The person in charge may allow undiagnosed food employees who are initially symptomatic and whose symptoms have resolved to return to work in a full capacity 24 hours after symptoms resolve.

However, diagnosis with a listed pathogen invokes additional requirements before the person in charge may allow diagnosed food employees to return to work in full capacity.

Asymptomatic food employees diagnosed with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other STEC may not return to work in a full capacity for at least 24 hours after symptoms resolve. The person in charge shall only allow these food employees to work on a restricted basis 24 hours after symptoms resolve and they shall only allow this if not in a food establishment that serves a highly susceptible population. These restricted food employees remain restricted until they are medically cleared or otherwise meet the criteria for removal from restriction as specified under subparagraphs 2-201.13(D) (1)-(2); 2-201.13(E)(1)-(2); or 2-201.13(F)(1)-(2).

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[4]In order to comply with Title I of the Americans with Disabilities Act, an exclusion must also be removed if the employee is entitled to a reasonable accommodation that would eliminate the risk of transmitting the disease. Reasonable accommodation may include reassignment to another position in which the individual would not work around food. The steps an employer must take when an excluded employee requests reasonable accommodation are briefly described in Annex 3, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Annex. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. Equal Employment Opportunity Commission.

In a food establishment that serves a highly susceptible population, food employees who are diagnosed with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other STEC and initially symptomatic with vomiting or diarrhea, shall not work on a restricted basis after being asymptomatic for at least 24 hours. These food employees must remain excluded until they are medically cleared or otherwise meet the criteria for removal from exclusion from a highly susceptible population under subparagraph 2-201.13(D)(1)-(2), 2-201.13(E)(1)-(2), or 2-201.13 (F)(1)-(2).

Food employees diagnosed with **hepatitis A virus** are always excluded if diagnosed within 14 days of exhibiting any illness symptom, until at least 7 days after the onset of jaundice, or until medically cleared as specified under subparagraphs 2-201.13(B)(1)-(4).

Food employees diagnosed with **hepatitis A virus** are always excluded if diagnosed within 14 days of exhibiting any illness symptom, until at least 7 days after the onset of jaundice, or until medically cleared as specified under subparagraphs 2-201.13(B)(1)-(3). A food employee with an anicteric infection with the hepatitis A virus has a mild form of hepatitis A without jaundice. Food employees diagnosed with an anicteric infection with the hepatitis A virus are excluded if they are within 14 days of any symptoms. Anicteric, diagnosed food employees shall be removed from exclusion if more than 14 days have passed since they became symptomatic, or if medically cleared. Asymptomatic food employees diagnosed with an active infection with the hepatitis A virus are also excluded until medically cleared.

Food employees diagnosed with typhoid fever (caused by a ***Salmonella* Typhi** infection) are always excluded, even without expressing gastrointestinal symptoms, since these symptoms are not typically exhibited with typhoid fever. Outbreaks of foodborne illness involving typhoid fever (***Salmonella* Typhi**) have been traced to asymptomatic food employees who have transmitted the pathogen to food, causing illness. The high virulence combined with the extremely high infectivity of ***S.* Typhi** warrant exclusion from the food establishment until the food employee has been cleared by a physician or has completed antibiotic therapy.

Asymptomatic shedders are food employees who do not exhibit the symptoms of foodborne illness but who are identified through diagnosis, or laboratory confirmation of their stools to have Norovirus, or any one of the four bacterial pathogens identified in Chapter 2 in their gastrointestinal system.

The risk that food employees who are asymptomatic shedders will transmit a communicable disease varies depending upon the hygienic habits of the worker, the food itself and how it is prepared, the susceptibility of the population served, and the infectivity of the organism. Exclusion in a food establishment that serves a highly susceptible population affords protection to people who are immune-suppressed. Restriction in a food establishment that does not serve a highly susceptible population affords protection for the general population and the immune-suppressed subset of the general population provided there is adequate attention to personal hygiene and avoidance of bare-hand contact with RTE foods.

To minimize the risk in all food establishments of the transmission of foodborne disease by an asymptomatic shedder and based on the factors listed above, all known asymptomatic shedders of the four bacterial pathogens are either restricted or excluded, depending on the population served. Requiring restriction for asymptomatic shedders of all three of the bacterial pathogens results in a uniform criterion and is consistent with APHA-published recommendations in the "Control of Communicable Diseases Manual."

Hands and Arms **2-301.11 Clean Condition.**

The hands are particularly important in transmitting foodborne pathogens. Food employees with dirty hands and/or fingernails may contaminate the food being prepared. Therefore, any activity which may contaminate the hands must be followed by thorough handwashing in accordance with the procedures outlined in the Code.

Even seemingly healthy employees may serve as reservoirs for pathogenic microorganisms that are transmissible through food. Staphylococci, for example, can be found on the skin and in the mouth, throat, and nose of many employees. The hands of employees can be contaminated by touching their nose or other body parts.

2-301.12 Cleaning Procedure.

Handwashing is a critical factor in reducing fecal-oral pathogens that can be transmitted from hands to RTE food as well as other pathogens that can be transmitted from environmental sources. Many employees fail to wash their hands as often as necessary and even those who do may use flawed techniques.

In the case of a food worker with one hand or a hand-like prosthesis, the Equal Employment Opportunity Commission has agreed that this requirement for thorough handwashing can be met through reasonable accommodation in accordance with the Americans with Disabilities Act. Devices are available which can be attached to a lavatory to enable the food worker with one hand to adequately generate the necessary friction to achieve the intent of this requirement.

The greatest concentration of microbes exists around and under the fingernails of the hands. The area under the fingernails, known as the “subungal space”, has by far the largest concentration of microbes on the hand and this is also the most difficult area of the hand to decontaminate. Fingernail brushes, if used properly, have been found to be effective tools in decontaminating this area of the hand. Proper use of single-use fingernail brushes, or designated individual fingernail brushes for each employee, during the handwashing procedure can achieve up to a 5-log reduction in microorganisms on the hands.

There are two different types of microbes on the hands, transient and resident microbes. Transient microbes consist of contaminating pathogens which are loosely attached to the skin surface and do not survive or multiply. A moderate number of these organisms can be removed with adequate handwashing. Resident microbes consist of a relatively stable population that survive and multiply on the skin and they are not easily washed off the hands. Resident microbes on the hands are usually not a concern for potential contamination in food service.

All aspects of proper handwashing are important in reducing microbial transients on the hands. However, friction and water have been found to play the most important role. This is why the amount of time spent scrubbing the hands is critical in proper handwashing. It takes more than just the use of soap and running water to remove the transient pathogens that may be present. It is the abrasive action obtained by vigorously rubbing the surfaces being cleaned that loosens the transient microorganisms on the hands.

Research has shown a minimum 10-15 second scrub is necessary to remove transient pathogens from the hands and when an antimicrobial soap is used, a minimum of 15 seconds is required. Soap is important for the surfactant effect in removing soil from the hands and a warm water temperature is important in achieving the maximum surfactant effect of the soap.

Every stage in handwashing is equally important and has an additive effect in transient microbial reduction. Therefore, effective handwashing must include scrubbing, rinsing, and drying the hands. When done properly, each stage of handwashing further decreases the transient microbial load on the hands. It is equally important to avoid recontaminating hands by avoiding direct hand contact with heavily contaminated environmental sources, such as manually operated handwashing sink faucets, paper towel dispensers, and rest room door handles after the handwashing procedure. This can be accomplished by obtaining a paper towel from its dispenser before the handwashing procedure, then, after handwashing, using the paper towel to operate the hand sink faucet handles and restroom door handles.

Handwashing done properly can result in a 2-3 log reduction in transient bacteria and a 2-log reduction in transient viruses and protozoa. With heavy contamination of transient microbial pathogens, (i.e., > 10^4 microbes, as found on hands contaminated with bodily wastes and infected bodily fluids) handwashing may be ineffective in completely decontaminating the hands. Therefore, a further intervention such as a barrier between hands and ready-to-eat food is necessary.

2-301.13 Special Handwash Procedures.

This section is reserved.

In earlier editions of the Code, FDA's model contained a provision for a Special Procedure in certain situations. Pursuant to a 1996 Conference for Food Protection (CFP) Recommendation, the text of this Code provision is removed and the section is reserved. It is FDA's intent to further research the matter and to submit the findings to the CFP for reconsideration of the matter.

2-301.14 When to Wash.

The hands may become contaminated when the food employee engages in specific activities. The increased risk of contamination requires handwashing immediately before, during, or after the activities listed. The specific examples listed in this Code section are not intended to be all inclusive. Employees must wash their hands after any activity which may result in contamination of the hands.

2-301.15 Where to Wash.

Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross contamination. It is important that handwashing be done only at a properly equipped handwashing facility in order to help ensure that food employees effectively clean their hands. Handwashing sinks are to be conveniently located, always accessible for handwashing, maintained so they provide proper water temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since this may result in avoidable contamination of the sink and the food prepared therein. Service sinks may not be used for food employee handwashing since this practice may introduce additional hand contaminants because these sinks may be used for the disposal of mop water, toxic chemicals, and a variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food preparation areas and toilet rooms and discharges from ill persons.

2-301.16 Hand Antiseptics.

In the 2005 Food Code, the use of the term “hand sanitizer” was replaced by the term “hand antiseptic” to eliminate confusion with the term “sanitizer,” a defined term in the Food Code, and to more closely reflect the terminology used in the FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use, Federal Register: June 17, 1994.

The term “sanitizer” is typically used to describe control of bacterial contamination of inert objects or articles, or equipment and utensils, and other cleaned food-contact surfaces. The Food Code definition of “sanitizer” requires a minimum microbial reduction of 5 logs, which is equal to a 99.999% reduction. The FDA bases the 5-log reduction on the AOAC International’s “Official Methods of Analysis 2003,” which requires a minimum 5-log reduction in microorganisms to achieve “sanitization.”

Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement. However, removing microorganisms from human skin is a totally different process and sterilization of human skin is nearly impossible to achieve without damaging the skin. Many antimicrobial hand agents typically achieve a much smaller reduction in microorganisms than the 5-log reduction required for “sanitization.” Therefore, the effect achieved from using antimicrobial hand agents is not consistent with the definition of “sanitization” in the Food Code.

The word “antiseptic” is a Greek term, meaning “against putrefaction”, and eventually evolved into a second definition, meaning, “a substance used to destroy pathogenic microorganisms.” The term “antiseptic” is often used to describe agents used on skin to prevent infection of the skin.

“Antiseptic” is defined under section 201 (o) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 (o)), as: “The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation of a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.”

Section 333.403 of the FDA Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use, Federal Register: June 17, 1994, defines a “health-care antiseptic” as an antiseptic-containing drug product applied topically to the skin to help prevent infection or to help prevent cross contamination. An “antiseptic handwash” or “health-care personnel handwash drug product” is defined in Section 333.403 of the Monograph as an antiseptic containing preparation designed for frequent use; it reduces the number of transient microorganisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is a broad spectrum, and persistent antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin.

Replacing the term “hand sanitizer” with the term “hand antiseptic” allows the use of a more scientifically appropriate term that is used to describe reduction of microorganisms on the skin and will improve clarification and regulation of these products.

The provisions of § 2-301.16 are intended to ensure that an antimicrobial product applied to the hands is 1) safe and effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will come into direct contact with food. Because of the need to protect workers and to ensure safe food, hand antiseptics must comply with both the human drug and the food safety provisions of the law. The prohibition against bare hand contact contained in ¶ 3-301.11(B) applies only to an exposed ready-to-eat food.

As a Drug Product

There are two means by which a hand antiseptic is considered to be safe and effective when applied to human skin:

1. A hand antiseptic may be approved by FDA under a new drug application based on data showing safety and effectiveness and may be listed in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations*. (http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. This document is maintained by the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs. Also known as the “Orange Book,” this document provides “product-specific” listings rather than listings by compound and it is published annually with monthly supplements. However, as of the end of 1998, no hand antiseptics are listed in this publication since no new drug applications have been submitted and approved for these products.

2. A hand antiseptic active ingredient may be identified by FDA in the monograph for OTC (over-the-counter) Health-Care Antiseptic Drug Products under the antiseptic handwash category. Since hand antiseptic products are intended and labeled for topical antimicrobial use by food employees in the prevention of disease in humans, these products are "drugs" under the Federal Food, Drug, and Cosmetic Act § 201(g). As drugs, hand antiseptics and dips must be manufactured by an establishment that is duly registered with the FDA as a drug manufacturer; their manufacturing, processing, packaging, and labeling must be performed in conformance with drug Good Manufacturing Practices (GMP's); and the product must be listed with FDA as a drug product.

Products having the same formulation, labeling, and dosage form as those that existed in the marketplace on or before December 4, 1975, for hand antiseptic use by food handlers, are being evaluated under the Over-the-Counter (OTC) Drug Review by FDA's Center for Drug Evaluation and Research. However, as of May 2005, a final OTC drug monograph for these products has not been finalized. Therefore, FDA has not made a final determination that any of these products are generally recognized as safe and effective (GRAS/E).

GRAS/E antimicrobial ingredients for hand sanitizer use by food handlers will be identified in a future final monograph issued under the OTC Drug Review. Information about whether a specific product is covered by the proposed monograph may be obtained from the tentative final monograph (TFM) for "Health Care Antiseptic Drug Products for OTC Human Use; Proposed Rule." This TFM, which was published in the ***Federal Register*** of June 17, 1994 (59 FR 31402), describes the inclusion of hand sanitizers in this Review on page 31440 under Comment 28 of Part II. Information about whether a specific product is included in this proposed monograph may also be available from the manufacturer.

Questions regarding acceptability of a hand antiseptic with respect to OTC compliance may be directed to the Office of Unapproved Drugs and Labeling Compliance, Center for Drug Evaluation & Research Food and Drug Administration 10903 New Hampshire Ave., Building 51, 5th Floor, Silver Spring, MD 20993. Specific product label/promotional information and the formulation are required for determining a product's regulatory status.

<u>As a Food Additive</u>

To be subject to regulation under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the substances in a hand antiseptic must *reasonably* be expected to become a component of food based upon the product's intended use.

Where the substances in a hand antiseptic are reasonably expected to become a component of food based upon the product's intended use, circumstances under which those substances may be legally used include the following:

1. The intended use of a substance may be exempted from regulation as a food additive under 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*. A review by FDA's Center for Food Safety and Applied Nutrition is required in order to determine whether such an exemption can be granted.

2. The intended use of a substance, including substances that contact food such as those in hand antiseptics, may be "generally recognized as safe (GRAS)" within the meaning of the FFDCA. A partial listing of substances with food uses that are generally recognized as safe may be found in CFR Parts 182, 184, and 186.

These lists are not exhaustive because the FFDCA allows for independent GRAS determinations.

For the use of a substance to be GRAS within the meaning of the FFDCA, there must be publicly available data that demonstrate that the substance is safe for its intended use. There also must be a basis to conclude that there is a consensus among qualified experts that these publicly available data establish safety. If the use of a substance in food is GRAS, it is not subject to premarket review by FDA. While there is no legal requirement to notify FDA of an independent GRAS determination, a number of firms have chosen to do so with the expectation of receiving a response letter from FDA (see FDA's Inventory of GRAS Notices at (http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm). Although such a letter does not affirm the independent GRAS determination, it is an opportunity for the firm to receive comment from FDA regarding the materials supporting its determination.

3. The intended use of a substance may be the subject of a prior sanction, which is an explicit approval by the FDA or the United States Department of Agriculture (USDA) prior to September 6, 1958. All known prior sanctions are published under 21 CFR Part 181.

4. A substance may be the subject of a Food Contact Substance Notification that became effective in accordance with the FFDCA Section 409 (h). Substances that are the subject of an effective food-contact substance notification are listed, along with conditions of safe use, in the FDA Inventory of Effective Food Contact Substance (FCS) Notifications. This list is available on-line at: Inventory of Effective Food Contact Substance (FCS) Notifications (http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm). A food-contact substance that is the subject of an effective notification submitted under FFDCA 409(h) does not include similar or identical substances manufactured or prepared by any person other than the manufacturer identified in that notification.

The Division of Food Contact Substance Notifications does not certify or provide approvals for specific products. However, if the intended use of a substance in contact with food meets the requirements of 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*, FDA may provide a letter to a firm stating that the intended use of this product is exempt from regulation as a food additive. However, the product must be the subject of a new drug application or under FDA's OTC Drug Review to be legally marketed.

Questions regarding the regulatory status of substances in hand antiseptics as food additives may be directed to the Division of Food Contact Substance Notifications, HFS-275, 5100 Paint Branch Parkway, College Park, MD 20740. It may be helpful or necessary to provide label/promotional information when inquiring about a specific substance.

Fingernails **2-302.11** **Maintenance.**

The requirement for fingernails to be trimmed, filed, and maintained is designed to address both the cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability concerns and may harbor pathogenic organisms.

Jewelry **2-303.11** **Prohibition.**

Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms transmissible through food.

The term "jewelry" generally refers to the ornaments worn for personal adornment and medical alert bracelets do not fit this definition. However, the wearing of such bracelets carries the same potential for transmitting disease-causing organisms to food. If a food worker wears a medical alert or medical information bracelet, the conflict between this need and the Food Code's requirements can be resolved through reasonable accommodation in accordance with the Americans with Disabilities Act. The person in charge should discuss the Food Code requirement with the employee and together they can work out an acceptable alternative to a bracelet. For example, the medical alert information could be worn in the form of a necklace or anklet to provide the necessary medical information without posing a risk to food. Alternatives to medical alert bracelets are available through a number of different companies (*e.g.,* an internet search using the term "medical alert jewelry" leads to numerous suppliers).

An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for consumers, such as chipped and/or broken teeth and internal cuts and lesions.

Outer Clothing **2-304.11** **Clean Condition.**

Dirty clothing may harbor diseases that are transmissible through food. Food employees who inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In addition, employees wearing dirty clothes send a negative message to consumers about the level of sanitation in the establishment.

Food Contamination Prevention **2-401.11** **Eating, Drinking, or Using Tobacco.**

Proper hygienic practices must be followed by food employees in performing assigned duties to ensure the safety of the food, prevent the introduction of foreign objects into the food, and minimize the possibility of transmitting disease through food. Smoking or eating by employees in food preparation areas is prohibited because of the potential that the hands, food, and food-contact surfaces may become contaminated. Insanitary personal practices such as scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered sneezing or coughing may result in food contamination. Poor hygienic practices by employees may also adversely affect consumer confidence in the establishment.

Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas food employees are allowed to drink from closed containers that are carefully handled.

2-401.12 Discharges from the Eyes, Nose, and Mouth.

Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by food employees can directly contaminate exposed food, equipment, utensils, linens, and single-service and single-use articles. When these poor hygienic practices cannot be controlled, the employee must be assigned to duties that minimize the potential for contaminating food and surrounding surfaces and objects.

Hair Restraints **2-402.11 Effectiveness.**

Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect vehicle of contamination. Food employees may contaminate their hands when they touch their hair. A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching their hair.

Animals **2-403.11 Handling Prohibition.**

Dogs and other animals, like humans, may harbor pathogens that are transmissible through food. Handling or caring for animals that may be legally present is prohibited because of the risk of contamination of food employee hands and clothing.

2-501.11 Clean-up of Vomiting and Diarrheal Events.

When an employee, customer, or other individual vomits or has a diarrheal event in a food establishment, there is a real potential for the spread of harmful pathogens in the establishment. Putting the proper response into action in a timely manner can help reduce the likelihood that food may become contaminated and that others may become ill as a result of the accident.

According to the CDC, Norovirus is the leading cause of foodborne disease outbreaks in the United States. More specifically, Noroviruses are the most common cause of sporadic cases and outbreaks of acute gastroenteritis. Norovirus is the most common cause of gastroenteritis in people of all ages and it is responsible for greater than 50% of all foodborne gastroenteritis outbreaks. CDC estimates that 21 million cases of acute gastroenteritis are due to Norovirus infection.

Noroviruses can be highly contagious, and it is thought that an inoculum of as few as 10-18 viral particles may be sufficient to infect an individual. Transmission occurs via foodborne and person-to-person routes, airborne inhalation of vomitus droplets, and also through contact with contaminated environmental surfaces. Good evidence exists for transmission due to aerosolization of vomitus that presumably results in droplets contaminating surfaces or entering the oral mucosa and being swallowed.

In addition, the potential transmission level of Norovirus shed in the feces at levels up to 1 trillion viral particles per gram of feces and one projectile vomiting incident can contaminate the environment with 300,000 viral particles. One study found that employees who reported having cleaned up vomitus were more likely to contract illness that those who did not.

Norovirus causes acute onset of vomiting (often explosive) and diarrhea (also often explosive) which can contaminate surfaces and become airborne increasing the chances of additional infections. A recent study has also shown that the bathroom environment was identified as a major reservoir of human Norovirus, even in the absence of an ill individual on site. Studies have shown that Norovirus can survive on fomite surfaces for up to at least 5 days at room temperature and that routine cleaning, without a disinfectant specifically to address Norovirus, may be ineffective in eliminating its presence on fomite surfaces and can even serve as a means of spreading the virus to other fomites.

Effective clean up of vomitus and fecal matter in a food establishment should be handled differently from routine cleaning procedures. It should involve a more stringent cleaning and disinfecting process. Some compounds that are routinely used for sanitizing food-contact surfaces and disinfecting countertops and floors, such as certain quaternary ammonium compounds, may not be effective against Norovirus. It is therefore important that food establishments have procedures for the cleaning and disinfection of vomitus and/or diarrheal contamination events that address, among other items, the use of proper disinfectants at the proper concentration.

Consumers are at risk of contracting Norovirus illness from direct exposure to vomitus or from exposure to airborne Norovirus from vomitus. Additionally, exposed food employees are also at risk of contracting Norovirus illness and can subsequently transfer the virus to ready-to-eat food items served to consumers.

The Food Code specifies that the Person in Charge is to exclude or restrict a food employee who exhibits, or reports a symptom, or who reports a diagnosed illness or a history of exposure to Norovirus. A clean-up and response plan is intended to address situations where a food employee or other individual becomes physically ill in areas where food may be prepared, stored or served. Once such an episode has occurred, timely effective clean-up is imperative.

When developing a plan that addresses the need for the cleaning and disinfection of a vomitus and/or diarrheal contamination event, a food establishment should consider:

- the procedures for containment and removal of any discharges, including airborne particulates;
- the procedure for cleaning, sanitizing, and, as necessary, the disinfection of any surfaces that may have become contaminated;
- the procedures for the evaluation and disposal of any food that may have been exposed to discharges;
- the availability of effective disinfectants, personal protective equipment, and other cleaning and disinfecting equipment and appurtenances intended for response and their proper use;
- procedures for the disposal and/or cleaning and disinfection of tools and equipment used to clean up vomitus or fecal matter;
- the circumstances under which a food employee is to wear personal protective equipment for cleaning and disinfecting of a contaminated area;
- notification to food employees on the proper use of personal protective equipment and procedures to follow in containing, cleaning, and disinfecting a contaminated area;
- the segregation of areas that may have been contaminated so as to minimize the unnecessary exposure of employees, customers and others in the facility to the discharges or to surfaces or food that may have become contaminated;
- minimizing risk of disease transmission through the exclusion and restriction of ill employees as specified in §2-201.12 of the Food Code;
- minimizing risk of disease transmission through the prompt removal of ill customers and others from areas of food preparation, service and storage; and
- the conditions under which the plan will be implemented.

When a food employee has been diagnosed, has recent history or exposure to, or is the suspect source of a confirmed disease outbreak of Norovirus, it must be reported to the person in charge per the FDA Food Code in subparagraphs 2-201.11 (A)(2)(a), 2-201.11(A)(4)(a), 2-201.11(A)(5)(a), and ¶2-201.11(B). If a food employee has been diagnosed with Norovirus it must also be reported to the regulatory authority. Refer to public health reasons for §2-201.11 Responsibility of the Person in Charge, Food Employees, and Conditional Employees for more information about appropriate employee health policies.

Condition	**3-101.11**	**Safe, Unadulterated, and Honestly Presented.**
Sources	**3-201.11**	**Compliance with Food Law.**

Refer to the public health reason for § 3-401.11.

Source

A primary line of defense in ensuring that food meets the requirements of § 3-101.11 is to obtain food from approved sources, the implications of which are discussed below. However, it is also critical to monitor food products to ensure that, after harvesting and processing, they do not fall victim to conditions that endanger their safety, make them adulterated, or compromise their honest presentation. The regulatory community, industry, and consumers should exercise vigilance in controlling the conditions to which foods are subjected and be alert to signs of abuse. FDA considers food in hermetically sealed containers that are swelled or leaking to be adulterated and actionable under the Federal Food, Drug, and Cosmetic Act. Depending on the circumstances, rusted and pitted or dented cans may also present a serious potential hazard.

Food, at all stages of production, is susceptible to contamination. The source of food is important because pathogenic microorganisms may be present in the breeding stock of farm animals, in feeds, in the farm environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which plant crops are grown. Chemical contaminants that may be present in field soils, fertilizers, irrigation water, and fishing waters can be incorporated into food plants and animals.

Sources of molluscan shellfish are a particular concern because shellfish are frequently consumed raw or in an undercooked state and thus receive neither heat treatment nor any other process that would destroy or inactivate microbial pathogens. For safety, these foods must be accompanied by certification that documents that they have been harvested from waters that meet the water quality standards contained in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. Certification also provides confidence that processing, packaging, and shipping have been conducted under sanitary conditions.

Food should be purchased from commercial supplies under regulatory control. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food. Because commercial items seldom are eaten right away, the home kitchen's limited capacity for maintaining food at proper temperatures may result in considerable microbial growth and toxin production by microorganisms introduced through the diverse sources of contamination. Controlled processing is required for the safe preparation of food entering commerce.

Labeling - General

Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows consumers to make informed decisions about what they eat. Many consumers, as a result of an existing medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In addition, consumers have a basic right to be protected from misbranding and fraud.

Except for certain species of large tuna and raw molluscan shellfish, if fish are intended for raw consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. Labeling should accompany the product to advise as to whether the product was frozen properly. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Fish

Except for raw molluscan shellfish, certain species of large tuna, certain aquacultured fish, and fish eggs that have been removed from the skein and rinsed, if fish are intended for raw or undercooked consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. Labeling or other information should accompany the product to advise as to whether the product was frozen properly. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Juice

On July 8, 1998, FDA announced in the Federal Register a final rule that revised its food labeling regulations to require a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. FDA took this action to inform consumers, particularly those at greatest risk, of the hazard posed by such juice products. FDA expects that providing this information to consumers will allow them to make informed decisions on whether to purchase and consume such juice products, thereby reducing the incidence of foodborne illnesses and deaths caused by the consumption of these juices.

On July 18, 2001 FDA announced a final rule designed to improve the safety of fruit and vegetable juice and juice products. Under the rule, juice processors must use Hazard Analysis and Critical Control Point (HACCP) principles for juice processing. Processors making shelf-stable juices or concentrates that use a single thermal processing step are exempt from the microbial hazard requirements of the HACCP regulation. Retail establishments where packaged juice is made and only sold directly to consumers (such as juice bars) are not required to comply with this regulation.

Rather, the Food Code requires fresh fruit or vegetable juices that are packaged at retail (untreated juices or beverages containing untreated juices that are offered to consumers as prepackaged foods) to be processed under HACCP with a 5 log reduction in pathogens of concern OR bear the warning statement as specified in 21 CFR Section 101.17(g). That statement is: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." Refer to Chapter 1 for the definition of juice. It is important to note that the definition of "juice" includes puréed fruits and vegetables, which are commonly prepared for service to highly susceptible populations.

Food establishments that serve a highly susceptible population (HSP) cannot serve prepackaged juice that bears the warning label and they must serve only pasteurized juice. For juice only, this population includes children who are age 9 or less and receive food in a school, day care setting, or similar facility that provides custodial care.

Unpackaged juice (glasses of juice prepared at a juice bar, for example) does not require the 5 log reduction nor a warning statement or other consumer advisory (juice is not an animal food and therefore not covered by section 3-603.11) when prepared and served at retail. Usually the juice is served by the glass or in small batches compared to a commercial juice processor. The risk of using "drops" and damaged fruits or vegetables is much less at retail because of buyer specs that provide higher quality produce, meaning that fruits for juicing are less likely to be of a lower quality or damaged.

Additional information is available in the document, "Guidance for Industry: Exemptions from the Warning Label Requirement for Juice - Recommendations for Effectively Achieving a 5-Log Pathogen Reduction; Final Guidance", October 7, 2002 which can be found at:
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm058962.htm or obtained from the FDA Office of Nutritional Products Labeling and Dietary Supplements.

Labeling for Meat and Poultry

Retail food establishments that process and package meat or poultry in a form that is not ready-to-eat, are obligated by Federal regulation to label the product with safe food handling instructions. USDA issued final rules on August 8, 1994 requiring all raw meat or poultry products have a safe-handling label or sticker or be accompanied by a leaflet that contains information on proper handling and cooking procedures. The intent of this requirement is to ensure that all consumers are alerted to the fact that such products may contain bacteria and that food safety hinges upon their thoroughly cooking the product, regardless of where they obtain the products. That is, the labeling would exist if they obtain their meat and poultry at an establishment that handles only prepackaged and prelabeled products or if they obtain their meat or poultry at an operation such as a supermarket with a meat processing operation or from a small neighborhood butcher.

Labeling Guidance for Irradiated Raw Meat and Meat Products

In December 1999, the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) issued a final regulation to permit the use of ionizing radiation to reduce foodborne pathogens, including *Escherichia coli O*157:H7, and extend the shelf life of raw refrigerated and frozen meat and meat products (Irradiation of Meat Food Products 64 *Federal Register* 72150, December 23, 1999).

The final regulations are published in Title 9 of the Code of Federal Regulations (9 CFR 424.21 Use of food ingredients and sources of radiation and provide that raw refrigerated products may receive a maximum absorbed dose of no more than 4.5 kGy, and that frozen product receive no more than 7.0 kGy, in accordance with the FDA restrictions provided for in Title 21 of the Code of Federal Regulations (21 CFR 179.26(a) Ionizing radiation for the treatment of food, (a) Energy sources). The regulations further require that all irradiated meat and meat products bear labeling that reflects that the product was irradiated, or that the product contains an irradiated meat or poultry product. This labeling requirement is applicable even at retail facilities where irradiated coarse ground beef might be finely ground for retail sale, or in cases where irradiated product is combined with other non-irradiated meat or poultry product for retail sale.

In cases where the entire package of product is irradiated, the labeling must include both a statement and the international symbol, called the radura. Additionally, the product name must include the word “irradiated,” or the labeling must bear a disclosure statement such as, “treated with radiation” or “treated by irradiation.” If either statement is used, the logo must be placed in conjunction with the statement. If an irradiated meat or meat product is used to formulate a multi-ingredient product with other non-irradiated components, the irradiated meat ingredient must be identified as such in the ingredients statement, but the logo is not required. For example, the ingredients statement for a Chicken and Beef Sausage product that contains irradiated beef would be, Ingredients: chicken, irradiated beef, seasonings (salt, pepper, spice), and the logo would not be required to be present.

All labels for products produced at federally inspected establishments bearing statements about irradiation must be submitted to USDA/FSIS for evaluation and approval prior to use.

Optional labeling statements about the purpose of the irradiation process may be included on the labeling of irradiated products provided they are not false or misleading and have been evaluated first by USDA/FSIS. If such statements indicate a specific benefit from irradiation, such as a reduction of microbial pathogens, such statements must be substantiated by processing documentation and validated through the processing and Hazard Analysis and Critical Control Point (HACCP) system. Such validation and documentation of the HACCP system would only be applicable in federally inspected establishments.

Because irradiation can substantially reduce and, in some situations, eliminate any detectable level of pathogenic bacteria, it is important that the meat products be held at the proper refrigerated temperatures to prevent growth of any pathogens present, and that the packaging is not compromised. Although co-mingling irradiated beef with non-irradiated meat or poultry is not prohibited under the current regulations, USDA/FSIS believes that such a process would decrease the benefit of irradiation by potentially exposing the irradiated product to pathogenic bacteria. While FSIS considers such comingling to be highly unlikely, if it did occur, a statement advising the consumer that the product contains both irradiated and non-irradiated components would be required.

The Radura, International Symbol:

Further information about labeling irradiated raw meat is available through Directive 7700.1, Irradiation of Meat and Poultry Products, on the USDA/FSIS website at http://www.fsis.usda.gov/wps/wcm/connect/058dd732-7fc8-4787-a283-30ed50d6f7e0/7700.1Rev1.pdf?MOD=AJPERES. Irradiation Questions & Answers can be found at http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/irradiation-and-food-safety.

Labeling for Raw Shell Eggs

The Code of Federal Regulations 21 CFR 101.17 **Food Labeling warning, notice, and safe handling statements**, paragraph (h) *Shell* eggs state in subparagraph (1), "The label of all shell eggs, whether in intrastate or interstate commerce, shall bear the following statement: 'SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria; keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.'" Further, in subparagraph (4) it states, "Shell eggs that have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (h) of this section."

Labeling for Whole-muscle, Intact Beef Steaks

In order for a food establishment operator to know that a steak is a whole-muscle, intact cut of beef that can therefore be undercooked and served without a consumer advisory, the incoming product must be labeled. Processors can accommodate this need at the retail level by developing proposed labels, obtaining the necessary USDA Food Safety Inspection Service review and approval, and appropriately affixing the labels to their products.

Refer also to public health reason for § 3-602.11.

3-201.12 Food in a Hermetically Sealed Container.

Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern is the lethal toxin of ***Clostridium botulinum***, an organism whose spores (i.e., survival stages for non-growth conditions) are found throughout the environment. Even slight underprocessing of low acid food which is canned can be dangerous, because spoilage microbes are killed and there are no signs to warn consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these foods are not processed to be commercially sterile, they must be received frozen or under proper refrigeration.

Refer also to the public health reason for §§ 3-101.11 and 3-201.11.

3-201.13 Fluid Milk and Milk Products.

Milk, which is a staple for infants and very young children with incomplete immunity to infectious diseases, is susceptible to contamination with a variety of microbial pathogens such as Shiga toxin-producing ***Escherichia coli***, ***Salmonella*** spp., and ***Listeria monocytogenes***, and provides a rich medium for their growth. This is also true of milk products. Pasteurization is required to eliminate pathogen contamination in milk and products derived from milk. Dairy products are normally perishable and must be received under proper refrigeration conditions.

3-201.14 Fish.

After December 18, 1997, all processors of fish are required by 21 CFR 123 to have conducted a hazard analysis of their operation, identify each hazard that is reasonably likely to occur, and implement a HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have complied with this requirement. Hazards known to be associated with specific fish species are discussed in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and drugs.

The seafood implicated in histamine poisoning are the scombroid toxin-forming species, defined in 21 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family **Scombridae**, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that allow the growth of mesophilic bacteria.

Ciguatera toxin is carried to humans by contaminated fin fish from the extreme southeastern U.S., Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel, large groupers, and snappers are particularly likely to contain ciguatoxin. Many other species of large predatory fishes may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack, and snapper are frequently ciguatoxic, and many other species both large and small are suspect. Mackerel and barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

RECREATIONALLY CAUGHT FISH

Recreationally caught fish received for sale or service may be approved by the regulatory authority. The EPA recognizes that fish are a healthy part of our diet and recognizes fishing as an all-American recreational pastime, however, they add the cautionary note that some individuals, such as pregnant women and small children, may need to limit their intake of certain noncommercial fish. Recreationally caught fish may contain possible contaminants that may pose health risks. Fish advisories can be found in EPA Listing of Fish Advisories the EPA website at: http://www.epa.gov/waterscience/fish/.

States issue fish consumption advisories if elevated concentrations of chemicals such as mercury or dioxin are found in local fish. For most people, the risk from mercury by eating fish is not a health concern. Yet, some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system. Therefore, the FDA and the EPA recently advised women who may become pregnant, pregnant women, nursing mothers, and young children to avoid some types of fish and eat fish and shellfish that are lower in mercury. (http://www.epa.gov/waterscience/fishadvice/advice.html).

State-issued advisories apply primarily to non-commercial fish obtained through sport, recreation, and subsistence activities. Each advisory is different; it may recommend unrestricted, limited, or totally restricted consumption; may be targeted to everyone or limited to women, children, or other people at risk; and may apply to certain species or sizes of fish or a specific waterbody.

States may issue safe-eating guidelines in addition to issuing fish advisories. A fish advisory is issued to warn the public of the potential human health risks from chemical contamination of certain species from particular types of waterbodies such as lakes, rivers, and/ or coastal waters within the State. In contrast, a safe-eating guideline is issued to inform the public that fish from specific waterbodies have been tested for chemical contaminants and the fish from these waters are safe to eat without consumption restrictions.

Regulatory authorities are encouraged to monitor and review the National Listing of Fish Advisories (See August 2004 EPA Fact Sheet at http://www.epa.gov/waterscience/fish/advisories/factsheet.pdf as well as the local listings, as part of the decision-making process regarding the approval of recreationally caught fish being used in food establishments.

3-201.15 Molluscan Shellfish.

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses.
Pathogens from the harvest area are of particular concern in molluscan shellfish because: 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

To minimize the risk of molluscan shellfish containing pathogens of sewage origin, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times or under certain restrictions from others. Shellfish Control Authorities then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been allowed.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the name, address, and certification number of the shucker-packer or repacker.

Pathogens, such as ***Vibrio vulnificus***, ***Vibrio parahaemolyticus***, ***Vibrio cholerae***, and ***Listeria monocytogenes*** that may be present in low numbers at the time that molluscan shellfish are harvested, may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. The length of time is dependant upon either the month of the year or the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

Paralytic shellfish poisoning (PSP) results from shellfish feeding upon toxic microorganisms such as dinoflagellates. In the U.S., PSP is generally associated with the consumption of molluscan shellfish from the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, dungeness crabs, tanner crabs, and red rock crabs.

Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

For diarrhetic shellfish poisoning there has been no documented occurrence to date in the U.S. However, instances have been documented in Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada.

Amnesic shellfish poisoning (ASP) is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of Mexico, although the algae that produce the toxin have been found there. ASP toxin has recently been identified as a problem in the viscera of dungeness crab, tanner crab, red rock crab, and anchovies along the west coast of the United States.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite, cooperative action plan involving Federal and State public health officials and the shellfish industry. Those groups work together to improve shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

3-201.16 Wild Mushrooms.

Over 5000 species of fleshy mushrooms grow naturally in North America. The vast majority have never been tested for toxicity. It is known that about 15 species are deadly and another 60 are toxic to humans whether they are consumed raw or cooked. An additional 36 species are suspected of being poisonous, whether raw or cooked. At least 40 other species are poisonous if eaten raw, but are safe after proper cooking.

Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species. In most parts of the country there is at least one organization that includes individuals who can provide assistance with both identification and program design. Governmental agencies, universities, and mycological societies are examples of such groups.

Regulatory authorities have expressed their difficulty in regulating wild harvested mushrooms at retail. There are many different approaches in regulating the sale and service of wild harvested mushrooms. The differences in approach could be due to geography, the type of wild mushrooms that typically grow in a particular region and/or local/state laws that are enforced. The Conference for Food Protection (CFP) has attempted to develop a national model or standards for regulatory programs to address and recognize wild harvested mushroom identification. The difficulty in trying to get consensus on national model/standards lies in the question of what is the best national model/standard available that state/local regulatory authorities can apply in a meaningful way to ensure wild harvested mushrooms sold at retail are obtained from a safe source.

With the change in the codified text, the regulatory authority will have the flexibility to apply their laws and/or policies for wild harvested mushroom identification. At a minimum, when developing a wild harvest mushroom identification program, the following elements should be addressed:

- Developing resources & criteria to select wild mushroom species for service or sale,

- Establishing record-keeping and traceability to assure safety of wild harvested mushrooms,
- Written buyer specifications that include:
    a. Identification by the scientific name and the common name of the mushroom species,
    b. A statement that the mushroom was identified while in the fresh states,
    c. The name and contact information of the person who identified the mushroom and the mushroom seller, and
    d. A statement as to the qualifications and training of the identifier, specifically related to mushroom identification.
- Development of qualifications and training curriculum that could be used for further training of mushroom identifiers

In addition, the CFP has guidance material titled "Draft Model Guidance for Wild Harvested Mushrooms" posted on their website at www.foodprotect.org so state and local regulatory authorities can use the information to develop and implement their own wild harvested mushroom program. The guidance document is still a work in progress.

Refer also to the public health reason for §§ 3-101.11 and 3-201.11.

3-201.17 Game Animals.

The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the human host. In addition to the risk posed to consumers of game that is not subject to an inspection program, there is risk to those who harvest and prepare wild game because they may contract infectious diseases such as rabies or tularemia.

Specifications for Receiving **3-202.11 Temperature.**

Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all, types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant levels in properly refrigerated foods that are not out of date. USDA published a final rule (63 FR 45663, August 27, 1998 Shell Eggs; Refrigeration and Labeling Requirements) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7.2ºC (45ºF).

High temperatures for a long enough time, such as those associated with thorough cooking, kill or inactivate many types of microorganisms. However, cooking does not always destroy the toxins produced in foods by certain bacteria (such as the enterotoxins of ***Staphylococcus aureus***). Cooking or hot holding that follows temperature abuse may not make the food safe. Keeping cooked foods hot as required in the Code prevents significant regrowth of heat-injured microorganisms and prevents recontamination with bacteria that are newly introduced.

3-202.12 Additives.

It is imperative for safety that food supplies come from sources that are in compliance with laws regarding chemical additives and contaminants.

Food additives are substances which, by their intended use, become components of food, either directly or indirectly. They must be strictly regulated. In excessive amounts or as a result of unapproved application, additives may be harmful to the consumer. Unintentional contaminants or residues also find their way into the food supply. The tolerances or safe limits designated for these chemicals are determined by risk assessment evaluations based on toxicity studies and consumption estimates.

Food and Color additives must be used in compliance with a federal food, or color additive regulation, an effective food-contact notification, or a threshold of regulation exemption. Such regulations, notifications, and exemptions are generally composed of three parts: the *identity* of the substance, *specifications* including purity or physical properties, and *limitations* on the conditions of use. In order for a food, or color additive use to be in compliance, the use must comply with all three criteria.

Federal Food Additive regulations are found in Title 21 CFR, Parts 172-180. Color additive regulations are found in Title 21 CFR Parts 73-Subpart A, 74-Subpart A, 81 and 82. Effective food-contact notifications are listed at http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=fcsListing&displayAll=false&page=17, and threshold of regulation exemptions are listed at http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ThresholdRegulationExemptions/ucm093685.htm.

Other substances that are added to food include those prior sanctioned for use in food by either the FDA or USDA, or those generally recognized as safe for their intended use in food. Some of these are listed in Title 21 CFR Parts 181-186, Title 9 CFR Section 424.21(b) and at http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm. Tolerances and exemptions from tolerance for pesticide chemical residues in or on food are found in Title 40 CFR Part 180. Substances that are prohibited form use in human food are listed in Title 21 CFR Part 189.

3-202.13 Eggs.

Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good growth medium for many types of bacteria. Damaged eggs must not be used as food.

The Definition of "Restricted Egg" contains several terms that are explained in this paragraph. An egg may be restricted because it is a/an:

(i) "Check" meaning an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.

(ii) "Dirty egg or Dirties" meaning an egg that has a shell that is unbroken and has adhering dirt, foreign material, or prominent stains.

(iii) "Incubator reject" meaning an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.

(iv) "Inedible" meaning eggs of the following descriptions: Black rots, yellow rots, white rots, mixed rots, sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).

(v) "Leaker" meaning an egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.

(vi) "Loss" meaning an egg that is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

On December 5, 2000 Federal regulations were amended to require that shell egg cartons bear safe handling instructions and be placed under refrigeration at 45°F or lower upon delivery at retail establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

- 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5 Inappplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or destruction of shell eggs…
- 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling statements, (h) *Shell eggs*.
- 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

The labeling rule became effective September 4, 2001, and the refrigeration rule became effective June 4, 2001. These rules are one part of a larger farm-to-table approach for ensuring the safety of our nation's egg supply. The public health goal is a 50 percent reduction in all salmonellosis and a 50 percent reduction in ***Salmonellae* Enteritidis** illnesses by 2010.

3-202.14 Eggs and Milk Products, Pasteurized.

Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other harmful microorganisms likely to be in these time/temperature control for safety foods. Freezing and drying of unpasteurized products will stop microbial growth and may reduce their bacterial populations; however, some organisms will survive because neither process invariably kills bacteria. Under certain conditions, freezing and drying may preserve microbes. An alternative to pasteurization may be applicable to certain cheese varieties cured or aged for a specified amount of time prior to marketing for consumption.

3-202.15 Package Integrity.

Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the contained food. If the integrity of the packaging has been compromised, contaminants such as ***Clostridium botulinum*** may find their way into the food. In anaerobic conditions (lack of oxygen), botulism toxin may be formed.

Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods. Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many cases, suspect packaging may have to be inspected by trained persons using magnifying equipment. Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate can damage or imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate that not enough heat was applied during processing (underprocessing). Suspect cans must be returned and not offered for sale.

3-202.16 Ice.

Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice that comes into contact with food to cool it or that is used directly for consumption must be as safe as drinking water that is periodically tested and approved for consumption.

3-202.17 Shucked Shellfish, Packaging and Identification.

Plastic containers commonly used throughout the shellfish industry for shucked product bear specific information regarding the source of the shellfish as required by the NSSP Guide for the Control of Molluscan Shellfish. These containers must be nonreturnable so that there is no potential for their subsequent reuse by shellfish packers which could result in shucked product that is inaccurately identified by the label. The reuse of these containers within the food establishment must be assessed on the basis of the Food Code's criteria for multi-use containers and the likelihood that they will be properly relabeled to reflect their new contents.

3-202.18 Shellstock Identification.

Accurate source identification of the harvesting area, harvester, and dealers must be contained on molluscan shellstock identification tags so that if a shellfish-borne disease outbreak occurs, the information is available to expedite the epidemiological investigation and regulatory action.

3-202.19 Shellstock, Condition.

Dirty, damaged, or dead shellstock can contaminate and degrade live and healthy shellstock and lead to foodborne illness. Harvesters have the primary responsibility for culling shellstock, but this responsibility continues throughout the distribution chain.

3-202.110 Juice Treated.

Refer to public health reason for § 3-801.11.

Original Containers and Records

3-203.11 Molluscan Shellfish, Original Container.

Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their source. Proper identification is needed for tracing the origin and determining conditions of shellfish processing and shipment. If the lots are commingled at retail, traceability is undermined and the root of the problem may remain undetected. If no causative factors are identified in the food establishment, tracing the incriminated lot helps in identifying products that need to be recalled or growing waters that may need to be closed to harvesting.

When shucked shellfish are prepackaged in consumer self service containers, the labeling information as specified under section 3-202.17 must be recorded on a log sheet to correlate with the date of sale of the consumer sized containers.

3-203.12 Shellstock, Maintaining Identification.

Accurate records that are maintained in a manner that allows them to be readily matched to each lot of shellstock provide the principal mechanism for tracing shellstock to its original source. If an outbreak occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus infections, which have an incubation period that is significantly longer than other shellfish-borne diseases, to come to light. The 90 day requirement is based on the following considerations:

Shelf-life of the product	14 days
Incubation period	56 days
Medical diagnosis and confirmation	5 days
Reporting	5 days
Epidemiological investigation	10 days
Total	90 days

In reality and as stated in the provision, the 90-day "clock" starts at the time the container of shellstock is emptied. Starting from the date of harvest is not correct because the shellstock may be sold/consumed in less than the 14 days of shelf life cited in the chart above. Therefore, the 90 days may expire and the tag discarded before an illness is reported and investigated.

Shellstock could be frozen in the food establishment during the 14-day estimated shelf life period, which would effectively stop the clock on the shelf life. The shellstock could be thawed and consumed past the 14-day shelf life. In this case, the 90 days would expire before consumption if the clock started 90 days from the harvest date.

Freezing shellstock in the food establishment is not usually done because, although oysters-in-the-shell can be frozen with fair results, they do not have the same texture and appearance of a fresh oyster when thawed. Commercially frozen oysters are frozen rapidly to retain product quality.

Preventing Contamination by Employees

3-301.11 Preventing Contamination from Hands.

In November 1999, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) concluded that bare hand contact with ready-to-eat foods can contribute to the transmission of foodborne illness and agreed that the transmission could be interrupted. The NACMCF recommended exclusion/restriction of ill food workers as the first preventative strategy and recognized that this intervention has limitations, such as trying to identify and manage asymptomatic food workers.

The three interdependent critical factors in reducing foodborne illness transmitted through the fecal-oral route, identified by the NACMCF, include exclusion/restriction of ill food workers; proper handwashing; and no bare hand contact with ready-to-eat foods. Each of these factors is inadequate when utilized independently and may not be effective. However, when all three factors are combined and utilized properly, the transmission of fecal-oral pathogens can be controlled. Depending on the microbial contamination level on the hands, handwashing with plain soap and water, as specified in the Food Code, may not be an adequate intervention to prevent the transmission of pathogenic microbes to ready-to-eat foods via hand contact with ready-to-eat foods. Handwashing as specified in the Food Code will reduce microbial contamination of the hands by 2-3 logs.

Food employees and conditional employees infected with fecal-oral pathogens can shed viral and protozoan pathogens in the feces at levels up to 10^8 viral particles or oocysts per gram of feces. Having a high potential contamination level on the hands combined with a very low infectious dose necessary to cause infection are the reasons that FDA believes that handwashing alone is not an effective single barrier in the transmission of these fecal-oral pathogens. The infective dose for ***Giardia*** and ***Cryptosporidium*** is believed to be as low as 1-10 oocysts, and as few as 10 virus particles can infect an individual with Norovirus or hepatitis A.

The CDC now estimates that Norovirus is the leading cause of foodborne illness in the United States. Contaminated hands are a significant factor in the transmission of enteric viruses, including Norovirus and hepatitis A virus. Further, contamination of food by an infected food worker is the most common mode of transmission of hepatitis A in foodborne disease outbreaks. Research has shown the viral transfer rate from contaminated hands to ready-to-eat food to be about 10% and that proper handwashing will significantly reduce the chance of transmitting pathogenic viruses. However, with heavy initial contamination of the hands, especially in the subungal space of the fingers, a basic 2-3 log reduction handwash procedure may not be adequate to prevent the transmission of viral foodborne illness.

Even though bare hands should never contact exposed, ready-to-eat food, thorough handwashing is important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the food.

If a ready-to-eat food is being added as an ingredient to a food item that is subsequently subjected to a pathogen kill step (such as adding cheese or other ready-to-eat toppings to a pizza dough or adding vegetables to a raw meat dish before cooking) then strict prohibition of bare hand contact is not necessary. Cooking foods to the temperatures required in the Food Code will reduce the likelihood of survival of pathogens that might be transferred from an employee's hands to the surface of the ready-to-eat foods. The exception specifically targets bare hand contact with ready-to-eat food at the time it is added as an ingredient to food that will be cooked in the food establishment to the minimum temperatures specified in the Food Code. The exception does not apply when adding ready-to-eat foods as ingredients to foods that will only be lightly heated, melted, or browned rather than cooked to the minimum temperatures specified in this section. Nor does this exception apply when adding ready-to-eat foods as ingredients to foods that are intended for preparation by the consumer offsite. When proper heat treatment is used in combination with the exclusion/restriction of ill food workers and proper handwashing, the proper heat treatment provides an additional means of interrupting disease transmission.

Refer to the public health reasons for §§ 2-301.11, 2-301.12, and 2-301.14.

3-301.11(E) Prior Approval for Food Employees to Touch Ready-to-Eat Food with Bare Hands

Infected food employees are the source of contamination in approximately one in five foodborne disease outbreaks reported in the United States with a bacterial or viral cause.[1] Most of these outbreaks involve enteric, i.e., fecal-oral agents. These are organisms that employees were shedding in their stools at the time the food was prepared. Because of poor or nonexistent handwashing procedures, workers spread these organisms to the food. In addition, infected cuts, burns, or boils on hands can also result in contamination of food. Viral, bacterial, and parasitic agents can be involved.

Traditionally, food regulations have required two methods of preventing the spread of foodborne disease by this mode of transfer, i.e., they have prohibited food workers from preparing food when they are infectious and have required thorough and frequent handwashing. In order to strengthen fecal-oral transmission interventions, the Food Code provides focused and specific guidance about ill workers and when handwashing must occur. As a final barrier, bare-hand contact with ready-to-eat food (i.e., food that is edible without washing or is not subsequently subjected to a pathogen kill step) is prohibited and suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment are required to be used.

[1]Based on CDC Summary Surveillance for Foodborne-Disease Outbreaks – United States, 1988-1992 and New York State Department of Health data 1980-1991 published: Weingold, Guzewich, Fudala, 1994, Use of Foodborne Disease Data for HACCP Risk Assessment. J. Food Prot. 53: 820-830.

Because highly susceptible populations include persons who are immunocompromised, the very young and the elderly, establishments serving these populations may not use alternatives to the no bare hand contact with ready-to-eat food requirement.

Acceptability of an alternative procedure to no bare hand contact requires prior approval from the regulatory authority based on the food establishment having a written employee health policy that details how the establishment complies with management of ill employees as specified under sections 2-201.11 - .13 and management of handwashing practices as specified under Part 2-3 of the Code. The approval should also be based on evidence provided through written procedures and documentation that at least all of the following are addressed:

(A) **Personal Cleanliness, i.e., handwashing** procedures, including frequency and methodology of handwashing that ensure food employees keep their hands and fingertips clean and handwashing occurs at the times specified in section 2-301.14, including after using the toilet and between tasks that may recontaminate the hands.

(B) **Hygienic Practices** as specified in Part 2-4.

(C) **Employee Health** regarding:

(1) **Reporting of diseases and medical conditions,** and

(2) **Exclusions and restrictions,** i.e., that food employees and conditional employees report their health status as specified in section 2-201.11; ill food employees are restricted or excluded as specified in section 2-201.12; and the exclusions and restrictions are removed as specified in section 2-201.13;

(D) **How the alternative practices and procedures will control the hazard through an active managerial control program.** Such a program includes monitoring and verifying the institution of the provisions described in paragraphs A-C above and satisfies the following:

(1) The public health hazard associated with bare hand contact specific to the food establishment operation is identified and understood. The regulatory authority needs assurance that the permit holder recognizes that the hazard being addressed is the possible contamination of ready-to-eat food by viral and parasitic as well as bacterial pathogens that are transferred from employees' hands.

(2) The ready-to-eat foods that will be contacted with bare hands are identified and both procedures and practices are in place so that food employees wash their hands before returning to their work station and cross-contamination from touching raw and ready-to-eat food is precluded.

For example, identifying the specific type of food to be prepared, such as tacos, and the specific location, such as a situation where a food employee is assigned solely to the designated taco work station. The work station is located immediately adjacent to the taco assembly unit and the employee will be preparing only the specified ready-to-eat food using bare hands.

Another example could be a food employee who is responsible solely for assembling a variety of ready-to-eat foods.

(3) Institution of an effective training program for food employees that emphasizes not working when ill with any of the gastrointestinal symptoms listed in the Code, and explains good hygienic practices, proper handwashing procedures, and safe food preparation procedures. This should include a documented training plan that specifies how management responsibility for training has been designated, training program content, and the frequency of administration including periodic refresher sessions.

(E) The alternative procedure should clearly describe monitoring, documentation, and verification actions to ensure that the practices and procedures are followed. Corrective actions need to be predetermined for situations where the practices and procedures are not followed, e.g., an ill employee is found preparing foods.

(F) Documentation of the practices, procedures, and corrective actions related to an alternative to no bare hand contact with ready-to-eat food must be maintained and readily available at the food establishment at all times for use by the person in charge and for review by the regulatory authority.

Preventing Food and Ingredient Contamination

3-302.11 Packaged and Unpackaged Food – Protection Separation, Packaging, and Segregation.

It is important to separate foods in a ready-to-eat form from raw animal foods during storage, preparation, holding and display to prevent them from becoming contaminated by pathogens that may be present in or on the raw animal foods. An exception is permitting the storage and display of frozen, commercially packaged raw animal food adjacent to or above frozen, commercially packaged ready-to-eat food. The freezer equipment should be designed and maintained to keep foods in the frozen state. Corrective action should be taken if the storage or display unit loses power or otherwise fails. Raw or ready-to-eat foods or commercially processed bulk-pack food that is packaged on-site presents a greater risk of cross-contamination. Additional product handling, drippage during the freezing process, partial thawing or incomplete seals on the package increase the risk of cross-contamination from these products packaged in-house.

With regard to the storage of different types of raw animal foods as specified under subparagraph 3-302.11(A)(2), it is the intent of this Code to require separation based on anticipated microbial load and raw animal food type (species). Separating different types of raw animal foods from one another during storage, preparation, holding and display will prevent cross-contamination from one to the other. The required separation is based on a succession of cooking temperatures as specified under § 3-401.11 which are based on thermal destruction data and anticipated microbial load. For example, to prevent cross-contamination, fish and pork, which are required to be cooked to an internal temperature of 145°F for 15 seconds, shall be stored above or away from raw poultry, which is required to be cooked to an internal temperature of 165°F for 15 seconds due to its considerably higher anticipated microbial load. In addition, raw animal foods having the same cooking temperature, such as pork and fish, shall be separated from one another during storage and preparation by maintaining adequate spacing or by placing the food in separate containers because of the potential for allergen cross-contamination or economic adulteration via inadvertent species substitution.

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons delivering, stocking, or opening packages or overwraps. Packaging must be appropriate for preventing the entry of microbes and other contaminants such as chemicals. These contaminants may be present on the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when the packaging is opened. The removal of food product overwraps may also damage the package integrity of foods under the overwraps if proper care is not taken.

3-302.12 Food Storage Containers, Identified with Common Name of Food.

Certain foods may be difficult to identify after they are removed from their original packaging. Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the consumer has specifically requested that it not be used, may result in severe medical consequences.

The mistaken use of food from unlabeled containers could result in chemical poisoning. For example, foodborne illness and death have resulted from the use of unlabeled salt, instead of sugar, in infant formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble cleaning compounds are also of particular concern.

3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.

Raw or undercooked eggs that are used in certain dressings or sauces are particularly hazardous because the virulent organism ***Salmonella* Enteritidis** may be present in raw shell eggs. Pasteurized eggs provide an egg product that is free of pathogens and is a ready-to-eat food. The pasteurized product should be substituted in a recipe that requires raw or undercooked eggs.

3-302.14 Protection from Unapproved Additives.

Refer to the public health reason for § 3-202.12.

Use of unapproved additives, or the use of approved additives in amounts exceeding those allowed by food additive regulations could result in foodborne illness, including allergic reactions. For example, many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning" of fruits and vegetables or to cause ground meat to look "redder" or fresher.

The concern for misuse of additives also applies to food establishments operating under a variance and to Annex 6 Food Processing Criteria which addresses the use of sodium nitrite or other curing agents in smoking and curing operations. However, if this process is done incorrectly, it could cause illness or death because of excessive nitrite or because the food is insufficiently preserved.

3-302.15 Washing Fruits and Vegetables.

Pathogenic microorganisms, such as *Salmonella* spp., and chemicals such as pesticides, may be present on the exterior surfaces of raw fruits and vegetables. It has been assumed that washing removes the majority of organisms and/or chemicals present; however, more recent studies have demonstrated washing to fall short of their complete removal. Biofilm development by *Salmonella* allows bacterial cells to survive under adverse environmental conditions and also reduces the ability to remove pathogens by washing, even with antimicrobial agents. All fresh produce, except commercially washed, pre-cut, and bagged produce, must be thoroughly washed under running, potable water or with chemicals as specified in Section 7-204.12, or both, before eating, cutting or cooking. Even if you plan to peel or otherwise alter the form of the produce, it is still important to remove soil and debris first.

Infiltration of microorganisms can occur through stem scars, cracks, cuts or bruises in certain fruits and vegetables during washing. Once internalized, bacterial pathogens cannot be removed by further washing or the use of sanitizing solutions. To reduce the likelihood of infiltration, wash water temperature should be maintained at 10°F warmer than the pulp temperature of any produce being washed. Because certain fruits and vegetables are susceptible to infiltration of microorganisms during soaking or submersion, it is recommended that soaking or submerging produce during cleaning be avoided. It is important to follow practices that minimize pathogens in the water or on the surface of produce. It is important that proper handwashing procedures are followed, in accordance with Section 2-301.12 Cleaning Procedure, before and after handling fresh produce.

Scrubbing with a clean brush is only recommended for produce with a tough rind or peel, such as carrots, cucumbers or citrus fruits that will not be bruised easily or penetrated by brush bristles. Scrubbing firm produce with a clean produce brush and drying with a clean cloth towel or fresh disposable towel can further reduce bacteria that may be present. Washing fresh fruits and vegetables with soap, detergent or other surfactants should be avoided as they facilitate infiltration and may not be approved for use on food. Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations. Unless otherwise stipulated in 21 CFR 173.315, chemicals used to wash or peel fruits and vegetables should not exceed the minimum amount required to accomplish the intended effect, need to be accurately tested for proper concentration, and must adhere to any indications as dictated on the product label.

Many pre-cut, bagged produce items are pre-washed. If so, these products will be identified as such on the package label, and can be used as ready-to-eat without further washing. The label should also state if further washing is recommended or necessary. Precut or prewashed produce in open bags should not be washed before use. After being cut, certain produce such as melons, leafy greens and tomatoes are considered time/temperature control for safety food (TCS) requiring time/temperature control for safety and should be refrigerated at 41°F or lower to prevent any pathogens that may be present from multiplying. For more retail food guidance on the storage and handling of tomatoes, leafy greens, and other produce, you may consult the FDA Program Information Manual, Retail Food Protection Storage and Handling of Tomatoes, dated October 5, 2007, available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113843.htm, the document, Time as a Public Health Control for Cut Tomatoes, dated June 8, 2010 available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm215053.htm
and the FDA Program Information Manual, Recommendations for the Temperature Control of Cut Leafy Greens during Storage and Display in Retail Food Establishments dated July 7, 2010 available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm218750.htm

On October 26, 1998 a voluntary guidance document for the produce industry which addresses microbial hazards and good agricultural and management practices commonly used by fresh fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance contains useful information related to washing fruits and vegetables as well as the application of antimicrobial agents and was updated on August 19, 2003. This "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables", October 26, 1998, is available from FDA's Food Safety Initiative staff and also on the Internet at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064574.htm.

Additionally, in February 2008, the FDA Center for Food Safety and Applied Nutrition (CFSAN) issued "Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables," which covers fresh-cut fruits and vegetables that have been minimally processed (e.g. no kill step) and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. This guide is available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm.

On January 11, 2006 FDA/CFSAN published additional safe handling advice on the purchase, storage, and preparation of fresh produce, as well as Q & A's for consumers on their website at: http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm114299.htm. This document is available in PDF (3.5 MB) format (also available in Spanish) and provides additional information on the cleaning of fresh produce.

Preventing Contamination from Ice Used as a Coolant	**3-303.11**	**Ice Used as Exterior Coolant, Prohibited as Ingredient.**

Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and other contaminants. For example, ice used to store or display fish or packaged foods could become contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient, it could contaminate the final product.

3-303.12 Storage or Display of Food in Contact with Ice and Water.

Packages that are not watertight may allow entry of water that has been exposed to unsanitary exterior surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water to the food that is unclaimed in the food's formulation and label.

Unpackaged foods such as fresh fish are often stored and/or displayed on ice. A potential for increasing the microbial load of a food exists because, as the ice melts, pathogens from one food may be carried by water to other foods. The potential for contamination is reduced by continuous draining of melting ice.

Preventing Contamination From Equipment, Utensils, and Linens

3-304.11 Food Contact with Equipment and Utensils.

Pathogens can be transferred to food from utensils that have been stored on surfaces which have not been cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly from used tableware or food containers.

Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such contamination. The handles of utensils, even if manipulated with gloved hands, are particularly susceptible to contamination.

Probe-type price or identification tags are defined as a utensil. This means that if such tags are for multiuse, they must meet the criteria listed in Parts 4-1 Materials for Construction and Repair, and 4-2 Design and Construction. Probe-type price or product identification tags can cause microbial, chemical, or physical contamination if not properly designed, constructed, and maintained.

The Food Code defines gloves as a "utensil" and therefore gloves must meet the applicable requirements related to utensil construction, cleaning, and storage.

3-304.12 In-Use Utensils, Between-Use Storage.

Refer to the public health reason for § 3-304.11.

Once a food employee begins to use a utensil such as a ladle, spatula, or knife, that has been previously cleaned and sanitized, it is then considered an in-use utensil. In-use utensils, used on a continuous or intermittent basis during preparation or dispensing, must be cleaned and sanitized on a schedule that precludes the growth of pathogens that may have been introduced onto utensil surfaces. In-use utensils may be safely stored in hot water maintained at 135°F or above during intermittent use because microbial growth is controlled at such temperatures.

A food utensil should be designed and used to prevent bare hand contact with ready-to-eat food or to minimize contact with food that is not in a ready-to-eat form. On-site evaluations can be made to determine if a utensil is improperly designed for the task or whether a food employee is misusing an appropriately designed utensil.

3-304.13 Linens and Napkins, Use Limitation.

Because of their absorbency, linens and napkins used as liners that contact food must be replaced whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to become fomites.

3-304.14 Wiping Cloths, Use Limitation.

Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must be stored in a sanitizer solution of adequate concentration between uses. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper sanitizer concentration should be ensured by checking the solution periodically with an appropriate chemical test kit.

Wiping down a surface with a reusable wet cloth that has been properly stored in a sanitizer solution is an acceptable practice for wiping up certain types of food spills and wiping down equipment surfaces. However, this practice does not constitute cleaning and sanitizing of food contact surfaces where and when such is required to satisfy the methods and frequency requirements in Parts 4-6 and 4-7 of the Food Code.

The same is true of the practice of wiping down a surface using dry disposable towels and a spray bottle containing pre-mixed sanitizing solution. This practice is not prohibited, however it alone does not constitute proper cleaning and sanitizing of food contact surfaces where and when such is required to satisfy the methods and frequency requirements in Parts 4-6 and 4-7 of the Food Code.

Further, for the purpose of wiping up food spills from surfaces in situations where full cleaning and sanitizing is not required (such as when a soft drink overflows onto the side of a cup or onto a countertop) the use of dry cloths and disposable towels is also acceptable as long as the cloth or towel is used for no other purpose. Again, this does not constitute a proper cleaning and sanitizing procedure for a food contact surface, when such is called for in 4-6 and 4-7 of the Food Code.

In order to effectively clean and sanitize food contact surfaces, where and when required to satisfy the requirements in Parts 4-6 and 4-7 of the Food Code, the surface must be first cleaned properly to remove organic material. In most cases this requires use of detergents or other cleaners such as described in Section 4-603.14 of the Food Code. After the surface is clean to sight and touch, a sanitizing solution of adequate temperature with the correct chemical concentration should then be applied to the surface. The sanitizing solution must stay on the surface for a specific contact time as specified in this Code and in accordance with the manufacturer's EPA-registered label, as applicable.

3-304.15 Gloves, Use Limitation.

Refer to the public health reason for § 3-304.11.

Gloves used in touching ready-to-eat food are defined as a "utensil" and must meet the applicable requirements related to utensil construction, good repair, cleaning, and storage.

Multiuse gloves, especially when used repeatedly and soiled, can become breeding grounds for pathogens that could be transferred to food. Soiled gloves can directly contaminate food if stored with ready-to-eat food or may indirectly contaminate food if stored with articles that will be used in contact with food. Multiuse gloves must be washed, rinsed, and sanitized between activities that contaminate the gloves. Hands must be washed before donning gloves. Gloves must be discarded when soil or other contaminants enter the inside of the glove.

Slash-resistant gloves are not easily cleaned and sanitized. Their use with ready-to-eat foods could contaminate the food.

Natural Rubber Latex (NRL) Gloves

Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves (refer to Annex 2, 3-304.15). This information should be taken into consideration when deciding whether single-use gloves made of latex will be used during food preparation.

Although many allergic reactions occur as a result of occupational exposure, CFSAN is actively reviewing its current policy on the use of disposable NRL gloves in food operations in light of the possible transmission of the latex protein via food. To gain additional information regarding allergic reactions allegedly due to the ingestion of food contaminated by NRL in retail settings, CFSAN has been collecting reports of such reactions from consumers who have contacted the Agency. Several offices within CFSAN will continue to collaborate in reviewing incoming data. The results of these activities and other related efforts will be used to determine if policy changes regarding the use of latex in food operations, based on food safety considerations, are warranted.

The FDA, Office of Food Additive Safety, Division of Food Contact Notification, reviews gloves submitted for food-contact use in the food industry on the basis of the glove's formulation or components. FDA regulates NRL gloves used for medical purposes only.

FDA is aware of the following information related to occupational hazards (not food safety hazards) associated with the use of NRL gloves:

- The National Institute for Occupational Safety and Health (NIOSH) published a 1997 Alert titled "Preventing Allergic Reactions to Natural Rubber Latex in the Workplace" (NIOSH publication number 97-135) which is found at http://www.cdc.gov/niosh/docs/97-135/.

- The American College of Allergy, Asthma and Immunology (ACAAI) and the American Academy of Allergy Asthma and Immunology (AAAAI) issued a joint statement discouraging the routine use of NRL gloves by food handlers. (1997) http://www.acaai.org/public/physicians/joint.htm.

  The AAAAI provides information on latex allergies on the web at http://www.aaaai.org/patients/allergic_conditions/latex_allergy.stm.

  The ACAAI provides information on latex allergies on the web at http://www.acaai.org/public/facts/latex.htm.

- An OSHA Technical Information Bulletin recommends reducing allergy potential by reducing unnecessary exposure to NRL. Stating "Food service workers ... do not need to use NRL gloves for food handling..." (1999) http://www.latexallergylinks.org/LA-TIB.html.

OSHA addresses gloves in the following Federal regulation, which can be found at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9788.

OSHA Regulations (Standards - 29 CFR)
Standard Number: 1910.138
Standard Title: Hand Protection.

SubPart Number: I
SubPart Title: Personal Protective Equipment

(a) General requirements. Employers shall select and require employees to use appropriate hand protection when employees' hands are exposed to hazards such as those from skin absorption of harmful substances; severe cuts or lacerations; severe abrasions; punctures; chemical burns; thermal burns; and harmful temperature extremes.

(b) Selection. Employers shall base the selection of the appropriate hand protection on an evaluation of the performance characteristics of the hand protection relative to the task(s) to be performed, conditions present, duration of use, and the hazards and potential hazards identified.

3-304.16 Using Clean Tableware for Second Portions and Refills.

Refer to the public health reason for § 3-304.11.

3-304.17 Refilling Returnables.

Food establishments may provide multi-use to-go containers to consumers with the intention that the containers are to be returned to the food establishment for refilling or reuse. These containers are likely to be soiled when the consumer returns the container to the food establishment. As a result, pathogens may be transferred to food by consumers or employees directly, or indirectly, from used take-home food containers. The existing provisions in the Food Code, specifically the cleaning and sanitization provisions in Parts 4-6 and 4-7, if carried out properly upon return of a used container, are sufficient to ensure that the container is safe to refill or reuse if performed in conjunction with a visual inspection by a food employee to verify that the container still meets the intent of the provisions in Parts 4-1 and 4-2. Reusing single-service and single-use articles is prohibited by the Food Code.

The refilling of consumer-owned, personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups, and promotional beverage glasses, by a consumer or food employee introduces the possibility of contamination of the filling equipment or product by improperly cleaned containers or the improper operation of the equipment. To prevent this contamination and possible health hazards to the consumer, the refilling of consumer-owned, personal take-out beverage containers is limited to beverages that are not potentially hazardous (time/temperature control for safety) foods. Equipment must be designed to prevent the contamination of the equipment and means must be provided to clean the containers at the facility.

Preventing Contamination from the Premises

3-305.11 Food Storage.
3-305.12 Food Storage, Prohibited Areas.

Pathogens can contaminate and/or grow in food that is not stored properly. Drips of condensate and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

3-305.13 Vended Time/Temperature Control for Safety Food, Original Container.

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended time/temperature control for safety food allows microbes that may be present an opportunity to contaminate the food. Pathogens could be present on the hands of the individual packaging the food, the equipment used, or the exterior of the original packaging. In addition, time/temperature control for safety foods are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

3-305.14 Food Preparation.

Food preparation activities may expose food to an environment that may lead to the food's contamination. Just as food must be protected during storage, it must also be protected during preparation. Sources of environmental contamination may include splash from cleaning operations, drips form overhead air conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing food in a building that is not constructed according to Food Code requirements.

Preventing Contamination by Consumers

3-306.11 Food Display.

During display, food can be contaminated even when there is no direct hand contact. Many microbes can be conveyed considerable distances on air currents through fine sprays or aerosols. These may originate from people breathing or sneezing, water sprays directed at drains, or condensate from air conditioners. Even wind gusts across sewage deposits and fertilized fields have been known to contaminate food in adjacent establishments where food was unprotected.

3-306.12 Condiments, Protection.

Unpackaged condiments are exposed to contamination by consumers who could be suffering from a disease transmissible through food. Once the condiments are contaminated, subsequent consumers using the condiments may be exposed to pathogens. Condiments in individual packages are protected from consumer contamination.

On- or off-site facilities for refilling condiment dispensers must be adequately equipped to ensure that the filling operation does not introduce contaminants.

3-306.13 Consumer Self-Service Operations.

Raw foods of animal origin usually contain pathogens. In addition, these foods, if offered for consumer self-service, could cross contaminate other foods stored in the same display. Because raw foods of animal origin are assumed to be contaminated and do provide an ideal medium for the growth of pathogenic organisms, they should not be available for consumer self-service. Self-service operations of ready-to-eat foods also provide an opportunity for contamination by consumers. The risk of contamination can be reduced by supplying clean utensils and dispensers and by employee monitoring of these operations to ensure that the utensils and dispensers are properly used.

Bean sprouts that are displayed in produce areas for consumer self-service are time/temperature control for safety foods and appropriate refrigeration must be maintained. However, they are not considered ready-to-eat since they are intended to be washed by the consumer before consumption.

3-306.14 Returned Food and Re-Service or Sale.

Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus. Any unpackaged foods, even bakery goods in a bread basket that are not time/temperature control for safety foods and that have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic microorganisms from the initial consumer to the next if the food is served again.

Preventing Contamination from Other Sources

3-307.11 Miscellaneous Sources of Contamination.

This Code section provides a category in which to capture sources of contamination not specifically delineated in Subparts 3-301 through 306. Codes prior to 1993 had such a provision for addressing food contamination for reasons other than those elsewhere specified. Regardless of its specificity, a Code can not anticipate all the diverse means by which food can become contaminated after receipt.

Cooking	**3-401.11**	**Raw Animal Foods.**
	3-401.12	**Microwave Cooking.**
	3-401.13	**Plant Food Cooking for Hot Holding.**

Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the food, and the food's bulk which affects the time to achieve the needed internal product temperature. Other factors to be considered include post-cooking heat rise and the time the food must be held at a specified internal temperature.

Greater numbers and varieties of pathogens generally are found on poultry than on other raw animal foods. Therefore, a higher temperature, in combination with the appropriate time is needed to cook these products.

To kill microorganisms, food must be held at a sufficient temperature for the specified time. Cooking is a scheduled process in which each of a series of continuous time/temperature combinations can be equally effective. For example, in cooking a beef roast, the microbial lethality achieved at 112 minutes after it has reached 54.4°C (130°F) is the same lethality attained as if it were cooked for 4 minutes after it has reached 62.8°C (145°F). Cooked beef and roast beef, including sectioned and formed roasts, chunked and formed roasts, lamb roasts and cooked corned beef can be prepared using one of the time and temperature combinations listed in the chart in § 3-401.11 to meet a 6.5-$\log_{10}$ reduction of Salmonella. The stated temperature is the minimum that must be achieved and maintained in all parts of each piece of meat for a least the stated time. The source of the time and temperature parameters is from the USDA/FSIS Appendix A. Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products found at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/compliance-guides-index.

Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. Different species of microorganisms have different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of bacteria, the trophozoite of protozoa, or the larval form of worms) is less resistant than the same organism's survival form (the bacterial spore, protozoan cyst, or worm egg).

Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the cooking vessel and the moisture content of food aid thermal destruction.

Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food, cooking must bring *all* parts of the food up to the required temperatures for the correct length of time.

The temperature and time combination criteria specified in Part 3-4 of this Code are based on the destruction of *Salmonellae*. This organism, if present in raw shell eggs, is generally found in relatively low numbers. Other foods, uncomminuted fish and meats including commercially raised game animal meat, specified as acceptable for cooking at this temperature and time parameter are expected to have a low level of internal contamination. The parameters are expected to provide destruction of the surface contaminants on these foods. Part 3-4 includes temperature and time parameters that provide "D" values (decimal log reduction values) that may surpass 7D. For example, at 63°C(145°F), a time span of 15 seconds will provide a 3D reduction of ***Salmonella* Enteritidis** in eggs.

The requirements specified under ¶ 3-401.11(D) acknowledge the rights of an informed consumer to order and consume foods as preferred by that consumer based on the consumer's health status and understanding of the risks associated with eating raw or partially-cooked animal foods.

In consumer self-service operations, such as buffets, salad bars, sushi bars, or display cases, the consumer advisory as specified under section 3-603.11 must be posted or available at the self-service unit where the raw or partially cooked food is held for service and readily accessible to consumers prior to making their food selections. In a catered situation, such as a wedding reception, guests are responsible for making their own requests or selections.

Slow-cooked roasts - Heating Deviations and Slow Come Up Time

(Source: USDA/FSIS Appendix A Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products found at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/compliance-guides-index.

Heating deviations, which most often involve slow come-up time or an inordinate dwell time within the optimum temperature range for microorganism growth can foster the multiplication of many pathogens. This multiplication sometimes can be so prodigious that even recooking may be ineffective in rendering the product safe. Also, certain toxigenic bacteria can release toxins into the product. Some of these toxins, such as those of ***Staphylococcus aureus***, are extremely heat stable and are not inactivated by normal recooking temperatures.

Further, the sampling of product following a heating deviation may not yield sufficient information to determine the safety of the product in question. Heating deviations can favor the multiplication of many types of bacteria. It would be difficult and expensive to sample for all of them. Depending on the circumstances, establishments may want to use computer modeling to estimate the relative multiplication of bacteria. For example, in a past incident involving an extreme heating deviation, product was put in an oven in which the temperature was inadvertently set to 95°F for about 12 hours. Computer modeling was easily applied in this case because much of the dwell time was at one temperature. The USDA/FSIS determined that within a 6-hour time frame (with other growth conditions assumed to be favorable), the relative multiplication of many pathogens of concern could have exceeded 5-logs. Clearly the product could not be salvaged by reprocessing and was therefore destroyed. Under changing conditions of temperature, however, computer modeling becomes more difficult. One approach is to average lag/log times over small increments such as 5° and add these times to get an approximation of possible total relative growth over a larger increment of time. Establishments must keep in mind that the population of bacteria before processing is generally unknown and that assumptions in the high range often are used as input parameters in the modeling.

Seared Steak

The provision for allowing seared steaks was reviewed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and USDA. Paragraph 3-401.11(C) includes their recommendations.

USDA comments included, “For the purposes of this discussion, steak is a whole beef muscle. It does not include whole beef muscle that has been pinned, injected, or chopped and formed. It may be cut cross grain, such as sirloin, chuck, or porterhouse; or it may be cut with the grain, such as flank, skirt, or Chateaubriand. Other species, such as poultry, pork, and lamb are not included.”

NACMCF comments included, “Due to the low probability of pathogenic organisms being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces. Grill or char marks may be applied to the complete surface searing. The meat should be seared on both top and bottom surfaces utilizing a heating environment (e.g., grill or broiling oven) that imparts a temperature at the surface of the intact steak of at least 145°F to achieve a cooked color change on all external surfaces. The searing of all surfaces should be continuous until the desired degree of doneness and appearance are attained. This is considered a ready-to-eat food.”

As reflected in the definition of “whole-muscle, intact beef steak,” marination is a food safety concern when the fascia (exterior surface) of the steak is broken by scoring or other means which allows the marinade to penetrate, and potentially contaminate, the interior of the steak. In such cases, the Code allowance for undercooking without a consumer advisory is negated.

Pork

In pork, ***Trichinella spiralis***, ***Toxoplasma gondii***, and ***Taenia solium***, parasites causing foodborne illness, are inactivated at temperatures below 145°F. Therefore, pork roasts can be cooked like beef roasts (e.g., 145°F for 3 minutes) and pork chops cooked like steaks to achieve an internal temperature of 145°F for 15 seconds.

Based on the Goodfellow and Brown study, a 5D reduction of organisms is achieved at 68°C (155°F) for 15 seconds for the following foods: ratites and injected meats and comminuted: fish, meat, game animals commercially raised for food, and game animals that come under a USDA voluntary inspection program. Ratites such as ostrich, emu, and rhea are included in this list of raw animals foods because when cooked to a temperature greater than 68°C (155°F), ratites exhibit a (metallic) "off" taste.

When USDA established the time and temperature parameters for 9 CFR 318.23 Heat-Processing and Stabilization Requirements for Uncurred Meat Patties (known as the "patty rule"), the Agency based the 5D for Salmonella on extrapolations applied to the research done by Goodfellow and Brown to account for the lack of a "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear relationship between the patty rule and roast beef time and temperature parameters. The patty rule also provided for an 8D reduction in the number of Shiga toxin-producing ***Escherichia coli***. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements.

Temperature for Comminuted Meat at Less Than 1 Second

In the "Report of the Task Force on Technical Issues Arising from the National Advisory Committee on Microbiological Criteria for Foods” (NACMCF) Review of the Meat Patty Proposal" (undated), it is stated on page 7, in Option (A), that:

> “Based on the 1998 research data ... and an assumption that instantaneous is defined as eight seconds, manufacturers would be required to process fully-cooked meat patties at a temperature of 157°F. Given the lack of any significant margin of safety in this process, there should be no deviation below the 158°F requirement.”

In November, 1997, the NACMCF Meat and Poultry Subcommittee revisited the time and temperatures for cooking hamburger and advised FDA that cooking hamburger to 158°F for less than one second is an adequate cook based on the following:

1. The cooking recommendations contained in the Food Code and in USDA guidance provide a large margin of safety for killing vegetative enteric pathogens;

2. The concept of integrated lethality (the kill imparted during the entire heating and cooling process) adds to the margin of safety; and

3. The time component of the time and temperature requirement will be exceeded before the temperature can be determined.

The parameters for cooking poultry, wild game animal meats, stuffed food products, etc., of 74°C (165°F) or above for 15 seconds yield greater than a 7D reduction.

Children's Menu

The 2005 FDA Food Code Section 3-401.11 (D) "Raw Animal Foods" allows operators to serve raw or partially cooked animal food items on their customer's request, as long as the establishment does not serve a "Highly Susceptible Population" and the customer is informed of the risks associated with consuming undercooked items.

The definition of "Highly Susceptible Population" however, only includes young children who are of pre-school age and who obtain food under custodial care (as from a child daycare center). This definition does not address pre-school and older children eating in retail food establishments (such as restaurants), where it is common practice to offer menu items intended for children (e.g. "Kids Menu").

The Food Code seeks to increase current protection of children beyond custodial care facilities and establish needed safeguards in all retail food establishments. The importance of this issue can be demonstrated for numerous combinations of raw animal foods and associated pathogens. The greatest impact on children however, is undercooked ground beef, where the specific organism of concern is *Escherichia coli* O157:H7.

Children are at relatively high risk for infection with *E.coli* O157:H7. It is possibly the leading cause of acute kidney failure and Hemolytic Uremic Syndrome (HUS) in children [10]. Infection with *E. coli* O157:H7 can result with mild to severe symptoms such as: non-bloody or bloody diarrhea to HUS, which is a condition that includes destruction of red blood cells, problems with blood clotting and kidney failure. About 2% to 20% of patients that are infected with *E. coli* O157:H7 develop HUS [6]. The risk of illness from *E. coli* O157:H7 in ground beef has been shown to be about 2.5 times higher for preschool children and infants than for the rest of the population [6]. The CDC has reported the following *E. coli* 0157:H7 infection rates per 100,000 by age range: 8.2 for young children 1-9 years old and 3.0 for older children 10-20 years of age [4].

Precluding undercooked foods from being offered on a children's menu may result in increased protection to children from foodborne illness, particularly *E. coli* O157:H7, which can result in severe consequences in children.

3-401.12 Microwave Cooking.

The rapid increase in food temperature resulting from microwave heating does not provide the same cumulative time and temperature relationship necessary for the destruction of microorganisms as do conventional cooking methods. In order to achieve comparable lethality, the food must attain a temperature of 74°C (165°F) in all parts of the food. Since cold spots may exist in food cooking in a microwave oven, it is critical to measure the food temperature at multiple sites when the food is removed from the oven and then allow the food to stand covered for two minutes post microwave heating to allow thermal equalization and exposure. Although some microwave ovens are designed and engineered to deliver energy more evenly to the food than others, the important factor is to measure and ensure that the final temperature reaches 74°C (165°F) throughout the food.

"The factors that influence microwave thermal processes include many of the same factors that are important in conventional processes (mass of objects, shape of objects, specific heat and thermal conductivity, etc.). However, other factors are unique in affecting microwave heating, due to the nature of the electric field involved in causing molecular friction. These factors are exemplified by moisture and salt contents of foods, which play a far more important role in microwave than conventional heating." (Reference: Heddelson and Doores, see Annex 2)

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are fresh, frozen, or canned and that are heated for hot holding need only to be cooked to the temperature required for hot holding. These foods do not require the same level of microorganism destruction as do raw animal foods since these fruits and vegetables are ready-to-eat at any temperature. Cooking to the hot holding temperature of 57°C (135°F) prevents the growth of pathogenic bacteria that may be present in or on these foods. In fact, the level of bacteria will be reduced over time at the specified hot holding temperature.

3-401.14 Non-Continuous Cooking of Raw Animal Foods.

Close attention must be paid to control of biological hazards when a food establishment cooks raw animal foods using a process in which the food is partially cooked then cooled with the expectation of fully cooking the food at a later date or time. Section 3-401.14 requires that establishments wishing to use a non-continuous process for the cooking of raw animal foods establish and follow a written plan that ensures each stage of the process is completed within time and temperature parameters that adequately prevent pathogen survival and growth. Section 3-401.14 also requires that establishments take special precautions to ensure that raw animal foods that have only been initially heated to temperatures that are not lethal to the pathogens of concern are clearly identified so that they will not be inadvertently sold or served to the consumer in a partially cooked state.

To ensure the food does not dwell for extended periods within temperature ranges that favor pathogen growth, § 3-401.14 establishes limits on the time permitted to initially heat the food (initial "come-up" time) and the time permitted to cool the product to temperatures that are safe for refrigerated storage. Together, these limits should prevent food from remaining at temperatures at which pathogen growth to harmful levels may occur.

The criteria in § 3-401.14 were developed with consideration of the United States Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) *Performance Standards for Partially Cooked and Char-Marked Meat Patties and Partially Cooked Poultry Breakfast Strips* found in 9 CFR 318.23 and 9 CFR 381.150. (http://edocket.access.gpo.gov/cfr_2008/janqtr/pdf/9cfr318.23.pdf, http://www.access.gpo.gov/nara/cfr/waisidx_08/9cfr381_08.html)

The maximum one hour time limit for the initial heating stage was established based on estimates from predictive microbial modeling. It is intended to limit the cumulative growth of *Clostridium perfringens* that may occur during the come-up time and the subsequent cooling of the product in accordance with the requirements in ¶ 3-501.14(A). Unless properly controlled, processes in which animal foods are heated to sub-lethal temperatures and times and then cooled may create an environment for the growth of ***Clostridium perfringens, Clostridium botulinum*** and other spore forming, toxigenic bacteria.

The product temperature achieved during the initial heating process may not be sufficient to destroy vegetative cells of ***Clostridium botulinum***, ***Clostridium perfringens***, and ***Bacillus cereus,*** if present***.*** The concern is the generation of a large number of vegetative cells of ***Clostridium perfringens*** and/or ***Clostridium botulinum*** before the final cooking stage. For ***Clostridium botulinum***, if enough vegetative cells are produced, toxigenesis can occur in the product before the product is fully cooked. The toxin is not destroyed at the minimum required cooking temperatures. For ***Clostridium perfringens***, if a large number of vegetative cells are consumed, illness can result. In either case a high number of vegetative cells may challenge the lethality step of the ultimate cooking process to the extent that it will be unable to completely eliminate all of these vegetative cells. The cumulative growth of these bacterial pathogens must be taken into account during both the initial heating and cooling steps. The hazard may be compounded with an extended initial "come-up" time and/or a prolonged cooling stage. Hence the degree of hazard may be dependent upon the ultimate effect of the initial heating and cooling, as well as the final cooking step.

A full and adequate cook during the final cooking step is of critical importance to ensure destruction of any pathogens that may have survived and proliferated during any initial heating and cooling stages of the non-continuous cooking process. Section 3-401.14 requires that animal foods cooked by a non-continuous cooking process achieve a minimum final cook temperature that heats all parts of the food to a temperature and for a time specified under ¶¶3-401.11 (A)-(C). This requirement also precludes serving animal foods that have undergone non-continuous cooking in an undercooked or raw state. In other words, animal foods cooked using a non-continuous process are not covered in the exceptions provided for in ¶ 3-401.11(D) that allow for serving undercooked animal foods upon consumer request and with an adequate consumer advisory.

Section 3-401.14 requires that an establishment using non-continuous cooking processes also establish procedures for identifying foods that have only been partially cooked and cooled. This is necessary to ensure these foods are not mistaken by food workers for foods that have been fully cooked and therefore ready-to-eat without a full cook. Partially cooked foods may appear to be fully cooked.

Requiring that food establishments obtain prior approval by the regulatory authority before employing non-continuous cooking processes will help to ensure that the establishment has the proper procedures in place, as well as the necessary facilities and capacity to monitor the appropriate cooling, cooking, separation and product identification of the foods. in accordance with the requirements.

Freezing **3-402.11 Parasite Destruction.**

Refer to the public health reason for § 3-201.11.

Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service as an alternative public health control to that which is provided by adequate cooking. Candling or other visual inspection techniques are not adequate to avoid the risk of parasites from fish which have not been frozen.

The recommended control strategies refer to the ambient air temperature during freezing and to the length of time that the fish is held at the appropriate freezer temperature, or the length of time that the fish is held after it is solid frozen, whichever it appropriate. The parasite hazard is not considered to be reasonably likely to occur if the finished product is fish eggs that have been removed from the skein (the tissue that contains the egg mass) and rinsed.

In response to information provided to the FDA Office of Seafood, the Fish and Fisheries Products Hazards and Controls Guidance lists certain species of tuna as not being susceptible to parasites of concern and therefore exempted from the freezing requirements that apply to other fish species that are consumed raw.

The Fish and Fisheries Products Hazards and Controls Guidance states that species that normally have parasites as a result of consuming infected prey, apparently do not have the same parasite hazard when raised on pelleted food in an aquaculture operation. On the other hand, aquacultured fish that are fed processing waste and by-catch fish may have a parasite hazard, even when wild caught fish of that species do not normally have a parasite hazard. Feed must not contain any live parasites. For example, the use of fresh fish meat in feed could transmit such parasites. Only heat treated feed or feed otherwise produced in a manner that would kill parasite intermediate stages infective to the aquacultured fish, such as most pelleted feeds, should be used.

Additionally, it should be noted that the Fish and Fisheries Products Hazards and Controls Guidance, Edition 4, Tables 3-2 and 3-3 (Chapter 3) lists those species for which FDA has information that a potential parasite hazard exists. Fish species in Tables 3-2 and 3-3 that do not have specific parasite hazards listed are not necessarily safe when consumed raw or undercooked. This is because fish species in Tables 3-2 and 3-3 were not listed with a parasite hazard if the species were generally cooked before consumption. In addition, in some cases, there is insufficient information or data to be able to denote a specific parasite hazard or deem the species as naturally parasite-free. The exemptions to freezing as specified in ¶ 3-402.11(B) of the *Food Code* are inclusive of and in harmony with the information and recommendations provided in the Fish and Fisheries Products Hazards and Controls Guidance.

Based on FDA's current assessment, parasites are not considered a significant hazard in molluscan shellfish or in scallop products consisting only of the shucked abductor muscle. Therefore these products are not required to be subject to the parasite destruction procedures specified under ¶3-402.11(A) prior to sale or service in a raw or partially cooked form.

Based on FDA's current assessment, parasites are not considered a significant hazard in molluscan shellfish or in scallop products consisting only of the shucked abductor muscle. Therefore these products are not required to be subject to the parasite destruction procedures specified under ¶3-402.11(A) prior to sale or service in a raw or partially cooked form.

3-402.12 Records, Creation and Retention.

Records must be maintained to verify that the critical limits required for food safety are being met. Records provide a check for both the operator and the regulator in determining that monitoring and corrective actions have taken place.

While the Country of Origin Labeling requirements, http://www.ams.usda.gov/COOL/ effective Sept. 30, 2004, mandate identification of wild and farm-raised fish and shellfish, the requirements do not address contents of pelleted feed used in the aquaculture operation. Documentation must be available in the food establishment from the source-through-purchase specifications or labeling that pelleted feed used did not contain fresh fish or plankton. Follow the guidance provided in the Fish and Fisheries Products Hazards and Controls Guidance, Table #3-1 – Potential Vertebrate Species Related Hazards and Table #3-2 – Potential Invertebrate Species Related Hazards.

Reheating **3-403.11 Reheating for Hot Holding.**

When food is held, cooled, and reheated in a food establishment, there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective in reducing the numbers of ***Clostridium perfringens*** that may grow in meat, poultry, or gravy if these products were improperly cooled. Vegetative cells of ***C. perfringens*** can cause foodborne illness when they grow to high numbers. Highly resistant ***C. perfringens*** spores will survive cooking and hot holding. If food is abused by being held at improper holding temperatures or improperly cooled, spores can germinate to become rapidly multiplying vegetative cells.

Although proper reheating will kill most organisms of concern, some toxins such as that produced by ***Staphylococcus aureus***, cannot be inactivated through reheating of the food. It is imperative that food contamination be minimized to avoid this risk.

The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods. This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product, are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition if temperature abuse occurs.

Shelf-stable, commercially prepared ready-to eat foods in hermetically sealed containers will have received a controlled retort process that destroys all bacterial pathogens, both vegetative cells and spores, to provide a commercially sterile product. Refrigerated, commercially processed, ready-to-eat, TCS food will have received controlled thermal processing that destroys vegetative bacterial cells and a controlled cooling process that prevents the germination of any spores present. Packaging prevents recontamination and refrigeration prevents spore germination. Because there is limited risk of contamination in these types of products, reheating such foods to the minimum hot holding temperature of 135°F is considered adequate when reheating for hot holding. This should be the case for product that remains in the container or package after it is opened, provided the proper steps are taken to protect the remaining portions from contamination and they are maintained at the appropriate cold holding temperatures as specified in the Food Code.

Refer also to the public health reason for § 3-401.12.

3-404.11 Treating Juice.

Refer to the public health reason for § 3-801.11.

Temperature and Time Control	**3-501.11**	**Frozen Food.**
	3-501.12	**Time/Temperature Control for Safety Food, Slacking.**
	3-501.13	**Thawing.**

Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are preserved.

ROP Fish

Retailers should be aware that when a manufacturer packages fish and fishery products a hazard analysis is required under 21 CFR Parts 123 and 1240, Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (the Seafood HACCP Rule) to provide for control for nonproteolytic *C. botulinum.* Factors that make formation of *C. botulinum* toxin reasonably likely to occur during finished product storage and distribution are those that may result from the use of a reduced oxygen packaging (ROP) environment in a food that does not contain barriers to growth of *C. botulinum.*

The processing control for *C. botulinum* can be either freezing, refrigeration alone or refrigeration in combination with chemical inhibitors, (e.g. salt, water activity control). The Fish and Fishery Products Hazards and Control Guidance, Fourth Edition, Chapter 13, addresses freezing as a control strategy for frozen product. This control is intended to prevent exposure of the product to conditions conducive to the production of toxin by nonproteolytic strains of *C. botulinum* in the closed ROP package.

If freezing was chosen by the manufacturer as the barrier to control for nonproteolytic strains of *C. botulinum*, then each individual package of the ROP fish should be labeled to be kept frozen and thawed according to the manufacturer's label instructions. Typically ROP fish will come into retail food establishments in a frozen state with a label that indicates to "thaw immediately before use" or indicates that the product needs to be "kept frozen, and thawed under refrigeration immediately before use."

If a "Keep Frozen" label is not present on each individual ROP package unit, it may or may not be acceptable to store under refrigeration, depending in part on whether there are barriers such as pH or water activity to growth of *C botulinum* in addition to refrigeration.

As an added safeguard to prevent the possibility of *C. botulinum* toxin formation, the Food Code requires that any frozen ROP fish that does not have barriers to growth of *C. botulinum* in addition to refrigeration be completely removed from the ROP environment or package prior to thawing. This is to discourage the practice of thawing frozen ROP fish and holding it at 41ºF or less for a prolonged time period and/or selling it as a refrigerated product.

3-501.14 Cooling.

Safe cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive time for cooling of time/temperature control for safety foods has been consistently identified as one of the leading contributing factors to foodborne illness. During slow cooling, time/temperature control for safety foods are subject to the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation temperatures, 21°C - 52°C (70°F - 125°F), is to be avoided. If the food is not cooled in accordance with this Code requirement, pathogens may grow to sufficient numbers to cause foodborne illness.

The Food Code provision for cooling provides for cooling from 135ºF to 41°F or 45°F in 6 hours, with cooling from 135ºF to 70°F in 2 hours. The 6-hour cooling parameter, with an initial 2-hour rapid cool, allows for greater flexibility in meeting the Code. The initial 2-hour cool is a critical element of this cooling process. An example of proper cooling might involve cooling from 135ºF to 70ºF in 1 hour, in which case 5 hours remain for cooling from 70ºF to 41ºF or 45ºF. Conversely, if cooling from 135ºF to 41°F or 45°F is achieved in 6 hours, but the initial cooling to 70ºF took 3 hours, the food safety hazards may not be adequately controlled.

If the cooking step prior to cooling is adequate and no recontamination occurs, all but the spore-forming organisms such as ***Clostridium perfringens*** or ***Bacillus cereus*** should be killed or inactivated. However, under substandard sanitary conditions, other pathogens such as ***Salmonella*** or ***Listeria monocytogenes*** may be reintroduced. Thus, cooling requirements are based on growth characteristics of organisms that may survive or be a post-cook contaminate and grow rapidly under temperature abuse conditions.

Shell Eggs

FDA has approved the use of ionizing radiation for shell eggs. This approval means that FDA has not found the ionizing radiation process to be unsafe for shell eggs. However, shell eggs that have been subjected to the approved ionizing radiation process are not considered to have been pasteurized. Shell egg pasteurization requires the egg to have been subjected to a 5-log kill process for ***Salmonella* Enteritidis**, while the approved ionizing radiation process may deliver only 2 or 3 logs reduction. Therefore, eggs treated by ionizing radiation process alone must be held under refrigeration, as it cannot be guaranteed that ***Salmonella* Enteritidis** will be eliminated in all treated eggs. Further, irradiated eggs must be labeled in accordance with 21 CFR 179.26 *Ionizing radiation for the treatment of food*.

Hard-boiled eggs with shell intact may be cooled in ambient air and are not considered to be a time/temperature control for safety food after cooling. Hard-boiled eggs may be cooled in drinking water but are considered to be a time/temperature control for safety food after cooling because pathogens, which may be present in the water, may pass through the egg shell during cooling.

***Salmonella* Enteritidis** has been shown to have an extended lag phase in shell eggs due to inhibitory characteristics of the albumen. Research indicates that the organisms are physically located near the exterior of the yolk membrane, in contact with the bacteriostatic components. Growth does not appear until the yolk membrane is weakened by age or physically breached and the yolk nutrients, such as iron, become available to the organisms.

Federal regulations effective August 27, 1999, require shell eggs to be transported and distributed under refrigeration at an ambient temperature not to exceed 45°F. Packed shell eggs must be labeled indicating that refrigeration is required. Imported shell eggs packed for consumer use are required to include a certification that the eggs, at all times after packing, have been stored and transported at an ambient temperature of no greater than 45°F.

On December 5, 2000 federal regulations were amended to require that shell egg cartons bear safe handling instructions and be placed under refrigeration at 45°F or lower upon delivery at retail establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

- 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5 Inappplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or destruction of shell eggs…
- 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling statements, (h) *Shell eggs*.
- 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

Shell eggs must be placed immediately after receipt in refrigerated equipment that is capable of maintaining an ambient air temperature of 45°F. With the newly established Federal requirement for eggs to be in an ambient storage and transportation temperature of 45°F, and with refrigeration of eggs at retail as described above, the overall time that eggs are stored at temperatures that allow the growth of ***Salmonella*** spp. should be shortened. Additionally, this requirement negates the need to "cool" shell eggs upon receipt, although food establishment operators should maximize the circulation of cooled air in refrigeration units by separating flats, cases, and multiple cartons of eggs.

CFSAN/FSIS Joint Position Paper on Cooling

The processing of most ready-to-eat products includes a heat treatment or cooking step to eliminate pathogenic and spoilage microorganisms. However, this heat treatment does not eliminate spores of ***Clostridium botulinum*** and ***Clostridium perfringens*** and other spore-forming bacteria. Furthermore, these organisms can thrive in the warm product since other competing organisms have been eliminated. Non-refrigerated, anaerobic conditions are conducive to their growth and multiplication.

To prevent the growth and multiplication of spore-forming organisms, product should be cooled rapidly after cooking. When there is inadequate cooling, spores can germinate and the resulting vegetative cells can multiply to hazardous levels. The presence of sufficient numbers of ***C. botulinum*** or other spore-forming organisms may lead to production of harmful toxins. Therefore, ensuring no growth of these organisms will provide the greatest amount of safety.

The USDA/FSIS Performance Standards for the Production of Certain Meat and Poultry Products require a stabilization step (cooling) after the lethality step. The stabilization requirements allow for no growth of ***C. botulinum*** and no more than 1 log growth of ***C. perfringens***. The performance standard of no more than 1 log growth of ***C. perfringens*** was based on the following reasons:

1. The Centers for Disease Control and Prevention (CDC) suggested viable counts of 10^5 or greater of ***C. perfringens*** per gram as one of the criteria for incriminating ***C. perfringens*** as a causative agent of foodborne illness in finished product. However, foods responsible for ***C. perfringens*** outbreaks were found usually to contain 10^6 vegetative ***C. perfringens*** cells per gram.

In FSIS microbiological raw product surveys, samples were found to contain more than 1000 ***C. perfringens*** per gram. There is some probability that greater than 10^4 ***C. perfringens*** per gram can occur in the raw product on rare occasions. It is a conservative assumption that the great majority of ***C. perfringens*** in the raw product are spores.

2. Heating activates spores that, during cooling, become vegetative cells that can multiply to hazardous levels. If there are more than 10^4 ***C. perfringens*** (spores) per gram on raw product, it is possible that there may be more than 10^4 vegetative ***C. perfringens*** per gram in the product if it is improperly cooled after cooking.

3. Based on the CDC recommended upper limit of 10^5 which should not be exceeded, it was determined that a limit of no more than 1 $\log_{10}$ growth of ***C. perfringens*** would be appropriate to ensure that there would be no more than 10^5 ***C. perfringens*** per gram on the finished product after cooling.

4. The performance standard was discussed with experts on clostridia research. The experts agreed that limiting the relative growth of ***C. perfringens*** to no more than 1 $\log_{10}$ would be reasonable and somewhat conservative with respect to product safety. (64 FR 732, January 6, 1999, Performance Standards for the Production of Certain Meat and Meat Products).

The FSIS compliance guideline for the cooling performance standards, which can be found at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/compliance-guides-index. Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization), is that product must be cooled from 130ºF to 80°F in 1.5 hours and from 80ºF to 40°F in 5 hours. This cooling rate can be applied universally to cooked products like partially cooked or fully cooked, intact or non-intact meat and poultry products. The guideline results in continuous and rapid cooling of the product in the temperature range where the spore-forming organisms can grow rapidly.

The former USDA guideline of cooling from 120ºF to 55°F in no more than 6 hours is also included in the new compliance guidelines. In using this guideline, chilling should begin within 90 minutes after the cooking cycle is completed, and cooling should continue until product reaches 40°F. The 6-hour rule begins when the product reaches 120ºF, and product should not be shipped until the product reaches 40°F. This older cooling guideline results in a significantly smaller margin of safety, especially if the product is non-intact. In using this older guideline, the establishment has to ensure that cooling is as rapid as possible, especially between 120ºF and 80°F, and should monitor the cooling closely to prevent any deviation. If product remains between these temperatures for more than an hour, compliance with the performance standard is less certain.

The FSIS cooling guideline **for meat and poultry products containing 100 ppm added nitrite** is 130ºF to 80°F in 5 hours and from 80ºF to 45°F in 10 hours, a total of 15 hours cooling time. This cooling process provides a narrow margin of safety. In case of cooling deviations, the establishment should assume that their process has exceeded the performance standard for controlling the growth of ***C. perfringens***, and should take corrective action. However, the **presence of nitrite** should ensure compliance with the performance standard for ***C. botulinum***.

The Food Code provision for cooling is similar, though not identical to the FSIS cooling compliance guidelines. It provides for cooling from 135ºF to 70°F in 2 hours and from 135ºF to 41°F or 45°F in 6 hours and is based on the same food safety concerns as FSIS' guidance. The Food Code provides prescriptive cooling time/temperature combinations without a HACCP plan in place. Federally inspected meat and poultry establishments are required to implement a HACCP plan for their operations.

The Conference for Food Protection (CFP) at its 2000 meeting recommended that FSIS and FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the data on safe cooling times for cooked, time/temperature control for safety foods. The review would include data from a study, submitted to the CFP, showing that cooling of a meat product from 130ºF to 45°F can safely take place in 15 hours based on a study by V.K. Juneja, et al., 1994. According to the authors of the study, continuous cooling of a meat product from 130ºF to 45°F in 15 hours permitted about 1 log growth of ***C. perfringens***.

In response to the CFP recommendation, the FSIS Administrator and CFSAN agreed that the data referenced in the CFP recommendation do not support a change in the FSIS guidance or the Food Code § 3-501.14 and considered it inadvisable to ask the NACMCF to undertake the task requested for several reasons:

1. The study did not address growth of ***C. botulinum***.

2. The results are from a carefully controlled laboratory study in which cooling of the product was steady and continuous, conditions difficult to maintain in most commercial processing or retail environments even with data loggers and other control mechanisms in place.

3. The study was done only on ground beef and may not be applicable to other meat and poultry or to other time/temperature control for safety foods.

As an alternative response, CFSAN and FSIS advised CFP that they would provide this written position paper to clarify their joint position on the cooling issues.

3-501.15 Cooling Methods.

Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool because of the mass and volume from which heat must be removed. By reducing the volume of the food in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e., the time required for cooling and the time the food is exposed to optimal temperatures for bacterial multiplication or toxin production are increased.

Alternatives to conventional methods include avoiding the need to cool larger masses by preparing smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice water bath. Commercial refrigeration equipment is designed to hold cold food temperatures, not cool large masses of food. Rapid chilling equipment is designed to cool the food to acceptable temperatures quickly by using very low temperatures and high rates of air circulation.

3-501.16 Time/Temperature Control for Safety Food, Hot and Cold Holding.

Bacterial growth and/or toxin production can occur if time/temperature control for safety food remains in the temperature "Danger Zone" of 5°C to 57°C (41°F to 135°F) too long. Up to a point, the rate of growth increases with an increase in temperature within this zone. Beyond the upper limit of the optimal temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

Cold Holding

Maintaining TCS foods under the cold temperature control requirements prescribed in this code will limit the growth of pathogens that may be present in or on the food and may help prevent foodborne illness. All microorganisms have a defined temperature range in which they grow, with a minimum, maximum, and optimum. An understanding of the interplay between time, temperature, and other intrinsic and extrinsic factors is crucial to selecting the proper storage conditions for a food product. Temperature has dramatic impact on both the generation time of an organism and its lag period.

When considering growth rate of microbial pathogens, time and temperature are integral and must be considered together. Increases in storage and/or display temperature will decrease the shelf life of refrigerated foods since the higher the temperature, the more permissive conditions are for growth.

The exception for holding time/temperature control for safety food in specially designed dispensing equipment recognizes technology designs that maintain the safety of aseptically-packaged fluid foods when the equipment is manufactured and operated in conformance with the NSF/ANSI Standard No. 18. NSF/ANSI 18 was revised in 2006, with FDA input, to address the storage of certain types of time/temperature for safety food or beverages in dispensing equipment without temperature control. The key condition for FDA allowing this exemption from 3-501.16 is that the equipment conforms to the requirements as specified in NSF/ANSI 18.

Except for raw shell eggs, control of the growth of ***Listeria monocytogenes*** (*Lm*) is the basis for the list of cold holding temperature and time combinations in paragraph 3-501.17(A). The list addresses time, in addition to temperature, as a control for the growth of *Lm* in refrigerated, ready-to-eat, time/temperature control for safety food. The Code provisions for cold holding focus on environmental conditions that allow 1 log of growth of *Lm*, and do not set an acceptable number of *Lm* in food. Neither do they imply that *Lm* is in the product.

The times and temperatures in the 1999 Food Code were based on the USDA Pathogen Modeling Program (PMP), which is conservative in estimating how soon *Lm* begins to grow and how fast. The PMP was based largely on observations of microbial growth in broth cultures, but some observations in specific foods were also included. The PMP allows for some variation in temperature, pH, and water activity, and gives a conservative estimate of safe times and temperatures for holding foods. The 1999 Food Code estimated safe times and temperatures that would allow 3 logs of growth, based on the PMP.

During 2000, CFSAN researched published literature and compiled a listing of the growth potential of *Lm* in various food commodities using real food data. Based on this information, the 1999 Food Code times and temperatures of 41ºF for 7 days and 45ºF for 4 days were validated, but the underlying performance standard changed for the commodities studied. The research-based, food-specific times and temperatures allow no more than 1 log of growth instead of the 3 log growth predicted in the PMP. This more stringent performance standard of 1 log is consistent with the USDA/FSIS performance standard and the fact that the infectious dose of *Lm* remains unknown.

FDA concluded that the 1999 Code time/temperature criteria hold true and provide both a greater level of safety and a more realistic basis for regulatory requirements without compromising public health protection.

In October 2003, FDA, in cooperation with the USDA/FSIS and CDC, released the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods (risk assessment) at
http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/UCM197329.pdf.

This initiative included the development of 23 separate risk assessments and analysis of the relative risks of serious illness and death associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

The risk assessment identified several broad factors that affect consumer exposure to *Lm* at the time of food consumption. Two of these factors, refrigerated storage temperature and duration of refrigerated storage before consumption, have a direct bearing on cold holding time/temperature combinations used in food establishments.

FDA continues to have concerns about the potential for growth of *Lm* in refrigerated, ready-to-eat, time/temperature control for safety food, prepared and packaged in a food processing plant and held in a food establishment. Data from the risk assessment (see the following Annex 3, 3-501.16, Table 1) show a significant reduction in the projected cases of listeriosis when refrigerated storage is limited to 41ºF. Based on these data and conclusions from the risk assessment, FDA continues to recommend that food establishments limit the cold storage of time/temperature control for safety foods, ready-to-eat foods to a maximum temperature of 41ºF.

3-501.16 – Table 1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures*

MMaximum Refrigerator Temperature	Cases of Listeriosis[a]		
	MMedian	55th Percentile	995th Percentile
Baseline[b]	2105	3/4[c]	3/4[c]
7 ˚C (45 ˚F) maximum	656	331	761
5 ˚C (41 ˚F) maximum	28	1	126

[a]Values for the median, upper and lower uncertainty levels.
[b]The baseline uses the full empirical distribution of refrigerator temperatures from the Audits International (1999) survey.
[c]The baseline number of cases of listeriosis is fixed based on CDC surveillance data.
*The scenario assumed the distribution of storage times is the same for all three temperature sets.
Source: Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods September 2003. Table VI-1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures.

Regarding shell eggs, USDA published a final rule (63 FR 45663, August 27, 1998 Refrigeration and Labeling Requirements for Shell Eggs) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7ºC (45ºF). This regulation, however, does not apply to eggs while held at all retail establishments.

FDA is concerned that without continued refrigeration up until the time that the eggs are cooked, there would be an opportunity for the egg's defenses to degrade and growth of ***Salmonella* Enteritidis** to occur. The agency reviewed research indicating that ***Salmonella Enteritidis*** multiplies at temperatures of 10ºC (50ºF) and above but can be inhibited at lower temperatures, e.g., 8ºC (46ºF), 7ºC (45ºF), and 4ºC (39ºF). Based on this research and USDA's temperature requirement during transport, FDA implemented regulations that establish a maximum ambient air temperature of 7ºC (45ºF) for eggs stored and displayed at retail establishments. Amended Federal regulations 21 CFR Part 115.50 issued on December 5, 2000 and became effective on June 4, 2001.

Although Congress did not expressly preempt State law in this area, FDA found preemption is needed because State and local laws that are less stringent than the Federal requirements will not support the important public health goals of these regulations. FDA does not believe that preemption of State and local refrigeration and labeling requirements that are the same as or more stringent than the requirements of these regulations is necessary, as enforcement of such State and local requirements will support the food safety goals of these regulations. Accordingly, the preemptive effect of this rule is limited to State or local requirements that are not as stringent as the requirements of these regulations; requirements that are the same as or more stringent than FDA's requirements remain in effect.

Historical Record of Cold Holding Temperature Provisions

The 1976 Food Service Sanitation Manual recommended 45°F as the cold holding temperature. Based on the available science at the time, the 1993 Food Code lowered the cold holding temperature to 41°F.

However, stakeholders raised concerns that many of the refrigerators currently in place in food establishments would not be capable of maintaining food at that temperature. There was also concern that most of the open-top buffet and food prep table-type units being built at the time could not reliably maintain food at 41°F or less. Industry pointed out that operators needed to recover investments in new refrigeration equipment purchased just before or after a state adopted the 41°F provision.

Consequently, the Conference of Food Protection (CFP) recommended the 1997 Food Code incorporate the option of having a 5-year phase-in period for the 41°F requirement to allow for upgrading of existing equipment, and the FDA agreed.

By 2006, many states adopted and implemented the phase-in period, the 5 years had expired and they were requiring cold holding at 41°F or less. In addition, NSF/ANSI Standard 7 was revised in 1997 and again in 1999 to ensure that equipment conforming to the Standard, including open-top and display units, could achieve the desired performance under conditions typically found in the food service and retail environments. Thus, there are mechanisms in place to allow industry flexibility in holding foods out of temperature control and the exemption for holding at 45°F was no longer necessary, given equipment capabilities, existing provisions of the Food Code that could be utilized (e.g., variances, time as a public health control), and the impact on public health. Additionally, the FDA believed this exemption was no longer necessary and perhaps was detrimental to public health protection in light of what had been learned about the growth and survival of *Listeria monocytogenes* (LM) in refrigerated foods.

In 2006, the CFP recommended (CFP Issue 2006-I-033) and FDA agreed that the option of maintaining 45°F as a cold holding temperature be deleted from § 3-501.16. In the Supplement to the 2005 Food Code, the option to maintain 45°F as the cold holding temperature was deleted from the Food Code and 41°F became the standard for cold holding.

Hot Holding

In a January 2001 report, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) recommended that the minimum hot holding temperature specified in the Food Code:

- Be greater than the upper limit of the range of temperatures at which ***Clostridium perfringens*** and ***Bacillus cereus*** may grow; and
- Provide a margin of safety that accounts for variations in food matrices, variations in temperature throughout a food product, and the capability of hot holding equipment to consistently maintain product at a desired target temperature.

C. perfringens has been reported to grow at temperatures up to 52°C (126°F). Growth at this upper limit requires anaerobic conditions and follows a lag phase of at least several hours. The literature shows that lag phase duration and generation times are shorter at incubation temperatures below 49°C (120°F) than at 52°C (125°F). Studies also suggest that temperatures that preclude the growth of ***C. perfringens*** also preclude the growth of ***B. cereus***.

CDC estimates that approximately 250,000 foodborne illness cases can be attributed to ***C. perfringens*** and ***B. cereus*** each year in the United States. These spore-forming pathogens have been implicated in foodborne illness outbreaks associated with foods held at improper temperatures. This suggests that preventing the growth of these organisms in food by maintaining adequate hot holding temperatures is an important public health intervention.

Taking into consideration the recommendations of NACMCF and the 2002 Conference for Food Protection meeting, FDA believes that maintaining food at a temperature of 57°C (135°F) or greater during hot holding is sufficient to prevent the growth of pathogens and is therefore an effective measure in the prevention of foodborne illness.

3-501.17	**Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking.**
3-501.18	**Ready-to-Eat, Time/Temperature Control for Safety Food, Disposition.**

Refer to Annex 7, Chart 4-C.

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as ***Listeria monocytogenes***, is significantly slowed but not stopped by refrigeration. Over a period of time, this and similar organisms may increase their risk to public health in ready-to-eat foods.

Based on a predictive growth curve modeling program for ***Listeria monocytogenes***, ready-to-eat, time/temperature control for safety food may be kept at 5°C (41°F) a total of 7 days. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by date marking to ensure its safety based on the total amount of time it was held at refrigeration temperature, and the opportunity for ***Listeria monocytogenes*** to multiply, before freezing and after thawing. Time/temperature control for safety refrigerated foods must be consumed, sold or discarded by the expiration date.

Date marking is the mechanism by which the Food Code requires active managerial control of the temperature and time combinations for cold holding. Industry must implement a system of identifying the date or day by which the food must be consumed, sold, or discarded. Date marking requirements apply to containers of processed food that have been opened and to food prepared by a food establishment, in both cases if held for more than 24 hours, and while the food is under the control of the food establishment. This provision applies to both bulk and display containers. It is not the intent of the Food Code to require date marking on the labels of consumer size packages.

A date marking system may be used which places information on the food, such as on an overwrap or on the food container, which identifies the first day of preparation, or alternatively, may identify the last day that the food may be sold or consumed on the premises. A date marking system may use calendar dates, days of the week, color-coded marks, or other effective means, provided the system is disclosed to the Regulatory Authority upon request, during inspections.

FDA/USDA/CDC *Listeria monocytogenes* Risk Assessment

In September, 2003, FDA, in cooperation with USDA/FSIS and CDC, released the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods at http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/UCM197329.pdf. This initiative included the development of 23 separate risk assessments and analysis of the relative risks of serious illness and death associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

In examining these closely, FDA showed that 5 factors are important in measuring the public health impact to consumers from foodborne listeriosis. These factors are: (1) amounts and frequency of consumption of a ready-to-eat food; (2) frequency and levels of ***L. monocytogenes*** in a ready-to-eat food; (3) potential of the food to support growth of the bacterium during refrigeration; (4) refrigerated storage temperature; and (5) duration of refrigerated storage before consumption.

Based on these 5 factors, the 23 categories of ready-to-eat foods were ranked according to their relative risk of contamination and growth of ***Listeria monocytogenes***. The risk categories used were: very high risk; high risk; moderate risk; low risk; and very low risk.

Impact of the Listeria monocytogenes Risk Assessment on Date Marking

Based on the results of the risk assessment and the recommendations from the 2004 Conference for Food Protection meeting, it was necessary to re-evaluate date marking in an effort to focus the provision on very high and high risk foods, while at the same time, exempting foods that present a very low, or low risk of contamination and growth of ***Listeria monocytogenes***. Based on this evaluation, date marking provisions of the Food Code do not apply to the following foods:

Deli Salads Prepared and Packaged in a Food Processing Plant

Examples of deli salads include ham salad, chicken salad, egg salad, seafood salad, pasta salad, potato salad, and macaroni salad, manufactured according to 21 CFR 110. According to data from the risk assessment, deli salads prepared and packaged by a food processing plant contain sufficient acidity, along with the addition of preservatives (e.g., sorbate, benzoates), to prevent the growth of ***Listeria monocytogenes***. There are estimates that 85% of all deli salads are prepared and packaged in a food processing plant and do not support growth. Based on discussions with deli salad manufacturers and trade associations, it is a nearly universal practice for food processing plants preparing and packaging deli salads to add one or more preservatives that inhibit the growth of ***Listeria monocytogenes***. Based on their wide use within this segment of the industry and their effectiveness at inhibiting the growth of ***Listeria monocytogenes***, all deli salads prepared and packaged in a food processing plant are exempt from date marking. However, all deli salads prepared in a food establishment require date marking.

Hard and Semi-Soft Cheeses

In December, 1999, FDA issued an exemption from date marking for certain types of hard and semi-soft cheeses (http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113942.htm), based on the presence of several factors that may control the growth of ***Listeria monocytogenes***. These factors may include organic acids, preservatives, competing microorganisms, pH, water activity, or salt concentration. The results of the risk assessment support this interpretation and therefore, hard and semi-soft cheeses each manufactured according to 21 CFR 133 are exempt from date marking.

List of Hard Cheeses Exempt from Date Marking	List of Semi-Soft Cheeses Exempt from Date Marking
Asadero	Asiago soft
Abertam	Battelmatt
Appenzeller	Bellelay (blue veined)
Asiago medium or old	Blue
Bra	Brick
Cheddar	Camosum
Christalinna	Chantelle
Colby	Edam
Cotija Anejo	Fontina
Cotija	Gorgonzola (blue veined)
Coon	Gouda
Derby	Havarti
Emmentaler	Konigskase
English Dairy	Limburger
Gex (blue veined)	Milano
Gloucester	Manchego
Gjetost	Monterey
Gruyere	Muenster
Herve	Oka
Lapland	Port du Salut
Lorraine	Provolone
Oaxaca	Queso de Bola
Parmesan	Queso de la Tierra
Pecorino	Robbiole
Queso Anejo	Roquefort (blue veined)
Queso Chihuahua	Samsoe
Queso de Prensa	Tilsiter
Romanello	Trappist
Romano	
Reggiano	
Sapsago	
Sassenage (blue veined)	
Stilton (blue veined)	
Swiss	
Tignard (blue veined)	
Vize	
Wensleydale (blue veined)	

Cultured Dairy Products

Cultured dairy products include yogurt, sour cream, and buttermilk, each manufactured according to 21 CFR 131. Many of these products often are low pH foods manufactured with lactic acid fermentation. Data from the risk assessment show that ***Listeria monocytogenes*** does not grow in these foods and therefore, these products are exempt from date marking.

Preserved Fish Products

Preserved fish products include pickled herring and dried, or salted cod, and other acidified fish products, manufactured according to 21 CFR 114. Data from the risk assessment show that the high salt and/or acidity of these products does not allow for the growth of ***Listeria monocytogenes*** and therefore, these products are exempt from date marking. This exemption does not apply to hot or cold smoked fish products, nor does it apply to fish products that are dried, marinated, or otherwise preserved on-site, in a food establishment, such as ceviche.

Shellstock

Although ***Listeria monocytogenes*** has been isolated from shellstock there have been no reported Listeriosis cases linked to the consumption of this product at retail. The competitive microflora present in and on shellstock inhibits the growth of ***Listeria monocytogenes*** to harmful levels when the product is held under refrigeration at retail. Therefore shelllstock are exempt from date marking.

USDA-regulated products

Date marking provisions of the Food Code do not apply to shelf stable ready-to-eat meat and poultry products. Shelf stable ready-to-eat meat and poultry products are not required by USDA to be labeled “Keep Refrigerated.” For these products, the nitrite and salt in the cure and the lower pH resulting from fermentation give additional protection against microbial growth. Some fermented sausages and salt-cured products are shelf stable, do not require refrigeration, and do not bear the label “Keep Refrigerated.” To be shelf stable, a product manufactured under USDA inspection must have a process that results in a product that meets one of the recognized objective criteria for shelf stability, such as water activity, moisture-protein ratio (MPR), or combination of MPR and pH (acidity). Therefore they are exempt from the Food Code date marking requirements.

Shelf stable fermented sausages such as pepperoni and dry salami do not have to be refrigerated or date marked. Shelf stable salt-cured products such as prosciutto, country cured ham, or Parma ham do not require refrigeration or Food Code date marking. Other salt-cured products include basturma, breasaola, coppa, and capocolla.

Some ready-to-eat fermented sausages and salt-cured products must be refrigerated and therefore bear the USDA-required label “Keep Refrigerated.” Examples of these products are cooked bologna, cooked salami, and sliced country ham which are ready-to-eat fermented products that need refrigeration. Bologna is a cooked, perishable sausage and there are other salamis, e.g., cotto that are perishable.

The intact casing on shelf-stable sausages may be overwrapped to protect the cut face of the sausage. With shelf stable (non-time/temperature control for safety food) sausages, the intact casing provides a barrier to contamination (although not an absolute one), the exposed face is likely to be sliced again within 4 or 7 days, and contamination is minimized because only the face is exposed. The coagulated protein that occurs on the surface of some nonshelf stable cooked sausages is not a casing.

Slices of cured and fermented sausages that require refrigeration and are kept for 24 hours or longer do need to be date marked.

If open dating information is applied to lunchmeats at a federally inspected meat or poultry establishment, the information must comply with the requirements in 9 CFR 317.8 and 381.129. However, such dating is not required by USDA/FSIS and if applied, would not supercede or replace date marking requirements established by the Food Code or by State/local authorities that apply after the food is opened in a retail establishment.

Manufacturer’s use-by dates

It is not the intent of this provision to give a product an extended shelf life beyond that intended by the manufacturer. Manufacturers assign a date to products for various reasons, and spoilage may or may not occur before pathogen growth renders the product unsafe. Most, but not all, sell-by or use-by dates are voluntarily placed on food packages.

Although most use-by and sell-by dates are not enforceable by regulators, the manufacturer's use-by date is its recommendation for using the product while its quality is at its best. Although it is a guide for quality, it could be based on food safety reasons. It is recommended that food establishments consider the manufacturer’s information as good guidance to follow to maintain the quality (taste, smell, and appearance) and salability of the product. If the product becomes inferior quality-wise due to time in storage, it is possible that safety concerns are not far behind.

It is not the intention of this provision that either the manufacturer’s date or the date marked by the food establishment be placed on consumer packages.

3-501.19 Using Time as a Public Health Control.

The 2000 Conference for Food Protection (CFP) meeting recommended that FDA ask the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the Food Code provision that addresses using time alone as a public health control, section 3-501.19. In response to the CFP recommendation, FDA in consultation with USDA/FSIS, determined that there is sufficient scientific information available to support the current provision in the Food Code without requesting consideration by the NACMCF. As an alternative response, FDA informed the CFP that it would provide the following position paper on using time alone as a public health control.

Position Paper

Food Code section 3-501.19 allows time/temperature control for safety food that is ready-to-eat (RTE) to be stored without temperature control for up to 4 hours, after which it must be discarded or consumed or for up to 6 hours for refrigerated food, if the food is 5°C (41°F) when initially removed from temperature control, and as long as the food temperature does not exceed 21°C (70°F). The following information is provided to explain the reasoning in allowing time alone to be used as a public health control for food safety.

Background Information

Food kept without temperature control allows product to warm or cool as it equilibrates with the environment. Each temperature scenario incurs different risks in regard to the type of foodborne pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions, growth depends on the amount of time the food spends in an optimum growth temperature range during its equilibration with its surroundings. Several factors influence the rate of temperature change in a food, such as the type of food, thickness of the food, and temperature differential between the food and its surroundings. When evaluating the safety of a 4-hour limit for food with no temperature control, products and environmental parameters must be selected to create a worst-case scenario for pathogens growth and possible toxin production.

Holding Cold Food Without Temperature Control

When a food is removed from refrigerated storage and begins to warm to room temperature, ***Listeria monocytogenes*** is a primary organism of concern. Even while food is held at refrigeration temperatures, the growth potential of ***L. monocytogenes*** warrants concern for time/temperature control for safety foods RTE foods. Although the FDA and USDA have a zero tolerance for ***L. monocytogenes*** in RTE food, conditions are permitted in the Food Code that would allow ***L. monocytogenes*** cells 1 log of growth (3.3 generations). ***Salmonella*** is also a concern especially with products containing eggs. However ***L. monocytogenes*** grows more rapidly than ***Salmonella*** at refrigeration and room temperatures. By ensuring minimal ***Listeria*** growth in food, the threat from ***Salmonella*** would be negligible. Warming conditions will allow food to remain exposed to temperatures that allow ***B. cereus*** to produce emetic toxin. However the 4-hour time constraint in the Food Code is sufficient to prevent any toxin formation.

For food refrigerated at 41ºF or 45°F then transferred to an ambient temperature of 75°F for 4 hours, the growth rate of ***L. monocytogenes*** remains slow enough to ensure that the critical limit of 1 log growth is not reached. Published generation times at 75°F for ***L. monocytogenes*** in food were not found, however published values at 68ºF and 70°F in egg and milk products confirmed slow ***L. monocytogenes*** growth at room temperatures.

Using the USDA Pathogen Modeling Program (PMP) and assuming the optimum conditions of pH 6.8, 0.5% NaCl, 0.0% nitrite, ***L. monocytogenes*** would require more than 4 hours to grow 1 log at 75°F. The PMP is based on broth studies and not on food products. Therefore, the growth rates reported at various temperatures by the PMP are faster than growth rates in most food products. Another factor exaggerating the growth rate in this warming scenario as predicted by the PMP is the assumption that the food product spent all 4 hours at 75°F. Obviously food equilibrates with the surrounding environment at a gradual rate and would not equilibrate instantly.

Unfortunately there are no models that take changing temperatures into consideration when predicting growth. Likewise there are very few published papers dealing with the growth of organisms in food during warming. The conservative nature of the 4-hour limit for keeping foods without temperature control allows for a needed margin of safety if the temperature of the environment is higher than 75°F.

It is important to note that time/temperature control for safety foods held without cold holding temperature control for a period of 4 hours do not have any temperature control or monitoring. These foods can reach any temperature when held at ambient air temperatures as long as they are discarded or consumed within the four hours.

Holding Hot Food without Temperature Control

The second scenario for food without temperature control exists when food is cooked according to Food Code recommendations, then kept at room temperature for 4 hours before discarding. Foodborne pathogens of concern for an uncontrolled temperature scenario are sporeformers including ***Clostridium perfringens*** and ***Bacillus cereus***. Food cooked according to Food Code guidelines should be free of vegetative cells. However, the heat requirements are not sufficient to kill spores of ***C. perfringens*** or ***B. cereus*** and may actually serve as a heat shock that activates the spores. ***B. cereus*** is found commonly in outbreaks attributed to inadequate hot holding of starchy foods like rice, and has been isolated in a multitude of food products. ***C. perfringens*** is found commonly in outbreaks attributed to inadequate hot holding of beef and poultry. Despite the prevalence of both spores in nature, ***C. perfringens*** cases are estimated to be more numerous than ***B. cereus*** cases by a factor of 10.

B. cereus can produce emetic toxin in food, and the optimum temperature for the production of toxin is between 77°F and 86°F. However, the time needed to produce the toxin is longer than the time the food will be exposed to any temperature range with a 4-hour holding limit. Both ***C. perfringens*** and ***B. cereus*** produce enterotoxin inside the intestine of the infected host if substantial numbers of vegetative cells are present in the food (10^{5-7} CFU/g). Although the reported levels of both spores in raw foods vary in the literature, generally the level expected in food can be assumed to be low (around 10-1000 CFU/g). This implies that conditions allowing 1 log growth of either spore could be tolerated in food.

During the time without temperature control, the temperature of the food could decrease slowly enough to expose spores of both organisms to optimal growth conditions for a significant length of time. Like warming, several variables exist that determine the rate of heat transfer. Because of the wide variety of foods prepared it would be impossible to generalize how fast a typical product loses temperature after cooking. As with warming, it is prudent to imagine a worst-case scenario where heat loss is slowed. A beef roast slow cooked to 130°F for the appropriate time according to the Food Code was used as consideration for possible spore growth. Cooking roast beef to 130°F can create an anaerobic environment in both the meat and gravy. The low internal temperature creates a small temperature differential with the environment (assumed at 75°F), allowing for a slower decrease in the food's temperature.

After evaluating published studies as well as data collected at the FDA, the surface of a roast beef or rolled meat product would lose heat quickly enough to discourage significant growth of either ***C. perfringens*** or ***B. cereus***. If all spores were distributed on the surface of the product by either pre- or post-cooking contamination, storing this product for 4 hours at room conditions would be considered safe. Likewise, products that are stirred or products that lose heat faster than a roast would also be considered safe.

---------- End of position paper ---------

At the 2004 meeting of the CFP, a committee submitted and the Conference accepted a document that examined scientific research related to the growth of ***Listeria monocytogenes***, and the influence of time and temperature on its growth.

The 2004 CFP report stated that the USDA-PMP program can be used as a tool to estimate time periods for a 1-log increase in growth for ***Listeria monocytogenes*** in ideal (laboratory media) growth conditions. Using this modeling approach, at 41°F, 45°F, and 50°F, the time for a 1-log increase was, 87.8, 53.9, and 34.7 hours, respectively. At room temperature (70°F) a 1-log increase was noted at 5.2 hours and at ideal growth temperatures (95°F), the reported time for a 1-log increase was 3.0 hours. In general, the data from the USDA-PMP program provides very conservative growth data and, in most cases, growth would be expected to be less rapid in a food system. This table does provide comparative information relative to growth rates at different holding temperatures in the event that time was used as a factor in managing food safely.

The report further recommended that food could safely be held for up to 6 hours without external temperature control as long as the food temperature did not exceed 70°F. Based on that report and data from the Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods September 2003, the Food Code allows time/temperature control for safety food to be stored up to 6 hours without external temperature control provided that the food temperature does not exceed 70°F and the food is discarded or consumed at the end of the 6 hours.

The Safety of the Time as a Public Health Control Provision from Cooking Temperatures (135°F or above) to Ambient

FDA conducted in-house laboratory experiments to test the safety of the existing TPHC provisions of 4 hours without temperature control starting with an initial temperature of 135°F or above. *Clostridium perfringens* was chosen to represent a worst case scenario pathogen for foods allowed to cool from cooking temperatures to ambient without temperature control, because its spores can survive normal cooking procedures, it can grow at relatively high temperatures (>120°F) and it has a short lag period. *C. perfringens* spores were inoculated into foods that were cooked and then cooled to yield a cooling curve that would promote outgrowth as quickly as possible. The growth data suggest that the existing 4-hour TPHC provision will be safe for 6 hours after cooking, with the additional 2-hour margin of safety built-in for consumer handling.

Consumer Handling Practices

An Audits International study was funded in 1999 by FDA to determine the food handling practices of consumers purchasing food at retail and returning home to refrigerate their items. Forty-six (46) states are represented, and the data comprises several food groups purchased from different grocery-store types. The food groups represented were: pre-packaged lunch meat, deli-counter products, seafood, fresh meat, pre-packaged deli product, liquid dairy, semi-solid dairy product, ice cream, frozen entrées, frozen novelties and whipped topping.

The study evaluated information regarding time and food temperature at retail food stores, time to reach home refrigeration, temperature after transport home, location and type of retail establishment where purchase was made and type of product purchased.

For product temperature at retail and after transportation, 5 product categories were used: pre packaged lunch meat, pre packaged deli product, deli counter products, seafood and fresh meat. These categories were considered most applicable to the TPHC recommendations. The temperature ranges for these products at retail and after transport to the home are summarized in Figures 1 and 2 respectively. The data suggest that with current retail refrigeration practices, 25% of items are held above 45°F (Figure 1). The data also show that by the time the product arrives at the home, 98% of products were at 65°F or less (Figure 2).

The time of transport for all food categories from the retail establishment to home refrigeration was also recorded. The data summarized in Figure 3 shows that over 97% of the foods purchased were ready to be placed in refrigeration within 2 hours of purchase. For this histogram, all food categories except for frozen entrées were included. Because all foods end up bagged and transported together, the time each product was transported to the home was considered a valid data point and therefore used. Based on the data, a benchmark was established that TCS foods purchased in a food establishment would be either consumed, or placed under temperature control, within 2 hours.

Figure 1. Temperatures of refrigerated products at retail (Audits International).

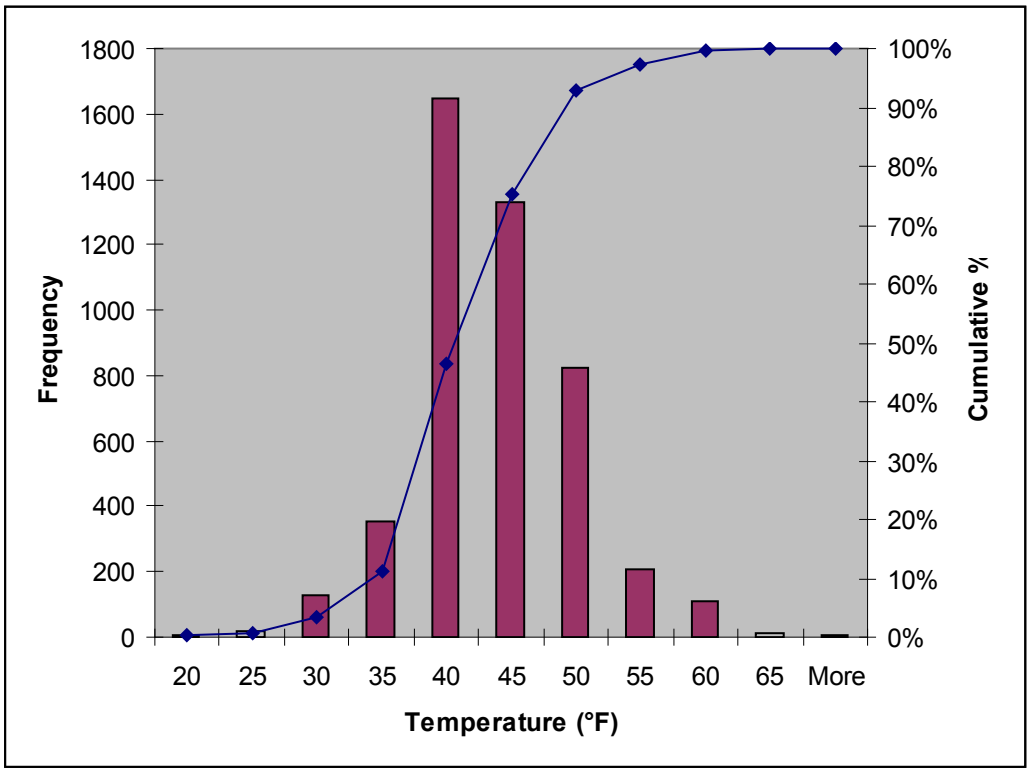


Figure 2. Product temperatures after transport to the home (Audits International).

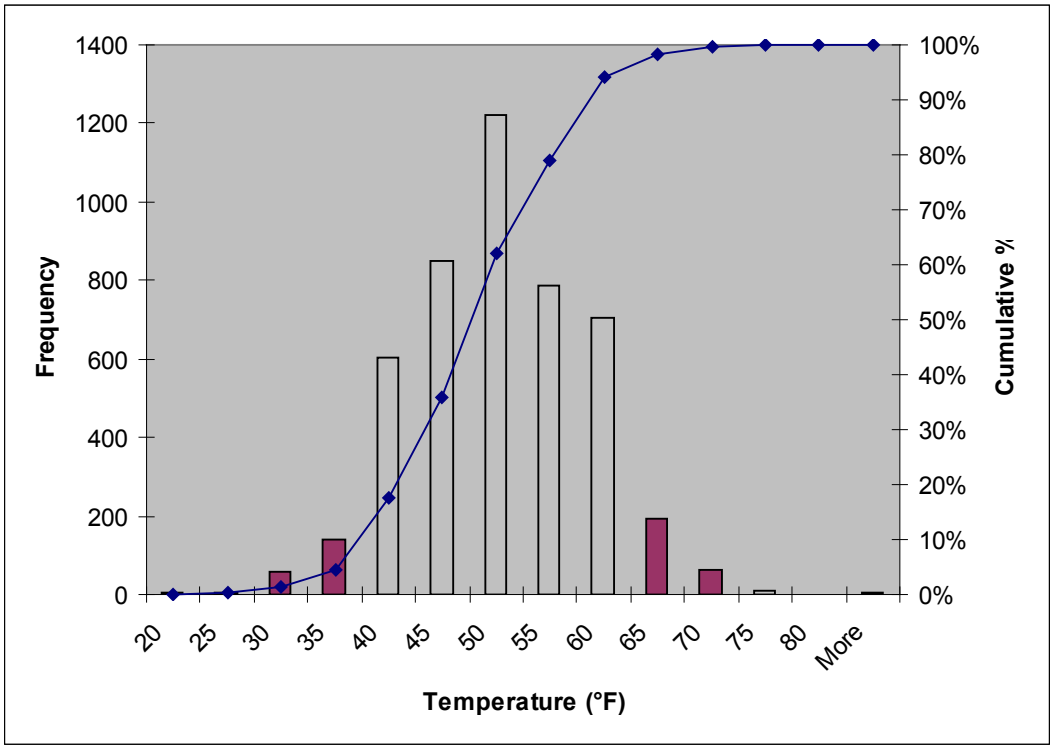
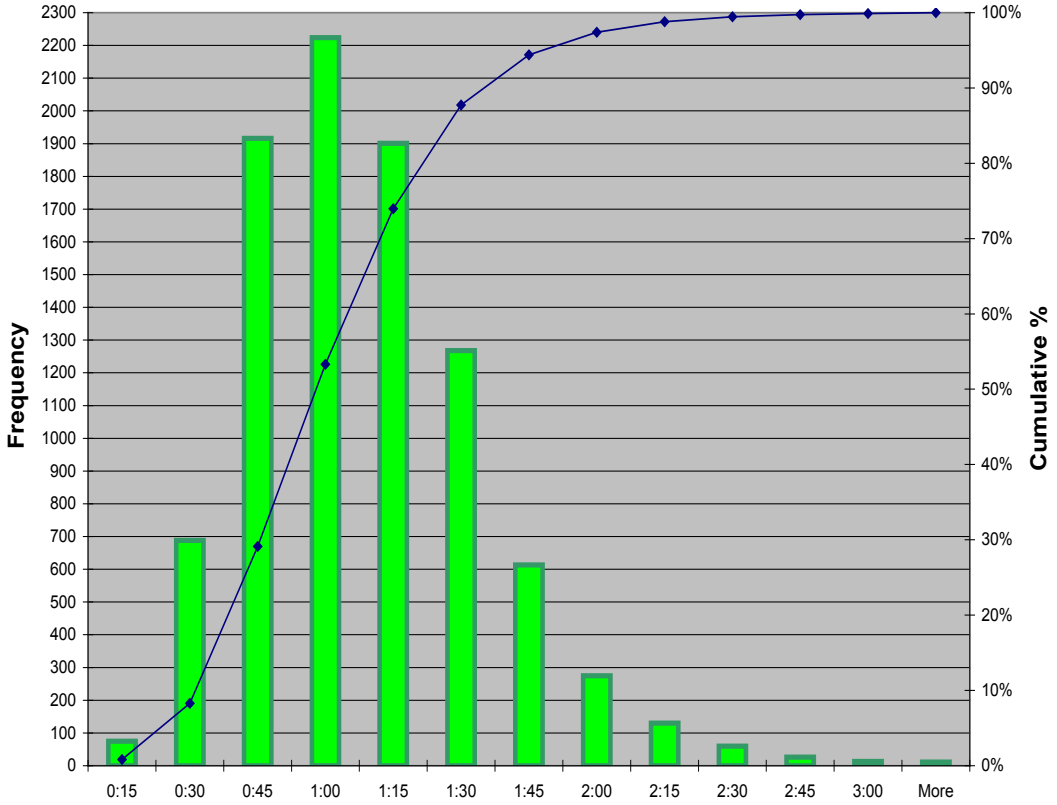


Figure 3. Times reported for transport of grocery items from the retail outlet to the home (Audits International).



The Safety of the Time as a Public Health Control Provision from Refrigeration Temperatures (41°F or less) to Ambient

As noted above, the current TPHC provision has two time provisions. Food can be kept with no temperature stipulations for 4 hours in a food establishment, at which time the food must be cooked and served, served if RTE, or discarded within the four hours. However, if food does not exceed 70°F, it may be held for 6 hours and cooked and served, served if RTE or discarded within the six hours. For foods warming from refrigeration to ambient temperatures, the data from the Audits International study outlined above, along with simulations from the USDA Pathogen Modeling Program (PMP), were used to determine the safety of the existing TPHC recommendations.

Assuming pathogen growth in foods going from refrigeration (41°F or less) to ambient temperature, the following parameters were used for the PMP simulation:

- 65°F was used as the temperature for the entire simulation;
- 2 hours were added to all times (4h or 6h) allowed in the current TPHC recommendation, to factor in transportation time (per the Audits International study outlined above);

- The data were generated from PMP broth models (pH 6.8), with the minimal NaCl and no sodium nitrite.

Table 1 summarizes the predicted growth of *Bacillus cereus* (vegetative), *Escherichia coli*, *Listeria monocytogenes*, Salmonella spp., *Shigella flexneri*, and *Staphylococcus aureus*, using the PMP and based on the assumptions discussed above. The data predicted that less than 1-log growth would be seen for each organism, during the 8 hour time period. Thus, the data show that the current 4 and 6 hour TPHC provisions from 41°F or less to ambient, allow minimal growth of a number of pathogens of concern.

Table 1. The USDA Pathogen Modeling Program estimation of growth (Log CFU/g) of several pathogens for 6 hours or 8 hours, at 65°F.

Pathogens	6 Hours	8 hours
B. cereus (vegetative cells)	0.62	0.87
E. coli	0.35	0.52
L. monocytogenes	0.47	0.71
Salmonella Spp.	0.25	0.41
S. flexneri	0.26*	0.34*
S. aureus	0.38*	0.51*

* Model predictions were in 5 hour increments, the 6 and 8 hour data was extrapolated between 5 hour and 10 hour predictions.

References

U.S. Department of Agriculture. 1997. *Pathogen Modeling Program.* USDA Agricultural Research Service, Wyndmoor, PA.

Food and Drug Administration. 2006. Growth of *Clostridium perfringens* inoculated into beef roasts and meatloaf (unpublished data).

---------- End of Summary of Consumer Handling Practices study **----------**

Raw eggs

Recipes in which more than one egg is combined carry an increased risk of illness and possible serious consequences for certain people. It is due to this increased risk, and documented occurrences of foodborne illness and death among highly susceptible populations from temperature-abused raw shell eggs contaminated with ***Salmonella* Enteritidis**, that the use of time as a public health control in institutional settings is not allowed.

Specialized Processing Methods **3-502.11 Variance Requirement.**

Specific food processes that require a variance have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.

The concept of variances may be new to some regulatory authorities. Some jurisdictions may not have a formal process to respond to industry requests for variances, although informal allowances may have been allowed in specific situations. Recognizing the opportunity to use the variance process may require additional rulemaking, or at least policy development, at the jurisdictional level. Rulemaking can be used to outline the procedures for a variance request, including the information required in section 8-103.11. In addition, the rulemaking process can address the regulatory authority's responsibility to consider an industry's variance application and an appeals process in case a variance is not given due consideration or is denied. The Conference for Food Protection Variance Committee recommended that regulatory agencies adopt a variance review process. General guidance regarding administrative procedures is given below.

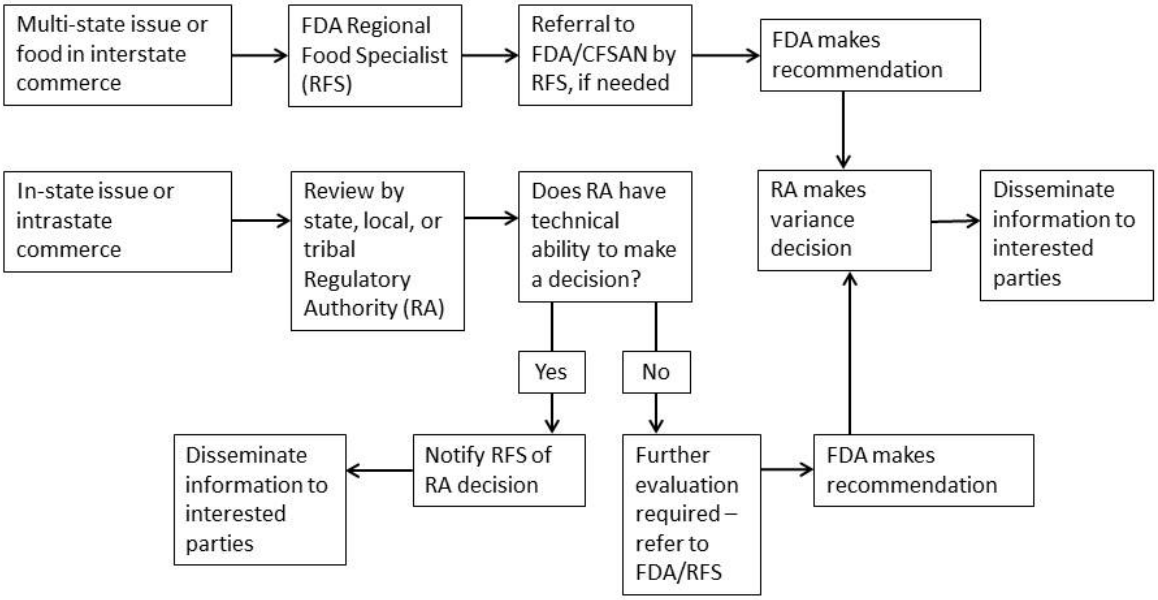
Regulatory authorities considering implementing variances have encountered issues relating to their authority or technical, scientific ability to evaluate or validate a variance request. From any variance request there may emerge a set of complex issues and scientific competencies beyond the ability of the regulatory authority to validate. The Conference for Food Protection Variance Committee recommended that rulemaking should reflect a multi-level matrix of regulatory agencies ranging from local regulatory authorities through FDA and reflected that recommendation in the following flow chart. The regulatory authority is encouraged to seek input and guidance from authoritative sources such as processing authorities, professional associations, or academia. Within the Variance Committee's model, the process for seeking FDA advice begins with the Regional Food Specialists.

Except for the Interstate Travel Program, FDA generally does not directly regulate retail and food service establishments, including entertaining variances for that segment of the industry. FDA is still exploring processes for handling variances on a national basis such as those received from national chain businesses. In conjunction with the 2000 CFP Variance Committee, FDA will continue to explore ways to provide assistance and guidance to regulators regarding access to scientific and technical resources in order to make science-based decisions regarding variances.

FDA recommends that regulatory authorities develop a written administrative process that is consistent with, and addresses the information contained in, Food Code sections 8-103.10, 8-103.11, and 8-103.12, and follow a process consistent with the recommendations of the CFP Variance Committee as shown in its flow chart.

3-502.11 Chart 1 – A Model Flow Process for State Regulators to Address Variances

Developed by the CFP Variance Committee



Model Administrative Procedures for Regulators to Address Variances

1) Designate an agency team and assign a leader to address variance requests.

2) Establish an agency review process leading to approval or denial of variance applications. For food safety issues, include recommendations for consulting with food processing authorities, food scientists, academia, professional organizations, other government agencies including the FDA Regional Food Specialist, or other experts external to the agency.

3) Set reasonable timelines for decision making. Determine if the variance application addresses an intrastate or interstate issue.

   a) For variances that have interstate or national implications, especially those that address food safety, regulators are urged to contact and work closely with their FDA Regional Food Specialist to determine if a national policy related to the issue exists. Regulators are encouraged to be consistent with national policies, guidelines, or opinions.
   b) For variances that address intrastate issues, regulators are also encouraged to determine if other State or national guidance exists, and to stay consistent with it.

4) Make the agency's decision. Inform the applicant.

   a) If the variance request is approved, determine the starting date and document all special provisions with which the applicant must comply.
   b) If the variance request is denied, inform the applicant as to the reasons for the denial, the applicant's right to appeal, and the appeal process.

5) Inform other interested parties, including the FDA Regional Food Specialist.

   a) For variances having interstate or national implications, especially those that address food safety, regulators are urged to inform their FDA Regional Food Specialist so that FDA is aware of, and can appropriately disseminate the information regarding food safety variances that may affect food establishments in other jurisdictions, such as national chains.

   b) For variances that address intrastate issues, regulators are encouraged to share the information as if it were an interstate issue.

6) Document all agency actions and decisions in the facility's file. Consider including documentation of special variance provisions on the establishment's permit to operate.

7) If the variance is approved, inform the inspector assigned to that facility and train the inspector on the variance provisions, including the implementation of the industry's HACCP plan, if required.

8) Establish procedures to periodically review the status of the variance, determine if it successfully accomplishes its public health objective, and ensure that a health hazard or nuisance does not result from its implementation.

9) Establish written procedures for withdrawing approval of the variance if it is not successful.

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal environment of the package contains less than the normal ambient oxygen level (typically 21% at sea level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere packaging (CAP), cook chill processing (CC), and sous vide (SV). Using ROP methods in food establishments has the advantage of providing extended shelf life to many foods because it inhibits spoilage organisms that are typically aerobic. ROP may also offer benefits related to time and labor savings, portion control and quality retention. However, ROP can also increase the potential for the growth of certain pathogens in the absence of the growth of competing spoilage organisms. For example, if certain controls are not in place, the formation of ***C. botulinum*** toxin may occur before spoilage renders the product unacceptable to the consumer.

The type of food, the production and packaging methods used, and the packaging material can impact the level of oxygen present within a package and within the food matrix. Combinations of some or all of these variables may result in an oxygen level within a package, or within a food matrix, that is less than 21%. While ROP may involve different foods and different packaging materials, each process is characterized by the deliberate removal of oxygen from or the reduction in the oxygen level in the package or the food matrix at the time of packaging.

Certain foodborne pathogens that are anaerobes or facultative anaerobes are able to multiply under either aerobic or anaerobic conditions. Therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic ***C. botulinum*** and ***L. monocytogenes*** are able to multiply well below 5°C (41°F). For this reason, ***C. botulinum*** and ***L. monocytogenes*** are the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

Reduced Oxygen Packaging with Two Barriers

When followed as written, the ROP methods in this section all provide controls for the growth and/or toxin production of ***C. botulinum*** and ***L. monocytogenes*** without a variance. Paragraph 3-502.12 (B) identifies an ROP method with secondary barriers that will control ***C. botulinum*** and ***L. monocytogenes*** when used in conjunction with a food storage temperature of 5°C (41°F) or less. These barriers are:

- a_w of 0.91 or less;
- pH of 4.6 or less;
- cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or

- high levels of competing microorganisms such as those found on raw meat or raw poultry or raw vegetables.

The barriers described above are effective controls for **C. *botulinum*** and **L. *monocytogenes*** in reduced oxygen packaged foods because**:**

- ***C. botulinum*** will not produce toxin below an a_w of 0.91*,* and the minimum a_w for growth of ***L. monocytogenes*** is 0.92.
- ***C. botulinum*** will not produce toxin when the pH is 4.6 or below and ***L. monocytogenes*** will generally not grow at this pH under refrigeration temperatures.
- Nitrite, used in meat and poultry curing, inhibits the outgrowth of ***C. botulinum*** spores.
- Most foodborne pathogens do not compete well with other microorganisms. Therefore foods that have a high level of spoilage organisms or lactic acid bacteria that grow under ROP conditions can safely be packaged using ROP and held for up to 30 days at 5°C (41°F).

Other intrinsic or extrinsic factors can also control the growth and/or toxin production of ***C. botulinum*** and ***L. monocytogenes****.*

Foods that are not time/temperature control for safety food (TCS) should not support the growth of ***C. botulinum*** and ***L. monocytogenes.*** Therefore the reduced oxygen packaging HACCP requirements of sections 3-502.11 or 3-502.12, apply only to TCS foods.

Reduced Oxygen Packaging with One Barrier (Cook-Chill and Sous Vide)

Some foods may not have secondary barriers to prevent the growth of ***C. botulinum*** and ***L. monocytogenes,*** such as a_w, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses. When these foods are packaged using a reduced oxygen packaging process, time/temperature becomes the critical controlling factor for growth of ***C. botulinum*** and ***L. monocytogenes****.* Non-proteolytic ***C. botulinum*** spores are able to germinate and produce toxin at temperatures down to 3ºC (38ºF). Therefore, holding ROP foods at 3ºC (38ºF) or less should prevent the formation of ***C. botulinum*** toxin. ***L. monocytogenes*** is able to grow, although very slowly, at temperatures down to - 1ºC (30ºF). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential. Three separate options are provided in (D)(2)(e).

These time-temperature combinations will provide equivalent food safety protection without need for a variance. (***L. monocytogenes*** will be eliminated by the cooking procedures specified in ¶¶3-401.11(A), (B) and (C) and recontamination will be prevented by filling the product into the bag while it is still hot (cook-chill) or by cooking in the sealed bag (sous vide). ***C. botulinum*** will not grow under the specified time-temperature combinations.)

Since there may not be other controlling factors for ***C. botulinum*** and ***L. monocytogenes*** in a cook-chill or sous vide packaged product, continuous monitoring of temperature control and visual examination to verify refrigeration temperatures is important. New technology makes it possible to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook-chill and sous vide products at 1°C (34°F) or 5°C (41°F) or less. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures that can be displayed using computer software. Since surveys have shown that temperature control in home kitchens is not always adequate, food packaged using cook-chill or sous vide processing methods cannot be distributed outside the control of the food establishment doing the packaging.

Reduced Oxygen Packaging with Cheese

Cheeses, as identified in ¶ 3-502.12(E), that meet the Standards of Identity for hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187, respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of factors could include some or all of the following:

- a lower pH;
- salt (NaCl) added during processing;
- low moisture content;
- added preservatives; and
- live competing cultures.

The extended shelf life for vacuum packaged hard and semisoft cheeses is based on the intrinsic factors in these cheeses plus the refrigeration temperature of 41°F or less to maintain safety. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey, Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of ***L. monocytogenes*** under modified atmosphere conditions.

Reduced Oxygen Packaging with Fish

Unfrozen raw fish and other seafood are specifically excluded from ROP at retail because of these products' natural association with non-proteolytic ***C. botulinum*** (primarily type E) which grows at 3°C (37-38°F). ROP of fish and seafood that are frozen before, during and after the ROP packaging process does not present this hazard.

HACCP Plans with Reduced Oxygen Packaging

A Hazard Analysis and Critical Control Point (HACCP) plan is essential when using ROP processing procedures. ***C. botulinum*** and ***L. monocytogenes*** are potential hazards which must be controlled in most TCS foods. Critical control points, critical limits, monitoring, record keeping, corrective actions, and verification procedures will vary based on the type of food and type of ROP technology used. Developing a HACCP plan and providing a copy to the regulatory authority prior to implementation provides notice to the regulatory authority that the food establishment intends to conduct ROP operations and makes it possible to verify that the appropriate ROP procedures are being followed and that the requirements of §3-502.12 are being met.

When a food establishment intends to conduct ROP and hold the product for more than 48 hours without using one of the secondary barriers defined in section 3-502.12 (the criteria specified in paragraph 3-502.12(D) combined with holding the product at 5°C (41°F) or less, or hard or semisoft cheeses manufactured using Standards of Identity for those cheeses), it is important that an application for a variance (under section 3-502.11) provide evidence that the ROP methodology intended for use is safe.

The Relationship Between Time and Reduced Oxygen Packaging

Time is also a factor that must be considered in ROP at retail. The use of date labels on VP, MAP, and CAP products and assuring those dates do not exceed the manufacturer's "sell by" or "use by" date is intended to limit the shelf life to a safe time period (based on a time in which growth will not occur or involves the presence of two barriers to growth). When these ROP products are frozen, there is no longer a restricted shelf life. The shelf life limits for cook-chill and sous-vide foods are based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 1°C (34°F) or less for 30 days or 5°C (41°F) or less for 7 days after packaging, with stringent temperature monitoring and recording requirements. These criteria allow both institutional-sized cook-chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast chillers to safely use cook-chill and sous-vide processes.

3-502.12 (F) exempts refrigerated, ROP foods that are always removed from the package within 48 hours of packaging from the requirements in section 3-502.12 because growth and toxin formation by anaerobic pathogens in that limited time frame is not considered a significant hazard in such foods.

Accurate	**3-601.11**	**Standards of Identity.**
Representation	**3-601.12**	**Honestly Presented.**
Labeling	**3-602.11**	**Food Labels.**
	3-602.12	**Other Forms of Information.**

The identity of a food in terms of origin and composition is important for instances when a food may be implicated in a foodborne illness outbreak and for nutritional information requirements. Ingredient information is needed by consumers who have allergies to certain food or ingredients. The appearance of a food should not be altered or disguised because it is a cue to the consumer of the food's identity and condition.

Food Labels and other forms of Information

Food labels serve as a primary means by which consumers can make informed decisions about their food selections. Many items in a food establishment are provided by the food employee to the consumer upon consumer request. When a consumer orders a specific food or specific amount of food from a food employee, that employee may put the food in a wrapper or carry-out container at the time the order is placed. This food is not considered “packaged”, per the Food Code definition; it was merely wrapped or placed in a carry-out container to facilitate service and delivery of the food to the consumer in a protected manner. When food is under the direct control of the operator and provided to the consumer upon consumer request, the consumer has an opportunity to ask about ingredients, nutrients, allergens and weight.

Alternatively, some food items are enclosed in a container or wrapping for use in the display of that item for consumer self-service. In these instances, the label provides an important source of information for consumers to answer questions about ingredients, allergens, weight, and manufacturer.

List of Ingredients

A list of ingredients on the label enables a consumer to make an informed decision about a packaged food product. Therefore it is important that the list of ingredients accurately describe all of the ingredients present in the food. In some instances, an ingredient itself may be composed of two or more ingredients, or sub-ingredients. The 21 CFR 101.4(b)(2), calls for the sub-ingredients to be declared on the label - d. One example includes parenthetically listing the individual sub-ingredients in descending order of predominance after the common or usual name of the main ingredient, as illustrated here:

- Bread pudding: bread (*wheat flour, water, yeast, salt, honey*), milk, eggs, and sugar

Another example is to incorporate the common or usual name of each sub ingredient into the list of ingredients in descending order of predominance in the finished food without listing the ingredient itself, as illustrated here :

- Bread pudding: milk, wheat flour, water, eggs, sugar, yeast, salt, and honey.

Food Allergen Labeling

The Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282) require that all affected packages of food labeled on or after January 1, 2006 identify on the label the names of the food sources of any major food allergens (i.e., the following eight foods and any protein derived from them: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans) used as ingredients in the food. Providing the name of the food source on the label of packaged foods alerts consumers to the presence of a major food allergen and may prevent an inadvertent exposure. The names of the food sources are the same as the names of the eight foods that are major food allergens, with the exception that for fish, crustacean shellfish, and tree nuts, their respective food source names are the specific species of fish (e.g., bass, flounder, or cod), the specific species of crustacean shellfish (e.g., crab, lobster, or shrimp), and the specific types of tree nuts (e.g., almonds, pecans, or walnuts).

Nutrition Labeling

Certain requirements in the CFR relating to aspects of nutrition labeling became effective in May, 1997. The following attempts to provide guidance regarding those requirements and exemptions as they relate to the retail environment and to alert regulators to authority that has been given to them by the Nutrition Labeling and Education Act (NLEA) of 1990. The statute and the CFR should be reviewed to ensure a comprehensive understanding of the labeling requirements.

I. The following foods need not comply with nutrition labeling in the CFR referenced in subparagraph 3-602.11(B)(6) if they do not bear a nutrient claim, health claim, or other nutrition information:

(A) Foods packaged in a food establishment if:

(1) The food establishment has total annual sales to consumers of no more than $500,000 (or no more than $50,000 in food sales alone), and

(2) The label of the food does not bear a reference to the manufacturer or processor other than the food establishment;

(B) Low-volume food products if:

(1) The annual sales are less than 100,000 units for which a notification claiming exemption has been filed with FDA's Office of Nutritional Products Labeling and Dietary Supplements Food Labeling by a small business with less than 100 full-time equivalent employees, or

(2) The annual sales are less than 10,000 units by a small business with less than 10 full-time equivalent employees;

(C) Foods served in food establishments with facilities for immediate consumption such as restaurants, cafeterias, and mobile food establishments, and foods sold only in those establishments;

(D) Foods similar to those specified in the preceding bullet but that are sold by food establishments without facilities for immediate consumption such as bakeries and grocery stores if the food is:

(1) Ready-to-eat but not necessarily for immediate consumption,

(2) Prepared primarily in the food establishment from which it is sold, and

(3) Not offered for sale outside the food establishment;

(E) Foods of no nutritional significance such as coffee;

(F) Bulk food for further manufacturing or repacking; and

(G) Raw fruits, vegetables, and fish.

II. Game animal meats shall provide nutrition information which may be provided by labeling displayed at the point of purchase such as on a counter card, sign, tag affixed to the food, or some other appropriate device.

III. Food packaged in a food processing plant or another food establishment, shall meet the requirements specified in § 3-602.11 and enforcement by the regulatory authority is authorized in the NLEA, Section 4. State Enforcement.

Canthaxanthin and Astaxanthin

Canthaxanthin and Astaxanthin are color additives for salmonid fish. According to the FDA Regulatory Fish Encyclopedia, the family Salmonidae includes pink salmon, coho salmon, sockeye salmon, chinook salmon, Atlantic salmon, chum salmon, rainbow trout, cutthroat trout, and brown trout. These color additives may be in the feed that is fed to aquacultured fish. When those fish are placed into a bulk container for shipment, the bulk container will bear a label declaring the presence of canthaxanthin.

Providing this information on the label of fish packaged and offered for sale at retail will inform the consumer of the presence of these additives

21 CFR 73.75 promulgates requirements for the use of canthaxanthin in salmonid fish. 21 CFR 73.35 promulgates requirements for the use of astaxanthin in salmonid fish. For additional information, see the Federal Register announcement 63 FR 14814, March 27, 1998, Listing of Color Additives Exempt from Certification, Canthaxanthin.

Safe Handling Instructions

Refer to public health reason for § 3-201.11 Labeling for Meat and Poultry.

Consumer Advisory	**3-603.11**	**Consumption of Raw or Undercooked Animal Foods.**

Refer to the public health reason for § 3-401.11.

Purpose:

At issue is the role of government agencies, the regulated industry, and others in providing notice to consumers that animal-derived foods that are not subjected to adequate heat treatment pose a risk because they may contain biological agents that cause foodborne disease. The deliverance of a balanced message that communicates fairly to all consumers and, where epidemiologically supported, attempts to place risk in perspective based on the consumer's health status and the food being consumed is part of the challenge. Notification of risk must be achieved via a meaningful message and in a manner that is likely to affect behavior. The following information is to alert the reader to the options available to food establishments in advising consumers of the increased possibility of foodborne illness when animal-derived foods are eaten raw or undercooked.

Background:

Although no specific advisory language was recommended, beginning with the 1993 Food Code, FDA included a codified provision for a point-of-purchase consumer advisory and stated in Annex 3:

> "FDA has requested comments and will consider the responses as well as other information that is available related to the risks involved and methods of risk communication to determine what action may be necessary by FDA to effectively inform consumers."

Consumer Focus Groups:

During 1996 - 1998, FDA conducted two different consumer focus group studies. Because the first set of focus groups (conducted before the 1997 Code) were not receptive to the language recommended at the 1996 Conference for Food Protection (CFP) meeting, that language was not included in the 1997 Code. Before the 1998 CFP meeting, the Agency convened a second set of focus groups with a modified approach. The latter set expressed similar thoughts as those in the earlier set and a pattern for consumer acceptance and receptiveness to menu-based advisories emerged.

It became apparent that there is a general appreciation for "**disclosure**" of what consumers view as "hidden ingredients, " for example, whether a particular menu item contains raw egg. In addition to disclosure being viewed as helpful, consumers are accepting, if not appreciative, of a "**reminder**" that consuming raw or undercooked animal-derived foods carries an increased risk of foodborne illness. In the food establishment venue, consumers are less willing to accept a message that extends beyond a reminder and becomes a lesson or an educational message.

Satisfactory Compliance:

FDA submitted to the 1998 CFP meeting an Issue that asked the Conference to discuss an approach that incorporated the knowledge obtained from the consumer testing. It was the consensus of the CFP that **satisfactory compliance with the Code's consumer advisory provision is fulfilled when both a disclosure and reminder are provided**, as described in § 3-603.11 of the Code. **Disclosure is** achieved when there is clear identification of animal-derived foods that are sold or served raw or undercooked, and of items that either contain or <u>may contain</u> (to allow for ingredient substitution) such raw or undercooked ingredients. A third option for the consumer "reminder" was added later. The **reminder is** a notice about the relationship between thorough cooking and food safety.

Two options were endorsed for disclosure and two for the reminder. One of the reminder options is a menu statement that advises consumers that food safety information about the disclosed items is available upon request. Essential criteria for such written information are available from FDA through the Retail Food Protection Team by writing to: FDA/CFSAN, 5100 Paint Branch Parkway, (HFS-320) College Park, Maryland 20740. All brochures must meet these essential criteria. The other option is a short notice alerting consumers to the increased risk of consuming the disclosed menu items.

In response to concerns raised by the Interstate Shellfish Sanitation Conference (ISSC) in an October 8, 1998 letter to FDA, a third option has been added to allow for a statement that links an increased risk of illness to consumption of raw or undercooked animal foods by persons with certain medical conditions.

The information contained in both the disclosure and reminder should be publicly available and readable so that consumers have benefit of the total message (disclosure and reminder) before making their order selections.

It is not possible to anticipate all conceivable situations. Therefore, there will always be need for discussion between the food establishment and the Regulatory Authority as to the most effective way to meet the objectives of satisfactory compliance.

The *Implementation Guidance for the Consumer Advisory Provision of the FDA Food Code* (section 3-603.11 in the FDA Model Food Code), is a resource intended to assist regulators and industry in the implementation of the Consumer Advisory provision. It is recommended that it be used in conjunction with the FDA Food Code. It is available from FDA through the Retail Food Protection Team by writing to: FDA/CFSAN, 5100 Paint Branch Parkway, (HFS-320) College Park, Maryland 20740.

Locating the Advisory:

Disclosure of raw or undercooked animal-derived foods or ingredients and reminders about the risk of consuming such foods belong at the point where the food is selected by the consumer. Both the disclosure and the reminder need to accompany the information from which the consumer makes a selection. That information could appear in many forms such as a menu, a placarded listing of available choices, or a table tent.

Educational Messages:

Educational messages are usually longer, more didactic in nature, and targeted to consumers who have been alerted to the food safety concern and take the initiative to obtain more detailed information. It is expected that, in most cases, educational messages that are provided pursuant to § 3-603.11 (i.e., in situations where the option for referring the consumer to additional information is chosen), will be embodied in brochures that will not be read at the site where the immediate food choice is being made. Nonetheless, such messages are viewed as an important facet of arming consumers with the information needed to make informed decisions and, because the information is being requested by the consumer, it would be expected to play a role in subsequent choices.

Applicability:

Food Establishments:

The consumer advisory is intended to apply to all food establishments where raw or undercooked animal foods or ingredients are sold or served for human consumption in a raw or undercooked form. This includes all types of food establishments whenever there is a reasonable likelihood that the food will be consumed without subsequent, thorough cooking - such as restaurants, raw bars, quick-service operations, carry-outs, and sites where groceries are obtained that have operations such as delicatessens or seafood departments.

"*... Otherwise Processed to Eliminate Pathogens... ":*

This phrase is included in § 3-603.11 to encompass new technologies and pathogen control/reduction regimens as they are developed and validated as fulfilling a specific performance standard for pathogens of concern. Pasteurization of milk is an example of a long-standing validated process. For purposes of the Food Code, the level of pathogen reduction that is required before a raw or undercooked animal food is allowed to be offered without a consumer advisory must be equivalent to the levels provided by § 3-401.11 for the type of food being prepared.

The absorbed dose levels of radiation approved by FDA on December 3, 1997 for red meat are insufficient to reduce the level of most vegetative pathogens to a point that is equivalent to the reductions achieved in ¶¶ 3-401.11(A) and (B). Irradiated poultry provides a 3D kill which does not provide the level of protection of the 7D kill that results from the cooking regimen in the Food Code. Therefore, irradiated meat and poultry are not allowed to be offered in a ready-to-eat form without a consumer advisory. It is intended that future Food Code revisions will address time/temperature requirements that take into consideration the pathogen reduction that occurs with irradiated foods.

Recognition of Other Processes:

Animal-derived foods may undergo validated processes that target a specific pathogen. In such instances, along with the required consumer advisory may appear additional language that accurately describes the process and what it achieves. For example, a technology for reducing ***Vibrio vulnificus*** in oysters to nondetectable levels has been validated. FDA concurs that shellfish subjected to that process can be labeled with a truthful claim that appropriately describes the product. That is, a statement could be made such as, "pasteurized to reduce ***Vibrio vulnificus***" or "temperature treated to reduce ***Vibrio vulnificus****.* " Such a claim must be in accordance with labeling laws and regulations, accurate, and not misleading. The claim would not, however, negate the need for a consumer advisory because the treatment only reduces the level of one pathogenic organism.

Product-specific Advisories:

Consumer advisories may be tailored to be product-specific if a food establishment either has a limited menu or offers only certain animal-derived foods in a raw or undercooked ready-to-eat form. For example, a raw bar serving molluscan shellfish on the half shell, but no other raw or undercooked animal food, could elect to confine its consumer advisory to shellfish. The raw bar could also choose reminder, option #3, which would highlight the increased risk incurred when persons with certain medical conditions ingest shellfish that has not been adequately heat treated.

Terminology:

It should be noted that the actual on-site (e.g., on-the-menu) advisory language differs from the language in the codified provision, § 3-603.11. In the insert page for § 3-603.11, the **Reminder** options 2 and 3 use terms for foods that are less specific than the terms used in the actual code section. That is, the words "meat" rather than "beef, lamb, and pork" and "seafood" rather than "fish" are used. Categorical terms like "meat" are simpler and may be more likely used in conversation, making them suitable for purposes of a menu notice.

Milk:

In addition, "milk" is not mentioned in the actual on-site advisory language. The sale or transportation of final packaged form of unpasteurized milk into interstate commerce is specifically prohibited by 21 CFR 1240.61. Also the consumption of raw milk is not recommended by FDA (this statement is in the form of an official FDA position statement found at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm2007973.htm. Nonetheless, approximately 25 states allow unpasteurized milk in intrastate commerce which usually involves direct dairy farm-to-consumer procurement.

In the event that a food establishment governed by § 3-603.11 of this Code operates in conjunction with a dairy farm in a State that allows the in-State sale or service of unpasteurized milk, or in the case where a State allows unpasteurized milk to be marketed via retail-level food establishments, consumers need to be advised of the risk associated with drinking unpasteurized milk. In these situations, the actual advisory language needs to be amended to include milk (refer to Consumer Advisory Reminder, paragraph 3-603.11(C), options 2 or 3).

Molluscan Shellstock:

In addition to areas of retail food stores such as delis in supermarkets, the consumer advisory is to be provided when a seafood department or seafood market offers raw molluscan shellstock for sale or service. There is a risk of death from ***Vibrio*** infections from consuming raw molluscan shellstock for persons who have certain medical conditions.

Disposition **3-701.11** **Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.**

Pathogens may be transmitted from person to person through contaminated food. The potential spread of illness is limited when food is discarded if it may have been contaminated by employees who are infected, or are suspected of being infected, or by any person who otherwise contaminates it.

Additional Safeguards **3-801.11** **Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.**

Refer to the public health reason for § 3-201.11.

The Code provisions that relate to highly susceptible populations are combined in this section for ease of reference and to add emphasis to special food safety precautions that are necessary to protect those who are particularly vulnerable to foodborne illness and for whom the implications of such illness can be dire.

As a safeguard for highly susceptible populations from the risk of contracting foodborne illness from juice, prepackaged juice is required to be obtained pasteurized or in a commercially sterile, shelf-stable form in a hermetically sealed container. It is important to note that the definition of a "juice" means it is served as such or used as an ingredient in beverages. Puréed fruits and vegetables, which are commonly prepared as food for service to highly susceptible populations, are not juices and do not require HACCP plans or compliance with 21 CFR Part 120. There are documented cases of foodborne illness throughout the United States that were associated with the consumption of various juice products contaminated with microorganisms such as ***Cryptosporidium***, Shiga toxin-producing ***Escherichia coli***, ***Salmonella*** spp., and ***Vibrio cholera***. As new information becomes available, the Food Code will be modified or interim interpretive guidance will be issued regarding foodborne illness interventions for on-site juicing and puréeing.

The 21 CFR 120 regulation applies to products sold as juice or used as an ingredient in beverages. This includes fruit and vegetable purees that are used in juices and beverages, but is not intended to include freshly prepared fruit or vegetable purees that are prepared on-site in a facility for service to a highly susceptible population.

In lieu of meeting the requirements of 21 CFR 120, juices that are produced as commercially sterile products (canned juices) are acceptable for service to a highly susceptible population. Persons providing pureed meals to highly susceptible populations may also wish to use fruit and vegetables that are produced as commercially sterile products (canned fruit or vegetables) as a means of enhancing food safety.

Salmonella often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. In 1986 there was a large multistate outbreak of ***Salmonella* Enteritidis** traced to stuffed pasta made with raw eggs and labeled "fully cooked." Eggs remain a major source of these infections, causing large outbreaks when they are combined and undercooked as was the case in the 1986 outbreak linked to stuffed pasta. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

Operators of food establishments serving highly susceptible populations may wish to discuss buyer specifications with their suppliers. Such specifications could stipulate eggs that are produced only by flocks managed under a ***Salmonella* Enteritidis** control program that is recognized by a regulatory agency that has animal health jurisdiction. Such programs are designed to reduce the presence of ***Salmonella* Enteritidis** in raw shell eggs. In any case, the food establishment operator must use adequate time and temperature controls within the establishment to minimize the risk of a foodborne illness outbreak relating to ***Salmonella* Enteritidis**.

Since 1995, raw seed sprouts have emerged as a recognized source of foodborne illness in the United States. The FDA and CDC have issued health advisories that persons who are at a greater risk for foodborne disease should avoid eating raw alfalfa sprouts until such time as intervention methods are in place to improve the safety of these products. Further information is available at the FDA website, http://www.fda.gov, by entering “sprouts” in the search window.

Although the Code’s allowance for the Regulatory Authority to grant a variance (refer to §§ 8-103.10 - .12, 8-201.14, and 8-304.11) is applicable to all Code provisions, variance requests related to the preparation of food for highly susceptible populations must be considered with particular caution and scrutiny. With all variances, the hazard(s) must be clearly identified and controlled by a HACCP plan that is instituted in conjunction with a standard operating plan that implements good retail practices. Variances that will impact a highly susceptible population must be considered in light of the fact that such a population is at a significantly higher risk of contracting foodborne illnesses and suffering serious consequences including death from those illnesses, than is the general population.

Subparagraph 3-801.11(F)(3) requires a HACCP plan for the use of raw shell eggs when eggs are combined in food establishments serving highly susceptible populations. A variance is not required since the HACCP plan criteria are specific, prescriptive, and conservative and require a cooking temperature and time to ensure destruction of ***Salmonella* Enteritidis**.

3-801.11(G) and (H) Re-service of food

The Food Code addresses two issues concerning persons in isolation:

1. Contamination from an isolated patient to others outside.

The re-service of any food including unopened, original, intact packages in sound condition, of non-temperature controlled for safety food from a person in isolation or quarantine for use by anyone else (other patients, clients, or consumers) is <u>not</u> permitted. The "isolation or quarantine" terminology in the Code text refers to a patient-care setting that isolates the patient, thereby preventing spread of key pathogens to other patients and healthcare workers. Once food packages come to a contact isolation room, they stay there until the patient uses or discards them. If packages of food are still in the room when the patient is discharged or moved from isolation, they must be discarded.

2. Contamination from the outside into a room with a patient in a "protective environment" isolation setting which protects the patient from contacting pathogens from other patients, healthcare workers, or other persons.

Packages of food from any patients, clients or other consumers should not be re-served to persons in protective environment isolation. Precautions similar to the isolation setting apply to this setting, i.e., once an unopened, original, intact package of condiment is delivered to this patient, the package stays there until used or discarded. New (not re-served) packages of food should be delivered to this patient each time.

To summarize the key difference between the two scenarios:

- Food packages served to patients in contact isolation may not be re-served to other patients because of the potential for disease transmission to other patients.

- Patients in protective environments should not be re-served with food packages from other patients because of the potential for disease transmission to the protective environment patient.

Chapter 4 Equipment, Utensils, and Linens

Multiuse **4-101.11 Characteristics.**

Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared which could lead to foodborne illness. In addition, some materials can affect the taste of the food being prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes contaminated.

Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

4-101.12 Cast Iron, Use Limitation.

Equipment and utensils constructed of cast iron meet the requirement of durability as intended in section 4-101.11. However, the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean. On the other hand, when cast iron use is limited to cooking surfaces the residues in the porous surface are not of significant concern as heat destroys potential pathogens that may be present.

4-101.13 Lead, Use Limitation.

Historically, lead has been used in the formulation or decoration of these types of utensils. Specifically, lead-based paints that were used to decorate the utensils such as color glazes have caused high concentrations of lead to leach into the food they contain.

Lead poisoning continues to be an important public health concern due to the seriousness of associated medical problems. Lead poisoning is particularly harmful to the young and has caused learning disabilities and medical problems among individuals who have consumed high levels. The allowable levels of lead are specific to the type of utensil, based on the average contact time and properties of the foods routinely stored in each item listed.

FDA has established maximum levels (see FDA Compliance Policy Guide Section 545.450 Pottery (Ceramics); Imported and Domestic – Lead Contamination (CPG 7117.07) for leachable lead in ceramicware, and pieces that exceed these levels are subject to recall or other agency enforcement action. The levels are based on how frequently a piece of ceramicware is used, the type and temperature of the food it holds, and how long the food stays in contact with the piece. For example, cups, mugs, and pitchers have the most stringent action level, 0.5 parts per million, because they can be expected to hold food longer, allowing more time for lead to leach. Also, a pitcher may be used to hold fruit juice. And a coffee mug is generally used every day to hold a hot acidic beverage, often several times a day.

The FDA allows use of lead glazes because they're the most durable, but regulates them tightly to ensure their safety. Commercial manufacturers employ extremely strict and effective manufacturing controls that keep the lead from leaching during use. Small potters often can't control the firing of lead glazes as well so their ceramics are more likely to leach illegal lead levels, although many do use lead-free glazes.

In 21 CFR 109.16, FDA requires high-lead-leaching decorative ceramicware to be permanently labeled that it's not for food use and may poison food. Such items bought outside the United States may not be so labeled, potentially posing serious risk if used for food.

Pewter refers to a number of silver-gray alloys of tin containing various amounts of antimony, copper, and lead. The same concerns about the leaching of heavy metals and lead that apply to brass, galvanized metals, copper, cast iron, ceramics, and crystal also apply to pewter. As previously stated, the storage of acidic moist foods in pewter containers could result in food poisoning (heavy metal poisoning).

Solder is a material that is used to join metallic parts and is applied in the melted state to solid metals. Solder may be composed of tin and lead alloys.

4-101.14 Copper, Use Limitation.

High concentrations of copper are poisonous and have caused foodborne illness. When copper and copper alloy surfaces contact acidic foods, copper may be leached into the food. Carbon dioxide may be released into a water supply because of an ineffective or nonexistent backflow prevention device between a carbonator and copper plumbing components. The acid that results from mixing water and carbon dioxide leaches copper from the plumbing components and the leachate is then transferred to beverages, causing copper poisoning. Backflow prevention devices constructed of copper and copper alloys can cause, and have resulted in, the leaching of both copper and lead into carbonated beverages.

Brass is an alloy of copper and zinc and contains lead which is used to combine the two elements. Historically, brass has been used for items such as pumps, pipe fitting, and goblets. All 3 constituents are subject to leaching when they contact acidic foods, and food poisoning has resulted from such contact.

The steps in beer brewing include malting, mashing, fermentation, separation of the alcoholic beverage from the mash, and rectification. During mashing, it is essential to lower the pH from its normal 5.8 in order to optimize enzymatic activity. The pH is commonly lowered to 5.1-5.2, but may be adjusted to as low as 3.2. The soluble extract of the mash (wort) is boiled with hops for 1 to 22 hours or more. After boiling, the wort is cooled, inoculated with brewers yeast, and fermented. The use of copper equipment during the prefermentation and fermentation steps typically result in some leaching of copper.

Because copper is an essential nutrient for yeast growth, low levels of copper are metabolized by the yeast during fermentation. However, studies have shown that copper levels above 0.2 mg/L are toxic or lethal to the yeast. In addition, copper levels as low as 3.5 mg/L have been reported to cause symptoms of copper poisoning in humans. Therefore, the levels of copper necessary for successful beer fermentation (i.e., below 0.2 mg/L) do not reach a level that would be toxic to humans.

Today, domestic beer brewers typically endeavor to use only stainless steel or stainless steel-lined copper equipment (piping, fermenters, filters, holding tanks, bottling machines, keys, etc.) in contact with beer following the hot brewing steps in the beer making process. Some also use pitch-coated oak vats or glass-lined steel vats following the hot brewing steps. Where copper equipment is not used in beer brewing, it is common practice to add copper (along with zinc) to provide the nutrients essential to the yeast for successful fermentation.

4-101.15 Galvanized Metal, Use Limitation.

Galvanized means iron or steel coated with zinc. Metals such as iron and steel are coated with zinc to prevent rusting. Under certain conditions, zinc may leach from galvanized food-contact surfaces into foods that are high in water content. The risk of leaching increases with increased acidity of foods contacting the galvanized food-contact surface. On contact with acidic foods and beverages, the zinc may be converted to zinc salts which are readily absorbed by the body

Zinc is generally considered to be non-toxic, and in fact is a required mineral for many processes that occur in the human body. However, zinc is known to be toxic when ingested in large quantities. Symptoms of zinc poisoning include vomiting, nausea, lethargy, fatigue, and epigastric pain. Most reports of zinc poisoning implicate contaminated food that resulted from storage in a galvanized metal container.

Also see http://www.cdc.gov/mmwr/preview/mmwrhtml/00000082.htm

4-101.16 Sponges, Use Limitation.

Sponges are difficult, if not impossible, to clean once they have been in contact with food particles and contaminants that are found in the use environment. Because of their construction, sponges provide harborage for any number and variety of microbiological organisms, many of which may be pathogenic. Therefore, sponges are to be used only where they will not contaminate cleaned and sanitized or in-use, food-contact surfaces such as for cleaning equipment and utensils before rinsing and sanitizing.

4-101.17 Wood, Use Limitation.

The limited acceptance of the use of wood as a food-contact surface is determined by the nature of the food and the type of wood used. Moist foods may cause the wood surface to deteriorate and the surface may become difficult to clean. In addition, wood that is treated with preservatives may result in illness due to the migration of the preservative chemicals to the food; therefore, only specific preservatives are allowed.

4-101.18 Nonstick Coatings, Use Limitation.

Perfluorocarbon resin is a tough, nonporous and stable plastic material that gives cookware and bakeware a surface to which foods will not stick and that cleans easily and quickly. FDA has approved the use of this material as safe for food-contact surfaces. The Agency has determined that neither the particles that may chip off nor the fumes given off at high temperatures pose a health hazard. However, because this nonstick finish may be scratched by sharp or rough-edged kitchen tools, the manufacturer's recommendations should be consulted and the use of utensils that may scratch, abrasive scouring pads, or cleaners avoided.

4-101.19 Nonfood-Contact Surfaces.

Nonfood-contact surfaces of equipment routinely exposed to splash or food debris are required to be constructed of nonabsorbent materials to facilitate cleaning. Equipment that is easily cleaned minimizes the presence of pathogenic organisms, moisture, and debris and deters the attraction of rodents and insects.

Single-Service and Single-Use

4-102.11 Characteristics.

The safety and quality of food can be adversely affected through single service and single use articles that are not constructed of acceptable materials. The migration of components of those materials to food they contact could result in chemical contamination and illness to the consumer. In addition, the use of unacceptable materials could adversely affect the quality of the food because of odors, tastes, and colors transferred to the food.

Durability and Strength **4-201.11 Equipment and Utensils.**

Equipment and utensils must be designed and constructed to be durable and capable of retaining their original characteristics so that such items can continue to fulfill their intended purpose for the duration of their life expectancy and to maintain their easy cleanability. If they can not maintain their original characteristics, they may become difficult to clean, allowing for the harborage of pathogenic microorganisms, insects, and rodents. Equipment and utensils must be designed and constructed so that parts do not break and end up in food as foreign objects or present injury hazards to consumers. A common example of presenting an injury hazard is the tendency for tines of poorly designed single service forks to break during use.

4-201.12 Food Temperature Measuring Devices.

Food temperature measuring devices that have glass sensors or stems present a likelihood that glass will end up in food as a foreign object and create an injury hazard to the consumer. In addition, the contents of the temperature measuring device, e.g., mercury, may contaminate food or utensils.

Cleanability **4-202.11 Food-Contact Surfaces.**

The purpose of the requirements for multiuse food-contact surfaces is to ensure that such surfaces are capable of being easily cleaned and accessible for cleaning. Food-contact surfaces that do not meet these requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces which have imperfections such as cracks, chips, or pits allow microorganisms to attach and form biofilms. Once established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and sanitizing efforts. The requirement for easy disassembly recognizes the reluctance of food employees to disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.

4-202.12 CIP Equipment.

Certain types of equipment are designed to be cleaned in place (CIP) where it is difficult or impractical to disassemble the equipment for cleaning. Because of the closed nature of the system, CIP cleaning must be monitored via access points to ensure that cleaning has been effective throughout the system.

The CIP design must ensure that all food-contact surfaces of the equipment are contacted by the circulating cleaning and sanitizing solutions. Dead spots in the system, i.e., areas which are not contacted by the cleaning and sanitizing solutions, could result in the buildup of food debris and growth of pathogenic microorganisms. There is equal concern that cleaning and sanitizing solutions might be retained in the system, which may result in the inadvertent adulteration of food. Therefore, the CIP system must be self-draining.

4-202.13 "V" Threads, Use Limitation.

V-type threads present a surface which is difficult to clean routinely; therefore, they are not allowed on food-contact surfaces. The exception provided for hot oil cooking fryers and filtering systems is based on the high temperatures that are used in this equipment. The high temperature in effect sterilizes the equipment, including debris in the "V" threads.

4-202.14 Hot Oil Filtering Equipment.

To facilitate and ensure effective cleaning of this equipment, Code requirements, §§ 4-202.11 and 4-202.12 must be followed. The filter is designed to keep the oil free of undesired materials and therefore must be readily accessible for replacement. Filtering the oil reduces the likelihood that off-odors, tastes, and possibly toxic compounds may be imparted to food as a result of debris buildup. To ensure that filtering occurs, it is necessary for the filter to be accessible for replacement.

4-202.15 Can Openers.

Once can openers become pitted or the surface in any way becomes uncleanable, they must be replaced because they can no longer be adequately cleaned and sanitized. Can openers must be designed to facilitate replacement.

4-202.16 Nonfood-Contact Surfaces.

Hard-to-clean areas could result in the attraction and harborage of insects and rodents and allow the growth of foodborne pathogenic microorganisms. Well-designed equipment enhances the ability to keep nonfood-contact surfaces clean.

4-202.17 Kick Plates, Removable.

The use of kick plates is required to allow access for proper cleaning. If kick plate design and installation does not meet Code requirements, debris could accumulate and create a situation that may attract insects and rodents.

Accuracy 4-203.11 Temperature Measuring Devices, Food.

The Metric Conversion Act of 1975 (amended 1988, 1996, and 2004, 15 USC 205a et seq) requires that all Federal government regulations use the Celsius scale for temperature measurement. The Fahrenheit scale is included in the Code for those jurisdictions using the Fahrenheit scale for temperature measurement.

The small margin of error specified for thermometer accuracy is due to the lack of a large safety margin in the temperature requirements themselves. The accuracy specified for a particular food temperature measuring device is applicable to its entire range of use, that is, from refrigeration through cooking temperatures if the device is intended for such use.

4-203.12 Temperature Measuring Devices, Ambient Air and Water.

A temperature measuring device used to measure the air temperature in a refrigeration unit is not required to be as accurate as a food thermometer because the unit's temperature fluctuates with repeated opening and closing of the door and because accuracy in measuring internal food temperatures is of more significance.

The Celsius scale is the federally recognized scale based on The Metric Conversion Act of 1975 (amended 1988, 1996, and 2004, 15 USC 205a et seq) which requires the use of metric values. The ±1.5°C requirement is more stringent than the 3°F previously required since ±1.5°C is equivalent to ±2.7°F. The more rigid accuracy results from the practical application of metric equivalents to the temperature gradations of Celsius thermometers.

If Fahrenheit thermometers are used, the 3°F requirement applies because of the calibrated intervals of Fahrenheit thermometers.

The accuracy specified for a particular air or water temperature measuring device is applicable to its intended range of use. For example, a cold holding unit may have a temperature measuring device that measures from a specified frozen temperature to 20°C (68°F). The device must be accurate to specifications within that use range.

4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment.

Flow pressure is a very important factor with respect to the efficacy of sanitization. A pressure below the design pressure results in inadequate spray patterns and incomplete coverage of the utensil surfaces to be sanitized. Excessive flow pressure will tend to atomize the water droplets needed to convey heat into a vapor mist that cools before reaching the surfaces to be sanitized.

Functionality **4-204.11 Ventilation Hood Systems, Drip Prevention.**

The dripping of grease or condensation onto food constitutes adulteration and may involve contamination of the food with pathogenic organisms. Equipment, utensils, linens, and single service and single use articles that are subjected to such drippage are no longer clean.

4-204.12 Equipment Openings, Closures and Deflectors.

Equipment openings and covers must be designed to protect stored or prepared food from contaminants and foreign matter that may fall into the food. The requirement for an opening to be flanged upward and for the cover to overlap the opening and be sloped to drain prevents contaminants, especially liquids, from entering the food-contact area.

Some equipment may have parts that extend into the food-contact areas. If these parts are not provided with a watertight joint at the point of entry into the food-contact area, liquids may contaminate the food by adhering to shafts or other parts and running or dripping into the food.

An apron on parts extending into the food-contact area is an acceptable alternative to the watertight seal. If the apron is not properly designed and installed, condensation, drips, and dust may gain access to the food.

4-204.13 Dispensing Equipment, Protection of Equipment and Food.

This requirement is intended to protect both the machine-dispensed, unpackaged, liquid foods and the machine components from contamination. Barriers need to be provided so that the only liquid entering the food container is the liquid intended to be dispensed when the machine's mechanism is activated. Recessing of the machine's components and self-closing doors prevent contamination of machine ports by people, dust, insects, or rodents. If the equipment components become contaminated, the product itself will be exposed to possible contamination.

A direct opening into the food being dispensed allows dust, vermin, and other contaminants access to the food.

NSF/ANSI 18-*Manual Food and Beverage Dispensing Equipment* is the standard for manual food and beverage dispensing equipment which has been designed to maintain the safety of aseptically packaged fluid foods without refrigeration even after the hermetic seal is broken.

NSF/ANSI 18 was revised in 2006 to specifically address dispensing equipment designed to hold time/temperature control for safety food or beverages in a homogeneous liquid form without temperature control. NSF/ANSI 18 requires that such equipment designs include a number of safeguards that prevent the contamination of specially packaged food stored within the dispensing equipment. The Standard also requires that the dispensing equipment have lockout mechanisms that preclude the dispensing of the product if such safeguards fail or if a prescribed duration of storage is exceeded.

The American National Standards Institute (ANSI) recognizes NSF/ANSI 18 as the sole American National Standard for the sanitary design of manual food and beverage dispensers.

4-204.14 Vending Machine, Vending Stage Closure.

Since packaged foods dispensed from vending machines could attract insects and rodents, a self-closing door is required as a barrier to their entrance.

4-204.15 Bearings and Gear Boxes, Leakproof.

It is not unusual for food equipment to contain bearings and gears. Lubricants necessary for the operation of these types of equipment could contaminate food or food-contact surfaces if the equipment is not properly designed and constructed.

4-204.16 Beverage Tubing, Separation.

Beverage tubing and coldplate cooling devices may result in contamination if they are installed in direct contact with stored ice. Beverage tubing installed in contact with ice may result in condensate and drippage contaminating the ice as the condensate moves down the beverage tubing and ends up in the ice.

The presence of beverage tubing and/or coldplate cooling devices also presents cleaning problems. It may be difficult to adequately clean the ice bin if they are present. Because of the high moisture environment, mold and algae may form on the surface of the ice bins and any tubing or equipment stored in the bins.

4-204.17 Ice Units, Separation of Drains.

Liquid waste drain lines passing through ice machines and storage bins present a risk of contamination due to potential leakage of the waste lines and the possibility that contaminants will gain access to the ice through condensate migrating along the exterior of the lines.

Liquid drain lines passing through the ice bin are, themselves, difficult to clean and create other areas that are difficult to clean where they enter the unit as well as where they abut other surfaces. The potential for mold and algal growth in this area is very likely due to the high moisture environment. Molds and algae that form on the drain lines are difficult to remove and present a risk of contamination to the ice stored in the bin.

4-204.18 Condenser Unit, Separation.

A dust-proof barrier between a condenser and food storage areas of equipment protects food and food-contact areas from contamination by dust that is accumulated and blown about as a result of the condenser's operation.

4-204.19 Can Openers on Vending Machines.

Since the cutting or piercing surfaces of a can opener directly contact food in the container being opened, these surfaces must be protected from contamination.

4-204.110 Molluscan Shellfish Tanks.

Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria.

Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of pathogenic microorganisms in shellfish held in display tanks is of concern. If shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination must be controlled or eliminated. Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

4-204.111 Vending Machines, Automatic Shutoff.

Failure to store time/temperature control for safety food at safe temperatures in a vending machine could result in the growth of pathogenic microorganisms that may result in foodborne illness. The presence of an automatic control that prevents the vending of food if the temperature of the unit exceeds Code requirements precludes the vending of foods that may not be safe.

It is possible and indeed very likely that the temperature of the storage area of a vending machine may exceed Code requirements during the stocking and servicing of the machine. The automatic shut off, commonly referred to as the "public health control," provides a limited amount of time that the ambient temperature of a machine may exceed Code requirements. Strict adherence to the time requirements can limit the growth of pathogenic microorganisms.

4-204.112 Temperature Measuring Devices.

The placement of the temperature measuring device is important. If the device is placed in the coldest location in the storage unit, it may not be representative of the temperature of the unit. Food could be stored in areas of the unit that exceed Code requirements. Therefore, the temperature measuring device must be placed in a location that is representative of the actual storage temperature of the unit to ensure that all time/temperature control for safety foods are stored at least at the minimum temperature required in Chapter 3.

Installing an air thermometer in some open display refrigerators can be difficult without physically impairing the usability of the case and interfering with cleaning and sanitation. Use of a temperature monitoring system that uses probe-like sensors that are placed in material resembling the density of food is an acceptable alternative. Thus, the direct temperature of the substitute product is measured by use of this product mimicking method.

A permanent temperature measuring device is required in any unit storing time/temperature control for safety food because of the potential growth of pathogenic microorganisms should the temperature of the unit exceed Code requirements. In order to facilitate routine monitoring of the unit, the device must be clearly visible.

The exception to requiring a temperature measuring device for the types of equipment listed is primarily due to equipment design and function. It would be difficult and impractical to permanently mount a temperature measuring device on the equipment listed. The futility of attempting to measure the temperature of unconfined air such as with heat lamps and, in some cases, the brief period of time the equipment is used for a given food negate the usefulness of ambient temperature monitoring at that point. In such cases, it would be more practical and accurate to measure the internal temperature of the food.

The importance of maintaining time/temperature control for safety foods at the specified temperatures requires that temperature measuring devices be easily readable. The inability to accurately read a thermometer could result in food being held at unsafe temperatures.

Temperature measuring devices must be appropriately scaled per Code requirements to ensure accurate readings.

The required incremental gradations are more precise for food measuring devices than for those used to measure ambient temperature because of the significance at a given point in time, i.e., the potential for pathogenic growth, versus the unit's temperature. The food temperature will not necessarily match the ambient temperature of the storage unit; it will depend on many variables including the temperature of the food when it is placed in the unit, the temperature at which the unit is maintained, and the length of time the food is stored in the unit.

4-204.113 Warewashing Machine, Data Plate Operating Specifications.

The data plate provides the operator with the fundamental information needed to ensure that the machine is effectively washing, rinsing, and sanitizing equipment and utensils. The warewashing machine has been tested, and the information on the data plate represents the parameters that ensure effective operation and sanitization and that need to be monitored.

4-204.114 Warewashing Machines, Internal Baffles.

The presence of baffles or curtains separating the various operational cycles of a warewashing machine such as washing, rinsing, and sanitizing are designed to reduce the possibility that solutions from one cycle may contaminate solutions in another. The baffles or curtains also prevent food debris from being splashed onto the surface of equipment that has moved to another cycle in the procedure.

4-204.115 Warewashing Machines, Temperature Measuring Devices.

The requirement for the presence of a temperature measuring device in each tank of the warewashing machine is based on the importance of temperature in the sanitization step. In hot water machines, it is critical that minimum temperatures be met at the various cycles so that the cumulative effect of successively rising temperatures causes the surface of the item being washed to reach the required temperature for sanitization. When chemical sanitizers are used, specific minimum temperatures must be met because the effectiveness of chemical sanitizers is directly affected by the temperature of the solution.

4-204.116 Manual Warewashing Equipment, Heaters and Baskets.

Hot water sanitization is accomplished in water of not less than 77°C (170°F) and an integral heating device is necessary to ensure that the minimum temperature is reached.

The rack or basket is required in order to safely handle the equipment and utensils being washed and to ensure immersion. Water at this temperature could result in severe burns to employees operating the equipment.

4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers.

The presence of adequate detergents and sanitizers is necessary to effect clean and sanitized utensils and equipment. The automatic dispensing of these chemical agents, plus a method such as a flow indicator, flashing light, buzzer, or visible open air delivery system that alerts the operator that the chemicals are no longer being dispensed, ensures that utensils are subjected to an efficacious cleaning and sanitizing regimen.

4-204.118 Warewashing Machines, Flow Pressure Device.

Flow pressure is a very important factor impacting the efficacy of sanitization in machines that use fresh hot water at line-pressure as a final sanitization rinse. (See discussion in Public Health Reason for section 4-203.13.) It is important that the operator be able to monitor, and the food inspector be able to check, final sanitization rinse pressure as well as machine water temperatures. ANSI/NSF Standard #3, a national voluntary consensus standard for Commercial Spray-Type Dishwashing Machines, specifies that a pressure gauge or similar device be provided on this type machine and such devices are shipped with machines by the manufacturer. Flow pressure devices installed on the upstream side of the control (solenoid) valve are subject to damage and failure due to the water hammer effect caused throughout the dishwashing period each time the control valve closes. The IPS valve provides a ready means for checking line-pressure with an alternative pressure measuring device. A flow pressure device is not required on machines that use only a pumped or recirculated sanitizing rinse since an appropriate pressure is ensured by a pump and is not dependent upon line-pressure.

4-204.121 Vending Machines, Liquid Waste Products.

The presence of internal waste containers allows for the collection of liquids that spill within the vending machine. Absence of a waste container or, where required, a shutoff valve which controls the incoming liquids could result in wastes spilling within the machine, causing a condition that attracts insects and rodents and compounds cleaning and maintenance problems.

4-204.122 Case Lot Handling Equipment, Movability.

Proper design of case lot handling equipment facilitates moving case lots for cleaning and for surveillance of insect or rodent activity.

4-204.123 Vending Machine Doors and Openings.

The objective of this requirement is to provide a barrier against the entrance into vending machines of insects, rodents, and dust. The maximum size of the openings deters the entrance of common pests.

Acceptability **4-205.10 Food Equipment, Certification and Classification.**

Under ANSI document CA-1 ANSI Policy and Criteria for Accreditation of Certification Programs, it has been stipulated that:

"For food equipment programs, standards that establish sanitation requirements shall be specified government standards or standards that have been ratified by a public health approval step. ANSI shall verify that this requirement has been met by communicating with appropriate standards developing organizations and governmental public health bodies."

The term certified is used when an item of food equipment has been evaluated against an organization's own standard. The term classified is used when one organization evaluates an item of food equipment against a standard developed by another organization.

Equipment **4-301.11 Cooling, Heating, and Holding Capacities.**

The ability of equipment to cool, heat, and maintain time/temperature control for safety foods at Code-required temperatures is critical to food safety. Improper holding and cooking temperatures continue to be major contributing factors to foodborne illness. Therefore, it is very important to have adequate hot or cold holding equipment with enough capacity to meet the heating and cooling demands of the operation.

4-301.12 Manual Warewashing, Sink Compartment Requirements.

The 3 compartment requirement allows for proper execution of the 3-step manual warewashing procedure. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water and therefore diluting the strength and efficacy of the chemical sanitizer that may be used.

Alternative manual warewashing equipment, allowed under certain circumstances and conditions, must provide for accomplishment of the same 3 steps:

1. Application of cleaners and the removal of soil;

2. Removal of any abrasive and removal or dilution of cleaning chemicals; and

3. Sanitization.

Refer also to the public health reason for § 4-603.16.

4-301.13 Drainboards.

Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other and from the food preparation area in order to preclude contamination of cleaned items and of food.

Drainboards allow for the control of water running off equipment and utensils that have been washed and also allow the operator to properly store washed equipment and utensils while they air-dry.

4-301.14 Ventilation Hood Systems, Adequacy.

If a ventilation system is inadequate, grease and condensate may build up on the floors, walls and ceilings of the food establishment, causing an insanitary condition and possible deterioration of the surfaces of walls and ceilings. The accumulation of grease and condensate may contaminate food and food-contact surfaces as well as present a possible fire hazard.

Refer also to the public health reason for § 4-204.11.

4-301.15 Clothes Washers and Dryers.

To protect food, soiled work clothes or linens must be efficiently laundered. The only practical way of efficiently laundering work clothes on the premises is with the use of a mechanical washer and dryer.

Refer also to the public health reason for § 4-401.11.

Utensils, Temperature Measuring Devices, and Testing Devices

4-302.11 Utensils, Consumer Self-Service.

Appropriate serving utensils provided at each container will, among other things, reduce the likelihood of food tasting, use of fingers to serve food, use of fingers to remove the remains of one food on the utensil so that it may be used for another, use of soiled tableware to transfer food, and cross contamination between foods, including a raw food to a cooked time/temperature control for safety food.

4-302.12 Food Temperature Measuring Devices.

The presence and accessibility of food temperature measuring devices is critical to the effective monitoring of food temperatures. Proper use of such devices provides the operator or person in charge with important information with which to determine if temperatures should be adjusted or if foods should be discarded.

When determining the temperature of thin foods, those having a thickness less than 13 mm (1/2 inch), it is particularly important to use a temperature sensing probe designed for that purpose. Bimetal, bayonet style thermometers are not suitable for accurately measuring the temperature of thin foods such as hamburger patties because of the large diameter of the probe and the inability to accurately sense the temperature at the tip of the probe. However, temperature measurements in thin foods can be accurately determined using a small-diameter probe 1.5 mm (0.059 inch), or less, connected to a device such as thermocouple thermometer.

4-302.13 Temperature Measuring Devices, Manual Warewashing.

Water temperature is critical to sanitization in warewashing operations. This is particularly true if the sanitizer being used is hot water. The effectiveness of cleaners and chemical sanitizers is also determined by the temperature of the water used. A temperature measuring device is essential to monitor manual warewashing and ensure sanitization.

Effective mechanical hot water sanitization occurs when the surface temperatures of utensils passing through the warewashing machine meet or exceed the required 71°C(160°F). Parameters such as water temperature, rinse pressure, and time determine whether the appropriate surface temperature is achieved. Although the Food Code requires integral temperature measuring devices and a pressure gauge for hot water mechanical warewashers, the measurements displayed by these devices may not always be sufficient to determine that the surface temperatures of utensils are reaching 71°C(160°F). The regular use of irreversible registering temperature indicators provides a simple method to verify that the hot water mechanical sanitizing operation is effective in achieving a utensil surface temperature of 71ºC (160ºF).

4-302.14 Sanitizing Solutions, Testing Devices.

Testing devices to measure the concentration of sanitizing solutions are required for 2 reasons:

1. The use of chemical sanitizers requires minimum concentrations of the sanitizer during the final rinse step to ensure sanitization; and

2. Too much sanitizer in the final rinse water could be toxic.

Location **4-401.11** **Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.**

Food equipment and the food that contacts the equipment must be protected from sources of overhead contamination such as leaking or ruptured water or sewer pipes, dripping condensate, and falling objects. When equipment is installed, it must be situated with consideration of the potential for contamination from such overhead sources.

If a clothes washer and dryer are installed adjacent to exposed food, clean equipment, utensils, linens, and unwrapped single-service and single-use articles, it could result in those items becoming contaminated from soiled laundry. The reverse is also true, i.e., items being laundered could become contaminated from the surrounding area if the washer and dryer are not properly located.

Installation **4-402.11** **Fixed Equipment, Spacing or Sealing.**

This section is designed to ensure that fixed equipment is installed in a way that:

1. Allows accessibility for cleaning on all sides, above, and underneath the units or minimizes the need for cleaning due to closely abutted surfaces;

2. Ensures that equipment that is subject to moisture is sealed;

3. Prevents the harborage of insects and rodents; and

4. Provides accessibility for the monitoring of pests.

4-402.12 **Fixed Equipment, Elevation or Sealing.**

The inability to adequately or effectively clean areas under equipment could create a situation that may attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food.

The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed equipment. It may be necessary to elevate the equipment. When elevating equipment is not feasible or prohibitively expensive, sealing to prevent contamination is required.

The economic impact of the requirement to elevate display units in retail food stores, coupled with the fact that the design, weight, and size of such units are not conducive to casters or legs, led to the exception for certain units located in consumer shopping areas, provided the floor under the units is kept clean. This exception for retail food store display equipment including shelving, refrigeration, and freezer units in the consumer shopping areas requires a rigorous cleaning schedule.

4-501.11 Good Repair and Proper Adjustment.

Proper maintenance of equipment to manufacturer specifications helps ensure that it will continue to operate as designed. Failure to properly maintain equipment could lead to violations of the associated requirements of the Code that place the health of the consumer at risk. For example, refrigeration units in disrepair may no longer be capable of properly cooling or holding time/temperature control for safety foods at safe temperatures.

The cutting or piercing parts of can openers may accumulate metal fragments that could lead to food containing foreign objects and, possibly, result in consumer injury.

Adequate cleaning and sanitization of dishes and utensils using a warewashing machine is directly dependent on the exposure time during the wash, rinse, and sanitizing cycles. Failure to meet manufacturer and Code requirements for cycle times could result in failure to clean and sanitize. For example, high temperature machines depend on the buildup of heat on the surface of dishes to accomplish sanitization. If the exposure time during any of the cycles is not met, the surface of the items may not reach the time-temperature parameter required for sanitization. Contact time is also important in warewashing machines that use a chemical sanitizer since the sanitizer must contact the items long enough for sanitization to occur. In addition, a chemical sanitizer will not sanitize a dirty dish; therefore, the cycle times during the wash and rinse phases are critical to sanitization.

4-501.12 Cutting Surfaces.

Cutting surfaces such as cutting boards and blocks that become scratched and scored may be difficult to clean and sanitize. As a result, pathogenic microorganisms transmissible through food may build up or accumulate. These microorganisms may be transferred to foods that are prepared on such surfaces.

4-501.13 Microwave Ovens.

Failure of microwave ovens to meet the CFR standards could result in human exposure to radiation leakage, resulting in possible medical problems to consumers and employees using the machines.

4-501.14 Warewashing Equipment, Cleaning Frequency.

During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.

4-501.15 Warewashing Machines, Manufacturers' Operating Instructions.

To ensure properly cleaned and sanitized equipment and utensils, warewashing machines must be operated properly. The manufacturer affixes a data plate to the machine providing vital, detailed instructions about the proper operation of the machine including wash, rinse, and sanitizing cycle times and temperatures which must be achieved.

4-501.16 Warewashing Sinks, Use Limitation.

If the wash sink is used for functions other than warewashing, such as washing wiping cloths or washing and thawing foods, contamination of equipment and utensils could occur.

4-501.17 Warewashing Equipment, Cleaning Agents.

Failure to use detergents or cleaners in accordance with the manufacturer's label instructions could create safety concerns for the employee and consumer. For example, employees could suffer chemical burns, and chemical residues could find their way into food if detergents or cleaners are used carelessly.

Equipment or utensils may not be cleaned if inappropriate or insufficient amounts of cleaners or detergents are used.

4-501.18 Warewashing Equipment, Clean Solutions.

Failure to maintain clean wash, rinse, and sanitizing solutions adversely affects the warewashing operation. Equipment and utensils may not be sanitized, resulting in subsequent contamination of food.

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature required in the Code is essential for removing organic matter. If the temperature is below 110°F, the performance of the detergent may be adversely affected, e.g., animal fats that may be present on the dirty dishes would not be dissolved.

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The chemicals used may not adequately perform their function if the temperature is too low. Therefore, the manufacturer's instructions must be followed. The temperatures vary according to the specific equipment being used.

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures.

If the temperature during the hot water sanitizing step is less than 77°C (171°F), sanitization will not be achieved. As a result, pathogenic organisms may survive and be subsequently transferred from utensils to food.

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

The temperature of hot water delivered from a warewasher sanitizing rinse manifold must be maintained according to the equipment manufacturer's specifications and temperature limits specified in this section to ensure surfaces of multiuse utensils such as kitchenware and tableware accumulate enough heat to destroy pathogens that may remain on such surfaces after cleaning.

The surface temperature must reach at least 71ºC (160ºF) as measured by an irreversible registering temperature measuring device to affect sanitization. When the sanitizing rinse temperature exceeds 90ºC (194ºF) at the manifold, the water becomes volatile and begins to vaporize reducing its ability to convey sufficient heat to utensil surfaces. The lower temperature limits of 74ºC (165ºF) for a stationary rack, single temperature machine, and 82ºC (180ºF) for other machines are based on the sanitizing rinse contact time required to achieve the 71ºC (160ºF) utensil surface temperature.

4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure.

If the flow pressure of the final sanitizing rinse is less than that required, dispersion of the sanitizing solution may be inadequate to reach all surfaces of equipment or utensils.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

With the passage of the Food Quality Protection Act of 1996 and the related Antimicrobial Regulation Technical Correction Act of 1998, Federal regulatory responsibility for chemical hard surface sanitizers was moved from FDA (CFSAN/OFAS) to EPA (Office of Pesticides Programs, Antimicrobial Division). As a result, the relevant Federal regulation has moved from 21 CFR 178.1010 to 40 CFR 180.940. The Food Code contains provisions that were not captured in either 21 CFR 178.1010 or 40 CFR 180.940, such as pH, temperature, and water hardness. There is need to retain these provisions in the Code.

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. Provisions for pH, temperature, and water hardness in section 4-501.114 have been validated to achieve sanitization; however, these parameters are not always included on EPA-registered labels. Therefore, it is critical to sanitization that the sanitizers are used consistently with the EPA-registered label, and if pH, temperature, and water hardness (for quat) are not included on the label, that the solutions meet the standards required in the Code.

With respect to chemical sanitization, section 4-501.114 addresses the proper use conditions for the sanitizing solution, i.e., chemical concentration range, pH, and temperature <u>minimum</u> levels and, with respect to quaternary ammonium compounds (quats), the <u>maximum</u> hardness level. If these parameters are not as specified in the Code or on the EPA-registered label, then this provision is violated.

By contrast, paragraph 4-703.11(C) addresses contact <u>time</u> in seconds. For chemical sanitization, this paragraph is only violated when the specified contact time is not met.

Section 7-204.11 addresses whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940.

EPA sanitizer registration assesses compliance with 40 CFR 180.940, therefore if the product is used at the appropriate concentration for the application on the EPA-registered label, it is not necessary to consult 40 CFR 180.940 for further compliance verification. If a sanitarian determined that a solution exceeded the concentration for the application on the EPA-registered label or is used for an application that is not on the EPA-registered label, section 7-204.11 would be violated.

To summarize, a sanitizing solution that is too weak would be a violation of section 4-501.114. A solution that is too strong would be a violation of section 7-204.11. Section 7-202.12 would not be violated due to the existence of section 7-204.11 that specifically addresses the use chemical sanitizers.

A variety of hard food contact surface sanitizers such as sodium hypochlorite or hypochlorous acid, can be generated on-site by technologies known as electrolyzed water, electro chemically activated water, and electro activated water in pesticide generating devices. Paragraph 4-501.114(F) addresses the efficacy and use of these on-site generated solutions and Section 4-703.11 requires that the conditions of use yields sanitization as defined in paragraph 1-201.10(B), i.e., a 5 log (99.999%) reduction.

Because EPA does not require registration of solutions generated and used on-site, the user of the equipment should look to the device manufacturer for data to validate the efficacy of the solution produced by the device as well as the conditions for use of the solution (e.g., concentration, temperature, contact time, pH, and other applicable factors). These data should be available on-site in the food establishment.

Any data used to validate efficacy of on-site generated sanitizer solutions should include validation testing that includes all factors that could impact the efficacy of the sanitizer solution, including water hardness, pH, temperature, and a time element because efficacy can reduce with time. The report should also clearly identify the minimum acceptable concentration of active ingredient required for that product to pass the test. This testing is best performed under Good Laboratory Practices. See the EPA web site at http://www.epa.gov/compliance/monitoring/programs/fifra/glp.html. According to the web site, "EPA's Good Laboratory Practice Standards (GLPS) compliance monitoring program ensures the quality and integrity of test data submitted to the Agency in support of a pesticide product registration under FIFRA section 5 of the Toxic Substances Control Act (TSCA), and pursuant to testing consent agreements and test rules issued under section 4 of TSCA."

Verifying the adequacy of chlorine-based solutions can be accomplished on an on-going basis by confirming that the concentration, temperature, and pH of the sanitizing solutions comply with paragraph 4-501.114 (A) using acceptable test methods and equipment.

The manufacturer should provide methods (e.g., test strips, kits, etc.) to verify that the equipment consistently generates a solution on-site at the necessary concentration to achieve sanitization.

Devices can be used for years to produce chemicals intended for the washing of fruits and vegetables, (e.g., hypochlorous acid, ozone, and chlorine dioxide). Other devices that are capable of producing hard food contact surface cleaning and sanitizing solutions on-site (e.g., chlorine, hypochlorous acid that are generated by processes known as electrolyzed water, electro chemically activated water, and electro activated water).

A device used to generate hard food contact surface sanitizers on-site is considered a pesticide device. The Environmental Protection Agency (EPA) defines a device in 40 CFR 152.500, Requirements for devices, as "(a) A device is defined as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom."

The EPA does not require the registration of pesticide devices; however, these devices must be produced in a registered establishment. The data plate should list the establishment number. Additionally, device label requirements are established by section 2(q)(1) and section 12 of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as well as 40 CFR 152.500 Requirements for Devices and 156.10 Labeling Requirements. No statement that is false or misleading can appear in a device's labeling. Statements that are subject to this regulation include, but are not limited to:

- The name, brand, or trademark under which the product is sold ·
- An ingredient statement
- Statements concerning effectiveness of the product
- Hazard and precautionary statements for human and domestic animals
- Environmental and exposure hazards
- The directions for use

Maintaining and cleaning devices used for the on-site generation of sanitizing solutions in accordance with manufacturer's specifications will help to ensure that they continue to generate the sanitizer chemicals in the form and concentration for which their efficacy was assessed.

4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers.

Some chemical sanitizers are not compatible with detergents when a 2 compartment operation is used. When using a sanitizer that is different from the detergent-sanitizer of the wash compartment, the sanitizer may be inhibited by carry-over, resulting in inadequate sanitization.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer solution.

Utensils and Temperature and Pressure Measuring Devices **4-502.11 Good Repair and Calibration.**

A utensil or food temperature measuring device can act as a source of contamination to the food it contacts if it is not maintained in good repair. Also, if temperature or pressure measuring devices are not maintained in good repair, the accuracy of the readings is questionable. Consequently, a temperature problem may not be detected, or conversely, a corrective action may be needlessly taken.

4-502.12 Single-Service and Single-Use Articles, Required Use.

In situations in which the reuse of multiuse items could result in foodborne illness to consumers, single-service and single-use articles must be used to ensure safety.

4-502.13 Single-Service and Single-Use Articles, Use Limitation.

Articles that are not constructed of multiuse materials may not be reused as they are unable to withstand the rigors of multiple uses, including the ability to be subjected to repeated washing, rinsing, and sanitizing.

4-502.14 Shells, Use Limitation.

The reuse of mollusk and crustacean shells as multiuse utensils is not allowed in food establishments. This prohibition does not apply to the removal of the oyster or other species from the shell for preparation, then returning the same animal to the same shell for service.

The shell itself may be potentially unsafe for use as a food utensil because of residues from natural and environmental contamination occurring after the mollusk or crustacean is removed. In addition, natural shells are not durable or easily cleanable as specified under section 4-502.13. When mollusk or crustacean shells (from commercial sources) are re-used by filling them with shucked shellfish, the food is considered misleading and not honestly presented.

Objective **4-601.11 Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.**

The objective of cleaning focuses on the need to remove organic matter from food-contact surfaces so that sanitization can occur and to remove soil from nonfood contact surfaces so that pathogenic microorganisms will not be allowed to accumulate and insects and rodents will not be attracted.

Frequency **4-602.11** **Equipment Food-Contact Surfaces and Utensils.**

Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers, or other food-contact surfaces. Food-contact surfaces and equipment used for time/temperature control for safety foods should be cleaned as needed throughout the day but must be cleaned no less than every 4 hours to prevent the growth of microorganisms on those surfaces.

Refrigeration temperatures slow down the generation time of bacterial pathogens, making it unnecessary to clean every four hours. However, the time period between cleaning equipment and utensils may not exceed 24 hours. A time-temperature chart is provided in subparagraph 4-602.11(D)(2) to accommodate operations that use equipment and utensils in a refrigerated room or area that maintains a temperature between 41°F or less and 55°F.

Surfaces of utensils and equipment contacting food that is not time/temperature control for safety food such as iced tea dispensers, carbonated beverage dispenser nozzles, beverage dispensing circuits or lines, water vending equipment, coffee bean grinders, ice makers, and ice bins must be cleaned on a routine basis to prevent the development of slime, mold, or soil residues that may contribute to an accumulation of microorganisms. Some equipment manufacturers and industry associations, e.g., within the tea industry, develop guidelines for regular cleaning and sanitizing of equipment. If the manufacturer does not provide cleaning specifications for food-contact surfaces of equipment that are not readily visible, the person in charge should develop a cleaning regimen that is based on the soil that may accumulate in those particular items of equipment.

Regarding the possible adulteration from one species of meat to another between cleaning of food-contact surfaces, USDA/FSIS does not automatically consider species adulteration as a health hazard. FSIS stated in an Advance Notice of Proposed Rulemaking that species adulteration falls into a gray area between safety and economic adulteration (65 FR 14486, March 17, 2000, Other Consumer Protection Activities). FSIS will review public comments received on the species adulteration issue and further review the scientific literature and risk assessment mechanisms before declaring species adulteration a health hazard. Meanwhile, species adulteration is generally considered by FSIS as an economic issue. However, investigations by FSIS of species adulteration incidents may include a determination regarding the impact of species adulteration as a health hazard on a case-by-case basis.

The 2012 Conference for Food Protection (CFP) requested that FDA amend §4-602.11 of the Food Code to require that equipment food contact surfaces and utensils that have contacted raw animal foods that are major food allergens be cleaned before use with other raw animal foods (Issue 2012-III-024). FDA recognizes that in addition to their intended use as ingredients, the unintended presence of major food allergens in foods may occur through cross-contact. Cross-contact describes the inadvertent introduction of an allergen into a product that would not intentionally contain that allergen as an ingredient. While most cross-contact can be avoided through control of the environment during food production and preparation, the CFP request only addresses allergen cross-contact from raw animal foods that are major food allergens and therefore, falls short of comprehensive allergen cross-contact control for all eight (8) major food allergens. Although limited in scope, such a change supports the continued efforts of FDA to work in cooperation with the Conference for Food Protection toward control of food allergens in retail food establishments. Therefore, §4-602.11 was amended to require that food contact surfaces of equipment and utensils that have contacted raw animal foods that are major food allergens, such as raw fish, must be cleaned and sanitized prior to contacting other types of raw animal foods.

Refer also to Annex 4 - Management of Food Safety Principles for Food Allergens as Food Safety Hazards.

4-602.12 Cooking and Baking Equipment.

Food-contact surfaces of cooking equipment must be cleaned to prevent encrustations that may impede heat transfer necessary to adequately cook food. Encrusted equipment may also serve as an insect attractant when not in use. Because of the nature of the equipment, it may not be necessary to clean cooking equipment as frequently as the equipment specified in § 4-602.11.

4-602.13 Nonfood-Contact Surfaces.

The presence of food debris or dirt on nonfood contact surfaces may provide a suitable environment for the growth of microorganisms which employees may inadvertently transfer to food. If these areas are not kept clean, they may also provide harborage for insects, rodents, and other pests.

Methods **4-603.11 Dry Cleaning.**

Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not time/temperature control for safety foods. Under some circumstances, attempts at wet cleaning may create microbiological concerns.

4-603.12 Precleaning.

Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be cleaned, detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be presoaked or scrubbed with an abrasive.

4-603.13 Loading of Soiled Items, Warewashing Machines.

Items to be washed in a warewashing machine must receive unobstructed exposure to the spray to ensure adequate cleaning. Items which are stacked or trays which are heavily loaded with silverware cannot receive complete distribution of detergent, water, or sanitizer and cannot be considered to be clean.

4-603.14 Wet Cleaning.

Because of the variety of cleaning agents available and the many different types of soil to be removed it is not possible to recommend one cleaning agent to fit all situations. Each of the different types of cleaners works best under different conditions (i.e., some work best on grease, some work best in warm water, others work best in hot water). The specific chemical selected should be compatible with any other chemicals to be used in the operation such as a sanitizer or drying agent.

4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment.

Some pieces of equipment are fixed or too large to be cleaned in a sink. Nonetheless, cleaning of such equipment requires the application of cleaners for the removal of soil and rinsing for the removal of abrasive and cleaning chemicals, followed by sanitization.

4-603.16 Rinsing Procedures.

It is important to rinse off detergents, abrasive, and food debris after the wash step to avoid diluting or inactivating the sanitizer.

Objective **4-701.10 Food-Contact Surfaces and Utensils.**

Effective sanitization procedures destroy organisms of public health importance that may be present on wiping cloths, food equipment, or utensils after cleaning, or which have been introduced into the rinse solution. It is important that surfaces be clean before being sanitized to allow the sanitizer to achieve its maximum benefit.

Frequency **4-702.11** **Before Use After Cleaning.**

Sanitization is accomplished after the warewashing steps of cleaning and rinsing so that utensils and food-contact surfaces are sanitized before coming in contact with food and before use.

Methods **4-703.11** **Hot Water and Chemical.**

Efficacious sanitization depends on warewashing being conducted within certain parameters. Time is a parameter applicable to both chemical and hot water sanitization. The time hot water or chemicals contact utensils or food-contact surfaces must be sufficient to destroy pathogens that may remain on surfaces after cleaning. Other parameters, such as rinse pressure, temperature, and chemical concentration are used in combination with time to achieve sanitization.

When surface temperatures of utensils passing through warewashing machines using hot water for sanitizing do not reach the required 71ºC (160ºF), it is important to understand the factors affecting the decreased surface temperature. A comparison should be made between the machine manufacturer's operating instructions and the machine's actual wash and rinse temperatures and final rinse pressure. The actual temperatures and rinse pressure should be consistent with the machine manufacturer's operating instructions and within limits specified in §§ 4-501.112 and 4-501.113.

If either the temperature or pressure of the final rinse spray is higher than the specified upper limit, spray droplets may disperse and begin to vaporize resulting in less heat delivery to utensil surfaces. Temperatures below the specified limit will not convey the needed heat to surfaces. Pressures below the specified limit will result in incomplete coverage of the heat-conveying sanitizing rinse across utensil surfaces.

Objective **4-801.11** **Clean Linens.**

Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness.

Frequency **4-802.11** **Specifications.**

Linens, cloth gloves, and cloth napkins are to be laundered between uses to prevent the transfer of pathogenic microorganisms between foods or to food-contact surfaces. The laundering of wet wiping cloths before being used with a fresh solution of cleanser or sanitizer is designed to reduce the microbiological load in the cleanser and sanitizer and thereby reduce the possible transfer of microorganisms to food and nonfood-contact surfaces.

Methods **4-803.11** **Storage of Soiled Linens**.

Soiled linens may directly or indirectly contaminate food. Proper storage will reduce the possibility of contamination of food, equipment, utensils, and single-service and single-use articles.

4-803.12 **Mechanical Washing**.

Proper laundering of wiping cloths will significantly reduce the possibility that pathogenic microorganisms will be transferred to food, equipment, or utensils.

4-803.13 **Use of Laundry Facilities**.

Washing and drying items used in the operation of the establishment on the premises will help prevent the introduction of pathogenic microorganisms into the environment of the food establishment.

Drying **4-901.11** **Equipment and Utensils, Air-Drying Required.**

Items must be allowed to drain and to air-dry before being stacked or stored. Stacking wet items such as pans prevents them from drying and may allow an environment where microorganisms can begin to grow. Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to equipment or utensils.

4-901.12 **Wiping Cloths, Air-Drying Locations.**

Cloths that are air-dried must be dried so that they do not drip on food or utensils and so that the cloths are not contaminated while air-drying.

Lubricating and Reassembling **4-902.11** **Food-Contact Surfaces.**

Food-contact surfaces must be lubricated in a manner that does not introduce contaminants to those surfaces.

4-902.12 **Equipment.**

Equipment must be reassembled in a way that food-contact surfaces are not contaminated.

Storing **4-903.11** **Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.**

Clean equipment and multiuse utensils which have been cleaned and sanitized, laundered linens, and single-service and single-use articles can become contaminated before their intended use in a variety of ways such as through water leakage, pest infestation, or other insanitary condition.

4-903.12 **Prohibitions.**

The improper storage of clean and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may allow contamination before their intended use. Contamination can be caused by moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic materials, litter, dust, and other materials. The contamination is often related to unhygienic employee practices, unacceptable high-risk storage locations, or improper construction of storage facilities.

Preventing Contamination

4-904.11 **Kitchenware and Tableware.**
4-904.12 **Soiled and Clean Tableware.**
4-904.13 **Preset Tableware.**

The presentation or setting of single-service and single-use articles and cleaned and sanitized utensils shall be done in a manner designed to prevent the contamination of food- and lip-contact surfaces.

4-904.14 **Rinsing Equipment and Utensils after Cleaning and Sanitizing.**

The rinsing of cleaned and sanitized utensils and equipment in a manner that may contaminate the surfaces before they are used, such as running them under a faucet or by dipping them in a vessel of water, is prohibited. The application of a post-sanitizing rinse is restricted to warewashing machines because there will be little opportunity for contamination of the potable water rinse if applied within the confines of a compliant warewashing machine. Provided the sanitization is achieved before the rinse is applied and as long as any chemical sanitizers are used in accordance with an EPA-registered label, the sanitary state of utensils and equipment should not be altered by applying a potable water rinse after the required final sanitizing rinse within a warewashing machine.

Chapter 5 Water, Plumbing, and Waste

Source **5-101.11 Approved System.**

Water, unless it comes from a safe supply, may serve as a source of contamination for food, equipment, utensils, and hands. The major concern is that water may become a vehicle for transmission of disease organisms. Water can also become contaminated with natural or man-made chemicals. Therefore, for the protection of consumers and employees, water must be obtained from a source regulated by law and must be used, transported, and dispensed in a sanitary manner.

5-101.12 System Flushing and Disinfection.

During construction, repair, or modification, water systems may become contaminated with microbes from soil because pipes are installed underground or by chemicals resulting from soldering and welding. Floods and other incidents may also cause water to become contaminated. Chemical contaminants such as oils may also be present on or in the components of the system. To render the water safe, the system must be properly flushed and disinfected before being placed into service.

5-101.13 Bottled Drinking Water.

Bottled water is obtained from a public water system or from a private source such as a spring or well. Either means of production must be controlled by public health law to protect the consumer from contaminated water.

Quality **5-102.11 Standards.**

Bacteriological and chemical standards have been developed for public drinking water supplies to protect public health. All drinking water supplies must meet standards required by law.

5-102.12 Nondrinking Water.

Food establishments may use nondrinking water for purposes such as air-conditioning or fire protection. Nondrinking water is not monitored for bacteriological and chemical quality or safety as is drinking water. Consequently, certain safety precautions must be observed to prevent the contamination of food, drinking water, or food-contact surfaces by nondrinking water. Identifying the piping designated as nondrinking waterlines and inspection for cross connections are examples of safety precautions.

Irrigation water used in the cultivation of fresh produce, e.g. herb gardens or other onsite gardens, is another example of nondrinking water. Whenever water comes into contact with fresh produce, its quality dictates the potential for pathogen contamination. Water has the potential to be a direct source of contamination and vehicle for spreading contamination. Research has shown that irrigation water can increase the frequency of pathogen contamination of harvested produce, and may contain or convey pathogens, such as *Salmonella* spp. Where used, irrigation water should be adequate and approved for its intended use in accordance with Good Agricultural Practices (GAPs) that minimize the potential for contaminated water to contact the edible portion of the crop. FDA's "*Guide to Minimize Microbial Food Safety Hazards for Fresh-cut Fruit and Vegetables*" provides useful information about GAPs and safely growing, harvesting, washing, sorting, packing and distributing produce. It is available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm.

5-102.13 Sampling.

Wells and other types of individual water supplies may become contaminated through faulty equipment or environmental contamination of ground water. Periodic sampling is required by law to monitor the safety of the water and to detect any change in quality. The controlling agency must be able to ascertain that this sampling program is active and that the safety of the water is in conformance with the appropriate standards. Laboratory results are only as accurate as the sample submitted. Care must be taken not to contaminate samples. Proper sample collection and timely transportation to the laboratory are necessary to ensure the safety of drinking water used in the establishment.

5-102.14 Sample Report.

The most recent water sampling report must be kept on file to document a safe water supply.

Quantity and Availability

5-103.11 Capacity.

Availability of sufficient water is a basic requirement for proper sanitation within a food establishment. An insufficient supply of safe water will prevent the proper cleaning of items such as equipment and utensils and of food employees' hands.

Hot water required for washing items such as equipment and utensils and employees' hands, must be available in sufficient quantities to meet demand during peak water usage periods. Booster heaters for warewashers that use hot water for sanitizing are designed to raise the temperature of hot water to a level that ensures sanitization. If the volume of water reaching the booster heater is not sufficient or hot enough, the required temperature for sanitization can not be reached.

Manual washing of food equipment and utensils is most effective when hot water is used. Unless utensils are clean to sight and touch, they cannot be effectively sanitized.

5-103.12 Pressure.

Inadequate water pressure could lead to situations that place the public health at risk. For example, inadequate pressure could result in improper handwashing or equipment operation. Sufficient water pressure ensures that equipment such as mechanical warewashers operate according to manufacturer's specifications.

Distribution, Delivery, and Retention **5-104.11 System.**

Inadequate water systems may serve as vehicles for contamination of food or food-contact surfaces. This requirement is intended to ensure that sufficient volumes of water are provided from supplies shown to be safe, through a distribution system which is protected.

5-104.12 Alternative Water Supply.

Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport vehicles and containers, may result in contamination of safe water and render it hazardous to human health.

Materials **5-201.11 Approved.**

Plumbing systems and hoses conveying water must be made of approved materials and be smooth, durable, nonabsorbent, and corrosion-resistant. If not, the system may constitute a health hazard because unsuitable surfaces may harbor disease organisms or it may be constructed of materials that may, themselves, contaminate the water supply.

Design, Construction, and Installation **5-202.11 Approved System and Cleanable Fixtures.**

Water within a system will leach minute quantities of materials out of the components of the system. To make sure none of the leached matter is toxic or in a form that may produce detrimental effects, even through long-term use, all materials and components used in water systems must be of an approved type. New or replacement items must be tested and approved based on current standards.

Improperly designed, installed, or repaired water systems can have inherent deficiencies such as improper access openings, dead spaces, and areas difficult or impossible to clean and disinfect. Dead spaces allow water quality to degrade since they are out of the constant circulation of the system. Fixtures such as warewashing sinks that are not easily cleanable may lead to the contamination of food products.

5-202.12 Handwashing Facility, Installation.

Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands. ASTM Standards for testing the efficacy of handwashing formulations specify a water temperature of 40°C ± 2°C (100 to 108°F).

An inadequate flow or temperature of water may lead to poor handwashing practices by food employees. A mixing valve or combination faucet is needed to provide properly tempered water for handwashing. Steam mixing valves are not allowed for this use because they are hard to control and injury by scalding is a possible hazard.

5-202.13 Backflow Prevention, Air Gap.

During periods of extraordinary demand, drinking water systems may develop negative pressure in portions of the system. If a connection exists between the system and a source of contaminated water during times of negative pressure, contaminated water may be drawn into and foul the entire system. Standing water in sinks, dipper wells, steam kettles, and other equipment may become contaminated with cleaning chemicals or food residue. To prevent the introduction of this liquid into the water supply through back siphonage, various means may be used.

The water outlet of a drinking water system must not be installed so that it contacts water in sinks, equipment, or other fixtures that use water. Providing an air gap between the water supply outlet and the flood level rim of a plumbing fixture or equipment prevents contamination that may be caused by backflow.

5-202.14 Backflow Prevention Device, Design Standard.

In some instances an air gap is not practical such as is the case on the lower rinse arm for the final rinse of warewashers. This arm may become submerged if the machine drain becomes clogged. If this failure occurs, the machine tank would fill to the flood level rim, which is above the rinse arm. A backflow prevention device is used to avoid potential backflow of contaminated water when an air gap is not practical. The device provides a break to the atmosphere in the event of a negative pressure within the system. Minerals contained in water and solid particulate matter carried in water may coat moving parts of the device or become lodged between them over time. This may render the device inoperative.

To minimize such an occurrence, only devices meeting certain standards of construction, installation, maintenance, inspection, and testing for that application may be used. The necessary maintenance can be facilitated by installing these devices in accessible locations.

5-202.15 Conditioning Device, Design.

Water conditioning devices must be designed for easy disassembly for servicing so that they can be maintained in a condition that allows them to perform the function for which they were designed.

Numbers and Capacities

5-203.11 Handwashing Sinks.

Because handwashing is such an important intervention in the control of foodborne illness, sufficient handwashing sinks must be available to make handwashing not only possible, but likely to occur at all appropriate times and places as outlined in Sections 2-301.14 and 2-301.15.

According to Greig et el. (July 2007) an analysis of 816 reported outbreaks of infected worker-associated outbreaks from 1927-2006 found that over 61% of these outbreaks came from food service facilities and catered events, and another 11% of them are attributed to schools, day care centers and health care institutions. The two most frequently reported risk factors associated with these implicated food workers was bare hand contact with food, and failure to properly wash hands.

Green et al (JFP, March 2007) found that handwashing was more likely to occur in restaurants whose food workers received food safety training, had more than one handwashing sink, and had a handwashing sink in the observed worker's sight. This suggests that improving food worker hand hygiene requires more than food safety education.

5-203.12 Toilets and Urinals.

Adequate, sanitary toilet facilities are necessary for the proper disposal of human waste, which carries pathogenic microorganisms, and for preventing the spread of disease by flies and other insects.

5-203.13 Service Sink.

Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Waste water must be disposed of in a sanitary manner that will not contaminate food or food equipment. A service sink or curbed cleaning facility with a drain allows for such disposal.

5-203.14 Backflow Prevention Device, When Required.

The delivery end of hoses attached to hose bibbs on a drinking water line may be dropped into containers filled with contaminated water or left in puddles on the floor or in other possible sources of contamination. A backflow prevention device must be installed on the hose bibb to prevent the back siphonage of contaminated liquid into the drinking water system during occasional periods of negative pressure in the water line.

5-203.15 Backflow Prevention Device, Carbonator.

When carbon dioxide is mixed with water, carbonic acid, a weak acid, is formed. Carbonators on soft drink dispensers form such acids as they carbonate the water to be mixed with the syrups to produce the soft drinks. If carbon dioxide backs up into a copper water line, carbonic acid will dissolve some of the copper. The water containing the dissolved copper will subsequently be used in dispensing soft drinks and the first few customers receiving the drinks are likely to suffer with the symptoms of copper poisoning.

An air gap or a vented backflow prevention device meeting ASSE Standard No. 1022 will prevent this occurrence, thereby reducing incidences of copper poisoning.

Location and Placement

5-204.11 Handwashing Sinks.

Hands are a common vehicle for the transmission of pathogens to foods in an establishment. Hands can become soiled with a variety of contaminants during routine operations. The transfer of contaminants can be limited by providing food employees with handwashing sinks that are properly equipped and conveniently located.

A handwashing sink that is properly located is one that is available to food employees who are working in food preparation, food dispensing, and warewashing areas. Handwashing sinks that are blocked by portable equipment or stacked full of soiled utensils and other items, are rendered unavailable for employee use. Nothing must block the approach to a handwashing sink thereby discouraging its use, plus it must be kept clean and well stocked with soap and sanitary towels to-facilitate frequent use. Therefore, a handwashing sink that is located in the immediate work area, or between work areas that the Code states must be equipped with handwashing sinks, depending upon the size and function of the facility, would be considered properly located. Such placement of handwashing sinks facilitates frequent handwashing by food employees in all work areas.

5-204.12 Backflow Prevention Device, Location.

Backflow prevention devices are meant to protect the drinking water system from contamination caused by backflow. If improperly placed, backflow prevention devices will not work. If inconveniently located, these devices may not be accessed when systems are extended, altered, serviced, or replaced. Over a period of time, unserviced devices may fail and system contamination may occur.

5-204.13 Conditioning Device, Location.

When not located for easy maintenance, conditioning devices will be inconvenient to access and devices such as filters, screens, and water softeners will become clogged because they are not properly serviced.

Operation and Maintenance

5-205.11 Using a Handwashing Sink.

Facilities must be maintained in a condition that promotes handwashing and restricted for that use. Convenient accessibility of a handwashing facility encourages timely handwashing which provides a break in the chain of contamination from the hands of food employees to food or food-contact surfaces. Sinks used for food preparation and warewashing can become sources of contamination if used as handwashing facilities by employees returning from the toilet or from duties which have contaminated their hands.

5-205.12 Prohibiting a Cross Connection.

Nondrinking water may be of unknown or questionable origin. Waste water is either known or suspected to be contaminated. Neither of these sources can be allowed to contact and contaminate the drinking water system.

5-205.13 Scheduling Inspection and Service for a Water System Device.

Water system devices, such as filters and backflow preventers, are affected by the water in the system. How devices are affected depends on water quality, especially pH, hardness, and suspended particulate matter in the water. Complexity of the device is also a factor. Manufacturer recommendations, as well as inspection and maintenance schedules for these devices, must be strictly followed to prevent failure during operation.

Cleaning	**5-205.14**	**Water Reservoir of Fogging Devices, Cleaning.**

Water reservoirs that have poor water exchange rates, such as reservoirs for some humidifiers or aerosol or fogging devices, and that are directly or indirectly open to the atmosphere, may be contaminated with respiratory pathogens such as ***Legionella pneumophila***. This organism is extremely infectious and can be transmitted through very small droplets of a fogger or humidifier. It is important that the manufacturer's cleaning and maintenance schedule be scrupulously followed to prevent a reservoir from colonization by this bacterium.

	5-205.15	**System Maintained in Good Repair.**

Improper repair or maintenance of any portion of the plumbing system may result in potential health hazards such as cross connections, backflow, or leakage. These conditions may result in the contamination of food, equipment, utensils, linens, or single-service or single-use articles. Improper repair or maintenance may result in the creation of obnoxious odors or nuisances, and may also adversely affect the operation of warewashing equipment or other equipment which depends on sufficient volume and pressure to perform its intended functions.

Materials	**5-301.11**	**Approved.**

Materials used in the construction of a mobile water tank are affected by the water they contact. Tank liners may deteriorate and flake. Metals or platings can be toxic. To prevent the degradation of the quality of the water, it is important that the materials used in the construction of the tank are suitable for such use.

Design and Construction	**5-302.11**	**Enclosed System, Sloped to Drain.**
	5-302.12	**Inspection and Cleaning Port, Protected and Secured.**

The tank must be a closed system from the filling inlet to the outlet to prevent contamination of water. It is important that the bottom of the tank be sloped to the outlet to allow the tank to drain completely, to facilitate the proper cleaning and disinfection of the tank, and to prevent the retention of water or solutions after cleaning.

Some tanks are designed with an access opening to facilitate the cleaning and servicing of the water tank. The access must be constructed to prevent the opening from becoming a source of contamination of the water.

5-302.13 "V" Type Threads, Use Limitation.

V-type threads are difficult to clean if contaminated with food or waste. To prevent the contamination of the drinking water, this type of thread should only be used on water tank inlets and outlets if the connection is permanent which eliminates exposed, difficult-to-clean threads.

5-302.14 Tank Vent, Protected.

Water tanks are equipped with a vent to preclude distortion during filling or draining. The vent should be equipped with a suitable screen or filter to protect the tank against the entry of insects or other vermin that may contaminate the water supply.

5-302.15 Inlet and Outlet, Sloped to Drain.

Both the inlet and outlet must be sloped to drain to prevent the pooling of possibly contaminated water or sanitizing solution.

5-302.16 Hose, Construction and Identification.

Hoses used to fill potable water tanks should be dedicated for that one task and should be identified for that use only to prevent contaminating the water. Hoses must be made of a material that will not leach detrimental substances into the water.

Numbers and Capacities

5-303.11 Filter, Compressed Air.

Compressor pistons are lubricated with oil to minimize wear. Some of the oil is carried into the air lines and if not intercepted may contaminate the tank and water lines.

5-303.12 Protective Cover or Device.

Protective equipment provided for openings of the water supply must be in use to prevent contamination which may be present where the supply is exposed to the environment, i.e., at water inlets or outlets or the ends of transfer hoses.

5-303.13 Mobile Food Establishment Tank Inlet.

Mobile units may be particularly vulnerable to environmental contamination if soiled hose connections are coupled to the tank inlet.

Operation and Maintenance **5-304.11 System Flushing and Disinfection.**

Contaminants of various types may be introduced into a water system during construction or repair or other incidents. The system must be flushed and sanitized after maintenance and before it is placed into service to prevent contamination of the water introduced into the tank.

5-304.12 Using a Pump and Hoses, Backflow Prevention.

When a water system includes a pump, or a pump is used in filling a water tank, care must be taken during hookup to prevent negative pressure on the supplying water system. Backflow prevention to protect the water supply is especially necessary during cleaning and sanitizing operations on a mobile system.

5-304.13 Protecting Inlet, Outlet, and Hose Fitting.

When not connected for use, water inlets, outlets, and hose fittings should be closed to the environment. Unless capped or otherwise protected, filling inlets, outlets, and hoses may become contaminated by dust or vermin.

5-304.14 Tank, Pump, and Hoses, Dedication.

Hoses, pumps, and tanks used for food or water may not be used for other liquids because this may contaminate the water supply. If a hose, tank, or pump has been used to transfer liquid food, the equipment must be cleaned and sanitized before using it for water delivery. Failure to properly clean and sanitize the equipment would introduce nutrients, and possibly bacteria, into the water as well as inactivate residual chlorine from public water supplies.

Mobile Holding Tank **5-401.11 Capacity and Drainage.**

Liquid waste from a mobile or temporary food establishment must be stored in a properly constructed waste tank to discourage the attraction of flies and other vermin. The waste tank must be 15% larger than the water storage tank to allow for storage of wastes and used water from the drinking water supply tank. The drain from the waste tank must be larger than the filling hose to prevent the use of the drinking water filling hose to drain the waste tank.

Retention, Drainage, and Delivery

5-402.10 Establishment Drainage System.

The drainage system must be designed and installed properly to prevent the backup of sewage and the possible contamination of foods or food-contact surfaces in the establishment.

5-402.11 Backflow Prevention.

Improper plumbing installation or maintenance may result in potential health hazards such as cross connections, back siphonage or backflow. These conditions may result in the contamination of food, utensils, equipment, or other food-contact surfaces. It may also adversely affect the operation of equipment such as warewashing machines.

The exception in paragraph 5-402.11(B) allows for a direct connection to the sanitary sewer system for floor drains originating in refrigerated spaces that are constructed as an integral part of the building structure. Examples of refrigerated spaces that are considered an integral part of the building include refrigerated prep rooms, meat cutting rooms, and refrigerated storage rooms. The exception specifically targets refrigerated spaces that are considered an integral part of the building. It does not apply to prefabricated walk-in refrigerators and freezers with prefabricated floors. It is not intended to apply to pieces of equipment, including those which may be located in a refrigerated room and which indirectly drain to a floor drain within the room. Drainage from equipment is addressed under paragraph 5-402.11(A).

5-402.12 Grease Trap.

Failure to locate a grease trap so that it can be properly maintained and cleaned could result in the harborage of vermin and/or the failure of the sewage system.

5-402.13 Conveying Sewage.
5-402.14 Removing Mobile Food Establishment Waste.

Improper disposal of waste provides a potential for contamination of food, utensils, and equipment and, therefore, may cause serious illness or disease outbreaks. Proper removal is required to prevent contamination of ground surfaces and water supplies, or creation of other insanitary conditions that may attract insects and other vermin.

5-402.15 Flushing a Waste Retention Tank.

Thoroughly flushing the liquid waste retention tank will prevent the buildup of deposits within the tank which could affect the proper operation of the tank.

Disposal Facility	**5-403.11**	**Approved Sewage Disposal System.**

Many diseases can be transmitted from one person to another through fecal contamination of food and water. This transmission can be indirect. Proper disposal of human wastes greatly reduces the risk of fecal contamination. This Code provision is intended to ensure that wastes will not contaminate ground surfaces or water supplies; pollute surface waters; be accessible to children or pets; or allow rodents or insects to serve as vectors of disease from this source.

	5-403.12	**Other Liquid Waste and Rainwater.**

Liquid food wastes and rainwater can provide a source of bacterial contamination and support populations of pests. Proper storage and disposal of wastes and drainage of rainwater eliminate these conditions.

Facilities on the Premises	**5-501.10**	**Indoor Storage Area.**
	5-501.11	**Outdoor Storage Surface.**
	5-501.12	**Outdoor Enclosure.**
	5-501.13	**Receptacles.**
	5-501.14	**Receptacles in Vending Machines.**
	5-501.15	**Outside Receptacles.**
	5-501.16	**Storage Areas, Rooms, and Receptacles, Capacity and Availability.**
	5-501.17	**Toilet Room Receptacle, Covered.**
	5-501.18	**Cleaning Implements and Supplies.**
	5-501.19	**Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.**
	5-501.110	**Storage Refuse, Recyclables, and Returnables.**
	5-501.111	**Areas, Enclosures, and Receptacles, Good Repair.**
	5-501.112	**Outside Storage Prohibitions.**
	5-501.113	**Covering Receptacles.**
	5-501.114	**Using Drain Plugs.**
	5-501.115	**Maintaining Refuse Areas and Enclosures.**
	5-501.116	**Cleaning Receptacles.**

Proper storage and disposal of garbage and refuse are necessary to minimize the development of odors, prevent such waste from becoming an attractant and harborage or breeding place for insects and rodents, and prevent the soiling of food preparation and food service areas. Improperly handled garbage creates nuisance conditions, makes housekeeping difficult, and may be a possible source of contamination of food, equipment, and utensils.

Storage areas for garbage and refuse containers must be constructed so that they can be thoroughly cleaned in order to avoid creating an attractant or harborage for insects or rodents. In addition, such storage areas must be large enough to accommodate all the containers necessitated by the operation in order to prevent scattering of the garbage and refuse.

All containers must be maintained in good repair and cleaned as necessary in order to store garbage and refuse under sanitary conditions as well as to prevent the breeding of flies.

Garbage containers should be available wherever garbage is generated to aid in the proper disposal of refuse.

Outside receptacles must be constructed with tight-fitting lids or covers to prevent the scattering of the garbage or refuse by birds, the breeding of flies, or the entry of rodents. Proper equipment and supplies must be made available to accomplish thorough and proper cleaning of garbage storage areas and receptacles so that unsanitary conditions can be eliminated.

Removal	**5-502.11**	**Frequency.**
	5-502.12	**Receptacles or Vehicles.**

Refuse, recyclables, and returnable items, such as beverage cans and bottles, usually contain a residue of the original contents. Spillage from these containers soils receptacles and storage areas and becomes an attractant for insects, rodents, and other pests. The handling of these materials entails some of the same problems and solutions as the handling of garbage and refuse. Problems are minimized when all of these materials are removed from the premises at a reasonable frequency.

Facilities for Disposal and Recycling	**5-503.11**	**Community or Individual Facility.**

Alternative means of solid waste disposal must be conducted properly to prevent environmental consequences and the attraction of insects, rodents, and other pests.

Chapter 6 Physical Facilities

Indoor Areas	**6-101.11**	**Surface Characteristics.**

Floors, walls, and ceilings that are constructed of smooth and durable surface materials are more easily cleaned.

Floor surfaces that are graded to drain and consist of effectively treated materials will prevent contamination of foods from dust and organisms from pooled moisture.

The special requirements for carpeting materials and nonabsorbent materials in areas subject to moisture are intended to ensure that the cleanability of these surfaces is retained.

Although food served from temporary food establishments is subject to the same potential for contamination as food served in permanent establishments, the limited capabilities and short duration of operation are recognized by less stringent requirements for surface characteristics.

Outdoor Areas **6-102.11 Surface Characteristics.**

The requirements concerning surface characteristics of outdoor areas are intended to facilitate maintenance and minimize the accumulation of dust and mud on walking and driving areas, provide durable exterior building surfaces, and prevent the attracting, harboring, or breeding of insects, rodents, and other pests where refuse, recyclables, or returnables are stored.

Cleanability **6-201.11 Floors, Walls, and Ceilings.**
6-201.12 Floors, Walls, and Ceilings, Utility Lines.

Floors that are of smooth, durable construction and that are nonabsorbent are more easily cleaned. Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.

6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed.

When cleaning is accomplished by spraying or flushing, coving and sealing of the floor/wall junctures is required to provide a surface that is conducive to water flushing. Grading of the floor to drain allows liquid wastes to be quickly carried away, thereby preventing pooling which could attract pests such as insects and rodents or contribute to problems with certain pathogens such as ***Listeria monocytogenes***.

6-201.14 Floor Carpeting, Restrictions and Installation.

Requirements and restrictions regarding floor carpeting are intended to ensure that regular and effective cleaning is possible and that insect harborage is minimized. The restrictions for areas not suited for carpeting materials are designed to ensure cleanability of surfaces where accumulation of moisture or waste is likely.

6-201.15 Floor Covering, Mats and Duckboards.

Requirements regarding mats and duckboards are intended to ensure that regular and effective cleaning is possible and that accumulation of dirt and waste is prevented.

6-201.16 Wall and Ceiling Coverings and Coatings.
6-201.17 Walls and Ceilings, Attachments.
6-201.18 Walls and Ceilings, Studs, Joists, and Rafters.

Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and effectively cleaned. Special requirements related to the attachment of accessories and exposure of wall and ceiling studs, joists, and rafters are intended to ensure the cleanability of these surfaces.

Functionality **6-202.11 Light Bulbs, Protective Shielding.**

Shielding of light bulbs helps prevent breakage. Light bulbs that are shielded, coated, or otherwise shatter-resistant are necessary to protect exposed food, clean equipment, utensils and linens, and unwrapped single-service and single-use articles from glass fragments should the bulb break.

6-202.12 Heating, Ventilating, Air Conditioning System Vents.

Heating and air conditioning system vents that are not properly designed and located may be difficult to clean and result in the contamination of food, food preparation surfaces, equipment, or utensils by dust or other accumulated soil from the exhaust vents.

6-202.13 Insect Control Devices, Design and Installation.

Insect electrocution devices are considered supplemental to good sanitation practices in meeting the Code requirement for controlling the presence of flies and other insects in a food establishment.

Improper design of the device and dead insect collection tray could allow dead insect parts and injured insects to escape, rendering the device itself a source of contamination.

Exposed food and food-contact surfaces must be protected from contamination by insects or insect parts. Installation of the device over food preparation areas or in close proximity to exposed food and/or food-contact surfaces could allow dead insects and/or insect parts to be impelled by the electric charge, fall, or be blown from the device onto food or food-contact surfaces.

6-202.14 Toilet Rooms, Enclosed.

Completely enclosed toilet facilities minimize the potential for the spread of disease by the movement of flies and other insects between the toilet facility and food preparation areas.

6-202.15 Outer Openings, Protected.

Insects and rodents are vectors of disease-causing microorganisms which may be transmitted to humans by contamination of food and food-contact surfaces. The presence of insects and rodents is minimized by protecting outer openings to the food establishment.

In the National Fire Protection Association's NFPA 101, Life Safety Code, 2009 Edition, doors to exit enclosures such as stairs, horizontal exits, or exit passageways are required to be self closing. The Life Safety Code does not require exterior doors used as exits to be self closing, but they can be.

The intent of subparagraph 6-202.15(A)(3) is to protect food establishments from the entry of insects and rodents by keeping doors closed when not in use. Self-closing devices allow a door to return to its closed position after use. If an exterior door is not routinely used for entry or exit because its use is restricted by the fire protection authority for emergency use only, it is not a portal for the entry of pests and does not need a self-closing device. Doors not requiring a self-closing device include exterior emergency exit doors that open into a public way from a fire and that meet the criteria in ¶ 6-202.15(C).

6-202.16 Exterior Walls and Roofs, Protective Barrier.

Walls and roofs provide a barrier to protect the interior and foods from the weather, windblown dirt and debris, and flying insects.

6-202.17 Outdoor Food Vending Areas, Overhead Protection.

The potential for contamination from airborne dust and particulates or inclement weather is present in outside areas. Overhead protection minimizes the potential for contamination of food under such conditions.

6-202.18 Outdoor Servicing Areas, Overhead Protection.

Pooled water, which may result if overhead protection is not provided for outdoor servicing areas, attracts wild animals and birds and creates a condition suitable for the breeding of insects.

6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.

If foot traffic is allowed to occur from undrained areas, contamination will be tracked into the establishment. Surfaces graded to drain minimize these conditions. Pooled water on exterior walking and driving surfaces may also attract rodents and breed insects.

6-202.110 Outdoor Refuse Areas, Curbed and Graded to Drain.

If refuse areas are not graded properly, waste water will pool and attract insects and rodents.

6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibited.
6-202.112 Living or Sleeping Quarters, Separation.

Areas or facilities that are not compatible with sanitary food establishment operations must be located or separated from other areas of the establishment to preclude potential contamination of food and food-contact surfaces from poisonous or toxic materials, dust or debris, the presence of improperly designed facilities and equipment, and the traffic of unauthorized and/or unnecessary persons or pets.

Further, Article IV of the Amendments to the U.S. Constitution ensures the right of persons to be secure in their homes against unreasonable search and seizure. This provision could hinder the regulatory authority's access to conduct routine inspections of a food establishment operated in the living area of a private home. A search warrant may be the only mechanism by which to gain entry; yet, it may be difficult to obtain and might not authorize the necessary inspectional activities.

Handwashing Sinks **6-301.10 Minimum Number.**

Refer to the public health reason for § 5-203.11.

6-301.11 Handwashing Cleanser, Availability.

Hand cleanser must always be present to aid in reducing microorganisms and particulate matter found on hands.

6-301.12 Hand Drying Provision.

Provisions must be provided for hand drying so that employees will not dry their hands on their clothing or other unclean materials.

It is known that wet hands transfer bacteria more readily than dry hands. The residual moisture found on the hands after washing allows for bacterial and viral transfer to food or solid surfaces by touch. The method in which hands are dried is a critical factor in reducing chances of cross-contamination by hands to food and environmental surfaces (Patrick et al., (1997)).

With regard to the addition of air knife technology for hand drying, data reviewed by FDA scientists at the FDA's National Center for Food Safety Technology (Moffitt Center) demonstrates that the use of this technology in hand dryers has been found to be equivalent to the hand drying treatment in existing heated-air devices.

While the Food Code does not specifically address the configuration or ergonomic design of hand drying devices, technologies employing air knife systems do not appear to accommodate the drying of one's arms and may not be large enough to accommodate surrogate prosthetic devices for hands and arms to fit within the hand-dryer. In the case where food employees are expected to wash their forearms or are fitted with a surrogate prosthetic device, the food establishment would need to provide an alternate means for drying of the arms and certain prosthetic devices.

6-301.14 Handwashing Signage.

A sign or poster is required to remind food employees to wash their hands.

6-301.20 Disposable Towels, Waste Receptacle.

Waste receptacles at handwashing sinks are required for the collection of disposable towels so that the paper waste will be contained, will not contact food directly or indirectly, and will not become an attractant for insects or rodents.

Toilets and Urinals **6-302.10 Minimum Number.**

Refer to the public health reason for § 5-203.12.

6-302.11 Toilet Tissue, Availability.

To minimize hand contact with fecal waste, toilet tissue is necessary for hygienic cleaning following use of toilet facilities. Toilet tissue must be supplied to meet the demand.

Lighting **6-303.11 Intensity.**

Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as reading labels; discerning the color of substances; identifying toxic materials; recognizing the condition of food, utensils, and supplies; and safely conducting general food establishment operations and clean-up.

Properly distributed light makes the need for cleaning apparent by making accumulations of soil conspicuous.

Ventilation **6-304.11** **Mechanical.**

When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls, ceilings, and other equipment is minimized; obnoxious odors or toxic fumes are effectively removed; and no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.

Balancing of the exhaust and make-up air must be ensured so that the system can operate efficiently.

Dressing Areas and Lockers **6-305.11** **Designation.**

Street clothing and personal belongings can contaminate food, food equipment, and food-contact surfaces. Proper storage facilities are required for articles such as purses, coats, shoes, and personal medications.

Service Sinks **6-306.10** **Availability.**

A service sink or curbed facility is required so that the cleanliness of the food establishment can be maintained, attractants for insects and rodents minimized, and contamination of food and equipment by accumulated soil prevented. Liquid wastes generated during cleaning must be disposed of in a sanitary manner to preclude contamination of food and food equipment. A service sink is provided to prevent the improper disposal of wastes into other sinks such as food preparation and handwashing sinks.

Handwashing Sinks **6-401.10** **Conveniently Located.**

Facilities must be located in or adjacent to toilet rooms and convenient to the different work stations of the food employee for proper and routine handwashing to prevent contamination of the food and food-contact surfaces.

Toilet Rooms **6-402.11** **Convenience and Accessibility.**

Toilet rooms must be conveniently accessible to food employees at all times to encourage employee use of appropriate facilities for the disposing of human wastes as needed followed by the washing of hands.

Employee Accommodations **6-403.11 Designated Areas**.

Because employees could introduce pathogens to food by hand-to-mouth-to-food contact and because street clothing and personal belongings carry contaminants, areas designated to accommodate employees' personal needs must be carefully located. Food, food equipment and utensils, clean linens, and single-service and single-use articles must not be in jeopardy of contamination from these areas.

Distressed Merchandise **6-404.11 Segregation and Location.**

Products which are damaged, spoiled, or otherwise unfit for sale or use in a food establishment may become mistaken for safe and wholesome products and/or cause contamination of other foods, equipment, utensils, linens, or single-service or single-use articles. To preclude this, separate and segregated areas must be designated for storing unsalable goods.

Refuse, Recyclables, and Returnables **6-405.10 Receptacles, Waste Handling Units, and Designated Storage Areas.**

Waste materials and empty product containers are unclean and can be an attractant to insects and rodents. Food, equipment, utensils, linens, and single-service and single-use articles must be protected from exposure to filth and unclean conditions and other contaminants. This Code provision addresses these concerns by requiring the facility to be segregated, to be located to allow cleaning of adjacent areas, and to preclude creation of a nuisance.

Premises, Structures, Attachments,* and *Fixtures, - Methods **6-501.11 Repairing.**

Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is intended to ensure that the physical facilities are properly maintained in order to serve their intended purpose.

6-501.12 Cleaning, Frequency and Restrictions.

Cleaning of the physical facilities is an important measure in ensuring the protection and sanitary preparation of food. A regular cleaning schedule should be established and followed to maintain the facility in a clean and sanitary manner. Primary cleaning should be done at times when foods are in protected storage and when food is not being served or prepared.

6-501.13 Cleaning Floors, Dustless Methods.

Dustless floor cleaning methods must be used so that food; equipment, utensils, and linens; and single-service and single-use articles are not contaminated.

6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

Both intake and exhaust ducts can be a source of contamination and must be cleaned regularly. Filters that collect particulate matter must be cleaned or changed frequently to prevent overloading of the filter. Outside areas under or adjacent to exhaust duct outlets at the exterior of the building must be maintained in a clean and sanitary manner to prevent pest attraction.

6-501.15 Cleaning Maintenance Tools, Preventing Contamination.

Maintenance tools used to repair the physical facilities must be cleaned in a separate area to prevent contamination of food and food preparation and warewashing areas.

6-501.16 Drying Mops.

Mops can contaminate food and food preparation areas if not properly cleaned and stored after use. Mops should be cleaned and dried in a sanitary manner away from food flow areas.

6-501.17 Absorbent Materials on Floors, Use Limitation.

Cleanliness of the food establishment is important to minimize attractants for insects and rodents, aid in preventing the contamination of food and equipment, and prevent nuisance conditions. A clean and orderly food establishment is also conducive to positive employee attitudes which can lead to increased attention to personal hygiene and improved food preparation practices. Use of specified cleaning procedures is important in precluding avoidable contamination of food and equipment and nuisance conditions.

Temporary floor coverings such as sawdust can contaminate food, attract insects and rodents, and become a nuisance to the food operation.

6-501.18 Cleaning of Plumbing Fixtures.

Handwashing facilities are critical to food protection and must be maintained in operating order at all times so they will be used.

Refer also to the public health reason for § 5-205.11.

Toilet facilities must be of sanitary design and kept clean and in good repair to prevent food contamination and to motivate employees to use sanitary practices in the establishment.

Hand contact with contaminated surfaces can result in self-inoculation by touching of the nose and mouth. The spread of *Shigella sonnei* in a nursery school has been traced to contaminated toilets. Experiments by Gerba, et al and Barker and Bloomfield have shown that when bacteria and viruses were seeded into a household toilet, the detection of bacteria and viruses in the fallout droplets from the aerosols produced when flushing remain airborne long enough to settle on surfaces throughout the bathroom. Barker and Bloomfield also demonstrated that *Salmonella* Enteritidis could be isolated from the air surrounding a household toilet after flushing the toilet.

Noroviruses which are a major cause of gastroenteritis can be transmitted by fecal-oral, airborne inhalation, person-to-person and environmental-to-person routes. Norovirus, which is highly infectious, is shed in vomitus and stool in high numbers. A study was conducted by J. Barker et al to look at the transmission of norovirus via fingers, cloths and contact surfaces. The results indicated that where fingers come into contact with virus-contaminated toilet tissue, norovirus is consistently transferred via the fingers to a melamine surface and from there to other typical hand-contact surfaces such as taps, door handles and telephone receivers. In this study epidemiological evidence suggests that environmental spread from an infective person occurs by settling of aerosol particles on to contact surfaces. Hands can then spread the virus when they touch toilet seats or flush handles contaminated by splash from vomit or aerosol particles generated during toilet flushing.

6-501.19 Closing Toilet Room Doors.

Toilet room doors must remain closed except during cleaning operations to prevent insect and rodent entrance and the associated potential for the spread of disease.

6-501.110 Using Dressing Rooms and Lockers.

Street clothing and personal belongings can contaminate food, food equipment, and food preparation surfaces and consequently must be stored in properly designated areas or rooms.

6-501.111 Controlling Pests.

Insects and other pests are capable of transmitting disease to humans by contaminating food and food-contact surfaces. Effective measures must be taken to eliminate their presence in food establishments.

6-501.112 Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.

Dead rodents, birds, and insects must be removed promptly from the facilities to ensure clean and sanitary facilities and to preclude exacerbating the situation by allowing carcasses to attract other pests.

6-501.113 Storing Maintenance Tools.

Brooms, mops, vacuum cleaners, and other maintenance equipment can contribute contamination to food and food-contact surfaces. These items must be stored in a manner that precludes such contamination.

To prevent harborage and breeding conditions for rodents and insects, maintenance equipment must be stored in an orderly fashion to permit cleaning of the area.

6-501.114 Maintaining Premises, Unnecessary Items and Litter.

The presence of unnecessary articles, including equipment which is no longer used, makes regular and effective cleaning more difficult and less likely. It can also provide harborage for insects and rodents.

Areas designated as equipment storage areas and closets must be maintained in a neat, clean, and sanitary manner. They must be routinely cleaned to avoid attractive or harborage conditions for rodents and insects.

6-501.115 Prohibiting Animals.

Animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food-contact surfaces. The restrictions apply to live animals with limited access allowed only in specific situations and under controlled conditions and to the storage of live and dead fish bait. Employees with service animals are required under § 2-301.14 to wash their hands after each contact with animals to remove bacteria and soil.

Animals shed hair continuously and may deposit liquid or fecal waste, creating the need for vigilance and more frequent and rigorous cleaning efforts.

The definition for "service animal" is adapted from 28 CFR 36.104 adopted pursuant to the Americans with Disabilities Act (ADA) of 1990 (42 U.S.C. 12101 et seq.). A service animal performs some of the functions that persons with a disability cannot perform for themselves, such as those provided by "seeing eye dogs"; alerting persons with hearing impairments to sounds; pulling wheelchairs or carrying and picking up things for persons with mobility impairments; and assisting persons with mobility impairments with balance. A service animal is not considered to be a pet.

Under Title III of the ADA, privately owned businesses that serve the public are prohibited from discriminating against individuals with disabilities. The ADA requires these businesses to allow people with disabilities to bring their service animals onto business premises in whatever areas customers are generally allowed. Some, but not all, service animals wear special collars or harnesses. Some, but not all, are licensed or certified and have identification papers.

Decisions regarding a food employee or applicant with a disability who needs to use a service animal should be made on a case-by-case basis. An employer must comply with health and safety requirements, but is obligated to consider whether there is a reasonable accommodation that can be made. Guidance is available from the U.S. Department of Justice, Civil Rights Division, Disability Rights Section or the U.S. Equal Employment Opportunity Commission, the Federal agency which has the lead in these matters, in documents such as, "Commonly Asked Questions About Service Animals in Places of Business"; "The Americans with Disabilities Act Questions and Answers"; "A Guide to Disability Rights Laws"; and "Americans with Disabilities Act Title III Technical Assistance Manual, 1994 Supplement." The ADA Information Line is 800-514-0301 (voice) or 800-514-0383 (TDD) and the Internet Home Page address is http://adata.org/.

Chapter 7 Poisonous or Toxic Materials

Original Containers **7-101.11** **Identifying Information, Prominence.**

The accidental contamination of food or food-contact surfaces can cause serious illness. Prominent and distinct labeling helps ensure that poisonous and toxic materials including personal care items are properly used.

Working Containers **7-102.11** **Common Name.**

It is common practice in food establishments to purchase many poisonous or toxic materials including cleaners and sanitizers in bulk containers. Working containers are frequently used to convey these materials to areas where they will be used, resulting in working containers being stored in different locations in the establishment. Identification of these containers with the common name of the material helps prevent the dangerous misuse of the contents.

Storage **7-201.11 Separation.**

Separation of poisonous and toxic materials in accordance with the requirements of this section ensures that food, equipment, utensils, linens, and single-service and single-use articles are properly protected from contamination. For example, the storage of these types of materials directly above or adjacent to food could result in contamination of the food from spillage.

Presence and Use **7-202.11 Restriction.**

The presence in the establishment of poisonous or toxic materials that are not required for the maintenance and operation of the establishment represents an unnecessary risk to both employees and consumers.

Preserving food safety depends in part on the appropriate and proper storage and use of poisonous or toxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the manufacturer on the material's label. If additional poisonous or toxic materials are present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

7-202.12 Conditions of Use.

Failure to properly use poisonous or toxic materials can be dangerous. Many poisonous or toxic materials have general use directions on their label. Failure to follow the stated instructions could result in injury to employees and consumers through direct contact or the contamination of food.

Particular precautions must be taken during the application of poisonous or toxic materials to prevent the contamination of food and other food-contact surfaces. Residues of certain materials are not discernible to the naked eye and present an additional risk to the employee and consumer.

Because of the toxicity of restricted use pesticides, they can only be applied by certified operators. A certified operator would be aware of the dangers involved in the contamination of food and food-contact surfaces during the application of these materials. Improperly applied pesticides present health risks to employees as well as consumers and special precautions must be taken when restricted use pesticides are applied.

Container Prohibitions **7-203.11 Poisonous or Toxic Material Containers.**

Use of poisonous or toxic material containers to store, transport, or dispense food is prohibited because of the potential for contamination of the food. The risk of serious medical consequences to anyone consuming food stored in these containers coupled with the lack of confidence that all of the material could or would be removed in the wash and sanitizing procedures are reasons for prohibiting this practice.

Chemicals **7-204.11 Sanitizers, Criteria.**

See explanation in §4-501.114.

Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.

Section 7-204.11 addresses whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40 CFR 180.940, Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food contact sanitizing solutions) or 40 CFR 180.2020, Non-food determinations. Because there is no EPA registration of solutions generated and used on-site, the user of the equipment should look to the equipment manufacturer for data to validate the efficacy of the solution that is generated by the device as well as the conditions for use of the solution.

Some sanitizers produced by on-site generators are based on gases dissolved in solution. These may present toxicology issues if the gases can come out of solution and into the air at high concentrations. Occupational Safety and Health Administration (OSHA) limits on gases like ozone and chlorine dioxide are outlined in 29 CFR 1910.1000, Air contaminants. Although the amount of dissolved gas in solution may be very low when evenly distributed through out all the air in a site, the gas may not be evenly distributed. This may lead to localized concentrations, e.g., immediately over a three compartment sink, that exceed OSHA limits. It is the responsibility of the permit holder and equipment supplier to ensure that the equipment is used in a safe manner so that OSHA limits will not be exceeded anywhere in the permit holder's facility.

7-204.12 Chemicals for Washing Fruits and Vegetables, Criteria.
7-204.13 Boiler Water Additives, Criteria.
7-204.14 Drying Agents, Criteria.

If the chemical wash, boiler water additive, or drying agent used is not made up of components that are approved as food additives or generally recognized as safe, illness may result. This could be due to residues that may remain from the use of compounds such as unrecognized drying agents. This is why only those chemicals that are approved food additives or food-contact substances, generally recognized as safe, prior sanctioned or exempted by the threshold of regulation process can be used. Information regarding food contact substances notification may be found on the FDA website under the Food Topic in Ingredients and Packaging section at: http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/default.htm

Chemicals that are not generally recognized as safe, or not authorized by FDA for these uses may be submitted for review by filing a Food Additive Petition, a Food Contact Notification (FCN), or a request for exemption under the Threshold of Regulation. Wash chemicals, boiler water additives, and drying agents are classified as food additives because of the possibility that they may end up in food. Therefore, they are subject to review before being used or listed in the CFR. If the chemicals are hard food-contact sanitizers, or washes for raw agricultural commodities (RACs) that are used on a farm or in a packing house, then this is under the jurisdiction of the EPA.

21 CFR 173 Secondary Direct Food Additives Permitted in Food for Human Consumption includes a number of regulations permitting certain food additives to be used for washing fruits and vegetables. In an effort to be consistent with federal law a change was made in Section 7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria to include all of 21 CFR 173 so as not to exclude the use of other permitted food additives. There is also another mechanism for approval of antimicrobial agents for washing fruits and vegetables (i.e., the food contact notification program) as well as GRAS ingredients permitted as antimicrobials or for general food use. This revision allows for the use of ingredients that are GRAS for this use and food contact substances which were the subject of an effective food contact notification for this use. 21 CFR 173 includes permitted food additives such as those listed in 21 CFR 173.315 Chemicals used in the washing or to assist in the peeling of fruits and vegetables. This section specifically identifies some of the chemicals that may be used in washing fruits and vegetables, regardless of whether the chemicals are commercially produced or generated on site. Sodium hypochlorite is listed in 21 CFR 173.315 for use in washing fruits and vegetables at levels not exceeding the minimum amount required to accomplish the intended technical effect. FDA has no objection to the use of calcium hypochlorite in the place of sodium hypochlorite under 21 CFR 173.315.

On December 4, 2012, the FDA amended the food additive regulations to provide for the safe use of sodium dodecylbenzenesulfonate (SDBS) (CAS No. 25155-30-0) as an antimicrobial agent for use in wash water for fruits and vegetables without the requirement of a potable water rinse. 21 CFR Section 173.405 specifically identifies this additive as an antimicrobial agent used in wash water for fruits and vegetables. The additive may be used at a level not to exceed 111 milligrams per kilogram in the wash water. Fruits and vegetables treated by the additive do not require a potable water rinse. Use of this additive is limited to use in commissaries, cafeterias, restaurants, retail food establishments, nonprofit food establishments and other food service operations in which food is prepared for or served directly to the consumer. To ensure safe use of the additive, refer to the label or labeling of the additive and/or antimicrobial pesticide container for adequate directions. Information on the label is required in accordance to provisions within 21 CFR 173.405 and the Federal Food, Drug and Cosmetic Act. Although the petitioned use of SDBS is regulated under Section 409 of the FD & C Act as a food additive, this intended use of SDBS may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA requirements pertain to EPA registered pesticide products that have uses subject to EPA or both FDA and EPA regulations. Therefore, manufacturers intending to use this food additive for this intended use should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

Boiler water additives that may be safely used in the preparation of steam that may contact food, and their condition of use, are identified in 21 CFR 173.310 Boiler Water Additives.

Lubricants **7-205.11** **Incidental Food Contact, Criteria.**

Lubricants used on food equipment may directly or indirectly end up in the food. Therefore, the lubricants used must be approved as food additives or generally recognized as safe and listed in the CFR. Lubricants that are not safe present the possibility of foodborne illness if they find their way into the food.

Pesticides **7-206.11** **Restricted Use Pesticides, Criteria.**
7-206.12 **Rodent Bait Stations.**

Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on food-contact surfaces and ultimately in the food being prepared or served.

7-206.13 Tracking Powders, Pest Control and Monitoring.

The use of tracking powder pesticides presents the potential for the powder to be dispersed throughout the establishment. Consequently, the powder could directly or indirectly contaminate food being prepared. This contamination could adversely affect both the safety and quality of the food and, therefore, tracking powder pesticides are not allowed.

Medicines **7-207.11 Restriction and Storage.**

Medicines that are not necessary for the health of employees present an unjustified risk to the health of other employees and consumers due to misuse and/or improper storage.

There are circumstances that require employees or children in a day care center to have personal medications on hand in the establishment. To prevent misuse, personal medications must be labeled and stored in accordance with the requirements stated for poisonous or toxic materials. Proper labeling and storage of medicines to ensure that they are not accidentally misused or otherwise contaminate food or food-contact surfaces.

7-207.12 Refrigerated Medicines, Storage.

Some employee medications may require refrigerated storage. If employee medications are stored in a food refrigerator, precautions must be taken to prevent the contamination of other items stored in the same refrigerator.

First Aid Supplies **7-208.11 Storage.**

First aid supplies for employee use must be identified and stored in accordance with the requirements of this Code in order to preclude the accidental contamination of food, food equipment, and other food-contact surfaces.

Other Personal Care Items **7-209.11 Storage.**

Employee personal care items may serve as a source of contamination and may contaminate food, food equipment, and food-contact surfaces if they are not properly labeled and stored.

Storage and Display	**7-301.11**	**Separation.**

Poisonous or toxic materials held for sale on store shelves or stored in stock rooms present a risk of contamination of food, equipment, utensils, linens, and single-service and single-use articles if not stored properly.

Chapter 8 Compliance and Enforcement

Construction	**8-201.12**	**Contents of the Plans and Specifications.**
Inspection and Approval	**8-203.10**	**Preoperational Inspections.**

In conjunction with the Conference for Food Protection Plan Review committee, FDA has participated in developing a document that is intended to assist regulators in reviewing food establishment plans, and industry in understanding what is expected in the plan review process. For several years, this FDA/CFP Food Establishment Plan Review Guide – 2000 has been used in the FDA State Training Team Plan Review courses. It can be accessed through http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm101639.htm.

At the plan review stage, the regulatory authority may be dealing with an agent of the permit applicant who is seeking a building permit and who is not in a position to discuss plans for safely conducting the food operation. Nonetheless, the plan review step presents a unique opportunity to lay a foundation that enables the proposed operation to proactively sustain compliance with the Code over time. Standard operating procedures (SOPs) are a part of that foundation and ideally are developed in tandem with designing the facility. Consequently, as an integral part of the plan review process, discussion needs to occur about such procedures and their scope.

SOPs need to be developed by the time of the preoperational inspection and put into effect when the food operation begins. It is recommended that such procedures be written, available for reference by the person in charge, conveyed to the appropriate employees, and available for review by the regulatory authority during inspections. Operating procedures should include definitive practices and expectations that ensure that:

(1) The transmission of foodborne disease is prevented by managing job applicants and food employees as specified under Subpart 2-201,

(2) Food is received from approved sources as specified under § 3-201.11,

(3) Food is managed so that the safety and integrity of the food from the time of delivery to the establishment throughout its storage, preparation, and transportation to the point of sale or service to the consumer is protected,

(4) Time/temperature control for safety food is maintained, including freezing, cold holding, cooking, hot holding, cooling, reheating, and serving in conformance with the temperature and time requirements specified under Parts 3-4 and 3-5,

(5) Warewashing is effective, including assurance that the chemical solutions and exposure times necessary for cleaning and sanitizing utensils and food-contact surfaces of equipment are provided as specified under Parts 4-6 and 4-7, and

(6) Records that are specified under §§ 3-203.11, 3-203.12, and 5-205.13 are retained for inspection.

During the plan review stage, the regulatory authority and a management representative of the proposed food establishment should discuss available training options that may be used to train food employees and the person in charge regarding food safety as it relates to their assigned duties. By the time of the preoperational inspection, operating procedures for training should include definitive practices and expectations of how the management of the proposed food establishment plans to comply with ¶ 2-103.11(L) of this Code which requires the person in charge to assure that food employees are properly trained in food safety as it relates to their assigned duties.

8-304.11 Responsibility of the Permit Holder

It is important that regulatory agencies comply with applicable laws related to disclosure of public information. Making inspection reports available to the public promotes transparency and allows the public to be better informed about the businesses they patronize and the government agencies that serve the public. The intent is to improve industry and regulatory practices related to food safety at the foodservice and retail level.

8-402.10 Competency of Inspectors.

Regulatory agencies are encouraged to use Standard #2 of the draft *FDA's Recommended National Retail Food Regulatory Program Standards* (http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm) to ensure employees who inspect food establishments are properly trained. Regulatory inspectors are also encouraged to seek food safety certification through a nationally recognized and accredited program.

8-501.20 Restriction or Exclusion of Food Employee, or Summary Suspension of Permit.

See discussion in Annex 3, § 2-201.12.

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Annex

4 Management of Food Safety Practices – Achieving Active Managerial Control of Foodborne Illness Risk Factors

1. ACTIVE MANAGERIAL CONTROL

(A) What is the common goal of operators and regulators of retail food and food service establishments and what is presently being done to achieve this goal?

The common goal of operators and regulators of retail and food service establishments is to produce safe, quality food for consumers. Since the onset of regulatory oversight of retail and food service operations, regulatory inspections have emphasized the recognition and correction of food safety violations that exist at the time of the inspection. Recurring violations have traditionally been handled through re-inspections or enforcement activities such as fines, suspension of permits, or closures. Operators of retail and food service establishments routinely respond to inspection findings by correcting violations, but often do not implement proactive systems of control to prevent violations from recurring. While this type of inspection and enforcement system has

done a great deal to improve basic sanitation and to upgrade facilities in the United States, it emphasizes reactive rather than preventive measures to food safety. Additional measures must be taken on the part of operators and regulators to better prevent or reduce foodborne illness. Annex 5 of the Food Code provides additional information on conducting risk-based inspections. It should be reviewed in conjunction with the material found in this Annex to better understand the role of the regulator in facilitating active managerial control by the operator.

(B) Who has the ultimate responsibility for providing safe food to the consumer?

The responsibility of providing safe food to the consumer is shared by many people in every stage in the production of food, including consumers, themselves. Since most consumers receive their food from retail and food service establishments, a significant share of the responsibility for providing safe food to the consumer rests with these facilities. Working together with their regulatory authorities, operators of retail and food service establishments can make the greatest impact on food safety.

(C) How can foodborne illness be reduced?

The Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993-1997, "Surveillance for Foodborne-Disease Outbreaks – United States," identifies the most significant contributing factors to foodborne illness. Five of these broad categories of contributing factors directly relate to food safety concerns within retail and food service establishments and are collectively termed by the FDA as "foodborne illness risk factors." These five broad categories are:

- Food from Unsafe Sources
- Inadequate Cooking
- Improper Holding Temperatures
- Contaminated Equipment
- Poor Personal Hygiene.

In 1998, FDA initiated a project designed to determine the incidence of foodborne illness risk factors in retail and food service establishments. Inspections focusing on the occurrence of foodborne illness risk factors were conducted in establishments throughout the United States. The results of this project are published in the 2000 *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors*, commonly referred to as the "FDA Baseline Report." The Baseline Report is available from FDA through the following website: http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf. The data collection project was repeated in 2003 and the results are published in the *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).* This second report is available from FDA through the following website:

http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm089696.htm.

The data collection was repeated again in 2008 and published in a 2009 report This was followed by a Trend Analysis Report covering 1998-2008 that was published in October 2010. The CDC Surveillance Report and the results from the FDA Risk Factor Studies support the concept that operators of retail and food service establishments must be proactive and implement food safety management systems that will prevent, eliminate, or reduce the occurrence of foodborne illness risk factors. By reducing the occurrence of foodborne illness risk factors, foodborne illness can also be reduced.

(D) How can the occurrence of foodborne illness risk factors be reduced?

To effectively reduce the occurrence of foodborne illness risk factors, operators of retail and food service establishments must focus their efforts on achieving active managerial control. The term "active managerial control" is used to describe industry's responsibility for developing and implementing food safety management systems to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors.

Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

There are many tools that can be used by industry to provide active managerial control of foodborne illness risk factors. Regulatory inspections and follow-up activities must also be proactive by using an inspection process designed to assess the degree of active managerial control that retail and food service operators have over the foodborne illness risk factors. In addition, regulators must assist operators in developing and implementing voluntary strategies to strengthen existing industry systems to prevent the occurrence of foodborne illness risk factors. Elements of an effective food safety management system may include the following:

- Certified food protection managers who have shown a proficiency in required information by passing a test that is part of an accredited program
- Standard operating procedures (SOPs) for performing critical operational steps in a food preparation process, such as cooling
- Recipe cards that contain the specific steps for preparing a food item and the food safety critical limits, such as final cooking temperatures, that need to be monitored and verified
- Purchase specifications
- Equipment and facility design and maintenance
- Monitoring procedures

- Record keeping
- Employee health policy for restricting or excluding ill employees
- Manager and employee training
- On-going quality control and assurance
- Specific goal-oriented plans, like Risk Control Plans (RCPs), that outline procedures for controlling foodborne illness risk factors.

A food safety management system based on Hazard Analysis and Critical Control Point (HACCP) principles contains many of these elements and provides a comprehensive framework by which an operator can effectively control the occurrence of foodborne illness risk factors.

2. INTRODUCTION TO HACCP

(A) What is HACCP and how can it be used by operators and regulators of retail food and food service establishments?

Hazard Analysis and Critical Control Point (HACCP) is a systematic approach to identifying, evaluating, and controlling food safety hazards. Food safety hazards are biological, chemical, or physical agents that are reasonably likely to cause illness or injury in the absence of their control. Because a HACCP program is designed to ensure that hazards are prevented, eliminated, or reduced to an acceptable level before a food reaches the consumer, it embodies the preventive nature of "active managerial control."

Active managerial control through the use of HACCP principles is achieved by identifying the food safety hazards attributed to products, determining the necessary steps that will control the identified hazards, and implementing on-going practices or procedures that will ensure safe food.

Like many other quality assurance programs, HACCP provides a common-sense approach to identifying and controlling problems that are likely to exist in an operation. Consequently, many food safety management systems at the retail level already incorporate some, if not all, of the principles of HACCP. Combined with good basic sanitation, a solid employee training program, and other prerequisite programs, a food safety management system based on HACCP principles will prevent, eliminate, or reduce the occurrence of foodborne illness risk factors that lead to out-of-control hazards.

HACCP represents an important tool in food protection that small independent businesses as well as national companies can use to achieve active managerial control of risk factors. The *Food Code* requires a comprehensive HACCP plan when conducting certain specialized processes at retail such as when a variance is granted or

when a reduced oxygen packaging method is used. However, in general, the implementation of HACCP at the retail level is voluntary. FDA endorses the voluntary implementation of food safety management systems based on HACCP principles as an effective means for controlling the occurrence of foodborne illness risk factors that result in out-of-control hazards.

While the operator is responsible for developing and implementing a system of controls to prevent foodborne illness risk factors, the role of the regulator is to assess whether the system the operator has in place is achieving control of foodborne illness risk factors. Using HACCP principles during inspections will enhance the effectiveness of routine inspections by incorporating a risk-based approach. This helps inspectors focus their inspection on evaluating the effectiveness of food safety management systems implemented by industry to control foodborne illness risk factors.

The principles of HACCP are also an integral part of the draft *FDA's Recommended Voluntary National Retail Food Regulatory Program Standards*. For regulatory program managers, the use of risk-based inspection methodology based on HACCP principles is a viable and practical option for evaluating the degree of active managerial control operators have over the foodborne illness risk factors. The complete set of *Program Standards* is available from FDA through the following website: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm.

(B) What are the Seven HACCP Principles?

In November 1992, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) defined seven widely accepted HACCP principles that explained the HACCP process in great detail. In 1997, NACMCF reconvened to review the 1992 document and compare it to current HACCP guidance prepared by the CODEX Committee on Food Hygiene. Based on this review, NACMCF again endorsed HACCP and defined HACCP as a systematic approach to the identification, evaluation, and control of food safety. Based on a solid foundation of prerequisite programs to control basic operational and sanitation conditions, the following seven basic principles are used to accomplish this objective:

Principle 1: Conduct a hazard analysis
Principle 2: Determine the critical control points (CCPs)
Principle 3: Establish critical limits
Principle 4: Establish monitoring procedures
Principle 5: Establish corrective actions
Principle 6: Establish verification procedures
Principle 7: Establish record-keeping and documentation procedures.

This Annex will provide a brief overview of each of the seven principles of HACCP. A more comprehensive discussion of these principles is available from FDA by accessing the NACMCF guidance document on the FDA Web Page at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/ucm072557.htm. Following the overview, a practical scheme for applying and implementing the HACCP principles in retail and food service establishments is presented.

(C) What are Prerequisite Programs?

In order for a HACCP system to be effective, a strong foundation of procedures that address the basic operational and sanitation conditions within an operation must first be developed and implemented. These procedures are collectively termed "prerequisite programs." When prerequisite programs are in place, more attention can be given to controlling hazards associated with the food and its preparation. Prerequisite programs may include such things as:

- Vendor certification programs
- Training programs
- Allergen management
- Buyer specifications
- Recipe/process instructions
- First-In-First-Out (FIFO) procedures
- Other Standard Operating Procedures (SOPs).

Basic prerequisite programs should be in place to:

- Protect products from contamination by biological, chemical, and physical food safety hazards
- Control bacterial growth that can result from temperature abuse
- Maintain equipment.

Additional information about prerequisite programs and the types of activities usually included in them can be found in the FDA's Retail HACCP manuals discussed later in this Annex or by accessing the NACMCF guidance document on the FDA Web Page.

3. THE HACCP PRINCIPLES

(A) Principle #1: Conduct a Hazard Analysis

(1) What is a food safety hazard?

A hazard is a biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(2) What are biological hazards?

Biological hazards include bacterial, viral, and parasitic microorganisms. See Table 1 in this Annex for a listing of selected biological hazards. Bacterial pathogens comprise the majority of confirmed foodborne disease outbreaks and cases. Although cooking destroys the vegetative cells of foodborne bacteria to acceptable levels, spores of spore-forming bacteria such as *Bacillus cereus*, *Clostridium botulinum*, and *Clostridium perfringens* survive cooking and may germinate and grow if food is not properly cooled or held after cooking. The toxins produced by the vegetative cells of *Bacillus cereus*, *Clostridium botulinum*, and *Staphylococcus aureus* may not be destroyed to safe levels by reheating. Post-cook recontamination with vegetative cells of bacteria such as *Salmonellae* and *Campylobacter jejuni* is also a major concern for operators of retail and food service establishments.

Viruses such as norovirus, hepatitis A, and rotavirus are directly related to contamination from human feces. Recent outbreaks have also shown that these viruses may be transmitted via droplets in the air. In limited cases, foodborne viruses may occur in raw commodities contaminated by human feces (e.g., shellfish harvested from unapproved, polluted waters). In most cases, however, contamination of food by viruses is the result of cross-contamination by ill food employees or unclean equipment and utensils. Unlike bacteria, a virus cannot multiply outside of a living cell. Cooking as a control for viruses may be ineffective because many foodborne viruses seem to exhibit heat resistance exceeding cooking temperature requirements, under laboratory conditions. Obtaining food from approved sources, practicing no bare hand contact with ready-to-eat food as well as proper handwashing, and implementing an employee health policy to restrict or exclude ill employees are important control measures for viruses.

Parasites are most often animal host-specific, but can include humans in their life cycles. Parasitic infections are commonly associated with undercooking meat products or cross-contamination of ready-to-eat food with raw animal foods, untreated water, or contaminated equipment or utensils. Like viruses, parasites do not grow in food, so control is focused on destroying the parasites and/or preventing their introduction. Adequate cooking destroys parasites. In addition, parasites in fish to be consumed raw or undercooked can also be destroyed by effective freezing techniques. Parasitic

contamination by ill employees can be prevented by proper handwashing, no bare hand contact with ready-to-eat food, and implementation of an employee health policy to restrict or exclude ill employees.

Annex 4, Table 1a – 1c. Selected Biological Hazards Found at Retail, Associated Foods, and Control Measures

Annex 4, Table 1a. Selected Bacterial Hazards Found at Retail, Associated Foods, and Control Measures

HAZARD	ASSOCIATED FOODS	CONTROL MEASURES
Bacillus cereus (intoxication caused by heat stable, preformed emetic toxin and infection by heat labile, diarrheal toxin)	Meat, poultry, starchy foods (rice, potatoes), puddings, soups, cooked vegetables	Cooking, cooling, cold holding, hot holding
Campylobacter jejuni	Poultry, raw milk	Cooking, handwashing, prevention of cross-contamination
Clostridium botulinum	Vacuum-packed foods, reduced oxygen packaged foods, under-processed canned foods, garlic-in-oil mixtures, time/temperature abused baked potatoes/sautéed onions	Thermal processing (time + pressure), cooling, cold holding, hot holding, acidification and drying, etc.
Clostridium perfringens	Cooked meat and poultry, Cooked meat and poultry products including casseroles, gravies	Cooling, cold holding, reheating, hot holding
E. coli O157:H7 (other shiga toxin-producing *E. coli*)	Raw ground beef, raw seed sprouts, raw milk, unpasteurized juice, foods contaminated by infected food workers via fecal-oral route	Cooking, no bare hand contact with RTE foods, employee health policy, handwashing, prevention of cross-contamination, pasteurization or treatment of juice
Listeria monocytogenes	Raw meat and poultry, fresh soft cheese, paté, smoked seafood, deli meats, deli salads	Cooking, date marking, cold holding, handwashing, prevention of cross-contamination
Salmonella spp.	Meat and poultry, seafood, eggs, raw seed sprouts, raw vegetables, raw milk, unpasteurized juice	Cooking, use of pasteurized eggs, employee health policy, no bare hand contact with RTE foods, handwashing, pasteurization or treatment of juice
Shigella spp.	Raw vegetables and herbs, other foods contaminated by infected workers via fecal-oral route	Cooking, no bare hand contact with RTE foods, employee health policy, handwashing
Staphylococcus aureus (preformed heat stable toxin)	RTE TCS foods touched by bare hands after cooking and further time/temperature abused	Cooling, cold holding, hot holding, no bare hand contact with RTE food, handwashing
Vibrio spp.	Seafood, shellfish	Cooking, approved source, prevention of cross-contamination, cold holding

RTE = ready-to-eat TCS = time/temperature control for safety food

Annex 4, Table 1b. Selected Parasitic Hazards Found at Retail, Associated Foods, and Control Measures

HAZARD	ASSOCIATED FOODS	CONTROL MEASURES
Anisakis simplex	Various fish (cod, haddock, fluke, pacific salmon, herring, flounder, monkfish)	Cooking, freezing
Taenia spp.	Beef and pork	Cooking
Trichinella spiralis	Pork, bear, and seal meat	Cooking

RTE = ready-to-eat TCS = time/temperature control for safety food

Annex 4, Table 1c. Selected Viral Hazards Found at Retail, Associated Foods, and Control Measures

HAZARD	ASSOCIATED FOODS	CONTROL MEASURES
Hepatitis A and E	Shellfish, any food contaminated by infected worker via fecal-oral route	Approved source, no bare hand contact with RTE food, minimizing bare hand contact with foods not RTE, employee health policy, handwashing
Other Viruses (Rotavirus, Norovirus, Reovirus)	Any food contaminated by infected worker via fecal-oral route	No bare hand contact with RTE food, minimizing bare hand contact with foods not RTE, employee health policy, handwashing

RTE = ready-to-eat TCS = time/temperature control for safety food

(3) What are Chemical Hazards?

Chemical hazards may be naturally occurring or may be added during the processing of food. High levels of toxic chemicals may cause acute cases of foodborne illness, while chronic illness may result from low levels.

The Code of Federal Regulations (http://www.access.gpo.gov/nara/cfr/cfr-table-search.html), Title 21 Food and Drugs, provides guidance on naturally occurring poisonous or deleterious substances, e.g., 21 CFR Parts 109 Unavoidable Contaminants in Food for Human Consumption and Food Packaging Material, and 184 Direct Food Substances Affirmed as Generally Recognized as Safe. The CFR also provide allowable limits for many of the chemicals added during processing, e.g., 21 CFR Part 172 Food Additives Permitted for Direct Addition to Food For Human Consumption.

FDA's Compliance Policy Guidelines also provide information on naturally occurring chemicals (http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm). See Chapter 5 – Foods, Colors and Cosmetics. Examples include sections:

- 540.600 Fish, Shellfish, Crustaceans, and Other Aquatic Animals – Fresh, Frozen or Processed – Methyl Mercury,
- 555.400 Foods – Adulteration with Aflatoxin, and
- 570.200 Aflatoxin in Brazil Nuts, .375 Peanuts and Peanut Products, and .500 Pistachio Nuts.

Table 2 of this Annex provides additional examples of chemical hazards, both naturally occurring and added.

(4) Food Allergens As Food Safety Hazards

Recent studies indicate that over 11 million Americans suffer from one or more food allergies. A food allergy is caused by a naturally-occurring protein in a food or a food ingredient, which is referred to as an "allergen." For unknown reasons, certain individuals produce immunoglobulin E (IgE) antibodies specifically directed to food allergens. When these sensitive individuals ingest sufficient concentrations of foods containing these allergens, the allergenic proteins interact with IgE antibodies and elicit an abnormal immune response. A food allergic response is commonly characterized by hives or other itchy rashes, nausea, abdominal pain, vomiting and/or diarrhea, wheezing, shortness of breath, and swelling of various parts of the body. In severe cases, anaphylactic shock and death may result.

Many foods, with or without identifiable allergens, have been reported to cause food allergies. However, FDA believes there is scientific consensus that the following foods can cause a serious allergic reaction in sensitive individuals; these foods account for 90% or more of all food allergies:

- Milk
- Egg
- Fish (such as bass, flounder, or cod)
- Crustacean shellfish (such as crab, lobster, or shrimp)
- Tree nuts (such as almonds, pecans, or walnuts)
- Wheat
- Peanuts
- Soybeans.

Consumers with food allergies rely heavily on information contained on food labels to avoid food allergens. Each year, FDA receives reports from consumers who have experienced an adverse reaction following exposure to a food allergen. Frequently, these reactions occur either because product labeling does not inform the consumer of the presence of the allergenic ingredient in the food or because of the cross-contact of a food with an allergenic substance not intended as an ingredient of the food during processing and preparation.

In August 2004, the Food Allergen Labeling and Consumer Protection Act (Public Law 108-282, Title II) was enacted, which defines the term "major food allergen." The definition of "major food allergen" adopted for use in the Food Code (see paragraph 1-201.10(B)) is consistent with the definition in the new law. The following requirements are included in the new law:

- For foods labeled on or after January 1, 2006, food manufacturers must identify in plain language on the label of the food any major food allergen used as an ingredient in the food, including a coloring, flavoring, or incidental additive.
- FDA is to conduct inspections to ensure that food facilities comply with practices to reduce or eliminate cross-contact of a food with any major food allergens that are not intentional ingredients of the food.
- Within 18 months of the date of enactment of the new law (i.e., by February 2, 2006), FDA must submit a report to Congress that analyzes the results of its food inspection findings and addresses a number of specific issues related to the production, labeling, and recall of foods that contain an undeclared major food allergen.
- Within 2 years of the date of enactment of the new law (i.e., by August 2, 2006), FDA must issue a proposed rule, and within 4 years of the date of enactment of the new law (i.e., by August 2, 2008), FDA must issue a final rule to define and permit the use of the term "gluten-free" on food labeling.
- FDA is to work in cooperation with the Conference for Food Protection (CFP) to pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments.

Annex 4, Table 2a-b. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Annex 4, Table 2a. Naturally Occurring Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Naturally Occurring Chemical Hazards	Associated Foods	Control measures
Scombrotoxin	Primarily associated with tuna fish, mahi-mahi, blue fish, anchovies bonito, mackerel; Also found in cheese	Check temperatures at receiving; store at proper cold holding temperatures; buyer specifications: obtain verification from supplier that product has not been temperature abused prior to arrival in facility.
Ciguatoxin	Reef fin fish from extreme SE US, Hawaii, and tropical areas; barracuda, jacks, king mackerel, large groupers, and snappers	Ensure fin fish have not been caught: • Purchase fish from approved sources. • Fish should not be harvested from an area that is subject to an adverse advisory.
Tetrodoxin	Puffer fish (Fugu; Blowfish)	Do not consume these fish.
Mycotoxins Aflatoxin	Corn and corn products, peanuts and peanut products, cottonseed, milk, and tree nuts such as Brazil nuts, pecans, pistachio nuts, and walnuts. Other grains and nuts are susceptible but less prone to contamination.	Check condition at receiving; do not use moldy or decomposed food.
Patulin	Apple juice products	Buyer Specification: obtain verification from supplier or avoid the use of rotten apples in juice manufacturing.

Naturally Occurring Chemical Hazards	Associated Foods	Control measures
Toxic mushroom species	Numerous varieties of wild mushrooms	Do not eat unknown varieties or mushrooms from unapproved source.
Shellfish toxins Paralytic shellfish poisoning (PSP) Diarrhetic shellfish poisoning (DSP) Neurotoxin shellfish poisoning (NSP) Amnesic shellfish poisoning (ASP)	Molluscan shellfish from NE and NW coastal regions; mackerel, viscera of lobsters and Dungeness, tanner, and red rock crabs Molluscan shellfish in Japan, western Europe, Chile, NZ, eastern Canada Molluscan shellfish from Gulf of Mexico Molluscan shellfish from NE and NW coasts of NA; viscera of Dungeness, tanner, red rock crabs and anchovies.	Ensure molluscan shellfish are: • from an approved source; and • properly tagged and labeled.
Pyrrolizidine alkaloids	Plants food containing these alkaloids. Most commonly found in members of the Borginaceae, Compositae, and Leguminosae families.	Do not consume of food or medicinals contaminated with these alkaloids.
Phtyohaemmagglutinin	Raw red kidney beans (Undercooked beans may be more toxic than raw beans)	Soak in water for at least 5 hours. Pour away the water. Boil briskly in fresh water, with occasional stirring, for at least 10 minutes.
Allergens	Foods containing or contacted by: Milk Egg Fish Crustacean shellfish Tree nuts Wheat Peanuts Soybeans	Use a rigorous sanitation regime to prevent cross contact between allergenic and non-allergenic ingredients.

Annex 4, Table 2b. Added Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Added Chemical Hazards	Associated Foods	Control measures
Environmental contaminants: Pesticides, fungicides, fertilizers, insecticides, antibiotics, growth hormones	Any food may become contaminated.	Follow label instructions for use of environmental chemicals. Soil or water analysis may be used to verify safety.
PCBs	Fish	Comply with fish advisories.
Prohibited substances (21 CFR 189)	Numerous substances are prohibited from use in human food; no substance may be used in human food unless it meets all applicable requirements of the FD&C Act.	Do not use chemical substances that are not approved for use in human food.
Toxic elements/compounds Mercury	Fish exposed to organic mercury: shark, tilefish, king mackerel and swordfish. Grains treated with mercury based fungicides	Pregnant women/women of childbearing age/nursing mothers, and young children should not eat shark, swordfish, king mackerel or tilefish because they contain high levels of mercury. Do not use mercury containing fungicides on grains or animals.
Copper	High acid foods and beverages	Do not store high acid foods in copper utensils; use backflow prevention device on beverage vending machines.
Lead	High acid food and beverages	Do not use vessels containing lead.

Added Chemical Hazards	Associated Foods	Control measures
Preservatives and Food Additives: Sulfiting agents (sulfur dioxide, sodium and potassium bisulfite, sodium and potassium metabisulfite)	Fresh fruits and Vegetables Shrimp Lobster Wine	Sulfiting agents added to a product in a processing plant must be declared on labeling. Do not use on raw produce in food establishments.
Nitrites/nitrates Niacin	Cured meats, fish, any food exposed to accidental contamination, spinach Meat and other foods to which sodium nicotinate is added	Do not use more than the prescribed amount of curing compound according to labeling instructions. Sodium nicotinate (niacin) is not currently approved for use in meat or poultry with or without nitrates or nitrates.
Flavor enhancers Monosodium glutamate (MSG)	Asian or Latin American food	Avoid using excessive amounts
Chemicals used in retail establishments (e.g., lubricants, cleaners, sanitizers, cleaning compounds, and paints	Any food could become contaminated	Address through SOPs for proper labeling, storage, handling, and use of chemicals; retain Material Safety Data Sheets for all chemicals.

(5) What are Physical Hazards?

Illness and injury can result from foreign objects in food. These physical hazards can result from contamination or poor procedures at many points in the food chain from harvest to consumer, including those within the food establishment. As establishments develop their food safety management systems, Annex 4, Table 3 can be used to aid in the identification of sources of potential physical hazards to the food being prepared, served, or sold. Annex 4, Table 3 provides some examples of common physical hazards.

Annex 4, Table 3. Main Materials of Concern as Physical Hazards and Common Sources[a, b]

Material	Injury Potential	Sources
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, lights, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth Cuts, infection; may require surgery to remove	Fields, buildings, machinery, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

[a] Adapted from Corlett (1991).

[b] Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

(6) What is the purpose of the hazard analysis principle?

The purpose of hazard analysis is to develop a list of food safety hazards that are reasonably likely to cause illness or injury if not effectively controlled.

(7) How is the hazard analysis conducted?

The process of conducting a hazard analysis involves two stages:

1. Hazard Identification
2. Hazard Evaluation

Hazard identification can be thought of as a brain storming session. This stage focuses on identifying the food safety hazards that might be present in the food given the food preparation process used, the handling of the food, the facility, and general characteristics of the food itself. During this stage, a review is made of the ingredients used in the product, the activities conducted at each step in the process, the equipment

used, the final product, and its method of storage and distribution, as well as the intended use and consumers of the product.
Based on this review, a list of potential biological, chemical, or physical hazards is made at each stage in the food preparation process.

In stage two, the hazard evaluation, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence. The purpose of this stage is to determine which of the potential hazards listed in stage one of the hazard analysis warrant control in the HACCP plan. Severity is the seriousness of the consequences of exposure to the hazard. Considerations made when determining the severity of a hazard include understanding the impact of the medical condition caused by the illness, as well as the magnitude and duration of the illness or injury. Consideration of the likely occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature. Hazards that are not reasonably likely to occur are not considered in a HACCP plan. During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage, and persons likely to consume the product should be considered to determine how each of these factors may influence the likely occurrence and severity of the hazard being controlled.

Upon completion of the hazard analysis, a list of significant hazards that must be considered in the HACCP plan is made, along with any measure(s) that can be used to control the hazards. These measures, called control measures, are actions or activities that can be used to prevent, eliminate, or reduce a hazard. Some control measures are not essential to food safety, while others are. Control measures essential to food safety like proper cooking, cooling, and refrigeration of ready-to-eat, time/temperature control for safety foods are usually applied at critical control points (CCPs) in the HACCP plan (discussed later). The term control measure is used because not all hazards can be prevented, but virtually all can be controlled. More than one control measure may be required for a specific hazard. Likewise, more than one hazard may be addressed by a specific control measure (e.g., proper cooking).

(B) Principle #2: Determine Critical Control Points (CCPs)

(1) What is the Critical Control Point (CCP)?

A critical control point (CCP) means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk. Control can be applied at this point and is <u>essential</u> to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Each CCP will have one or more control measures to assure that the identified hazards are prevented, eliminated, or reduced to acceptable levels. Common examples of CCPs include cooking, cooling, hot holding, and cold holding of ready-to-eat time/temperature control for safety foods. Due to vegetative and spore- and toxin-forming bacteria that are associated with raw animal foods, it is apparent that

the proper execution of control measures at each of these operational steps is essential to prevent or eliminate food safety hazards or reduce them to acceptable levels.

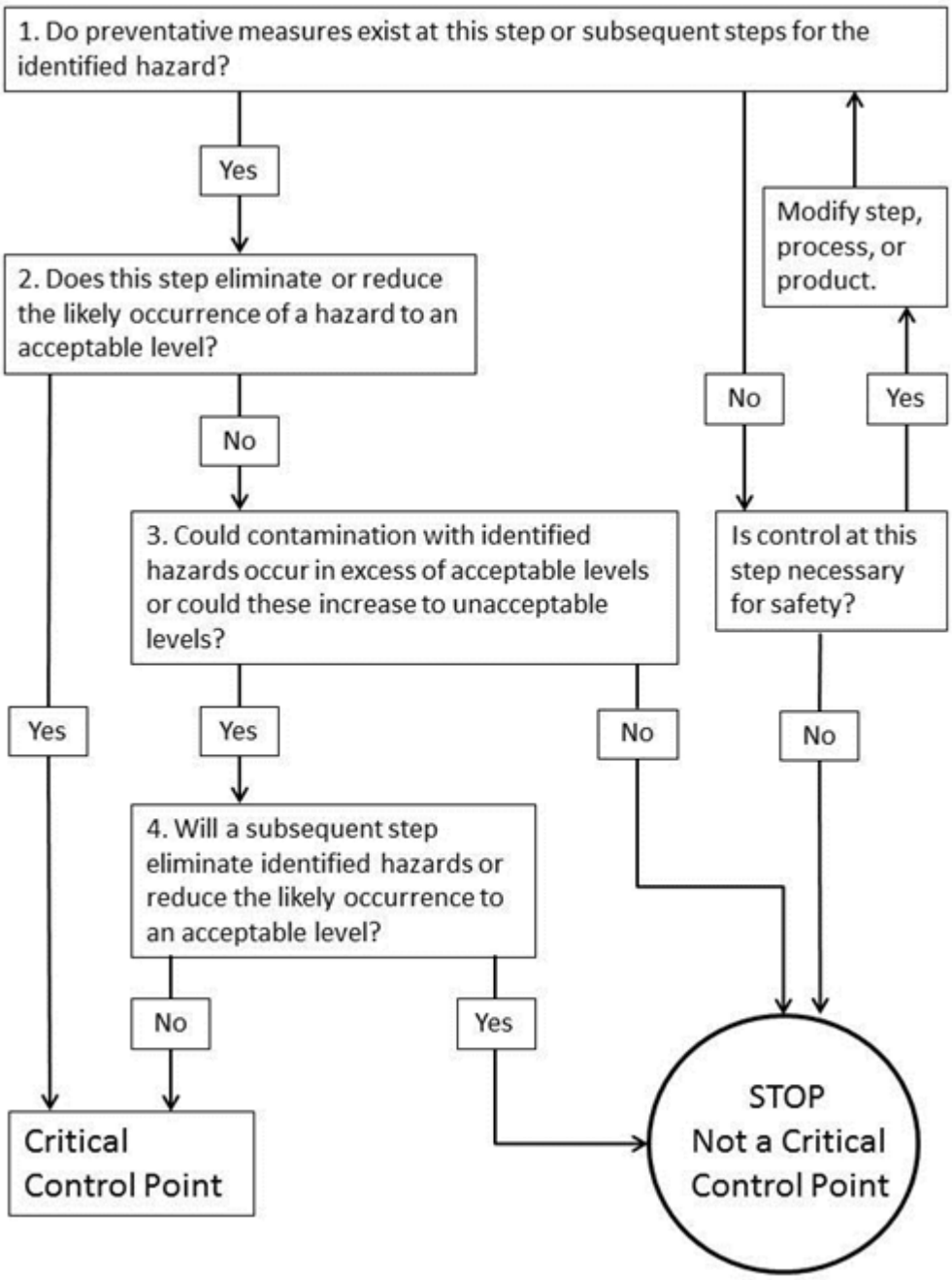
(2) Are quality issues considered when determining CCPs?

CCPs are only used to address issues with product safety. Actions taken on the part of the establishment such as first-in first-out (FIFO) or refrigerating non-time/temperature control for safety foods are to ensure food quality rather than food safety and therefore should not be considered as CCPs unless they serve a dual-purpose of ensuring food safety.

(3) Are the CCPs the same for everyone?

Different facilities preparing similar food items may identify different hazards and the CCPs. This can be due to differences in each facility's layout, equipment, selection of ingredients, and processes employed. In mandatory HACCP systems, there may be rigid regulatory requirements regarding what must be designated a CCP. In voluntary HACCP systems, hazard control may be accomplished at CCPs or through prerequisite programs. For instance, one facility may decide that it can best manage the hazards associated with cooling through a standardized procedure in its prerequisite programs rather than at a CCP in its HACCP plan. One tool that can be used to assist each facility in the identification of CCPs unique to its operation is a CCP decision tree.

Annex 4 – CCP Decision Tree 1



* Decision tree adapted from NACMCF

(C) Principle #3: Establish Critical Limits

(1) What is a critical limit and what is its purpose?

A critical limit is a prescribed parameter (e.g., minimum and/or maximum value) that must be met to ensure that food safety hazards are controlled at each CCP. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. Each control measure at a CCP has one or more associated critical limits. Critical limits may be based upon factors like temperature, time, moisture level, water activity (a_w), or pH. They must be scientifically-based and measurable.

(2) What are examples of critical limits?

Examples of critical limits are the time/temperature parameters for cooking chicken (165 ^{o}F for 15 seconds). In this case, the critical limit designates the *minimum* criteria required to eliminate food safety hazards or reduce them to an acceptable level. The critical limit for the acidification of sushi rice, a pH of $\leq$4.6, sets the *maximum* limit for pH necessary to control the growth of spore- and toxin-forming bacteria. Critical limits may be derived from regulatory standards such as the FDA *Food Code*, other applicable guidelines, performance standards, or experimental results.

(D) Principle #4: Establish Monitoring Procedures

(1) What is the purpose of monitoring?

Monitoring is the act of observing and making measurements to help determine if critical limits are being met and maintained. It is used to determine whether the critical limits that have been established for each CCP are being met.

(2) What are examples of monitoring activities?

Examples of monitoring activities include visual observations and measurements of time, temperature, pH, and water activity. If cooking chicken is determined to be a CCP in an operation, then monitoring the internal temperature of a select number of chicken pieces immediately following the cook step would be an example of a monitoring activity. Alternatively, the temperature of an oven or fryer and the time required to reach an internal temperature of 165 ^{o}F could also be monitored.

(3) How is monitoring conducted?

Typically, monitoring activities fall under two broad categories:

- measurements
- observations

Measurements usually involve time and temperature but also include other parameters such as pH. If an operation identifies the acidification of sushi rice as a CCP and the critical limit as the final pH of the product being ≤ 4.6, then the pH of the product would be measured to ensure that the critical limit is met.

Observations involve visual inspections to monitor the presence or absence of a food safety activity. If date marking is identified as a CCP in a deli operation for controlling *Listeria monocytogenes* in ready-to-eat deli meats, then the monitoring activity could involve making visual inspections of the date marking system to monitor the sell, consume, or discard dates.

(4) How often is monitoring conducted?

Monitoring can be performed on a continuous or intermittent basis. Continuous monitoring is always preferred when feasible as it provides the most complete information regarding the history of a product at a CCP. For example, the temperature and time for an institutional cook-chill operation can be recorded continuously on temperature recording charts.

If intermittent monitoring is used, the frequency of monitoring should be conducted often enough to make sure that the critical limits are being met.

(5) Who conducts monitoring?

Individuals directly associated with the operation (e.g., the person in charge of the establishment, chefs, and departmental supervisors) are often selected to monitor CCPs. They are usually in the best position to detect deviations and take corrective actions when necessary. These employees should be properly trained in the specific monitoring techniques and procedures used.

(E) Principle #5: Establish Corrective Actions

(1) What are corrective actions?

Corrective actions are activities that are taken by a person whenever a critical limit is not met. Discarding food that may pose an unacceptable food safety risk to consumers is a corrective action. However, other corrective actions such as further cooking or reheating a product can be used provided food safety is not compromised. For example, a restaurant may be able to continue cooking hamburgers that have not reached an internal temperature of 155 ^{o}F for 15 seconds until the proper temperature is met. Clear instructions should be developed detailing who is responsible for performing the corrective actions, the procedures to be followed, and when.

(F) Principle #6: Establish Verification Procedures

(1) What is verification?

Verification includes those activities, other than monitoring, that determine the validity of the HACCP plan and show that the system is operating according to the plan. Validation is a component of verification which focuses on collecting and evaluating scientific and technical information to determine if the HACCP system, when properly implemented, will effectively control the hazards. Clear instructions should be developed detailing who is responsible for conducting verification, the frequency of verification, and the procedures used.

(2) What is the frequency of verification activities? What are some examples of verification activities?

Verification activities are conducted frequently, such as daily, weekly, monthly, and include the following:

- observing the person doing the monitoring and determining whether monitoring is being done as planned
- reviewing the monitoring records to determine if they are completed accurately and consistently
- determining whether the records show that the frequency of monitoring stated in the plan is being followed
- ensuring that corrective action was taken when the person monitoring found and recorded that the critical limit was not met
- validating that the critical limits are achieving the desired results of controlling the identified hazard
- confirming that all equipment, including equipment used for monitoring, is operated, maintained, and calibrated properly.

(G) Principle #7: Establish Record Keeping Procedures

(1) Why are records important?

Maintaining documentation of the activities in a food safety management system can be vital to its success. Records provide documentation that appropriate corrective actions were taken when critical limits were not met. In the event that an establishment is implicated in a foodborne illness, documentation of activities related to monitoring and corrective actions can provide proof that reasonable care was exercised in the operation of the establishment. Documenting activities provides a mechanism for verifying that the activities in the HACCP plan were properly completed. In many cases, records can serve a dual purpose of ensuring quality and food safety.

(2) What types of records are maintained as part of a food safety management system?

There are at least 5 types of records that could be maintained to support a food safety management system:

- records documenting the activities related to the prerequisite programs
- monitoring records
- corrective action records
- verification and validation records
- calibration records.

4. THE PROCESS APPROACH – A PRACTICAL APPLICATION OF HACCP AT RETAIL TO ACHIEVE ACTIVE MANAGERIAL CONTROL

(A) Why Focus on HACCP Principles at Retail and Food Service?

FDA recognizes that there are important differences between using HACCP principles in a food safety management system developed for food manufacturing plants and applying these same principles in food safety management system developed for use in retail and food service establishments.

Since the 1980's, operators and regulators have been exploring the use of the HACCP principles in restaurants, grocery stores, institutional care facilities, and other retail food establishments. During this time, much has been learned about how these principles can be used in these varied operations, collectively referred to as retail food establishments. Most of this exploration has centered around the focal question of how to stay true to the NACMCF definitions of HACCP and still make the principles useful to an industry that encompasses the broadest range of conditions.

Unlike industries such as canning, other food processing, and dairy plants, the retail industry is not easily defined by specific commodities or conditions. Consider the following characteristics that retail food establishments share that set them apart from most food processors:

1. Employee and management turnover is exceptionally high in food establishments, especially for entry level positions. This means the many employees or managers have little experience and food safety training must be continuously provided.
2. Many establishments are start-up businesses operating without benefit of a large corporate support structure and having a relatively low profit margin and perhaps less capital to work with than other segments of the food industry.
3. There is an almost endless number of production techniques, products, menu items, and ingredients used which are not easily adapted to a simple, standardized approach. Changes occur frequently and little preparation time is available.

FDA fully recognizes the diversity of retail and food service establishments and their varying in-house resources to implement HACCP. That recognition is combined with an understanding that the success of such implementation is dependent upon establishing realistic and useful food safety strategies that are customized to the operation.

(B) What is the Process Approach?

When conducting the hazard analysis, food manufacturers usually use food commodities as an organizational tool and follow the flow of each product. This is a very useful approach for producers or processors since they are usually handling one product at a time. By contrast, in retail and food service operations, foods of all types are worked together to produce the final product. This makes a different approach to the hazard analysis necessary. Conducting the hazard analysis by using the food preparation processes common to a specific operation is often more efficient and useful for retail and food service operators. This is called the "process approach" to HACCP.

The process approach can best be described as dividing the many food flows in an establishment into broad categories based on activities or stages in the preparation of the food, then analyzing the hazards, and placing managerial controls on each grouping.

(C) What are the three food preparation processes most often used in retail and food service establishments and how are they determined?

The flow of food in a retail or food service establishment is the path that food follows from receiving through service or sale to the consumer. Several activities or stages make up the flow of food and are called operational steps.
Examples of operational steps include receiving, storing, preparing, cooking, cooling, reheating, holding, assembling, packaging, serving, and selling. The terminology used for operational steps may differ between food service and retail food store operations.

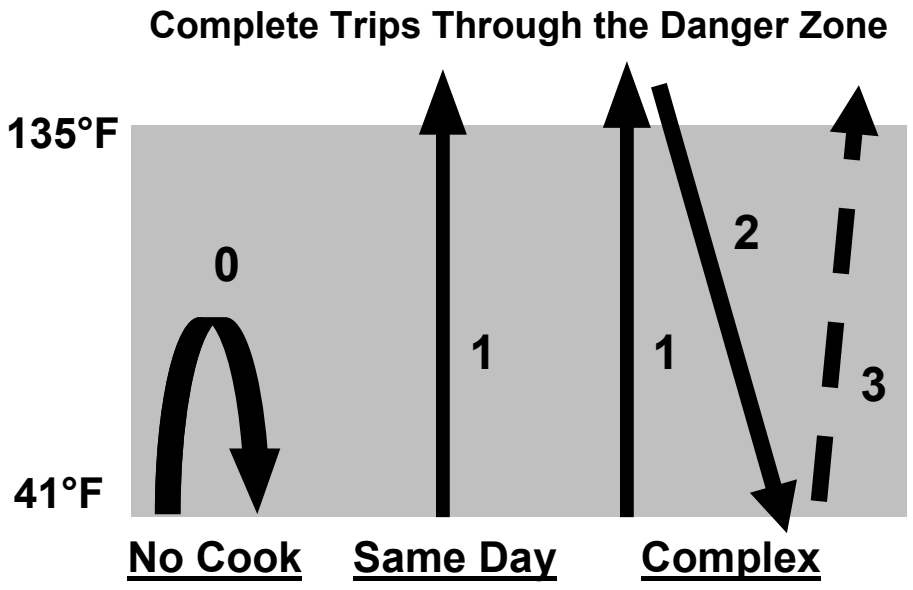
Most food items produced in a retail or food service establishment can be categorized into one of three preparation processes based on the number of times the food passes through the temperature danger zone between 41°F and 135°F:

- **Process 1: Food Preparation with No Cook Step**
  Example flow: Receive – Store – Prepare – Hold – Serve
  (other food flows are included in this process, but there is no cook step to destroy pathogens)

- **Process 2: Preparation for Same Day Service**
  Example flow: Receive – Store – Prepare – Cook – Hold – Serve
  (other food flows are included in this process, but there is only one trip through the temperature danger zone)

- **Process 3: Complex Food Preparation**
  Example flow: Receive – Store – Prepare – Cook – Cool – Reheat – Hot Hold – Serve
  (other food flows are included in this process, but there are always two or more complete trips through the temperature danger zone)

A summary of the three food preparation processes in terms of number of times through the temperature danger zone can be depicted in a Danger Zone diagram. Although foods produced using process 1 may *enter* the danger zone, they do not pass all the way through it. Foods that go through the danger zone only once are classified as Same Day Service, while foods that go through more than once are classified as Complex food preparation.



The three food preparation processes conducted in retail and food service establishments are not intended to be all-inclusive. For instance, quick service facilities may have "cook and serve" processes specific to their operation. These processes are likely to be different from the "Same Day Service" preparation processes in full service restaurants since many of their foods are generally cooked and hot held before service. In addition, in retail food stores, operational steps such as packaging and assembly may be included in all of the food preparation processes before the product is sold to the consumer. It is also very common for a retail or food service operator to use multiple food preparation processes to create a single menu item.

(D) How is a hazard analysis conducted in process HACCP?

In the process approach to HACCP, conducting a hazard analysis on individual food items is time and labor intensive and is generally unnecessary. Identifying and controlling the hazards in each food preparation process achieves the same control of risk factors as preparing a HACCP plan for each individual product.

Example: An establishment has dozens of food items (including baked chicken and baked meatloaf) in the "Preparation for Same Day Service" category. Each of the food items may have unique hazards, but regardless of the individual hazards, control via proper cooking and holding will generally ensure the safety of <u>all</u> of the foods in this category. An illustration of this concept follows:

- Even though they have unique hazards, baked chicken and meatloaf are items frequently grouped in the “Same Day Service” category (Process 2).

- *Salmonella* spp. and *Campylobacter,* as well as spore-formers, such as *Bacillus cereus* and *Clostridium perfringens*, are significant biological hazards in chicken.

- Significant biological hazards in meatloaf include *Salmonella* spp., *E. coli* O157:H7, *Bacillus cereus,* and *Clostridium perfringens.*

- Despite their different hazards, the control measure used to kill pathogens in both these products is cooking to the proper temperature.

- Additionally, if the products are held after cooking, then proper hot holding or time control is also required to prevent the outgrowth of spore-formers that are not destroyed by cooking.

As with product-specific HACCP, critical limits for cooking remain specific to each food item in the process. In the scenario described above, the cooking step for chicken requires a final internal temperature of 165°F for 15 seconds to control the pathogen load for *Salmonella* spp. Meatloaf, on the other hand, is a ground beef product and requires a final internal temperature of 155°F for 15 seconds to control the pathogen load for both *Salmonella* spp. and *E. coli* O157:H7. Some operational steps such as refrigerated storage or hot holding have critical limits that apply to all foods.

Annex 4, Table 4 further illustrates this concept. Note that the only unique control measure applies to the critical limit of the cooking step for each of the products. Other food safety hazards and control measures may exist that are not depicted here:

Annex 4, Table 4: Examples of Hazards and Control Measures for Same Day Service Items

Baked Meatloaf (Process 2: Preparation for Same Day Service)

Example Biological Hazards	Example Control Measures
Salmonella spp.	Refrigeration at 41°F or below
E. coli O157:H7	Cooking at 155°F for 15 seconds
Clostridium perfringens	Hot Holding at 135°F or above OR Time Control
Bacillus cereus	Hot Holding at 135°F or above OR Time Control
Various fecal-oral route pathogens	Good personal hygiene (No bare hand contact with ready-to-eat food, proper handwashing, exclusion/restriction of ill employees)

Baked Chicken (Process 2: Preparation for Same Day Service)

Example Biological Hazards	Example Control Measures
Salmonella spp.	Refrigeration at 41°F or below
Campylobacter	Cooking at 165°F for 15 seconds
Clostridium perfringens	Hot Holding at 135°F or above OR Time Control
Bacillus cereus	Hot Holding at 135°F or above OR Time Control
Various fecal-oral route pathogens	Good personal hygiene (No bare hand contact with ready-to-eat food, proper handwashing, exclusion/restriction of ill employees)

(E) How is the process approach helpful to industry in determining the measures that must be implemented to actively manage the foodborne illness risk factors that result in out-of-control hazards?

Even though variations in foods and in the three food preparation process flows used to prepare them are common, the control measures will generally be the same based on the number of times the food goes through the temperature danger zone. Several of the most common control measures associated with each food preparation process are discussed in this Annex. Retail or food service establishments should use these simple control measures as the core of their food safety management systems; however, there may be other risk factors unique to an operation or process that are not listed here. Each operation should be evaluated independently.

In developing a voluntary food safety management system, active managerial control of risk factors common to each process can be achieved by implementing control measures at certain operational steps designated as critical control points (CCPs) or by implementing prerequisite programs. This is explained in more detail in the Operator's Manual discussed in Part 5 of this Annex.

(F) Facility-wide Considerations

In order to have active managerial control over personal hygiene and cross-contamination, certain control measures must be implemented in all phases of the operation. All of the following control measures should be implemented regardless of the food preparation process used:

- **No bare hand contact with ready-to-eat foods (or use of a pre-approved, alternative procedure)** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Proper handwashing** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Restriction or exclusion of ill employees** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Prevention of cross-contamination** of ready-to-eat food or clean and sanitized food-contact surfaces with soiled cutting boards, utensils, aprons, etc., or raw animal foods.

(G) Food Preparation Process 1 – Food Preparation with No Cook Step

Example Flow: RECEIVE → STORE → PREPARE → HOLD → SERVE

Several food flows are represented by this particular process. Many of these food flows are common to both retail food stores and food service facilities, while others only apply to retail operations. Raw, ready-to-eat food like sashimi, raw oysters, and salads are grouped in this category. Components of these foods are received raw and will not be cooked before consumption.

Foods cooked at the processing level but that undergo no further cooking at the retail level before being consumed are also represented in this category. Examples of these kinds of foods are deli meats, cheeses, and other pasteurized dairy products (such as yogurt). In addition, foods that are received and sold raw but are to be cooked by the consumer after purchase, e.g., hamburger meat, chicken, and steaks, are also included in this category.

All the foods in this category lack a cook step *while at the retail or food service facility*; thus, there are no complete trips through the danger zone. Purchase specifications can be required by the retail or food service establishment to ensure that foods are received as safe as possible. Without a kill step to destroy pathogens, preventing further contamination by ensuring that employees follow good hygienic practices is an important control measure.

Cross-contamination must be prevented by properly storing ready-to-eat food away from raw animal foods and soiled equipment and utensils. Foodborne illness may result from ready-to-eat food being held at unsafe temperatures for long periods of time due to the outgrowth of bacteria.

In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring active managerial control over the following:

- **Cold holding or using time alone** to control bacterial growth and toxin production
- **Food source** (e.g., shellfish due to concerns with viruses, natural toxins, and *Vibrio* and for certain marine finfish intended for raw consumption due to concerns with ciguatera toxin)
- **Receiving temperatures** (e.g., certain species of marine finfish due to concerns with scombrotoxin)
- **Date marking** of ready-to-eat TCS food held for more than 24 hours to control the growth of psychrophiles such as *Listeria monocytogenes*
- **Freezing** certain species of fish intended for raw consumption due to parasite concerns

- **Cooling** from ambient temperature to prevent the outgrowth of spore-forming or toxin-forming bacteria.

(H) Food Preparation Process 2 – Preparation for Same Day Service

Example Flow: RECEIVE → STORE → PREPARE → COOK → HOLD → SERVE

In this food preparation process, food passes through the danger zone only once in the retail or food service facility before it is served or sold to the consumer. Food is usually cooked and held hot until served, e.g., fried chicken, but can also be cooked and served immediately. In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring active managerial control over the following:

- **Cooking** to destroy bacteria and parasites

- **Hot holding or using time alone** to prevent the outgrowth of spore-forming bacteria.

Approved food source, proper receiving temperatures, and proper cold holding before cooking would also be important if dealing with certain marine finfish due to concerns with ciguatera toxin and scombrotoxin.

(I) Food Preparation Process 3 – Complex Food Preparation

Example Flow: RECEIVE → STORE → PREPARE → COOK → COOL → REHEAT → HOT HOLD → SERVE

Foods prepared in large volumes or in advance for next day service usually follow an extended process flow. These foods pass through the temperature danger zone more than one time; thus, the potential for the growth of spore-forming or toxigenic bacteria is greater in this process. Failure to adequately control food product temperatures is one of the most frequently encountered risk factors contributing to foodborne illness. Food handlers should minimize the time foods are at unsafe temperatures.

In addition to the facility-wide considerations, a food safety management system involving this food preparation process should focus on ensuring active managerial control over the following:

- **Cooking** to destroy bacteria and parasites
- **Cooling** to prevent the outgrowth of spore-forming or toxin-forming bacteria
- **Hot and cold holding or using time alone** to control bacterial growth and toxin formation

- **Date marking** of ready-to-eat TCS food held for more than 24 hours to control the growth of psychrophiles such as *Listeria monocytogenes*
- **Reheating** for hot holding, if applicable.

Approved food source, proper receiving temperatures, and proper cold holding before cooking would also be important if dealing with certain marine finfish due to concerns with ciguatera toxin and scombrotoxin.

5. FDA RETAIL HACCP MANUALS

(A) What guidance has been developed by FDA to assist operators of retail and food service establishments in achieving active managerial control of foodborne illness risk factors?

FDA, in partnership with Federal, State, and local regulators, industry, academia, and consumers, has written a guidance document entitled, *"Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments."* Commonly referred to as the "Operator's Manual," this document is designed to assist operators with developing or enhancing food safety management systems based on the process approach to HACCP. The manual presents a step-by-step procedure for writing and voluntarily implementing a food safety management system based on the principles of HACCP. The desired outcome is an operator who employs a preventive rather than a reactive strategy to food safety.

The Operator's Manual embodies FDA's current thinking on the application of HACCP principles at retail. It advocates the voluntary use of HACCP principles using the process approach as a practical and effective means of reducing the occurrence of foodborne illness risk factors leading to out-of-control hazards. The Operator's Manual is strictly for the voluntary implementation of HACCP principles at retail and should not be used to develop HACCP plans that are required through Federal, State, or local regulations, ordinances, or laws. The document can be found on the FDA Web Page at http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006811.htm.

(B) What guidance has been developed by FDA to assist regulators of retail and food service establishments in assessing industry's active managerial control of foodborne illness risk factors?

FDA has written a document for regulators of retail and food service establishments entitled, *"Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems."* Commonly referred to as the "Regulator's Manual," this document was written to provide a risk-based inspectional "roadmap" for evaluating the

degree of active managerial control an operator has over foodborne illness risk factors.

In addition, the manual advocates the use of voluntary intervention strategies, including the development of food safety management systems or risk control plans to bring about a long-term behavior change that will result in a reduction in the occurrence of risk factors. In cases where an operator may want their inspector to provide them with feedback on their voluntarily-implemented food safety management system, the manual provides regulators with information on how to validate and verify an existing system.

The document can be found on the FDA Web Page at:
http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006812.htm.

Annex 5 of the Food Code outlines the basis for conducting successful risk-based inspections and is provided to assist industry in achieving active managerial control of foodborne illness risk factors as outlined in the draft *Recommended National Retail Food Regulatory Program Standards* and the *Regulator's Manual*.

6. ADVANTAGES OF USING THE PRINCIPLES OF HACCP

(A) What advantages does using HACCP principles offer operators of retail and food service establishments?

Rather than relying solely on periodic feedback from inspections by regulatory agencies, an establishment operator who implements a food safety management system based on HACCP principles emphasizes continuous problem solving and prevention. Additionally, HACCP enhances and encourages communication between industry and regulators.

A food safety management system based on HACCP principles offers many other advantages to industry. One advantage is that such a system may provide a method for achieving active managerial control of multiple risk factors associated with an entire operation. Other advantages include:

- Reduction in product loss
- Increase in product quality
- Better inventory control
- Consistency in product preparation
- Increase in profit
- Increased employee awareness and participation in food safety.

(B) What advantages does using HACCP principles offer regulators of retail and food service establishments?

Traditional inspections are relatively resource-intensive, inefficient, and reactive rather than preventive in nature. Using traditional inspection techniques allows for a satisfactory "snapshot" assessment of the requirements of the code at the time of the inspection. Unfortunately, unless an inspector asks questions and inquires about the activities and procedures being utilized by the establishment even at times when the inspector is not there, there is no way to know if an operator is achieving *active* managerial control.

With the limited time often available for conducting inspections, regulators must focus their attention on those areas that clearly have the greatest impact on food safety – foodborne illness risk factors. By knowing that there are only a few control measures that are essential to food safety and focusing on these during the inspection, an inspector can assess the operator's active managerial control of the foodborne illness risk factors.

Regulators can provide invaluable feedback to an operator through their routine inspections. This is especially useful when utilizing a risk-based approach. By incorporating HACCP principles into routine inspections, an inspector can provide an operator with the constructive input needed to establish the control system necessary to bring the foodborne illness risk factors back under continuous control.

7. SUMMARY

In order to make a positive impact on foodborne illness, retail and food service operators must achieve active managerial control of the risk factors contributing to foodborne illness. Combined with basic sanitation, employee training, and other prerequisite programs, the principles of HACCP provide an effective system for achieving this objective.

The goal in applying HACCP principles in retail and food service is to have the operator take purposeful actions to ensure safe food. The process approach simplifies HACCP principles for use in retail and food service. This practical and effective method of hazard control embodies the concept of active managerial control by providing an on-going system of simple control measures that will reduce the occurrence of risk factors that lead to out-of-control hazards.

The role of retail and food service regulatory professionals is to conduct risk-based inspections using HACCP principles to assess the degree of control industry has over the foodborne illness risk factors. Regulators can assist industry in achieving active managerial control of risk factors by using a risk-based inspection approach to identify strengths and weaknesses and suggesting possible solutions and improvements.

8. ACKNOWLEDGMENTS

Much of this Annex is adapted from the National Advisory Committee on Microbiological Criteria for Foods, Hazard Analysis and Critical Control Point Principles and Guidelines, adopted August 14, 1997.

The physical hazards table (Table 3) was provided courtesy of "Overview of Biological, Chemical, and Physical Hazards" in "HACCP Principles and Applications," Merle Pierson and Donald A. Corlett, Jr. (Eds.), 1992. p. 8-28. Chapman and Hall, New York.

Based on a recommendation from the Retail HACCP Committee of the Conference for Food Protection, the two HACCP Manuals have been endorsed by the Conference.

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National Technical Information Service
U.S. Department of Commerce
703-487-4650.

The **Fish and Fishery Products Hazards and Controls Guide,** Third Edition, June 2001 is available electronically at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm252338.htm

The **Fish and Fishery Products Hazards and Controls Guidance,** Fourth Edition, April 2011 is available electronically at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm . Single copies may be obtained as long as supplies last from FDA district offices and from:

U.S. Food and Drug Administration
Office of Seafood
5100 Paint Branch Parkway
College Park, MD 20740-3835

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Annex

5 Conducting Risk-Based Inspections

1. PURPOSE AND SCOPE

This Annex provides regulatory program managers and front-line inspection staff with guidance on planning, scheduling, conducting, and evaluating risk-based inspections. The *FDA's Voluntary National Retail Food Regulatory Program Standards* (Program Standards) (http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm) provide additional recommendations to assist regulatory program managers in the planning and development of a risk-based inspection program.

The primary focus of this Annex is to provide inspectors with methods for conducting risk-based inspections. Various strategies that can be used by regulatory professionals to assist operators in achieving active managerial control of foodborne illness risk factors are also included in this Annex.

As presented in Annex 4, the Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993-1997, "Surveillance for Foodborne Disease Outbreaks – United States" (http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4901a1.htm) identifies the most frequently reported contributing factors to foodborne illness. Five of these broad categories of contributing factors directly relate to food safety concerns within retail and food service establishments and are collectively termed by the FDA as "foodborne illness risk factors."

These five broad categories are:

- Food from Unsafe Sources
- Inadequate Cooking
- Improper Holding Temperatures
- Contaminated Equipment
- Poor Personal Hygiene.

The FDA manual, *Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems* (FDA's Regulator's Manual) (http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006812.htm), provides additional information on conducting risk-based inspections. Annex 4 of the Food Code provides additional information on Hazard Analysis and Critical Control Point (HACCP) principles and the process approach to HACCP. It should be reviewed in conjunction with the material found in this Annex to better prepare for performing risk-based inspections.

The "Retail Food Program Resource Guide," a CD-ROM containing pertinent FDA documents referenced in this Annex, is available for use by federal, state, local, and tribal regulatory agencies. It is produced by and available through FDA Regional Retail Food Specialists or the FDA Division of Federal-State Relations (HFC-150); U.S. Food and Drug Administration; 5600 Fishers Lane, Room 12-07; Rockville, Maryland *20857;* PHONE (301) 827-6906; (FAX) (301) 443-2143.

2. RISK-BASED ROUTINE INSPECTIONS

Inspections have been a part of food safety regulatory activities since the earliest days of public health. The term "routine inspection" has been used to describe periodic inspections conducted as part of an on-going regulatory scheme.

Program managers should strive to have adequate staffing and resources to allow all inspectors ample time to thoroughly evaluate establishments and ask as many questions as needed to fully understand establishments' operations. For most jurisdictions, however, inspectors continue to have limited time in which to complete inspections. This does not negate the need to thoroughly identify and assess the control of foodborne illness risk factors during each inspection.

It is a false assumption that inspectors cannot conduct risk-based inspections in a limited timeframe. Even with limited time, inspectors can focus their inspections on assessing the degree of active managerial control an operator has over the foodborne illness risk factors. By focusing inspections on the control of foodborne illness risk factors, inspectors can be assured that they are making a great impact on reducing foodborne illness.

As described in Annex 4, active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their businesses to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

Developing and implementing food safety management systems to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors is recommended to achieve active managerial control. Regulatory inspections and follow-up activities must be proactive by using an inspection process designed to evaluate the implementation of Food Code interventions and the degree of active managerial control that retail and foodservice operators have over foodborne illness risk factors. The five Food Code interventions below were new interventions introduced with the 1993 Food Code and they are just as important today as they were in 1993. They encompass a wide-range of control measures specifically designed to protect consumer health:

- Demonstration of Knowledge
- Implementation of Employee Health Policies
- Hands as a Vehicle of Contamination
- Time/Temperature Relationships
- Consumer Advisory.

When Food Code interventions are not being implemented or if behaviors, activities, or procedures likely to cause foodborne illness are observed, inspectors should verify that the operator takes immediate corrective action so that consumers do not become sick or injured. Observations made on the day of the inspection, as well as information gained about the behaviors, activities, and procedures that occur at other times, allow inspectors to assess the strengths and weaknesses of the food safety management system that is in place.

An operator should be made aware of the inspectional findings both during, and at the conclusion of, the inspection and strategies for achieving compliance in the future should be discussed. Corrective actions taken during the inspection and repeat violations should be noted on the inspection report. Repeat violations should trigger further compliance and enforcement actions.

The inspection process is also an opportunity to educate the operator on the public health reasons supporting the Code requirements. If operators are afforded the chance to ask questions about general food safety matters, they may clearly understand the public health significance of non-compliance.

Lastly, if the operator demonstrates a history of violations related to foodborne illness risk factors, the inspection process can be used to assist the operator with implementing long-term control systems to prevent those risk factors from occurring in the future.

3. WHAT IS NEEDED TO PROPERLY CONDUCT A RISK-BASED INSPECTION?

A. Schedule Inspections Based on Risk

Studies have shown that the types of food served, the food preparation processes used, the volume of food, and the population served all have a bearing on the occurrence of foodborne illness risk factors in retail and foodservice establishments. Standard 3 of the Program Standards requires that regulatory jurisdictions develop and use a process that groups food establishments into at least three categories based on potential and inherent food safety risks. In addition, Standard 3 requires that regulatory jurisdictions assign inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk. With limited resources, creating a variable inspection frequency for each category will allow inspection staff to effectively spend more time in high risk establishments that pose the greatest potential risk of causing foodborne illness.

Table 1 of this Annex provides an example of risk categories and assignment of inspection frequency based on risk. In this example, the type of food served, food preparation processes conducted, and history of compliance related to foodborne illness risk factors are used as the basis of categorizing risk. Each jurisdiction is encouraged to develop risk categories tailored to their specific program needs and resources and to reassess the risk categories on an annual basis.

Regardless of the risk category initially assigned to food establishments, regulatory jurisdictions sometimes consider whether the establishment has implemented a voluntary food safety management system like HACCP, to justify a decrease in inspection frequency. Likewise, the following factors are among many that regulatory jurisdictions sometimes use to justify an increase in inspection frequency:

- History of non-compliance with provisions related to foodborne illness risk factors or critical items
- Specialized processes conducted
- Food preparation a day in advance of service
- Large number of people served
- History of foodborne illness and/or complaints
- Highly susceptible population served.

Annex 5, Table 1. Risk Categorization of Food Establishments

RISK CATEGORY	DESCRIPTION	FREQUENCY #/YR
1	Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only pre-packaged, non- time/temperature control for safety (TCS) foods. Establishments that prepare only non-TCS foods. Establishments that heat only commercially processed, TCS foods for hot holding. No cooling of TCS foods. Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors.	1
2	Examples may include retail food store operations, schools not serving a highly susceptible population, and quick service operations. Limited menu. Most products are prepared/cooked and served immediately. May involve hot and cold holding of TCS foods after preparation or cooking. Complex preparation of TCS foods requiring cooking, cooling, and reheating for hot holding is limited to only a few TCS foods. Establishments that would otherwise be grouped in Category 3 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of active managerial control of foodborne illness risk factors is achieved and documented.	2
3	An example is a full service restaurant. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods. Variety of processes require hot and cold holding of TCS food. Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of active managerial control of foodborne illness risk factors is achieved and documented.	3
4	Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments serving a highly susceptible population or that conduct specialized processes, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.	4

B. Have the Proper Equipment

In order to conduct risk-based inspections, each inspector must be provided with the proper equipment to assess the control of foodborne illness risk factors within food establishments. See Program Standard 8 at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm for recommendations of equipment needed by inspectors. At a minimum, each inspector should be provided with the following essential equipment:

- Thermocouple with the appropriate probes for the food being tested
- Alcohol swabs or other suitable equipment for sanitizing probe thermometers
- Chemical test kits for different chemical sanitizer types
- Heat-sensitive tape or maximum registering thermometer
- Flashlight
- Head cover, such as baseball cap, hair net, or equivalent.

Other equipment may be provided to inspectors on an "as needed" basis. While it is desirable for each inspector to have the following equipment, depending on the resources available to the agency, this equipment may be shared in a central office as appropriate:

- Pressure gauge for determining in-line pressure of hot water at injection point of warewashing machine (5-30 psi)
- Light meter
- Measuring device for measuring distances
- Time/temperature data logger
- pH meter
- Water activity meter
- Camera
- Computers with or without an electronic inspection system
- Black light
- Foodborne illness investigation kits
- Sample collection kits
- Cell phones.

C. Provide Adequate Training

Standard 2 of the Program Standards explains that regulatory staff shall have the knowledge, skills, and ability to adequately perform their required duties. Inspectors need the proper training before they can be expected to conduct risk-based inspections. Training includes a combination of classroom training, in-field training, standardization, and continuing education. For specific training recommendations refer to Program Standard 2 at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm and its accompanying Appendix B at the aforementioned website.

(1) Classroom Training

The first phase of staff training should provide an orientation to the program with a review of program history, structure, and relationships to other food-related programs. Specific emphasis should be on the program's goals and objectives. The basic training curriculum should include the following components:

- Prevailing statutes, regulations, or ordinances
- Public health principles
- Communication skills
- Epidemiology
- Microbiology
- HACCP.

FDA's ORA-U (http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm121831.htm) provides basic curriculum components free of charge to regulators via the internet. This allows state, local, and tribal health departments to conserve their time and funding resources instead of developing their own training courses. It also allows inspectors to access training as needed. Distance learning allows government agencies and industries to cost-effectively disseminate the most current technical and regulatory information on an as-needed basis.

(2) Field Training and Experience

The second phase of training should move the new inspector into the field with a training officer. On-site training should focus on specific inspection tasks such as interviewing, making observations, measuring conditions such as temperatures and sanitizer strength, assessing the control operators have over the foodborne illness risk factors, ensuring implementation of Food Code interventions, and completing the inspection form. If an electronic database is used by the agency, training in its use should be included in this phase.

The evaluation of food safety management systems based on HACCP principles should be part of the field training experience. The trainee and the trainer should review establishment menus, operations, recipes, and standard operating procedures. Inspectors should be able to demonstrate proficiency in gathering information about the food preparation processes, including accurate charting of the food flows and determination of the Critical Control Points (CCPs) and critical limits in an operation. This part of the training should also include a familiarization with the compliance and enforcement protocol in place in the jurisdiction including recommendation of voluntary strategies to prevent risk factor occurrence.

(3) Standardization

The third part of staff training should include standardization. This process improves uniformity in the application and interpretation of applicable regulations, inspection methodology, and report writing. The Program Standards recommend that staff conducting inspections undergo a standardization process similar to the one described in the *FDA Procedures for Standardization and Certification of Retail Food Inspection/ Training Officers* (http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/InspectionsQualityAssurance/ucm2006814.htm). Standardization should be completed after the trainee completes classroom and field training.

(4) Continuing Education

The training process for inspection staff should be continuous. The final phase of training should include a mechanism to ensure that learning is ongoing and staff is kept abreast of food safety issues and the latest science.

D. Ensure Adequate Program Resources

As indicated in Standard 8 of the Program Standards, regulatory agencies should have adequate funding, staff, and equipment necessary to support a risk-based retail food safety program designed to reduce the occurrence of foodborne illness risk factors. Program management should do everything they can to secure funding and resources to support regulatory food programs.

Standard 8 of the Program Standards also states that the program budget should provide the necessary resources to develop and maintain a retail food safety program that has a staffing level of one full-time equivalent (FTE) devoted to food for every 280 - 320 inspections performed. Inspections, for purposes of this calculation, include routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews, and other direct establishment contact time such as on-site training.

4. RISK-BASED INSPECTION METHODOLOGY

A. Focus the Inspection

Conducting a risk-based inspection requires inspectors to focus their efforts on evaluating the degree of active managerial control that operators have over foodborne illness risk factors. In addition, it is essential that the implementation of Food Code interventions also be verified during each inspection. Inspectors need to spend the majority of their time observing the behaviors, practices, and procedures that are likely to lead to out-of-control foodborne illness risk factors and asking management and food employees questions to supplement actual observations.

Retail and food service operators implement “control measures” to ensure food safety. Control measures are actions or activities that are used to prevent, eliminate, or reduce food safety hazards. Inspectors need to determine the control measures that should be implemented to prevent the occurrence of foodborne illness risk factors in each food preparation process. In order to determine the foodborne illness risk factors common to each operation, it is important for inspectors to understand that the food preparation processes and all the associated control measures initiated by a retail or food service operator represent a food safety management system. It will be necessary for inspectors to ask questions in order to gain information about the system already in place. Once the degree of active managerial control is determined, inspectors will be able to assist operators with strengthening their existing food safety management systems.

B. Lead by Example

Nonverbal communication is just as important as verbal communication in relaying important food safety principles to retail and food service operators. By setting the example during inspections, inspectors not only demonstrate competency, but they also relay important food safety information to the person in charge and food employees. The following are ways that inspectors set the example during inspections:

- Washing their hands when entering the food preparation area at the beginning of the inspection and after engaging in any activities that might contaminate their hands
- Not working when they are suffering from symptoms such as diarrhea, fever, vomiting, or jaundice or if they are diagnosed with a disease transmittable by food
- Being careful not to touch ready-to-eat (RTE) food with their bare hands
- Washing and sanitizing their thermocouple probe at the start of the inspection and between foods
- Using a proper hair restraint and practicing good personal hygiene
- Being careful not to contaminate clean and sanitized food contact-surfaces with unclean hands or their inspection equipment.

C. Conduct Inspections at Variable Times

Inspectors should enter the food establishment during hours of operation or at other reasonable times. Inspectors should show identification and provide the permit holder or person in charge with a verbal or written notice of the purpose of the inspection. Procedures outlined in the Food Code and in the jurisdiction’s procedures should be followed if access to conduct an inspection is denied. Refusal should be documented on the inspection report and an administrative or judicial inspection order obtained.

In planning for inspections, inspectors should consider the importance of timing. Several operational steps at retail such as receiving, preparation, and cooling can be evaluated only during limited time periods. In order to properly evaluate critical

processes that occur outside of the normal 8 a.m. to 5 p.m. working hours, an inspector should be allowed the flexibility to conduct inspections early in the morning, late in the evening, and even on weekends.

D. Establish Inspection Priorities and Use Inspection Time Wisely

With the limited time allotted for inspections, inspectors must develop clear priorities to make the most efficient use of their time in each food establishment. Although basic sanitation issues generally do not change during the course of an inspection, critical behaviors, practices, and procedures leading to foodborne illness risk factors may be only observable during limited time periods of the preparation or cooling process. For this reason, assessment of the active managerial control of foodborne illness risk factors should generally be performed before reviewing basic sanitation issues.

To effectively set priorities, the following four activities should be completed early in the inspection:

(1) Establish an open dialogue with the person in charge
(2) Review previous inspection records
(3) Conduct a menu or food list review
(4) Conduct a quick walk-though.

(1) Establish an Open Dialogue with the Person in Charge

The tone of the inspection is often set during the first few minutes of the inspection. A professional but personable approach is the balance which should be maintained. Genuine interest in the food establishment and the staff translates into good relations which may be helpful in conveying the goal of promoting public health. Having an open dialogue with the person in charge during all phases of the inspection gives inspectors an opportunity to learn important information about the existing food safety management system.

It is important to know both the strengths and weaknesses of the existing food safety management system early in the inspection in order to focus the inspection on weak areas. Questions about practices and procedures related to foodborne illness risk factors and Food Code interventions such as the establishment's employee health policy and consumer advisory notice should be asked during all phases of the inspection. It is important to ask enough questions to fully understand the system being utilized in the food establishment. This is especially true when evaluating whether the employees are adhering to the established no bare hand contact and handwashing policies. Asking the person in charge questions about important activities such as receiving, cooling, and preparation is also important in relaying the importance of out-of-control foodborne illness risk factors.

The person in charge should be encouraged to accompany inspectors during the inspection. This may ultimately save time since violations can be pointed out and

corrected as they are observed. In addition, the importance of violations related to foodborne illness risk factors and Food Code interventions is more apparent if they are pointed out during the inspection rather than waiting until the end. Violations should be marked on the inspection form even if immediate corrective actions are taken. Corrective actions taken should also be recorded on the inspection form. Inspectors can also use this time to share knowledge about critical processes. By communicating the public health rationale behind the regulations, inspectors will leave the person in charge with a clear understanding for why active managerial control of foodborne illness risk factors must be a top priority in the day-to-day operation of the business.

Early in the inspection, inspectors should inquire about activities that are presently occurring. Processes that occur over time like cooling and reheating also need to be assessed over time; thus, inspectors should ask in the beginning of the inspection if any foods are currently being cooled or reheated.

It is important for inspectors to allow the operator a chance to discuss issues related to food safety. One-way communication in which inspectors do all the talking is not conducive to a risk-based philosophy. An effective risk-based inspection is dependent on inspectors' ability to maintain two-way communication in order to properly assess behaviors, processes, and procedures that occur in the food establishment.

(2) Review Previous Inspection Reports

In order to detect trends of out-of-control foodborne illness risk factors, it is important for inspectors to review past inspection reports before conducting an inspection. This can be done in the office or on-site in the food establishment. This activity is especially important in jurisdictions where inspectors rotate from one inspection to the next. If the same foodborne illness risk factor is out-of-control during more than one inspection, it is strongly recommended that the operator develop an intervention strategy to prevent its recurrence. Intervention strategies are discussed later in this Annex.

Knowledge of what has been corrected from the last inspection also gives inspectors an opportunity to provide positive feedback to the operator and allows inspectors to track corrected violations in accordance with their jurisdiction's policies and procedures.

(3) Conduct a Menu/Food List Review

Menus, including all written and verbal lists of foods prepared and offered in a food establishment, can be reviewed in a fairly simple manner. The review can either be done simultaneously with a quick walk-through of the operation or at the beginning of the inspection as a discussion with management. The menu/food list also does not need to be reviewed during every inspection. If a review was done during a recent inspection, inspectors should inquire about new items, seasonal items, substitutions, or changes in preparation since the last menu review was conducted.

A review of the menu/food list allows inspectors to begin to group food items into one of three broad process categories (discussed in Annex 4 of the Food Code and later in this Annex). Mentally grouping products by process assists inspectors in focusing the inspection on the control measures critical to each process. Conducting a review of the menu/food list also allows inspectors to establish inspection priorities by identifying:

- High-risk foods or high-risk food preparation processes
- Operational steps requiring further inquiry such as receiving, preparation, cooking, and cooling.

By identifying high-risk foods or high-risk food preparation processes, inspectors can focus the inspection on those foods or processes that are more likely to cause foodborne illness if uncontrolled. The menu/food list review might be the only time inspectors are made aware of specialized processes such as formulating a food so that it is not time/temperature control for safety food (TCS) or high-risk seasonal menu items such as "raw oysters on the half shell." Foods such as shellstock and certain fish for raw consumption require documentation that should be reviewed during the inspection. If Caesar salad or hollandaise sauce is served, further inquiry is needed regarding the preparation of these items since they are sometimes prepared with raw or undercooked eggs.

Several operational steps like receiving, preparation, cooking, and cooling may not be inspected as vigorously in retail and food service inspections due, in part, to the hours of the day in which these steps occur. If a food establishment is inspected in the afternoon hours, for example, receiving and food preparation might have already occurred. In order to evaluate the establishment's active managerial control of foodborne illness risk factors, it is imperative that inspectors ask enough questions to obtain information about the operational steps that they cannot directly observe during the current inspection.

(4) Conduct a Quick Walk-through

As inspectors discuss the menu or food list and establishes open communication with the person in charge, it is suggested that they conduct a quick walk-through of the food establishment to observe what is going on at that time. Conducting a quick walk-through is especially important to observe several activities that might otherwise go unnoticed or unobserved until later in the inspection, including:

- Receiving
- Food preparation and handling
- Cooking
- Cooling
- Reheating.

Speaking directly to the food service employees preparing the food is also an excellent way to assess the effectiveness of the establishment's food safety training and standard operating procedures for critical processes such as cooling. Noting that receiving or food preparation is occurring at the beginning of the inspection allows inspectors an opportunity to take advantage of viewing "real-life" production processes and will help inspectors to obtain a clear picture of the establishment's true practices. Receiving and food preparation only occur during limited times, so inspectors may want to stop and observe these operational steps while they are happening.

Early in the inspection, temperatures of time/temperature control for safety foods (TCS) should be taken. For example, if inspecting in the morning, inspectors should check the temperatures of last night's stored leftovers. If inspecting in the afternoon, inspectors should check the temperatures of foods prepared that morning that are now cooling. Also, inspectors should ask whether any foods are currently being cooked or reheated.

E. Determine Process Flows

Many retail and food service establishments have implemented effective food safety management systems by establishing controls for the food preparation methods and processes common to their operation. Control of food preparation processes rather than individual food items is often called the "process approach" to HACCP. The process approach using the principles of HACCP can best be described as dividing the many food items in an operation into food preparation processes then analyzing the foodborne illness risk factors associated with each process. By placing managerial controls on specific operational steps in the flow of food, foodborne illness can be prevented.

As presented in Annex 4 of the Food Code, most food items produced in a retail or food service establishment can be categorized into one of three preparation processes based on the number of times the food passes through the temperature danger zone between 41° F and 135° F. In conducting risk-based inspections, it is necessary for an inspector to be knowledgeable regarding how food is prepared in the operation. Knowing how products are prepared in an establishment allows inspectors to focus their inspections on the critical procedures and steps in the preparation of those products.

F. Determine Foodborne Illness Risk Factors In Process Flows

Annex 4 of the Food Code details the essential control measures specific to each food preparation process, in addition to essential facility-wide control measures. Inspectors should generally focus their inspections on verifying that operators have implemented control measures to control for foodborne illness risk factors common to the processes conducted in each operation. There may be other foodborne illness risk factors unique to specific operations; thus, inspectors should independently evaluate each operation and food preparation process conducted.

G. Assess Active Managerial Control of Foodborne Illness Risk Factors and Implementation of Food Code Interventions

Although some food establishments have formal HACCP plans, many do not. Even without a HACCP system, every food establishment needs to have active managerial control of foodborne illness risk factors. This may be achieved through several means, such as training programs, manager oversight, or standard operating procedures. For example, some food establishments incorporate control measures into individual recipes, production schedules, or employee job descriptions to achieve active managerial control.

While a person in charge may require the maintenance of in-house written records by employees to ensure that monitoring is being performed using the correct method and at the proper frequency, foodborne illness risk factors may be managed without the use of formal record keeping. Monitoring, whether through direct observations or by taking appropriate measurements, is by far the most important step in ensuring food safety. If an operator is effectively monitoring all critical activities in the food establishment and taking corrective actions when needed, safe food will result. With a few exceptions, maintaining formal records at retail is not required; therefore, records may not be in place for use during the inspection. As a result, it will be necessary to use direct observations and interviewing to determine whether a food establishment is adequately monitoring foodborne illness risk factors in their existing food safety management system.

This section provides a comprehensive discussion of how to assess the active managerial control of each of the foodborne illness risk factors and the implementation of each of the Food Code interventions. Assessment of active managerial control involves more than determining compliance with Food Code provisions. In assessing whether the operator has active managerial control, inspectors should observe whether the operator has established the appropriate control measures and critical limits and whether appropriate monitoring and corrective action procedures are in place and followed. In addition, inspectors should assess whether managers and employees are knowledgeable of food safety principles and critical practices and procedures necessary to prevent foodborne illness. If during the inspection inspectors observes that control measures are not being implemented appropriately to control risk factor occurrence, immediate corrective action must be taken.

(1) Demonstration of Knowledge

It is the responsibility of the person in charge to ensure compliance with the Code. Knowledge and application of Food Code provisions are vital to preventing foodborne illness and injury. Data collected by FDA suggest that having a certified food manager on-site has a positive effect on the occurrence of certain foodborne illness risk factors in the industry.

In order to assess whether the person in charge demonstrates knowledge, inspectors should verify that the person in charge has one or more of the following:

- A valid food protection manager certificate
- No priority item violations during the current inspection
- Correct responses to food safety related questions as presented in ¶ 2-102.11(C) of the Food Code.

(2) Assessing Safe Sources and Receiving Temperatures

The time and day of the inspection is important when assessing whether foods are received from safe sources and in sound condition. Foods may be received in the food establishment on set days. Inspectors should ask questions to ascertain the day or days that deliveries are received and also the receiving procedures in place by the food establishment. Inspections can be scheduled at times when it is known that products will be received by the food establishment. If food is being delivered during the inspection, inspectors should:

- Verify internal product temperatures
- Examine package integrity upon delivery
- Look for signs of temperature abuse (e.g., large ice crystals in the packages of frozen products)
- Examine delivery truck and products for potential for cross-contamination
- Observe the food establishment's behaviors and practices as they relate to the establishment's control of contamination and holding and cooling temperatures of received products
- Review receiving logs and other documents, product labels, and food products to ensure that foods are received from regulated food processing plants (no foods prepared at home) and at the proper temperature.

When evaluating approved sources for shellfish, such as clams, oysters, and mussels, inspectors should ask whether shellfish are served at any time during the year. If so, inspectors should review the tags or labels to verify that the supplier of the shellfish is certified and on the most current Interstate Certified Shellfish Shippers List found at (http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006753.htm). Inspectors should note whether all required information is provided on the tags or label (harvester's certification number, harvest waters and date, type and quantity of shellfish and similar information for each dealer that handles the shellfish after the harvester). Shellstock tags should also be retained for 90 days in chronological order.

With regard to fish, inspectors should verify that fish are commercially caught and harvested and received from reputable vendors. If fish are being delivered during the inspection or if they were received just before inspectors' arrival, temperatures should be taken, especially if there are finfish such as tuna, mahi-mahi, bluefish, mackerel, and snapper. These fish are subject to scombrotoxin formation if time/temperature abused.

Inspectors should verify freshness by conducting an organoleptic inspection of the gills, eyes, and bodies of the fish.

Inspector should verify that fish, except for certain species of tuna, intended for raw or undercooked consumption have been frozen for the required time and temperature parameters to destroy parasites by either reviewing freezing records or verifying that a letter of guarantee from the purveyor is kept on file. If freezing is conducted on-site, inspectors should verify that the freezing records are maintained for at least 90 days beyond the date of sale or service.

With regard to the service of game or wild mushrooms, inspectors should ask if these products are served at any time during the year. If so, inspectors should verify that they are from an approved source by reviewing invoices.

With regard to juice and milk products, inspectors should verify that fluid milk and milk products are pasteurized and received at the proper temperature. For packaged juice, inspectors should verify that the juice was pasteurized or otherwise treated to achieve a 5-log reduction of the most resistant microorganism.

During the inspection, inspectors should inquire as to the source of foods that have been removed from their original containers. If at any time during the inspection there is any doubt as to the source of certain products, inspectors should ask for invoices or receipts to demonstrate their source. Certain products, such as flat breads, waffles, pies, and cakes may require special cooking equipment to prepare. If suitable equipment is not on-site to prepare such products and the products are not stored in original containers, then inspectors should inquire as to the source of these products.

Food from unapproved, unsafe, or otherwise unverifiable sources should be discarded or put on hold or under embargo until appropriate documentation is provided. In addition, inspectors should ensure that management and employees are aware of the risk of serving or selling food from unapproved sources. Fish that are intended to be consumed raw or undercooked and for which no freezing certification or equipment is found on-site, can be used in menu items that will be fully cooked. If cooking is not an option due to the menu items served, the fish should be discarded.

(3) Assessing Contaminated Equipment and Potential for Cross-Contamination

This risk factor involves the proper storage and use of food products and equipment to prevent cross-contamination. The cleaning, sanitization, and storage of food-contact surfaces of equipment and utensils in a manner to prevent transmission of foodborne pathogens or contamination is also included in this risk factor.

As inspectors walk through the food establishment, they should examine food storage areas for proper storage, separation, segregation, and protection from contamination. Inspectors should look to see that raw animal foods and ready-to-eat foods are

separated during receiving, storage, and preparation. For example, cooked shrimp should not be returned to the same container that previously held uncooked product. Cutting boards should be washed, rinsed, and sanitized between trimming uncooked chicken and cooked steak.

In addition, raw animal foods should be separated by cooking temperatures such that foods requiring a higher cooking temperature, like chicken, should be stored below or away from foods requiring a lower temperature, like pork and beef. If TCS foods are not being cooled, they should be covered or packaged while in cold storage.

Following the flow of food as it is prepared in the food establishment may alert inspectors to opportunities for cross-contamination. When contamination has occurred between raw and ready-to-eat food, inspectors should assess whether the food can be reconditioned. In some cases, depending on the affected food, it may be possible to reheat the food to eliminate any hazards. If the food cannot be reconditioned, then the food should be discarded.

Inspectors should verify that exposed food such as chips, bread, and dipping sauces are not re-served to the consumer. Consumer self-service operations are addressed in the Code with regard to the types of food offered for consumer self-service, the protection of food on display, and the required monitoring by employees of such operations.

A visual check of the food-contact surfaces of equipment and utensils should be made to verify that the utensils are maintained clean and sanitized using the approved manner and frequency. Utensils that are observed to have debris, grease, or other visible contamination should be rewashed and resanitized.

Observations should be made to determine whether practices are in place to eliminate the potential for contamination of utensils, equipment, and single-service items by environmental contaminants, employees, and consumers. When clean equipment and utensils are stored where they are subject to environmental contamination such as near handwashing sinks or prep sinks, inspectors should have the operator rearrange the equipment in a manner to prevent cross-contamination. Depending on the circumstances, the operator may need to rewash and resanitize the equipment.

Inspectors should observe handwashing operations. If handwashing sinks and fixtures are located where splash may contaminate food contact surfaces or food, then splash guards should be installed or food-contact surfaces should be relocated to prevent cross-contamination.

Inspectors should pay particular attention to prep sinks, especially those that are currently in use at the time of the inspection. Built-up grime is a visible sign that the sink is not being washed, rinsed, and sanitized appropriately before use. If there are designated vegetable or meat sinks, inspectors should verify that the placement of sinks

and food preparation areas do not facilitate opportunities for cross-contamination from one to the other.

With regard to the cleaning and sanitization of food-contact surfaces, inspectors should verify the compliance of any warewashing operations by ensuring that cleaning and sanitizing procedures for all food-contact surfaces conform to the requirements in the Food Code. Questions should be asked to assess how utensils and cookware are washed, rinsed, and sanitized in the food establishment. When assessing the warewashing procedure and equipment, inspectors should pay particular attention to cooking and baking equipment that is too large to fit in the dishmachine or sinks. It is a good idea to have the person responsible for dishwashing demonstrate the procedure that is followed in the food establishment by setting up the sinks and watching the dishwashing procedure.

(4) Assessing Cooking Temperatures

Food cooking temperatures and times should be verified by inspectors during each inspection. Every effort should be made to assess the cooking temperatures of a variety of products served in the food establishment.

To assess cooking, inspections must occur at times when food is being cooked. It is also important to conduct inspections during busy times, such as lunch and dinner, as there may be a tendency for the operator to rush the cooking of foods during these times.

Critical limits for cooking TCS foods in the Food Code include specifications that all parts of the food be heated to a certain temperature. For large roasts, temperature measurement should take into account post-cooking heat rise which allows the temperature to reach equilibrium throughout the food. The critical limit of time at the terminal temperature must also be measured during inspections. For example, a roast beef cooked at 54°C (130°F) is required to be held at this temperature for 112 minutes to ensure destruction of pathogens. Cooking times and temperatures should be noted on the inspection report.

The correct temperature measuring device and technique are essential in accurately determining the temperatures of TCS foods. The geometric center or thickest part of a product are the points of measurement of product temperature particularly when measuring critical limits for cooking.

Inspectors should take internal temperatures of products using a thermocouple or thermistor with a probe suitable for the product thickness. A thin diameter probe should be used for temperature measurements of hamburger patties and fish filets. Alternately, although less desirable, an inspector may use a suitable, calibrated bimetal stem thermometer for checking cooking temperatures of thick foods. Infrared thermometers are inappropriate for measuring internal cooking temperatures.

In order to better assess cooking during all phases of the inspection, inspectors could enlist the help of cooperative food employees to notify them of foods that have finished cooking. This allows inspectors to continue with the inspection in other areas of the operation yet continue to verify that proper cooking temperatures are being met.

Food establishments should routinely monitor cooking temperatures. Inspections should verify that monitoring is occurring by involving the person in charge in these activities during the regulatory inspection. The presence of required thermometers and their proper use should be assessed.

Comparisons should be made between inspectors' calibrated temperature measuring device and those used by the food establishment. Notation of deviations should be made on the inspection report. Inspectors should ask food establishment personnel to demonstrate proper calibration of their temperature measuring devices.

If required cooking temperatures are not met, inspectors should have the operator continue cooking the food until the proper temperature is reached. Additionally, inspectors should explain the public health significance of inadequate cooking to management and food employees.

(5) Assessing Holding Time and Temperatures and Date Marking

Hot and cold holding temperatures, as well as cooling time and temperatures, of TCS foods should be thoroughly checked with a thermocouple, thermistor, or other appropriate temperature measuring device during each inspection. This includes the temperature of TCS food during transport, e.g., hot holding carts being used to transport food to patient rooms in a hospital, satellite kitchens, or off-site catering events. As a rule, every effort should be made to assess every hot and cold holding unit in the food establishment during a risk-based inspection.

Use of an infrared thermometer for verifying holding temperatures is not consistent with Food Code requirements since verifying only the surface temperature of the food may not alert inspectors to problems that exist under the food's surface. Such problems could stem from improper cooling, in the case of cold-held foods, or improper reheating, in the case of hot-held foods. In addition, inspectors should not stir a food before taking its temperature since it is important to know the temperature of the food before it is agitated.

The geometric center of a product is usually the point of measurement of product temperature particularly when measuring the critical limit for cold holding.

The hot holding critical limit may need additional measurements taken at points farthest from the heat source, e.g., near the product surface for food held on a steam table. Temperatures monitored between packages of food, such as cartons of milk or packages of meat, may indicate the need for further examination. However, the temperature of a TCS food itself, rather than the temperature between packages, is

necessary for regulatory citations. In large holding units and on steam tables, it is necessary to take the temperatures of foods in various locations to ensure that the equipment is working properly. If deviations are noted in the product temperatures, it is important to take extra steps to find out whether the problem is the result of equipment failure or whether a breakdown in a process such as cooling or reheating is the reason for the problem.

Corrective actions for foods found in violation should be required based on the jurisdiction's regulatory food code. If foods are to be discarded, forms such as those used for stop sale or embargo may need to be completed and signed by the person in charge in accordance with the jurisdiction's regulatory food code. In order to properly evaluate the degree of time and temperature abuse and the proper disposition of the affected food, several issues must be considered. Answers to these questions, in combination with observations made during the inspection, should provide inspectors with enough information to make the appropriate recommendation for on-site correction:

- Are there any written procedures in place for using time alone as a public health control and, if so, are they being followed properly?
- What are the ingredients of the food and how was it made?
- Is it likely that the food contains *Clostridium perfringens*, *Clostridium botulinum*, or *Bacillus cereus* as hazards?
- Has there been an opportunity for post-cook contamination with raw animal foods or contaminated equipment?
- If there has been an opportunity for post-cook contamination, can the hazards of concern be eliminated by reheating?
- Are the food employees practicing good personal hygiene including frequent and effective handwashing?
- Was the food reheated or cooked to the proper temperature before being allowed out of temperature control?
- What is the current temperature of the food when taken with a probe thermometer?
- How long has the food been out of temperature control (ask both the manager and food employees)? Are the answers of the food employees and the manager consistent with one another?
- Is it likely that food has cooled to its current temperature after being out of temperature control for the alleged time?
- Will the food be saved as leftovers?
- How long before the food will be served?
- Given what is known about the food, the food's temperature, the handling of the food, and the alleged time out of temperature, is it reasonably likely that the food already contains hazards that cannot be destroyed by reheating?

Even if food can be reconditioned by reheating, steps should be taken by the person in charge to ensure compliance in the future. Examples include repairing malfunctioning or inoperative equipment or implementing a risk control plan (RCP) to modify

preparation procedures or to institute a procedure for monitoring holding temperatures of food.

If using time only or time-temperature combinations in lieu of temperature for controlling the growth and toxin-formation of pathogenic bacteria, strict controls must be in place and followed. Inspectors should verify that the written procedures are on-site and followed in accordance with the Food Code.

Date marking is the mechanism by which active managerial control of time-temperature combinations can prevent the growth of *Listeria monocytogenes* in TCS, ready-to-eat foods during cold storage. With exceptions, all ready-to-eat, TCS foods prepared on-site and held for more than 24 hours should be date marked to indicate the day or date by which the foods need to be served or discarded. Inspectors should ask questions to ascertain whether the system in place to control for *L. monocytogenes* meets the intent of the Food Code. Food that should be date marked and is not should be discarded.

(6) Assessing Reheating for Hot Holding

In order to assess a food establishment's control of reheating for hot holding, the time of day that the inspection occurs is a key factor. Every effort should be made to schedule an inspection during pre-opening preparation. If inspections are conducted during pre-opening preparation or other preparation periods, inspectors should ask questions regarding the history of hot-held foods. Foods in compliance for minimum hot holding temperatures may have in fact been improperly reheated before being placed into hot holding units or steam tables.

If items are found "reheating" on the steam table, further inquiry is needed to assess whether the equipment in question is capable of reheating the food to the proper temperature within the maximum time limit. Corrective action for foods found out of compliance for reheating for hot holding would depend on how long the food had been out of temperature and other factors. In most cases, however, the food may be rapidly reheated and hot held.

(7) Assessing Cooling

Improper cooling remains a major contributor to bacterial foodborne illness. Cooling temperatures and times need to be closely evaluated during every inspection. In order to assess whether a food establishment has control over cooling, the time of day that the inspection occurs is critical. Early morning inspections allow an opportunity to verify that leftovers from the night before were cooled properly or cooled using a proper cooling method. Alternatively, afternoon inspections may allow an inspector to verify cooling of products that may have been prepared that morning.
Because many food establishments prepare bulk products only on certain days of the week, it is essential that inspectors become as familiar as possible with each operation and schedule their inspections accordingly.

Due to the time parameters involved in cooling, inspectors should always inquire at the beginning of the inspection whether there are any products currently being cooled. This allows inspectors an opportunity to take initial temperatures of the products and still have time to re-check temperatures later in the inspection in order to verify that critical limits are being met.

Problems with cooling can often be discovered through inquiry alone. Even when no cooling is taking place, inspectors should ask the food employees and managers questions about the cooling procedures in place.

When examining cold holding units, bulk containers and buckets, tightly packed pans, shrouded rolling racks, or closed rolling cabinets should warrant further temperature and time investigation. Bulk containers and buckets should be opened since they are commonly reused for food storage and cooling.

The geometric center of a product is often chosen as the point of measurement of product temperature particularly when measuring the critical limits for cooling. For foods that are being cooled, temperature profiles throughout the product may show proper temperatures at outer edges and hot spots at the core of the product. Inspectors can verify cooling by first taking a temperature measurement in the geometric center of the product, then at various points around the perimeter of the product. Warmer temperatures in the center of the product, in combination with cooler temperatures around the perimeter, indicate that a product is cooling. Additional questions should be asked to ascertain the cooling time parameters of the food in question. Information gained from food employees and management, in combination with temperature measurements taken, should form the basis for assessing compliance of cooling during an inspection.

The following guidance may be used for determining the appropriate corrective action for improper cooling. Cooked hot food may be reheated to 165 ºF for 15 seconds and the cooling process started again using a different cooling method if the food is:

- Above 70 ºF and two hours or less into the cooling process; and
- Above 41 ºF and six hours or less into the cooling process.

Cooked hot food should be discarded immediately if the food is:

- Above 70 ºF and more than two hours into the cooling process; or
- Above 41 ºF and more than six hours into the cooling process.

A different, more accelerated, cooling method may be used for prepared ready-to-eat foods if the food is above 41 ºF and less than four hours into the cooling process; however, such foods should be discarded if the food is above 41 ºF and more than four hours into the cooling process.

(8) Assessing Personal Hygiene, Hands As a Vehicle of Contamination, and Proper Implementation of Employee Health Policies

Special attention should be given to the potential for hands as a vehicle of contamination. An effective management system for prevention of hand contamination involves three elements:

- Employee health policy
- Proper handwashing
- No bare hand contact with ready-to-eat foods.

There are a wide range of communicable diseases and infections that can be transmitted by an infected food employee. Proper management of the risks associated with ill food employees begins with employing healthy people and implementing a policy that excludes or restricts ill employees as specified in Chapter 2 of the Food Code. Employees must be aware of the symptoms, illnesses, or conditions that must be reported to the person in charge. In addition, the person in charge must be knowledgeable regarding the appropriate action to take should certain symptoms, illnesses, or conditions be reported.

With regard to the employee health policy, inspectors should ask a series of open-ended questions to ascertain whether the employee health policy in place complies with the Food Code. The following are example questions that may be asked:

- What kind of policy do you have in place for handling sick employees?
- Is there a written policy? (Note: a written policy is not required in the Food Code, but having a written policy may give an indication of the formality of the policy being discussed.)
- Describe how managers and food employees are made knowledgeable about their duties and responsibilities under the employee health policy.
- Are food employees asked if they are experiencing certain symptoms or illnesses upon conditional offer of employment? If so, what symptoms or illnesses are food employees asked about? Is there a written record of this inquiry?
- What are food employees instructed to do when they are sick?
- What conditions or symptoms are reported?
- What may some indicators be of someone who is working while ill?
- When are employees restricted from working with exposed food or food-contact surfaces? When are they excluded from working in the food establishment?
- For employees that are sick and cannot come to work, what policy is in place for allowing them to return and for notifying the regulatory authority?

Special attention should be given to the potential for hands as a vehicle of contamination. Ensuring that hands are washed using the proper procedure and at the

appropriate times must be a top priority during every inspection. Data show that viruses can be tenacious even in the presence of good handwashing. Inspectors should observe employee use of utensils and gloves during the preparation and service of ready-to-eat foods and ingredients, such as salads and sandwiches.

If ready-to-eat food is touched with bare hands, inspectors will need to address several questions in order to make the appropriate on-site correction recommendation. The answers to the following questions should provide enough information to determine the likelihood of occurrence of hazards transmitted by bare hands and should be the basis for making a recommendation for on-site correction:

- Does the facility have an employee health policy to identify, restrict, and exclude ill employees?
- Did the employees working with the food in question effectively wash their hands and are handwashing facilities adequate?
- Is there an approved, alternate procedure to no bare hand contact in place and was it followed before the bare hand contact?
- Has there been an opportunity for the employee's hands to become contaminated?

Inspectors should examine the location of handwashing sinks in relation to where food is being prepared. Many jurisdictions use a basic distance measurement as a guideline when considering the location and number of handwashing sinks required in a food establishment during the plan review process. While this information can be used to assist with the review process, it should not be used as the sole basis for determining whether there are an adequate number of handwashing sinks or whether the handwashing sinks are conveniently located.

Special emphasis should be placed on spacing in and around fixed equipment, the expected staffing, and the flow of food throughout a food establishment. For instance, a kitchen may be 30 feet in length and 12 feet wide. Although the size of the kitchen may dictate only one handwashing sink using a basic distance measurement, if a prep table the length of the line is placed between the line and the handwashing sink, the handwashing sink may not be conveniently located. Likewise, one handwashing sink located at the end of cook line is useless to employees working at the other end if there is limited space for employees to go around one another during busy periods.

(9) Assessing Compliance with Approved Procedures

When conducting certain specialized processes, variances and HACCP plans are required by the Code. This is because such processes carry a considerable risk if not conducted under strict controls. For food establishments conducting specialized processes, each inspection should involve a review of the written variance, if applicable,

and the implementation of the HACCP plan to ensure that food safety hazards are being consistently controlled.

(10) Assessing Special Requirements Related to Highly Susceptible Populations (HSP)

Food establishments that serve highly susceptible populations (HSP) must adhere to additional requirements as specified under Part 3-8 of the Code. Every effort should be made to inspect such facilities during preparation, service, or other applicable times to assess these additional requirements as well as those in other sections of the Food Code.

Because those persons who are very young, elderly, or who live in a facility that provides custodial care are extremely vulnerable to foodborne illness because of age or health status, it is important that risk factors be controlled on-site in a timely manner. Inspections of HSP facilities should be conducted by inspectors knowledgeable in the control of foodborne illness risk factors who take extra care to assure that the most vulnerable segment of the population are not at risk.

(11) Assessing Labeling, Storage, and Use of Poisonous and Toxic Chemicals

During each inspection, the proper labeling, storage, and use of poisonous and toxic chemicals should be verified. Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label. Working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies should be clearly and individually identified with the common name of the material. Only chemicals that are necessary to the operation and maintenance of a food establishment, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, should be in the food establishment. Medicines necessary for the health of employees may be allowed in a food establishment, but they should be labeled and stored to prevent contamination of food and food-contact surfaces.

Inspectors should verify that solutions containing poisonous and toxic chemicals, like mop water, are discarded in an appropriate service sink to prevent contamination of food and food-contact surfaces. In addition, inspectors should check delivery trucks to verify that food is protected from chemical contamination during shipment. Any food that has been cross-contaminated with poisonous or toxic chemicals should be discarded or rejected immediately.

(12) Assessing Compliance with Consumer Advisory

Inspectors should ascertain whether animal foods such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish are served or sold raw, undercooked, or without otherwise

being processed to eliminate pathogens, either in ready-to-eat form or as an ingredient in another ready-to-eat food. Inspectors should review the menu or food list to verify that a consumer advisory with a disclosure and reminder is present as specified under § 3-603.11 of the Food Code.

In addition to reviewing the menu or food list, inspectors should ask whether raw or undercooked foods are served or sold routinely or seasonally. It is useful to know foods that are often served in this manner such as oysters-on-the half shell, hollandaise sauce, béarnaise sauce, eggnog, salad dressings, hamburgers to order, or sunny-side-up eggs.

H. Evaluating Basic Sanitation and Facilities (Good Retail Practices)

An important part of a risk-based, routine inspection is to review how the food establishment actively monitors the active managerial control of foodborne illness risk factors and interventions; however, overall sanitation should not be overlooked. Systems to control basic operational and sanitation conditions within a food establishment, referred to as Good Retail Practices (GRPs), are the foundation of a successful food safety management system. GRPs found to be out-of-compliance may give rise to conditions that may lead to foodborne illness, e.g., sewage backing up in the kitchen. Just as monitoring is required by the food establishment to ensure that foodborne illness risk factors are controlled and interventions are in place, monitoring of basic sanitation conditions in the food establishment allows the operator an excellent opportunity to detect weaknesses and initiate actions for improvement. Basic operational and sanitation programs must be in place to:

- Protect products from contamination by biological, chemical, and physical food safety hazards
- Control bacterial growth that can result from temperature abuse during storage
- Maintain equipment, especially equipment used to maintain product temperatures.

Examples of concerns addressed by the basic operation and sanitation programs mentioned above include the following:

- Pest control
- Food protection (CORE ITEM)
- Equipment maintenance
- Water
- Plumbing
- Toilet facilities
- Sewage
- Garbage and refuse disposal
- Physical facilities.

5. ACHIEVING ON-SITE AND LONG-TERM COMPLIANCE

A. Developing an Effective Compliance and Enforcement Protocol

Compliance and enforcement are essential elements of a regulatory program and encompass all voluntary and regulatory enforcement actions taken to achieve compliance with regulations. Standards 3 and 6 of the Program Standards explain the need of regulatory jurisdictions to establish a compliance and enforcement protocol that results in credible follow-up for each violation noted during an inspection, especially violations related to foodborne illness risk factors and Food Code interventions. Lack of follow-up on the part of the regulatory agency signals to the operator that the priority item and priority foundation item violations noted were not important.

The resolution of out-of-compliance foodborne illness risk factors and Food Code interventions must be documented in each food establishment record. The desired outcome of Standard 6 is an effective compliance and enforcement program that is implemented consistently to achieve compliance with regulatory requirements.

Compliance and enforcement options may vary depending on state and local law. It is essential that regulatory jurisdictions develop a written compliance and enforcement protocol that details the order in which both voluntary corrections may be taken on the part of the operator and involuntary enforcement actions are to be taken on the part of the regulatory authority. Involuntary enforcement actions include, but are not limited to, such activities as warning letters, re-inspections, citations, administrative fines, permit suspensions, and hearings.

Food establishment with a history of noncompliance at a level predetermined by the jurisdiction or with the number of foodborne illness risk factors and interventions violated warranting a regulatory action, signals the need either a strong regulatory response or an alternate approach to compliance to protect public health, e.g., active managerial control, behavioral change.

Voluntary corrections taken on the part of the operator include, but are not limited to, such activities as on-site corrections at the time of inspection, voluntary destruction, risk control plans, and remedial training. Obtaining voluntary corrections by the operator can be very effective in achieving long-term compliance. Voluntary corrections by the operator are referred to in FDA's Regulator's Manual as "intervention strategies." Intervention strategies can be divided into two groups:

- Those designed to achieve immediate on-site correction
- Those designed to achieve long-term compliance.

Successful intervention strategies for out-of-control foodborne illness risk factors can be tailored to each operation's resources and needs. This will require inspectors to work

with the operator to identify weaknesses in the existing food safety management system and consulting with the operator to strengthen any weak areas noted.

B. On-site Correction

On-site corrections are intended to achieve immediate corrective action of out-of-control foodborne illness risk factors posing an immediate, serious danger to the consumer during the inspection. Usually these violations are "operational" rather than structural and can be addressed by management at the time of the inspection.

It is essential to consumer protection and to regulatory credibility for on-site correction to be obtained for any out-of-control foodborne illness risk factors before completing the inspection and leaving the food establishment. Obtaining on-site correction conveys the seriousness of the violation to management. Failure to require on-site correction when an out-of-control risk factor has been identified implies that the risk factor has little importance to food safety.

When recommending on-site correction, effective communication regarding out-of-control foodborne illness risk factors is essential and can be accomplished best by:

- Discussing food safety concerns in words that can be easily understood by the person in charge and employees

- Conveying the seriousness of the out-of-control foodborne illness risk factors in terms of increased risk of illness or injury.

During the discussion of inspection findings with the person in charge, inspectors should keep the discussion focused on correction of violations that present an immediate danger to the consumer. Discussion of less serious code violations should be deferred until out-of-control foodborne illness risk factors are discussed and on-site correction is obtained.

In most cases, selecting the most appropriate on-site correction when out-of-control foodborne illness risk factors are observed will be straightforward; however, in instances such as improper cooling, the appropriate corrective action may be more complicated. Since determining on-site correction depends on a number of factors, an inspector may need to conduct a hazard analysis of the food in order to determine the appropriate course of action to take.

C. Intervention Strategies for Achieving Long-term Compliance

While on-site correction of out-of-control foodborne illness risk factors is essential to consumer protection, achieving long-term compliance and behavior change is equally important. Overcoming several misconceptions about long-term compliance will help in achieving a desirable change of behavior. For example, in jurisdictions using a 44-item inspection report in which only observed violations are marked, it is often taken for

granted that if there are no violations marked, the foodborne illness risk factors are being controlled. This is not necessarily true since the observation of code violations is subject to many variables such as the time of day, day of the week, or duration of the inspection. An inspection system that records only observed violations rather than the actual status of all foodborne illness risk factors, such as whether the risk factor was in compliance, not observed, or not applicable to the operation, may be unable to detect some foodborne illness risk factors that are continually or cyclically out of control.

Another misconception is that training alone will result in foodborne illness risk factors being controlled. While training may help, there is no guarantee that knowledge acquired will equate to knowledge applied in the workplace. In order for knowledge to translate into changed behavior, it must be reinforced and the behavior must be repeated for a period of time sufficient for the behavior to become an ingrained pattern. Another assumption is that regulatory enforcement actions such as citations or administrative hearings or on-site corrections alone will automatically result in future management control. Unfortunately, there is no assurance that any of these actions will result in the long-term control of foodborne illness risk factors.

Long-term compliance may best be achieved through voluntary actions by the operator. If an operator supports the concept that a food safety management system is needed, there is a better chance that long-term compliance will be achieved. The following are ways operators can better ensure long-term active managerial control of foodborne illness risk factors.

(1) Change Equipment and Layout

Critical limits are difficult to achieve when equipment does not work properly. Proper calibration of equipment is vital to achieving food safety. When calibration is unsuccessful or is not feasible, equipment should be replaced. In addition to equipment malfunctioning, poor equipment layout can present opportunities for cross contamination and must be considered. For example:

- Hamburgers with uniform thickness and weight are not all reaching a safe cooking temperature in a given time. Upon examination, it is determined that the grill is distributing heat unevenly. A new element is installed to correct the problem.

- Splash from a nearby handwashing sink is seen on a prep table. A splash guard is installed to prevent cross contamination from the handwashing sink to the prep table.

(2) Establish Buyer Specifications

Written specifications for the goods and services purchased by a food establishment prevent many problems. For example:

- Fish posing a parasite hazard and intended for raw consumption have not been frozen for the specified time and temperature and no freezing equipment is on-site at the food establishment. Buyer specifications are established to place the responsibility for freezing the fish on the supplier.

- Lobster tails, hamburgers, or other products cooked with a set time parameter on a conveyor are not reaching the proper temperature in the specified time because they are larger than the size for which the conveyor is calibrated. Buyer specifications are established to restrict the size of products received from the supplier.

(3) Develop and Implement Recipe/Process Instructions

Simple control measures integrated into recipes and processes can improve management control over foodborne illness risk factors. For example:

- Process instructions that specify using color-coded cutting boards for separating raw animal foods from ready-to-eat products are developed to control the potential for cross contamination.

- Pasteurized eggs are substituted in recipes that call for raw or undercooked eggs to reduce the risk of foodborne illness.

- Commercially precooked chicken is used in recipes calling for cooked chicken such as chicken salad to reduce the risk of contaminating food-contact surfaces and ready-to-eat food with raw chicken.

- Pasta is chilled in an ice bath immediately after cooking and before apportioning into single servings. This is specified in the procedures for cooking spaghetti.

(4) Establish First-In-First-Out (FIFO) Procedures

Product rotation is important for both quality and safety reasons. “First-In-First-Out” (FIFO) means that the first batch of product prepared and placed in storage should be the first one sold or used. Date marking foods as required by the Food Code facilitates the use of a FIFO procedure in refrigerated, ready-to-eat, TCS foods. The FIFO concept limits the potential for pathogen growth, encourages product rotation, and documents compliance with time/temperature requirements.

(5) Develop and Implement Standard Operating Procedures (SOPs)

Following standardized, written procedures for performing various tasks ensures that quality, efficiency, and safety criteria are met each time the task is performed. Although every operation is unique, the following list contains some common management areas that can be controlled with SOPs:

- Personnel (disease control, cleanliness, training)
- Facility maintenance
- Sanitary conditions (general cleaning schedule, chemical storage, pest control, sanitization of food-contact surfaces)
- Sanitary facilities (approved water supply and testing, if applicable, scheduled in-house inspection of plumbing, sewage disposal, handwashing and toilet facilities, trash removal)
- Equipment and utensil maintenance.

SOPs can also be developed to detail procedures for controlling foodborne illness risk factors:

- Procedures are implemented for measuring temperatures at a given frequency and for taking appropriate corrective actions to prevent hazards associated inadequate cooking.

- Adequate handwashing is achieved by following written procedures that dictate frequency, proper technique, and monitoring.

(6) Develop and Implement Risk Control Plans (RCPs)

An RCP is a concisely written management plan developed by the retail or food service operator with input from inspectors that describes a management system for controlling specific out-of-control foodborne illness risk factors. An RCP is intended to be a voluntary strategy that inspectors and the person in charge jointly develop to promote long-term compliance for *specific* out-of-control foodborne illness risk factors. For example, if food is improperly cooled in the establishment, a system of monitoring and record keeping outlined in an RCP can ensure that new procedures are established to adequately cool the food in the future. An RCP should require that the basic control systems in the plan be implemented for a designated period of time (e.g., 60 – 90 days) and allow inspector oversight. The longer the plan is implemented, the more likely it is that the new controls will become "habits" that continue to be used in the food establishment after inspector oversight ends.

An RCP should stress simple control measures that can be integrated into the daily routine. It should be brief, no more than one page for each risk factor, and address the following points in very specific terms:

- What is the risk factor to be controlled?
- How is the risk factor controlled?
- Who is responsible for the control?
- What monitoring and record keeping is required?
- Who is responsible for monitoring and completing records?
- What corrective actions should be taken when deviations are noted?

- How long is the plan to continue?
- How are the results of the RCP communicated to inspectors?

By implementing an RCP, the retail or food service operator will have the opportunity to determine the appropriate corrective action for the identified problem and design an implementation strategy to best suit the establishment and operation. Since the RCP is tailored to meet the needs of the food establishment, the operator takes complete ownership of the plan and is ultimately responsible for its development and implementation. The role of inspectors are to consult with the operator by suggesting ways that the risk factor(s) might be controlled.

By creating an RCP, the operator realizes that a problem exists in the established food safety management system and commits to a specific correction plan rather than merely acknowledging a single violation. Follow up by telephone or in person indicates to the operator that inspectors are interested in seeing the plan succeed. This also gives inspectors an opportunity to answer any questions and offer feedback to the operator to make the RCP more useful. An example of an RCP, along with a blank template that can be used by regulatory jurisdictions, is found in FDA's Regulator's Manual: http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006812.htm

(7) Develop and Implement Comprehensive Voluntary Food Safety Management Systems based on HACCP Principles

The *Food Code* only requires HACCP plans for a few specialized processes; however, the development of voluntary HACCP plans is always encouraged. FDA Operator's Manual, *"Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments"* is written to aid food establishment managers in the development of food safety management systems based on HACCP principles. A retail or food service operator, in consultation with an appropriate regulatory authority or other food safety professional, can use this document to establish an effective food safety management system to control for all foodborne illness risk factors. This document is available from FDA through the following website:
http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006811.htm

6. INSPECTION FORM AND SCORING

A. The Inspection Form

The inspection form is the official document utilized by a regulatory agency for documentation of compliance of the food establishment with regulatory requirements. The goal of the inspection form is to clearly, concisely, and fairly present the compliance status of the food establishment and to convey compliance information to the permit holder or person in charge at the conclusion of the inspection.

The inspection report should be kept in the food establishment's files for subsequent compliance actions and review before the next inspection. Individual inspection reports are to be made available for public review in accordance with Freedom of Information criteria.

Annex 7 of the Food Code provides an inspection form that may be completed for routine, follow-up, and compliance inspections. This inspection form meets requirements established in Standards 3 and 6 of the Program Standards.

B. Debiting Methodology

If a violation exists during an inspection, it should always be marked on the inspection report, even if corrected on site. Violations existing at the time of the inspection probably would have persisted if it were not for the inspection. Slight violations, such as one dirty utensil among hundreds of clean utensils, does not indicate that the food establishment is significantly deviating from the Code requirements; therefore, discretion in marking is required.

It is very important to investigate the root causes of violations and mark them appropriately. Without taking this extra step, inspectors will merely point out violations and will not identify weaknesses in the management system in place. If long-term control of the behaviors or practices leading to the violations is expected, inspectors must identify the causes.

C. Scoring

Regulatory agencies may use scoring methods to rate food establishments. Depending on the system used, establishment scoring may provide an indication of how well a food establishment is complying with the food safety rules of the regulatory agency.

Some agencies use a system of compliance tools as provided in Chapter 8 and Annex 1 of the Food Code to protect public health. The inspection score may serve as the basis for triggering follow-up inspections or other forms of regulatory sanctions when they fall too far from the accepted levels. In addition, scoring may provide a mechanism for consumers to make informed choices regarding where they want to eat.

Use of scoring systems also has negative consequences. For example, it is possible for a food establishment to receive a high numerical or letter score while exhibiting some very serious deficiencies. In recognition of this drawback, some jurisdictions forego scoring systems in favor of demerits or debit systems without assigning a final score. This focuses attention on the items needing correction. Compliance and enforcement decisions can still be based on the increasing levels of identified deficiencies. Whatever method or system of establishment rating is used, policies regarding follow-up and enforcement actions should be established in writing, linked to the rating system, and administered consistently.

7. CLOSING CONFERENCE

The closing conference should include a detailed discussion of the food establishment's plans for correcting violations found during the inspection. The evidence collected or observed during the inspection and the alternatives available for compliance should be emphasized. On-site corrections made during the inspection should be acknowledged on the inspection report and in the closing conference.

The compliance plan should address changes in procedures that will prevent the recurrence of noted violations. The food establishment's compliance plans should be formally documented on the inspection report form. Follow-up letters may be necessary to elicit fulfillment of these agreements. It is important to stress to the operator that long-term correction of violations related to foodborne illness risk factors and Food Code interventions is far more important than corrections of core items.

8. SUMMARY

Although a retail and food service operator has the responsibility for establishing a food safety management system for controlling foodborne illness risk factors, inspectors have a vital, multi-faceted role in consumer protection. It is essential that inspectors are provided with the proper training, equipment, time, and resources to adequately perform their jobs.

The primary role of inspectors is to ensure that the operator has effective control of foodborne illness risk factors. Once inspectors have established a dialogue with the person in charge and employees, conducted a menu/food list review, and established a dialogue with the person in charge, inspectors will have enough information to mentally place menu items into one of the three process flows. The inspection can then focus on assessing the operator’s active managerial control of foodborne illness risk factors associated with each process.

Once out-of-control foodborne illness risk factors are identified, the role of inspectors shifts to assisting the operator with strengthening the existing food safety management system through intervention strategies designed to achieve immediate and long-term compliance. With inspector’s assistance, a retail and food service operator can achieve long-term behavioral change resulting in a reduction in risk factor occurrence and an increase in public health protection.

Annex

6 Food Processing Criteria

1. INTRODUCTION

From its inception, the retail segment of the food industry has prepared foods in consumer-sized portions, using commercially available equipment for cutting, grinding, slicing, cooking, and refrigeration, and applying herbs and spices readily available to consumers at their local grocery.

Over the past score of years, retail segment operators have expanded into food manufacturing/processing-type operations, often using sophisticated new technologies and equipment that are sometimes microprocessor-controlled. Many now desire to alter the atmospheres within food packages, or apply federally regulated chemical food additives as a method of food preservation. Food processing operations now being conducted or proposed include cook-chill; vacuum packaging; sous vide; smoking and curing; brewing, processing, and bottling alcoholic beverages, carbonated beverages, or drinking water; and custom processing of animals.

The Food Code specifies that a HACCP plan acceptable to the regulatory authority be the basis for approving food manufacturing/processing operations at retail. The HACCP plans are to be provided and accepted in two ways as follows.

(A) Reduced Oxygen Packaging

Section 3-502.12 of the Food Code provides the criteria that are to be met in the HACCP plans of those operators who are conducting reduced oxygen packaging (ROP) operations. Unless prior approval of the HACCP plan is required by the regulatory authority, the HACCP plan covering this operation along with the related records documenting monitoring and corrective actions need only be available and acceptable to the regulatory authority at the time of inspection.

(B) Other Food Manufacturing/Processing Operations

Except for ROP as discussed in (A) above, the Food Code specifies under §§ 3-502.11, 8-103.10, 8-103.11, and 8-201.13 that the food establishment operator must obtain a variance from the regulatory authority for all food manufacturing/processing operations based on the prior approval of a HACCP plan.

The purpose of this Annex is to provide processing criteria for different types of food manufacturing/processing operations for use by those preparing and reviewing HACCP plans and proposals. Criteria for additional processes will be provided as they are developed, reviewed, and accepted.

2. REDUCED OXYGEN PACKAGING

(A) Introduction

ROP which provides an environment that contains little or no oxygen, offers unique advantages and opportunities for the food industry but also raises many microbiological concerns. Products packaged using ROP may be produced safely if proper controls are in effect. Producing and distributing these products with a HACCP approach offer an effective, rational, and systematic method for the assurance of food safety. Non-time/temperature control for safety food, defined in Chapter 1, does not require a variance or HACCP Plan for ROP. This Annex will provide guidelines for effective food safety controls for retail food establishments covering the receipt, processing, packaging, holding, displaying, and labeling of food in reduced oxygen packages.

(B) Definitions

The term ROP can be used to describe any packaging procedure that results in a reduced oxygen level in a sealed package. The term is often used because it is an inclusive term and can include packaging options such as:

(1) *Cook-chill* packaging, in which cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

(2) *Controlled Atmosphere Packaging (CAP)* in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material.

(3) *Modified Atmosphere Packaging (MAP)* in which the atmosphere of a package of food is modified so that its composition is different from air but the

atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes reduction in the proportion of oxygen, total replacement of oxygen, or in increase in the proportion of other gases such as carbon dioxide or nitrogen.

(4) *Sous Vide* , in which raw or partially cooked food is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

(5) *Vacuum Packaging* in which air is removed from the package of food and the package is hermetically sealed so that a vacuum remains inside the package.

(C) Benefits of ROP

ROP can create a significantly anaerobic environment that prevents the growth of aerobic spoilage organisms, which generally are Gram-negative bacteria such as pseudomonads or aerobic yeast and molds. These organisms are responsible for off-odors, slime, and texture changes, which are signs of spoilage.

ROP can be used to prevent degradation or oxidative processes in food products. Reducing the oxygen in and around a food retards the amount of oxidative rancidity in fats and oils. ROP also prevents color deterioration in raw meats caused by oxygen. An additional effect of sealing food in ROP is the reduction of product shrinkage by preventing water loss.

These benefits of ROP allow an extended shelf life for vacuum packaged (VP), modified atmosphere packaged (MAP) and controlled atmosphere packaged (CAP) foods displayed for retail sale. Cook chill (CC) and sous vide (SV) processed food cannot be sold directly to consumers or other businesses but the extended shelf life and quality benefits internal service and use of the products. Providing an extended shelf life for ready-to-eat convenience foods and advertising foods as "Fresh – Never Frozen" are examples of economic and quality advantages.

(D) Safety Concerns

Use of ROP with some foods can markedly increase safety concerns. Unless time/temperature control for safety foods are protected inherently, simply placing them in ROP without regard to microbial growth will increase the risk of foodborne illnesses. ROP processors and regulators must assure that during distribution of foods or while foods are held by retailers or consumers, refrigerated temperatures must be consistently maintained. In fact, a serious concern is that the increased use of vacuum packaging at retail supermarket deli-type operations may be followed by temperature abuse in the establishment or by the consumer. Consequently, at least one barrier or multiple hurdles resulting in a barrier needs to be incorporated into the production process for products packaged using ROP. The incorporation of several sub-inhibitory barriers, none of which could individually inhibit microbial growth but which in combination provide a full barrier to growth (the hurdle concept), is necessary to ensure food safety.

Some products in ROP contain no preservatives and frequently do not possess any intrinsic inhibitory barriers (such as, pH, a_w, or salt concentrations) that either alone or in combination will inhibit microbial growth. Thus, product safety is not provided by natural or formulated characteristics.

A reduced oxygen atmosphere provides the potential for growth of several important foodborne pathogens. Some of these pathogens such as ***Listeria monocytogenes*** are psychrotrophic and grow slowly at temperatures near the freezing point of foods. Additionally, the inhibition of the spoilage bacteria is significant because without these competing organisms, tell-tale signs signaling that the product is no longer fit for consumption will not occur.

The use of one form of ROP, vacuum packaging, is not new. Many food products have a long and safe history of being vacuum packaged in ROP. However, the early use of vacuum packaging for smoked fish had disastrous results, causing a long-standing moratorium on certain uses of this technology at the retail level.

(1) *Refrigerated Holding Requirements for Foods in ROP*

Safe use of ROP technology demands that adequate refrigeration be maintained during the entire shelf-life of time/temperature control for safety foods to ensure product safety.

Bacteria, with the exception of those that can form spores, are eliminated by pasteurization. However, pathogens may survive in the final product if pasteurization is inadequate, poor quality raw materials or poor handling practices are used, or post-processing contamination occurs. Even if foods that are in ROP receive adequate thermal processing, a particular concern is present at retail when employees open manufactured products and repackage them. This operation presents the potential for post-processing contamination by pathogens.

If products in ROP are subjected to mild temperature abuse, i.e., 5°-12°C (41°-53°F), at any stage during storage or distribution, foodborne pathogens, including ***Bacillus cereus***, ***Salmonella*** spp., ***Staphylococcus aureus***, and ***Vibrio parahaemolyticus***, can grow slowly. Marginal refrigeration that does not facilitate growth may still allow ***Salmonella*** spp., ***Campylobacter*** spp., and ***Brucella*** spp. to survive for long periods of time.

Published surveys indicate that refrigeration practices at retail need improvement. Some refrigerated products offered in convenience stores were found at or above 7.2°C (45°F) 50% of the time; in several cases temperatures as high as 10°C (50°F) were observed. Delicatessen display cases have been shown to demonstrate poor temperature control. Foods have been observed above 10°C (50°F) and above 12.8°C (55°F) in several instances. Supermarket fresh meat cases appear to have a relatively good record of temperature control. However, even these foods can occasionally be found above 10°C (50°F).

Temperature abuse is common throughout distribution and retail markets. Strict adherence to temperature control and shelf-life must be observed and documented by the establishment using ROP. Buyer specifications for refrigerated distribution systems as well as internal time/temperature controls should be implemented by the establishment. Information on temperature control should also be provided to the consumer. Currently these controls are not extensively used.

(2) *Control of **Clostridium botulinum** and **Listeria monocytogenes** in Reduced Oxygen Packaged Foods*

There has been an increased interest in ROP at retail using conventional refrigeration units for holding. Refrigerated foods packaged at retail may be chilled either after they are physically prepared and repackaged, or packaged after a cooking step. In either case ***Clostridium botulinum*** and ***Listeria monocytogenes*** are the pathogens of concern for ROP products.

Clostridium botulinum is the causative agent of botulism, a severe food poisoning characterized by double vision, paralysis, and occasionally death. The organism is an anaerobic spore-forming bacteria that produces a potent neurotoxin. The spores are ubiquitous in nature, relatively heat-resistant, and can survive most minimal heat treatments that destroy vegetative cells. Certain strains of ***C. botulinum*** (type E and non-proteolytic types B and F), which have been primarily associated with fish, are psychrotrophic and can grow and produce toxin at temperatures as low as 3.3°C (38°F). Other strains of ***C. botulinum*** (type A and proteolytic types B and F) can grow and produce toxin at temperatures slightly above 10°C (50°F). If present, ***C. botulinum*** could potentially grow and render a food PACKAGED and held in ROP toxigenic because most other competing organisms are inhibited by ROP. Therefore, the food could be toxic yet appear organoleptically acceptable.
This is particularly true of psychrotrophic strains of ***C. botulinum*** that do not produce tell-tale proteolytic enzymes which result in a distinct bad odor. Because botulism is

potentially deadly, foods held in anaerobic conditions merit regulatory concern and vigilance.

The potential for ***Clostridium botulinum*** toxin to develop also exists when ROP is used after heat treatments such as pasteurization, or sous vide processing of foods which will not destroy the spores of ***C. botulinum***. Mild heat treatments (heat shocks) in combination with ROP may actually select for ***C. botulinum*** by killing off competitors. If the applied heat treatment does not produce commercial sterility, the food requires refrigeration below 3.3°C (38°F) to prevent spore germination and toxin formation and ensure product safety. For this reason, sous vide products are frequently frozen and held in frozen storage until use.

There is a further microbial concern with ROP at retail. Processed products such as meats and cheeses which have undergone an adequate cooking step to kill ***L. monocytogenes*** can be re-contaminated when opened, sliced, and repackaged at retail. Thus, a simple packaging or repackaging operation can present an opportunity for recontamination with pathogens if strict sanitary safeguards are not in place. Hard and semi-soft cheeses that meet the Standards of Identity for those cheeses in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese and 21 CFR 133.187 Semi-soft cheeses may be packaged using ROP without a variance. Refer to Annex 3 Public Health Reasons, Sections 3-501.17 and 3-501.18 for a partial list of hard and semi-soft cheeses.

Processors of products using ROP should build in extra safeguards if they plan to rely on refrigeration as the sole barrier that ensures product safety. This approach requires very rigorous temperature controls of products and refrigeration equipment. If extended shelf life is sought, a temperature of 3.3°C (38°F) or lower must be maintained at all times to prevent outgrowth of ***C. botulinum*** and the subsequent production of toxin. ***Listeria monocytogenes*** can grow at even lower temperatures; consequently, appropriate use-by dates must be established. Growth barriers are provided by hurdles such as low pH, a_w, or short shelf life, and constant monitoring of the product temperature. Any one hurdle, or a combination of several, may be used with refrigeration to control pathogenic outgrowth.

(3) *Design of Heat Processes for Foods in Reduced Oxygen Packages*

Heat processes for sous vide or cook-chill operations must be designed so that, at a minimum, all vegetative pathogens are destroyed by a pasteurization process and temperature control is verified. When temperature is the only barrier and no other intrinsic or extrinsic factors add protection against the growth of foodborne pathogens and formation of toxin, the product may not be sold to other business entities or to the consumer in the ROP package because of the inability to verify temperature control.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), chartered by the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (DHHS), commented on the microbial safety of refrigerated foods

containing cooked, uncured meat or poultry products that are packaged for extended refrigerated shelf life and are ready-to-eat or prepared with little or no additional heat treatment. NACMCF recommended guidelines for evaluating the ability of thermal processes to inactivate ***L. monocytogenes*** in extended shelf life refrigerated foods. Specifically, it recommended a proposed requirement for demonstrating that an ROP process provides a heat treatment sufficient to achieve a 4 decimal log reduction (4D) of ***L. monocytogenes***.

Other scientific reports recommend more extensive thermal processing. Thermal processes for sous vide practiced in Europe are designed to achieve a 12-13 log reduction (12-13D) of the target organism ***Streptococcus faecalis***. It is reasoned that thermal inactivation of this organism would ensure destruction of all other vegetative pathogens.

Food manufacturers with adequate in-house research and development programs may have the ability to design their own thermal processes. However, small retailers and supermarkets may not be able to perform the microbiological challenge studies necessary to provide the same level of food safety. If a retail establishment wishes to use an ROP process with different time-temperature parameters from those provided in Section 3-502.12 of the Food Code, microbiological inoculation studies should be performed by, or in conjunction with, an appropriate process authority or person knowledgeable in food microbiology who is acceptable to the regulatory authority.

Finally, if foods are held long enough, even under proper refrigeration, extended shelf life may be a problem. A study on fresh vegetables inoculated with ***L. monocytogenes***, conducted to determine the effect of MAP on shelf life, found that MAP lengthened the time that all vegetables were considered acceptable, but that populations of ***L. monocytogenes*** increased during that extended storage.

(4) *Consumer Handling Practices and In-Home Refrigerator Temperatures*

Extended shelf life provided by ROP is cause for concern because of the potential for abuse by the consumer. Consumers often cannot, or do not, maintain adequate refrigeration of time/temperature control for safety foods at home. Under the best of circumstances, home refrigerators can be expected to range between 5° and 10°C (41°-50°F). One study reported that home refrigerator temperatures in 21% of the households surveyed were 10°C (50°F). Another study reported more than 1 of 4 home refrigerators are above 7.2^{o}C (45°F) and almost 1 of 10 are above 10°C (50°F). Thus, refrigeration alone cannot be relied on for ensuring microbiological safety after foods in ROP leave the establishment.

Consumers have come to expect that certain packages of foods would be safe without refrigeration. Low-acid canned foods have been thermally processed, which renders the food shelf-stable. Retort heating ensures the destruction of ***C. botulinum*** spores as well as all other foodborne pathogens. Yet consumers may not understand that most products that are packaged in ROP are not commercially sterile or shelf-stable and must be refrigerated. A clear label statement to keep the product refrigerated must be provided to consumers.

The use of ROP has been extensively studied by regulators and the food industry over the past several years. Recommendations have been adapted from the Association of Food and Drug Officials "Retail Guidelines - Refrigerated Foods in Reduced Oxygen Packages" and New York State Department of Agriculture and Markets "Proposed Reduced Oxygen Packaging Regulations." As provided in the Food Code, some ROP operations may be conducted under provision 3-502.12 Reduced Oxygen Packaging, Criteria. Food that is packaged by an ROP method under these provisions is considered safe while it is under the control of the establishment and, if the labeling instructions are followed, while under the control of the consumer.

(E) Safety Barrier Verification

The safety barriers for all ROP processed foods under a variance at retail must be verified in writing. Independent laboratory analysis using methodology approved by the regulatory authority such as official methods of the AOAC International (AOAC) can also be used to verify incoming product. ROP processed foods which comply with one of the methods in Section 3-502.12 do not require written verification.

Any changes in product formulation or processing procedures should be reflected in the HACCP plan and may require further product testing for validation. A record of all safety barrier verifications should be updated every 12 months. This record must be available to the regulatory authority for review at the time of inspection.

(F) USDA Process Exemption

Meat and poultry products cured at a food processing plant regulated by the U.S. Department of Agriculture using substances specified in 9 CFR 424, Preparation and Processing Operations, are exempt from the safety barrier verification requirements. Other ROP operations may be developed that do not meet the provisions of Section 3-502.12 of the Code and that will require a variance and prior approval by the regulatory authority under Section 3-502.11.

(G) Recommendations for ROP Without Multiple Barriers

(1) *Employee Training*

If ROP is used in a food establishment, employees assigned to packaging of the foods must have documented proof that demonstrates familiarity with ROP guidelines in this Annex and the potential hazards associated with these foods. A description of the training and course content provided to the employees must either be available for review or have prior approval by the regulatory authority.

(2) *Refrigeration Requirements*

Refrigeration times and temperatures to inhibit ***C. botulinum*** and ***L. monocytogenes*** must be based on laboratory inoculation study data or follow one of the ROP methods in Section 3-502.12 which specifies the time and temperature combinations. The ROP package must be marked with a use-by date within either the manufacturer's labeled use-by date or as determined by the laboratory data, whichever comes first. Alternatively, foods packaged by ROP may be kept frozen if freezing is used as the declared primary safety barrier.

(3) *Labeling - Refrigeration Statements*

All foods offered for sale in ROP which rely on refrigeration at 5°C (41°F) or less as a barrier to microbial growth must bear the statement "Important - Must be kept refrigerated at 5°C (41°F)" or "Important - Must be kept frozen," in the case of foods which rely on freezing as a primary safety barrier. The statement must appear on the principal display panel in bold type on a contrasting background. Foods packaged using cook chill or sous vide processing methods which have lower refrigeration requirements below 5°C (41°F) as a condition of safe shelf life must be monitored for temperature history and must not be offered for retail sale in the package or sold to a different business entity. The labeling statement regarding cold holding temperatures is not required for food packaged using cook chill or sous vide processing.

(4) *Labeling - "Use-by date"*

The shelf life of ROP foods is based on storage temperature for a certain time and other intrinsic factors of the food (pH, a_w, cured with salt and nitrite, high levels of competing organisms, organic acids, natural antibiotics or bacteriocins, salt, preservatives, etc.). Each package of food in ROP must bear a "use-by" date. In some cases such as cook chill or sous vide processing when none of these intrinsic factors are present, a temperature lower than 3ºC (38ºF) must be the controlling factor for ***C.* botulinum** and ***L. monocytogenes*** growth and/or toxin formation. This “use by” date cannot exceed the number of days specified in one of the ROP methods in Section 3-502.12 or must be based on laboratory inoculation studies. The date assigned by a retail repacker cannot extend beyond the manufacturer's recommended expiration or "pull date" for the food. The "use-by" date must be listed on the principal display panel

in bold type on a contrasting background for any product sold to consumers. Any label on packages intended for consumer sale must contain a combination of a "sell-by" date and use-by instructions which makes it clear that the product must be consumed within the number of days determined to be safe as specified under Section 3-502.12 of the Food Code. Foods, especially fish, that are frozen before or immediately after packaging and remain frozen until use should bear a label statement, “Important, keep frozen until used, thaw under refrigeration immediately before use.” Raw meat and poultry packaged using ROP methods must be labeled with safe handling instructions found in 9 CFR 317.2(l) and 9 CFR 381.125(b).

(H) Foods Which Require a Variance Under Code Section 3-502.11 if Packaged in Reduced Oxygen Atmosphere

(1) Unfrozen processed fish and smoked fish may not be packed by ROP unless retail food establishments have an approved variance application and HACCP plan to show ***C. botulinum*** spore germination and toxin production or ***L. monocytogenes*** growth will not occur and are inspected by the regulatory authority. Establishments packaging such fish products, and smoking and packing establishments, must be licensed in accordance with applicable law.

(2) Soft cheeses such as ricotta, cottage cheese, cheese spreads, and combinations of cheese with other ingredients such as vegetables, meat, or fish at retail must be approved for ROP through an approved variance application and HACCP plan and be inspected by the regulatory authority.

(3) Meat or poultry products which are smoked or cured at retail, except that raw food of animal origin which is cured in a USDA-regulated processing plant, or establishment approved by the regulatory authority to cure these foods, may be smoked in accordance with approved time/temperature requirements and packaged in ROP at retail if approved by the regulatory authority. Smoking which meets the time/temperature parameters in Section 3-401.11 does not require a variance. Cold smoking where the temperature achieved by the product is greater than 41ºF requires a variance. Curing using nitrite or nitrate always requires a variance.

(I) Hazard Analysis and Critical Control Point (HACCP) Operation

All food establishments packaging food in a reduced oxygen atmosphere must develop a HACCP plan and maintain the plan at the processing site for review by the regulatory authority. For ROP operations, the plan must include the requirements specified under ¶ 8-201.14(D). In addition, the HACCP plan may also include:

(1) A complete description of the processing, packaging, and storage procedures designated as critical control points, with attendant critical limits, corrective action plans, monitoring and verification schemes, and records required;

(2) A list of equipment and food-contact packaging supplies used, including compliance standards that may be required by the regulatory authority, i.e., a recognized third party equipment evaluation organization such as NSF International;

(3) A description of the lot identification system;

(4) A description of the employee training program;
(5) A listing and proportion of food-grade gasses used; and

(6) A standard operating procedure for method and frequency of cleaning and sanitizing food-contact surfaces in the designated processing area.

(J) Precautions Against Contamination at Retail

Only unopened packages of commercially processed, ready-to-eat deli meats or cheeses obtained from sources that comply with the applicable laws relating to food safety should be used for ROP packaging at retail. If it is necessary to stop packaging for a period in excess of one-half hour, the remainder of that product should be diverted for another use in the retail establishment. Cook chill products that are cooked before packaging (ready-to-eat) should also be protected from cross-contamination before being packaged.

(K) Disposition of Expired Product at Retail

Processed reduced oxygen foods that exceed the "use-by" date or manufacturer's "pull date" cannot be sold in any form and must be disposed of in a proper manner.

(L) Dedicated Area/Restricted Access

All aspects of reduced oxygen packaging shall be conducted in an area specifically designated for this purpose. There shall be an effective separation to prevent cross contamination between raw and cooked foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in food packaged by an ROP method. Some ROP procedures such as sous vide may require a "sanitary zone" or dedicated room with restricted access to prevent contamination.

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3. SMOKING AND CURING

(A) Introduction

Meat and poultry are cured by the addition of salt alone or in combination with one or more ingredients such as sodium nitrite, sugar, curing accelerators, and spices. These are used for partial preservation, flavoring, color enhancement, tenderizing and improving yield of meat. The process may include dry curing, immersion curing, direct addition, or injection of the curing ingredients. Curing mixtures are typically composed of salt (sodium chloride), sodium nitrite, and seasonings. The preparation of curing mixtures must be carefully controlled. A number of proprietary mixtures which are uniform in composition are available. The maximum residual sodium nitrite in the finished product is limited to 200 ppm by the USDA Food Safety and Inspection Service (FSIS). A sodium nitrite concentration of 120 ppm is usually sufficient for most purposes. Specific requirements for added nitrite may be found in USDA regulations, 9 CFR 424. It is important to use curing methods which achieve uniform distribution of the curing mixture in the meat or poultry product.

(B) Definitions

Cured meat and poultry can be divided into three basic categories: (1) uncomminuted smoked products; (2) sausages; and (3) uncomminuted unsmoked processed meats.

(1) *Uncomminuted smoked products* - include bacon, beef jerky, hams, pork shoulders, turkey breasts, turkey drumsticks.

(2) *Sausages* - include both finely ground and coarse ground products. Finely ground sausages include bologna, frankfurters, luncheon meats and loaves, sandwich spreads, and viennas. Coarse ground sausages include chorizos, kielbasa, pepperoni, salami, and summer sausages.

(3) *Cured sausages* - may be categorized as: (1) raw, cured; (2) cooked, smoked; (3) cooked, unsmoked; and (4) dry, semidry, or fermented.

(4) *Uncomminuted, unsmoked processed products* - include corned beef, pastrami, pig's feet, corned tongues. This category of products may be sold as either raw ready-to-cook or ready-to-eat.

(C) Incorporation of Cure Ingredients

Regardless of preparation method, cure ingredients must be distributed throughout the product. Cure ingredients may be introduced into sausage products during mixing or comminuting. Proper and thorough mixing is necessary whether the cure is added to the formulation in dry or solution form. Muscle cuts may be cured by immersion into a curing (pickle) solution. These methods depend on slow diffusion of the curing agents through the product. Products must be properly refrigerated during immersion curing.

Several methods may be used to shorten curing times. These include hot immersion curing greater than 49°C (>120°F), injection by arterial pumping (e.g., hams), and stitch pumping by a series of hollow needles. If the injection method is used, injection needles must be frequently monitored during processing to ensure that they are not fouled or plugged.

Tumbling or massaging may also be used as an aid to hasten curing. Proper sanitation must be observed to prevent contamination during this operation.

The dry curing method, a similar process, may also be used. In this case, curing ingredients are rubbed over cuts and surfaces of meat held under refrigeration. Precautions must include wearing sanitary gloves when meat is handled. Product temperature maintenance is critical.

(D) Smoking

Smoking is the process of exposing meat products to wood smoke. Depending on the method, some products may be cooked and smoked simultaneously, smoked and dried without cooking, or cooked without smoking. Smoke may be produced by burning wood chips or using an approved liquid smoke preparation. Liquid smoke preparations may also be substituted for smoke by addition directly onto the product during formulation in lieu of using a smokehouse or another type of smoking vessel. As with curing operations, a standard operating procedure must be established to prevent contamination during the smoking process.

(E) Fermentation and Dehydration

Meat may be fermented or dehydrated for preservation. The purpose of fermentation is to reduce the pH to below 4.6 and inhibit bacteria harmful to health as well as bacteria which can cause spoilage. Meat products may also be cured and then dehydrated to prevent germination and growth of bacterial spores. Many fermented and dehydrated meats are made without a cooking step. Sanitary practices in the production of these products are extremely important because ***Staphylococcus aureus*** can be introduced. ***Staphylococcus aureus*** produces an enterotoxin that is heat stable and thus will not be inactivated by subsequent cooking.

Processed pork products require treatment to destroy ***Trichinella spiralis***. At retail, products which contain raw pork and which are not subsequently cooked must be produced from certified trichina-free pork or treated to destroy trichinae. USDA regulations, 9 CFR 318.10(c)(3), establish various requirements for destroying trichina in pork by heating, freezing, drying, or smoking.

Some fermented and dry cured products are processed without cooking. The labeling for these products should include instructions to the consumer to cook thoroughly before consumption.

(F) Recommendations for Safe Curing of Meat and Poultry

(1) *Posting of Acceptable Products*

A list of products approved by the regulatory authority, or by an approved knowledgeable authority on curing acceptable to the regulatory authority, must be posted in the processing area of the establishment.

(2) *Employee Training*

Employees assigned to cure meat or poultry must demonstrate familiarity with these guidelines and the potential hazards associated with curing foods. A description of the training and course content provided to the employees must be available for review by the regulatory authority.

(3) *HACCP*

A HACCP plan is needed for all curing operations. The following recommendations must be met to cure meat and poultry products in the establishment. References are available from local USDA extension offices, public libraries, and college or university food or meat science departments to develop HACCP plans for curing meat and poultry.

(a) *Critical Control Points*

The following are critical control points to be addressed:

(i) Purchase of prepared cure mixes; or

(ii) If cure mixes are blended on the premises instead of acquired pre-mixed, mixing must be carefully controlled by using calibrated weighing devices.

(iii) Cure ingredients must be stored in a dry location. Cure must be discarded if the package is wet or appears to have been wetted.

(b) *Raw Material Handling*

(i) Thawing must be monitored and controlled to ensure thoroughness and to prevent temperature abuse. Improperly thawed meat could cause insufficient cure penetration. Temperature abuse can cause spoilage or growth of pathogens.

(ii) Meat must be fresh. Curing may not be used to salvage meat that has excessive bacterial growth or spoilage.

(c) Formulating, Preparation and Curing

(i) A formulation and preparation procedure must be documented.

(ii) All equipment and utensils must be cleaned and sanitized.

(iii) Pieces must be prepared to uniform sizes to ensure uniform cure penetration. This is extremely critical for dry and immersion curing.

(iv) Calibrated scales must be used to weigh ingredients.

(v) A schedule or recipe must be established for determining the exact amount of curing formulation to be used for a specified weight of meat or meat mixture.

(vi) Methods and procedures must be strictly controlled to ensure uniform cure.

(vii) Mixing of curing formulation with comminuted ingredients must be controlled and monitored.

(viii) All surfaces of meat must be rotated and rubbed at intervals of sufficient frequency to ensure cure penetration when a dry curing method is used.

(ix) Immersion curing requires periodic mixing of the batch to facilitate uniform curing.

(x) The application of salt during dry curing of muscle cuts requires that the temperature of the product be strictly controlled between 1.7°C (35°F) and 7.2°C (45°F). The lower temperature is set to limit microbial growth and the upper temperature is set for the purpose of ensuring cure penetration. Refer to USDA regulations 9 CFR 318.10(c)(3)(iv) for specific details on dry curing.

(xi) Curing solutions must be discarded daily unless they remain with the same batch of product during its entire curing process.

(xii) Injection needles must be inspected for plugging when stitch pumping or artery pumping of muscle cuts is performed.

(xiii) Sanitary casings must be provided for sausage, chub or loaf forming.

(xiv) Casings may not be stripped for reuse in forming additional chubs or sausages from batch to batch.

(xv) Hot curing of bacon bellies, hams, or any other products must be performed at >49°C (120°F) as specified in 9 CFR 318.

(d) *Cooking and/or Smoking*

(i) When smokehouses are initially installed or structurally modified, calibration of product heating characteristics must be ascertained by competent food technologists. Tests should be run with full range of anticipated product loading. Verification of even airflow and moisture should be recorded in operational records of the smokehouse for these various loads.

(ii) Procedures for delivering the appropriate thermal treatment of cooked meats in conformance with the *Food Code* must be developed and used. (Also see 9 CFR 318.17 and 318.23 for USDA requirements for meat products.) A minimum of 73.9°C (165°F) should be used for cured poultry products.

(iii) Cooking equipment that provides even temperature control of the heating medium must be used.

(iv) Products must be adequately separated to prevent overlap in the cooking media whether immersed in hot water, sprayed with hot water, steamed, or oven heated.

(v) Calibrated temperature measuring devices must be used for

determining internal product temperatures.

(vi) Temperature measuring device probes must be sanitized to prevent contaminating products when internal temperatures are measured.

(vii) Calibrated temperature measuring devices must be used for measuring temperatures of the heating medium.

(viii) Raw products must be separated from cooked products.

(ix) Time/temperature parameters of the cooking process must be monitored and recorded. In some processes, the heating medium temperature should also monitored.

(e) *Cooling*

(i) Cooling must be done in accordance with recommendations in the *Food Code* or under a variance. The USDA Cooling Guideline, FSIS Directive 7110.3 for special procedures for cured products, provides specific guidance.

(ii) Written cooling procedures must be established.

(iii) Chill water used in water sprays or immersion chilling which is in direct contact with products in casings or products cooked in an impervious package must be properly chlorinated.

(iv) Chill water temperature must be monitored and controlled.

(v) Chill water may not be reused until properly chlorinated. Reclaimed chill water must be discarded daily.

(vi) Product must be placed in a manner that allows chilled water or air to uniformly contact the product for assurance of uniform cooling.

(vii) Internal temperatures must be monitored during cooling by using calibrated temperature measuring devices.

(viii) Adequate cooling medium circulation must be maintained and monitored.

(ix) Temperatures of the cooling medium must be monitored and recorded in accordance with a written procedure.

(x) Handling of product must be minimized during cooling, peeling of

casing, and packaging. Sanitary gloves must be used in these procedures.

(f) *Fermentation and Drying*

(i) Temperature and time must be controlled and logs must be maintained that record the monitoring of this process.

(ii) Humidity must be controlled by use of a humidistat. Monitoring of the process must be recorded in a written log.

(iii) Product must be kept separated to allow adequate air circulation during the process.

(iv) Use of an active and pure culture must be ensured to effect a rapid pH drop of the product. Use of commercially produced culture is necessary and the culture must be used according to the manufacturer's instructions.

(v) Determination of the pH of fermented sausages at the end of the fermentation cycle must be recorded.

(vi) Handling of products must be minimized and only done with sanitary gloves or sanitized utensils.

(vii) Dry (unfermented) products may not be hot smoked until the curing and drying procedures are completed.

(viii) Semi-dry fermented sausage must be heated after fermentation to a time/temperature sufficient to control growth of pathogenic and spoilage organisms of concern.

(4) *Dedicated Area/Restricted Access*

All aspects of curing operations must be conducted in an area specifically designated for this purpose. There must be an effective separation to prevent cross contamination between raw and cooked foods or cured and uncured foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in curing foods.

(5) *Equipment Cleaning and Sanitizing*

The procedures for cleaning and sanitization must be accomplished according to parts 4-6 and 4-7 of the Food Code.

(G) References

Judge, M., E. Aberle, J. Forrest, H. Hedrick, and R. Merkel, 1984. *Principles of Meat Science*. Kendall/Hunt Publishing Company, Dubuque, IA.

Price, J. and B. Schweigert, 1978. *The Science of Meat and Meat Products*. Food and Nutrition Press, Inc., Westport, CT.

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Annex

7 Model Forms, Guides, and Other Aids

1) Employee health information and Application form for bare hand contact Procedure

   a) Form 1-A CONDITIONAL EMPLOYEE OR FOOD EMPLOYEE INTERVIEW
   b) Form 1-B CONDITIONAL EMPLOYEE OR FOOD EMPLOYEE REPORTING AGREEMENT
   c) Form 1-C CONDITIONAL EMPLOYEE OR FOOD EMPLOYEE MEDICAL REFERRAL
   d) Form 1-D APPLICATION FOR BARE HAND CONTACT PROCEDURE

2) Adoption information

   a) Form 2-A ADOPTION BY REFERENCE
   b) Form 2-B ADOPTION BY SECTION-BY-SECTION REFERENCE

3) Inspection information

   a) Form 3-A FOOD ESTABLISHMENT INSPECTION REPORT
   b) Guide 3-B INSTRUCTIONS FOR MARKING THE FOOD ESTABLISHMENT INSPECTION REPORT, INCLUDING FOOD CODE REFERENCES FOR RISK FACTORS/INTERVENTIONS AND GOOD RETAIL PRACTICES

4) Summary information

   a) Chart 4-A SUMMARY CHART FOR MINIMUM COOKING FOOD TEMPERATURES AND HOLDING TIMES REQUIRED BY CHAPTER 3
   b) Chart 4-B SUMMARY CHART FOR MINIMUM FOOD TEMPERATURES AND HOLDING TIMES REQUIRED BY CHAPTER 3 FOR REHEATING FOODS FOR HOT HOLDING
   c) Chart 4-C SUMMARY CHART – READY-TO-EAT, TIME/TEMPERATURE, CONTROL FOR SAFETY FOOD (TCS) DATE MARKING § 3-501.17(A) – (E) AND DISPOSITION § 3-501.18
   d) Chart 4-D FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX
   e) Summary of Changes in the FDA Food Code

The documents provided in this Annex are intended to facilitate adoption of the Food Code and the application of its provisions as they relate to conditional employees' and food employees' health and to food establishment inspections.

Forms 1-A through 1-C are designed to assist those responsible for managing employees in order to prevent foodborne disease. The Food Code specifies that the **permit holder is responsible** for requiring conditional employees or food employees to report certain symptoms, diagnoses, and past illnesses, as they relate to diseases transmitted through food by infected workers. The **conditional employee or food employee is personally responsible** for reporting this information to the person in charge.

Form 1-D is a user-aid for a regulatory agency when considering a request to allow bare hand contact with ready-to-eat food.

Forms 2-A and 2-B can be used for the Code adoption process and Form 3-A is provided for use in recording HACCP information and inspectional observations and has been updated for consistency with changes made in the Supplement to the 2009 Food Code.

Guide 3-B, *Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices* has been updated to be consistent with changes made in the Supplement to the 2009 Food Code. The major headings from the Food Establishment Inspection Report form are condensed in Guide 3-B to key word phrases to assist the person conducting inspections in locating the Food Code citation that corresponds to a given violation and recording inspectional observations.

Guide 3-B is intended to be used during inspections to ensure that observations of the provisions of the Code are not overlooked during the inspection and accurately recorded on the Food Code Establishment Inspection Report form.

FORM 1-A

Conditional Employee and Food Employee Interview

Preventing Transmission of Diseases through Food by Infected Food Employees or Conditional Employees with Emphasis on Illness due to Norovirus, *Salmonella* Typhi (*S.* Typhi), *Shigella* spp., ShigaToxin-producing *Escherichia coli* (STEC), nontyphoidal *Salmonella* or Hepatitis A Virus

The purpose of this interview is to inform conditional employees and food employees to advise the person in charge of past and current conditions described so that the person in charge can take appropriate steps to preclude the transmission of foodborne illness.

Conditional Employee Name (print) _____
Food Employee Name (print) _____
Address _____
Telephone *Daytime:*_____ *Evening:* _____
Date _____

Are you suffering from any of the following symptoms? (Circle one)

		If YES, Date <u>of Onset</u>
Diarrhea?	**YES / NO**	_____
Vomiting?	**YES / NO**	_____
Jaundice?	**YES / NO**	_____
Sore throat with fever?	**YES / NO**	_____

Or

Infected cut or wound that is open and draining, or lesions containing pus on the hand, wrist, an exposed body part, or other body part and the cut, wound, or lesion not properly covered? **YES / NO**
(Examples: *boils and infected wounds, however small)*

<u>In the Past</u>:

Have you ever been diagnosed as being ill with typhoid fever (*S.*Typhi) **YES / NO**
If you have, what was the date of the diagnosis? _____
If within the past 3 months, did you take antibiotics for *S.* Typhi*?* **YES / NO**
If so, how many days did you take the antibiotics? _____
If you took antibiotics, did you finish the prescription? _____ **YES / NO**

<u>History of Exposure</u>:

1. Have you been suspected of causing, or have you been exposed to, a confirmed foodborne disease outbreak recently? **YES / NO**
If YES, date of outbreak: _____

a. If YES, what was the cause of the illness and did it meet the following criteria?
Cause: _____

i.	**Norovirus (last exposure within the past 48 hours)**	**Date of illness outbreak** _____
ii.	***E. coli* O157:H7 infection (last exposure within the past 3 days)**	**Date of illness outbreak** _____
iii.	**Hepatitis A virus (last exposure within the past 30 days)**	**Date of illness outbreak** _____
iv.	**Typhoid fever (last exposure within the past 14 days)**	**Date of illness outbreak** _____
v.	**Shigellosis (last exposure within the past 3 days)**	**Date of illness outbreak** _____

b. If YES, did you:

- **i. Consume food implicated in the outbreak? _____**
- **ii. Work in a food establishment that was the source of the outbreak? _____**
- **iii. Consume food at an event that was prepared by person who is ill? _____**

2. Did you attend an event or work in a setting, recently where there was a confirmed disease outbreak? YES / NO

If so, what was the cause of the confirmed disease outbreak? _____

If the cause was one of the following five pathogens, did exposure to the pathogen meet the following criteria?

- **a. Norovirus (last exposure within the past 48 hours) YES / NO**
- **b. *E. coli* O157:H7 (or other STEC (last exposure within the past 3 days) YES / NO**
- **c. *Shigella* spp. (last exposure within the past 3 days) YES / NO**
- **d. *S.* Typhi (last exposure within the past 14 days) YES / NO**
- **e. Hepatitis A virus (last exposure within the past 30 days) YES / NO**

Do you live in the same household as a person diagnosed with Norovirus, shigellosis, typhoid fever, hepatitis A, or illness due to *E. coli* O157:H7 or other STEC?
YES / NO Date of onset of illness _____

3. Do you have a household member attending or working in a setting where there is a confirmed disease outbreak of Norovirus, typhoid fever, shigellosis, STEC infection, or hepatitis A?
YES / NO Date of onset of illness _____

Name, Address, and Telephone Number of your Health Practitioner or doctor:
Name _____
Address _____
Telephone – *Daytime:* _____ *Evening:* _____

Signature of Conditional Employee _____ Date _____

Signature of Food Employee _____ Date _____

Signature of Permit Holder or Representative _____ Date _____

FORM 1-B

Conditional Employee or Food Employee Reporting Agreement

Preventing Transmission of Diseases through Food by Infected Conditional Employees or Food Employees with Emphasis on Illness due to Norovirus, *Salmonella* Typhi, *Shigella* spp., or Shiga toxin-producing *Escherichia coli* (STEC), nontyphoidal *Salmonella* or Hepatitis A Virus

The purpose of this agreement is to inform conditional employees or food employees of their responsibility to notify the person in charge when they experience any of the conditions listed so that the person in charge can take appropriate steps to preclude the transmission of foodborne illness.

I AGREE TO REPORT TO THE PERSON IN CHARGE:

Any Onset of the Following Symptoms, Either While at Work or Outside of Work, Including the Date of Onset:

1. Diarrhea
2. Vomiting
3. Jaundice
4. Sore throat with fever
5. Infected cuts or wounds, or lesions containing pus on the hand, wrist , an exposed body part, or other body part and the cuts, wounds, or lesions are not properly covered (*such as boils and infected wounds, however small)*

Future Medical Diagnosis:

Whenever diagnosed as being ill with Norovirus, typhoid fever (*Salmonella* Typhi), shigellosis (*Shigella* spp. infection), *Escherichia* coli O157:H7 or other STEC infection, nontyphoidal *Salmonella* or hepatitis A (hepatitis A virus infection)

Future Exposure to Foodborne Pathogens:

1. Exposure to or suspicion of causing any confirmed disease outbreak of Norovirus, typhoid fever, shigellosis, *E.* coli O157:H7 or other STEC infection, or hepatitis A.
2. A household member diagnosed with Norovirus, typhoid fever, shigellosis, illness due to STEC, or hepatitis A.
3. A household member attending or working in a setting experiencing a confirmed disease outbreak of Norovirus, typhoid fever, shigellosis, *E.* coli O157:H7 or other STEC infection, or hepatitis A.

I have read (or had explained to me) and understand the requirements concerning my responsibilities under the **Food Code** and this agreement to comply with:

1. Reporting requirements specified above involving symptoms, diagnoses, and exposure specified;
2. Work restrictions or exclusions that are imposed upon me; and
3. Good hygienic practices.

I understand that failure to comply with the terms of this agreement could lead to action by the food establishment or the food regulatory authority that may jeopardize my employment and may involve legal action against me.

Conditional Employee Name (please print) _____

Signature of Conditional Employee _____ **Date** _____

Food Employee Name (please print) _____

Signature of Food Employee _____ **Date** _____

Signature of Permit Holder or Representative _____ **Date** _____

FORM 1-C

Conditional Employee or Food Employee Medical Referral

Preventing Transmission of Diseases through Food by Infected Food Employees with Emphasis on Illness due to Norovirus, Typhoid fever (*Salmonella* Typhi), Shigellosis (*Shigella* spp.), *Escherichia coli* O157:H7 or other Shiga Toxin-producing *Escherichia* coli (STEC), nontyphoidal *Salmonella* and Hepatitis A Virus

The **Food Code** specifies, under ***Part 2-2 Employee Health Subpart 2-201 Disease or Medical Condition***, that Conditional Employees and Food Employees obtain medical clearance from a health practitioner licensed to practice medicine, unless the Food Employees have complied with the provisions specified as an alternative to providing medical documentation, whenever the individual:

1. Is chronically suffering from a symptom such as **diarrhea;** *or*
2. Has a **current illness** involving Norovirus, typhoid fever **(*Salmonella* Typhi)**, shigellosis **(*Shigella*** spp.**)** ***E. coli* O157:H7** infection (or other STEC), nontyphoidal *Salmonella* or hepatitis A virus (hepatitis A), *or*
3. Reports ***past illness*** involving typhoid fever **(*S.* Typhi)** within the past three months (while salmonellosis is fairly common in U.S., typhoid fever, caused by infection with ***S.* Typhi**, is rare).

Conditional Employee being referred: (Name, please print) _____

Food Employee being referred: (Name, please print) _____

4. Is the employee assigned to a food establishment that serves a population that meets the Food Code definition of a **highly susceptible population** such as a day care center with preschool-age children, a hospital kitchen with immunocompromised persons, or an assisted living facility or nursing home with older adults?
YES ☐ **NO** ☐

Reason for Medical Referral: The reason for this referral is checked below:

☐ Is chronically suffering from vomiting or diarrhea; or (specify) _____
☐ Diagnosed or suspected Norovirus, typhoid fever, shigellosis, ***E. coli*** O157:H7 (or other STEC) infection, nontyphoidal *Salmonella* or hepatitis A. (Specify)
_____
☐ Reported past illness from typhoid fever within the past 3 months. (Date of illness) _____
☐ Other medical condition of concern per the following description: _____

Health Practitioner's Conclusion: (Circle the appropriate one; refer to reverse side of form)

☐ Food employee is free of **Norovirus** infection, typhoid fever **(*S.* Typhi** infection**), *Shigella*** spp. infection, ***E. coli*** O157:H7 (or other **STEC** infection), nontyphoidal *Salmonella* infection or **hepatitis A** virus infection, and may work as a food employee without restrictions.
☐ Food employee is an asymptomatic shedder of ***E.*** coli O157:H7 (or other **STEC**), ***Shigella*** spp., or Norovirus, and is restricted from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles in food establishments that do not serve highly susceptible populations.
☐ Food employee is not ill but continues as an asymptomatic shedder of ***E. coli*** O157:H7 (or other **STEC**), ***Shigella*** spp. and should be excluded from food establishments that serve highly susceptible populations such as those who are preschool-age, immunocompromised, or older adults and in a facility that provides preschool custodial care, health care, or assisted living.
☐ Food employee is an asymptomatic shedder of **hepatitis A** virus and should be excluded from working in a food establishment until medically cleared.
☐ Food employee is an asymptomatic shedder of **Norovirus** and should be excluded from working in a food establishment until medically cleared, or for at least 24 hours from the date of the diagnosis.
☐ Food employee is suffering from Norovirus, typhoid fever, shigellosis, ***E. coli*** O157:H7 (or other **STEC** infection), or **hepatitis A** and should be excluded from working in a food establishment.
☐ Food employee is diagnosed with an infection from nontyphoidal *Salmonella* and is asymptomatic and

should be restricted from working in food establishments serving a highly susceptible population and food establishments not serving a highly susceptible population.

COMMENTS: (In accordance with Title I of the Americans with Disabilities Act (ADA) and to provide only the information necessary to assist the food establishment operator in preventing foodborne disease transmission, please confine comments to explaining your conclusion and estimating when the employee may be reinstated.)

_____

_____

_____

_____

_____

_____

_____

_____

Signature of Health Practitioner _____ **Date** _____

Paraphrased from the FDA Food Code for Health Practitioner's Reference

From Subparagraph 2-201.11(A)(2) Organisms of Concern:

Any foodborne pathogen, with special emphasis on these ~~5~~6 organisms:

1. **Norovirus** 2. ***S.* Typhi** 3. ***Shigella*** spp. 4. ***E. coli*** O157:H7 (or other STEC) 5. **Hepatitis A** virus 6. Nontyphoidal *Salmonella*

From Subparagraph 2-201.11(A)(1) Symptoms:

Have any of the following symptoms:

Diarrhea **Vomiting** **Jaundice** **Sore throat with fever**

From Subparagraph 2-201.11(A)(4)-(5) Conditions of Exposure of Concern:

(1) Suspected of causing a foodborne outbreak or being exposed to an outbreak caused by Norovirus, S. Typhi, *Shigella* spp., E. coli o157:H7 (or other STEC), Hepatitis A virus , at an event such as a family meal, church supper, or festival because the person:
Prepared or consumed an implicated food;
or consumed food prepared by a person who is infected or ill with the organism that caused the outbreak or who is suspected of being a carrier;

(2) Lives with, and has knowledge about, a person who is diagnosed with illness caused by Norovirus, S. Typhi, *Shigella* spp., E. coli o157:H7 (or other STEC), Hepatitis A virus ; or

(3) Lives with, and has knowledge about, a person who works where there is an outbreak caused by Norovirus, S. Typhi, *Shigella* spp., E. coli o157:H7 (or other STEC), Hepatitis A virus -

From Subparagraph 2-201.12 Exclusion and Restriction:

Decisions to exclude or restrict a food employee are made considering the available evidence about the person=s role in actual or potential foodborne illness transmission. Evidence includes:

Symptoms **Diagnosis** **Past illnesses** **Stool/blood tests**

In facilities serving highly susceptible populations such as day care centers and health care facilities, a person for whom there is evidence of foodborne illness is almost always excluded from the food establishment.

In other establishments such as restaurants and retail food stored, that offer food to typically healthy consumers, a person might only be restricted from certain duties, based on the evidence of foodborne illness.

Exclusion from any food establishment is required when the person is:

- Exhibiting or reporting diarrhea or vomiting;
- Diagnosed with illness caused by *S.* Typhi; or
- Jaundiced within the last 7 days.

For ***Shigella*** spp. or ***Escherichia coli*** O157:H7 or other STEC infections, the person's stools must be negative for 2 consecutive cultures taken no earlier than 48 hours after antibiotics are discontinued, and at least 24 hours apart or the infected individual must have resolution of symptoms for more than 7 days or at least 7 days have passed since the employee was diagnosed.

FORM 1-D	Application for Bare Hand Contact Procedure (As specified in Food Code ¶ 3-301.11(E))

Please type or print legibly using black or blue ink

1. **Establishment Name:** _____

2. **Establishment Address:** _____

3. **Responsible Person:** _____ **Phone:** _____
   Legal Representative Business

4. **List Procedure and Specific Ready-To-Eat-Foods** to be considered for use of bare hand contact with ready-to-eat foods:
_____
_____
_____

5. **Handwashing Facilities**:

(a) There is a handwashing sink located immediately adjacent to the posted bare hand contact procedure and the hand sink is maintained in accordance with provisions of the Code. (§ 5-205.11, § 6-301.11, § 6-301.12, § 6-301.14) ☐ YES ☐ NO (Include diagram, photo or other information)

(b) All toilet rooms have one or more handwashing sinks in, or immediately adjacent to them, and the sinks are equipped and maintained in accordance with provisions of the Code. (§ 5-205.11, § 6-301.11, § 6-301.12, § 6-301.14) ☐ YES ☐ NO

6. **Employee Health Policy:** The written employee health policy must be attached to this form along with documentation that food employees and conditional employees acknowledge their responsibilities. (§ 2-201.11, § 2-201.12, § 2-201.13)

7. **Employee Training**: Provide documentation that food employees have received training in:

- The risks of contacting the specific ready-to-eat foods with bare hands
- Personal health and activities as they relate to diseases that are transmissible through food.
- Proper handwashing procedures to include how, when, where to wash, & fingernail maintenance. (§ 2-301.12, § 2-301.14, § 2-301.15, § 2-302.11)
- Prohibition of jewelry. (§ 2-303.11)
- Good hygienic practices. (§ 2-401.11, § 2-401.12)

8. **Documentation of Handwashing Practices:** Provide documentation that food employees are following proper handwashing procedures prior to food preparation and other procedures as necessary to prevent cross-contamination during all hours of operation when the specific ready-to-eat foods are prepared or touched with bare hands.

9. **Documentation of Additional Control Measures:** Provide documentation to demonstrate that food employees are utilizing two or more of the following control measures when contacting ready-to-eat foods with bare hands:

- Double handwashing;
- Use of nailbrushes;
- Use of hand antiseptic after handwashing;
- Incentive programs such as paid leave encouraging food employees not to work when they are ill; or
- Other control measures approved by the regulatory authority.

Statement of Compliance:

I certify all of the following: All food employees are individually trained in the risks of contacting ready-to-eat foods with bare hands, personal health and activities as they relate to diseases that are transmissible through food, proper handwashing procedures, prohibition of jewelry, and good hygienic practices. A record of this training is kept on site. I understand that bare hand contact with ready-to-eat food is prohibited except for those items listed in section four (4) above. A handwashing sink is located immediately adjacent to the posted bare hand contact procedure. All handwashing sinks are maintained with hot water, soap, and drying devices. I understand that documentation is needed for handwashing practices and additional control measures. I understand that records to document handwashing are kept current and kept on site.

SIGNATURE:_____ DATE _____
(Signature of legal representative of the facility listed above)

Regulatory Authority (RA) Use Only:

Permit Number: _____

File Review Conducted on History of Handwashing Compliance: ☐ Yes ☐ No

Site Visit Conducted ☐ Yes ☐ No Comments: _____

☐ Approved: Effective Date: _____ RA name _____

☐ Not Approved: Reason for Denial:
_____

FORM 2-A	Adoption by Reference

This "short form" may be used by governmental bodies adopting the Food Code where authorized by law. Use of the adoption by reference form may substantially reduce the cost of publishing and printing.

The description of the Food Code, below, includes Chapter 8 and the Chapter 8 annex (Annex 1). Modifications to the description may be necessary, based on what provisions are being adopted and whether they are being adopted as law or regulation.

Section 2 lists provisions that may require modifications to be consistent with existing law or that require insertion of dollar amounts.

(JURISDICTION) FOOD CODE

(**statute/regulation/ordinance**) Number

ADOPTING THE 2009 EDITION OF THE "FOOD CODE" REGULATING THE RETAIL SALE, COMMERCIAL AND INSTITUTIONAL SERVICE, AND VENDING OF FOOD; DEFINING PERMIT HOLDER, PERSON IN CHARGE, EMPLOYEE, FOOD, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, FOOD ESTABLISHMENT, SAFE MATERIAL, SANITIZATION, AND OTHER TERMS; AND PROVIDING STANDARDS FOR EMPLOYEE FOOD SAFETY KNOWLEDGE, HEALTH, AND PRACTICES; FOOD SOURCES, PREPARATION, HOLDING TEMPERATURES, AND PROTECTION; EQUIPMENT DESIGN, CONSTRUCTION, INSTALLATION, CLEANING, AND SANITIZATION; WATER, AND LIQUID AND SOLID WASTES; FACILITIES CONSTRUCTION AND MAINTENANCE, AND STORAGE AND USE OF POISONOUS AND TOXIC MATERIALS; REQUIRING A PERMIT TO OPERATE A FOOD ESTABLISHMENT; AND PROVIDING FOR THE RESTRICTION OR EXCLUSION OF EMPLOYEES, THE EXAMINATION AND CONDEMNATION OF FOOD, AND THE ENFORCEMENT OF THIS CODE INCLUDING THE SETTING OF PENALTIES.

The **(governing body)** of the **(jurisdiction)** does ordain as follows:

SECTION 1. ADOPTION OF FOOD CODE

That a certain document, three copies of which are on file in the office of the **(jurisdiction's keeper of records)** of the **(type of jurisdiction)** of **(name of jurisdiction)** being marked and designated as the *Food Code, 2009 Recommendations of the United States Public Health Service/Food and Drug Administration* as published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration be, and is hereby adopted as, the Food Code of **(type of jurisdiction)** of **(name of jurisdiction)** in the State of **(state name)**; for regulating the design, construction, management, and operation of food establishments, and providing for plans submission and approval and the issuance of permits and collection of fees therefore.

SECTION 2. INSERTIONS AND CHANGES

That the following provisions are hereby revised as follows:

Paragraph 8-911.10(B)(1) and (2) Insert **(Dollar Amount)**
Paragraph 8-913.10(B) Insert **(Dollar Amounts)**
Subparagraph 8-911.10(B)(2) Insert **(Number of Year(s))**

SECTION 3. INCONSISTENT CODES REPEALED

That **(statute/regulation/ordinance)** number **(present code number)** of the **(jurisdiction)** titled, **(complete title of the food code[s] in effect at the present time so they will be repealed by definite mention)** and all other codes or portions of codes in conflict herewith are hereby repealed in that respect only.

SECTION 4. CERTIFICATION OF ADOPTION AND PUBLISHING

That the **(jurisdiction's keeper of records)** shall certify the adoption of this **(statute/regulation/ordinance** and cause the same to be published as required by law.

SECTION 5. EFFECTIVE DATE

That this Code and the rules, regulations, provisions, requirements, orders, and matters established and adopted hereby shall take effect and be in full force and effect **(time period)** from and after the date of its final passage and approval.

PASSED AND APPROVED BY **(name of adopting authority)** on this **(day)** of **(month, year)**.

BY:

Examples of how some jurisdictions have set fines, sentences, and penalties:

California law provides:

A. For Wholesale Food Violations:

Criminal fines and sentence for violations of up to **$1,000** and up to **one** year imprisonment if there is shown an intent to defraud or mislead, and

Civil penalties of up to **$1,000** per day for certain violations.

B. For Retail Food Violations:

Criminal fines and sentence for violations of not less than twenty-five dollars ($25) or more than one thousand dollars ($1000) for each offense, or by imprisonment in the county jail for a term not exceeding six months, or by both such fine and imprisonment.

Maryland law provides:

Criminal fines and sentence for certain misdemeanors of up to **$10,000** and **one** year imprisonment, and in the case of repeat code violation convictions, up to **$25,000** and **three** years imprisonment; and

Civil penalties of up to **$5,000** for each violation and for each day the violation continues.

Texas law provides:

Criminal fines and sentence for certain violations of up to **$10,000** and **two** years imprisonment; and

Assessment of five "severity" levels of administrative or civil penalties with base amounts ranging from **$1,250** through **$10,000.** Base amounts can be decreased or increased by as much as 50% considering factors such as past performance, good faith, direct impact on health and safety, high-risk populations involved, etc.

Though rarely used with retail food establishments, **Federal** law provides under the *Criminal Fine Enforcement Act of 1984* for a fine up to **$100,000** for a misdemeanor by a corporation or individual not resulting in death and, for misdemeanors resulting in death, a fine of up to **$250,000** for individuals and **$500,000** for corporations.

FORM 2-B	Adoption by Section-by-Section Reference

This "long form" may be used by governmental bodies adopting the Food Code section-by-section.

The description of the "Food Code," below, includes Chapter 8 and the Chapter 8 annex (Annex 1). Modifications to the description may be necessary, based on what provisions are being adopted and whether they are being adopted as law or regulation.

Section 2 lists provisions that may require modifications to be consistent with existing law or that require insertion of dollar amounts.

(JURISDICTION) FOOD CODE

(statute/regulation/ordinance) Number

ADOPTING A CODE REGULATING THE RETAIL SALE, COMMERCIAL AND INSTITUTIONAL SERVICE, AND VENDING OF FOOD; DEFINING PERMIT HOLDER, PERSON IN CHARGE, EMPLOYEE, FOOD, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, FOOD ESTABLISHMENT, SAFE MATERIAL, SANITIZATION, AND OTHER TERMS; AND PROVIDING STANDARDS FOR EMPLOYEE FOOD SAFETY KNOWLEDGE, HEALTH, AND PRACTICES; FOOD SOURCES, PREPARATION, HOLDING TEMPERATURES, AND PROTECTION; EQUIPMENT DESIGN, CONSTRUCTION, INSTALLATION, CLEANING AND SANITIZATION; WATER, AND LIQUID AND SOLID WASTES; FACILITIES CONSTRUCTION AND MAINTENANCE, AND STORAGE AND USE OF POISONOUS AND TOXIC MATERIALS; REQUIRING A PERMIT TO OPERATE A FOOD ESTABLISHMENT; AND PROVIDING FOR THE RESTRICTION OR EXCLUSION OF EMPLOYEES, THE EXAMINATION AND CONDEMNATION OF FOOD, AND THE ENFORCEMENT OF THIS CODE INCLUDING THE SETTING OF PENALTIES.

The **_(governing body)_** of the **_(jurisdiction)_** does ordain as follows:

(REPRINT THE *FOOD CODE, ___(date)___ RECOMMENDATIONS OF THE UNITED STATES PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION,* SECTION-BY-SECTION)

SECTION 2. INSERTIONS AND CHANGES

That the following provisions may need to be completed as follows:

Paragraph 8-911.10(B)(1) and (2) Insert (**Dollar Amount**)
Paragraph 8-913.10(B) Insert **(Dollar Amounts)**
Subparagraph 8-911.10(B)(2) Insert **(Number of Year(s))**

SECTION 3. INCONSISTENT CODES REPEALED

That **_(statute/regulation/ordinance)_** number **_(present code number)_** of the **_(jurisdiction)_** titled, **(complete title of the food code[s] in effect at the present time so they will be repealed by definite mention)** and all other codes or portions of codes in conflict herewith are hereby repealed in that respect only.

SECTION 4. CERTIFICATION OF ADOPTION AND PUBLISHING

That the **(jurisdiction's keeper of records)** shall certify the adoption of this **(statute/regulation/ordinance)** and cause the same to be published as required by law.

SECTION 5. EFFECTIVE DATE

That this Code and the rules, regulations, provisions, requirements, orders, and matters established and adopted hereby shall take effect and be in full force and effect **(time period)** from and after the date of its final passage and approval.

PASSED AND APPROVED BY **(name of adopting authority)** on this **(day)** of **(month, year)**.

BY:

Examples of how some jurisdictions have set fines, sentences, and penalties:

California law provides:

A. For Wholesale Food Violations:

Criminal fines and sentence for violations of up to **$1,000** and up to **one** year imprisonment if there is shown an intent to defraud or mislead, and

Civil penalties of up to **$1,000** per day for certain violations.

B. For Retail Food Violations:

Criminal fines and sentence for violations of not less than twenty-five dollars ($25) or more than one thousand dollars ($1000) for each offense, or by imprisonment in the county jail for a term not exceeding six months, or by both such fine and imprisonment.

Maryland law provides:

Criminal fines and sentence for certain misdemeanors of up to **$10,000** and **one** year imprisonment, and in the case of repeat code violation convictions, up to **$25,000** and **three** years imprisonment; and

Civil penalties of up to **$5,000** for each violation and for each day the violation continues.

Texas law provides:

Criminal fines and sentence for certain violations of up to **$10,000** and **two** years imprisonment; and

Assessment of five "severity" levels of administrative or civil penalties with base amounts ranging from **$1,250** through **$10,000.** Base amounts can be decreased or increased by as much as 50% considering factors such as past performance, good faith, direct impact on health and safety, high-risk populations involved, etc.

Though rarely used with retail food establishments, **Federal** law provides under the *Criminal Fine Enforcement Act of 1984* for a fine up to **$100,000** for a misdemeanor by a corporation or individual not resulting in death and, for misdemeanors resulting in death, a fine of up to **$250,000** for individuals and **$500,000** for corporations.

FORM 3-A	Food Establishment Inspection Report

The food establishment inspection report is the official regulatory authority document regarding compliance of the establishment with agency requirements. The goal of the report is to clearly, concisely, and fairly present the compliance status of the establishment and to convey compliance information to the permit holder or person in charge at the conclusion of the inspection. The Food Establishment Inspection Report form is provided as a model for use during routine, follow-up, and investigative inspections.

Refer to Annex 5 for further information.

FORM 3-A

Food Establishment Inspection Report

Page _____ of _____

As Governed by State Code Section XXX.XXX	No. of Risk Factor/Intervention Violations		Date _____
Do Good County	No. of Repeat Risk Factor/Intervention Violations		Time In _____
12344 Any Street, Our Town, State 11111	Score *(optional)*		Time Out _____

Establishment	Address	City/State	Zip Code	Telephone

License/Permit #	Permit Holder	Purpose of Inspection	Est. Type	Risk Category

FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS

Circle designated compliance status (IN, OUT, N/O, N/A) for each numbered item — Mark "X" in appropriate box for COS and/or R

IN=in compliance **OUT**=not in compliance **N/O**=not observed **N/A**=not applicable **COS**=corrected on-site during inspection **R**=repeat violation

	Compliance Status		COS	R
	Supervision			
1	IN OUT	Person in charge present, demonstrates knowledge, and performs duties		
2	IN OUT N/A	Certified Food Protection Manager		
	Employee Health			
3	IN OUT	Management, food employee and conditional employee; knowledge, responsibilities and reporting		
4	IN OUT	Proper use of restriction and exclusion		
5	IN OUT	Procedures for responding to vomiting and diarrheal events		
	Good Hygienic Practices			
6	IN OUT N/O	Proper eating, tasting, drinking, or tobacco use		
7	IN OUT N/O	No discharge from eyes, nose, and mouth		
	Preventing Contamination by Hands			
8	IN OUT N/O	Hands clean & properly washed		
9	IN OUT N/A N/O	No bare hand contact with RTE food or a pre-approved alternative procedure properly allowed		
10	IN OUT	Adequate handwashing sinks properly supplied and accessible		
	Approved Source			
11	IN OUT	Food obtained from approved source		
12	IN OUT N/A N/O	Food received at proper temperature		
13	IN OUT	Food in good condition, safe, & unadulterated		
14	IN OUT N/A N/O	Required records available: shellstock tags, parasite destruction		
	Protection from Contamination			
15	IN OUT N/A N/O	Food separated and protected		
16	IN OUT N/A	Food-contact surfaces; cleaned & sanitized		

	Compliance Status		COS	R
17	IN OUT	Proper disposition of returned, previously served, reconditioned & unsafe food		
	Time/Temperature Control for Safety			
18	IN OUT N/A N/O	Proper cooking time & temperatures		
19	IN OUT N/A N/O	Proper reheating procedures for hot holding		
20	IN OUT N/A N/O	Proper cooling time and temperature		
21	IN OUT N/A N/O	Proper hot holding temperatures		
22	IN OUT N/A N/O	Proper cold holding temperatures		
23	IN OUT N/A N/O	Proper date marking and disposition		
24	IN OUT N/A N/O	Time as a Public Health Control; procedures & records		
	Consumer Advisory			
25	IN OUT N/A	Consumer advisory provided for raw/undercooked food		
	Highly Susceptible Populations			
26	IN OUT N/A	Pasteurized foods used; prohibited foods not offered		
	Food/Color Additives and Toxic Substances			
27	IN OUT N/A	Food additives: approved & properly used		
28	IN OUT N/A	Toxic substances properly identified, stored, & used		
	Conformance with Approved Procedures			
29	IN OUT N/A	Compliance with variance/specialized process/HACCP		

Risk factors are important practices or procedures identified as the most prevalent contributing factors of foodborne illness or injury. Public health interventions are control measures to prevent foodborne illness or injury.

GOOD RETAIL PRACTICES

Good Retail Practices are preventative measures to control the addition of pathogens, chemicals, and physical objects into foods.

Mark "X" in box if numbered item is **not** in compliance — Mark "X" in appropriate box for COS and/or R — **COS**=corrected on-site during inspection **R**=repeat violation

			COS	R
		Safe Food and Water		
30		Pasteurized eggs used where required		
31		Water & ice from approved source		
32		Variance obtained for specialized processing methods		
		Food Temperature Control		
33		Proper cooling methods used; adequate equipment for temperature control		
34		Plant food properly cooked for hot holding		
35		Approved thawing methods used		
36		Thermometers provided & accurate		
		Food Identification		
37		Food properly labeled; original container		
		Prevention of Food Contamination		
38		Insects, rodents, & animals not present		
39		Contamination prevented during food preparation, storage & display		
40		Personal cleanliness		
41		Wiping cloths: properly used & stored		
42		Washing fruits & vegetables		

			COS	R
		Proper Use of Utensils		
43		In-use utensils: properly stored		
44		Utensils, equipment & linens: properly stored, dried, & handled		
45		Single-use/single-service articles: properly stored & used		
46		Gloves used properly		
		Utensils, Equipment and Vending		
47		Food & non-food contact surfaces cleanable, properly designed, constructed, & used		
48		Warewashing facilities: installed, maintained, & used; test strips		
49		Non-food contact surfaces clean		
		Physical Facilities		
50		Hot & cold water available; adequate pressure		
51		Plumbing installed; proper backflow devices		
52		Sewage & waste water properly disposed		
53		Toilet facilities: properly constructed, supplied, & cleaned		
54		Garbage & refuse properly disposed; facilities maintained		
55		Physical facilities installed, maintained, & clean		
56		Adequate ventilation & lighting; designated areas used		

Person in Charge (Signature) **Date:**

Inspector (Signature) **Follow-up: YES NO (Circle one) Follow-up Date:**

Food Establishment Inspection Report

Page _____ of _____

As Governed by State Code Section XXX.XXX Do Good County 12344 Any Street, Our Town, State, 11111	License/Permit #	Date _____

Establishment	Address	City/State	Zip Code	Telephone

TEMPERATURE OBSERVATIONS

Item/Location	Temp	Item/Location	Temp	Item/Location	Temp

OBSERVATIONS AND CORRECTIVE ACTIONS

Item Number	Violations cited in this report must be corrected within the time frames below or as stated in Section 8-405.11 of the Food Code.

Person in Charge (Signature) **Date**

Inspector (Signature) **Date**

Food Establishment Inspection Report

Page _____ of _____

As Governed by State Code Section XXX.XXX Do Good County 12344 Any Street, Our Town, State, 11111	License/Permit #	Date _____

Establishment	Address	City/State	Zip Code	Telephone

OBSERVATIONS AND CORRECTIVE ACTIONS

Item Number	Violations cited in this report must be corrected within the time frames below or as stated in Section 8-405.11 of the Food Code.

Person in Charge (Signature) **Date**

Inspector (Signature) **Date**

Guide

3-B Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices

Guide 3-B is intended to be used during inspections to ensure that observations of the provisions of the Code are not overlooked during the inspection and accurately recorded on the Food Code Establishment Inspection Report form.

The major headings from the Food Establishment Inspection Report form are condensed in Guide 3-B into key word phrases to assist the person conducting inspections in locating the Food Code citation that corresponds to a given violation and recording inspectional observations. The risk designations (Priority (P), Priority Foundation (Pf) and Core (C)) have been added to each applicable code section for reference when recording observations in the inspection report.

GUIDE 3-B Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices

All references and code sections in these marking instructions are based on the 2009 Food Code and its Supplement.

A. GENERAL MARKING INSTRUCTIONS

HEADER Information

Establishment	Complete this section using the "usual/common name" or "Doing Business As" name of the business. This information should be the same as the license/permit application completed at the initiation of the business.
Address	Street address of the actual business location
Zip Code	Actual business location
Telephone	Contact phone number for the establishment
License/Permit #	License number or tracking identification
Permit Holder	Name of Owner or Operator as shown on application
Purpose	The reason for the inspection – routine, re-inspection, complaint, or follow-up, etc.
Est. Type	Description or code for describing the type of facility (e.g. restaurant, market, vehicle, temporary food facility)
Risk Category	Designation of risk/priority level for determining frequency of inspection
Number of Risk Factor/ Intervention Violations	The number of boxes marked OUT in items 1-27 should be counted and the total number placed here
Number of Repeat Risk Factor/Intervention Violations	The number of boxes marked R (repeat) in items 1-27 should be counted and the total number placed here
Score (optional)	A score is optional for this form. If a jurisdiction has a scoring system, it should be incorporated into the inspection form and the score of an inspection placed here.
Date	The date of the inspection including month, day, and year
Time In	The actual time the inspection begins
Time Out	The actual time the inspection ends

B. RISK FACTORS AND INTERVENTIONS

Risk factors are food preparation practices and employee behaviors most commonly reported to the Centers for Disease Control and Prevention (CDC) as contributing factors in foodborne illness outbreaks. Risk factors include: Food from Unsafe Sources, Improper Holding Temperatures, Inadequate Cooking, Contaminated Equipment, and Poor Personal Hygiene. These items are prominent on the Food Establishment Inspection Report because maintaining these items in compliance is vital to preventing foodborne illness. Additionally, five key public health interventions were introduced in the 1993 Food Code that supplemented the other interventions long-established by the Food and Drug Administration (FDA) model codes and guidances to protect consumer health. The five key interventions are: Demonstration of Knowledge, Employee Health Controls, Controlling Hands as a Vehicle of Contamination, Time and

Temperature Parameters for Controlling Pathogens, and the Consumer Advisory.

For each item on the inspection report form in the Foodborne Illness Risk Factors and Public Health Interventions section, the inspector should indicate one of the following for **COMPLIANCE STATUS: "IN"** which means that the item is in compliance; **"OUT"** which means that the item is not in compliance; "**N.O.**" which means that the item was not observed during the inspection; or **"N.A."** which means that the item is not applicable for the facility. If N.A. or N.O. is not listed as an option for a particular item, this means that this item must be evaluated during the inspection and a compliance status must be determined. **If the item is marked "OUT", document details of each violation for the item number in the "Observations and Corrective Actions" section on the second page of the inspection report.** Compliance status should be determined as a result of observations that establish a pattern of non-compliance. Consideration should be given to the seriousness of the observation with regard to prevention of foodborne illness.

For items marked **"OUT**,**"** further indicate the status of the violation by marking an **"X"** in the corresponding box for Corrected On-Site (**COS)** during the inspection and/or Repeat violation **(R)**. Marking **COS** indicates that all violations cited under that particular item number have been corrected and verified before completing the inspection. The actual corrective action taken for each violation should be documented in the "Observations and Corrective Actions" section of the inspection report. For example, Item #10 *Handwashing sink* is marked out of compliance because the establishment does not have soap and paper towels at the handwashing sink. The person in charge partially corrects the problem by putting soap at the sink, but does not replace the paper towels or provide any other effective means for drying hands. The corrective action taken for the soap is documented in the narrative on the form, but **COS** is **not** marked for Item #10 because all violations under that item were not corrected. Marking **R** indicates that the same violation under a particular item number was cited on the last inspection report. Using the same scenario, on the subsequent inspection if the provision of soap and paper towels is not in violation, but employees are not washing hands in the correct sink (which is also cited under Item #8 *Handwashing sink*), **R** would **not** be marked because this is a new violation which was not cited on the previous inspection report.

C. MARKING INSTRUCTIONS FOR EACH RISK FACTOR AND INTERVENTION ON THE INSPECTION REPORT

Supervision

1. PIC present, demonstrates knowledge, and performs duties

IN/OUT This item must be marked IN or OUT of compliance. The person in charge (PIC) has three assigned responsibilities – Presence; Demonstration of Knowledge; and Duties. This item is marked OUT of compliance if any **one** of the responsibilities is not met.

A. Person in charge is present. This item is marked OUT of compliance if there is no PIC per 2-101.11(A) and (B).

B. Demonstration of Knowledge. The PIC has three options for demonstrating knowledge. This item is marked IN compliance if the PIC meets at least **one** of the options. The three options for demonstration of knowledge allowed by the Food Code are:
   1. Certification by an ACCREDITED PROGRAM as specified in 2-102-20.
   2. Complying with this Code by having no violations of priority items during the current inspection; or

3. Correct responses to the inspector's questions regarding public health practices and principles applicable to the operation. The inspector should assess this item by asking open-ended questions that would evaluate the PIC's knowledge in each of the areas enumerated in ¶ 2-102.11(C)(1), (4)-(16). Questions can be asked during the initial interview, menu review, or throughout the inspection as appropriate. The Inspector should ask a sufficient number of questions to enable the inspector to make an informed decision concerning the PIC's knowledge of the Code requirements and public health principles as they apply to the operation. The dialogue should be extensive enough to reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.

C. Duties of the PIC. This item must be marked IN or OUT of compliance based on the interaction and observation with the PIC and food employee. The inspector needs to determine the systems or controls the PIC has put into practice regarding oversight and/or routine monitoring of the Duties listed in § 2-103.11. This is accomplished by 1) discussion with the PIC, and 2) verified through observation that the systems or controls are actually being implemented. This concept is commonly referred to as Active Managerial Control. This item must be marked OUT of compliance when there is a pattern of non-compliance and obvious failure by the PIC to ensure employees are complying with the duties listed in § 2-103.11. Since marking this item out of compliance requires judgment, it is important that this item not be marked for an isolated incident, but rather for an overall evaluation of the PIC's ability to ensure compliance with the duties described in § 2-103.11.

N.A. **Do Not Mark** this item N.A.
N.O. **Do Not Mark** this item N.O.

Applicable Code Section:

2-101.11	Assignment (Pf)
2-102.11(A), B) and (C)(1), (4)-(16)	Demonstration (Pf)
2-103.11 (A)-(O)	Person-In-Charge-Duties (Pf)

2. Certified Food Protection Manager

IN/OUT This item must be marked IN or OUT of compliance. This item is marked IN compliance when it is observed that at least one employee that has supervisory and management responsibility and the authority to direct and control food preparation and service is a certified food protection manager. This item is marked OUT when it is observed that there is no employee with supervisory and management responsibility with the authority to direct and control food preparation that is deemed a certified food protection manager or the certified food protection manager certificate is deemed not to be from an accredited program.

N.A. This item may be marked N.A. if the establishment is deemed by the Regulatory Authority to not apply due to the minimal risk of causing, or contributing to foodborne illness based on the nature of the operation and extent of food operation.
N.O. **Do NOT MARK** this item N.O.

Applicable Code Section:
2-102.12(A) Certified Food Protection Manager (C)

Employee Health/Responding to Contamination Events

3. Management and food employee knowledge, and conditional employee; responsibilities and reporting.

IN/OUT This item must be marked IN or OUT of compliance. This item is marked IN compliance when the following criteria are met:

1. The PIC is aware of his or her responsibility to inform food employees and conditional employees of their responsibility to report certain symptoms or diagnosed diseases to the person in charge and for the PIC to report to the regulatory authority as specified under Food Code ¶ 2-103.11(M) and ¶¶ 2-201.11 (A),(B), (C), and (E); **and**

2. The PIC provides documentation or otherwise satisfactorily demonstrates during the inspection, that all food employees and conditional employees are informed of their responsibility to report to management information about their health and activities as it relates to diseases that are transmissible through food, as specified under ¶ 2-201.11(A). Satisfactory compliance may be documented by completion of Form 1-B, Conditional Employees or Food Employees Reporting Agreement, in Annex 7 of the 2009 Food Code for each employee or other similar State or local form containing the same information; **or**

3. In lieu of Form 1-B, compliance may be demonstrated by:

   a) Presenting evidence such as a curriculum and attendance rosters documenting that each employee has completed a training program which includes all the information required on Form 1-B regarding their reporting responsibilities; **or**

   b) Implementation of an employee health policy which includes a system of employee notification using a combination of training, signs, pocket cards, or other means to convey all of the required information on Form 1-B to all food employees and conditional employees. A signed acknowledgement by the employee should be part of any employee health policy.

The regulatory authority is encouraged to establish a policy of selecting one employee at random during each inspection and requesting the PIC verify, by one of the previously listed methods, that the selected employee has been **informed** of his or her responsibility to report symptoms, exposures, and diagnosed illnesses to management. The PIC is not expected to quote symptoms and diseases from memory, but should be able to locate that information on Form 1-B or similar documents used to demonstrate compliance.

Additional information is provided in Annex 3 of the Public Health Reasons for Subpart 2-201, including a number of questions, which may be used as a reference to assist the regulatory authority in determining compliance with this item.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

2-102.11(C)(2),(3) and (17)	Demonstration (Pf)
2-103.11(M)	Person in Charge-Duties (Pf)
2-201.11(A), (B), (C), & (E)	Responsibility of Permit Holder, Person in Charge, and Conditional Employees (P,Pf)

4. Proper use of restriction and exclusion

IN/OUT This item must be marked IN or OUT of compliance. Compliance must be based on first hand observations or information and cannot be based solely on responses from the PIC to questions regarding hypothetical situations or knowledge of the Food Code. This item is marked IN when the following criteria are observed at the time of the inspection:

- There are no ill employees.
- There are no employees experiencing symptoms with or without a diagnosis that require reporting, or reason for the PIC to exclude or restrict an employee
- A food employee who works in a food establishment serving a HSP or non-HSP, is restricted due to diagnoses with an infection from nontyphoidal *Salmonella* and is asymptomatic

This item should be marked OUT of compliance when:

- The inspector observes a working employee with specific reportable symptoms (subparagraph 2-201.11 (A)(1)); or
- The inspector becomes aware that an employee has reported information about his or her health and activities as it relates to diseases that are transmissible through food and the PIC has not acted to restrict/exclude an employee as required by the Food Code (§2-201.12 & §2-201.13); or
- The inspector becomes aware that the PIC has not notified the Regulatory Authority that an employee is jaundiced or diagnosed with an illness due to a pathogen as specified under subparagraphs 2-201.11 (A)(2)(a)-(f) of the Food Code.
- There are food employees working in the food establishment that have been diagnosed with an illness as specified in paragraphs 2-201.11(A)(2-5); Additionally, in food establishments exclusively serving a highly susceptible population, there are to be no food employees with an active sore throat with a fever working in the food establishment.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

2-201.11 (D) and (F)	Responsibility of Permit Holder, Person in Charge, and Conditional Employees-Responsibility of the PIC to Exclude or Restrict (P,)
2-201.12	Exclusions & Restrictions (P)
2-201.13	Removal, Adjustment, or Retention of Exclusions & Restrictions (P)

5, Clean-up of Vomiting and Diarrheal Events

IN/OUT This item should be marked IN or OUT of compliance. This items is marked IN compliance when it is demonstrated that the food establishment has procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the food establishment. Refer to the Public Health Reasons (§2-501.11 Clean up of Vomiting and Diarrheal Events) for suggested recommendations as to what the food establishment can include within their plan (this is not an exhaustive list).

This item is marked OUT of compliance if the establishment does not demonstrate the ability to provide procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the food establishment.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

Applicable Code Section:

2-501.11	Clean-up of Vomiting and Diarrheal Events (Pf)

Good Hygienic Practices

6. Proper eating, tasting, drinking, or tobacco use

IN/OUT This item should be marked IN or OUT of compliance based on direct observations or discussions of the appropriate hygienic practices of food employees. This item should be marked IN compliance when a food employee is observed drinking from a closed beverage container subsequently stored on a non-food-contact surface and separate from exposed food, clean equipment, and unwrapped single- service and single-use articles. This item should be marked OUT of compliance when food employees are observed improperly tasting food, eating, drinking, or smoking, or there is supporting evidence of these activities taking place in non-designated areas of the establishment. An open container of liquid in the kitchen preparation area does not necessarily constitute marking this item OUT. Further discussion with a food employee or the PIC may be needed to determine if the liquid, if labeled, is used as an ingredient in food, or may be an employee beverage that is consumed in another designated area. If the liquid is an open beverage that is consumed in a designated area, it must still be stored in a manner to prevent the contamination of food, equipment, utensils, linens and single-service/single-use articles.

N.A. **Do Not Mark** this item N.A.

N.O. This item may be marked N.O. for retail operations only in the **RARE** case when there are no food workers present at the time of inspection.

Applicable Code Sections:

2-401.11 Eating, Drinking, or Using Tobacco (C)

3-301.12 Preventing Contamination When Tasting (P)

7. No discharge from eyes, nose, and mouth

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food employees. This item should be marked IN compliance when no food employees are observed having persistent sneezing, coughing, or a runny nose that causes discharge from the eyes, nose or mouth. This item should be marked OUT of compliance when a food employee has persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose or mouth, subjecting food and food-contact surfaces to potential contamination.

N.A. **Do Not Mark** this item N.A.

N.O. This item may be marked N.O. for retail operations only in the **RARE** case when there are no food workers present at the time of inspection.

Applicable Code Sections:

2-401.12 Discharges from the Eyes, Nose, and Mouth (C)

Control of Hands as a Vehicle of Contamination

8. Hands clean and properly washed

IN/OUT This item should be marked IN or OUT of compliance. This item is marked IN compliance only when employees are observed using proper handwashing techniques at appropriate times and places. Hands are not required to be washed between each change of gloves, if it is observed that there was no change in the task being performed and no activities which could potentially result in cross contamination.

N.A. **Do Not Mark** this item N.A.

N.O. This item may be marked N.O. for retail operations only in the **RARE** case when there are no food workers present at the time of inspection. (If there are no food workers present, but the PIC accompanies the inspector on the inspection and touches food, clean equipment, or utensils without washing his/her hands, this item is marked OUT.)

Applicable Code Sections:

2-301.11 Clean condition-Hands and Arms (P)
2-301.12 Cleaning Procedure (P)
2-301.14 When to Wash (P)
2-301.15 Where to Wash (Pf)
2-301.16 Hand Antiseptics (Pf)

9. No bare hand contact with RTE foods or a pre-approved alternate properly followed

IN/OUT This item should be marked IN or OUT of compliance. This item is marked IN compliance only when food employees are observed using suitable utensils or gloves to prevent bare hand (or arm) contact with ready-to-eat foods or if the food employee contacts exposed RTE food with bare hands at the time the RTE food is being added as an ingredient to a food that:

- Contains a raw animal food and is to be cooked in the food establishment to heat all parts of the food to minimum temperatures specified in ¶¶3-401.11(A)-(B) or §3-401.12; or
- Does not contain a raw animal food but is to be cooked in the food establishment to heat all parts of the food to a temperature of at least 63°C (145°F).

This item is also marked IN compliance when food employees are observed properly following a pre-approved alternative procedure to no bare hand contact.

This item should be marked OUT of compliance if one food employee is observed ready-to-eat food with their bare hands in the absence of a prior approval and written procedures for bare hand contact. Refer to subparagraph 3-301.11 (E)(1)-(7) for a listing of conditions that must be met in order to receive prior approval by the Regulatory Authority. Bare hand contact by food employees serving a Highly Susceptible Population is prohibited and no alternative to bare hand contact is allowed. This item is also marked OUT when food employees contact exposed RTE food with bare hands that is to be added as ingredients to a food that is not properly heat treated as specified in Sub-¶3-301.11(D)(1)-(2).

N.A. This item may be marked N.A. for establishments that provide only packaged, or bulk food items that are not ready-to-eat.

N.O. This item may be marked N.O. for establishments that prepare ready-to-eat foods only, but no food preparation is performed at the time of inspection.

Applicable Code Sections:

3-301.11 Preventing Contamination from Hands (P, Pf, C)
3-801.11(D) Pasteurized Foods, Prohibited Re-Service, and Prohibited Foods (P)

10. Adequate handwashing sinks, properly supplied and accessible

IN/OUT This item must be marked IN or OUT of compliance based on observations in determining that handwashing sinks are properly equipped and conveniently located for employee use in food preparation, food dispensing and warewashing areas as well as in or immediately adjacent to toilet rooms. This item must be marked OUT of compliance when the facility is not stocked with soap, hand drying provisions or equipped with the required signage. In addition, if the handwashing sink is not located to be available to employees who are working in a food preparation area, food dispensing and warewashing areas and is blocked by portable equipment or stacked full of soiled utensils or other items, or the facility is unavailable for regular employee use, this item must be marked OUT of compliance.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

5-202.12 Handwashing Sinks, Installation ((Pf, C)
5-203.11 Handwashing Sinks-Numbers and Capacities (Pf)

5-204.11 Handwashing Sinks-Location and Placement (Pf)
5-205.11 Using a Handwashing Sink-Operation and Maintenance (Pf)
6-301.11 Handwashing Cleanser, Availability (Pf)
6-301.12 Hand Drying Provision (Pf)
6-301.13 Handwashing Aids and Devices, Use Restrictions (C)
6-301.14 Handwashing Signage (C)

Approved Source

11. Food obtained from approved source

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food products, food labels and packaging, water analyses, and discussion with the PIC or other food employees. This item should be marked IN compliance when the regulatory authority is able to determine approved food sources. A review of supplier names, shipment invoices, buyer specification plans, molluscan shellfish tags, proof of regulatory permit/licensure of a food source, etc. can be used to document approved food sources. Wild harvested mushrooms if sold or served have been approved by the regulatory authority. Milk and milk products must comply with Grade A Standards. This item should be marked OUT of compliance when an approved food source cannot be determined and if the regulatory authority did not approve the sale or service of wild harvested mushrooms and it is observed in the food establishment for sale and service.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

3-201.11 Compliance with Food Law (P, Pf,)
3-201.12 Food in a Hermetically Sealed Container (P)
3-201.13 Fluid Milk and Milk Products (P)
3-201.14 Fish (P)
3-201.15 Molluscan Shellfish (P)
3-201.16 Wild Mushrooms (P)
3-201.17 Game Animals (P, C)
3-202.13 Eggs (P)
3-202.14 Eggs and Milk Products, Pasteurized (P)
3-202.110 Juice Treated-Commercially Processed (P, Pf)
5-101.13 Bottled Drinking Water (P)

12. Food received at proper temperature

IN/OUT This item should be marked IN or OUT of compliance based on actual food temperature measurements of TCS foods being received. This item should be marked IN compliance when food is received and found at proper temperatures during the inspection (i.e. catered meal for child care center arrives during the inspection and the regulatory authority verifies receiving temperature). This item should be marked OUT of compliance if food is received and accepted, but an actual food temperature measurement of a TCS food by the regulatory authority at the time of delivery exceeds the temperature specifications for receiving as prescribed by the Code.

N.A. This item may be marked N.A. for retail operations when the establishment receives only foods that are not TCS food and that are not frozen.

N.O. This item may be marked N.O. if food is not received during the inspection.

Applicable Code Sections:

3-202.11 Temperature (P, Pf)

13. Food in good condition, safe and unadulterated

IN/OUT This item must be marked IN or OUT of compliance based on direct observations of the integrity of product packaging, wholesomeness, and signs of adulteration. This item must be marked IN compliance when a dent in a canned food has not compromised the hermetic seal; cuts made in outer cardboard packaging during opening of the case do not enter the inner product packaging; the true appearance, color, or quality of a food is not misrepresented; and food is honestly presented. This item must be marked OUT of compliance when the integrity of food packaging has been compromised or the true appearance, color, or quality of a food has been intentionally altered.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

3-101.11 Safe, Unadulterated and Honestly Presented (P)

3-202.15 Package Integrity (Pf)

14. Required records available: shellstock tags, parasite destruction

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of fish in storage, shellstock tags, and/or records of freezing of fish for parasite destruction. This item should be marked IN compliance if the permit holder provides a statement from supplier(s) identifying that fish sold as raw, raw-marinated or undercooked is frozen by supplier for parasite destruction; or there are freeze records maintained by the permit holder when fish are frozen for parasite destruction on the premises. This item should be marked OUT of compliance if there are no shellstock tags available, when the shellstock tags are incomplete, when there is evidence of commingling of shellstock, or when no records of freezing of fish for parasite destruction are available. Fish exempt from freezing requirements are found in paragraph 3-402.11(B).

N.A. This item may be marked N.A. when shellstock are not used in the establishment and the only fish sold as raw, raw-marinated or undercooked is the tuna species or aquacultured fish listed as exempted from freezing in the Food Code.

N.O. This item may be marked N.O. when shellstock or raw, raw-marinated and undercooked fish are sold periodically in the establishment, but are not being sold at the time of inspection and prior compliance through tags, invoices, or purchase records cannot be verified.

Applicable Code Sections:

3-202.18 Shellstock Identification (Pf, C)

3-203.12 Shellstock, Maintaining Identification (Pf)

3-402.11 Parasite Destruction (P, C)

3-402.12 Records, Creation, & Retention (Pf)

Protection from Contamination

15. Food separated and protected

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food storage and food handling practices. This item should be marked OUT of compliance when ready-to-eat foods are subject to potential contamination by raw animal foods; raw animal foods are observed not separated by type based on minimum cook temperatures by spacing or placing in separate containers; unpackaged comminuted or otherwise non intact meats are stored above unpackaged whole muscle intact cuts of meat; food is not packaged or covered during storage (unless in the process of cooling); or food is in contact with soiled equipment and utensils; or single-use gloves used for more than one task.

N.A. This item may be marked N.A. when there are no raw animal foods used in the facility and only prepackaged foods are sold.

N.O. This item is marked N.O. when raw animal foods are used or served seasonally and you are unable to determine compliance.

Applicable Code Sections:

3-302.11 Packaged and Unpackaged Food-Separation, Packaging, and Segregation (P, C)
3-304.11 Food Contact with Equipment, Utensils, and Linens (P)
3-304.15(A) Gloves, Use Limitation (P)
3-306.13(A) Consumer Self-Service Operations (P)

16. Food-contact surfaces: cleaned and sanitized

IN/OUT This item must be marked IN or OUT of compliance based on direct observations of food-contact surfaces of equipment and utensils; actual measurements/readings of chemical sanitizer concentration, hot water sanitizing temperature, pH, hardness, water pressure, etc. using test strips, heat-sensitive tapes, and equipment gauges; observations of cleaning and sanitizing procedures; and discussion of cleaning and sanitizing procedures and frequency with the PIC or other food employees. This item must be marked IN compliance when manual and/or mechanical methods of cleaning and sanitizing are effective, and performed at the prescribed frequency. There should be an overall assessment of the food-contact surfaces of equipment and utensils in clean storage and in use to determine compliance. For example, this item is not marked OUT of compliance based on one visibly soiled utensil, such as a plate or knife. This item must be marked OUT of compliance when manual and/or mechanical methods of cleaning and sanitizing food-contact surfaces of equipment and utensils are ineffective, or if one multiuse piece of equipment such as a slicer or can opener is visibly soiled and being used at the time of the inspection. This item is also marked OUT if it is observed that equipment or utensils that have come into contact with a major food allergen such as fish was not cleaned and sanitized prior to use for other types of raw animal foods.

N.A. This item may be marked N.A. only when there is no requirement to clean equipment and utensils such as when only prepackaged foods are sold.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures (P)
4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures (Pf)
4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure (C)
4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization-Temperature, pH, Concentration and Hardness (P, Pf)
4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers (C)
4-601.11(A) Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils (Pf)
4-602.11 Equipment Food-Contact Surfaces and Utensils-Frequency (P, C)
4-602.12 Cooking and Baking Equipment (C)

4-702.11 Before Use After Cleaning (P)
4-703.11 Hot Water and Chemical-Methods (P)

17. Proper disposition of returned, previously served, reconditioned, and unsafe food

IN/OUT This item must be marked IN or OUT of compliance. This item is marked OUT of compliance if food is found unsafe, adulterated, not honestly presented, from an unapproved source, or if ready-to-eat food is contaminated by employees and is not discarded or reconditioned according to an approved procedure, or if previously served unwrapped, unprotected food is observed being re-served.

N.A. **Do Not Mark** this item N.A.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

3-306.14 Returned Food and Re-service of Food (P)
3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food (P)

Time Temperature Control for Safety Food (TCS Food)

18. Proper cooking time and temperatures

NOTE: *The cooking temperatures of foods must be measured to determine compliance or noncompliance. Do not rely upon discussions with managers or cooks to make a determination of compliance or noncompliance. The temperature of raw animal foods in each species cooked during the inspection should be taken. For instance, if the facility fries chicken, scrambles eggs, bakes fish, grills hamburgers, and slow-roasts prime rib during the inspection – the cook temperatures of all of the products should be measured and recorded. Temperatures, both IN compliance and OUT of compliance, should be recorded in the "Temperature Observations" section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the "Observations and Corrective Actions" section on the second page of the inspection report. The time of inspections should be varied so that cooking can be observed.*

IN/OUT This item should be marked IN or OUT of compliance. This item should be marked OUT of compliance if the items checked do not meet the temperature requirements for cooking and the employee doing the cooking attempts to serve the product without returning the product to the cooking process. If a food is cooked below the required temperature but the facility has an approved Consumer Advisory or an approved variance with HACCP plan for that food item, mark the item IN compliance, record the temperature and document the reason it is IN compliance. Foods cooked with a non-continuous cooking process are marked OUT of compliance if the food item does not meet the time/temperature requirements for cooking as specified in 3-401.11(A)-(C) and if written procedures describing how the foods are prepared and stored after initial heating but prior to cooking for sale or service are not available for review.

N.A. This item may be marked N.A. when no raw animal foods are cooked in the establishment.

N.O. This item may be marked N.O. when you are unable to determine the cooking temperature of any food. The inspection should be arranged at an optimum time for measuring at least one cooked item.

Internal Cooking Temperature Specifications for Raw Animal Foods

Internal Cooking Temperature	Raw Animal Foods
145°F for 15 seconds	• Raw eggs cooked for immediate service • Fish, except as listed below • Meat, except as listed in the next 2 rows • Commercially raised game animals, rabbits
155°F for 15 seconds:	• Ratites (Ostrich, Rhea and Emu) • Injected meats • Mechanically tenderized meats • Raw eggs not for immediate service • Comminuted meat, fish, or commercially raised game animals
165°F for 15 seconds:	• Wild game animals • Poultry • Stuffed fish, meat, pork, pasta, ratites & poultry • Stuffing containing fish, meat, ratites & poultry

*** Whole Meat Roasts:** Refer to cooking charts in the *Food Code* ¶ 3-401.11(B)

Applicable Code Sections:
3-401.11 Raw Animal Foods-Cooking (P, Pf)
3-401.12 Microwave Cooking (C)
3-401.14 Non-Continuous Cooking of Raw Animal Foods (P, Pf)

19. Proper reheating procedures for hot holding

NOTE: The reheating temperatures of foods must be taken to determine compliance or noncompliance. Do not rely solely upon discussions with managers or cooks to determine compliance or noncompliance. Temperatures IN and OUT of compliance should be recorded in the "Temperature Observations" section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the "Observations and Corrective Actions" section of the inspection report.

IN/OUT This item should be marked IN or OUT of compliance based on actual temperature measurements of foods upon completion of the reheating process and prior to being placed in hot holding using a calibrated food temperature measuring device. This item should be marked OUT of compliance if the items checked are not reheated to the required temperatures or within 2 hours prior to hot holding.

N.A. This item may be marked N.A. when foods are not held over for a second service and/or reheating for hot holding is not performed in the establishment.

N.O. This item may be marked N.O. such as when foods are held over for a second service, but no foods are reheated during the time of inspection.

Applicable Code Sections:
3-403.11 Reheating for Hot Holding (P)

20. Proper cooling time and temperatures

NOTE: The requirement for cooling cooked TCS food, is that the food must be cooled from 135°F to 41°F or less in 6 hrs provided that the food is cooled from 135°F to 70°F within the first 2 hours. For example, if a facility cools chili from 135°F to 70°F in 1.5 hours; they then have 4.5 hours to get it from 70°F to 41°F or less. There are two critical limits that must be met with cooling. Discussions with the person in charge along with observations should be used to determine compliance. For instance, during discussion the person in charge says that a food product was cooled overnight in the walk-in cooler. The product is checked and the temperature is 50°F. Eight hours have elapsed from closing to opening. This item should be marked OUT because the product did not cool from 135°F to 70°F within two hours and from 135°F to 41°F or less within a total of 6 hours. Temperatures IN compliance and OUT of compliance should be recorded in the "Temperature Observations" section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the "Observations and Corrective Actions" section of the inspection report. Because the entire cooling process is difficult to observe during an inspection, at the onset of the inspection a determination of whether foods are currently being cooled should be made. If cooling is taking place, temperatures should be taken to make a determination of whether proper cooling is possible with procedures being used.

IN/OUT This item should be marked IN or OUT of compliance based on actual temperatures of TCS foods in the cooling process. The basis for determining IN or OUT of compliance can also be supported through discussion and/or record review which would provide the inspector reliable data of the "start time" for cooling from 135°F. See above NOTE for an example of using actual temperature and discussion with the PIC in determining OUT of compliance without actually being at the establishment during the entire cooling of TCS process, from start to finish.

N.A. This item may be marked N.A. when the establishment does **not** receive raw eggs, shellstock, or milk, prepares **no** TCS food from ambient temperature ingredients that require cooling, and does **not** cool cooked TCS food.

N.O. This item may be marked N.O. when the establishment does cool TCS food, but proper cooling per the prescribed temperature and time parameters cannot be determined during the length of the inspection.

Applicable Code Sections:

3-501.14 Cooling (P)

21. Proper hot holding temperatures

NOTE: Temperatures IN compliance and OUT of compliance should be recorded in the "Temperature Observations" section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the "Observations and Corrective Action" section of the inspection report.

IN/OUT This item should be marked IN or OUT of compliance based on actual food temperature measurements using a calibrated food temperature measuring device. This item should be marked IN compliance when the regulatory authority determines that, of the TCS food temperature measurements taken during the inspection, no hot holding temperatures are less than prescribed by the Code. This item is marked OUT of compliance if one TCS food is found out of temperature, unless Time as a Public Health Control (TPHC) is used for that TCS food.

N.A This item may be marked N.A. when the establishment does not hot hold food.

N.O. This item may be marked N.O. when the establishment does hot hold foods, but no foods are being held hot during the time of inspection. Inspections should be conducted during a time when hot holding temperatures can be taken.

Applicable Code Sections:
3-501.16(A)(1) Time/Temperature Control for Safety Food, Hot and Cold Holding (P)

22. Proper cold holding temperatures

NOTE: Temperatures IN compliance and OUT of compliance should be recorded in the "Temperature Observations" section of the inspection report. If there is insufficient space for the number of temperatures taken, additional temperatures should be documented in the "Observations and Corrective Action" section of the inspection report.

IN/OUT This item should be marked IN or OUT of compliance based on actual food temperature measurements using a calibrated food temperature measuring device. Discussions should be made with the PIC to determine if a food is in the process of cooling, TPHC is used, or there is an approved method to render a food so that it is not TCS food. This item should be marked IN compliance when the regulatory authority determines that, of the temperature measurements taken during the inspection, no cold holding temperatures are greater than prescribed by the Code. This item should be marked OUT of compliance if one TCS food is found out of temperature, with supportive evidence, unless TPHC is used for that TCS food.

N.A. This item may be marked N.A. when the establishment does **not** cold hold food.

N.O This item may be marked N.O. when the establishment does cold hold food, but no foods are being held cold during the time of inspection. Inspections should be conducted during a time when hot holding temperatures can be taken.

Applicable Code Sections:
3-501.16(A)(2) and (B) Time/Temperature Control for Safety Food, Hot and Cold Holding (P)

23. Proper date marking and disposition

IN/OUT This item should be marked IN or OUT of compliance. This item would be IN compliance when there is a system in place for date marking all foods that are required to be date marked and is verified through observation. If date marking applies to the establishment, the PIC should be asked to describe the methods used to identify product shelf-life or "consume-by" dating. The regulatory authority must be aware of food products that are listed as exempt from date marking. For disposition, mark IN when foods are all within date marked time limits or food is observed being discarded within date marked time limits or OUT of compliance, such as when date marked food exceeds the time limit or date-marking is not done.

N.A. This item may be marked N.A. when there is no ready-to-eat, TCS food prepared on-premise and held, or commercial containers of ready-to-eat, TCS food opened and held, over 24 hours in the establishment.

N.O. This item may be marked N.O. when the establishment does handle foods requiring date marking, but there are no foods requiring date marking in the facility at the time of inspection.

Applicable Code Sections:
3-501.17 Ready-To-Eat Time/Temperature Control for Safety Food, Date Marking (Pf)
3-501.18 Ready-To-Eat Time/Temperature Control for Safety Food, Disposition (P)

24. Time as a Public Health Control: procedures and records

IN/OUT This item should be marked IN or OUT of compliance based on direct observations, record review, a discussion with the PIC, and the review of any standard operating procedures to determine if the intent of the Code for use of TPHC is met. This provision only applies if it is the actual intention or conscious decision by the PIC to store TCS food out of temperature control using TPHC; otherwise, it may be a cold or hot holding issue. This item should be marked IN compliance if there is a written procedure at the food establishment that identifies the types of food products that will be held using time only, describes the procedure for how TPHC will be implemented, and if applicable delineates how food items, previously cooked and

cooled before time is used, are properly cooled; and food items (marked or identified) do not exceed the 4-hour limit at any temperature or 6-hour limit at 70°F or less. This item should be marked OUT of compliance when the PIC implies the use of TPHC but does not have an effective mechanism for indicating the point in time when the food is removed from temperature control to the 4 or 6-hour discard time, or a written procedure or an effective mechanism for using TPHC is not present at the facility.

N.A This item may be marked N.A. when the establishment does not use time only as the public health control.

N.O. This item may be marked N.O. when the establishment uses time only as the public health control, but is not using this practice at the time of inspection.

Applicable Code Sections:

3-501.19 Time as a Public Health Control (P, Pf, C)

Consumer Advisory

25. Consumer advisory provided for raw or undercooked food

IN/OUT This item should be marked IN or OUT of compliance based on a thorough review with the PIC of the posted, written and special/daily menus, to determine if untreated shell eggs, meats, fish, or poultry are used as an ingredient or ordered as a raw, raw-marinated, partially cooked, or undercooked food. The advisory also applies to shellstock offered for sale from a retail service case. This item should be marked IN compliance if the establishment provides an advisory that meets the intent of the Food Code for both the disclosure and reminder components. This item should be marked OUT of compliance when raw or undercooked foods are served or sold and there is no consumer advisory, the food item is not **disclosed**, or there is no **reminder** statement. The consumer advisory does not exempt the requirement for freezing for parasite control, nor should it be used for foods that have only gone through the initial heating and cooling stages of a non-continuous cooking process.

N.A. This item may be marked N.A. when a food establishment does not serve a ready-to-eat food that necessitates an advisory, i.e., an animal food that is raw, undercooked, or not otherwise processed to eliminate pathogens.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens (Pf)

Highly Susceptible Population

26 Pasteurized foods used; prohibited foods not offered

NOTE: Discussions with the PIC and employees regarding whether or not certain foods are served or certain practices occur in the establishment, along with observations should be used to determine compliance.

IN/OUT This item should be marked IN or OUT of compliance based on direct observations and discussions with the PIC and food employees regarding whether or not certain foods are served or certain practices occur in an establishment serving a highly susceptible population. Violations of bare hand contact by food employees serving a highly susceptible population ¶ 3-801.11(D) is marked under Item #7. This item should be marked IN compliance if only treated/pasteurized juices/juice beverages are served; only pasteurized eggs are used in recipes if eggs are undercooked and if eggs are combined, unless there is a cook step or HACCP plan to control *Salmonella* enteriditis; no raw or partially cooked animal foods or raw

seed sprouts are served; and no unopened packaged food is re-served following service to patients in medical isolation or quarantine.

N.A. This item may be marked N.A. if a highly susceptible population is not served.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

3-801.11(A), (B), (C), (E) and (G) Pasteurized Foods, Prohibited Re-Service, and Prohibited Food (P, C)

Food/Color Additives and Toxic Substances

27. Food additives: approved and properly used

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food ingredients in storage and listed as product ingredients supplemented by discussion with the PIC. This item is marked IN compliance if approved food and color additives are on site and used properly or if sulfites are on the premises, and they are not applied to fresh fruits/vegetables for raw consumption. Approved food additives are listed and have threshold limits in accordance with the CFRs, and does not apply to food additives that are considered Generally Recognized as Safe (GRAS), such as salt, pepper, etc. This item is marked OUT of compliance if unapproved additives are found on the premises or approved additives are improperly used, such as sulfites being applied to fresh fruits or vegetables.

N.A. This item may be marked N.A. if the food establishment does **not** use any additives or sulfites on the premises.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

3-202.12 Additives (P)

3-302.14 Protection from Unapproved Additives (P)

28. Toxic substances properly identified, stored, and used; held for retail sale, properly Stored

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food labeling, storage, reconstitution, and application of bulk and working containers of cleaning agents and sanitizers, personal care items, first aid supplies, medicines, pesticides, and potential toxic and poisonous substances. This item should be marked IN compliance when bulk and working containers of cleaning agents and sanitizers are labeled; sanitizing solutions are not exceeding the maximum concentrations; personal care items, first aid supplies, medicines, and chemicals are stored separate from and not above food, equipment, utensils, linens, and single-service and single-use articles; and restricted use pesticides are applied only by or under the supervision of a certified applicator. This item should be marked OUT of compliance if a cleaning agent or sanitizer is not properly identified and stored; if a sanitizing solution has a higher concentration than prescribed and medicines and first aid kits are improperly labeled and stored. Violations of solutions exceeding the recommended concentration in chemical washes for fruits and vegetables (§7-204.12) would be marked under Item #42.

N.A. This item may be marked N.A. if the establishment does not hold poisonous or toxic materials for retail sale.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

7-101.11 Identifying Information, Prominence-Original Containers (Pf)

7-102.11 Common Name-Working Containers (Pf)

7-201.11 Separation-Storage (P)

7.202.11 Restriction-Presence and Use (Pf)

7-202.12 Conditions of Use (P, Pf, C)
7-203.11 Poisonous or Toxic Material Containers-Container Prohibitions (P)
7-204.11 Sanitizers, Criteria-Chemicals (P)
7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria (P,)
7-204.13 Boiler Water Additives, Criteria (P)
7-204.14 Drying Agents, Criteria (P)
7-205.11 Incidental Food Contact, Criteria-Lubricants (P)
7-206.11 Restricted Use Pesticides, Criteria (P)
7-206.12 Rodent Bait Stations (P)
7-206.13 Tracking Powders, Pest Control and Monitoring (P, C)
7-207.11 Restriction and Storage-Medicines (P, Pf)
7-207.12 Refrigerated Medicines, Storage (P)
7-208.11 Storage-First Aid Supplies (P, Pf)
7-209.11 Storage-Other Personal Care Items (C)
7-301.11 Separation-Storage and Display, Stock and Retail Sale (P)

Conformance with Approved Procedures

29. Compliance with variance, specialized process, reduced oxygen packaging criteria or HACCP plan

NOTE Except for fish a HACCP plan is not required when a TCS food is packaged using a reduced oxygen packaging method and is labeled with production time and date, held at required cold holding temperature, and removed from ROP packaging within 48 hours after packaging at the food establishment.

IN/OUT This item should be marked IN or OUT of compliance based on direct observations of food preparation and storage, a discussion with the PIC to determine if there are specialized food processes [i.e. smoking food, curing food, reduced oxygen packaging, using food additives to render a food so that it is not TCS food, cook chill, sous vide, etc.] and the record review of standard operating procedures and HACCP documentation. This item should be marked IN compliance when observations of food operations and review of available records indicate compliance is being met with regards to specialized food processes and HACCP plans were submitted to the regulatory authority prior to conducting a ROP operation that conforms to procedures within §3-502.12.This item should be marked OUT of compliance if the inspection reveals specialized food processes that are not approved by the regulatory authority are performed or not conducted in accordance with the approved variance or a HACCP plan was not submitted to the regulatory authority prior to engaging in a ROP operation without a variance.

N.A. This item may be marked N.A. if the establishment is not required by the regulatory authority to have a variance or HACCP plan, juice is not packaged or reduced oxygen packaging is not done on the premises.

N.O. **Do Not Mark** this item N.O.

Applicable Code Sections:

3-404.11 Treating Juice (P, Pf)
3-502.11 Variance Requirement (Pf)
3-502.12 Reduced Oxygen Packaging, Criteria (P, Pf)
4-204.110(B) Molluscan Shellfish Tanks (Pf)
8-103.12 Conformance with Approved Procedures (P, Pf)
8-201.13 When a HACCP Plan is Required (C)
8-201.14 Contents of a HACCP Plan (Pf)

Good Retail Practices (GRPs)

D. MARKING INSTRUCTIONS FOR EACH GOOD RETAIL PRACTICE (GRP) ON THE INSPECTION REPORT

Good Retail Practices (GRPs) are systems to control basic operational and sanitation conditions within a facility, and if not controlled, they could be contributing factors to foodborne illness by introducing hazards (biological, chemical and physical), into the end product, either directly or indirectly. For example, equipment in disrepair, such as a cutting board with deep grooves/cuts, makes effective cleaning difficult or impossible, and thereby could introduce a bacterial hazard onto food that comes into contact with the board. In addition, in assessing GRPs, it is important to make an overall assessment of the conditions by looking for trends versus an isolated incident; and the potential public health impact. For example, a few missing floor tiles in a dry area may not rise to the level of a "violation"; however, missing floor tiles in an area where equipment is subject to in-place manual cleaning without the use of an enclosed clean in place (CIP) system, i.e., using pressure hoses over band saws, slicers, or mixers, could create conditions whereby a bacterial hazard could be introduced on to the food equipment. These items usually require judgment, and if uncorrected, the regulatory authority must decide whether or not these conditions would lead to potential contamination.

GRPs are the methods used in, or the facilities or controls used for, the receiving, preparation, storage, serving, packaging or holding of food which are designed to assure unsanitary conditions do not lead to the introduction of hazards or unintentional substances into the end product. The intention of this inspection form is to focus the inspector's attention on those factors that have been shown to be most often linked with causing foodborne illness. Since the major emphasis of an inspection should be on the Risk Factors that cause foodborne illness and the Public Health interventions that have the greatest impact on preventing foodborne illness, the GRPs have been given less importance on the inspection form and a differentiation between IN, OUT, N.A. and N.O. is not made in this area, with a few exceptions noted below. For marking the GRPs section, place an "X" in the box to the left of the numbered item if a code provision under that item is **OUT** of compliance. Document each violation of the code provision for the item number in the "Observations and Corrective Actions" section on the second page of the inspection report. For items marked **OUT** of compliance, further indicate the **VIOLATION STATUS** by marking an **"X"** in the corresponding box**: COS** = Corrected on site during inspection and **R =** Repeat violation per the same instructions as given in the Risk Factor section. References to the appropriate Food Code provisions that can be debited under each numbered GRP item are listed in Guide 3-B.

Note: Items 30, 32, and 33 will allow for either three or four marking options. Item 30 allows for IN OUT or N.A., and items 32 and 33 allow for IN, OUT, N.A .or N.O. For marking in the GRP Section place an "A" in the box to the left of the numbered item if the code provision under that item is **not applicable** or and "O" for **not observed**.

E. TEMPERATURE OBSERVATIONS

Item/location — Record the common name of the food as well as the condition, process, and location of the food at the time of monitoring e.g. hot holding, refrigerator, prep-table. Temperatures in compliance and out of compliance should be documented. If there is insufficient space for the number of temperatures taken, record the additional temperatures in the "Observations and Corrective Actions" section of the inspection report.

Food Temperature	Record the temperature indicated on the inspector's thermometer. Specify the measurement in °F or °C. *(Note: Food temperature measuring devices that are scaled only in Fahrenheit should be accurate to ±2°F in the intended range of use. Food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit should be accurate to ± 1°C in the intended range of use.)*

F. OBSERVATIONS AND CORRECTIVE ACTIONS

Include here specific descriptions of violations observed and recorded in the Risk Factors and Interventions section and Good Retail Practices check boxes. Also include corrective actions for the noted violations and temperatures if there is insufficient space in the allotted section for temperature recordings.

G. SIGNATURE BLOCK

Person in Charge	The PIC is the individual present at a food establishment who is responsible for the operation at the time of the inspection.
Inspector	The Inspector is the individual conducting the inspection.
Date	The date the inspection is completed.
Follow-up	The determination of whether to conduct a reinspection or other enforcement action.
Follow-up Date	The date the follow-up inspection will be conducted.

Safe Food and Water

30. Pasteurized eggs used where required

Certain menu items use eggs as an ingredient in the preparation of RTE foods, such as Caesar salad, Hollandaise sauce, etc. This is verified by discussion with the PIC and food employees regarding the substitution of pasteurized egg products for raw eggs in uncooked foods, unless allowed under ¶ 3-401.11(D)(2).

Applicable Code Section:

3-302.13 Pasteurized Eggs Substituted for Raw Eggs for Certain Recipes (P)

31. Water and ice from approved source

There are two types of systems: Public Water System or Non-Public Water System. Regardless of its source, it must meet drinking water standards established by EPA and applicable state drinking water quality standards. If a non-public system is used as Drinking water, the water is sampled / tested at least yearly and records retained on file at the food establishment or per state regulations. Consideration must be given to the supply containers, piping, hoses, etc., connected to the APPROVED source when water is made available for mobile and/or temporary food establishment without a permanent supply.

Applicable Code Sections:

3-202.16 Ice (P)
5-101.11 Approved System-Source (P)
5-102.11 Standards-Quality (P)
5-102.12 Nondrinking Water (P)
5-102.13 Sampling (Pf)
5-102.14 Sample Report (C)
5-104.12 Alternative Water Supply (Pf)

32. Variance obtained for specialized processing methods
When a Food Establishment wants to deviate from a requirement in the code, utilizes Specialized Processing Methods as specified in § 3-502.11 such as Smoking Food for Preservation, curing food etc. a variance must first be obtained from the regulatory authority. A HACCP plan may also be required as listed in ¶ 8-201.13(A) as part of the variance request.

N.A. This item may be marked N.A. if the establishment is not engaged in a specialized processing method, other operation requiring a variance and a HACCP plan or a process or processing method determined by the regulatory authority to require a variance and a HACCP plan.

Applicable Code Section:
8-103.11 Documentation of Proposed Variance and Justification (Pf)

Food Temperature Control

33. Proper cooling methods used; adequate equipment for temperature control
A determination must first be made that cooling food is part of the processing step. To assess whether or not the methods used facilitate the cooling criteria specified under § 3-501.14, a discussion with the PIC should support actual observations used in cooling foods. There should be enough equipment with sufficient capacity used for the cooling, heating and hot/cold holding of foods requiring temperature control as specified in Chapter 3 to meet the demands of the operation. Observations must support the determination of compliance status. Frozen food is solid to the touch.

Applicable Code Sections:
3-501.11 Frozen Food (C)
3-501.15 Cooling Methods (Pf, C)
4-301.11 Cooling, Heating, and Holding Capacities-Equipment (Pf)

34. Plant food properly cooked for hot holding
In determining compliance, observation along with an actual cooking temperature must be obtained.

N.A. This item may be marked N.A. if vegetables and fruits are **not** cooked for hot holding in the establishment.
N.O. This item may be marked N.O. when plant foods are cooked for hot holding, but are not available for observation during the inspection.

Applicable Code Section:
3-401.13 Plant Food Cooking for Hot Holding (Pf)

35. Approved thawing methods used
Observing and then gaining an understanding of the establishment's thawing method(s) will help in determining whether a violation exists from the approved thawing methods found under § 3-501.13 as well as the level of risk imposed. Keep in mind that various food products especially those destined for deep-fat frying are often slacked (not thawed) prior to cooking.

Applicable Code Sections:
3-501.12 Time/Temperature Control for Safety Food, Slacking (C)
3-501.13 Thawing (C)

N.A. This item may be marked N.A. if TCS food are **not** thawed.
N.O. This item may be marked N.O. if this food is thawed, but thawing was not observed during the inspection.

36. Thermometers provided and accurate
Thermometers provide a means for assessing active managerial control of TCS food temperatures. Determine compliance by observing the in-use storage location and verifying the scaling of the temperature measuring devices in the range of use to measure food, water, or ambient air temperatures. Food thermometers must be calibrated at a frequency to ensure accuracy. Food thermometers should be accessible for use by employees and have a probe size appropriate to the food item.

Applicable Code Sections:
4-203.11 Temperature Measuring Devices, Food-Accuracy (Pf)
4-203.12 Temperature Measuring Devices, Ambient Air and Water-Accuracy (Pf)
4-204-112 Temperature Measuring Devices-Functionality (Pf, C)
4-302.12 Food Temperature Measuring Devices (Pf)
4-502.11(B) Good Repair and Calibration (Pf)

Food Identification

37. Food properly labeled; original container
Packaged foods are required to conform to specific labeling laws. Foods packaged within the food establishment must also conform to the appropriate labeling laws, with considerations given to accuracy as well as not being misleading. In addition, all major food allergens, if present, must be accurately declared on the package. Working containers and bulk foods removed from their original packaging require some level of assessment as to how recognizable the food is without labeling by its common name. Molluscan shellfish and vended TCS foods must specifically be assessed based on their specific packaging and labeling requirements.

Applicable Code Sections:
3-202.17 Shucked Shellfish, Packaging and Identification (Pf, C)
3-203.11 Molluscan Shellfish, Original Container (C)
3-302.12 Food Storage Containers Identified with Common Name of Food (C)
3-305.13 Vended Time/Temperature Control for Safety Food, Original Container (C)
3-601.11 Standards of Identity (C)
3-601.12 Honestly Presented (C)
3-602.11 Food Labels (Pf, C)
3-602.12 Other Forms of Information (C)

Prevention of Food Contamination

38. Insects, rodents and animals not Present
An assessment is made through observation and discussion with the PIC for measures taken to control the presence of pests in the food establishment, including elimination of entry points and harborage areas, and removal of pests and its evidence. Insect trapping devices must not be located over food preparation areas.

Applicable Code Sections:
2-403.11 Handling Prohibition-Animals (Pf)
6-202.13 Insect Control Devices, Design and Installation (C)
6-202.15 Outer Openings, Protected (C)
6-202.16 Exterior Walls and Roofs, Protective Barrier (C)
6-501.111 Controlling Pests (Pf, C)
6-501.112 Removing Dead or Trapped Birds, Insects, Rodents and other Pest (C)
6-501.115 Prohibiting Animals (Pf)

39. Contamination prevented during food preparation, storage and display

The observation and understanding of the flow of food items from the point of receipt to the point of sale, service or distribution is necessary to determine whether a violation exists. Food is subject to direct and indirect sources of contamination in the establishment. Sources may be related to the working environment, packaging, adequacy of storage facilities, and exposure of food on display to contamination (i.e. salad bars).

Applicable Code Sections:

3-202.19	Shellstock, Condition (C)
3-303.11	Ice Used as Exterior Coolant, Prohibited as Ingredient (P)
3-303.12	Storage or Display of Food in Contact with Water or Ice (C)
3-304.13	Linens and Napkins, Use Limitations (C)
3-305.11	Food Storage-Preventing Contamination from the Premises (C)
3-305.12	Food Storage, Prohibited Areas (C)
3-305.14	Food Preparation (C)
3-306.11	Food Display-Preventing Contamination by Consumers (P)
3-306.12	Condiments, Protection (C)
3-306.13(B) and (C)	Consumer Self-Service Operations (Pf)
3-307.11	Miscellaneous Sources of Contamination (C)
6-404.11	Segregation and Location-Distressed Merchandise (Pf)

40. Personal cleanliness

Observation of facility personnel for clean outer clothing, effective hair restraints, prohibited jewelry and the condition or protection of fingernails must be made.

Applicable Code Sections:

2-302.11	Maintenance-Fingernails (Pf)
2-303.11	Prohibition-Jewelry (C)
2-304.11	Clean Condition-Outer Clothing (C)
2-402.11	Effectiveness-Hair Restraints (C)

41. Wiping cloths; properly used and stored

Wiping cloths are to be used for a designated purpose and properly used. When stored in solution, the solutions should be reasonably clean and maintained at the proper sanitizer concentration (§4-501.114). Solutions exceeding the recommended sanitizer concentrations would be marked on the Inspection Form under item no.26, Toxic substances properly identified, stored, and used. Sponges, if present, are not to be used in contact with clean/sanitized food contact surfaces.

Applicable Code Sections:

3-304.14	Wiping Cloths, Use Limitation (C)
4-101.16	Sponges Use Limitation (C)
4-901.12	Wiping Cloths, Air Drying Location (C)

42. Washing fruits and vegetables

Raw fruits and vegetables are to be washed prior to their preparation or offered as RTE. Chemicals are allowed for washing fruits and vegetables, along with simply washing them in water. Chemicals that are used in the wash water for fruits and vegetables must be listed and approved with threshold limits in accordance with the CFR's. Refer to the label or labeling of the additive for adequate directions and to assure safe use. Discussion with the PIC and food employees will help determine the establishment's practice.

Applicable Code Sections:

3-302.15	Washing Fruits and Vegetables (Pf)

7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria (P)

43. In-use utensils; properly stored
Based on the type of operation, there are a number of methods available for storage of in-use utensils during pauses in food preparation or dispensing, such as in the food, clean and protected, or under running water to prevent bacterial growth. If stored in a container of water, the water temperature must be at least 135°F. In-use utensils may not be stored in chemical sanitizer or ice between uses. Ice scoops may be stored handles up in an ice bin except for an ice machine.

Applicable Code Sections:
3-304.12 In-Use Utensils, Between-Use Storage (C)

44. Utensils, equipment and linens; properly stored, dried, handled
An assessment is made of the overall storage practices and handling of clean equipment and utensils, including tableware located in the various areas within an establishment, including the basement, wait station and dining room. Equipment must be air dried prior to storage, and linens must be properly cleaned and stored.

Applicable Code Sections:
4-801.11 Clean Linens (C)
4-802.11 Specifications-Laundering Frequency (C)
4-803.11 Storage of Soiled Linens (C)
4-803.12 Mechanical Washing (C)
4-901.11 Equipment and Utensils, Air-Drying Required (C)
4-903.11(A), (B) and (D) Equipment, Utensils, Linens and Single-Service and Single-Use Articles-Storing(C)
4-903.12 Prohibitions (C)
4-904.11 Kitchenware and Tableware-Preventing Contamination (C)
4-904.12 Soiled and Clean Tableware (C)
4-904.13 Preset Tableware (C)

45. Single-use/single-service articles; properly stored, used
These items are not designed to be cleaned and re-used; therefore, they must be properly stored and protected to prevent from possible contamination. Food establishments without facilities for cleaning and sanitizing kitchenware and tableware shall provide only single-use and single-service articles.

Applicable Code Sections:
4-502.12 Single-Service and Single-Use Articles, Required Use (P)
4-502.13 Single-Service and Single-Use Articles-Use Limitations (C)
4-502.14 Shells, Use Limitations (C)
4-903.11(A) and (C) Equipment, Utensils, Linens and Single-Service and Single-Use Articles-Storing (C)
4-903.12 Prohibitions (C)
4-904.11 Kitchenware and Tableware-Preventing Contamination (C)

46. Gloves used properly
The observation of food preparation activities and glove-use by food employees is necessary. There should be a discussion with the PIC on how gloves are used, if applicable, in food preparation activities. Gloves may serve as a source of cross-contamination if misused.

Applicable Code Sections:
3-304.15(B)-(D) Gloves, Use Limitations (C)

Utensils, Equipment and Vending

47. Food and non-food-contact surfaces cleanable, properly designed, constructed and used
Equipment and utensils must be properly designed and constructed, and in good repair. Proper installation and location of equipment in the food establishment are important factors to consider for ease of cleaning in preventing accumulation of debris and attractants for insects and rodents. The components in a vending machine must be properly designed to facilitate cleaning and protect food products (e.g., equipped with automatic shutoff, etc.) from potential contamination. Equipment must be properly used and in proper adjustment, such as calibrated food thermometers.

Applicable Code Sections:

3-304.16	Using Clean Tableware for Second Portions and Refills (C)
3-304.17	Refilling Returnables (C)
4-101.11	Characteristics-Materials for Construction and Repair (P, C)
4-101.12	Cast Iron, Use Limitations (C)
4-101.13	Lead, Use Limitation (P, C)
4-101.14	Copper Use Limitation (P)
4-101.15	Galvanized Metal, Use Limitation (P)
4-101.17	Wood, Use Limitation (C)
4-101.18	Nonstick Coatings, Use Limitation (C)
4-101.19	Nonfood-Contact Surfaces (C)
4-102.11	Characteristics-Single-Service and Single-Use (P, C)
4-201.11	Equipment and Utensils-Durability and Strength (C)
4-201.12	Food Temperature Measuring Devices (P)
4-202.11	Food-Contact Surfaces-Cleanability (Pf)
4-202.12	CIP Equipment (Pf, C)
4-202.13	"V" Threads, Use Limitation (C)
4-202.14	Hot Oil Filtering Equipment (C)
4-202.15	Can Openers (C)
4-202.16	Nonfood-Contact Surfaces (C)
4-202.17	Kick Plates Removable (C)
4-204.12	Equipment Openings, Closures and Deflectors (C)
4-204.13	Dispensing Equipment, Protection of Equipment and Food (P, C)
4-204.14	Vending Machine Vending Stage Closure (C)
4-204.15	Bearings and Gear Boxes, Leakproof (C)
4-204.16	Beverage Tubing, Separation (C)
4-204.17	Ice Units, Separation of Drains (C)
4-204.18	Condenser Unit, Separation (C)
4-204.19	Can Openers on Vending Machines (C)
4-204.110(A)	Molluscan Shellfish Tanks (P)
4-204.111	Vending Machines, Automatic Shutoff (P)
4-204.120	Equipment Compartments, Drainage (C)
4-204.121	Vending Machines, Liquid Waste Products (C)
4-204.122	Case Lot Handling Apparatuses, Movability (C)
4-204.123	Vending Machine Doors and Openings (C)
4-302.11	Utensils, Consumer Self-Service (Pf)
4-401.11	Equipment, Clothes Washers, Dryers and Storage Cabinets, Contamination Prevention-Location (C)
4-402.11	Fixed Equipment, Spacing or Sealing-Installation (C)
4-402.12	Fixed Equipment, Elevation or Sealing (C)

4-501.11 Good Repair and Proper Adjustment-Equipment (C)
4-501.12 Cutting Surfaces (C)
4-501.13 Microwave Ovens (C)
4-502.11(A) and (C) Good Repair and Calibration-Utensils and Temperature and Pressure Measuring Devices (C)
4-603.11 Dry Cleaning-Methods (C)
4-902.11 Food-Contact Surfaces-Lubricating and Reassembling (C)
4-902.12 Equipment-Lubricating and Reassembling (C)

48. Warewashing facilities, installed, maintained, used, test strips
Adequate warewashing facilities must be available and used for the cleaning and sanitization of food-contact surfaces, including the availability of means to monitor its use and the effectiveness of sanitization. For example, an irreversible registering temperature indicator is provided and readily accessible for measuring the utensil surface temperature for establishment that have a hot water mechanical warewashing operation. Observation of manual and mechanical warewashing methods are made to **assess** the procedure for cleaning and sanitizing equipment and utensils.

Applicable Code Sections:
4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment (C)
4-204.113 Warewashing Machine, Data Plate Operation Specifications (C)
4-204.114 Warewashing Machines, Internal Baffles (C)
4-204.115 Warewashing Machines, Temperature Measuring Devices (Pf)
4-204.116 Manual Warewashing Equipment, Heaters and Baskets (Pf)
4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers (Pf)
4-204.118 Warewashing Machines, Flow Pressure Device (C)
4-204.119 Warewashing Sinks and Drainboards, Self-Draining (C)
4-301.12 Manual Warewashing, Sink Compartment Requirements (Pf, C)
4-301.13 Drainboards (C)
4-302.13 Temperature Measuring Devices, Manual and Mechanical Warewashing (Pf)
4-302.14 Sanitizing Solutions, Testing Devices (Pf)
4-501.14 Warewashing Equipment, Cleaning Frequency (C)
4-501.15 Warewashing Machines, Manufacturers' Operating Instructions (C)
4-501.16 Warewashing Sinks, Use Limitation (C)
4-501.17 Warewashing Equipment, Cleaning Agents (Pf)
4-501.18 Warewashing Equipment, Clean Solutions (C)
4-501.19 Manual Warewashing Equipment, Wash Solution Temperature (Pf)
4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature (Pf)
4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration (Pf)
4-603.12 Precleaning (C)
4-603.13 Loading of Soiled Items, Warewashing Machines (C)
4-603.14 Wet Cleaning (C)
4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment (C)
4-603.16 Rinsing Procedures (C)

49. Non-food-contact surfaces clean
Observations should be made to determine if the frequency of cleaning is adequate to prevent soil accumulations on non-food-contact surfaces.

Applicable Code Sections:
4-601.11(B) and (C) Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils (C)
4-602.13 Nonfood Contact Surfaces (C)

Physical Facilities

50. Hot and cold water available; adequate pressure
Regardless of the supply system, the distribution of water to the facility must be protected and operated according to law. Adequate pressure is to be maintained at all fixtures during peak demand including the capacity to provide hot water at peak hot water demand.

Applicable Code Sections:
5-103.11 Capacity-Quantity and Availability (Pf)
5-103.12 Pressure (Pf)
5-104.11 System-Distribution, Delivery, and Retention (Pf)

51. Plumbing installed; proper backflow devices
The observation of an approved plumbing system, installed and maintained, including the equipment and devices connected to the potable water supply, is necessary to determine whether a violation exists. An assessment of the layout of the establishment and the water distribution system is made to determine if there are any points at which the potable water supply is subject to contamination or is in disrepair.

Applicable Code Sections:
5-101.12 System Flushing and Disinfection (P)
5-201.11 Approved-Materials (P)
5-202.11 Approved System and Cleanable Fixtures (P, C)
5-202.13 Backflow Prevention, Air Gap (P)
5-202.14 Backflow Prevention Device, Design Standard (P)
5-202.15 Conditioning Device, Design (C)
5-203.13 Service Sink (C)
5-203.14 Backflow Prevention Device, When Required (P)
5-203.15 Backflow Prevention Device. Carbonator (C)
5-204.12 Backflow Prevention Device, Location (C)
5-204.13 Conditioning Device, Location (C)
5-205.12 Prohibiting a Cross Connection (P, Pf)
5-205.13 Scheduling Inspection and Service for a Water System Device (Pf)
5-205.14 Water Reservoir of Fogging Devices, Cleaning (P)
5-205.15 System Maintained in Good Repair (P, C)
5-301.11 Approved-Materials, Mobile Water Tank and Mobile Food Establishment Water Tank (P, C)
5-302.11 Enclosed System, Sloped to Drain (C)
5-302.12 Inspection and Cleaning Port, Protected and Secured (C)
5-302.13 “V” Type Threads, Use Limitation (C)
5-302.14 Tank Vent, Protected (C)
5-302.15 Inlet and Outlet, Sloped to Drain (C)
5-302.16 Hose, Construction and Identification (P, C)
5-303.11 Filter, Compressed Air (P)
5-303.12 Protective Cover or Device (C)
5-303.13 Mobile Food Establishment Tank Inlet (C)
5-304.11 System Flushing and Sanitization-Operation and Maintenance (P)
5-304.12 Using a Pump and Hoses, Backflow Prevention (C)
5-304.13 Protecting Inlet, Outlet and Hose Fitting (C)
5-304.14 Tank, Pump and Hoses, Dedication (P)

52. Sewage and waste water properly disposed
There are two types of systems: public sewage treatment plant and an individual sewage disposal system. Observations of the facilities overall sewage and wastewater system is necessary to determine if a violation exists. Indications that a system is not functioning properly may include the presence of sewage

back-up into the establishment or outdoors on the ground. Condensate drippage and other non-sewage wastes must be drained to a system in accordance to LAW, and backflow prevention, if required, installed between the sewage system and drain of equipment holding food or utensils. Mobile wastewater holding tanks must also be assessed for capacity and maintenance.

Applicable Code Sections:

5-401.11	Capacity and Drainage (C)
5-402.11	Backflow Prevention (P)
5-402.12	Grease Trap (C)
5-402.13	Conveying Sewage (P)
5-402.14	Removing Mobile Food Establishment Wastes (Pf)
5-402.15	Flushing a Waste Retention Tank (C)
5-403.11	Approved Sewage Disposal System (P)
5-403.12	Other Liquid Wastes and Rainwater (C)

53. Toilet facilities: properly constructed, supplied, clean

A toilet facility should be assessed to determine if: it is not an attractant to insects; the number of fixtures are adequate; toilet tissue and a covered trash receptacle (ladies room only) are provided; fixtures are not being kept clean; and the door self-closes to prevent recontamination of hands.

Applicable Code Sections:

5-203.12	Toilets and Urinals (C)
5-501.17	Toilet Room Receptacle, Covered (C)
6-202.14	Toilet Rooms, Enclosed (C)
6-302.11	Toilet Tissue, Availability (Pf)
6-402.11	Conveniently Located (C)
6-501.18	Cleaning of Plumbing Fixtures (C)
6-501.19	Closing Toilet Room Doors (C)

54. Garbage/refuse properly disposed; facilities maintained

The assessment of the refuse collection and disposal areas for proper receptacles and maintenance is necessary to determine whether a violation exists. Since refuse areas may attract and harbor insects and pests, as well as create a public health nuisance, particular attention must be paid to the maintenance of the refuse facilities and area.

Applicable Code Sections:

5-501.11	Outdoor Storage Surface (C)
5-501.12	Outdoor Enclosure (C)
5-501.13	Receptacles (C)
5-501.14	Receptacles in Vending Machines (C)
5-501.15	Outside Receptacles (C)
5-501.16	Storage Areas, Rooms and Receptacles, Capacity and Availability (C)
5-501.18	Cleaning Implements and Supplies (C)
5-501.19	Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location(C)
5-501.110	Storage Refuse, Recyclables and Returnables (C)
5-501.111	Area, Enclosures and Receptacles, Good Repair (C)
5-501.112	Outside Storage Prohibitions (C)
5-501.113	Covering Receptacles (C)
5-501.114	Using Drain Plugs (C)
5-501.115	Maintaining Refuse Areas and Enclosures(C)
5-501.116	Cleaning Receptacles (C)
5-502.11	Frequency-Removal (C)

5-502.12 Receptacles or Vehicles (C)
5-503.11 Community or Individual Facility (C)
6-202.110 Outdoor refuse Areas, Curbed and Graded to Drain (C)

55. Physical facilities installed, maintained, and clean
Observations are made of the overall conditions or practices related to the physical facility (e.g., materials used, good repair, and maintained). It is important to make an overall assessment of the physical facility conditions to determine the level of compliance and the potential public health impact involved if compliance is not met. Storage of maintenance tools, use of laundry facilities, if applicable, disposal of mop water and separate living/sleeping quarters are included in this section.

Applicable Code Sections:
4-301.15 Clothes Washers and Dryers (C)
4-401.11(C) Equipment, Cloths Washers and Dryers, and Storage Cabinets, Contamination Prevention (C)
4-803.13 Use of Laundry Facilities (C)
6-101.11 Surface Characteristics-Indoor Areas (C)
6-102.11 Surface Characteristics-Outdoor Areas (C)
6-201.11 Floors, Walls and Ceilings-Cleanability (C)
6-201.12 Floors, Walls, and Ceilings, Utility Lines (C)
6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed (C)
6-201.14 Floor Carpeting, Restrictions and Installation (C)
6-201.15 Floor Covering, Mats and Duckboards (C)
6-201.16 Wall and Ceiling Coverings and Coatings (C)
6-201.17 Walls and Ceilings, Attachments (C)
6-201.18 Walls and Ceilings, Studs, Joists, and Rafters (C)
6-202.17 Outdoor Food Vending Areas. Overhead Protection (C)
6-202.18 Outdoor Servicing Areas, Overhead Protection (C)
6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain (C)
6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibition (P)
6-202.112 Living or Sleeping Quarters, Separation (C)
6-501.11 Repairing-Premises, Structures, Attachments, and Fixtures-Methods (C)
6-501.12 Cleaning, Frequency and Restrictions (C)
6-501.13 Cleaning Floors, Dustless Methods (C)
6-501.15 Cleaning Maintenance Tools, Preventing Contamination (Pf)
6-501.16 Drying Mops(C)
6-501.17 Absorbent Materials on Floors, Use Limitation (C)
6-501.113 Storing Maintenance Tools (C)
6-501.114 Maintaining Premises, Unnecessary Items and Litter (C)

56. Adequate ventilation and lighting; designated areas used
Observations should be made to ensure that the ventilation is adequately preventing an accumulation of condensation, grease or other soil from potentially contaminating food and the surrounding environment and that lights are at an adequate light intensity, and personal belongings are properly stored to maintain clean and sanitary facility and protect food and equipment.

Applicable Code Sections:
4-202.18 Ventilation Hood Systems, Filters (C)
4-204.11 Ventilation Hood Systems, Drip Prevention (C)
4-301.14 Ventilation Hood Systems, Adequacy (C)
6-202.11 Light Bulbs, Protective Shielding (C)
6-202.12 Heating, Ventilation, Air Conditioning System Vents (C)
6-303.11 Intensity-Lighting (C)

6-304.11	Mechanical-Ventilation (C)
6-305.11	Designation-Dressing Areas and Lockers (C)
6-403.11	Designated Areas-Employee Accommodations for eating / drinking/smoking (C)
6-501.14	Cleaning Ventilation Systems, Nuisance and Discharge Prohibition (C)
6-501.110	Using Dressing Rooms and Lockers (C)

Chart 4-A

Summary Chart for Minimum Cooking Food Temperatures and Holding Times Required by Chapter 3

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature
Raw Eggs prepared for immediate service **Commercially Raised Game Animals and Exotic Species of Game Animals** **Fish, Pork, and Meat** Not Otherwise Specified in this Chart or in ¶ 3-401.11(B)	**63°C (145°F)**	**15 seconds**
Raw Eggs not prepared for immediate service **Comminuted Commercially Raised Game Animals and Exotic Species of Game Animals** **Comminuted Fish and Meats** **Injected Meats** **Mechanically Tenderized Meats**	70°C (158°F) **68°C (155°F)** 66°C (150°F) 63°C (145°F)	< 1 second **15 seconds** 1 minute 3 minutes
Poultry **Baluts** **Stuffed Fish; Stuffed Meat; Stuffed Pasta;** **Stuffed Poultry; Stuffed Ratites** **Stuffing Containing Fish, Meat, Poultry, or Ratites** **Wild Game Animals**	**74°C (165°F)**	**15 seconds**
Food Cooked in A Microwave Oven	**74°C (165°F)**	**and hold for 2 minutes after removing from microwave oven**

Chart 4-B

Summary Chart for Minimum Food Temperatures and Holding Times Required by Chapter 3 for Reheating Foods for Hot Holding

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature	Maximum Time to Reach Minimum Temperature
¶ 3-403.11(A) and (D) Food that is cooked, cooled, and reheated	74°C (165°F)	15 seconds	2 hours
¶ 3-403.11(B) and (D) Food that is reheated in a microwave oven	74°C (165°F)	and hold for 2 minutes after reheating	2 hours
¶ 3-403.11(C) and (D) Food that is taken from a commercially processed, hermetically sealed container or intact package	57°C (135°F)	No time specified	2 hours
Roasts: Option A ¶ 3-403.11(E) Unsliced portions of meat roasts cooked as specified under ¶ 3-401.11(B)	Same oven parameters and minimum time and temperature conditions as specified under ¶ 3-401.11(B)	Same oven parameters and minimum time and temperature conditions as specified under ¶ 3-401.11(B)	Not applicable
Roasts: Option B ¶ 3-403.11(E) Unsliced portions of meat roasts cooked as specified under ¶ 3-401.11(B)	74°C (165°F)	15 seconds	2 hours

Chart 4-C **Summary Chart**
Ready-to-Eat, Time/temperature Control for Safety Food)
Date Marking § 3-501.17(A) – (E) and Disposition § 3-501.18

"IF" → **"THEN"**

(A) or (B) On site preparation and held > 24 hours, or commercial container is opened → @ ≤ 41°F for ≤ 7 days

or

(A) or (B) Remove from freezer → @ ≤ 41°F 7 days minus*

*Time from preparation, or opening commercial container, to freezing.

Example: The morning of October 1, a chicken was cooked, then cooled, refrigerated for 2 days at 41°F and then frozen. If the chicken is thawed October 10, the food must be consumed or discarded no later than midnight of October 14.

Date	Shelf Life Day	Action
Oct. 1	1	cook/cool
Oct. 2	2	cold hold at 41°F
Oct. 3		freeze
Oct. 10	3	thaw to 41°F
Oct. 11	4	cold hold
Oct. 12	5	cold hold
Oct. 13	6	cold hold
Oct. 14	7	consume or discard

Chart 4-D

FDA Food Code Mobile Food Establishment Matrix

This table is a plan review and inspectional guide for mobile food establishments based on the mobile unit's menu and operation. Mobile units range in type from push carts to food preparation catering vehicles.

To use the table, read down the columns based on the menu and operation in use. For example, if only prepackaged time/temperature control for safety food is served, then requirements listed in the **TCS Food Menu - *Prepackaged*** column apply. Likewise, if only food that is not time/temperature control for safety food is prepared on board, then requirements listed in the **Not TCS Menu - *Food Preparation*** column apply. Note that if a mobile food establishment has available for sale to the consumer both prepackaged time/temperature control for safety food and time/temperature control for safety food prepared on board, then the more stringent requirements of the **TCS Menu - *Food Preparation*** column apply.

It is important to remember that mobile units may also be subject to all Food Code provisions that apply to food establishments. Consult the local regulatory authority for specific local requirements.

The local regulatory authority's decision to require auxiliary support services such as a commissary or servicing area should be based on the menu, type of operation, and availability of on-board or on-site equipment.

NOTE: The Food Code definition of "Food Establishment" does not include an establishment that offers only prepackaged foods that are not time/temperature control for safety foods.

FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX			
Food Code	***Time/Temperature for Safety Food (TCS) Menu***		***Not TCS Food Menu***
Areas/Chapter	*Food Preparation*	*Prepackaged*	*Food Preparation*
Personnel	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (C)	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (C)	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (C)
Food	3-101.11 3-201.11-.16 3-202.16; Applicable Sections of Part 3-3; 3-501.16 3-501.18(A)	3-101.11 3-201.11-.16 3-303.12(A) 3-501.16 3-305.11; 3-305.12 (Applicable to Service Area or Commissary)	3-101.11; 3-201.11 3-202.16; Applicable Sections of Part 3-3
Temperature Requirements	3-202.11; Applicable Sections of Parts 3-4 & 3-5	3-202.11 3-501.16	NONE
Equipment Requirements	Applicable Sections of Parts 4-1 - 4-9 and 5-5	Applicable Sections of Parts 4-1 - 4-2; 4-6 and 5-5	Applicable Sections of Parts 4-1 - 4-2; 4-5 - 4-6 and 5-5
Water & Sewage	5-104.12 5-203.11(A) & (C) Part 5-3; 5-401.11 5-402.13-.15	5-104.12 5-203.11(A) & (C) Part 5-3; 5-401.11 5-402.13 -.15	5-104.12 5-203.11(A) & (C) Part 5-3; 5-401.11 5-402.13-.15
Physical Facility	6-101.11; 6-201.11 6-102.11(A) & (B) 6-202.15; 6-501.11 6-501.12; 6-501.111	6-101.11 6-102.11(A) & (B) 6-202.15 6-501.111	6-101.11; 6-201.11 6-102.11(A) & (B) 6-202.15; 6-501.11 6-501.12; 6-501.111
Toxic Materials	Applicable Sections of Chapter 7	Applicable Sections of Chapter 7	Applicable Sections of Chapter 7
Servicing	6-202.18 / As necessary to comply with the Food Code	6-202.18 / As necessary to comply with the Food Code	6-202.18 / As necessary to comply with the Food Code
Compliance and Enforcement	Applicable Sections of Chapter 8 and Annex 1	Applicable Sections of Chapter 8 and Annex 1	Applicable Sections of Chapter 8 and Annex 1

Summary of Changes In the FDA Food Code

This Summary provides a synopsis of the textual changes from the 2009 FDA Food Code and the Supplement to the 2009 Food Code Chapters and Annexes to the 2013 edition. The primary intent of this record is to capture the nature of the changes rather than to identify every word or editing change. ***This record should not be relied upon as an absolute comparison that identifies each and every change*.**

General:

- Numerous editing changes were made throughout the document for internal consistency, to correct some errors in the 2009 Code and for clarification.

- Section and paragraph numbers listed refer to the 2009 Code and its Supplement unless otherwise noted. The numbering system was removed from Chapter 1 definitions in the 2005 version of this Code. An explanation regarding the rationale can be found in Annex 3, 1-201.10(B).

- Updated the web links throughout the Code and Annexes.

- Converted several Tables, charts, and images throughout the Code to meet web accessibility requirements under Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d). Section 508 mandates that all federal agencies eliminate the barriers in accessing electronic and information technology.

Preface

Amended Preface sections 1, 3, 5, 6, and 8 to add updated information and revise dates to make current.

Chapter 1 Purpose and Definitions

Deleted **"Enterohemorrhagic *Escherichia coli*" *(EHEC)*** as use of EHEC terminology is outdated.

Amended "**Packaged**" in (1) to delete the term "securely" to avoid undue emphasis on nature of the package; Amended ***"Packaged"*** in (2) to remove the phrase "or other nondurable container" to clarify when foods packaged at retail need to be labeled so that it reads: ***"Packaged"*** *does not include wrapped or placed in a carry-out container to protect the* FOOD *during service or delivery to the* CONSUMER*, by a* FOOD EMPLOYEE*, upon* CONSUMER *request.*

Deleted the term **Potentially Hazardous Food (Time/Temperature Control for Safety Food)" (PHF/TCS)** and made a universal change throughout the Code to replace it with the term **"Time/Temperature Control for Safety Food" (TCS).** The definition remains the same.

Revised "**Reduced Oxygen Packaging**" subparagraph (2)(e), to delete the phrase "placed in a hermetically sealed, impermeable bag" and replace it with "vacuum packaged in an impermeable bag" so it clearly defines the sous vide process as outlined in Annex 6(2)(B)(4)(b). It now reads: "Sous vide PACKAGING, in which raw or partially cooked FOOD is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens."

Revised **"Shiga toxin-producing *Escherichia coli*"** (STEC) to reflect current nomenclature.

Chapter 2 Management and Personnel

2-201.11, 2-201.12, 2-201.13

Amended to add nontyphoidal *Salmonella* (NTS) as one of the reportable illnesses for action by the Person in Charge; Added Code language to address employee health controls for the exclusion and restriction of nontyphoidal *Salmonella,* and removal of exclusion and restriction from NTS.

2-301.14(H)

Amended to clarify that the requirement to wash hands before donning gloves is specific to the beginning of a task involving working with food and not during the task.

2-301.16(A)(2)

Amended to remove (A)(2)(b)(i-ii) and add new subparagraphs (A)(2)(b-e) to clarify and align the codified text with applicable CFR's and the FD&C Act with regard to the use of hand antiseptics as a food additive.

Chapter 3 Food

3-201.16(A)
Amended to remove existing 2009 ¶(A) language in reserve; Added new ¶(A) to recognize a regulatory authority's ability to approve the sale of wild mushrooms within a food establishment and regulate wild mushrooms according to their LAW.

3-301.11(D)
Amended to revise subparagraph (D)(2) to clarify that Paragraph (B) does not apply where a ready-to-eat food is added as an ingredient to another food that does not contain a raw animal food and the combined product will be heated to at least 63°C (145°F).

3-302.11
Amended to remove subparagraph (A)(3) and renumbered the remaining paragraphs as (4) – (8).

3-304.11
Amended to add a new ¶(C) to clarify that food may contact surfaces of linens and napkins as specified in §3-304.13 and added term "Linens" to the tag line.

3-304.13
Amended to clarify that napkins in this section refers to cloth napkins and they are by definition considered linens.

3-304.17
Amended to relocate the requirement regarding the cleaning of returnables into this section from §4-603.17.

Amended ¶3-304.17(A) to clarify conditions under which the re-use of returnables are permitted.

Amended ¶3-304.17(B) to establish conditions under which refilling of returnable take-home containers is permitted.

Amended to relocate the exception for filling a food-specific container with a beverage from ¶4-603.17(B) to ¶3-304.17(C).

Amended to renumber ¶3-304.17(C) as a new ¶3-304.17(D).

Amended to relocate the exception for filling consumer-owned, personal take-out containers that are not food-specific from ¶4-603.17(C) to ¶3-304.17(E).

3-401.14
Amended to revise ¶(D) to clarify that prior to sale or service, raw animal foods cooked using a non-continuous cooking process shall be cooked to a temperature and for a time as specified under ¶¶3-401.11 (A)-(C).

3-402.11
Amended ¶3-402.11(B) to add a new ¶(2) to clarify that scallop products consisting solely of the shucked adductor muscle are excluded from the requirements for parasite destruction and re-designated existing ¶¶(2)-(4) to be new ¶¶ (3)-(5).

3-403.11
Amended ¶3-403.11(C) to clarify that this provision applies to all commercially processed TCS foods that are ready-to-eat. Previous text suggested that it applied only immediately upon removal of the food from a sealed container.

3-501.13
Amended to add new ¶(E) specifying frozen fish packaged using a ROP method be removed from the ROP environment either prior to initiating thawing procedures under refrigeration as specified in ¶ (A) or prior to, or immediately upon completion of, its thawing using procedures specified in ¶ (B) of this section.

3-501.17
Amended to add new ¶(F) that exempts raw, live in-shell molluscan shellfish from date marking and re-designated former ¶(F) as new ¶(G).

Amended existing subparagraph 3-501.17 (F)(6) to clarify that the exemption from date marking for shelf stable dry fermented sausages produced in USDA-regulated facilities is not dependent on the product retaining the original casing; Renumbered existing ¶(F)(6) as new ¶(G)(6) as a result of the addition of new ¶ (F).

3-502.11
Amended to revise ¶(D) to make clear that only TCS foods prepared under ROP methods that do not control for growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* require a variance.

3-502.12
Amended ¶¶3-502.12(B), (D), and (E) lead-in paragraphs to reference new ¶ (F) of this section.

Amended ¶3-502.12(B) lead in paragraph and subparagraphs (B)(6)(c), (D)(1), and (E)(2) to reference ¶8-201.14(B) along with existing reference to ¶ (D).

Amended subparagraphs 3-502.12(B)(3)(b) and (B)(4) to delete 14 days and add 30 days.

Amended ¶ 3-502.12(B) to add new subparagraph 7 specifying that a HACCP plan be provided to the regulatory authority prior to implementation.

Amended ¶3-502.12(D) lead in paragraph to delete the word “FOOD” and replace it with the term “Time/Temperature control for safety food” to clarify that this section applies to TCS food.

Amended subparagraph 3-502.12(D)(2)(b) to specify only the cooking parameters in ¶¶ 3-401.11(A), (B) and (C) apply.

Amended subparagraph 3-502.12(D)(2)(e)(ii) to allow for cold holding at 41°F for 7 days after cooling to 41°F.

Amended to delete existing subparagraph 3-502.12(D)(2)(e)(iii) and amended subparagraph 3-502.12(D)(2)(e)(iv) to renumber it as the new subparagraph (D)(2)(e)(iii).

Amended to add new ¶(F) to identify the conditions under which a HACCP Plan is not required for ROP TCS foods.

3-602.11
Amended ¶3-602.11(B)(2),(3),(5), and (7) to clarify the information that a label should include.

Amended subparagraph 3-602.11(B)(2) to clarify what information must be included in the statement of ingredients. The term “sub ingredients” was added to this subparagraph to clarify that individual component ingredients of a main ingredient must be disclosed in the statement of ingredients. This clarification helps to make clear that all individual ingredients in a packaged food will be disclosed in the statement of ingredients.

Amended subparagraph 3-602.11(C)(2) to remove cross reference to subparagraph (B)(5) to correctly refer to what a labeling device such as a card, sign, or other method of notification needs to declare. This change corrects an inadvertent error that was created in the 2005 Food Code when a new subparagraph (B)(5) for food allergens was added and the subparagraph for nutritional labeling was renumbered to (B)(6), but the accompanying cross reference in (C)(2) was not changed to correctly cross reference (B)(1), (2), and (6), nutritional labeling.

Chapter 4 Equipment, Utensils, and Linens

4-302.13
Amended the tag line to add “mechanical warewashing”

Amended to redesignate the existing section into ¶(A) and new ¶(B) to require the availability of irreversible registering temperature indicators.

4-602.11
Amended ¶ 4-602.11(B) to change the cleaning and sanitizing frequency for food contact surfaces or utensils that are in contact with a raw animal food that is a major food allergen such as fish, followed by other types of raw animal foods. With this change, the exception to existing subparagraph (A)(1) found in ¶(B) now applies only to raw meat and poultry.

4-603.17
Amended to delete §4-603.17 and relocate its requirements into §3-304.17.

4-802.11
Amended ¶4-802.11(C) to clarify that napkins in this section refers to cloth napkins and they are by definition considered linens as mentioned in ¶3-304.11(C) and §3-304.13.

Chapter 5 Water, Plumbing, and Waste
No Changes.

Chapter 6 Physical Facilities
No Changes.

Chapter 7 Poisonous or Toxic Materials

7-204.12
Amended ¶7-204.12(A) to redesignate ¶(A) into a lead-in paragraph with four new subparagraphs: Added 21 CFR 173 Secondary Direct Food Additives Permitted in Food for Human Consumption as new subparagraph (A)(1); Added GRAS ingredients as new subparagraph (A)(2); Added effective food contact notifications as new subparagraph (A)(3); Added 40 CFR 156 Labeling Requirements for Pesticides and Devices as new subparagraph (A)(4) to allow the use of other antimicrobial agents allowed under the food contact notification program for washing fruits and vegetables as well as GRAS ingredients permitted as antimicrobials or for general food use.

Chapter 8 Compliance and Enforcement

8-201.13
Amended ¶8-201.13(B) to add new language to have the food establishment notify the Regulatory Authority through submission of a HACCP plan that they will be conducting ROP operations that conform with procedures in § 3-502.12.

8-304.11
Amended to add new ¶(K) to include a requirement for the permit holder to post a sign or placard notifying the public that inspectional information is available for review.

Annex 1 Compliance and Enforcement
No Changes.

Annex 2 References

Preface
Amended to redesignate numbers and alphabetize.

2-201.12 and 2-201.13
Amended to update three references and add twenty new references in support of including public health controls for the control of nontyphoidal *Salmonella* (NTS) in retail food establishments; references renumbered to keep alphabetical format.

3-401.11
Amended to redesignate numbers and alphabetize.

3-402.11
Amended to add one new reference (#6), the Fish and Fishery Products Hazards and Controls Guidance, 4th Edition, April 2011, and renumbered remaining references.

3-502.12
Amended to add two new references (#24, and #28) and renumbered the remaining references. The new references are regarding time to formation of *C. botulinum* toxin. These references provide support of the pH of 5 limit for the psychrotrophic strains of *C. botulinum* due to Code changes to allow a 7-day storage for ROP at 41°F and a 30-day hold for vacuum packaging and Cook-Chill/Sous Vide of foods with a pH of 5 or less.

4-603.17
Amended to move reference for deleted §4-603.17 to be under §3-304.17 since the two sections were merged into §3-304.17.

6-501.111
Amended to add new reference in support of this section on controlling pests.

7-204.12
Amended to add new reference to include 21 CFR 173.405, Secondary Direct Food Additives Permitted in Food for Human Consumption; Sodium Dodecylbenzenesulfonate.

3. Supporting Documents

Amended section **K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information,** to update with current USDA/FSIS information and documents. The update includes deleting existing paragraphs 5 and 6 and adding new paragraphs 5 and 6; Updated other existing paragraphs with editorial changes.

Amended to add new section, **S. CIFOR The Council to Improve Foodborne Outbreak Response (CIFOR) – Guidelines for Foodborne Outbreak Response**

Amended to add new section, **T. CIFOR Foodborne Illness Response Guidelines for Owners, Operators, and Managers of Food Establishments (CIFOR Industry Guidelines)**

Annex 3 Public Health Reasons/Administrative Guidelines

1-201.10
Packaged.
Amended to add a section on "Packaged" to clarify when foods packaged at retail need not be labeled and placed the text after the "Food Establishment and a food processing plant located within the same premises of a food establishment" section and before the "TCS" section.

2-2 Employee Health
Amended to add a description of nontyphoidal *Salmonella* between the descriptions of Norovirus and *Salmonella* Typhi.

Amended Part 2-2 and its related subparts and Tables/Decision Trees to be consistent with the changes in Chapter 2; Tables and Decision trees were revised to meet accessibility requirements for web posting.

Amended to update the list of *Pathogens Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens* from CDC, effective November 30, 2012.

Amended the pathogen descriptions in subpart 2-201.11 to be consistent with the Bad Bug Book, 2nd Edition, 2012.

2-301.14
Amended to clarify that subparagraph ¶2-301.14(H) requires handwashing immediately before, during, and immediately after, the activities listed.

2-301.16
Amended the "As a Food Additive" Section to add a new paragraph 4 to elaborate on the prior sanction requirements under the food additive provision in the Federal Food, Drug and Cosmetic Act as it relates to the substances in a hand antiseptic reasonably expected to become a component of food based upon the product's intended use; Renumbered the existing paragraph 4 as a new paragraph 5.

3-201.11
Amended to relocate information about safe food handling label instructions from Annex 3, §3-602.11 to Annex 3 §3-201.11.

3-201.16
Amended to delete last sentence in paragraph 2; revise paragraph 3; add new paragraphs 4-5; and delete existing paragraphs 4-8.

3-302.11
Amended to remove paragraph 3 to be consistent with change to delete subparagraph 3-302.11(A)(3).

3-304.17
Amended to describe the public health reasons for inclusion of an exception for reusing and refilling returned take-home containers with TCS- or non-TCS food; Relocated PHR text from §4-603.17 to §3-304.17.

3-401.14
Amended to revise paragraph 6 to clarify that during the final cooking step, raw animal FOODS cooked using a NON-CONTINUOUS COOKING process shall be cooked to a temperature and for a time as specified under ¶¶3-401.11 (A)-(C).

3-402.11
Amended to update paragraph 6 to be consistent with the Fish and Fisheries Products Hazards and Controls Guidance, Fourth edition.

Amended to add new paragraph 8 to explain why the requirements for parasite destruction do not apply to molluscan shellfish and scallop products consisting solely of the shucked adductor muscle.

3-403.11
Amended to add a new paragraph 4 to provide the public health reason for requiring a reheating temperature for commercially processed foods that is lower than that for foods prepared in the food establishment.

3-501.13
Amended to add three new paragraphs to address the removal of ROP frozen fish from its packaging before thawing to prevent *C. botulinum* toxin formation.

3-501.17
Amended to remove "PHF" from the Tagline so it references only TCS food.

Amended to add a new paragraph #13 under a new subheading "Shellstock" as public health rationale for exempting shellstock from date marking.

Amended paragraph 4 under subheading of USDA-regulated products to clarify that the exemption from date marking for shelf stable dry fermented sausages produced in USDA-regulated facilities is not dependent on the product retaining the original casing.

3-502.11
Amended with an editorial change to make a correction in the title of Chart 1 to accurately cross reference §3-502.11 rather than §3-501.11.

3-502.12
Amended the entire annex section to reorganize the information according to different concepts presented in the Annex, added sub-headings, and revised certain text within the existing paragraphs, such that changes are:

- In the introductory paragraphs,
    - amended paragraph 1 to add information about safety concerns when spoilage organisms are inhibited, and
    - amended paragraph 2 to delete information about oxygen transfer rate and add information about other ways oxygen is restricted not just by the packaging.

- Amended text under the new subheading, ROP with Two Barriers,
    - in paragraph 2, to provide examples of foods that have high levels of competing organisms and explained why the refrigerated shelf life time was increased from 14 calendar days to 30 calendar days for vacuum packaged ROP food, and
    - in paragraph 3, to address non-time/temperature control for safety food explaining why these foods do not require a variance or HACCP Plan for ROP.

- Amended the first sentence in paragraph 1 under the new subheading, ROP and Cheese, to remove "Naturally fermented" at the start of the sentence.

- Amended text under the new subheading, ROP with One Barrier (Cook-Chill and Sous Vide),
    - in paragraph 1 to change the four options to three options for inhibiting growth for cook/chill, sous vide processing, and

- in paragraph 2, to change the 38°F cold holding temperature noted to 41ºF, to be consistent with the changes made in subparagraph 3-502.12(D)(2)(e).

- Amended text under the new subheading, The Relationship Between Time and ROP, to add new text that provides information regarding short-term ROP storage and exemption from a HACCP Plan.

- Amended text under the new subheading, HACCP Plans with ROP,
  - in paragraph 1 to add information on submitting a HACCP Plan to the regulatory authority, and
  - in paragraph 2 to clarify information for when an operator submits an application for a variance.

- Amended text under the new subheading, ROP with Fish, for internal consistency.

3-602.11
Amended to reorganize the entire public health reasons and include new subheading titles; removed outdated information from the food allergen labeling subsection; included information about astaxanthin, a color additive used in salmonid fish under its new subheading; New cross-reference created in §3-602.11 to direct the reader to §3-201.11 under the new safe handling instructions subheading.

Amended to clarify why food held under the direct control of the operator is exempt from the labeling requirements in 3-602.11, while food enclosed in a container or wrapping and placed on display for consumer self service is subject to the labeling requirements under §3-602.11.

Added public health rationale to explain the importance of having an accurate list of food ingredients on the label. Two examples were provided to illustrate the method that food establishments may use to list the ingredients on the label.

4-101.15
Amended paragraph 1 and added new paragraph 2 to add information about zinc and zinc poisoning

4-302.13
Amended to change the tag line and to add a new paragraph 2 with the public health rationale for the new ¶4-302.13(B).

4-602.11
Amended to add new paragraphs 5 and 6 to clarify that food contact surfaces of equipment and utensils that have contacted a raw animal food that is a major food allergen such as raw fish must be cleaned and sanitized prior to contacting different types of raw animal foods.

4-603.17
Removed Annex 3, §4-603.17 and relocated the public health reasons text from §4-603.17 to §3-304.17.

7-204.12
Amended to update web link in paragraph 1, revise paragraph 3 and add a new paragraph 4 that speaks to allowing food additives and food contact substances as well as substances generally recognized as safe (GRAS) that are permitted under FDA's regulations for washing fruits and vegetables.

8-304.11
Amended to add new public health reasons to explain the intent of adding in new ¶(K) a requirement to post a sign/placard notifying the public that inspectional information is available for review.

Annex 4 Management of Food Practices-Achieving Active Managerial Control of Foodborne Illness Risk Factors

Amended to convert Table 1 through Table 4 and the CCP Decision Tree 1 to meet web accessibility requirements.

Amended section **9. Resources and References (C) FDA Publications** to update the list of resources and references to also reference the Fourth Edition of the Fish & Fishery Products Hazards and Controls Guidance, April 2011.

Annex 5 Conducting Risk-Based Inspection

No Changes.

Annex 6 Food Processing Criteria

Amended Section 2, Reduced Oxygen Packaging, (B) Definitions, (1) through (5) to revise the ROP definitions to be consistent with the ROP definition in Chapter 1 (1-201.10).

Annex 7 Models Forms, Guides, and Other Aids

Amended the Tables and Charts throughout to be consistent with web accessibility requirements.

Amended Forms 1-A, 1-B, and 1-C to revise the forms to be consistent with the changes in Chapter 2 in regards to the use of the term STEC and not EHEC and NTS, as applicable.

Amended Forms 2-A and 2-B to change use of term “Potentially hazardous food (time/temperature control for safety food” to “time/temperature control for safety food”.

Amended Form 3-A, *Food Establishment Inspection Report* form, for consistency with changes made in the Supplement with the 2009 Food Code to add two new entries and renumber the subsequent items. This change added in a new item #2 Certified Food Protection Manager, renumbered existing #2-3 as new items #3-4; added in a new item #5 Procedures for responding to vomiting and diarrheal events, renumbered existing items #4-54 as new #6-56.

Amended Guide 3-B, *Instructions for Marking the Food Establishment Inspection Report, Including Food Code References for Risk Factors/Interventions and Good Retail Practices* to add the risk designations (Priority (P), Priority Foundation (Pf) and Core (C)) to each applicable code section for reference when recording observations in the inspection report.

ADA = Americans with Disabilities Act
ASTM = American Society for Testing and Materials
CDC = Centers for Disease Control and Prevention
CFP = Conference for Food Protection
CFR = Code of Federal Regulations
HACCP = Hazard Analysis and Critical Control Point
IFT = Institute of Food Technologists
Lm = *Listeria monocytogenes*
NACMCF = National Advisory Committee on Microbiological Criteria for Foods
NSSP = National Shellfish Sanitation Program
OTC = Over The Counter
PMO = Pasteurized Milk Ordinance
PMP = Pathogen Modeling Program
ROP = Reduced Oxygen Packaging
USDA/FSIS = United States Department of Agriculture/Food Safety & Inspection Service

Most Editions of the Food Codes
Recommended by the
U.S. Public Health Service
are available from the
National Technical Information Service

The Food Code is revised and updated to represent the most recent and best advice to ensure that food at retail is safe and properly protected and presented. Most States and territories have adopted food codes patterned after the FDA Food Code.

Copies of the Food Code are available for public sale from the National Technical Information Service. For a complete listing of print and CD editions, go to the NTIS website at http://www.ntis.gov/products/food-code.aspx

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Food Code

U.S. Public Health Service

1999

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service • Food and Drug Administration

Washington, DC 20204

Food Code

1999 Recommendations of the
United States Public Health Service
Food and Drug Administration

The Food Code consists of model requirements for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer.

This model is offered for adoption by local, state, and federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction which have been delegated compliance responsibilities for food service, retail food stores, or food vending operations.

For public sale by:

U.S. Department of Commerce
Technology Administration
National Technical Information Service
5285 Port Royal Road, Springfield, VA 22161
(703) 605-6000, refer to report number PB99-115925

Preface

1. NATURE AND EXTENT OF FOODBORNE ILLNESS

Foodborne illness in the United States is a major cause of personal distress, preventable death, and avoidable economic burden. In 1994, the Council for Agricultural Science and Technology estimated 6.5 to 33 million people become ill from microorganisms in food, resulting in as many as 9,000 needless deaths every year.

For many victims, foodborne illness results only in discomfort or lost time from the job. For some, especially preschool age children, older adults in health care facilities, and those with impaired immune systems, foodborne illness is more serious and may be life threatening.

The annual cost of foodborne illness in terms of pain and suffering, reduced productivity, and medical costs is estimated to be in the billions of dollars. Federal researchers are currently evaluating and updating these costs.

The Centers for Disease Control and Prevention have consistently stated that where reported foodborne outbreaks were caused by mishandling of food, most of the time the mishandling occurred within the retail segment of the food industry (restaurants, markets, schools, churches, camps, institutions, and vending locations) where ready-to-eat food is prepared and provided to the public for consumption.

The Food and Drug Administration (FDA) endeavors to assist the approximately 75 state and territorial agencies and more than 3,000 local departments that assume primary responsibility for preventing foodborne illness and for licensing and inspecting establishments within the retail segment of the food industry. This industry segment consists of more than one million establishments and employs a work force of over 12 million.

2. PHS MODEL CODES HISTORY, PURPOSE, AND AUTHORITY

(A) History and Purpose

U.S. Public Health Service (PHS) activities in the area of food protection began at the turn of the century with studies on the role of milk in the spread of disease. These studies led to the conclusion that effective disease prevention requires the application of comprehensive food sanitation measures from production to consumption. Additional studies identified and evaluated measures which would most effectively control disease, including work which led to improved processes for pasteurization.

Next, model codes were developed to assist state and local governments in initiating and maintaining effective programs for prevention of foodborne illness. The first of these, which is now titled *Grade A Pasteurized Milk Ordinance - 1997 Recommendations of the PHS/FDA,* was initially published in 1924. Subsequently, the PHS published recommended model food codes that address the various components of the retail segment of the food industry. These code editions are listed chronologically on page iii. Through the years all states, hundreds of local jurisdictions, and many federal agencies have adopted some edition of model food codes recommended by the PHS.

Today, FDA's purpose in maintaining an updated model food code is to assist food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail segment of the food industry. The retail segment includes those establishments or locations in the food distribution chain where the consumer takes possession of the food.

The model Food Code is neither federal law nor federal regulation and is not preemptive. Rather, it represents FDA's best advice for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented. Although not federal requirements (until adopted by federal bodies for use within federal jurisdictions), the model Food Code provisions are designed to be consistent with federal food laws and regulations, and are written for ease of legal adoption at all levels of government. A list of jurisdictions that have reported to FDA their status in adopting the Food Code is available on the FDA CFSAN Web Page at http://www.cfsan.fda.gov under Federal/State Food Programs - Retail Food Safety References. The list is self-reported and FDA has not yet evaluated whether all the adopted codes are equivalent to the model Food Code.

Providing model food codes and model code interpretations and opinions is the mechanism through which FDA, as a lead federal food control agency, promotes uniform implementation of national food regulatory policy among the several thousand federal, state, and local agencies and tribes that have primary responsibility for the regulation or oversight of retail level food operations.

(B) Authority

PHS authority for providing assistance to state and local governments is derived from the Public Health Service Act [42 USC 243]. Section 311(a) states in part:
"... The Secretary shall ... assist states and their political subdivisions in the prevention and suppression of communicable diseases, and with respect to other public health matters, shall cooperate with and aid state and local authorities in the enforcement of their ... health regulations and shall advise the several states on matters relating to the preservation and improvement of the public health." Responsibility for carrying out the provisions of the Act relative to food protection was delegated within the PHS to the Commissioner of Food and Drugs in 1968 [21 CFR 5.10(a)(2) and (4)].

Under authority of the Economy Act, June 30, 1932 as amended [31 USC 1535], FDA provides assistance to federal agencies such as the General Services Administration and the Indian Health Service.

Assistance provided to local, state, and federal governmental bodies is also based on FDA's authorities and responsibilities under the Federal Food, Drug, and Cosmetic Act [21 USC 301].

3. PUBLIC HEALTH AND CONSUMER EXPECTATIONS

It is a shared responsibility of the food industry and the government to ensure that food provided to the consumer is safe and does not become a vehicle in a disease outbreak or in the transmission of communicable disease. This shared responsibility extends to ensuring that consumer expectations are met and that food is unadulterated, prepared in a clean environment, and honestly presented.

Under FDA's 1997 Mission Statement the agency is responsible for ensuring that:

> Foods are safe, wholesome, and sanitary...; regulated products are honestly, accurately, and informatively represented; and, these products are in compliance with the law and FDA regulations; noncompliance is identified and corrected; and any unsafe or unlawful products are removed from the marketplace.

Accordingly, the provisions of the Food Code provide a system of prevention and overlapping safeguards designed to minimize foodborne illness; ensure employee health, industry manager knowledge, safe food, nontoxic and cleanable equipment, and acceptable levels of sanitation on food establishment premises; and promote fair dealings with the consumer.

The Food Code addresses controls for risk factors identified by the Centers for Disease Control and Prevention as contributors to foodborne outbreaks that have been investigated and confirmed. Those factors are unsafe sources; inadequate cooking; improper holding; contaminated equipment; and poor personal hygiene. It further establishes 5 key public health interventions to protect consumer health, specifically, demonstration of knowledge; employee health controls; controlling hands as a vehicle of contamination; time and

temperature parameters for controlling pathogens; and the consumer advisory. The first two interventions are found in Chapter 2 and the last three in Chapter 3.

4. ADVANTAGE OF UNIFORM STANDARDS

The advantages of well-written, scientifically sound, and up-to-date model codes have long been recognized by industry and government officials.

Industry conformance with acceptable procedures and practices is far more likely where regulatory officials "speak with one voice" about what is required to protect the public health, why it is important, and which alternatives for compliance may be accepted.

Model codes provide a guide for use in establishing what is required. They are useful to business in that they provide accepted standards that can be applied in training and quality assurance programs. They are helpful to local, state, and federal governmental bodies that are developing or updating their own codes.

The model Food Code provides guidance on food safety, sanitation, and fair dealing that can be uniformly adopted for the retail segment of the food industry. The document is the cumulative result of the efforts and recommendations of many contributing individuals, agencies, and organizations with years of experience using earlier model code editions. It embraces the concept that our quality of life, state of health, and the public welfare are directly affected by how we collectively provide and protect our food.

5. MODIFICATIONS AND IMPROVEMENTS IN THIS EDITION

The revisions contained in this edition largely reflect the recommendations developed during the 1998 meeting of the Conference for Food Protection. The revisions also reflect input provided by those who have been intimately involved with studying, teaching, and using the earlier editions. Most of these enhancements involve added clarification or new information. Some reflect evolving regulatory policy contained in new or revised federal regulations.

The needed clarifications and missing Code provisions were identified by FDA and others during standardization and certification activities, State Training Branch courses, regional food protection seminars, the deliberations of food equipment standards organizations, and the verbal and written requests for clarification received by FDA field and headquarters components.

Changes in provisions related to federal laws and regulations administered by other federal agencies such as the United States Department of Agriculture were jointly developed with those agencies.

A summary of changes is provided at the end of the Food Code. General enhancements include:

(1) Added and improved definitions that are more precise and more consistent with terminology and definitions found in related laws and regulations;

(2) Modified provisions to make them more consistent with national requirements and standards administered by other federal agencies and international bodies; more flexible without compromising public health; and more internally consistent with other Food Code provisions;

(3) Clarified other provisions regarding their intent, thereby reducing confusion and the potential for inconsistent application;

(4) Improved user aids contained in the Annexes such as added references and updated public health reasons, model forms, guides, and lists; and

(5) Expanded the Index with additional terms to assist a broader base of users in finding topics of interest.

6. DISCUSSION OF THE CODE AS A HACCP MODEL AND THE INTENTION TO INCORPORATE OTHER MODELS

It is important to note that preapproval of HACCP plans for food establishments operating pursuant to a variance is provided for under the Food Code, but such plan preapproval is not a part of another HACCP regulatory model, the Fish and Fishery Products regulation 21 CFR 123, effective December 18, 1997. Additionally, there are differences between the two models in the required content of the HACCP plan. For example, the HACCP plans mandated by the Food Code must include flow diagrams, product formulations, training plans, and a corrective action plan. Flow diagrams and product formulations are suggested but not mandated components of the Fish and Fishery Products regulation.

These differences are necessitated by differences in the nature of the regulations and the regulatory structure set up to enforce them. HACCP plans developed under the Food Code variance process are provided to the regulatory authority to enable the regulatory authority to assess whether the establishment has designed a system of controls sufficient to ensure the safety of the product. The plans will be reviewed outside the food establishment and, in most cases, in the absence of any historical performance information for the product at that establishment. Therefore, the plan must contain sufficient detail to allow the regulator to fully understand the operations and the intended controls. Products requiring a variance are those which are deemed to be potentially hazardous and for which retail production would otherwise be prohibited.

To assist food establishments in applying HACCP principles at retail, FDA has issued a draft document entitled: Managing Food Safety: A HACCP Principles Guide for Operators of Food Service, Retail Food Stores, and Other Food Establishments at the Retail Level. This document is available from FDA and can be found on the FDA Web Page at http://vm.cfsan.fda.gov/~ear/retail.html.

Under the Fish and Fishery Products regulation, every seafood processor is required to perform a hazard analysis, and must have and implement a written HACCP Plan whenever a hazard analysis reveals a food safety hazard that is reasonably likely to occur. HACCP plans developed pursuant to the Fish and Fishery Products regulation are for all products in the class and are not for products for which production is presently prohibited. Plans will be reviewed on site, with records available to judge, among other things, the adequacy of past corrective actions.

It is intended that the Food Code will be amended to incorporate federal HACCP regulations and guidelines by inclusion in the text of the Food Code, by reference, or through the issuance of interpretations. This will provide alternatives to the preapproval of HACCP plans, such as simplified HACCP plans in line with the Fish and Fishery Products model, if the product is produced under a HACCP plan developed in conformance with such regulation or guideline. In so doing, the need for preapproved plans under the more intensive regimen of the Food Code will be significantly reduced.

7. CODE ADOPTION/CERTIFIED COPIES

The model Food Code is provided for use by food regulatory jurisdictions at all levels of government. At the state and local levels the model may be:

(A) Enacted into statute as an act of the state legislative body;

(B) Promulgated as a regulation, if the state legislative body has delegated rule-making authority to a governmental administrative agency; or

(C) Adopted as an ordinance, if the local legislative body has been delegated rule-making authority or regulatory powers.

Typically, code adoption bodies publish a notice of their intent to adopt a code, make copies available for public inspection, and provide an opportunity for public input prior to adoption. This is usually done in one of two ways.

The recommended method is the "short form" or "adoption by reference" approach where a simple statement is published stating that certified copies of the proposed code are on file for public review. This approach may be used by governmental bodies located in states that have enabling laws authorizing the adoption of codes by reference. An advantage to this approach is a substantial reduction in the cost of publishing and printing.

Certified copies of the Food Code for use in adopting the model by reference are available through the FDA Retail Food and Interstate Travel Team, HFS-627, 200 C Street, SW, Washington, DC 20204-0001. Refer to 2. *(A)* of this Preface to access a listing of jurisdictions' adoptions.

The alternative method is the "long form" or "section-by-section" approach where the proposed code is published in its entirety.

Both methods of adoption allow for the modification of specific provisions to accommodate existing law, administrative procedure, or regulatory policy. Annex 7 contains model adoption forms for use by governmental bodies who wish to use either of these methods.

8. INFORMATION TO ASSIST THE USER

Many of the improvements contained in the model Food Code as listed under item 5. above are provided to make the document easier to use. Other characteristics of the new edition, if they are understood by the user, make it easier to follow and apply. These include structure, nomenclature, and methodology.

Food Code provisions address essentially four areas: personnel (Chapter 2), food (Chapter 3), equipment/facilities/supplies (Chapters 4,5,6,7), and compliance and enforcement (Chapter 8). A new user will find it helpful to review the table of contents together with the Inspection Guide (Annex 7) in order to quickly gain an understanding of the scope and sequence of subjects included within these four areas.

The structural nomenclature of the document is as follows:

Chapter	9
Part	9-1
Subpart	9-101
Section (§)	9-101.11
Paragraph (¶)	9-101.11(A)
Subparagraph	9-101.11(A)(1)

Internal cross referencing is widely used throughout the document to eliminate the need for restating provisions. For example, fixtures and devices necessary for handwashing are relevant to both the plumbing (Chapter 5) and the facilities (Chapter 6) portions. To alert the reader to relevant information and provide a system by which each violation is recorded under the one most appropriate provision, the Code uses the phrase "...as specified under (followed by a Code cite such as a section or paragraph)." It must be determined within the context of the provision whether the cross reference simply provides information to explain the requirement or whether the observed violation is properly recorded against the provision that is cited after the word "under."

The Food Code presents requirements by principle rather than by subject. For example, equipment requirements are presented under headings such as Materials, Design and Construction, Numbers and Capacities, Location and Installation, and Maintenance and Operation rather than by refrigerators, sinks, and thermometers. In this way provisions need be stated only once rather than repeated for each piece or category of equipment. Where there are special requirements for certain equipment, the requirement is delineated under the appropriate principle (e.g., Design and Construction) and listed separately in the index.

Portions of some sections are written in *italics.* These provisions are not requirements, but are provided to convey relevant information about specific exceptions and alternative means for compliance.

Requirements contained in the Food Code are presented as being in one of 3 categories of importance: critical; "swing" (i.e., those that may or may not be critical depending on the circumstances); and noncritical. An asterisk ***** after a tagline (which is the language immediately following a section number that introduces the subject of the section) indicates that all of the provisions within that section are critical unless otherwise indicated, as follows:

> Any provisions that are "swing" items, are followed by the bold, superscripted letter **S** and any provisions that are noncritical are followed by the bold, superscripted letter **N**.

Any unmarked provisions within a section that has an asterisked tagline are critical. All provisions following a tagline that is not marked with an asterisk are noncritical.

Defined words and terms are capitalized in the text of the Food Code chapters to alert the reader to the fact that there is a specific meaning assigned to those words and terms and that the meaning of a provision is to be interpreted in the defined context. A concerted effort was also made to capitalize all forms and combinations of those defined words and terms that were intended to carry the weight of the definition.

The annexes located at the back of the document can provide tremendous assistance to those charged with applying Food Code provisions. No reference is made in the text of a provision to the annexes which support its requirements. This is necessary in order to keep future laws or other requirements based on the model Food Code "clean." However, the annexes are provided specifically to assist the regulatory authority apply the provisions uniformly and effectively.

It is, therefore, important for users to preview the subject and essence of each of the annexes before using the document. Some of the annexes (e.g., References, Public Health Reasons) are structured to present the information by the specific Food Code item number to which they apply. Other annexes provide information and materials intended to be helpful to the user such as model forms that can be used, a delineation of the principles of HACCP, guidelines for establishment inspection, and criteria for certain food processes for use in evaluating proposed HACCP plans.

9. THE CODE REVISION PROCESS

(A) Food Code Revision and Publication Cycles

FDA is revising the Food Code every 2 years. The revision will issue either as a supplement to the existing edition or as a new edition based on the extent of revision. Each new edition will incorporate the provisions of supplements issued between editions.

(B) Submission of Food Code Change Suggestions

FDA will continue to receive concerns and recommendations for modification of the Food Code from any individual or organization.

Given the purpose of the document as discussed in item 2. above, the Agency will be especially interested in addressing problems identified by those in government and industry who are responsible for implementing the Food Code. FDA will also be especially responsive to those needed policy and technical changes raised by an organization that uses a democratic process for addressing problems and concerns.

Included are organizations that provide a process that encourages representative participation in deliberations by government, industry, and academic and consumer interests, followed by public health ratification such as a state-by-state vote by officially designated delegates. The Conference for Food Protection (retail food issues), the National Conference on Interstate Milk Shipments (milk and dairy products issues), and the Interstate Shellfish Sanitation Conference (molluscan shellfish issues) are examples of such organizations. These organizations receive problems submitted by any interested individual, but specify the forms on which the issues must be detailed and provide specific time frames during which they may be submitted.

FDA encourages interested individuals to consider raising issues and suggesting solutions involving the federal-state cooperative programs based on FDA's model codes through these organizations.

10. ACKNOWLEDGMENTS

Many individuals devoted considerable time and effort in addressing concerns and developing recommendations that are now reflected in the Food Code. These individuals represent a wide diversity of regulators, educators, industry leaders, and consumer representatives acting through their agencies, companies, professional groups, or trade organizations. It is only through the dedicated efforts and contributions of experienced professionals that a scientifically sound, well focused, and up-to-date model code is possible. FDA acknowledges with gratitude the substantial assistance of those whose contribution to public health and food safety via the Food Code will span well into the next century.

JOINT INTRODUCTION

The Food and Drug Administration (FDA), Food Safety and Inspection Service (FSIS), and Centers for Disease Control and Prevention (CDC) are pleased to jointly announce the publication of the 1999 edition of the Food Code. The Food Code is a reference document for regulatory agencies responsible for overseeing food safety in retail outlets such as restaurants and grocery stores and institutions such as nursing homes and child care centers. It is neither federal law nor federal regulation and is not preemptive, but may be adopted and used by agencies at all levels of government that have responsibility for managing food safety risks at retail.

The FDA, FSIS, and CDC, in collaboration with the Conference for Food Protection, state and local public health and food control agencies, industry representatives, academia, and consumers have updated the 1999 Food Code to reflect the most current science and the best strategies to ensure a safer food supply in the United States. Major changes in this edition include the addition of specific criteria regarding the application and implementation of: the consumer advisory provisions, the prohibition of bare hand contact with ready-to-eat food, and provisions related to safely cooking hamburger and whole-muscle, intact beef steaks.

To protect consumers from foodborne diseases, we must strengthen the Nation's capacity to predict and prevent foodborne hazards and to monitor and rapidly react to outbreaks of foodborne diseases. To achieve the public health goal of reducing foodborne illness to the fullest extent possible, steps must be taken at each point in the farm-to-table chain where hazards can occur. Since publication of the last version of the Food Code in 1997, there has been important progress in our efforts to monitor and prevent foodborne diseases and ensure that consumers are provided the safest possible foods. These activities encompass the entire continuum of food production, food processing and manufacture, retail food stores, and food service to consumers and include:

> The President's National Food Safety Initiative -- which recommends adoption and implementation of the Food Code -- and corresponding Congressional appropriations;

The initiative to ensure the safety of domestic and imported fresh fruits and vegetables;

Creation of the Foodborne Outbreak Response Coordinating Group (FORC-G) to improve federal and state agencies' response to foodborne disease outbreaks;

Initiation of PulseNet, a public health laboratory network that "fingerprints" bacteria and permits more rapid and accurate detection of foodborne illness outbreaks;

Expansion of FoodNet, the collaborative Foodborne Disease and Active Surveillance Network, which measures the burden and sources of foodborne disease in the United States;

Establishment of the Joint Institute for Food Safety Research to coordinate food safety research and priority setting; and

Formation of the President's Council on Food Safety that will develop a strategic plan for federal food safety activities and recommend ways to enhance coordination and improve effectiveness in the food safety system.

One common theme of these initiatives is the need to better integrate the activities of the Federal agencies with those of State and local food safety agencies. Such integration can occur only when there is agreement among jurisdictions on regulatory standards. Adoption by all jurisdictions of the Food Code would result in uniform national standards and provide the foundation for a more uniform, efficient, and effective national food safety system.

The FDA, FSIS, and CDC endorse the Food Code because the Code provides public health and regulatory agencies with practical science-based advice and manageable, enforceable provisions for mitigating risk factors known to contribute to foodborne disease. In June 1998, the Secretary of Health and Human Services, Donna Shalala, and the Secretary of Agriculture, Dan Glickman, wrote to U.S. Governors asking them to support adoption of the Food Code by agencies in their state that have responsibility for the safety of food at retail. We are pleased to announce that in addition to the many federal agencies and tribal governments that have adopted the Code, as of September 1998, at least one agency in 14 states has adopted one of the editions of the Food Code and approximately 25 states have at least one agency in the process of adoption. The state and local agencies that have responsibility for regulating retail establishments that sell or serve food should use the Food Code as a model to help develop or update their own food safety rules and provide consistency among jurisdictions.

We congratulate those jurisdictions that have now adopted or are in the process of adopting the Food Code. We urge the rest to also consider its adoption. We stand ready to assist in that effort and look forward to further progress in achieving uniform, effective standards for food safety at retail nationwide.

Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services

Tom Billy
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture

Jeffrey P. Koplan, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
Department of Health and Human Services

Summary of Changes in the FDA Food Code

This Summary provides a synopsis of the textual changes from the 1997 FDA Food Code Chapters and Annexes to the 1999 edition. The primary intent of this record is to capture the nature of the changes rather than to identify every word or editing change. This record should not be relied upon as an absolute comparison that identifies each and every change.

General:

- Numerous editing changes were made throughout the document for internal consistency, to correct some errors in the '97 Code and for clarification.

- Italics and capitalization of *Salmonellae* are modified throughout the document, with the exception of Annex 2 where titles of published documents remain unchanged. The modifications reflect current, commonly recognized conventions used in the scientific community. Species of *Salmonellae* are not italicized and begin with a capital letter.

- Defined words and terms are in small capital letters throughout the Chapters and Annex 1 to highlight that they have a specific meaning within the context of the Code. Refer to the Preface, Information to Assist the Reader, for a discussion of this feature.

- Section numbers listed refer to the 1997 Code unless otherwise noted. Definition numbers listed refer to the 1999 Code. Renumbering occurred in the 1999 edition, based on the changes made.

Chapter 1:

1-201.10 - Definitions
(1) added "Accredited program" (CFP 98-02-06)
(21) revised "Easily movable" for consistency with NSF International's use of terms
(28) modified "Foodborne disease outbreak" for consistency with CDC (CFP 98-01-11)
(43) added "Juice"
(61) amended "Potentially hazardous food" regarding garlic-in-oil mixtures
(67) amended "Reduced oxygen packaging" to more fully explain the ROP processes
(74) deleted existing (81) "Support animal" and replaced it with new definition, "Service animal", for consistency with the ADA
(75) modified "Servicing area" to include vehicle and equipment cleaning
(81) modified "Single-service articles" to specify the intent for them to be discarded
(87) added "probe-type price and identification tags" to the definition of a "Utensil"
(90) added the definition of "Variance" from § 8-103.10 in § 1-201.10
(91) modified "Vending machine" to include optional manual operation
(94) added "Whole-muscle, intact beef"

Chapter 2:

2-103.11 added ¶¶ (K) and (L) (CFP 96-01-07)
2-201.11(D)(4) deleted (CFP 98-01-42)
2-201.13 added recognition of nurse practitioners, and physician assistants, if allowed by law, for purpose of medical documentation
2-201.15 deleted “or a person who applies for a job as a food employee” and “or is suspected of having” (CFP 98-01-41); changed language to “... shall notify ... that an employee...”
2-301.12 updated to include approved automatic handwashing facility (CFP 98-03-10); other related provisions in Chapters 2, 5, and 6 were changed to be consistent
2-301.14(D) amended to clarify that a person may drink from a closed container without washing hands each time (CP 98-01-40)
2-301.16 revised to clarify approval methods for hand sanitizers
2-302.11 formed a new ¶ (A) and added a new ¶ (B) to prohibit the wearing of fingernail polish or artificial fingernails (CFP 98-01-35)

Chapter 3:

3-201.11 added ¶ (E) to address labeling of whole-muscle, intact beef by a food processor and ¶ (F) to address labeling meat and poultry with safe handling instructions (CFP 98-01-29)
3-202.11(C) changed reference to § 3-401.16 to § 3-401.13
3-301.11 added an insert page to alert readers that Annex 3 contains a full discussion clarifying ¶ (B) and to provide a brief synopsis of that discussion
3-301.11(C) is identified as a swing item to allow for judgment regarding the significance of bare hand contact with food that is not ready-to-eat
3-304.11 ¶ (A) deleted and combined with ¶ (B) (CFP 98-03-16) to allow the use of probe-type price identification tags
3-304.12 ¶ (C) amended to clarify that both the in-use utensil and the food-contact surfaces must be cleaned and sanitized; added a new ¶ (F) to allow in-use utensils to be stored in water that is maintained at a temperature of at least 140°F (CFP 98-01-07)
3-304.14 changed the tagline; changed the word “moist” to “wet” in ¶¶ (B) and (C); added specificity about the concentration of the sanitizing solution; and added ¶ (D) to clarify that each time the sanitizing solution is changed, the wiping cloth needs to be evaluated to determine that it is clean (CFP 98-03-18)
3-304.16(A) amended to allow refilling by food employees under certain circumstances (CFP 98-01-19)
3-306.13(A) amended to include consumer self-service of raw, frozen, shell-on shrimp and lobster (CFP 98-01-26)
3-306.14 changed tagline and amended to allow transfer of certain food containers from one consumer to another (CFP 98-01-20)
3-401.11(A)(1)(b) added “pork” to be cooked to 145°F (CFP 98-03-03); (A)(2) deleted “pork” to be cooked at 155°F;(A)(2) amended the chart to include the temperature at which certain foods, e.g., hamburger can be cooked if the time is less than one second (CFP 98-03-23); (B) added “pork roasts” and “cured pork roasts” to beef roast cooking parameters
(CFP 98-03-03); added new ¶ C to allow the surface searing of a whole-muscle, intact beef steak without fully cooking the steak (CFP 98-03-25); (D) added to exempt seared steaks from a consumer advisory (CFP 98-03-20)
3-501.18 added new ¶ (G) to address the date marking of an existing portion of food to which new portions of food are added (CFP 98-01-18)

3-501.19 amended so that former ¶¶ (A)-(D) are now contained in ¶ A and added new ¶ B stating time may not be used as the public health control for raw eggs for a highly susceptible population
3-502.11 amended to clarify that a variance is not required if smoking food is done solely for flavor enhancement
3-502.12 amended to clarify that a HACCP plan is needed for ROP foods with two barriers to ***C. botulinum***
3-603.11 amended to exempt from the consumer advisory requirement, animal foods that are "otherwise processed to eliminate pathogens"; added a new insert page to alert the reader to what constitutes satisfactory compliance with the provision and direct the reader to Annex 3 for more discussion
3-801.11 expanded ¶ (A) to include all fruit and vegetable juice and prohibit prepackaged unpasteurized juice; amended ¶ (B) to require pasteurized eggs whenever raw eggs are combined, except for 3 specific situations; ¶ (D) expanded to prohibit raw seed sprouts (CFP 98-03-22); added new ¶ (E) to describe the restricted conditions under which raw eggs may be used

Chapter 4:

4-501.16(A) deleted the end statement "or dumping mop water" (CFP 98-01-05). This leaves the prohibition of dumping mop water in a warewashing sink as a critical item in § 6-501.15.
4-602.11(B) revised to clarify intent of cleaning frequency when equipment is contacting raw animal food that requires a higher cooking temperature than the previous food contacting the same equipment
4-602.11 ¶ (D) amended with time/temperature chart to allow cleaning frequency greater than 4 hours with refrigerated food-contact utensils and equipment (CFP 98-03-05)
4-602.11(D)(7) added new subparagraph to specify the cleaning frequency for the water container used to hold the 140°F water and the in-use utensil
4-802.11 amended ¶ (D) to clarify the cleaning frequency of wiping cloths (CFP 98-03-18)

Chapter 5

5-103.11 added requirement for hot water capacity as a critical item. Split provision into ¶¶ (A) and (B).
5-103.13 deleted and combined with 5-103.11

Chapter 6:

6-202.15(A) amended to refer to the paragraphs as they were redesignated; new ¶ (C) allows an exception to the use of self-closing devices on emergency doors used as exits under certain conditions (CFP 98-01-46); ¶ (C) ➜ ¶ (D); ¶ (D) ➜ ¶ (E)
6-301.14 added a new section requiring a handwashing sign to be posted (CFP 98-01-36)
6-501.115 added clarifying language in Subparagraph (B)(3) regarding service animals to be consistent with the ADA; added language in Subparagraph (B)(5) allowing certain animals on the premises

Chapter 8:

8-201.12 ¶ (E) redrafted to ease the paperwork burden on industry during plan review; relocated requirement for standard operating procedures to § 8-203.10; moved Subparagraphs (1)-(6) from ¶ (E); deleted ¶ (F) because the new ¶ 2-103.11(L) addresses training; ¶ (G) ➜ ¶ (F)

8-203.10 amended this section to require standard operating procedures by the time of the preopening inspection and to cross reference ¶ 8-201.12(E)
8-501.20, 8-501.30, and 8-501.40 added the word “Food” before “employee” where it was missing, for internal consistency

Annex 2:

References added for many code provisions

Annex 3:

1-201.10 added a discussion about accredited programs
2-201.11 modified language, including adding language about hands in contact with pustular lesions on parts of the body other than hands also posing a threat for introducing ***Staphylococcus aureus*** into food
3-201.11 added information regarding labeling for safe handling instructions on packages of meat and poultry; labeling juices that have not been pasteurized; and identifying whole-muscle, intact beef steaks (CFP 98-01-29)
3-202.11 added new federal regulation requiring shell eggs to be stored and transported in ambient air temperature of 45°F or below
3-301.11 added a discussion that clarifies the phrase in ¶ (B), “except when otherwise approved”
3-302.15 added reference to a guidance document regarding the washing of fruits and vegetables (CFP 98-03-14)
3-304.12 - 3-304.17 separated the public health reasons and added new language
3-401.11 added discussion regarding seared steak and hamburger cooking temperature and pork cooking
3-401.13 clarified that the hot holding temperature applies to fruits and vegetables that are fresh, frozen, or canned
3-501.14 modified in concert with current CFR regarding shell eggs
3-603.11 expanded with a current discussion of the purpose, background, satisfactory compliance with and applicability of the consumer advisory provision; explained that irradiated meat and poultry can not be offered in a ready-to-eat form without a consumer advisory
3-801.11 updated the discussion regarding the importance of using pasteurized juices in highly susceptible populations; added a discussion regarding federal juice labeling requirements, ***Salmonella* Enteritidis** in raw shell eggs, and raw seed sprouts
6-202.15 expanded to discuss how the National Fire Protection Association’s guidance is related to this section
6-501.115 discussed that new Code language allows a food establishment to have both a snack bar and a pet sales area or to sell food adjacent to animal displays; added discussion regarding compliance with ADA requirements for allowing service animals on the premises
7-204.12 clarified that the CFR has no maximum limit on the concentration of chlorine applied to fruits and vegetables
8-201.12 and 8-203.10 added new language regarding using the plan review process for discussion between the regulatory authority and the operator about long-term compliance with the Food Code; including operating procedures that address training

Annex 4:

Item 8 Temperature Measuring Devices (A) Sensor-Type Temperature Measuring Devices (4) Infrared Thermometers: added infrared thermometers to the listing of types of temperature measuring devices and provided a brief discussion of them

Annexes 5 and 6:

Made changes consistent with changes elsewhere in the document

Annex 7:

Form 1 in the purpose statement, after the word "Applicant," added the phrase "to whom a conditional offer of employment has been made" for consistency with the ADA and under the topic High-Risk Conditions, deleted the question concerning travel
Form 3 added "to whom a conditional offer of employment has been made" for consistency with the ADA; **Paraphrased From the FDA Food Code for Physician's Reference**, High-Risk Conditions Related to a Person's Activities, deleted (4) concerning travel
Guide 1 deleted reference to Subparagraph 2-201.11(D)(4) concerning travel
Guide 2 under Health Status # 3, deleted reference to Subparagraph 2-201.11(D)(4); recognized nurse practitioners and physician assistants for medical documentation
List deleted the word "endemic;" replaced reference to the 1995 version of CDC's Yellow Book with 1996-97 edition; stated criterion for denoting ***E. coli*** O157:H7 in some geographical areas; added language to clarify intended use of the list since travel is deleted from the Chapter 2 high-risk conditions
Charts 1 & 2 updated to reflect new temperatures for pork and instant kill at 158°F for certain foods
Chart 3 added new chart on "Ready-to-Eat, Potentially Hazardous Food, Date Marking and Disposition"

ADA = Americans with Disabilities Act
CFP = Conference for Food Protection
CFR = Code of Federal Regulations
ROP = Reduced Oxygen Packaging

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Chapter

1 Purpose and Definitions

Parts

1-1 TITLE, INTENT, SCOPE

Subparts

Title **1-101.10 Food Code.**

These provisions shall be known as the Food Code, hereinafter referred to as ?this Code."

Intent **1-102.10 Food Safety, Illness Prevention, and Honest Presentation.**

The purpose of this Code is to safeguard public health and provide to CONSUMERS FOOD that is safe, unADULTERATED, and honestly presented.

Scope **1-103.10 Statement.**

This Code establishes definitions; sets standards for management and personnel, FOOD operations, and EQUIPMENT and facilities; and provides for FOOD ESTABLISHMENT plan review, PERMIT issuance, inspection, EMPLOYEE restriction, and PERMIT suspension.

1-2 DEFINITIONS

Subpart

1-201 Applicability and Terms Defined

Applicability and Terms Defined **1-201.10 Statement of Application and Listing of Terms.**

(A) The following definitions apply in the interpretation and application of this Code.

(B) Terms Defined.

(1) **Accredited program.**

(a) **"Accredited program"** means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals.

(b) **"Accredited program"** refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, re-certification, discipline and grievance procedures; and test development and administration.

(c) **"Accredited program"** does not refer to training functions or educational programs.

(2) **Additive.**

(a) **"Food additive"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR 170.

(b) **"Color additive"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR 70.

(3) **"Adulterated"** has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 402.

(4) **"Approved"** means acceptable to the REGULATORY AUTHORITY based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

(5) **"a_w"** means water activity which is a measure of the free moisture in a FOOD, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol a_w.

(6) **"Beverage"** means a liquid for drinking, including water.

(7) **"Bottled drinking water"** means water that is SEALED in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

(8) **"Certification number"** means a unique combination of letters and numbers assigned by a SHELLFISH CONTROL AUTHORITY to a MOLLUSCAN SHELLFISH dealer according to the provisions of the National Shellfish Sanitation Program.

(9) **CIP.**

(a) **"CIP"** means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and SANITIZING solution onto or over EQUIPMENT surfaces that require cleaning, such as the method used, in part, to clean and SANITIZE a frozen dessert machine.

(b) ***"CIP"*** *does not include the cleaning of EQUIPMENT such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system.*

(10) **"CFR"** means CODE OF FEDERAL REGULATIONS. Citations in this Code to the CFR refer sequentially to the Title, Part, and Section numbers, such as 21 CFR 178.1010 refers to Title 21, Part 178, Section 1010.

(11) **"Code of Federal Regulations"** means the compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government which:

(a) Is published annually by the U.S. Government Printing Office; and

(b) Contains FDA rules in 21 CFR, USDA rules in 7 CFR and 9 CFR, EPA rules in 40 CFR, and Wildlife and Fisheries rules in 50 CFR.

(12) **Comminuted.**

(a) **"Comminuted"** means reduced in size by methods including chopping, flaking, grinding, or mincing.

(b) **"Comminuted"** includes FISH or MEAT products that are reduced in size and restructured or reformulated such as gefilte FISH, gyros, ground beef, and sausage; and a mixture of 2 or more types of MEAT that have been reduced in size and combined, such as sausages made from 2 or more MEATS.

(13) **"Confirmed disease outbreak"** means a FOODBORNE DISEASE OUTBREAK in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the FOOD as the source of the illness.

(14) **"Consumer"** means a PERSON who is a member of the public, takes possession of FOOD, is not functioning in the capacity of an operator of a FOOD ESTABLISHMENT or FOOD PROCESSING PLANT, and does not offer the FOOD for resale.

(15) **"Corrosion-resistant material"** means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the FOOD to be contacted, the normal use of cleaning compounds and SANITIZING solutions, and other conditions of the use environment.

(16) **"Critical control point"** means a point or procedure in a specific FOOD system where loss of control may result in an unacceptable health risk.

(17) **Critical Item.**

(a) **"Critical item"** means a provision of this Code, that, if in noncompliance, is more likely than other violations to contribute to FOOD contamination, illness, or environmental health HAZARD.

(b) **"Critical item"** is an item that is denoted in this Code with an asterisk *.

(18) **"Critical limit"** means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a CRITICAL CONTROL POINT to minimize the risk that the identified FOOD safety HAZARD may occur.

(19) **Drinking Water.**

(a) **"Drinking water"** means water that meets 40 CFR 141 National Primary Drinking Water Regulations.

(b) **"Drinking water"** is traditionally known as "potable water."

(c) **"Drinking water"** includes the term "water" except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.

(20) **"Dry storage area"** means a room or area designated for the storage of PACKAGED or containerized bulk FOOD that is not POTENTIALLY HAZARDOUS and dry goods such as SINGLE-SERVICE items.

(21) **Easily Cleanable.**

(a) **"Easily cleanable"** means a characteristic of a surface that:

(i) Allows effective removal of soil by normal cleaning methods;

(ii) Is dependent on the material, design, construction, and installation of the surface; and

(iii) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into FOOD based on the surface's APPROVED placement, purpose, and use.

(b) **"Easily cleanable"** includes a tiered application of the criteria that qualify the surface as EASILY CLEANABLE as specified under Subparagraph (a) of this definition to different situations in which varying degrees of cleanability are required such as:

(i) The appropriateness of stainless steel for a FOOD preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for CONSUMER dining; or

(ii) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the CONSUMER dining area.

(22) **"Easily movable"** means:

(a) Portable; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of EQUIPMENT for cleaning; and

(b) Having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the EQUIPMENT to be moved for cleaning of the EQUIPMENT and adjacent area.

(23) **"Employee"** means the PERMIT HOLDER, PERSON IN CHARGE, PERSON having supervisory or management duties, PERSON on the payroll, family member, volunteer, PERSON performing work under contractual agreement, or other PERSON working in a FOOD ESTABLISHMENT.

(24) **"EPA"** means the U.S. Environmental Protection Agency.

(25) **Equipment.**

(a) **"Equipment"** means an article that is used in the operation of a FOOD ESTABLISHMENT such as a freezer, grinder, hood, ice maker, MEAT block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, TEMPERATURE MEASURING DEVICE for ambient air, VENDING MACHINE, or WAREWASHING machine.

(b) ***"Equipment"*** *does not include items used for handling or storing large quantities of PACKAGED FOODS that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.*

(26) **Fish.**

(a) **"Fish"** means fresh or saltwater finfish, crustaceans and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption.

(b) **"Fish"** includes an edible human FOOD product derived in whole or in part from FISH, including FISH that have been processed in any manner.

(27) **"Food"** means a raw, cooked, or processed edible substance, ice, BEVERAGE, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

(28) **"Foodborne disease outbreak"** means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.

(29) **"Food-contact surface"** means:

(a) A surface of EQUIPMENT or a UTENSIL with which FOOD normally comes into contact; or

(b) A surface of EQUIPMENT or a UTENSIL from which FOOD may drain, drip, or splash:

(i) Into a FOOD, or

(ii) Onto a surface normally in contact with FOOD.

(30) **"Food employee"** means an individual working with unPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES.

(31) **Food Establishment.**

(a) **"Food establishment"** means an operation that stores, prepares, packages, serves, vends, or otherwise provides FOOD for human consumption:

(i) Such as a restaurant; satellite or catered feeding location; catering operation if the operation provides FOOD directly to a CONSUMER or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or FOOD bank; and

(ii) That relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(b) **"Food establishment"** includes:

(i) An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location *unless the vending or feeding location is PERMITTED by the REGULATORY AUTHORITY*; and

(ii) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the PREMISES; and regardless of whether there is a charge for the FOOD.

(c) ***"Food establishment"*** *does not include*:

(i) *An establishment that offers only prePACKAGED FOODS that are not POTENTIALLY HAZARDOUS*;

(ii) *A produce stand that only offers whole, uncut fresh fruits and vegetables*;

(iii) *A FOOD PROCESSING PLANT*;

(iv) *A kitchen in a private home if only FOOD that is not POTENTIALLY HAZARDOUS is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by LAW and if the CONSUMER is informed by a clearly visible placard at the sales or service location that the FOOD is prepared in a kitchen that is not subject to regulation and inspection by the REGULATORY AUTHORITY*;

(v) *An area where FOOD that is prepared as specified in Subparagraph (c)(iv) of this definition is sold or offered for human consumption*;

(vi) *A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers* FOOD *to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the* CONSUMER *is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the* FOOD *is prepared in a kitchen that is not regulated and inspected by the* REGULATORY AUTHORITY*; or*

(vii) *A private home that receives catered or home-delivered* FOOD.

(32) **Food Processing Plant.**

(a) **"Food processing plant"** means a commercial operation that manufactures, packages, labels, or stores FOOD for human consumption and does not provide FOOD directly to a CONSUMER.

(b) ***"Food processing plant"*** *does not include a* FOOD ESTABLISHMENT *as defined under Subparagraph 1-201.10(B)(31).*

(33) **Game Animal.**

(a) **"Game animal"** means an animal, the products of which are FOOD, that is not classified as cattle, sheep, swine, goat, horse, mule, or other equine in 9 CFR Subchapter A - Mandatory Meat Inspection, Part 301, as Poultry in 9 CFR Subchapter C - Mandatory Poultry Products Inspection, Part 381, or as FISH as defined under Subparagraph 1-201.10(B)(26).

(b) **"Game animal"** includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.

(c) **"Game animal"** does not include ratites such as ostrich, emu, and rhea.

(34) **"General use pesticide"** means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175.

(35) **"Grade A standards"** means the requirements of the United States Public Health Service/FDA "Grade A Pasteurized Milk Ordinance" and "Grade A Condensed and Dry Milk Ordinance" with which certain fluid and dry milk and milk products comply.

(36) **Group Residence.**

(a) **"Group residence"** means a private or public housing corporation or institutional facility that provides living quarters and meals.

(b) **"Group residence"** includes a domicile for unrelated PERSONS such as a retirement home or a long-term health care facility.

(37) **"HACCP plan"** means a written document that delineates the formal procedures for following the HAZARD Analysis CRITICAL CONTROL POINT principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

(38) **"Hazard"** means a biological, chemical, or physical property that may cause an unacceptable CONSUMER health risk.

(39) **"Hermetically sealed container"** means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned FOODS, to maintain the commercial sterility of its contents after processing.

(40) **"Highly susceptible population"** means a group of PERSONS who are more likely than other populations to experience foodborne disease because they are immunocompromised or older adults and in a facility that provides health care or assisted living services, such as a hospital or nursing home; or preschool age children in a facility that provides custodial care, such as a day care center.

(41) **"Imminent health hazard"** means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:

(i) The number of potential injuries, and

(ii) The nature, severity, and duration of the anticipated injury.

(42) **"Injected"** means manipulating a MEAT so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the MEAT such as by processes which may be referred to as "injecting," "pinning," or "stitch pumping."

(43) **"Juice"**, when used in the context of FOOD safety, means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrate of such liquid or purée. This definition does not apply to standards of identity.

(44) **"Kitchenware"** means FOOD preparation and storage UTENSILS.

(45) **"Law"** means applicable local, state, and federal statutes, regulations, and ordinances.

(46) **"Linens"** means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.

(47) **"Meat"** means the flesh of animals used as FOOD including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, *except fish, poultry, and wild game animals as specified under Subparagraphs 3-201.17(A)(3) and (4).*

(48) **"mg/L"** means milligrams per liter, which is the metric equivalent of parts per million (ppm).

(49) **"Molluscan shellfish"** means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, *except when the scallop product consists only of the shucked adductor muscle*.

(50) **Packaged.**

(a) **"Packaged"** means bottled, canned, cartoned, securely bagged, or securely wrapped, whether PACKAGED in a FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT.

(b) ***"Packaged"*** *does not include a wrapper, carry-out box, or other nondurable container used to containerize FOOD with the purpose of facilitating FOOD protection during service and receipt of the FOOD by the CONSUMER.*

(51) **"Permit"** means the document issued by the REGULATORY AUTHORITY that authorizes a PERSON to operate a FOOD ESTABLISHMENT.

(52) **"Permit holder"** means the entity that:

(a) Is legally responsible for the operation of the FOOD ESTABLISHMENT such as the owner, the owner's agent, or other PERSON; and

(b) Possesses a valid PERMIT to operate a FOOD ESTABLISHMENT.

(53) **"Person"** means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

(54) **"Person in charge"** means the individual present at a FOOD ESTABLISHMENT who is responsible for the operation at the time of inspection.

(55) **Personal Care Items.**

(a) **"Personal care items"** means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a PERSON'S health, hygiene, or appearance.

(b) **"Personal care items"** include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

(56) **"pH"** means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.

(57) **"Physical facilities"** means the structure and interior surfaces of a FOOD ESTABLISHMENT including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

(58) **"Plumbing fixture"** means a receptacle or device that:

(a) Is permanently or temporarily connected to the water distribution system of the PREMISES and demands a supply of water from the system; or

(b) Discharges used water, waste materials, or SEWAGE directly or indirectly to the drainage system of the PREMISES.

(59) **"Plumbing system"** means the water supply and distribution pipes; PLUMBING FIXTURES and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the PREMISES; and water-treating EQUIPMENT.

(60) **"Poisonous or toxic materials"** means substances that are not intended for ingestion and are included in 4 categories:

(a) Cleaners and SANITIZERS, which include cleaning and SANITIZING agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

(b) Pesticides, *except SANITIZERS*, which include substances such as insecticides and rodenticides;

(c) Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and PERSONAL CARE ITEMS that may be deleterious to health; and

(d) Substances that are not necessary for the operation and maintenance of the establishment and are on the PREMISES for retail sale, such as petroleum products and paints.

(61) **Potentially Hazardous Food.**

(a) **"Potentially hazardous food"** means a FOOD that is natural or synthetic and that requires temperature control because it is in a form capable of supporting:

(i) The rapid and progressive growth of infectious or toxigenic microorganisms;

(ii) The growth and toxin production of ***Clostridium botulinum***; or

(iii) In raw shell eggs, the growth of ***Salmonella*** **Enteritidis**.

(b) **"Potentially hazardous food"** includes an animal FOOD (a FOOD of animal origin) that is raw or heat-treated; a FOOD of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under Subparagraph (a) of this definition.

(c) ***"Potentially hazardous food"*** *does not include:*

(i) An air-cooled hard-boiled egg with shell intact;

(ii) A FOOD with an a_w value of 0.85 or less;

(iii) A FOOD with a pH level of 4.6 or below when measured at 24°C (75°F);

(iv) A FOOD, in an unopened HERMETICALLY SEALED CONTAINER, that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;

(v) A FOOD for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of ***S.*** **Enteritidis** *in eggs or* ***C. botulinum*** *can not occur, such as a FOOD that has an a_w and a pH that are above the levels specified under Subparagraphs (c)(ii) and (iii) of this definition and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or*

(vi) A FOOD that does not support the growth of microorganisms as specified under Subparagraph (a) of this definition even though the FOOD may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.

(62) **Poultry.**

(a) **"Poultry"** means:

(i) Any domesticated bird (chickens, turkeys, ducks, geese, or guineas), whether live or dead, as defined in 9 CFR 381 Poultry Products Inspection Regulations; and

(ii) Any migratory waterfowl, game bird, or squab such as pheasant, partridge, quail, grouse, or guineas, whether live or dead, as defined in 9 CFR 362 Voluntary Poultry Inspection Program.

(b) **"Poultry"** does not include ratites.

(63) **"Premises"** means:

(a) The physical facility, its contents, and the contiguous land or property under the control of the PERMIT HOLDER; or

(b) The physical facility, its contents, and the land or property not described under Subparagraph (a) of this definition if its facilities and contents are under the control of the PERMIT HOLDER and may impact FOOD ESTABLISHMENT personnel, facilities, or operations, and a FOOD ESTABLISHMENT is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

(64) **"Primal cut"** means a basic major cut into which carcasses and sides of MEAT are separated, such as a beef round, pork loin, lamb flank, or veal breast.

(65) **"Public water system"** has the meaning stated in 40 CFR 141 National Primary Drinking Water Regulations.

(66) **Ready-to-Eat Food.**

(a) **"Ready-to-eat food"** means FOOD that is in a form that is edible without washing, cooking, or additional preparation by the FOOD ESTABLISHMENT or the CONSUMER and that is reasonably expected to be consumed in that form.

(b) **"Ready-to-eat food"** includes:

(i) POTENTIALLY HAZARDOUS FOOD that is unPACKAGED and cooked to the temperature and time required for the specific FOOD under Subpart 3-401;

(ii) Raw, washed, cut fruits and vegetables;

(iii) Whole, raw fruits and vegetables that are presented for consumption without the need for further washing, such as at a buffet; and

(iv) Other FOOD presented for consumption for which further washing or cooking is not required and from which rinds, peels, husks, or shells are removed.

(67) **Reduced Oxygen Packaging.**

(a) **"Reduced oxygen packaging"** means:

(1) The reduction of the amount of oxygen in a PACKAGE by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding, 21% oxygen atmosphere, and

(2) A process as specified in Subparagraph (a)(1) of this definition that involves a FOOD for which ***Clostridium botulinum*** is identified as a microbiological HAZARD in the final PACKAGED form.

(b) **"Reduced oxygen packaging"** includes:

(i) Vacuum PACKAGING, in which air is removed from a PACKAGE of FOOD and the PACKAGE is HERMETICALLY SEALED so that a vacuum remains inside the PACKAGE, such as sous vide;

(ii) Modified atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the PACKAGING material or the respiration of the FOOD. Modified atmosphere PACKAGING includes: reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen; and

(iii) Controlled atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that until the PACKAGE is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material.

(68) **"Refuse"** means solid waste not carried by water through the SEWAGE system.

(69) **"Regulatory authority"** means the local, state, or federal enforcement body or

authorized representative having jurisdiction over the FOOD ESTABLISHMENT.

(70) **"Restricted use pesticide"** means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 Pesticides classified for restricted use, and that is limited to use by or under the direct supervision of a certified applicator.

(71) **"Safe material"** means:

(a) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any FOOD;

(b) An additive that is used as specified in § 409 or 706 of the Federal Food, Drug, and Cosmetic Act; or

(c) Other materials that are not ADDITIVES and that are used in conformity with applicable regulations of the Food and Drug Administration.

(72) **"Sanitization"** means the application of cumulative heat or chemicals on cleaned FOOD-CONTACT SURFACES that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

(73) **"Sealed"** means free of cracks or other openings that allow the entry or passage of moisture.

(74) **"Service animal"** means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to an individual with a disability.

(75) **"Servicing area"** means an operating base location to which a mobile FOOD ESTABLISHMENT or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding FOOD.

(76) **"Sewage"** means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

(77) **"Shellfish control authority"** means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of MOLLUSCAN SHELLFISH harvesters and dealers for interstate commerce.

(78) **"Shellstock"** means raw, in-shell MOLLUSCAN SHELLFISH.

(79) **"Shucked shellfish"** means MOLLUSCAN SHELLFISH that have one or both shells removed.

(80) **"Single-service articles"** means TABLEWARE, carry-out UTENSILS, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one PERSON use after which they are intended for discard.

(81) **Single-Use Articles.**

(a) **"Single-use articles"** means UTENSILS and bulk FOOD containers designed and constructed to be used once and discarded.

(b) **"Single-use articles"** includes items such as wax paper, butcher paper, plastic wrap, formed aluminum FOOD containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength, and cleanability specifications under §§ 4-101.11, 4-201.11, and 4-202.11 for multiuse UTENSILS.

(82) **"Slacking"** means the process of moderating the temperature of a FOOD such as allowing a FOOD to gradually increase from a temperature of -23°C (-10°F) to -4° C (25°F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen FOOD such as spinach.

(83) **"Smooth"** means:

(a) A FOOD-CONTACT SURFACE having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number 3 stainless steel;

(b) A nonFOOD-CONTACT SURFACE of EQUIPMENT having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and

(c) A floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

(84) **"Table-mounted equipment"** means EQUIPMENT that is not portable and is designed to be mounted off the floor on a table, counter, or shelf.

(85) **"Tableware"** means eating, drinking, and serving UTENSILS for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, and tumblers; and plates.

(86) **"Temperature measuring device"** means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of FOOD, air, or water.

(87) **"Temporary food establishment"** means a FOOD ESTABLISHMENT that operates for a period of no more than 14 consecutive days in conjunction with a single event or celebration.

(88) **"USDA"** means the U.S. Department of Agriculture.

(89) **"Utensil"** means a FOOD-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of FOOD, such as KITCHENWARE or TABLEWARE that is multiuse, SINGLE-SERVICE, or SINGLE-USE; gloves used in contact with FOOD; FOOD TEMPERATURE MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD.

(90) **"Variance"** means a written document issued by the REGULATORY AUTHORITY that authorizes a modification or waiver of one or more requirements of this Code if, in the opinion of the REGULATORY AUTHORITY, a health HAZARD or nuisance will not result from the modification or waiver.

(91) **"Vending machine"** means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of FOOD in bulk or in packages without the necessity of replenishing the device between each vending operation.

(92) **"Vending machine location"** means the room, enclosure, space, or area where one or more VENDING MACHINES are installed and operated and includes the storage areas and areas on the PREMISES that are used to service and maintain the VENDING MACHINES.

(93) **"Warewashing"** means the cleaning and SANITIZING of UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT.

(94) **"Whole-muscle, intact beef"** means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

Chapter

2 Management and Personnel

Parts

2-1 SUPERVISION

Subparts

Responsibility

2-101.11 Assignment.*

The PERMIT HOLDER shall be the PERSON IN CHARGE or shall designate a PERSON IN CHARGE and shall ensure that a PERSON IN CHARGE is present at the FOOD ESTABLISHMENT during all hours of operation.

Knowledge

2-102.11 Demonstration.*

Based on the risks of foodborne illness inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis CRITICAL CONTROL POINT principles, and the requirements

of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by compliance with this Code, by being a certified FOOD protection manager who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM, or by responding correctly to the inspector's questions as they relate to the specific FOOD operation. The areas of knowledge include:

(A) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a FOOD EMPLOYEE;

(B) Explaining the responsibility of the PERSON IN CHARGE for preventing the transmission of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne disease;

(C) Describing the symptoms associated with the diseases that are transmissible through FOOD;

(D) Explaining the significance of the relationship between maintaining the time and temperature of POTENTIALLY HAZARDOUS FOOD and the prevention of foodborne illness;

(E) Explaining the HAZARDS involved in the consumption of raw or undercooked MEAT, POULTRY, eggs, and FISH.

(F) Stating the required FOOD temperatures and times for safe cooking of POTENTIALLY HAZARDOUS FOOD including MEAT, POULTRY, eggs, and FISH.

(G) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of POTENTIALLY HAZARDOUS FOOD;

(H) Describing the relationship between the prevention of foodborne illness and the management and control of the following:

(1) Cross contamination,

(2) Hand contact with READY-TO-EAT FOODS,

(3) Handwashing, and

(4) Maintaining the FOOD ESTABLISHMENT in a clean condition and in good repair;

(I) Explaining the relationship between FOOD safety and providing EQUIPMENT that is:

(1) Sufficient in number and capacity, and

(2) Properly designed, constructed, located, installed, operated, maintained, and cleaned;

(J) Explaining correct procedures for cleaning and SANITIZING UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT;

(K) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;

(L) Identifying POISONOUS OR TOXIC MATERIALS in the FOOD ESTABLISHMENT and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to LAW;

(M) Identifying CRITICAL CONTROL POINTS in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code;

(N) Explaining the details of how the PERSON IN CHARGE and FOOD EMPLOYEES comply with the HACCP PLAN if a plan is required by the LAW, this Code, or an agreement between the REGULATORY AUTHORITY and the establishment; and

(O) Explaining the responsibilities, rights, and authorities assigned by this Code to the:

(1) FOOD EMPLOYEE,

(2) PERSON IN CHARGE, and

(3) REGULATORY AUTHORITY.

2-103.11 Person in Charge.

Duties

The PERSON IN CHARGE shall ensure that:

(A) FOOD ESTABLISHMENT operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under § 6-202.111;

(B) PERSONS unnecessary to the FOOD ESTABLISHMENT operation are not allowed in the FOOD preparation, FOOD storage, or WAREWASHING areas, except that brief visits and tours may be authorized by the PERSON IN CHARGE if steps are taken to ensure that exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES are protected from contamination;

(C) EMPLOYEES and other PERSONS such as delivery and maintenance PERSONS and pesticide applicators entering the FOOD preparation, FOOD storage, and WAREWASHING areas comply with this Code;

(D) EMPLOYEES are effectively cleaning their hands, by routinely monitoring the EMPLOYEES' handwashing;

(E) EMPLOYEES are visibly observing FOODS as they are received to determine that they are from APPROVED sources, delivered at the required temperatures, protected from contamination, unADULTERATED, and accurately presented, by routinely monitoring the EMPLOYEES' observations and periodically evaluating FOODS upon their receipt;

(F) EMPLOYEES are properly cooking POTENTIALLY HAZARDOUS FOOD, being particularly careful in cooking those FOODS known to cause severe foodborne illness and death, such as eggs and COMMINUTED MEATS, through daily oversight of the EMPLOYEES' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under § 4-203.11 and ¶ 4-502.11(B);

(G) EMPLOYEES are using proper methods to rapidly cool POTENTIALLY HAZARDOUS FOODS that are not held hot or are not for consumption within 4 hours, through daily oversight of the EMPLOYEES' routine monitoring of FOOD temperatures during cooling;

(H) CONSUMERS who order raw or partially cooked READY-TO-EAT FOODS of animal origin are informed as specified under § 3-603.11 that the FOOD is not cooked sufficiently to ensure its safety;

(I) EMPLOYEES are properly SANITIZING cleaned multiuse EQUIPMENT and UTENSILS before they are reused, through routine monitoring of solution temperature and exposure time for hot water SANITIZING, and chemical concentration, pH, temperature, and exposure time for chemical SANITIZING;

(J) CONSUMERS are notified that clean TABLEWARE is to be used when they return to self-service areas such as salad bars and buffets as specified under § 3-304.16;

(K) EMPLOYEES are preventing cross-contamination of READY-TO-EAT FOOD with bare hands by properly using suitable UTENSILS such as deli tissue, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT; and

(L) EMPLOYEES are properly trained in FOOD safety as it relates to their assigned duties.

2-2 EMPLOYEE HEALTH

Subpart

2-201 Disease or Medical Condition

Disease or Medical Condition

employer requires employee reporting of:

health status

employee is ill

2-201.11 Responsibility of the Person in Charge to Require Reporting by Food Employees and Applicants.*

The PERMIT HOLDER shall require FOOD EMPLOYEE applicants to whom a conditional offer of employment is made and FOOD EMPLOYEES to report to the PERSON IN CHARGE, information about their health and activities as they relate to diseases that are transmissible through FOOD. A FOOD EMPLOYEE or applicant shall report the information in a manner that allows the PERSON IN CHARGE to prevent the likelihood of foodborne disease transmission, including the date of onset of jaundice or of an illness specified under ¶ (C) of this section, if the FOOD EMPLOYEE or applicant:

(A) Is diagnosed with an illness due to:

(1) ***Salmonella* Typhi**,

(2) ***Shigella*** spp.,

(3) ***Escherichia coli*** O157:H7, or

(4) Hepatitis A virus;

employee has symptom of:

(B) Has a symptom caused by illness, infection, or other source that is:

• *intestinal illness*

(1) Associated with an acute gastrointestinal illness such as:

(a) Diarrhea,

(b) Fever,

(c) Vomiting,

(d) Jaundice, or

(e) Sore throat with fever, or

• *Boil or infected wound*

(2) A lesion containing pus such as a boil or infected wound that is open or draining and is:

(a) On the hands or wrists, *unless an impermeable cover such as a finger cot or stall protects the lesion and a* SINGLE-USE *glove is worn over the impermeable cover*,

(b) On exposed portions of the arms, *unless the lesion is protected by an impermeable cover*, or

(c) On other parts of the body, *unless the lesion is covered by a dry, durable, tight-fitting bandage*;

employee previously ill

(C) Had a past illness from an infectious agent specified under ¶ (A) of this section; or

activities

(D) Meets one or more of the following high-risk conditions:

employee at high risk of becoming ill:
• *prepared or consumed food that caused disease*

(1) Is suspected of causing, or being exposed to, a CONFIRMED DISEASE OUTBREAK caused by ***S*. Typhi**, ***Shigella*** spp., ***E. coli*** O157:H7, or hepatitis A virus including an outbreak at an event such as a family meal, church supper, or festival because the FOOD EMPLOYEE or applicant:

(a) Prepared FOOD implicated in the outbreak,

(b) Consumed FOOD implicated in the outbreak, or

(c) Consumed FOOD at the event prepared by a PERSON who is infected or ill with the infectious agent that caused the outbreak or who is suspected of being a shedder of the infectious agent,

• lives with ill person

(2) Lives in the same household as a PERSON who is diagnosed with a disease caused by ***S*. Typhi**, ***Shigella*** spp., ***E. coli*** O157:H7, or hepatitis A virus, or

• lives with person involved in disease outbreak

(3) Lives in the same household as a PERSON who attends or works in a setting where there is a confirmed disease outbreak caused by ***S*. Typhi**, ***Shigella*** spp., ***E. coli*** O157:H7, or hepatitis A virus.

2-201.12 Exclusions and Restrictions.*

The PERSON IN CHARGE shall:

excluding ill employees

(A) Exclude a FOOD EMPLOYEE from a FOOD ESTABLISHMENT if the FOOD EMPLOYEE is diagnosed with an infectious agent specified under ¶ 2-201.11(A);

restricting employees: (serving general population)

(B) Except as specified under ¶ (C) or (D) of this section, restrict a FOOD EMPLOYEE from working with exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES, in a FOOD ESTABLISHMENT if the FOOD EMPLOYEE is:

• with symptom of illness or

(1) Suffering from a symptom specified under ¶ 2-201.11(B), or

of past illness

(2) Not experiencing a symptom of acute gastroenteritis specified under Subparagraph 2-201.11(B)(1) but has a stool that yields a specimen culture that is positive for ***Salmonella* Typhi**, ***Shigella*** spp., or ***Escherichia coli*** O157:H7;

excluding employees: (serving high-risk population)

(C) If the population served is a HIGHLY SUSCEPTIBLE POPULATION, exclude a FOOD EMPLOYEE who:

• with symptom of illness or

(1) Is experiencing a symptom of acute gastrointestinal illness specified under Subparagraph 2-201.11(B)(1) and meets a high-risk condition specified under Subparagraphs 2-201.11(D)(1)-(3),

of past illness

(2) Is not experiencing a symptom of acute gastroenteritis specified under Subparagraph 2-201.11(B)(1) but has a stool that yields a specimen culture that is positive for ***S***. **Typhi**, ***Shigella*** spp., or ***E. coli*** O157:H7,

(3) Had a past illness from ***S***. **Typhi** within the last 3 months, or

(4) Had a past illness from ***Shigella*** spp. or ***E. coli*** O157:H7 within the last month; and

excluding and restricting jaundiced employees

(D) For a FOOD EMPLOYEE who is jaundiced:

(1) If the onset of jaundice occurred within the last 7 calendar days, exclude the FOOD EMPLOYEE from the FOOD ESTABLISHMENT, or

(2) If the onset of jaundice occurred more than 7 calendar days before:

(a) Exclude the FOOD EMPLOYEE from a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, or

(b) Restrict the FOOD EMPLOYEE from activities specified under ¶ 2-201.12(B), if the FOOD ESTABLISHMENT does not serve a HIGHLY SUSCEPTIBLE POPULATION.

2-201.13 Removal of Exclusions and Restrictions.

reinstating an ***excluded*** *employee who is:*

(A) The PERSON IN CHARGE may remove an exclusion specified under ¶ 2-201.12(A) if:

(1) The PERSON IN CHARGE obtains approval from the REGULATORY AUTHORITY; and

• no longer ill

or

• free of jaundice

(2) The PERSON excluded as specified under ¶ 2-201.12(A) provides to the PERSON IN CHARGE written medical documentation from a physician licensed to practice medicine or, if allowed by LAW, a nurse practitioner or physician assistant, that specifies that the excluded PERSON may work in an unrestricted capacity in a FOOD ESTABLISHMENT, including an establishment that serves a HIGHLY SUSCEPTIBLE POPULATION,

because the PERSON is free of the infectious agent of concern as specified in § 8-501.40.

reinstating a <u>restricted</u> employee who is
• free of symptoms

(B) The PERSON IN CHARGE may remove a restriction specified under:

(1) Subparagraph 2-201.12(B)(1) if the restricted PERSON:

(a) Is free of the symptoms specified under ¶ 2-201.11(B) and no foodborne illness occurs that may have been caused by the restricted PERSON,

(b) Is suspected of causing foodborne illness but:

(i) Is free of the symptoms specified under ¶ 2-201.11(B), and

• free of suspected infectious agent

(ii) Provides written medical documentation from a physician licensed to practice medicine or, if allowed by LAW, a nurse practitioner or physician assistant, stating that the restricted PERSON is free of the infectious agent that is suspected of causing the PERSON'S symptoms or causing foodborne illness, as specified in § 8-501.40, or

• has symptoms that are not caused by an infectious agent

(c) Provides written medical documentation from a physician licensed to practice medicine or, if allowed by LAW, a nurse practitioner or physician assistant, stating that the symptoms experienced result from a chronic noninfectious condition such as Crohn's disease, irritable bowel syndrome, or ulcerative colitis; or

• no longer a shedder

(2) Subparagraph 2-201.12(B)(2) if the restricted PERSON provides written medical documentation from a physician, licensed to practice medicine, or, if allowed by LAW, a nurse practitioner or physician assistant, according to the criteria specified in § 8-501.40 that indicates the stools are free of ***Salmonella* Typhi**, ***Shigella*** spp., or ***E*. *coli*** O157:H7, whichever is the infectious agent of concern.

reinstating an <u>excluded</u> employee serving: high-risk population

(C) The PERSON IN CHARGE may remove an exclusion specified under ¶ 2-201.12(C) if the excluded PERSON provides written medical documentation from a physician licensed to practice medicine or, if allowed by LAW, a nurse practitioner or physician assistant:

(1) That specifies that the PERSON is free of:

(a) The infectious agent of concern as specified in § 8-501.40, or

(b) Jaundice as specified under ¶ 2-201.13(D) if hepatitis A virus is the infectious agent of concern; or

(2) If the PERSON is excluded under Subparagraph 2-201.12(C)(1), stating that the symptoms experienced result from a chronic noninfectious condition such as Crohn's disease, irritable bowel syndrome, or ulcerative colitis.

reinstating an employee who is:

(D) The PERSON IN CHARGE may remove an exclusion specified under Subparagraph 2-201.12(D)(1) and Subparagraph 2-201.12(D)(2)(a) and a restriction specified under Subparagraph 2-201.12(D)(2)(b) if:

• *not suspect source of illness*

(1) No foodborne illness occurs that may have been caused by the excluded or restricted PERSON and the PERSON provides written medical documentation from a physician licensed to practice medicine or, if allowed by LAW, a nurse practitioner or physician assistant, that specifies that the PERSON is free of hepatitis A virus as specified in Subparagraph 8-501.40(D)(1); or

• *suspect source of illness*

(2) The excluded or restricted PERSON is suspected of causing foodborne illness and complies with the requirements in Subparagraphs 8-501.40(D)(1) and (D)(2).

2-201.14 Responsibility of a Food Employee or an Applicant to Report to the Person in Charge.*

A FOOD EMPLOYEE or a PERSON who applies for a job as a FOOD EMPLOYEE shall:

(A) In a manner specified under § 2-201.11, report to the PERSON IN CHARGE the information specified under ¶¶ 2-201.11(A)-(D); and

(B) Comply with exclusions and restrictions that are specified under ¶¶ 2-201.12(A)-(D).

2-201.15 Reporting by the Person in Charge.*

The PERSON IN CHARGE shall notify the REGULATORY AUTHORITY that a FOOD EMPLOYEE is diagnosed with an illness due to ***Salmonella***

Typhi, ***Shigella*** spp., ***Escherichia coli*** O157:H7, or hepatitis A virus.

2-3 PERSONAL CLEANLINESS

Subparts

Hands and Arms

2-301.11 Clean Condition.*

FOOD EMPLOYEES shall keep their hands and exposed portions of their arms clean.

2-301.12 Cleaning Procedure.*

(A) Except as specified in ¶ (B) of this section, FOOD EMPLOYEES shall clean their hands and exposed portions of their arms with a cleaning compound in a lavatory that is equipped as specified under ¶ 5-202.12 by vigorously rubbing together the surfaces of their lathered hands and arms for at least 20 seconds and thoroughly rinsing with clean water. EMPLOYEES shall pay particular attention to the areas underneath the fingernails and between the fingers.

(B) *If APPROVED and capable of removing the types of soils encountered in the FOOD operations involved, an automatic handwashing facility may be used by food employees to clean their hands.*

2-301.13 Special Handwash Procedures.*

Reserved.

2-301.14 When to Wash.*

FOOD EMPLOYEES shall clean their hands and exposed portions of their arms as specified under § 2-301.12 immediately before engaging in FOOD preparation including working with exposed FOOD, clean EQUIPMENT and UTENSILS, and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES and:

(A) After touching bare human body parts other than clean hands and clean, exposed portions of arms;

(B) After using the toilet room;

(C) After caring for or handling SERVICE ANIMALS or aquatic animals as specified in ¶ 2-403.11(B);

(D) Except as specified in ¶ 2-401.11(B), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;

(E) After handling soiled EQUIPMENT or UTENSILS;

(F) During FOOD preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;

(G) When switching between working with raw FOOD and working with READY-TO-EAT FOOD; and

(H) After engaging in other activities that contaminate the hands.

2-301.15 Where to Wash.

FOOD EMPLOYEES shall clean their hands in a handwashing lavatory or APPROVED automatic handwashing facility and may not clean their hands in a sink used for FOOD preparation, or in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste.

2-301.16 Hand Sanitizers.

(A) A hand sanitizer and a chemical hand sanitizing solution used as a hand dip shall:

(1) Comply with one of the following:

(a) Be an APPROVED drug that is listed in the FDA publication **Approved Drug Products with Therapeutic Equivalence Evaluations** as an APPROVED drug based on safety and effectiveness; or

(b) Have active antimicrobial ingredients that are listed in:

(i) The FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, or

(ii) The USDA **List of Proprietary Substances and Nonfood Compounds**, Miscellaneous Publication No. 1419; and

(2) Comply with one of the following:

(a) Have components that are exempted from the requirement of being listed in federal FOOD ADDITIVE regulations as specified in 21 CFR 170.39 - Threshold of regulation for substances used in food-contact articles; or

(b) Comply with and be listed in:

(i) 21 CFR 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers as regulated for use as a FOOD ADDITIVE with conditions of safe use, or

(ii) 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with FOOD; and

(3) Be applied only to hands that are cleaned as specified under § 2-301.12.

(B) If a hand sanitizer or a chemical hand sanitizing solution used as a hand dip does not meet the criteria specified under Subparagraph (A)(2) of this section, use shall be:

(1) Followed by thorough hand rinsing in clean water before hand contact with FOOD or by the use of gloves; or

(2) Limited to situations that involve no direct contact with FOOD by the bare hands.

(C) A chemical hand sanitizing solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 mg/L chlorine.

Fingernails

2-302.11 Maintenance.

(A) FOOD EMPLOYEES shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough.

(B) *Unless wearing intact gloves in good repair*, a FOOD EMPLOYEE may not wear fingernail polish or artificial fingernails when working with exposed FOOD.

Jewelry

2-303.11 Prohibition.

While preparing FOOD, FOOD EMPLOYEES may not wear jewelry on their arms and hands. *This section does not apply to a plain ring such as a wedding band.*

Outer Clothing

2-304.11 Clean Condition.

FOOD EMPLOYEES shall wear clean outer clothing to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

2-4 HYGIENIC PRACTICES

Subparts

Food Contamination Prevention

2-401.11 Eating, Drinking, or Using Tobacco.*

(A) Except as specified in ¶ (B) of this section, an EMPLOYEE shall eat, drink, or use any form of tobacco only in designated areas where the contamination of exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES; or other items needing protection can not result.

(B) *A FOOD EMPLOYEE may drink from a closed BEVERAGE container if the container is handled to prevent contamination of:*

(1) The EMPLOYEE'S hands;

(2) The container; and

(3) Exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

2-401.12 Discharges from the Eyes, Nose, and Mouth.*

FOOD EMPLOYEES experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth may not work with exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; or unwrapped SINGLE-SERVICE or SINGLE-USE ARTICLES.

Hair Restraints

2-402.11 Effectiveness.

(A) Except as provided in ¶ (B) of this section, FOOD EMPLOYEES shall wear hair restraints such as hats, hair coverings or nets, beard restraints, and clothing that covers body hair, that are designed and

worn to effectively keep their hair from contacting exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

(B) *This section does not apply to FOOD EMPLOYEES such as counter staff who only serve BEVERAGES and wrapped or* PACKAGED *FOODS, hostesses, and wait staff if they present a minimal risk of contaminating exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES*.

Animals

2-403.11 Handling Prohibition.*

(A) Except as specified in ¶ (B) of this section, FOOD EMPLOYEES may not care for or handle animals that may be present such as patrol dogs, SERVICE ANIMALS, or pets that are allowed as specified in Subparagraphs 6-501.115(B)(2)-(5).

(B) *FOOD EMPLOYEES with SERVICE ANIMALS may handle or care for their SERVICE ANIMALS and FOOD EMPLOYEES may handle or care for FISH in aquariums or MOLLUSCAN SHELLFISH or crustacea in display tanks if they wash their hands as specified under § 2-301.12 and ¶ 2-301.14(C).*

Chapter

3 Food

Parts

3-1 CHARACTERISTICS

Subparts

Condition **3-101.11 Safe, Unadulterated, and Honestly Presented.***

FOOD shall be safe, UNADULTERATED, and, as specified under § 3-601.12, honestly presented.

3-2 SOURCES, SPECIFICATIONS, AND ORIGINAL CONTAINERS AND RECORDS

Subparts

Sources

3-201.11 Compliance with Food Law.*

(A) FOOD shall be obtained from sources that comply with LAW.

(B) FOOD prepared in a private home may not be used or offered for human consumption in a FOOD ESTABLISHMENT.

(C) PACKAGED FOOD shall be labeled as specified in LAW, including 21 CFR 101 FOOD Labeling, 9 CFR 317 Labeling, Marking Devices, and Containers, and 9 CFR 381 Subpart N Labeling and Containers, and as specified under §§ 3-202.17 and 3-202.18.

(D) *Fish, other than MOLLUSCAN SHELLFISH, that are intended for consumption in their raw form and allowed as specified in Subparagraph 3-401.11(C)(1) may be offered for sale or service if they are obtained from a supplier that freezes the FISH as specified under § 3-402.11; or frozen on the PREMISES as specified under § 3-402.11 and records are retained as specified under § 3-402.12.*

(E) WHOLE-MUSCLE, INTACT BEEF steaks that are intended for consumption in an undercooked form without a CONSUMER advisory as specified in ¶ 3-401.11(C) shall be:

(1) Obtained from a FOOD PROCESSING PLANT that packages the steaks and labels them to indicate that they meet the definition of WHOLE-MUSCLE, INTACT BEEF; or

(2) If individually cut in a FOOD ESTABLISHMENT:

(a) Cut from WHOLE-MUSCLE INTACT BEEF that is labeled by a FOOD PROCESSING PLANT to indicate that the beef meets the definition of WHOLE-MUSCLE, INTACT BEEF,

(b) Prepared so they remain intact, and

(c) If PACKAGED for undercooking in a FOOD ESTABLISHMENT, labeled to indicate that they meet the definition of WHOLE-MUSCLE, INTACT BEEF.

(F) MEAT and POULTRY that is not a READY-TO-EAT FOOD and is in a PACKAGED form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in LAW, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

3-201.12 Food in a Hermetically Sealed Container.*

FOOD in a HERMETICALLY SEALED CONTAINER shall be obtained from a FOOD PROCESSING PLANT that is regulated by the FOOD regulatory agency that has jurisdiction over the plant.

3-201.13 Fluid Milk and Milk Products.*

Fluid milk and milk products shall be obtained from sources that comply with GRADE A STANDARDS as specified in LAW.

3-201.14 Fish.*

(A) FISH that are received for sale or service shall be:

(1) Commercially and legally caught or harvested; or

(2) APPROVED for sale or service.

(B) MOLLUSCAN SHELLFISH that are recreationally caught may not be received for sale or service.

3-201.15 Molluscan Shellfish.*

(A) MOLLUSCAN SHELLFISH shall be obtained from sources according to LAW and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

(B) MOLLUSCAN SHELLFISH received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List.

3-201.16 Wild Mushrooms.*

(A) Except as specified in ¶ (B) of this section, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an APPROVED mushroom identification expert.

(B) *This section does not apply to:*

(1) *Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the FOOD regulatory agency that has jurisdiction over the operation; or*

(2) *Wild mushroom species if they are in PACKAGED form and are the product of a FOOD PROCESSING PLANT that is regulated by the FOOD regulatory agency that has jurisdiction over the plant.*

3-201.17 Game Animals.*

(A) If GAME ANIMALS are received for sale or service they shall be:

(1) Commercially raised for food and:

(a) Raised slaughtered, and processed under a voluntary inspection program that is conducted by the agency that has animal health jurisdiction, or

(b) Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction, and

(c) Raised, slaughtered, and processed according to:

(i) LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem

examination by an APPROVED veterinarian or veterinarian's designee;

(2) Under a voluntary inspection program administered by the USDA for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and APPROVED" in accordance with 9 CFR 352 Voluntary Exotic Animal Program or rabbits that are "inspected and certified" in accordance with 9 CFR 354 Rabbit Inspection Program;

(3) As allowed by LAW, for wild GAME ANIMALS that are live-caught:

(a) Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction, and

(b) Slaughtered and processed according to:

(i) LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an APPROVED veterinarian or veterinarian's designee; or

(4) As ALLOWED by LAW, for field-dressed wild GAME ANIMALS under a routine inspection program that ensures the animals:

(a) Receive a postmortem examination by an APPROVED veterinarian or veterinarian's designee, or

(b) Are field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and

(c) Are processed according to LAWS governing MEAT and POULTRY as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program.

(B) A GAME ANIMAL may not be received for sale or service if it is a species of wildlife that is listed in 50 CFR 17 Endangered and Threatened Wildlife and Plants.

Specifications for Receiving

3-202.11 Temperature.*

(A) Except as specified in ¶ (B) of this section, refrigerated, POTENTIALLY HAZARDOUS FOOD shall be at a temperature of 5°C (41°F) or below when received.

(B) *If a temperature other than 5°C (41°F) for a POTENTIALLY HAZARDOUS FOOD is specified in LAW governing its distribution, such as LAWS governing milk, MOLLUSCAN SHELLFISH, and shell eggs, the FOOD may be received at the specified temperature.*

(C) POTENTIALLY HAZARDOUS FOOD that is cooked to a temperature and for a time specified under §§ 3-401.11 - 3-401.13 and received hot shall be at a temperature of 60°C (140°F) or above.

(D) A FOOD that is labeled frozen and shipped frozen by a FOOD PROCESSING PLANT shall be received frozen.

(E) Upon receipt, POTENTIALLY HAZARDOUS FOOD shall be free of evidence of previous temperature abuse.

3-202.12 Additives.*

FOOD may not contain unAPPROVED FOOD ADDITIVES or ADDITIVES that exceed amounts specified in 21 CFR 170-180 relating to FOOD ADDITIVES, generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181-186, substances that exceed amounts specified in 9 CFR 318.7 Approval of substances for use in the preparation of products, or pesticide residues that exceed provisions specified in 40 CFR 185 Tolerances for Pesticides in Food.

3-202.13 Shell Eggs.*

Shell eggs shall be received clean and sound and may not exceed the restricted egg tolerances for U.S. CONSUMER Grade B as specified in 7 CFR Part 56 - Regulations Governing the Grading of Shell Eggs and U.S. Standards, Grades, and Weight classes for Shell Eggs, and 7 CFR Part 59 - Regulations Governing the Inspection of Eggs and Egg Products.

3-202.14 Eggs and Milk Products, Pasteurized.*

(A) Liquid, frozen, and dry eggs and egg products shall be obtained pasteurized.

(B) Fluid and dry milk and milk products complying with GRADE A STANDARDS as specified in LAW shall be obtained pasteurized.

(C) Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in 21 CFR 135 - Frozen Desserts.

(D) Cheese shall be obtained pasteurized *unless alternative procedures to pasteurization are specified in the CFR, such as 21 CFR 133 - Cheeses and Related Cheese Products, for curing certain cheese varieties.*

3-202.15 Package Integrity.*

FOOD packages shall be in good condition and protect the integrity of the contents so that the FOOD is not exposed to ADULTERATION or potential contaminants.

3-202.16 Ice.*

Ice for use as a FOOD or a cooling medium shall be made from DRINKING WATER.

3-202.17 Shucked Shellfish, Packaging and Identification.

(A) Raw SHUCKED SHELLFISH shall be obtained in nonreturnable packages which bear a legible label that identifies the:

(1) Name, address, and CERTIFICATION NUMBER of the shucker-packer or repacker of the MOLLUSCAN SHELLFISH; and

(2) The "sell by" date for packages with a capacity of less than 1.87 L (one-half gallon) or the date shucked for packages with a capacity of 1.87 L (one-half gallon) or more.

(B) A package of raw SHUCKED SHELLFISH that does not bear a label

or which bears a label which does not contain all the information as specified under ¶ (A) of this section shall be subject to a hold order, as allowed by LAW, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

3-202.18 Shellstock Identification.*

(A) SHELLSTOCK shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester and each dealer that depurates, ships, or reships the SHELLSTOCK, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that list:

(1) Except as specified under ¶ (C) of this section, on the harvester's tag or label, the following information in the following order:

(a) The harvester's identification number that is assigned by the SHELLFISH CONTROL AUTHORITY,

(b) The date of harvesting,

(c) The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the SHELLFISH CONTROL AUTHORITY and including the abbreviation of the name of the state or country in which the shellfish are harvested,

(d) The type and quantity of shellfish, and

(e) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days;" and

(2) Except as specified in ¶ (D) of this section, on each dealer's tag or label, the following information in the following order:

(a) The dealer's name and address, and the CERTIFICATION NUMBER assigned by the SHELLFISH CONTROL AUTHORITY,

(b) The original shipper's CERTIFICATION NUMBER including the abbreviation of the name of the state or country in which the shellfish are harvested,

(c) The same information as specified for a harvester's tag under Subparagraphs (A)(1)(b)-(d) of this section, and

(d) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for 90 days."

(B) A container of SHELLSTOCK that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified under ¶ (A) of this section shall be subject to a hold order, as allowed by LAW, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

(C) If a place is provided on the harvester's tag or label for a dealer's name, address, and CERTIFICATION NUMBER, the dealer's information shall be listed first.

(D) *If the harvester's tag or label is designed to accommodate each dealer's identification as specified under Subparagraphs (A)(2)(a) and (b) of this section, individual dealer tags or labels need not be provided.*

3-202.19 Shellstock, Condition.

When received by a FOOD ESTABLISHMENT, SHELLSTOCK shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or SHELLSTOCK with badly broken shells shall be discarded.

Original Containers and Records

3-203.11 Molluscan Shellfish, Original Container.

(A) Except as specified in ¶¶ (B) and (C) of this section, MOLLUSCAN SHELLFISH may not be removed from the container in which they are received other than immediately before sale or preparation for service.

(B) *SHELLSTOCK may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a CONSUMER may be removed from the display or display container and provided to the CONSUMER if:*

(1) *The source of the SHELLSTOCK on display is identified as specified under § 3-202.18 and recorded as specified under § 3-203.12; and*

(2) *The SHELLSTOCK are protected from contamination.*

(C) *SHUCKED SHELLFISH may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a CONSUMER'S request if:*

(1) *The labeling information for the shellfish on display as specified under § 3-202.17 is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and*

(2) *The shellfish are protected from contamination.*

3-203.12 Shellstock, Maintaining Identification.*

(A) Except as specified under Subparagraph (B)(2) of this section, SHELLSTOCK tags shall remain attached to the container in which the shellstock are received until the container is empty.

(B) The identity of the source of SHELLSTOCK that are sold or served shall be maintained by retaining SHELLSTOCK tags or labels for 90 calendar days from the date the container is emptied by:

(1) Using an APPROVED record keeping system that keeps the tags or labels in chronological order correlated to the date when, or dates during which, the SHELLSTOCK are sold or served; and

(2) If SHELLSTOCK are removed from their tagged or labeled container:

(a) Using only 1 tagged or labeled container at a time, or

(b) Using more than 1 tagged or labeled container at a time and obtaining a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 based on a HACCP PLAN that:

(i) Is submitted by the PERMIT HOLDER and APPROVED as specified under § 8-103.11,

(ii) Preserves source identification by using a record keeping system as specified under Subparagraph (B)(1) of this section, and

(iii) Ensures that SHELLSTOCK from one tagged

or labeled container are not commingled with SHELLSTOCK from another container before being ordered by the CONSUMER.

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Clarification of ¶ 3-301.11(B) of the Food Code

with respect to the phrase "*Except...when otherwise APPROVED*"...

The following information is not part of Chapter 3 and is not intended to be included in the codified portion of the Food Code. In cases where the Food Code is adopted through incorporation by reference, this page may be removed.

In response to a 1996 Conference for Food Protection (CFP) Recommendation that ¶ 3-301.11(B) be modified to include the phrase "or when otherwise APPROVED," the 1997 Code was amended accordingly. A 1998 CFP Recommendation further suggested clarification of that added language.

This insert page is provided to alert the reader that FDA has issued, with this Code, clarification of that phrase and its application. Included in Annex 3 is a full discussion of both the Public Health Reasons associated with § 3-301.11 and Administrative Guidelines regarding the criteria under which bare hand contact with ready-to-eat food may be deemed acceptable in meeting the intent of § 3-301.11.

A HACCP-based approach is applied in the clarification in order to establish a system to control the principal hazard (i.e., fecal-oral transmission of foodborne pathogens) that is the target of the Code provision.

A second 1998 CFP Recommendation was made to consult the National Advisory Committee for the Microbiological Criteria for Foods (NACMCF) for its scientific recommendations surrounding the transmission of pathogens from food workers to consumers via ready-to-eat foods. FDA is preparing information with the intent that the NACMCF will review the matter and make recommendations that will be presented at the 2000 CFP meeting.

3-3 PROTECTION FROM CONTAMINATION AFTER RECEIVING

Subparts

Preventing Contamination by Employees

3-301.11 Preventing Contamination from Hands.*

(A) FOOD EMPLOYEES shall wash their hands as specified under § 2-301.12.

(B) *Except when washing fruits and vegetables as specified under § 3-302.15 or when otherwise APPROVED*, FOOD EMPLOYEES may not contact exposed, READY-TO-EAT FOOD with their bare hands and shall use suitable UTENSILS such as deli tissue, spatulas, tongs, SINGLE-USE gloves, or dispensing EQUIPMENT.

(C) FOOD EMPLOYEES shall minimize bare hand and arm contact with exposed FOOD that is not in a READY-TO-EAT form.[s]

3-301.12 Preventing Contamination when Tasting.*

A FOOD EMPLOYEE may not use a UTENSIL more than once to taste FOOD that is to be sold or served.

Preventing Food and Ingredient Contamination

3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.*

(A) FOOD shall be protected from cross contamination by:

(1) Separating raw animal FOODS during storage, preparation, holding, and display from:

(a) Raw READY-TO-EAT FOOD including other raw animal FOOD such as FISH for sushi or MOLLUSCAN SHELLFISH, or other raw READY-TO-EAT FOOD such as vegetables, and

(b) Cooked READY-TO-EAT FOOD;

(2) *Except when combined as ingredients*, separating types of raw animal FOODS from each other such as beef, FISH, lamb, pork, and POULTRY during storage, preparation, holding, and display by:

(a) Using separate EQUIPMENT for each type, or

(b) Arranging each type of FOOD in EQUIPMENT so that cross contamination of one type with another is prevented, and

(c) Preparing each type of FOOD at different times or in separate areas;

(3) Cleaning EQUIPMENT and UTENSILS as specified under ¶ 4-602.11(A) and SANITIZING as specified under § 4-703.11;

(4) Except as specified in ¶ (B) of this section, storing the FOOD in packages, covered containers, or wrappings;

(5) Cleaning HERMETICALLY SEALED CONTAINERS of FOOD of visible soil before opening;

(6) Protecting FOOD containers that are received PACKAGED together in a case or overwrap from cuts when the case or overwrap is opened;

(7) Storing damaged, spoiled, or recalled FOOD being held in the FOOD ESTABLISHMENT as specified under § 6-404.11; and

(8) Separating fruits and vegetables, before they are washed as specified under § 3-302.15 from READY-TO-EAT FOOD.

(B) *Subparagraph (A)(4) of this section does not apply to:*

(1) *Whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;*

(2) *PRIMAL CUTS, quarters, or sides of raw MEAT or slab bacon that are hung on clean, SANITIZED hooks or placed on clean, SANITIZED racks;*

(3) *Whole, uncut, processed MEATS such as country hams, and smoked or cured sausages that are placed on clean, SANITIZED racks;*

(4) *FOOD being cooled as specified under Subparagraph 3-501.15(B)(2); or*

(5) *SHELLSTOCK*.

3-302.12 Food Storage Containers, Identified with Common Name of Food.

Working containers holding FOOD or FOOD ingredients that are removed from their original packages for use in the FOOD ESTABLISHMENT, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar shall be identified with the common name of the FOOD *except that containers holding FOOD that can be readily and unmistakably recognized such as dry pasta need not be identified*.

3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.*

Pasteurized eggs or egg products shall be substituted for raw shell eggs in the preparation of FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, eggnog, ice cream, and egg-fortified BEVERAGES that are not:

(A) Cooked as specified under Subparagraphs 3-401.11(A)(1) or (2); or

(B) Included in Subparagraph 3-401.11(D).

3-302.14 Protection from Unapproved Additives.*

(A) FOOD shall be protected from contamination that may result from the addition of, as specified in § 3-202.12:

(1) Unsafe or unAPPROVED FOOD or COLOR ADDITIVES; and

(2) Unsafe or unAPPROVED levels of APPROVED FOOD and COLOR ADDITIVES.

(B) A FOOD EMPLOYEE may not:

(1) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a FOOD considered to be a good source of vitamin B_1; or

(2) Serve or sell FOOD specified under Subparagraph (B)(1) of this section that is treated with sulfiting agents before receipt by the FOOD ESTABLISHMENT, *except that grapes need not meet this subparagraph*.

3-302.15 Washing Fruits and Vegetables.

(A) Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in READY-TO-EAT form except as specified in ¶ (B) of this section and *except that whole, raw fruits and vegetables that are intended for washing by the CONSUMER before consumption need not be washed before they are sold*.

(B) *Fruits and vegetables may be washed by using chemicals as specified under § 7-204.12.*

Preventing Contamination from Ice Used as a Coolant

3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient.

After use as a medium for cooling the exterior surfaces of FOOD such as melons or FISH, PACKAGED FOODS such as canned BEVERAGES, or cooling coils and tubes of EQUIPMENT, ice may not be used as FOOD.

3-303.12 Storage or Display of FOOD in Contact with Water or Ice.

(A) PACKAGED FOOD may not be stored in direct contact with ice or water if the FOOD is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water.

(B) Except as specified in ¶¶ (C) and (D) of this section, unPACKAGED FOOD may not be stored in direct contact with undrained ice.

(C) *Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.*

(D) *Raw chicken and raw FISH that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale.*

Preventing Contamination from Equipment, Utensils, and Linens

3-304.11 Food Contact with Equipment and Utensils.*

FOOD shall only contact surfaces of EQUIPMENT and UTENSILS that are cleaned as specified under Part 4-6 of this Code and SANITIZED as specified under Part 4-7 of this Code.

3-304.12 In-Use Utensils, Between-Use Storage.

During pauses in FOOD preparation or dispensing, FOOD preparation and dispensing UTENSILS shall be stored:

(A) Except as specified under ¶ (B) of this section, in the FOOD with their handles above the top of the FOOD and the container;

(B) In FOOD that is not POTENTIALLY HAZARDOUS with their handles above the top of the FOOD within containers or EQUIPMENT that can be closed, such as bins of sugar, flour, or cinnamon;

(C) On a clean portion of the FOOD preparation table or cooking EQUIPMENT only if the in-use UTENSIL and the FOOD-CONTACT surface of the FOOD preparation table or cooking EQUIPMENT are cleaned and SANITIZED at a frequency specified under §§ 4-602.11 and 4-702.11;

(D) In running water of sufficient velocity to flush particulates to the drain, if used with moist FOOD such as ice cream or mashed potatoes;

(E) In a clean, protected location if the UTENSILS, such as ice scoops, are used only with a FOOD that is not POTENTIALLY HAZARDOUS; or

(F) In a container of water if the water is maintained at a temperature of at least 60°C (140°F) and the container is cleaned at a frequency specified under Subparagraph 4-602.11(D)(7).

3-304.13 Linens and Napkins, Use Limitation.

LINENS and napkins may not be used in contact with FOOD *unless they are used to line a container for the service of FOODS and the LINENS and napkins are replaced each time the container is refilled for a new CONSUMER*.

3-304.14 Wiping Cloths, Use Limitation.

(A) Cloths that are in use for wiping FOOD spills shall be used for no other purpose.

(B) Cloths used for wiping FOOD spills shall be:

(1) Dry and used for wiping FOOD spills from TABLEWARE and carry-out containers; or

(2) Wet and cleaned as specified under ¶ 4-802.11(D), stored in a chemical sanitizer at a concentration specified in § 4-501.114, and used for wiping spills from FOOD-CONTACT and nonFOOD-CONTACT SURFACES of EQUIPMENT.

(C) Dry or wet cloths that are used with raw animal FOODS shall be kept separate from cloths used for other purposes, and wet cloths used with raw animal FOODS shall be kept in a separate sanitizing solution.

(D) Wet wiping cloths used with a freshly made sanitizing solution and dry wiping cloths shall be free of FOOD debris and visible soil.

3-304.15 Gloves, Use Limitation.

(A) If used, SINGLE-USE gloves shall be used for only one task such as working with READY-TO-EAT FOOD or with raw animal FOOD, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation.

(B) Except as specified in ¶ (C) of this section, slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with FOOD that is subsequently cooked as specified under Part 3-4 such as frozen FOOD or a PRIMAL CUT of MEAT.

(C) *Slash-resistant gloves may be used with READY-TO-EAT FOOD that will not be subsequently cooked if the slash-resistant gloves have a SMOOTH, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a SMOOTH, durable, nonabsorbent glove, or a SINGLE-USE glove*.

(D) Cloth gloves may not be used in direct contact with FOOD *unless the FOOD is subsequently cooked as required under Part 3-4 such as frozen FOOD or a PRIMAL CUT of MEAT*.

3-304.16 Using Clean Tableware for Second Portions and Refills.

(A) Except for refilling a CONSUMER'S drinking cup or container without contact between the pouring UTENSIL and the lip-contact area of the drinking cup or container, FOOD EMPLOYEES may not use TABLEWARE, including SINGLE-SERVICE ARTICLES, soiled by the CONSUMER, to provide second portions or refills.

(B) Except as specified in ¶ (C) of this section, self-service CONSUMERS may not be allowed to use soiled TABLEWARE, including SINGLE-SERVICE ARTICLES, to obtain additional FOOD from the display and serving EQUIPMENT.

(C) *Drinking cups and containers may be reused by self-service CONSUMERS if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D)*.

3-304.17 Refilling Returnables.

(A) A take-home FOOD container returned to a FOOD ESTABLISHMENT may not be refilled at a FOOD ESTABLISHMENT with a POTENTIALLY HAZARDOUS FOOD.

(B) Except as specified in ¶ (C), a take-home FOOD container refilled with FOOD that is not POTENTIALLY HAZARDOUS shall be cleaned as specified under ¶ 4-603.17(B).

(C) *Personal take-out BEVERAGE containers, such as thermally insulated bottles, nonspill coffee cups, and promotional BEVERAGE glasses, may be refilled by EMPLOYEES or the CONSUMER if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D)*.

Preventing Contamination from the Premises

3-305.11 Food Storage.

(A) Except as specified in ¶¶ (B) and (C) of this section, FOOD shall be protected from contamination by storing the FOOD:

(1) In a clean, dry location;

(2) Where it is not exposed to splash, dust, or other contamination; and

(3) At least 15 cm (6 inches) above the floor.

(B) *FOOD in packages and working containers may be stored less than 15 cm (6 inches) above the floor on case lot handling EQUIPMENT as specified under § 4-204.122*.

(C) *Pressurized BEVERAGE containers, cased FOOD in waterproof containers such as bottles or cans, and milk containers in plastic crates may be stored on a floor that is clean and not exposed to floor moisture*.

3-305.12 Food Storage, Prohibited Areas.

FOOD may not be stored:

(A) In locker rooms;

(B) In toilet rooms;

(C) In dressing rooms;

(D) In garbage rooms;

(E) In mechanical rooms;

(F) Under sewer lines that are not shielded to intercept potential drips;

(G) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;

(H) Under open stairwells; or

(I) Under other sources of contamination.

3-305.13 Vended Potentially Hazardous Food, Original Container.

POTENTIALLY HAZARDOUS FOOD dispensed through a VENDING MACHINE shall be in the package in which it was placed at the FOOD ESTABLISHMENT or FOOD PROCESSING PLANT at which it was prepared.

3-305.14 Food Preparation.

During preparation, unPACKAGED FOOD shall be protected from environmental sources of contamination.

Preventing Contamination by Consumers

3-306.11 Food Display.

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the CONSUMER before consumption, FOOD on display shall be protected from contamination by the use of packaging; counter, service line, or salad bar FOOD guards; display cases; or other effective means.

3-306.12 Condiments, Protection.

(A) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected FOOD displays provided with the proper UTENSILS, original

containers designed for dispensing, or individual packages or portions.

(B) Condiments at a VENDING MACHINE LOCATION shall be in individual packages or provided in dispensers that are filled at an APPROVED location, such as the FOOD ESTABLISHMENT that provides FOOD to the VENDING MACHINE LOCATION, a FOOD PROCESSING PLANT that is regulated by the agency that has jurisdiction over the operation, or a properly equipped facility that is located on the site of the VENDING MACHINE LOCATION.

3-306.13 Consumer Self-Service Operations.*

(A) Raw, unPACKAGED animal FOOD, such as beef, lamb, pork, POULTRY, and FISH may not be offered for CONSUMER self-service. *This paragraph does not apply to CONSUMER self-service of READY-TO-EAT FOODS at buffets or salad bars that serve FOODS such as sushi or raw shellfish; ready-to-cook individual portions for immediate cooking and consumption on the PREMISES such as CONSUMER-cooked* MEATS *or CONSUMER-selected ingredients for Mongolian barbecue; or raw, frozen, shell-on shrimp or lobster*.

(B) CONSUMER self-service operations for READY-TO-EAT FOODS shall be provided with suitable UTENSILS or effective dispensing methods that protect the FOOD from contamination.[N]

(C) CONSUMER self-service operations such as buffets and salad bars shall be monitored by FOOD EMPLOYEES trained in safe operating procedures.[N]

3-306.14 Returned Food and Reservice of Food.*

(A) Except as specified in ¶ (B) of this section, after being served or sold and in the possession of a CONSUMER, FOOD that is unused or returned by the CONSUMER may not be offered as FOOD for human consumption.

(B) Except as specified under ¶ 3-801.11(C), *a container of FOOD that is not POTENTIALLY HAZARDOUS may be transferred from one CONSUMER to another if:*

(1) *The FOOD is dispensed so that it is protected from contamination and the container is closed between uses,*

such as a narrow-neck bottle containing catsup, steak sauce, or wine; or

(2) *The* FOOD*, such as crackers, salt, or pepper, is in an unopened original* PACKAGE *and is maintained in sound condition*.

Preventing Contamination from Other Sources

3-307.11 Miscellaneous Sources of Contamination.

FOOD shall be protected from contamination that may result from a factor or source not specified under Subparts 3-301 - 3-306.

3-4 DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN

Subparts

3-401 Cooking
3-402 Freezing
3-403 Reheating

Cooking

3-401.11 Raw Animal Foods.*

(A) Except as specified under ¶ (B) and in ¶¶ (C) and (D) of this section, raw animal FOODS such as eggs, FISH, MEAT, POULTRY, and FOODS containing these raw animal FOODS, shall be cooked to heat all parts of the FOOD to a temperature and for a time that complies with one of the following methods based on the FOOD that is being cooked:

(1) 63°C (145°F) or above for 15 seconds for:

(a) Raw shell eggs that are broken and prepared in response to a CONSUMER'S order and for immediate service, and

(b) Except as specified under Subparagraphs (A)(2) and (3) and ¶ (B) of this section, FISH, MEAT, and pork including GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1) and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2);

(2) 68°C (155°F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites and INJECTED MEATS; the following if they are COMMINUTED: FISH, MEAT, GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1), and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2); and raw eggs that are not prepared as specified under Subparagraph (A)(1)(a) of this section:

Minimum	
Temperature °C (°F)	**Time**
63 (145)	3 minutes
66 (150)	1 minute
70 (158)	< 1 second (instantaneous)

;or

(3) 74°C (165°F) or above for 15 seconds for POULTRY, wild GAME ANIMALS as specified under Subparagraphs 3-201.17(A)(3) and (4), stuffed FISH, stuffed MEAT, stuffed pasta, stuffed POULTRY, stuffed ratites, or stuffing containing FISH, MEAT, POULTRY, or ratites.

(B) Whole beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham, shall be cooked:

(1) In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature:

Oven Type	Oven Temperature Based on Roast Weight	
	Less than 4.5 kg (10 lbs)	4.5 kg (10 lbs) or More
Still Dry	177°C (350°F) or more	121°C (250°F) or more
Convection	163°C (325°F) or more	121°C (250°F) or more
High Humidity[1]	121°C (250°F) or less	121°C (250°F) or less
[1] Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.		

;and

(2) As specified in the following chart, to heat all parts of the FOOD to a temperature and for the holding time that corresponds to that temperature:

Temperature °C (°F)	Time[1] in Minutes	Temperature °C (°F)	Time[1] in Minutes	Temperature °C (°F)	Time[1] in Minutes
54 (130)	121	58 (136)	32	61 (142)	8
56 (132)	77	59 (138)	19	62 (144)	5
57 (134)	47	60 (140)	12	63 (145)	3
[1] *Holding time may include postoven heat rise.*					

(C) *A raw or undercooked WHOLE-MUSCLE, INTACT BEEF steak may be served or offered for sale in a READY-TO-EAT form if:*

(1) *The FOOD ESTABLISHMENT serves a population that is not a HIGHLY SUSCEPTIBLE POPULATION,*

(2) *The steak is labeled to indicate that it meets the definition of "WHOLE-MUSCLE, INTACT BEEF" as specified under ¶ 3-201.11(E), and*

(3) *The steak is cooked on both the top and bottom to a surface temperature of 63°C (145°F) or above and a cooked color change is achieved on all external surfaces.*

(D) *A raw animal* FOOD *such as raw egg, raw* FISH*, raw-marinated* FISH*, raw* MOLLUSCAN SHELLFISH*, or steak tartare; or a partially cooked* FOOD *such as lightly cooked* FISH*, soft cooked eggs, or rare* MEAT *other than* WHOLE-MUSCLE, INTACT BEEF *steaks as specified in ¶ (C) of this section, may be served or offered for sale in a* READY-TO-EAT *form if:*

(1) *The* FOOD ESTABLISHMENT *serves a population that is not a* HIGHLY SUSCEPTIBLE POPULATION*, and*

(2) *The* CONSUMER *is informed as specified under § 3-603.11 that to ensure its safety, the* FOOD *should be cooked as specified under ¶ (A) or (B) of this section; or*

(3) *The* REGULATORY AUTHORITY *grants a* VARIANCE *from ¶ (A) or (B) of this section as specified in § 8-103.10 based on a HACCP* PLAN *that:*

(a) *Is submitted by the* PERMIT HOLDER *and* APPROVED *as specified under § 8-103.11,*

(b) *Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe* FOOD*, and*

(c) *Verifies that* EQUIPMENT *and procedures for* FOOD *preparation and training of* FOOD EMPLOYEES *at the* FOOD ESTABLISHMENT *meet the conditions of the* VARIANCE*.*

3-401.12 Microwave Cooking.*

Raw animal FOODS cooked in a microwave oven shall be:

(A) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;

(B) Covered to retain surface moisture;

(C) Heated to a temperature of at least 74°C (165°F) in all parts of the food; and

(D) Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 60°C (140°F).

Freezing

3-402.11 Parasite Destruction.*

(A) Except as specified in ¶ (B) of this section, before service or sale in READY-TO-EAT form, raw, raw-marinated, partially cooked, or marinated-partially cooked FISH other than MOLLUSCAN SHELLFISH shall be frozen throughout to a temperature of:

(1) -20°C (-4°F) or below for 168 hours (7 days) in a freezer; or

(2) -35°C (-31°F) or below for 15 hours in a blast freezer.

(B) *If the FISH are tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna), Thunnus atlanticus, Thunnus maccoyii (Bluefin tuna, Southern), Thunnus obesus (Bigeye tuna), or Thunnus thynnus (Bluefin tuna, Northern), the FISH may be served or sold in a raw, raw-marinated, or partially cooked READY-TO-EAT form without freezing as specified under ¶ (A) of this section.*

3-402.12 Records, Creation and Retention.

(A) Except as specified in ¶ 3-402.11(B) and ¶ (B) of this section, if raw, raw-marinated, partially cooked, or marinated-partially cooked FISH are served or sold in READY-TO-EAT form, the PERSON IN CHARGE shall record the freezing temperature and time to which the FISH are subjected and shall retain the records at the FOOD ESTABLISHMENT for 90 calendar days beyond the time of service or sale of the FISH.

(B) *If the FISH are frozen by a supplier, a written agreement or statement from the supplier stipulating that the* FISH *supplied are frozen to a temperature and for a time specified under § 3-402.11 may substitute for the records specified under ¶ (A) of this section*.

Reheating

3-403.10 Preparation for Immediate Service.

Cooked and refrigerated FOOD that is prepared for immediate service in response to an individual CONSUMER order, such as a roast beef sandwich au jus, may be served at any temperature.

3-403.11 Reheating for Hot Holding.*

(A) Except as specified under ¶¶ (B) and (C) and in ¶ (E) of this section, POTENTIALLY HAZARDOUS FOOD that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) for 15 seconds.

(B) Except as specified under ¶ (C) of this section, POTENTIALLY HAZARDOUS FOOD reheated in a microwave oven for hot holding shall be reheated so that all parts of the FOOD reach a temperature of at least 74°C (165°F) and the FOOD is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating.

(C) READY-TO-EAT FOOD taken from a commercially processed, HERMETICALLY SEALED CONTAINER, or from an intact package from a FOOD PROCESSING PLANT that is inspected by the FOOD REGULATORY AUTHORITY that has jurisdiction over the plant, shall be heated to a temperature of at least 60°C (140°F) for hot holding.

(D) Reheating for hot holding shall be done rapidly and the time the FOOD is between the temperature specified under ¶ 3-501.16(B) or (C) and 74°C (165°F) may not exceed 2 hours.

(E) *Remaining unsliced portions of roasts of beef that are cooked as specified under ¶ 3-401.11(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under ¶ 3-401.11(B).*

3-5 LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

Subparts

3-501 Temperature and Time Control
3-502 Specialized Processing Methods

Temperature and Time Control

3-501.11 Frozen Food.

Stored frozen FOODS shall be maintained frozen.

3-501.12 Potentially Hazardous Food, Slacking.

Frozen POTENTIALLY HAZARDOUS FOOD that is slacked to moderate the temperature shall be held:

(A) Under refrigeration that maintains the FOOD temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified under ¶ 3-501.16(C); or

(B) At any temperature if the FOOD remains frozen.

3-501.13 Thawing.

Except as specified in ¶ (D) of this section, POTENTIALLY HAZARDOUS FOOD shall be thawed:

(A) Under refrigeration that maintains the FOOD temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified under ¶ 3-501.16(C); or

(B) Completely submerged under running water:

(1) At a water temperature of 21°C (70°F) or below,

(2) With sufficient water velocity to agitate and float off loose particles in an overflow, and

(3) For a period of time that does not allow thawed portions of READY-TO-EAT FOOD to rise above 5°C (41°F), or 7°C (45°F) as specified under ¶ 3-501.16(C), or

(4) For a period of time that does not allow thawed portions of a raw animal FOOD requiring cooking as specified under ¶ 3-401.11(A) or (B) to be above 5°C (41°F), or 7°C (45°F) as specified under ¶ 3-501.16(C), for more than 4 hours including:

(a) The time the FOOD is exposed to the running water and the time needed for preparation for cooking, or

(b) The time it takes under refrigeration to lower the FOOD temperature to 5°C (41°F), or 7°C (45°F) as specified under ¶ 3-501.16(C);

(C) As part of a cooking process if the FOOD that is frozen is:

(1) Cooked as specified under ¶ 3-401.11(A) or (B) or § 3-401.12, or

(2) Thawed in a microwave oven and immediately transferred to conventional cooking EQUIPMENT, with no interruption in the process; or

(D) *Using any procedure if a portion of frozen READY-TO-EAT FOOD is thawed and prepared for immediate service in response to an individual CONSUMER'S order.*

3-501.14 Cooling.*

(A) Cooked POTENTIALLY HAZARDOUS FOOD shall be cooled:

(1) Within 2 hours, from 60°C (140°F) to 21°C (70°F); and

(2) Within 4 hours, from 21°C (70°F) to 5°C (41°F) or less, or to 7°C (45°F) as specified under ¶ 3-501.16(C).

(B) POTENTIALLY HAZARDOUS FOOD shall be cooled within 4 hours to 5°C (41°F) or less, or to 7°C (45°F) as specified under ¶ 3-501.16(C) if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna.

(C) Except as specified in ¶ (D) of this section, a POTENTIALLY HAZARDOUS FOOD received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in ¶ 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less, or 7°C (45°F) or less as specified under ¶ 3-501.16(C).

(D) *Shell eggs need not comply with ¶ (C) of this section if the eggs are placed immediately upon their receipt in refrigerated EQUIPMENT that is capable of maintaining FOOD at 5°C (41°F) or less, or 7°C (45°F) or less as specified under ¶ 3-501.16(C).*

3-501.15 Cooling Methods.

(A) Cooling shall be accomplished in accordance with the time and temperature criteria specified under § 3-501.14 by using one or more of the following methods based on the type of FOOD being cooled:

(1) Placing the FOOD in shallow pans;

(2) Separating the FOOD into smaller or thinner portions;

(3) Using rapid cooling EQUIPMENT;

(4) Stirring the FOOD in a container placed in an ice water bath;

(5) Using containers that facilitate heat transfer;

(6) Adding ice as an ingredient; or

(7) Other effective methods.

(B) When placed in cooling or cold holding EQUIPMENT, FOOD containers in which FOOD is being cooled shall be:

(1) Arranged in the EQUIPMENT to provide maximum heat transfer through the container walls; and

(2) Loosely covered, or uncovered if protected from overhead contamination as specified under Subparagraph 3-305.11(A)(2), during the cooling period to facilitate heat transfer from the surface of the FOOD.

3-501.16 Potentially Hazardous Food, Hot and Cold Holding.*

Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under § 3-501.19, POTENTIALLY HAZARDOUS FOOD shall be maintained:

(A) At 60°C (140°F) or above, *except that roasts cooked to a temperature and for a time specified under ¶ 3-401.11(B) or reheated as specified in ¶ 3-403.11(E) may be held at a temperature of 54°C (130°F)*; or

(B) At 5°C (41°F) or less, except as specified under ¶ (C) of this section and §§ 3-501.17, 3-501.18, and 4-204.111.

(C) At 7°C (45°F) or between 7°C (45°F) and 5°C (41°F) in existing refrigeration EQUIPMENT that is not capable of maintaining the FOOD at 5°C (41°F) or less if:

(1) The EQUIPMENT is in place and in use in the FOOD ESTABLISHMENT; and

(2) Within 5 years of the REGULATORY AUTHORITY'S adoption of this Code, the EQUIPMENT is upgraded or replaced to maintain FOOD at a temperature of 5°C (41°F) or less.

3-501.17 Ready-to-Eat, Potentially Hazardous Food, Date Marking.*

on-premises preparation
• prepare and hold cold

(A) Except as specified in ¶ (E) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared and held refrigerated for more than 24 hours in a FOOD ESTABLISHMENT shall be clearly marked at the time of preparation to indicate the date by which the FOOD shall be consumed which is, including the day of preparation:

(1) 7 calendar days or less from the day that the FOOD is prepared, if the FOOD is maintained at 5°C (41°F) or less; or

(2) 4 calendar days or less from the day the FOOD is prepared, if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C).

(B) Except as specified in ¶ (E) of this section, a READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared in a FOOD ESTABLISHMENT and subsequently frozen, shall be clearly marked:

• prepare, freeze, thaw, immediate use

(1) When the FOOD is thawed, to indicate that the FOOD shall be consumed within 24 hours; or

• prepare, hold cold, freeze, thaw, hold cold

(2) When the FOOD is placed into the freezer, to indicate the length of time before freezing that the FOOD is held refrigerated and which is, including the day of preparation:

(a) 7 calendar days or less from the day of preparation, if the FOOD is maintained at 5°C (41°F) or less, or

(b) 4 calendar days or less from the day of preparation, if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C); and

(3) When the FOOD is removed from the freezer, to indicate the date by which the FOOD shall be consumed which is:

(a) 7 calendar days or less after the FOOD is removed from the freezer, minus the time before freezing, that the FOOD is

held refrigerated if the FOOD is maintained at 5°C (41°F) or less before and after freezing, or

(b) 4 calendar days or less after the FOOD is removed from the freezer, minus the time before freezing, that the FOOD is held refrigerated if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C) before and after freezing.

commercially processed food
• open and hold cold

(C) Except as specified in ¶¶ (E) and (F) of this section, a container of refrigerated, READY-TO-EAT POTENTIALLY HAZARDOUS FOOD prepared and PACKAGED by a FOOD PROCESSING PLANT shall be clearly marked, at the time the original container is opened in a FOOD ESTABLISHMENT, to indicate the date by which the FOOD shall be consumed which is, including the day the original container is opened:

(1) 7 calendar days or less after the original container is opened, if the FOOD is maintained at 5°C (41°F) or less; or

(2) 4 calendar days or less from the day the original container is opened, if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C).

(D) Except as specified in ¶¶ (E) and (F) of this section, a container of refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared and PACKAGED by a FOOD PROCESSING PLANT and subsequently opened and frozen in a FOOD ESTABLISHMENT shall be clearly marked:

• open, freeze, thaw, immediate use

(1) When the FOOD is thawed, to indicate that the FOOD shall be consumed within 24 hours; or

• open, hold cold, freeze, thaw, hold cold

(2) To indicate the time between the opening of the original container and freezing that the FOOD is held refrigerated and which is, including the day of opening the original container:

(a) 7 calendar days or less, after opening the original container if the FOOD is maintained at 5°C (41°F) or less, or

(b) 4 calendar days or less after opening the original container if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C); and

(3) When the FOOD is removed from the freezer, to indicate the date by which the FOOD shall be consumed which is:

(a) 7 calendar days, minus the time before freezing, that the FOOD is held refrigerated if the FOOD is maintained at 5°C (41°F) or less before and after freezing, or

(b) 4 calendar days, minus the time before freezing, that the FOOD is held refrigerated if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C) before and after freezing.

(E) *Paragraphs (A)-(D) of this section do not apply to individual meal portions served or rePACKAGED for sale from a bulk container upon a CONSUMER'S request.*

(F) *Paragraphs (C) and (D) of this section do not apply to whole, unsliced portions of a cured and processed product with original casing maintained on the remaining portion, such as bologna, salami, or other sausage in a cellulose casing.*

3-501.18 Ready-to-Eat, Potentially Hazardous Food, Disposition.*

(A) A FOOD specified under ¶ 3-501.17(A) shall be discarded if not consumed within:

(1) 7 calendar days from the date of preparation if the FOOD is maintained at 5°C (41°F) or less; or

(2) 4 calendar days from the date of preparation if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C).

(B) A FOOD specified under Subparagraph 3-501.17(B)(1) or (D)(1) shall be discarded if not consumed within 24 hours after thawing.

(C) A FOOD specified under Subparagraphs 3-501.17(B)(2) and (3) or (D)(2) and (3) shall be discarded on or before the most recent date marked on the FOOD container or PACKAGE if the FOOD is not consumed by that date.

(D) A FOOD specified under ¶ 3-501.17(C) shall be discarded if not consumed within, including the day of opening the original container:

(1) 7 calendar days after the date that the original PACKAGE is opened in a FOOD ESTABLISHMENT if the FOOD is maintained at 5°C (41°F) or less; or

(2) 4 calendar days after the date that the original PACKAGE is opened in a FOOD ESTABLISHMENT if the FOOD is maintained at 7°C (45°F) or less as specified under ¶ 3-501.16(C).

(E) A FOOD specified under ¶ 3-501.17(A), (B), (C), or (D) shall be discarded if the FOOD is:

(1) Marked with the date specified under ¶ 3-501.17(A), (B), (C), or (D) and the FOOD is not consumed before the most recent date expires;

(2) In a container or PACKAGE which does not bear a date or time; or

(3) Inappropriately marked with a date or time that exceeds the date or time specified under ¶ 3-501.17(A), (B), (C), or (D).

(F) Refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared in a FOOD ESTABLISHMENT and dispensed through a VENDING MACHINE with an automatic shut-off control that is activated at a temperature of:

(1) 5°C (41°F) shall be discarded if not sold within 7 days; or

(2) 7°C (45°F) shall be discarded if not sold within 4 days.

(G) A refrigerated, potentially hazardous, READY-TO-EAT FOOD ingredient or a portion of a refrigerated, potentially hazardous, READY-TO-EAT FOOD that is subsequently combined with additional ingredients or portions of FOOD shall retain the date marking of the earliest or first-prepared ingredient or portion and shall be discarded as specified under ¶¶ 3-501.18(A) - (F).

3-501.19 Time as a Public Health Control.*

(A) Except as specified under ¶ (B) of this section, if time only, rather than time in conjunction with temperature, is used as the public health control for a working supply of POTENTIALLY HAZARDOUS FOOD before cooking, or for READY-TO-EAT POTENTIALLY HAZARDOUS FOOD that is displayed or held for service for immediate consumption:

(1) The FOOD shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the FOOD is removed from temperature control,

(2) The FOOD shall be cooked and served, served if READY-TO-EAT, or discarded, within 4 hours from the point in time when the FOOD is removed from temperature control,

(3) The FOOD in unmarked containers or packages or marked to exceed a 4 hour limit shall be discarded, and

(4) Written procedures shall be maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request, that ensure compliance with:

(a) Subparagraphs (A)(1)-(4) of this section, and

(b) § 3-501.14 for FOOD that is prepared, cooked, and refrigerated before time is used as a public health control.

(B) In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION, time only, rather than time in conjunction with temperature, may not be used as the public health control for raw eggs.

Specialized Processing Methods

3-502.11 Variance Requirement.*

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement; curing FOOD; brewing alcoholic BEVERAGES; using FOOD ADDITIVES or adding components such as vinegar as a method of FOOD preservation rather than as a method of flavor enhancement or to render a FOOD so that it is not POTENTIALLY HAZARDOUS; packaging FOOD using a REDUCED OXYGEN PACKAGING method *except as specified under § 3-502.12 where a barrier to* ***Clostridium botulinum*** *in addition to refrigeration exists*; custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT; or preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE.

3-502.12 Reduced Oxygen Packaging, Criteria.*

Clostridium botulinum Controls

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that packages FOOD using a REDUCED OXYGEN PACKAGING method and ***Clostridium botulinum*** is identified as a microbiological HAZARD in the final

PACKAGED form shall ensure that there are at least two barriers in place to control the growth and toxin formation of ***C. botulinum***.

(B) A FOOD ESTABLISHMENT that packages FOOD using a REDUCED OXYGEN PACKAGING method and ***Clostridium botulinum*** is identified as a microbiological HAZARD in the final PACKAGED form shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that:

(1) Identifies the FOOD to be PACKAGED;

(2) Limits the FOOD PACKAGED to a FOOD that does not support the growth of ***Clostridium botulinum*** because it complies with one of the following:

(a) Has an a_w of 0.91 or less,

(b) Has a pH of 4.6 or less,

(c) Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the U.S.D.A. using substances specified in 9 CFR 318.7 Approval of substances for use in the preparation of products and 9 CFR 381.147 Restrictions on the use of substances in poultry products and is received in an intact package, or

(d) Is a FOOD with a high level of competing organisms such as raw MEAT or raw POULTRY;

(3) Specifies methods for maintaining FOOD at 5°C (41°F) or below;

(4) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:

(a) Maintain the FOOD at 5°C (41°F) or below, and

(b) Discard the FOOD if within 14 calendar days of its packaging it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption;

(5) Limits the shelf life to no more than 14 calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

(6) Includes operational procedures that:

(a) Prohibit contacting FOOD with bare hands,

(b) Identify a designated area and the method by which:

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, and

(ii) Access to the processing EQUIPMENT is restricted to responsible trained personnel familiar with the potential HAZARDS of the operation, and

(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; and

(7) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the:

(a) Concepts required for a safe operation,

(b) EQUIPMENT and facilities, and

(c) Procedures specified under Subparagraph (B)(6) of this section and ¶ 8-201.14(D).

(C) *Except for FISH that is frozen before, during, and after packaging*, a FOOD ESTABLISHMENT may not package FISH using a REDUCED OXYGEN PACKAGING method.

3-6 FOOD IDENTITY, PRESENTATION, AND ON-PREMISES LABELING

Subparts

Accurate Representation

3-601.11 Standards of Identity.

PACKAGED FOOD shall comply with standard of identity requirements in 21 CFR 131-169 and 9 CFR 319 Definitions and Standards of Identity or Composition, and the general requirements in 21 CFR 130 - Food Standards: General and 9 CFR 319 Subpart A - General.

3-601.12 Honestly Presented.

(A) FOOD shall be offered for human consumption in a way that does not mislead or misinform the CONSUMER.

(B) FOOD or COLOR ADDITIVES, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a FOOD.

Labeling

3-602.11 Food Labels.

(A) FOOD PACKAGED in a FOOD ESTABLISHMENT, shall be labeled as specified in LAW, including 21 CFR 101 - Food Labeling, and 9 CFR 317 Labeling, Marking Devices, and Containers.

(B) Label information shall include:

(1) The common name of the FOOD, or absent a common name, an adequately descriptive identity statement;

(2) If made from two or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the FOOD;

(3) An accurate declaration of the quantity of contents;

(4) The name and place of business of the manufacturer, packer, or distributor; and

(5) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(Q)(3)-(5), nutrition labeling as specified in 21 CFR 101 - FOOD Labeling and 9 CFR 317 Subpart B Nutrition Labeling.

(C) Bulk FOOD that is available for CONSUMER self-dispensing shall be prominently labeled with the following information in plain view of the CONSUMER:

(1) The manufacturer's or processor's label that was provided with the FOOD; or

(2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), and (5) of this section.

(D) *Bulk, unPACKAGED FOODS such as bakery products and unPACKAGED FOODS that are portioned to CONSUMER specification need not be labeled if:*

(1) *A health, nutrient content, or other claim is not made;*

(2) *There are no state or local LAWS requiring labeling; and*

(3) *The FOOD is manufactured or prepared on the PREMISES of the FOOD ESTABLISHMENT or at another FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT that is owned by the same PERSON and is regulated by the FOOD regulatory agency that has jurisdiction.*

3-602.12 Other Forms of Information.

(A) If required by LAW, CONSUMER warnings shall be provided.

(B) FOOD ESTABLISHMENT or manufacturers' dating information on FOODS may not be concealed or altered.

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Current Status of Consumer Advisory Language
Regarding § 3-603.11

The following information is not part of Chapter 3 and is not intended to be included in the codified portion of the Food Code. It is inserted here to provide a summary of recent events surrounding the matter of a consumer advisory, addressed in § 3-603.11 of the Code. In cases where the Food Code is adopted through incorporation by reference, this page may be removed.

A consensus as to what constitutes satisfactory compliance with § 3-603.11 was reached at the 1998 Conference for Food Protection (CFP) meeting. A third option for the consumer "reminder" was added later. This insert page is to alert the reader to the options available to food establishments in advising consumers of the increased possibility of foodborne illness when animal-derived foods are eaten raw or undercooked.

Included in Annex 3 is a full discussion of the evolution of the 1998 CFP consensus, satisfactory compliance, applicability of the Code provision, and the meaning and application of the phrase that appears in § 3-603.11, i.e., "or otherwise processed to eliminate pathogens."

There are two components to satisfactory compliance: Disclosure and Reminder.

Disclosure is satisfied when:

(1) Items are described, such as:
  (a) Oysters on the half-shell (raw oysters),
  (b) Raw-egg Caesar salad, and
  (c) Hamburgers (can be cooked to order); or

(2) Items are asterisked to a footnote that states that the items:
  (a) Are served raw or undercooked, or
  (b) Contain (or may contain) raw or undercooked ingredients.

Reminder is satisfied when the items requiring disclosure are asterisked to a footnote that states:

(1) Regarding the safety of these items, written information is available upon request;[1]

(2) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness; or

(3) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.

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[1]Essential criteria for such written information are being developed and will be made available, with a downloadable model brochure, on the CFSAN Web Page at http://www.cfsan.fda.gov. All brochures must meet these essential criteria.

Consumer Advisory

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.*

Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(3) and under ¶ 3-801.11(D), if an animal FOOD such as beef, eggs, FISH, lamb, milk, pork, POULTRY, or shellfish that is raw, undercooked, or not otherwise processed to eliminate pathogens is offered in a READY-TO-EAT form as a deli, menu, vended, or other item; or as a raw ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS by brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means of the significantly increased risk associated with certain especially vulnerable CONSUMERS eating such FOODS in raw or undercooked form.

3-7 CONTAMINATED FOOD

Subpart

3-701 Disposition

Disposition

3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.*

(A) A FOOD that is unsafe, ADULTERATED, or not honestly presented as specified under § 3-101.11 shall be reconditioned according to an APPROVED procedure or discarded.

(B) FOOD that is not from an APPROVED source as specified under §§ 3-201.11 through .17 shall be discarded.

(C) READY-TO-EAT FOOD that may have been contaminated by an EMPLOYEE who has been restricted or excluded as specified under § 2-201.12 shall be discarded.

(D) FOOD that is contaminated by FOOD EMPLOYEES, CONSUMERS, or other PERSONS through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded.

3-8 SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS

Subpart

3-801 Additional Safeguards

Additional Safeguards

3-801.11 Pasteurized Foods, Prohibited Reservice, and Prohibited Food.*

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

(A) PrePACKAGED JUICE or a prePACKAGED beverage containing JUICE, that bears a warning label as specified in 21 CFR, Section 101.17(g) Food Labeling, may not be served or offered for sale;

(B) Pasteurized shell eggs or pasteurized liquid, frozen, or dry eggs or egg products shall be substituted for raw shell eggs in the preparation of:

(1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, egg nog, ice cream, and egg-fortified BEVERAGES, and

(2) Except as specified in ¶ (E) of this section, recipes in which more than one egg is broken and the eggs are combined;

(C) FOOD in an unopened original package may not be re-served; and

(D) The following FOODS may not be served or offered for sale in a READY-TO-EAT form:

(1) Raw animal FOODS such as raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH, and steak tartare,

(2) A partially cooked animal FOOD such as lightly cooked FISH, rare MEAT, soft-cooked eggs that are made from raw shell eggs, and meringue, and

(3) Raw seed sprouts.

(E) *Subparagraph (B)(2) of this section does not apply if:*

(1) *The raw eggs are combined immediately before cooking for one* CONSUMER'S *serving at a single meal, cooked as specified under Subparagraph 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled eggs;*

(2) *The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a* READY-TO-EAT *form, such as a cake, muffin, or bread; or*

(3) The preparation of the food is conducted under a HACCP PLAN *that:*

(a) Identifies the FOOD *to be prepared,*

(b) Prohibits contacting READY-TO-EAT FOOD *with bare hands,*

(c) Includes specifications and practices that ensure:

(i) ***Salmonella*** **Enteritidis** *growth is controlled before and after cooking, and*

(ii) ***Salmonella*** **Enteritidis** *is destroyed by cooking the eggs according to the temperature and time specified in Subparagraph 3-401.11(A)(2),*

(d) Contains the information specified under ¶ 8-201.14(D) including procedures that:

(i) Control cross contamination of READY-TO-EAT FOOD *with raw eggs, and*

(ii) Delineate cleaning and SANITIZATION *procedures for* FOOD-CONTACT SURFACES, and

(e) Describes the training program that ensures that the FOOD EMPLOYEE *responsible for the preparation of the* FOOD *understands the*

procedures to be used.

Chapter

4 Equipment, Utensils, and Linens

Parts

4-1 MATERIALS FOR CONSTRUCTION AND REPAIR

Subparts

Multiuse

4-101.11 Characteristics.*

Materials that are used in the construction of UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT may not allow the migration of deleterious substances or impart colors, odors, or tastes to FOOD and under normal use conditions shall be:

(A) Safe;

(B) Durable, CORROSION-RESISTANT, and nonabsorbent;[N]

(C) Sufficient in weight and thickness to withstand repeated WAREWASHING;[N]

(D) Finished to have a SMOOTH, EASILY CLEANABLE surface;[N] and

(E) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.[N]

4-101.12 Cast Iron, Use Limitation.

(A) Except as specified in ¶¶ (B) and (C) of this section, cast iron may not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT.

(B) *Cast iron may be used as a surface for cooking.*

(C) *Cast iron may be used in UTENSILS for serving FOOD if the UTENSILS are used only as part of an uninterrupted process from cooking through service.*

4-101.13 Lead in Ceramic, China, and Crystal Utensils, Use Limitation.

Ceramic, china, crystal UTENSILS, and decorative UTENSILS such as hand painted ceramic or china that are used in contact with FOOD shall be lead-free or contain levels of lead not exceeding the limits of the following UTENSIL categories:

Utensil Category	Description	Maximum Lead mg/L
Hot Beverage Mugs	Coffee Mugs	0.5
Large Hollowware	Bowls ≥ 1.1 L (1.16 QT)	1
Small Hollowware	Bowls < 1.1 L (1.16 QT)	2.0
Flat Utensils	Plates, Saucers	3.0

4-101.14 Copper, Use Limitation.*

(A) Except as specified in ¶ (B) of this section, copper and copper alloys such as brass may not be used in contact with a FOOD that has a pH below 6 such as vinegar, fruit JUICE, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator.

(B) *Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.*

4-101.15 Galvanized Metal, Use Limitation.*

Galvanized metal may not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT that are used in contact with acidic FOOD.

4-101.16 Sponges, Use Limitation.

Sponges may not be used in contact with cleaned and SANITIZED or in-use FOOD-CONTACT SURFACES.

4-101.17 Lead in Pewter Alloys, Use Limitation.

Pewter alloys containing lead in excess of 0.05% may not be used as a FOOD-CONTACT SURFACE.

4-101.18 Lead in Solder and Flux, Use Limitation.

Solder and flux containing lead in excess of 0.2% may not be used as a FOOD-CONTACT SURFACE.

4-101.19 Wood, Use Limitation.

(A) Except as specified in ¶¶ (B), (C), and (D) of this section, wood and wood wicker may not be used as a FOOD-CONTACT SURFACE.

(B) *Hard maple or an equivalently hard, close-grained wood may be used for:*

(1) *Cutting boards; cutting blocks; bakers' tables; and* UTENSILS *such as rolling pins, doughnut dowels, salad bowls, and chopsticks; and*

(2) *Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110°C (230°F) or above.*

(C) *Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping containers in which they were received, until the fruits, vegetables, or nuts are used.*

(D) *If the nature of the* FOOD *requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw* FOOD *may be kept in:*

(1) *Untreated wood containers; or*

(2) *Treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800 Preservatives for wood.*

4-101.110 Nonstick Coatings, Use Limitation.

Multiuse KITCHENWARE such as frying pans, griddles, sauce pans, cookie sheets, and waffle bakers that have a perfluorocarbon resin coating shall be used with nonscoring or nonscratching UTENSILS and cleaning aids.

4-101.111 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES of EQUIPMENT that are exposed to splash, spillage, or other FOOD soiling or that require frequent cleaning shall be constructed of a CORROSION-RESISTANT, nonabsorbent, and SMOOTH material.

Single-Service and Single-Use

4-102.11 Characteristics.*

Materials that are used to make SINGLE-SERVICE and SINGLE-USE ARTICLES:

(A) May not:

(1) Allow the migration of deleterious substances, or

(2) Impart colors, odors, or tastes to FOOD;[N] and

(B) Shall be:

(1) Safe, and

(2) Clean.[N]

4-2 DESIGN AND CONSTRUCTION

Subparts

Durability and Strength

4-201.11 Equipment and Utensils.

EQUIPMENT and UTENSILS shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

4-201.12 Food Temperature Measuring Devices.*

FOOD TEMPERATURE MEASURING DEVICES may not have sensors or stems constructed of glass, *except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used*.

Cleanability

4-202.11 Food-Contact Surfaces.*

(A) Multiuse FOOD-CONTACT SURFACES shall be:

(1) SMOOTH;

(2) Free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections;

(3) Free of sharp internal angles, corners, and crevices;

(4) Finished to have SMOOTH welds and joints; and

(5) Except as specified in ¶ (B) of this section, accessible for cleaning and inspection by one of the following methods:

(a) Without being disassembled,

(b) By disassembling without the use of tools, or

(c) By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.

(B) *Subparagraph (A)(5) of this section does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes*.

4-202.12 CIP Equipment.

(A) CIP EQUIPMENT shall meet the characteristics specified under § 4-202.11 and shall be designed and constructed so that:

(1) Cleaning and SANITIZING solutions circulate throughout a fixed system and contact all interior FOOD-CONTACT SURFACES, and

(2) The system is self-draining or capable of being completely drained of cleaning and SANITIZING solutions; and

(B) CIP EQUIPMENT that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior FOOD-CONTACT SURFACES throughout the fixed system are being effectively cleaned.

4-202.13 "V" Threads, Use Limitation.

Except for hot oil cooking or filtering EQUIPMENT, "V" type threads may not be used on FOOD-CONTACT SURFACES.

4-202.14 Hot Oil Filtering Equipment.

Hot oil filtering EQUIPMENT shall meet the characteristics specified under § 4-202.11 or § 4-202.12 and shall be readily accessible for filter replacement and cleaning of the filter.

4-202.15 Can Openers.

Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement.

4-202.16 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES shall be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance.

4-202.17 Kick Plates, Removable.

Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being:

(A) Removable by one of the methods specified under Subparagraph 4-202.11(A)(5) or capable of being rotated open; and

(B) Removable or capable of being rotated open without unlocking EQUIPMENT doors.

4-202.18 Ventilation Hood Systems, Filters.

Filters or other grease extracting EQUIPMENT shall be designed to be readily removable for cleaning and replacement if not designed to be cleaned in place.

Accuracy

4-203.11 Temperature Measuring Devices, Food.

(A) FOOD TEMPERATURE MEASURING DEVICES that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to ±1°C in the intended range of use.

(B) FOOD TEMPERATURE MEASURING DEVICES that are scaled only in Fahrenheit shall be accurate to ±2°F in the intended range of use.

4-203.12 Temperature Measuring Devices, Ambient Air and Water.

(A) Ambient air and water TEMPERATURE MEASURING DEVICES that are scaled in Celsius or dually scaled in Celsius and Fahrenheit shall be designed to be easily readable and accurate to ±1.5°C in the intended range of use.

(B) Ambient air and water TEMPERATURE MEASURING DEVICES that are scaled only in Fahrenheit shall be accurate to ±3°F in the intended range of use.

4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment.

Pressure measuring devices that display the pressures in the water supply line for the fresh hot water SANITIZING rinse shall have increments of 7 kilopascals (1 pounds per square inch) or smaller and shall be accurate to ± 14 kilopascals (± 2 pounds per square inch) in the 100-170 kilopascals (15-25 pounds per square inch) range.

Functionality

4-204.11 Ventilation Hood Systems, Drip Prevention.

Exhaust ventilation hood systems in FOOD preparation and WAREWASHING areas including components such as hoods, fans, guards, and ducting shall be designed to prevent grease or condensation from draining or dripping onto FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

4-204.12 Equipment Openings, Closures and Deflectors.

(A) A cover or lid for EQUIPMENT shall overlap the opening and be sloped to drain.

(B) An opening located within the top of a unit of EQUIPMENT that is designed for use with a cover or lid shall be flanged upward at least 5 millimeters (two-tenths of an inch).

(C) Except as specified under ¶ (D) of this section, fixed piping, TEMPERATURE MEASURING DEVICES, rotary shafts, and other parts extending into EQUIPMENT shall be provided with a watertight joint at the point where the item enters the EQUIPMENT.

(D) If a watertight joint is not provided:

(1) The piping, TEMPERATURE MEASURING DEVICES, rotary shafts, and other parts extending through the openings shall be equipped with an apron designed to deflect condensation, drips, and dust from openings into the FOOD; and

(2) The opening shall be flanged as specified under ¶ (B) of this section.

4-204.13 Dispensing Equipment, Protection of Equipment and Food.

In EQUIPMENT that dispenses or vends liquid FOOD or ice in unPACKAGED form:

(A) The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the FOOD shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the FOOD;

(B) The delivery tube, chute, and orifice shall be protected from manual contact such as by being recessed;

(C) The delivery tube or chute and orifice of EQUIPMENT used to vend liquid FOOD or ice in unPACKAGED form to self-service CONSUMERS shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self-closing door if the EQUIPMENT is:

(1) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment, or

(2) Available for self-service during hours when it is not under the full-time supervision of a FOOD EMPLOYEE; and

(D) The dispensing EQUIPMENT actuating lever or mechanism and filling device of CONSUMER self-service BEVERAGE dispensing

EQUIPMENT shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

4-204.14 Vending Machine, Vending Stage Closure.

The dispensing compartment of a VENDING MACHINE including a machine that is designed to vend prePACKAGED snack FOOD that is not POTENTIALLY HAZARDOUS such as chips, party mixes, and pretzels shall be equipped with a self-closing door or cover if the machine is:

(A) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

(B) Available for self-service during hours when it is not under the full-time supervision of a FOOD EMPLOYEE.

4-204.15 Bearings and Gear Boxes, Leakproof.

EQUIPMENT containing bearings and gears that require lubricants shall be designed and constructed so that the lubricant can not leak, drip, or be forced into FOOD or onto FOOD-CONTACT SURFACES.

4-204.16 Beverage Tubing, Separation.

BEVERAGE tubing and cold-plate BEVERAGE cooling devices may not be installed in contact with stored ice. *This section does not apply to cold plates that are constructed integrally with an ice storage bin*.

4-204.17 Ice Units, Separation of Drains.

Liquid waste drain lines may not pass through an ice machine or ice storage bin.

4-204.18 Condenser Unit, Separation.

If a condenser unit is an integral component of EQUIPMENT, the condenser unit shall be separated from the FOOD and FOOD storage space by a dustproof barrier.

4-204.19 Can Openers on Vending Machines.

Cutting or piercing parts of can openers on VENDING MACHINES shall be protected from manual contact, dust, insects, rodents, and other contamination.

4-204.110 Molluscan Shellfish Tanks.

(A) Except as specified under ¶ (B) of this section, MOLLUSCAN SHELLFISH life support system display tanks may not be used to display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the CONSUMER that the shellfish are for display only.

(B) MOLLUSCAN SHELLFISH life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with a VARIANCE granted by the REGULATORY AUTHORITY as specified in § 8-103.10 and a HACCP PLAN that:

(1) Is submitted by the PERMIT HOLDER and APPROVED as specified under § 8-103.11; and

(2) Ensures that:

(a) Water used with FISH other than MOLLUSCAN SHELLFISH does not flow into the molluscan tank,

(b) The safety and quality of the shellfish as they were received are not compromised by the use of the tank, and

(c) The identity of the source of the SHELLSTOCK is retained as specified under § 3-203.12.

4-204.111 Vending Machines, Automatic Shutoff.*

(A) A machine vending POTENTIALLY HAZARDOUS FOOD shall have an automatic control that prevents the machine from vending FOOD:

(1) If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that can not maintain FOOD temperatures as specified under Chapter 3; and

(2) If a condition specified under Subparagraph (A)(1) of this section occurs, until the machine is serviced and restocked with FOOD that has been maintained at temperatures specified under Chapter 3.

(B) When the automatic shutoff within a machine vending POTENTIALLY HAZARDOUS FOOD is activated:

(1) In a refrigerated VENDING MACHINE, the ambient temperature may not exceed 5°C (41°F) or 7°C (45°F) as specified under ¶ 3-501.16(C) for more than 30 minutes immediately after the machine is filled, serviced, or restocked; or

(2) In a hot holding VENDING MACHINE, the ambient temperature may not be less than 60°C (140°F) for more than 120 minutes immediately after the machine is filled, serviced, or restocked.

4-204.112 Temperature Measuring Devices.

(A) In a mechanically refrigerated or hot FOOD storage unit, the sensor of a TEMPERATURE MEASURING DEVICE shall be located to measure the air temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot FOOD storage unit.

(B) Except as specified in ¶ (C) of this section, cold or hot holding EQUIPMENT used for POTENTIALLY HAZARDOUS FOOD shall be designed to include and shall be equipped with at least one integral or permanently affixed TEMPERATURE MEASURING DEVICE that is located to allow easy viewing of the device's temperature display.

(C) *Paragraph (B) of this section does not apply to EQUIPMENT for which the placement of a TEMPERATURE MEASURING DEVICE is not a practical means for measuring the ambient air surrounding the FOOD because of the design, type, and use of the EQUIPMENT, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated FOOD transport containers, and salad bars*.

(D) TEMPERATURE MEASURING DEVICES shall be designed to be easily readable.

(E) FOOD TEMPERATURE MEASURING DEVICES and water TEMPERATURE MEASURING DEVICES on WAREWASHING machines shall have a numerical scale, printed record, or digital readout in increments no greater than 1°C or 2°F in the intended range of use.

4-204.113 Warewashing Machine, Data Plate Operating Specifications.

A WAREWASHING machine shall be provided with an easily accessible and readable data plate affixed to the machine by the manufacturer that indicates the machine's design and operating specifications including the:

(A) Temperatures required for washing, rinsing, and SANITIZING;

(B) Pressure required for the fresh water SANITIZING rinse *unless the machine is designed to use only a pumped SANITIZING rinse;* and

(C) Conveyor speed for conveyor machines or cycle time for stationary rack machines.

4-204.114 Warewashing Machines, Internal Baffles.

WAREWASHING machine wash and rinse tanks shall be equipped with baffles, curtains, or other means to minimize internal cross contamination of the solutions in wash and rinse tanks.

4-204.115 Warewashing Machines, Temperature Measuring Devices.

A WAREWASHING machine shall be equipped with a TEMPERATURE MEASURING DEVICE that indicates the temperature of the water:

(A) In each wash and rinse tank; and

(B) As the water enters the hot water SANITIZING final rinse manifold or in the chemical SANITIZING solution tank.

4-204.116 Manual Warewashing Equipment, Heaters and Baskets.

If hot water is used for SANITIZATION in manual WAREWASHING operations, the SANITIZING compartment of the sink shall be:

(A) Designed with an integral heating device that is capable of maintaining water at a temperature not less than 77°C (171°F); and

(B) Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.

4-204.117 Warewashing Machines, Sanitizer Level Indicator.

A WAREWASHING machine that uses a chemical for SANITIZATION and that is installed after adoption of this Code by the REGULATORY AUTHORITY, shall be equipped with a device that indicates audibly or visually when more chemical SANITIZER needs to be added.

4-204.118 Warewashing Machines, Flow Pressure Device.

(A) WAREWASHING machines that provide a fresh hot water SANITIZING rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the WAREWASHING machine; and

(B) If the flow pressure measuring device is upstream of the fresh hot water SANITIZING rinse control valve, the device shall be mounted in a 6.4 millimeter or one-fourth inch Iron Pipe Size (IPS) valve.

(C) *Paragraphs (A) and (B) of this section do not apply to a machine that uses only a pumped or recirculated SANITIZING rinse.*

4-204.119 Warewashing Sinks and Drainboards, Self-Draining.

Sinks and drainboards of WAREWASHING sinks and machines shall be self-draining.

4-204.120 Equipment Compartments, Drainage.

EQUIPMENT compartments that are subject to accumulation of moisture due to conditions such as condensation, FOOD or BEVERAGE drip, or water from melting ice shall be sloped to an outlet that allows complete draining.

4-204.121 Vending Machines, Liquid Waste Products.

(A) VENDING MACHINES designed to store BEVERAGES that are PACKAGED in containers made from paper products shall be equipped with diversion devices and retention pans or drains for container leakage.

(B) VENDING MACHINES that dispense liquid FOOD in bulk shall be:

(1) Provided with an internally mounted waste receptacle for the collection of drip, spillage, overflow, or other internal wastes; and

(2) Equipped with an automatic shutoff device that will place the machine out of operation before the waste receptacle overflows.

(C) Shutoff devices specified under Subparagraph (B)(2) of this section shall prevent water or liquid FOOD from continuously running if there is a failure of a flow control device in the water or liquid FOOD system or waste accumulation that could lead to overflow of the waste receptacle.

4-204.122 Case Lot Handling Equipment, Moveability.

EQUIPMENT, such as dollies, pallets, racks, and skids used to store and transport large quantities of PACKAGED FOODS received from a supplier in a cased or overwrapped lot, shall be designed to be moved by hand or by conveniently available EQUIPMENT such as hand trucks and forklifts.

4-204.123 Vending Machine Doors and Openings.

(A) VENDING MACHINE doors and access opening covers to FOOD and container storage spaces shall be tight-fitting so that the space

along the entire interface between the doors or covers and the cabinet of the machine, if the doors or covers are in a closed position, is no greater than 1.5 millimeters or one-sixteenth inch by:

(1) Being covered with louvers, screens, or materials that provide an equivalent opening of not greater than 1.5 millimeters or one-sixteenth inch. Screening of 12 or more mesh to 2.5 centimeters (12 mesh to 1 inch) meets this requirement;

(2) Being effectively gasketed;

(3) Having interface surfaces that are at least 13 millimeters or one-half inch wide; or

(4) Jambs or surfaces used to form an L-shaped entry path to the interface.

(B) VENDING MACHINE service connection openings through an exterior wall of a machine shall be closed by sealants, clamps, or grommets so that the openings are no larger than 1.5 millimeters or one-sixteenth inch.

Acceptability

4-205.10 Food Equipment, Certification and Classification.

FOOD EQUIPMENT that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program will be deemed to comply with Parts 4-1 and 4-2 of this chapter.

4-3 NUMBERS AND CAPACITIES

Subparts

4-301 Equipment
4-302 Utensils, Temperature Measuring Devices, and Testing Devices

Equipment

4-301.11 Cooling, Heating, and Holding Capacities.

EQUIPMENT for cooling and heating FOOD, and holding cold and hot FOOD, shall be sufficient in number and capacity to provide FOOD temperatures as specified under Chapter 3.

4-301.12 Manual Warewashing, Sink Compartment Requirements.

(A) Except as specified in ¶ (C) of this section, a sink with at least 3 compartments shall be provided for manually washing, rinsing, and SANITIZING EQUIPMENT and UTENSILS.

(B) Sink compartments shall be large enough to accommodate immersion of the largest EQUIPMENT and UTENSILS. If EQUIPMENT or UTENSILS are too large for the WAREWASHING sink, a WAREWASHING machine or alternative EQUIPMENT as specified in ¶ (C) of this section shall be used.

(C) *Alternative manual WAREWASHING EQUIPMENT may be used when there are special cleaning needs or constraints and its use is APPROVED. Alternative manual WAREWASHING EQUIPMENT may include:*

(1) *High-pressure detergent sprayers;*

(2) *Low- or line-pressure spray detergent foamers;*

(3) *Other task-specific cleaning EQUIPMENT;*

(4) *Brushes or other implements;*

(5) *2-compartment sinks as specified under ¶¶ (D) and (E) of this section; or*

(6) *Receptacles that substitute for the compartments of a multicompartment sink.*

(D) Before a 2-compartment sink is used:

(1) The PERMIT HOLDER shall have its use APPROVED; and

(2) The nature of WAREWASHING shall be limited to batch operations for cleaning KITCHENWARE such as between cutting one type of raw MEAT and another or cleanup at the end of a shift, and:

(a) The number of items to be cleaned shall be limited,

(b) The cleaning and SANITIZING solutions shall be made up immediately before use and drained immediately after use, and

(c) A detergent-SANITIZER shall be used to SANITIZE and shall be applied as specified under § 4-501.115, or

(d) A hot water SANITIZATION immersion step shall be used as specified under ¶ 4-603.16(C).

(E) A 2-compartment sink may not be used for WAREWASHING operations where cleaning and SANITIZING solutions are used for a continuous or intermittent flow of KITCHENWARE or TABLEWARE in an ongoing WAREWASHING process.

4-301.13 Drainboards.

Drainboards, UTENSIL racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation shall be provided for necessary UTENSIL holding before cleaning and after SANITIZING.

4-301.14 Ventilation Hood Systems, Adequacy.

Ventilation hood systems and devices shall be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceilings.

4-301.15 Clothes Washers and Dryers.

(A) Except as specified in ¶ (B) of this section, if work clothes or LINENS are laundered on the PREMISES, a mechanical clothes washer and dryer shall be provided and used.

(B) *If on-PREMISES laundering is limited to wiping cloths intended to be used moist, or wiping cloths are air-dried as specified under § 4-901.12, a mechanical clothes washer and dryer need not be provided.*

Utensils, Temperature Measuring Devices, and Testing Devices

4-302.11 Utensils, Consumer Self-Service.

A FOOD dispensing UTENSIL shall be available for each container displayed at a CONSUMER self-service unit such as a buffet or salad bar.

4-302.12 Food Temperature Measuring Devices.

FOOD TEMPERATURE MEASURING DEVICES shall be provided and readily accessible for use in ensuring attainment and maintenance of FOOD temperatures as specified under Chapter 3.

4-302.13 Temperature Measuring Devices, Manual Warewashing.

In manual WAREWASHING operations, a TEMPERATURE MEASURING DEVICE shall be provided and readily accessible for frequently measuring the washing and SANITIZING temperatures.

4-302.14 Sanitizing Solutions, Testing Devices.

A test kit or other device that accurately measures the concentration in mg/L of SANITIZING solutions shall be provided.

4-4 LOCATION AND INSTALLATION

Subparts

4-401 Location
4-402 Installation

Location

4-401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.

(A) Except as specified in ¶ (B) of this section, EQUIPMENT, a cabinet used for the storage of FOOD, or a cabinet that is used to store cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be located:

(1) In locker rooms;

(2) In toilet rooms;

(3) In garbage rooms;

(4) In mechanical rooms;

(5) Under sewer lines that are not shielded to intercept potential drips;

(6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(7) Under open stairwells; or

(8) Under other sources of contamination.

(B) *A storage cabinet used for LINENS or SINGLE-SERVICE or SINGLE-USE ARTICLES may be stored in a locker room.*

(C) If a mechanical clothes washer or dryer is provided, it shall be located so that the washer or dryer is protected from contamination and only where there is no exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

Installation

4-402.11 Fixed Equipment, Spacing or Sealing.

(A) EQUIPMENT that is fixed because it is not EASILY MOVABLE shall be installed so that it is:

(1) Spaced to allow access for cleaning along the sides, behind, and above the EQUIPMENT;

(2) Spaced from adjoining EQUIPMENT, walls, and ceilings a distance of not more than 1 millimeter or one thirty-second inch; or

(3) SEALED to adjoining EQUIPMENT or walls, if the EQUIPMENT is exposed to spillage or seepage.

(B) TABLE-MOUNTED EQUIPMENT that is not EASILY MOVABLE shall be installed to allow cleaning of the EQUIPMENT and areas underneath and around the EQUIPMENT by being:

(1) SEALED to the table; or

(2) Elevated on legs as specified under ¶ 4-402.12(D).

4-402.12 Fixed Equipment, Elevation or Sealing.

(A) Except as specified in ¶¶ (B) and (C) of this section, floor-mounted EQUIPMENT that is not EASILY MOVABLE shall be SEALED to the floor or elevated on legs that provide at least a 15 centimeter (6 inch) clearance between the floor and the EQUIPMENT.

(B) *If no part of the floor under the floor-mounted EQUIPMENT is more than 15 centimeters (6 inches) from the point of cleaning access, the clearance space may be only 10 centimeters (4 inches)*.

(C) *This section does not apply to display shelving units, display refrigeration units, and display freezer units located in the CONSUMER shopping areas of a retail FOOD store, if the floor under the units is maintained clean*.

(D) Except as specified in ¶ (E) of this section, TABLE-MOUNTED EQUIPMENT that is not EASILY MOVABLE shall be elevated on legs that provide at least a 10 centimeter (4 inch) clearance between the table and the EQUIPMENT.

(E) *The clearance space between the table and* TABLE-MOUNTED EQUIPMENT *may be*:

(1) *7.5 centimeters (3 inches) if the horizontal distance of the table top under the* EQUIPMENT *is no more than 50 centimeters (20 inches) from the point of access for cleaning; or*

(2) *5 centimeters (2 inches) if the horizontal distance of the table top under the* EQUIPMENT *is no more than 7.5 centimeters (3 inches) from the point of access for cleaning*.

4-5 MAINTENANCE AND OPERATION

Subparts

Equipment

4-501.11 Good Repair and Proper Adjustment.

(A) EQUIPMENT shall be maintained in a state of repair and condition that meets the requirements specified under Parts 4-1 and 4-2.

(B) EQUIPMENT components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with manufacturer's specifications.

(C) Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate FOOD when the container is opened.

4-501.12 Cutting Surfaces.

Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and SANITIZED, or discarded if they are not capable of being resurfaced.

4-501.13 Microwave Ovens.

Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10 Microwave ovens.

4-501.14 Warewashing Equipment, Cleaning Frequency.

A WAREWASHING machine; the compartments of sinks, basins, or other receptacles used for washing and rinsing EQUIPMENT, UTENSILS, or raw FOODS, or laundering wiping cloths; and drainboards or other EQUIPMENT used to substitute for drainboards as specified under § 4-301.13 shall be cleaned:

(A) Before use;

(B) Throughout the day at a frequency necessary to prevent recontamination of EQUIPMENT and UTENSILS and to ensure that the EQUIPMENT performs its intended function; and

(C) If used, at least every 24 hours.

4-501.15 Warewashing Machines, Manufacturers' Operating Instructions.

(A) A WAREWASHING machine and its auxiliary components shall be operated in accordance with the machine's data plate and other manufacturer's instructions.

(B) A WAREWASHING machine's conveyor speed or automatic cycle times shall be maintained accurately timed in accordance with manufacturer's specifications.

4-501.16 Warewashing Sinks, Use Limitation.

(A) A WAREWASHING sink may not be used for handwashing.

(B) If a WAREWASHING sink is used to wash wiping cloths, wash produce, or thaw FOOD, the sink shall be cleaned as specified under § 4-501.14 before and after each time it is used to wash wiping cloths or wash produce or thaw FOOD. Sinks used to wash or thaw FOOD shall be SANITIZED as specified under Part 4-7 before and after using the sink to wash produce or thaw FOOD.

4-501.17 Warewashing Equipment, Cleaning Agents.

When used for WAREWASHING, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C), shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions.

4-501.18 Warewashing Equipment, Clean Solutions.

The wash, rinse, and SANITIZE solutions shall be maintained clean.

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The temperature of the wash solution in manual WAREWASHING EQUIPMENT shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions.

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

(A) The temperature of the wash solution in spray type warewashers that use hot water to SANITIZE may not be less than:

(1) For a stationary rack, single temperature machine, 74°C (165°F);

(2) For a stationary rack, dual temperature machine, 66°C (150°F);

(3) For a single tank, conveyor, dual temperature machine, 71°C (160°F); or

(4) For a multitank, conveyor, multitemperature machine, 66°C (150°F).

(B) The temperature of the wash solution in spray-type warewashers that use chemicals to SANITIZE may not be less than 49°C (120°F).

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures.*

If immersion in hot water is used for SANITIZING in a manual operation, the temperature of the water shall be maintained at 77°C (171°F) or above.

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

(A) Except as specified in ¶ (B) of this section, in a mechanical operation, the temperature of the fresh hot water SANITIZING rinse as it enters the manifold may not be more than 90°C (194°F), or less than:

(1) For a stationary rack, single temperature machine, 74°C (165°F); or

(2) For all other machines, 82°C (180°F).

(B) *The maximum temperature specified under ¶ (A) of this section, does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and SANITIZING of EQUIPMENT such as meat saws.*

4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure.

The flow pressure of the fresh hot water SANITIZING rinse in a WAREWASHING machine may not be less than 100 kilopascals (15 pounds per square inch) or more than 170 kilopascals (25 pounds per square inch) as measured in the water line immediately downstream or upstream from the fresh hot water SANITIZING rinse control valve.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.*

A chemical SANITIZER used in a SANITIZING solution for a manual or mechanical operation at exposure times specified under

¶ 4-703.11(C) shall be listed in 21 CFR 178.1010 Sanitizing solutions, shall be used in accordance with the EPA-approved manufacturer's label use instructions, and shall be used as follows:

(A) A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart;

Minimum Concentration	**Minimum Temperature**	
mg/L	pH 10 or less °C (°F)	pH 8 or less °C (°F)
25	49 (120)	49 (120)
50	38 (100)	24 (75)
100	13 (55)	13 (55)

(B) An iodine solution shall have a:

(1) Minimum temperature of 24°C (75°F),

(2) pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective, and

(3) Concentration between 12.5 mg/L and 25 mg/L;

(C) A quaternary ammonium compound solution shall:

(1) Have a minimum temperature of 24°C (75°F),

(2) Have a concentration as specified under § 7-204.11 and as indicated by the manufacturer's use directions included in the labeling, and

(3) Be used only in water with 500 mg/L hardness or less or in water having a hardness no greater than specified by the manufacturer's label;

(D) If another solution of a chemical specified under ¶¶ (A)-(C) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANITIZATION and the use of the solution shall be APPROVED; or

(E) If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the manufacturer's use directions included in the labeling.

4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers.

If a detergent-SANITIZER is used to SANITIZE in a cleaning and SANITIZING procedure where there is no distinct water rinse between the washing and SANITIZING steps, the agent applied in the SANITIZING step shall be the same detergent-SANITIZER that is used in the washing step.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device.

Utensils and Temperature and Pressure Measuring Devices

4-502.11 Good Repair and Calibration.

(A) UTENSILS shall be maintained in a state of repair or condition that complies with the requirements specified under Parts 4-1 and 4-2 or shall be discarded.

(B) FOOD TEMPERATURE MEASURING DEVICES shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.

(C) Ambient air temperature, water pressure, and water TEMPERATURE MEASURING DEVICES shall be maintained in good repair and be accurate within the intended range of use.

4-502.12 Single-Service and Single-Use Articles, Required Use.*

A FOOD ESTABLISHMENT without facilities specified under Parts 4-6 and 4-7 for cleaning and SANITIZING kitchenware and TABLEWARE shall provide only SINGLE-USE KITCHENWARE, SINGLE-SERVICE ARTICLES, and SINGLE-USE ARTICLES for use by FOOD EMPLOYEES and SINGLE-SERVICE ARTICLES for use by CONSUMERS.

4-502.13 Single-Service and Single-Use Articles, Use Limitation.

(A) SINGLE-SERVICE and SINGLE-USE ARTICLES may not be reused.

(B) The bulk milk container dispensing tube shall be cut on the diagonal leaving no more than one inch protruding from the chilled dispensing head.

4-502.14 Shells, Use Limitation.

Mollusk and crustacea shells may not be used more than once as serving containers.

4-6 CLEANING OF EQUIPMENT AND UTENSILS

Subparts

Objective

4-601.11 Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.*

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be clean to sight and touch.

(B) The FOOD-CONTACT SURFACES of cooking EQUIPMENT and pans shall be kept free of encrusted grease deposits and other soil accumulations.[N]

(C) NonFOOD-CONTACT SURFACES of EQUIPMENT shall be kept free of an accumulation of dust, dirt, FOOD residue, and other debris.[N]

Frequency

4-602.11 Equipment Food-Contact Surfaces and Utensils.*

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be cleaned:

(1) Except as specified in ¶ (B) of this section, before each use with a different type of raw animal FOOD such as beef, FISH, lamb, pork, or POULTRY;

(2) Each time there is a change from working with raw FOODS to working with READY-TO-EAT FOODS;

(3) Between uses with raw fruits and vegetables and with POTENTIALLY HAZARDOUS FOOD;

(4) Before using or storing a FOOD TEMPERATURE MEASURING DEVICE; and

(5) At any time during the operation when contamination may have occurred.

(B) *Subparagraph (A)(1) of this section does not apply if the FOOD-CONTACT SURFACE or UTENSIL is in contact with a succession of different raw animal FOODS each requiring a higher cooking temperature as specified under § 3-401.11 than the previous FOOD, such as preparing raw FISH followed by cutting raw poultry on the same cutting board*.

(C) Except as specified in ¶ (D) of this section, if used with POTENTIALLY HAZARDOUS FOOD, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be cleaned throughout the day at least every 4 hours.

(D) *Surfaces of UTENSILS and EQUIPMENT contacting POTENTIALLY HAZARDOUS FOOD may be cleaned less frequently than every 4 hours if:*

(1) *In storage, containers of POTENTIALLY HAZARDOUS FOOD and their contents are maintained at temperatures specified under Chapter 3 and the containers are cleaned when they are empty;*

(2) *UTENSILS and EQUIPMENT are used to prepare FOOD in a refrigerated room or area that is maintained at one of the temperatures in the following chart and:*

(a) The UTENSILS and EQUIPMENT are cleaned at the frequency in the following chart that corresponds to the temperature:

Temperature	Cleaning Frequency
5.0°C (41°F) or less	24 hours
>5.0°C - 7.2°C (>41°F - 45°F)	20 hours
>7.2°C - 10.0°C (>45°F - 50°F)	16 hours
>10.0°C - 12.8°C (>50°F - 55°F)	10 hours

; and

(b) The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the FOOD ESTABLISHMENT.

(3) *Containers in serving situations such as salad bars, delis, and cafeteria lines hold READY-TO-EAT POTENTIALLY HAZARDOUS FOOD that is maintained at the temperatures specified under Chapter 3, are intermittently combined with additional supplies of the same FOOD that is at the required temperature, and the containers are cleaned at least every 24 hours;*

(4) *TEMPERATURE MEASURING DEVICES are maintained in contact with FOOD, such as when left in a container of deli FOOD or in a roast, held at temperatures specified under Chapter 3;*

(5) *EQUIPMENT is used for storage of PACKAGED or unPACKAGED FOOD such as a reach-in refrigerator and the EQUIPMENT is cleaned at a frequency necessary to preclude accumulation of soil residues;*

(6) *The cleaning schedule is APPROVED based on consideration of:*

(a) *Characteristics of the EQUIPMENT and its use,*

(b) *The type of FOOD involved,*

(c) *The amount of FOOD residue accumulation, and*

(d) *The temperature at which the* FOOD *is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or*

(7) In-use UTENSILS *are intermittently stored in a container of water in which the water is maintained at 60°C (140°F) or more and the* UTENSILS *and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.*

(E) *Except when dry cleaning methods are used as specified under § 4-603.11*, surfaces of UTENSILS and EQUIPMENT contacting FOOD that is not POTENTIALLY HAZARDOUS shall be cleaned:[N]

(1) At any time when contamination may have occurred;

(2) At least every 24 hours for iced tea dispensers and CONSUMER self-service UTENSILS such as tongs, scoops, or ladles;

(3) Before restocking CONSUMER self-service EQUIPMENT and UTENSILS such as condiment dispensers and display containers; and

(4) In EQUIPMENT such as ice bins and BEVERAGE dispensing nozzles and enclosed components of EQUIPMENT such as ice makers, cooking oil storage tanks and distribution lines, BEVERAGE and syrup dispensing lines or tubes, coffee bean grinders, and water vending EQUIPMENT:

(a) At a frequency specified by the manufacturer, or

(b) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

4-602.12 Cooking and Baking Equipment.

(A) The FOOD-CONTACT SURFACES of cooking and baking EQUIPMENT shall be cleaned at least every 24 hours. *This section does not apply to hot oil cooking and filtering* EQUIPMENT *if it is cleaned as specified in Subparagraph 4-602.11(D)(6)*.

(B) The cavities and door seals of microwave ovens shall be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.

4-602.13 Nonfood-Contact Surfaces.

NonFOOD-CONTACT SURFACES of EQUIPMENT shall be cleaned at a frequency necessary to preclude accumulation of soil residues.

Methods

4-603.11 Dry Cleaning.

(A) If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only SURFACES that are soiled with dry FOOD residues that are not POTENTIALLY HAZARDOUS.

(B) Cleaning EQUIPMENT used in dry cleaning FOOD-CONTACT SURFACES may not be used for any other purpose.

4-603.12 Precleaning.

(A) FOOD debris on EQUIPMENT and UTENSILS shall be scrapped over a waste disposal unit, scupper, or garbage receptacle or shall be removed in a WAREWASHING machine with a prewash cycle.

(B) If necessary for effective cleaning, UTENSILS and EQUIPMENT shall be preflushed, presoaked, or scrubbed with abrasives.

4-603.13 Loading of Soiled Items, Warewashing Machines.

Soiled items to be cleaned in a WAREWASHING machine shall be loaded into racks, trays, or baskets or onto conveyors in a position that:

(A) Exposes the items to the unobstructed spray from all cycles; and

(B) Allows the items to drain.

4-603.14 Wet Cleaning.

(A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary such as the application

of detergents containing wetting agents and emulsifiers; acid, alkaline, or abrasive cleaners; hot water; brushes; scouring pads; high-pressure sprays; or ultrasonic devices.

(B) The washing procedures selected shall be based on the type and purpose of the EQUIPMENT or UTENSIL, and on the type of soil to be removed.

4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment.

If washing in sink compartments or a WAREWASHING machine is impractical such as when the EQUIPMENT is fixed or the UTENSILS are too large, washing shall be done by using alternative manual WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C) in accordance with the following procedures:

(A) EQUIPMENT shall be disassembled as necessary to allow access of the detergent solution to all parts;

(B) EQUIPMENT components and UTENSILS shall be scrapped or rough cleaned to remove FOOD particle accumulation; and

(C) EQUIPMENT and UTENSILS shall be washed as specified under ¶ 4-603.14(A).

4-603.16 Rinsing Procedures.

Washed UTENSILS and EQUIPMENT shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent-SANITIZER solution by using one of the following procedures:

(A) Use of a distinct, separate water rinse after washing and before SANITIZING if using:

(1) A 3-compartment sink,

(2) Alternative manual WAREWASHING EQUIPMENT equivalent to a 3-compartment sink as specified in ¶ 4-301.12(C), or

(3) A 3-step washing, rinsing, and SANITIZING procedure in a WAREWASHING system for CIP EQUIPMENT;

(B) Use of a detergent-SANITIZER as specified under § 4-501.115 if using:

(1) Alternative WAREWASHING EQUIPMENT as specified in ¶ 4-301.12(C) that is APPROVED for use with a detergent-SANITIZER, or

(2) A WAREWASHING system for CIP EQUIPMENT;

(C) Use of a nondistinct water rinse that is integrated in the hot water SANITIZATION immersion step of a 2-compartment sink operation;

(D) If using a WAREWASHING machine that does not recycle the SANITIZING solution as specified under ¶ (E) of this section, or alternative manual WAREWASHING EQUIPMENT such as sprayers, use of a nondistinct water rinse that is:

(1) Integrated in the application of the SANITIZING solution, and

(2) Wasted immediately after each application; or

(E) If using a WAREWASHING machine that recycles the SANITIZING solution for use in the next wash cycle, use of a nondistinct water rinse that is integrated in the application of the SANITIZING solution.

4-603.17 Returnables, Cleaning for Refilling.*

(A) Except as specified in ¶¶ (B) and (C) of this section, returned empty containers intended for cleaning and refilling with FOOD shall be cleaned and refilled in a regulated FOOD PROCESSING PLANT.

(B) *A FOOD-specific container for BEVERAGES may be refilled at a FOOD ESTABLISHMENT if:*

(1) *Only a BEVERAGE that is not a POTENTIALLY HAZARDOUS FOOD is used as specified under ¶ 3-304.17(A);*

(2) *The design of the container and of the rinsing EQUIPMENT and the nature of the BEVERAGE, when considered together, allow effective cleaning at home or in the FOOD ESTABLISHMENT;*

(3) *Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;*

(4) *The* CONSUMER*-owned container returned to the* FOOD ESTABLISHMENT *for refilling is refilled for sale or service only to the same* CONSUMER*; and*

(5) *The container is refilled by:*

(a) *An* EMPLOYEE *of the* FOOD ESTABLISHMENT*, or*

(b) *The owner of the container if the* BEVERAGE *system includes a contamination-free transfer process that can not be bypassed by the container owner.*

(C) CONSUMER*-owned containers that are not* FOOD*-specific may be filled at a water* VENDING MACHINE *or system.*

4-7 SANITIZATION OF EQUIPMENT AND UTENSILS

Subparts

Objective **4-701.10 Food-Contact Surfaces and Utensils.**

EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED.

Frequency **4-702.11 Before Use After Cleaning.***

UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT shall be SANITIZED before use after cleaning.

Methods

4-703.11 Hot Water and Chemical.*

After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in:

(A) Hot water manual operations by immersion for at least 30 seconds and as specified under § 4-501.111;

(B) Hot water mechanical operations by being cycled through EQUIPMENT that is set up as specified under §§ 4-501.15, 4-501.112, and 4-501.113 and achieving a UTENSIL surface temperature of 71°C (160°F) as measured by an irreversible registering temperature indicator; or

(C) Chemical manual or mechanical operations, including the application of SANITIZING chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under § 4-501.114 by providing:

(1) Except as specified under Subparagraph (C)(2) of this section, an exposure time of at least 10 seconds for a chlorine solution specified under ¶ 4-501.114(A),

(2) An exposure time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 38°C (100°F) or a pH of 8 or less and a temperature of at least 24°C (75°F),

(3) An exposure time of at least 30 seconds for other chemical SANITIZING solutions, or

(4) An exposure time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields SANITIZATION as defined in Subparagraph 1-201.10(B)(72).

4-8 LAUNDERING

Subparts

Objective

4-801.11 Clean Linens.

Clean LINENS shall be free from FOOD residues and other soiling matter.

Frequency

4-802.11 Specifications.

(A) LINENS that do not come in direct contact with FOOD shall be laundered between operations if they become wet, sticky, or visibly soiled.

(B) Cloth gloves used as specified in ¶ 3-304.15(D) shall be laundered before being used with a different type of raw animal FOOD such as beef, lamb, pork, and FISH.

(C) LINENS and napkins that are used as specified under § 3-304.13 and cloth napkins shall be laundered between each use.

(D) Wet wiping cloths shall be laundered daily.

(E) Dry wiping cloths shall be laundered as necessary to prevent contamination of FOOD and clean serving UTENSILS.

Methods

4-803.11 Storage of Soiled Linens.

Soiled LINENS shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of FOOD, clean EQUIPMENT, clean UTENSILS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

4-803.12 Mechanical Washing.

(A) Except as specified in ¶ (B) of this section, LINENS shall be mechanically washed.

(B) *In FOOD ESTABLISHMENTS in which only wiping cloths are laundered as specified in ¶ 4-301.15(B), the wiping cloths may be laundered in a mechanical washer, sink designated only for laundering wiping cloths, or a WAREWASHING or FOOD preparation sink that is cleaned as specified under § 4-501.14.*

4-803.13 Use of Laundry Facilities.

(A) Except as specified in ¶ (B) of this section, laundry facilities on the PREMISES of a FOOD ESTABLISHMENT shall be used only for the washing and drying of items used in the operation of the establishment.

(B) *Separate laundry facilities located on the PREMISES for the purpose of general laundering such as for institutions providing boarding and lodging may also be used for laundering FOOD ESTABLISHMENT items.*

4-9 PROTECTION OF CLEAN ITEMS

Subparts

Drying

4-901.11 Equipment and Utensils, Air-Drying Required.

After cleaning and SANITIZING, EQUIPMENT and UTENSILS:

(A) Shall be air-dried or used after adequate draining as specified in ¶ (a) of 21 CFR 178.1010 Sanitizing solutions, before contact with FOOD; and

(B) May not be cloth dried *except that* UTENSILS *that have been air-dried may be polished with cloths that are maintained clean and dry*.

4-901.12 Wiping Cloths, Air-Drying Locations.

Wiping cloths laundered in a FOOD ESTABLISHMENT that does not have a mechanical clothes dryer as specified in ¶ 4-301.15(B) shall be air-dried in a location and in a manner that prevents contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES and the wiping cloths. *This section does not apply if wiping cloths are stored after laundering in a sanitizing solution as specified under § 4-501.114.*

Lubricating and Reassembling

4-902.11 Food-Contact Surfaces.

Lubricants shall be applied to FOOD-CONTACT SURFACES that require lubrication in a manner that does not contaminate FOOD-CONTACT SURFACES.

4-902.12 Equipment.

EQUIPMENT shall be reassembled so that FOOD-CONTACT SURFACES are not contaminated.

Storing

4-903.11 Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.

(A) Except as specified in ¶ (D) of this section, cleaned EQUIPMENT and UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES shall be stored:

(1) In a clean, dry location;

(2) Where they are not exposed to splash, dust, or other contamination; and

(3) At least 15 cm (6 inches) above the floor.

(B) Clean EQUIPMENT and UTENSILS shall be stored as specified under ¶ (A) of this section and shall be stored:

(1) In a self-draining position that allows air drying; and

(2) Covered or inverted.

(C) SINGLE-SERVICE and SINGLE-USE ARTICLES shall be stored as specified under ¶ (A) of this section and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used.

(D) *Items that are kept in closed packages may be stored less than 15 cm (6 inches) above the floor on dollies, pallets, racks, and skids that are designed as specified under § 4-204.122.*

4-903.12 Prohibitions.

(A) Except as specified in ¶ (B) of this section, cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be stored:

(1) In locker rooms;

(2) In toilet rooms;

(3) In garbage rooms;

(4) In mechanical rooms;

(5) Under sewer lines that are not shielded to intercept potential drips;

(6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(7) Under open stairwells; or

(8) Under other sources of contamination.

(B) *Laundered LINENS and SINGLE-SERVICE and SINGLE-USE ARTICLES that are PACKAGED or in a facility such as a cabinet may be stored in a locker room.*

Handling

4-904.11 Kitchenware and Tableware.

(A) SINGLE-SERVICE and SINGLE-USE ARTICLES and cleaned and SANITIZED UTENSILS shall be handled, displayed, and dispensed so that contamination of FOOD- and lip-contact surfaces is prevented.

(B) Knives, forks, and spoons that are not prewrapped shall be presented so that only the handles are touched by EMPLOYEES and by CONSUMERS if CONSUMER self-service is provided.

(C) Except as specified under ¶ (B) of this section, SINGLE-SERVICE ARTICLES that are intended for FOOD- or lip-contact shall be furnished for CONSUMER self-service with the original individual wrapper intact or from an APPROVED dispenser.

4-904.12 Soiled and Clean Tableware.

Soiled TABLEWARE shall be removed from CONSUMER eating and drinking areas and handled so that clean TABLEWARE is not contaminated.

4-904.13 Preset Tableware.

IF TABLEWARE is preset:

(A) It shall be protected from contamination by being wrapped, covered, or inverted;

(B) Exposed, unused settings shall be removed when a CONSUMER is seated; or

(C) Exposed, unused settings shall be cleaned and SANITIZED before further use if the settings are not removed when a CONSUMER is seated.

Chapter

5 Water, Plumbing, and Waste

Parts

5-1 WATER

Subparts

Source **5-101.11 Approved System.***

DRINKING WATER shall be obtained from an APPROVED source that is:

(A) A PUBLIC WATER SYSTEM; or

(B) A nonPUBLIC WATER SYSTEM that is constructed, maintained, and operated according to LAW.

5-101.12 System Flushing and Disinfection.*

A DRINKING WATER system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system.

5-101.13 Bottled Drinking Water.*

BOTTLED DRINKING WATER used or sold in a FOOD ESTABLISHMENT shall be obtained from APPROVED sources in accordance with 21 CFR 129 - Processing and Bottling of Bottled DRINKING WATER.

Quality

5-102.11 Standards.*

Except as specified under § 5-102.12:

(A) Water from a PUBLIC WATER SYSTEM shall meet 40 CFR 141 - National Primary Drinking Water Regulations and state DRINKING WATER quality standards; and

(B) Water from a nonPUBLIC WATER SYSTEM shall meet state DRINKING WATER quality standards.

5-102.12 Nondrinking Water.*

(A) A nonDRINKING WATER supply shall be used only if its use is APPROVED.

(B) NonDRINKING WATER shall be used only for nonculinary purposes such as air conditioning, nonFOOD EQUIPMENT cooling, fire protection, and irrigation.

5-102.13 Sampling.

Except when used as specified under § 5-102.12, water from a nonPUBLIC WATER SYSTEM shall be sampled and tested at least annually and as required by state water quality regulations.

5-102.14 Sample Report.

The most recent sample report for the nonPUBLIC WATER SYSTEM shall be retained on file in the FOOD ESTABLISHMENT or the report shall be maintained as specified by state water quality regulations.

Quantity and Availability

5-103.11 Capacity.*

(A) The water source and system shall be of sufficient capacity to meet the peak water demands of the FOOD ESTABLISHMENT.

(B) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the FOOD ESTABLISHMENT.

5-103.12 Pressure.

Water under pressure shall be provided to all fixtures, EQUIPMENT, and nonFOOD EQUIPMENT that are required to use water *except that water supplied as specified under ¶¶ 5-104.12(A) and (B) to a TEMPORARY FOOD ESTABLISHMENT or in response to a temporary interruption of a water supply need not be under pressure*.

Distribution, Delivery, and Retention

5-104.11 System.

Water shall be received from the source through the use of:

(A) An APPROVED public water main; or

(B) One or more of the following that shall be constructed, maintained, and operated according to LAW:

(1) Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances,

(2) Water transport vehicles, and

(3) Water containers.

5-104.12 Alternative Water Supply.

Water meeting the requirements specified under Subparts 5-101, 5-102, and 5-103 shall be made available for a mobile facility, for a TEMPORARY FOOD ESTABLISHMENT without a permanent water supply, and for a FOOD ESTABLISHMENT with a temporary interruption of its water supply through:

(A) A supply of containers of commercially BOTTLED DRINKING WATER;

(B) One or more closed portable water containers;

(C) An enclosed vehicular water tank;

(D) An on-PREMISES water storage tank; or

(E) Piping, tubing, or hoses connected to an adjacent APPROVED source.

5-2 PLUMBING SYSTEM

Subparts

Materials

5-201.11 Approved.*

(A) A PLUMBING SYSTEM and hoses conveying water shall be constructed and repaired with APPROVED materials according to LAW.

(B) A water filter shall be made of SAFE MATERIALS.

5-202.11 Approved System and Cleanable Fixtures.*

(A) A PLUMBING SYSTEM shall be designed, constructed, and installed according to LAW.

(B) A PLUMBING FIXTURE such as a handwashing facility, toilet, or urinal shall be EASILY CLEANABLE.[N]

5-202.12 Handwashing Facility, Installation.

(A) A handwashing lavatory shall be equipped to provide water at a temperature of at least 43°C (110°F) through a mixing valve or combination faucet.

(B) A steam mixing valve may not be used at a handwashing lavatory.

(C) A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

(D) An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.

5-202.13 Backflow Prevention, Air Gap.*

An air gap between the water supply inlet and the flood level rim of the PLUMBING FIXTURE, EQUIPMENT, or nonFOOD EQUIPMENT shall be at least twice the diameter of the water supply inlet and may not be less than 25 mm (1 inch).

5-202.14 Backflow Prevention Device, Design Standard.

A backflow or backsiphonage prevention device installed on a water supply system shall meet American Society of Sanitary Engineering (A.S.S.E.) standards for construction, installation, maintenance, inspection, and testing for that specific application and type of device.

5-202.15 Conditioning Device, Design.

A water filter, screen, and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.

Numbers and Capacities

5-203.11 Handwashing Facilities.*

(A) Except as specified in ¶¶ (B) and (C) of this section, at least 1 handwashing lavatory, a number of handwashing lavatories necessary for their convenient use by EMPLOYEES in areas specified under § 5-204.11, and not fewer than the number of handwashing lavatories required by LAW shall be provided.

(B) *If APPROVED and capable of removing the types of soils encountered in the FOOD operations involved, automatic handwashing facilities may be substituted for handwashing lavatories in a FOOD ESTABLISHMENT that has at least one handwashing lavatory.*

(C) *If APPROVED, when FOOD exposure is limited and handwashing lavatories are not conveniently available, such as in some mobile or TEMPORARY FOOD ESTABLISHMENTS or at some VENDING MACHINE LOCATIONS, EMPLOYEES may use chemically treated towelettes for handwashing.*

5-203.12 Toilets and Urinals.*

At least 1 toilet and not fewer than the toilets required by LAW shall be provided. If authorized by LAW and urinals are substituted for toilets, the substitution shall be done as specified in LAW.

5-203.13 Service Sink.

At least 1 service sink or 1 curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

5-203.14 Backflow Prevention Device, When Required.*

A PLUMBING SYSTEM shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the FOOD ESTABLISHMENT, including on a hose bibb if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by LAW, by:

(A) Providing an air gap as specified under § 5-202.13; or

(B) Installing an APPROVED backflow prevention device as specified under § 5-202.14.

5-203.15 Backflow Prevention Device, Carbonator.*

Reserved.

Location and Placement

5-204.11 Handwashing Facilities.*

A handwashing facility shall be located:

(A) To allow convenient use by EMPLOYEES in FOOD preparation, FOOD dispensing, and WAREWASHING areas; and

(B) In, or immediately adjacent to, toilet rooms.

5-204.12 Backflow Prevention Device, Location.

A backflow prevention device shall be located so that it may be serviced and maintained.

5-204.13 Conditioning Device, Location.

A water filter, screen, and other water conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning.

Operation and Maintenance

5-205.11 Using a Handwashing Facility.

(A) A handwashing facility shall be maintained so that it is accessible at all times for EMPLOYEE use.

(B) A handwashing facility may not be used for purposes other than handwashing.

(C) An automatic handwashing facility shall be used in accordance with manufacturer's instructions.

5-205.12 Prohibiting a Cross Connection.*

(A) *Except as specified in 9 CFR 308.3(d) for firefighting*, a PERSON may not create a cross connection by connecting a pipe or conduit between the DRINKING WATER system and a nonDRINKING WATER SYSTEM or a water system of unknown quality.

(B) The piping of a nonDRINKING WATER SYSTEM shall be durably identified so that it is readily distinguishable from piping that carries DRINKING WATER.[N]

5-205.13 Scheduling Inspection and Service for a Water System Device.

A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the PERSON IN CHARGE.

5-205.14 Water Reservoir of Fogging Devices, Cleaning.*

(A) A reservoir that is used to supply water to a device such as a produce fogger shall be:

(1) Maintained in accordance with manufacturer's specifications; and

(2) Cleaned in accordance with manufacturer's specifications or according to the procedures specified under ¶ (B) of this section, whichever is more stringent.

(B) Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

(1) Draining and complete disassembly of the water and aerosol contact parts;

(2) Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution;

(3) Flushing the complete system with water to remove the detergent solution and particulate accumulation; and

(4) Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 mg/L hypochlorite solution.

5-205.15 System Maintained in Good Repair.*

A PLUMBING SYSTEM shall be:

(A) Repaired according to LAW; and

(B) Maintained in good repair.[s]

5-3 MOBILE WATER TANK AND MOBILE FOOD ESTABLISHMENT WATER TANK

Subparts

Materials

5-301.11 Approved.

Materials that are used in the construction of a mobile water tank, mobile FOOD ESTABLISHMENT water tank, and appurtenances shall be:

(A) Safe;

(B) Durable, CORROSION-RESISTANT, and nonabsorbent; and

(C) Finished to have a SMOOTH, EASILY CLEANABLE surface.

Design and Construction

5-302.11 Enclosed System, Sloped to Drain.

A mobile water tank shall be:

(A) Enclosed from the filling inlet to the discharge outlet; and

(B) Sloped to an outlet that allows complete drainage of the tank.

5-302.12 Inspection and Cleaning Port, Protected and Secured.

If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank and:

(A) Flanged upward at least 13 mm (one-half inch); and

(B) Equipped with a port cover assembly that is:

(1) Provided with a gasket and a device for securing the cover in place, and

(2) Flanged to overlap the opening and sloped to drain.

5-302.13 "V" Type Threads, Use Limitation.

A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached.

5-302.14 Tank Vent, Protected.

If provided, a water tank vent shall terminate in a downward direction and shall be covered with:

(A) 16 mesh to 25.4 mm (16 mesh to 1 inch) screen or equivalent when the vent is in a protected area; or

(B) A protective filter when the vent is in an area that is not protected from windblown dirt and debris.

5-302.15 Inlet and Outlet, Sloped to Drain.

(A) A water tank and its inlet and outlet shall be sloped to drain.

(B) A water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil, or grease.

5-302.16 Hose, Construction and Identification.

A hose used for conveying DRINKING WATER from a water tank shall be:

(A) Safe;

(B) Durable, CORROSION-RESISTANT, and nonaborbent;

(C) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;

(D) Finished with a SMOOTH interior surface; and

(E) Clearly and durably identified as to its use if not permanently attached.

Numbers and Capacities

5-303.11 Filter, Compressed Air.

A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and DRINKING WATER system when compressed air is used to pressurize the water tank system.

5-303.12 Protective Cover or Device.

A cap and keeper chain, closed cabinet, closed storage tube, or other APPROVED protective cover or device shall be provided for a water inlet, outlet, and hose.

5-303.13 Mobile Food Establishment Tank Inlet.

A mobile FOOD ESTABLISHMENT'S water tank inlet shall be:

(A) 19.1 mm (three-fourths inch) in inner diameter or less; and

(B) Provided with a hose connection of a size or type that will prevent its use for any other service.

Operation and Maintenance

5-304.11 System Flushing and Disinfection.*

A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification, and periods of nonuse.

5-304.12 Using a Pump and Hoses, Backflow Prevention.

A PERSON shall operate a water tank, pump, and hoses so that backflow and other contamination of the water supply are prevented.

5-304.13 Protecting Inlet, Outlet, and Hose Fitting.

If not in use, a water tank and hose inlet and outlet fitting shall be protected using a cover or device as specified under § 5-303.12.

5-304.14 Tank, Pump, and Hoses, Dedication.

(A) Except as specified in ¶ (B) of this section, a water tank, pump, and hoses used for conveying DRINKING WATER shall be used for no other purpose.

(B) *Water tanks, pumps, and hoses APPROVED for liquid FOODS may be used for conveying DRINKING WATER if they are cleaned and SANITIZED before they are used to convey water.*

5-4 SEWAGE, OTHER LIQUID WASTE, AND RAINWATER

Subparts

Mobile Holding Tank

5-401.11 Capacity and Drainage.

A SEWAGE holding tank in a mobile FOOD ESTABLISHMENT shall be:

(A) Sized 15 percent larger in capacity than the water supply tank; and

(B) Sloped to a drain that is 25 mm (1 inch) in inner diameter or greater, equipped with a shut-off valve.

Retention, Drainage, and Delivery

design, construction, and installation

5-402.10 Establishment Drainage System.

FOOD ESTABLISHMENT drainage systems, including grease traps, that convey SEWAGE shall be designed and installed as specified under ¶ 5-202.11(A).

5-402.11 Backflow Prevention.*

(A) Except as specified in ¶¶ (B) and (C) of this section, a direct connection may not exist between the SEWAGE system and a drain originating from EQUIPMENT in which FOOD, portable EQUIPMENT, or UTENSILS are placed.

(B) *If allowed by LAW, a WAREWASHING machine may have a direct connection between its waste outlet and a floor drain when the machine is located within 1.5 m (5 feet) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.*

(C) *If allowed by LAW, a WAREWASHING or culinary sink may have a direct connection.*

location and placement

5-402.12 Grease Trap.

If used, a grease trap shall be located to be easily accessible for cleaning.

operation and maintenance

5-402.13 Conveying Sewage.*

SEWAGE shall be conveyed to the point of disposal through an APPROVED sanitary SEWAGE system or other system, including use of SEWAGE transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to LAW.

5-402.14 Removing Mobile Food Establishment Wastes.

SEWAGE and other liquid wastes shall be removed from a mobile FOOD ESTABLISHMENT at an APPROVED waste SERVICING AREA or by a SEWAGE transport vehicle in such a way that a public health HAZARD or nuisance is not created.

5-402.15 Flushing a Waste Retention Tank.

A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation.

Disposal Facility

5-403.11 Approved Sewage Disposal System.*

design and construction

SEWAGE shall be disposed through an APPROVED facility that is:

(A) A public SEWAGE treatment plant; or

(B) An individual SEWAGE disposal system that is sized, constructed, maintained, and operated according to LAW.

5-403.12 Other Liquid Wastes and Rainwater.

Condensate drainage and other nonSEWAGE liquids and rainwater shall be drained from point of discharge to disposal according to LAW.

5-5 REFUSE, RECYCLABLES, AND RETURNABLES

Subparts

Facilities on the Premises
materials, design, construction, and installation

5-501.10 Indoor Storage Area.

If located within the FOOD ESTABLISHMENT, a storage area for REFUSE, recyclables, and returnables shall meet the requirements specified under §§ 6-101.11, 6-201.11 - 6-201.18, 6-202.15, and 6-202.16.

5-501.11 Outdoor Storage Surface.

An outdoor storage surface for REFUSE, recyclables, and returnables shall be constructed of nonabsorbent material such as concrete or asphalt and shall be SMOOTH, durable, and sloped to drain.

5-501.12 Outdoor Enclosure.

If used, an outdoor enclosure for REFUSE, recyclables, and returnables shall be constructed of durable and cleanable materials.

5-501.13 Receptacles.

(A) Except as specified in ¶ (B) of this section, receptacles and waste handling units for REFUSE, recyclables, and returnables and for use with materials containing FOOD residue shall be durable, cleanable, insect- and rodent-resistant, leakproof, and nonabsorbent.

(B) *Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the FOOD ESTABLISHMENT, or within closed outside receptacles.*

5-501.14 Receptacles in Vending Machines.

A REFUSE receptacle may not be located within a VENDING MACHINE, *except that a receptacle for BEVERAGE bottle crown closures may be located within a VENDING MACHINE.*

5-501.15 Outside Receptacles.

(A) Receptacles and waste handling units for REFUSE, recyclables, and returnables used with materials containing FOOD residue and used outside the FOOD ESTABLISHMENT shall be designed and constructed to have tight-fitting lids, doors, or covers.

(B) Receptacles and waste handling units for REFUSE and recyclables such as an on-site compactor shall be installed so that accumulation of debris and insect and rodent attraction and harborage are minimized and effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit.

numbers and capacities

5-501.16 Storage Areas, Rooms, and Receptacles, Capacity and Availability.

(A) An inside storage room and area and outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold REFUSE, recyclables, and returnables that accumulate.

(B) A receptacle shall be provided in each area of the FOOD ESTABLISHMENT or PREMISES where REFUSE is generated or commonly discarded, or where recyclables or returnables are placed.

(C) If disposable towels are used at handwashing lavatories, a waste receptacle shall be located at each lavatory or group of adjacent lavatories.

5-501.17 Toilet Room Receptacle, Covered.

A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

5-501.18 Cleaning Implements and Supplies.

(A) Except as specified in ¶ (B) of this section, suitable cleaning implements and supplies such as high pressure pumps, hot water, steam, and detergent shall be provided as necessary for effective cleaning of receptacles and waste handling units for REFUSE, recyclables, and returnables.

(B) *If APPROVED, off-PREMISES-based cleaning services may be used if on-PREMISES cleaning implements and supplies are not provided.*

location and placement

5-501.19 Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.

(A) An area designated for REFUSE, recyclables, returnables, and, except as specified in ¶ (B) of this section, a redeeming machine for recyclables or returnables shall be located so that it is separate from FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES and a public health HAZARD or nuisance is not created.

(B) *A redeeming machine may be located in the PACKAGED FOOD storage area or CONSUMER area of a FOOD ESTABLISHMENT if FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES are not subject to contamination from the machines and a public health HAZARD or nuisance is not created.*

(C) The location of receptacles and waste handling units for REFUSE, recyclables, and returnables may not create a public health HAZARD or nuisance or interfere with the cleaning of adjacent space.

operation and maintenance

5-501.110 Storing Refuse, Recyclables, and Returnables.

REFUSE, recyclables, and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents.

5-501.111 Areas, Enclosures, and Receptacles, Good Repair.

Storage areas, enclosures, and receptacles for REFUSE, recyclables, and returnables shall be maintained in good repair.

5-501.112 Outside Storage Prohibitions.

(A) Except as specified in ¶ (B) of this section, REFUSE receptacles not meeting the requirements specified under ¶ 5-501.13(A) such as receptacles that are not rodent-resistant, unprotected plastic bags and paper bags, or baled units that contain materials with FOOD residue may not be stored outside.

(B) *Cardboard or other packaging material that does not contain FOOD residues and that is awaiting regularly scheduled delivery to a recycling or disposal site may be stored outside without being in a covered receptacle if it is stored so that it does not create a rodent harborage problem.*

5-501.113 Covering Receptacles.

Receptacles and waste handling units for REFUSE, recyclables, and returnables shall be kept covered:

(A) Inside the FOOD ESTABLISHMENT if the receptacles and units:

(1) Contain FOOD residue and are not in continuous use; or

(2) After they are filled; and

(B) With tight-fitting lids or doors if kept outside the FOOD ESTABLISHMENT.

5-501.114 Using Drain Plugs.

Drains in receptacles and waste handling units for REFUSE, recyclables, and returnables shall have drain plugs in place.

5-501.115 Maintaining Refuse Areas and Enclosures.

A storage area and enclosure for REFUSE, recyclables, or returnables shall be maintained free of unnecessary items, as specified under § 6-501.114, and clean.

5-501.116 Cleaning Receptacles.

(A) Receptacles and waste handling units for REFUSE, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, or SINGLE-SERVICE and SINGLE-USE ARTICLES, and waste water shall be disposed of as specified under § 5-402.14.

(B) Soiled receptacles and waste handling units for REFUSE, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a buildup of soil or becoming attractants for insects and rodents.

Removal

5-502.11 Frequency.

REFUSE, recyclables, and returnables shall be removed from the PREMISES at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents.

5-502.12 Receptacles or Vehicles.

REFUSE, recyclables, and returnables shall be removed from the PREMISES by way of:

(A) Portable receptacles that are constructed and maintained according to LAW; or

(B) A transport vehicle that is constructed, maintained, and operated according to LAW.

Facilities for Disposal and Recycling

5-503.11 Community or Individual Facility.

Solid waste not disposed of through the SEWAGE system such as through grinders and pulpers shall be recycled or disposed of in an APPROVED public or private community recycling or REFUSE facility; or solid waste shall be disposed of in an individual REFUSE facility such as a landfill or incinerator which is sized, constructed, maintained, and operated according to LAW.

Chapter

6 Physical Facilities

Parts

6-1 MATERIALS FOR CONSTRUCTION AND REPAIR

Subparts

Indoor Areas

6-101.11 Surface Characteristics.

(A) Except as specified in ¶ (B) of this section, materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be:

(1) SMOOTH, durable, and EASILY CLEANABLE for areas where FOOD ESTABLISHMENT operations are conducted;

(2) Closely woven and EASILY CLEANABLE carpet for carpeted areas; and

(3) Nonabsorbent for areas subject to moisture such as FOOD preparation areas, walk-in refrigerators, WAREWASHING areas, toilet rooms, mobile FOOD ESTABLISHMENT SERVICING AREAS, and areas subject to flushing or spray cleaning methods.

(B) *In a* TEMPORARY FOOD ESTABLISHMENT*:*

(1) *If graded to drain, a floor may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other suitable* APPROVED *materials that are effectively treated to control dust and mud; and*

(2) *Walls and ceilings may be constructed of a material that protects the interior from the weather and windblown dust and debris.*

Outdoor Areas **6-102.11 Surface Characteristics.**

(A) The outdoor walking and driving areas shall be surfaced with concrete, asphalt, or gravel or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.

(B) Exterior surfaces of buildings and mobile FOOD ESTABLISHMENTS shall be of weather-resistant materials and shall comply with LAW.

(C) Outdoor storage areas for REFUSE, recyclables, or returnables shall be of materials specified under §§ 5-501.11 and 5-501.12.

6-2 DESIGN, CONSTRUCTION, AND INSTALLATION

Subparts

Cleanability **6-201.11 Floors, Walls, and Ceilings.**

Except as specified under § 6-201.14, the floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are SMOOTH and EASILY CLEANABLE, *except that antislip floor coverings or applications may be used for safety reasons.*

6-201.12 Floors, Walls, and Ceilings, Utility Lines.

(A) Utility service lines and pipes may not be unnecessarily exposed.

(B) Exposed utility service lines and pipes shall be installed so they do not obstruct or prevent cleaning of the floors, walls, or ceilings.

(C) Exposed horizontal utility service lines and pipes may not be installed on the floor.

6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed.

(A) In FOOD ESTABLISHMENTS in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than 1 mm (one thirty-second inch).

(B) The floors in FOOD ESTABLISHMENTS in which water flush cleaning methods are used shall be provided with drains and be graded to drain, and the floor and wall junctures shall be coved and SEALED.

6-201.14 Floor Carpeting, Restrictions and Installation.

(A) A floor covering such as carpeting or similar material may not be installed as a floor covering in FOOD preparation areas, walk-in refrigerators, WAREWASHING areas, toilet room areas where handwashing lavatories, toilets, and urinals are located, REFUSE storage rooms, or other areas where the floor is subject to moisture, flushing, or spray cleaning methods.

(B) If carpeting is installed as a floor covering in areas other than those specified under ¶ (A) of this section, it shall be:

(1) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method; and

(2) Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.

6-201.15 Floor Covering, Mats and Duckboards.

Mats and duckboards shall be designed to be removable and EASILY CLEANABLE.

6-201.16 Wall and Ceiling Coverings and Coatings.

(A) Wall and ceiling covering materials shall be attached so that they are EASILY CLEANABLE.

(B) *Except in areas used only for dry storage*, concrete, porous blocks, or bricks used for indoor wall construction shall be finished and SEALED to provide a SMOOTH, nonabsorbent, EASILY CLEANABLE surface.

6-201.17 Walls and Ceilings, Attachments.

(A) Except as specified in ¶ (B) of this section, attachments to walls and ceilings such as light fixtures, mechanical room ventilation system components, vent covers, wall mounted fans, decorative items, and other attachments shall be EASILY CLEANABLE.

(B) *In a CONSUMER area, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean.*

6-201.18 Walls and Ceilings, Studs, Joists, and Rafters.

Studs, joists, and rafters may not be exposed in areas subject to moisture. *This requirement does not apply to TEMPORARY FOOD ESTABLISHMENTS*.

Functionality

6-202.11 Light Bulbs, Protective Shielding.

(A) Except as specified in ¶ (B) of this section, light bulbs shall be shielded, coated, or otherwise shatter-resistant in areas where there is exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; or unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

(B) *Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing* FOOD *in unopened packages, if*:

(1) *The integrity of the packages can not be affected by broken glass falling onto them; and*

(2) *The packages are capable of being cleaned of debris from broken bulbs before the packages are opened*.

(C) An infrared or other heat lamp shall be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed.

6-202.12 Heating, Ventilating, Air Conditioning System Vents.

Heating, ventilating, and air conditioning systems shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of FOOD, FOOD-CONTACT SURFACES, EQUIPMENT, or UTENSILS.

6-202.13 Insect Control Devices, Design and Installation.

(A) Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device.

(B) Insect control devices shall be installed so that:

(1) The devices are not located over a FOOD preparation area; and

(2) Dead insects and insect fragments are prevented from being impelled onto or falling on exposed FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

6-202.14 Toilet Rooms, Enclosed.

A toilet room located on the PREMISES shall be completely enclosed and provided with a tight-fitting and self-closing door *except that this requirement does not apply to a toilet room that is located outside a*

FOOD ESTABLISHMENT and does not open directly into the FOOD ESTABLISHMENT such as a toilet room that is provided by the management of a shopping mall.

6-202.15 Outer Openings, Protected.

(A) Except as specified in ¶¶ (B), (C), and (E) and under ¶ (D) of this section, outer openings of a FOOD ESTABLISHMENT shall be protected against the entry of insects and rodents by:

(1) Filling or closing holes and other gaps along floors, walls, and ceilings;

(2) Closed, tight-fitting windows; and

(3) Solid, self-closing, tight-fitting doors.

(B) *Paragraph (A) of this section does not apply if a FOOD ESTABLISHMENT opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.*

(C) *Exterior doors used as exits need not be self-closing if they are:*

(1) Solid and tight-fitting;

(2) Designated for use only when an emergency exists, by the fire protection authority that has jurisdiction over the FOOD ESTABLISHMENT; and

(3) Restricted so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.

(D) Except as specified in ¶¶ (B) and (E) of this section, if the windows or doors of a FOOD ESTABLISHMENT, or of a larger structure within which a FOOD ESTABLISHMENT is located, are kept open for ventilation or other purposes or a TEMPORARY FOOD ESTABLISHMENT is not provided with windows and doors as specified under ¶ (A) of this section, the openings shall be protected against the entry of insects and rodents by:

(1) 16 mesh to 25.4mm (16 mesh to 1 inch) screens;

(2) Properly designed and installed air curtains; or

(3) Other effective means.

(E) *Paragraph (D) of this section does not apply if flying insects and other pests are absent due to the location of the* ESTABLISHMENT*, the weather, or other limiting condition.*

6-202.16 Exterior Walls and Roofs, Protective Barrier.

Perimeter walls and roofs of a FOOD ESTABLISHMENT shall effectively protect the establishment from the weather and the entry of insects, rodents, and other animals.

6-202.17 Outdoor Food Vending Areas, Overhead Protection.

If located outside, a machine used to vend FOOD shall be provided with overhead protection *except that machines vending canned* BEVERAGES *need not meet this requirement.*

6-202.18 Outdoor Servicing Areas, Overhead Protection.

SERVICING AREAS shall be provided with overhead protection *except that areas used only for the loading of water or the discharge of* SEWAGE *and other liquid waste, through the use of a closed system of hoses, need not be provided with overhead protection.*

6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.

Exterior walking and driving surfaces shall be graded to drain.

6-202.110 Outdoor Refuse Areas, Curbed and Graded to Drain.

Outdoor REFUSE areas shall be constructed in accordance with LAW and shall be curbed and graded to drain to collect and dispose of liquid waste that results from the REFUSE and from cleaning the area and waste receptacles.

6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibition.

A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for conducting FOOD ESTABLISHMENT operations.

6-202.112 Living or Sleeping Quarters, Separation.

Living or sleeping quarters located on the PREMISES of a FOOD ESTABLISHMENT such as those provided for lodging registration clerks or resident managers shall be separated from rooms and areas used for FOOD ESTABLISHMENT operations by complete partitioning and solid self-closing doors.

6-3 NUMBERS AND CAPACITIES

Subparts

Handwashing Facilities

6-301.10 Minimum Number.

Handwashing facilities shall be provided as specified under § 5-203.11.

6-301.11 Handwashing Cleanser, Availability.

Each handwashing lavatory or group of 2 adjacent lavatories shall be provided with a supply of hand cleaning liquid, powder, or bar soap.

6-301.12 Hand Drying Provision.

Each handwashing lavatory or group of adjacent lavatories shall be provided with:

(A) Individual, disposable towels;

(B) A continuous towel system that supplies the user with a clean towel; or

(C) A heated-air hand drying device.

6-301.13 Handwashing Aids and Devices, Use Restrictions.

A sink used for FOOD preparation or UTENSIL washing, or a service sink or curbed cleaning facility used for the disposal of mop water or similar wastes, may not be provided with the handwashing aids and devices required for a handwashing lavatory as specified under §§ 6-301.11 and 6-301.12 and ¶ 5-501.16(C).

6-301.14 Handwashing Signage.

A sign or poster that notifies FOOD EMPLOYEES to wash their hands shall be provided at all handwashing lavatories used by FOOD EMPLOYEES and shall be clearly visible to FOOD EMPLOYEES.

6-301.20 Disposable Towels, Waste Receptacle.

A handwashing lavatory or group of adjacent lavatories that is provided with disposable towels shall be provided with a waste receptacle as specified under ¶ 5-501.16(C).

Toilets and Urinals

6-302.10 Minimum Number.

Toilets and urinals shall be provided as specified under § 5-203.12.

6-302.11 Toilet Tissue, Availability.

A supply of toilet tissue shall be available at each toilet.

Lighting

6-303.11 Intensity.

The light intensity shall be:

(A) At least 110 lux (10 foot candles) at a distance of 75 cm (30 inches) above the floor, in walk-in refrigeration units and dry FOOD storage areas and in other areas and rooms during periods of cleaning;

(B) At least 220 lux (20 foot candles):

(1) At a surface where FOOD is provided for CONSUMER self-service such as buffets and salad bars or where fresh produce or PACKAGED FOODS are sold or offered for consumption;

(2) Inside EQUIPMENT such as reach-in and under-counter refrigerators;

(3) At a distance of 75 cm (30 inches) above the floor in areas used for handwashing, WAREWASHING, and EQUIPMENT and UTENSIL storage, and in toilet rooms; and

(C) At least 540 lux (50 foot candles) at a surface where a FOOD EMPLOYEE is working with FOOD or working with UTENSILS or EQUIPMENT such as knives, slicers, grinders, or saws where EMPLOYEE safety is a factor.

Ventilation

6-304.11 Mechanical.

If necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes, mechanical ventilation of sufficient capacity shall be provided.

Dressing Areas and Lockers

6-305.11 Designation.

(A) Dressing rooms or dressing areas shall be designated if EMPLOYEES routinely change their clothes in the establishment.

(B) Lockers or other suitable facilities shall be provided for the orderly storage of EMPLOYEES' clothing and other possessions.

Service Sinks **6-306.10 Availability.**

A service sink or curbed cleaning facility shall be provided as specified under § 5-203.13.

6-4 LOCATION AND PLACEMENT

Subparts

Handwashing Facilities **6-401.10 Conveniently Located.**

Handwashing facilities shall be conveniently located as specified under § 5-204.11.

Toilet Rooms **6-402.11 Convenience and Accessibility.**

Toilet rooms shall be conveniently located and accessible to EMPLOYEES during all hours of operation.

Employee Accommodations **6-403.11 Designated Areas.**

(A) Areas designated for EMPLOYEES to eat, drink, and use tobacco shall be located so that FOOD, EQUIPMENT, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES are protected from contamination.

(B) Lockers or other suitable facilities shall be located in a designated room or area where contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES can not occur.

Distressed Merchandise

6-404.11 Segregation and Location.

Products that are held by the PERMIT HOLDER for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

Refuse, Recyclables, and Returnables

6-405.10 Receptacles, Waste Handling Units, and Designated Storage Areas.

Units, receptacles, and areas designated for storage of REFUSE and recyclable and returnable containers shall be located as specified under § 5-501.19.

6-5 MAINTENANCE AND OPERATION

Subparts

6-501 Premises, Structures, Attachments, and Fixtures - Methods

Premises, Structures, Attachments, and Fixtures - Methods

6-501.11 Repairing.

The PHYSICAL FACILITIES shall be maintained in good repair.

6-501.12 Cleaning, Frequency and Restrictions.

(A) The PHYSICAL FACILITIES shall be cleaned as often as necessary to keep them clean.

(B) Cleaning shall be done during periods when the least amount of FOOD is exposed such as after closing. *This requirement does not apply to cleaning that is necessary due to a spill or other accident.*

6-501.13 Cleaning Floors, Dustless Methods.

(A) Except as specified in ¶ (B) of this section, only dustless methods of cleaning shall be used, such as wet cleaning, vacuum cleaning, mopping with treated dust mops, or sweeping using a broom and dust-arresting compounds.

(B) *Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:*

(1) *Without the use of dust-arresting compounds; and*

(2) *In the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.*

6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

(A) Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.

(B) If vented to the outside, ventilation systems may not create a public health HAZARD or nuisance or unLAWful discharge.

6-501.15 Cleaning Maintenance Tools, Preventing Contamination.*

FOOD preparation sinks, handwashing lavatories, and WAREWASHING EQUIPMENT may not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes.

6-501.16 Drying Mops.

After use, mops shall be placed in a position that allows them to air-dry without soiling walls, EQUIPMENT, or supplies.

6-501.17 Absorbent Materials on Floors, Use Limitation.

Except as specified in ¶ 6-501.13(B), sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials may not be used on floors.

6-501.18 Maintaining and Using Handwashing Facilities.

Handwashing facilities shall be kept clean, and maintained and used as specified under § 5-205.11.

6-501.19 Closing Toilet Room Doors.

Toilet room doors as specified under § 6-202.14 shall be kept closed *except during cleaning and maintenance operations*.

6-501.110 Using Dressing Rooms and Lockers.

(A) Dressing rooms shall be used by EMPLOYEES if the EMPLOYEES regularly change their clothes in the establishment.

(B) Lockers or other suitable facilities shall be used for the orderly storage of EMPLOYEE clothing and other possessions.

6-501.111 Controlling Pests.*

The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the PREMISES by:

(A) Routinely inspecting incoming shipments of FOOD and supplies;[N]

(B) Routinely inspecting the PREMISES for evidence of pests;[N]

(C) Using methods, if pests are found, such as trapping devices or other means of pest control as specified under §§ 7-202.12, 7-206.12, and 7-206.13; and

(D) Eliminating harborage conditions.[N]

6-501.112 Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.

Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the PREMISES at a frequency that prevents their accumulation, decomposition, or the attraction of pests.

6-501.113 Storing Maintenance Tools.

Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be:

(A) Stored so they do not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES; and

(B) Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

6-501.114 Maintaining Premises, Unnecessary Items and Litter.

The PREMISES shall be free of:

(A) Items that are unnecessary to the operation or maintenance of the establishment such as EQUIPMENT that is nonfunctional or no longer used; and

(B) Litter.

6-501.115 Prohibiting Animals.*

(A) Except as specified in ¶¶ (B) and (C) of this section, live animals may not be allowed on the PREMISES of a FOOD ESTABLISHMENT.

(B) *Live animals may be allowed in the following situations if the contamination of FOOD; clean EQUIPMENT, UTENSILS, and LINENS; and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES can not result:*

(1) *Edible* FISH *or decorative* FISH *in aquariums,* SHELLFISH *or crustacea on ice or under refrigeration, and* SHELLFISH *and crustacea in display tank systems;*

(2) *Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;*

(3) *In areas that are not used for* FOOD *preparation and that are usually open for customers, such as dining and sales areas,* SERVICE ANIMALS *that are controlled by the disabled* EMPLOYEE *or* PERSON*, if a health or safety* HAZARD *will not result from the presence or activities of the* SERVICE ANIMAL*;*

(4) *Pets in the common dining areas of* GROUP RESIDENCES *at times other than during meals if:*

(a) *Effective partitioning and self-closing doors separate the common dining areas from* FOOD *storage or* FOOD *preparation areas,*

(b) *Condiments,* EQUIPMENT*, and* UTENSILS *are stored in enclosed cabinets or removed from the common dining areas when pets are present, and*

(c) *Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; and*

(5) *In areas that are not used for* FOOD *preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly restricted, such as in a variety store that sells pets or a tourist park that displays animals.*

(C) *Live or dead* FISH *bait may be stored if contamination of* FOOD*; clean* EQUIPMENT*,* UTENSILS*, and* LINENS*; and unwrapped* SINGLE-SERVICE *and* SINGLE-USE ARTICLES *can not result.*

Chapter

7 Poisonous or Toxic Materials

Parts

7-1 LABELING AND IDENTIFICATION

Subparts

Original Containers

7-101.11 Identifying Information, Prominence.*

Containers of POISONOUS OR TOXIC MATERIALS and PERSONAL CARE ITEMS shall bear a legible manufacturer's label.

Working Containers

7-102.11 Common Name.*

Working containers used for storing POISONOUS OR TOXIC MATERIALS such as cleaners and SANITIZERS taken from bulk supplies shall be clearly and individually identified with the common name of the material.

7-2 OPERATIONAL SUPPLIES AND APPLICATIONS

Subparts

Storage

7-201.11 Separation.*

POISONOUS OR TOXIC MATERIALS shall be stored so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES by:

(A) Separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning;[s] and

(B) Locating the POISONOUS OR TOXIC MATERIALS in an area that is not above FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE or SINGLE-USE ARTICLES. *This paragraph does not apply to EQUIPMENT and UTENSIL cleaners and SANITIZERS that are stored in WAREWASHING areas for availability and convenience if the materials are stored to prevent contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.*

Presence and Use

7-202.11 Restriction.*

(A) Only those POISONOUS OR TOXIC MATERIALS that are required for the operation and maintenance of a FOOD ESTABLISHMENT, such as for the cleaning and SANITIZING of EQUIPMENT and UTENSILS and the control of insects and rodents, shall be allowed in a FOOD ESTABLISHMENT.[s]

(B) ¶ *(A) of this section does not apply to* PACKAGED POISONOUS OR TOXIC MATERIALS *that are for retail sale.*

7-202.12 Conditions of Use.*

POISONOUS OR TOXIC MATERIALS shall be:

(A) Used according to:

(1) LAW and this Code,

(2) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a FOOD ESTABLISHMENT,

(3) The conditions of certification, if certification is required, for use of the pest control materials, and

(4) Additional conditions that may be established by the REGULATORY AUTHORITY; and

(B) Applied so that:

(1) A HAZARD to EMPLOYEES or other PERSONS is not constituted, and

(2) Contamination including toxic residues due to drip, drain, fog, splash or spray on FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES is prevented, and for a restricted-use pesticide, this is achieved by:

(a) Removing the items,

(b) Covering the items with impermeable covers, or

(c) Taking other appropriate preventive actions, and

(d) Cleaning and SANITIZING EQUIPMENT and UTENSILS after the application.

(C) A RESTRICTED USE PESTICIDE shall be applied only by an applicator certified as defined in 7 USC 136(e) Certified Applicator, of the Federal Insecticide, Fungicide and Rodenticide Act, or a PERSON under the direct supervision of a certified applicator.

Container Prohibitions

7-203.11 Poisonous or Toxic Material Containers.*

A container previously used to store POISONOUS OR TOXIC MATERIALS may not be used to store, transport, or dispense FOOD.

Chemicals

7-204.11 Sanitizers, Criteria.*

Chemical SANITIZERS and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall meet the requirements specified in 21 CFR 178.1010 sanitizing solutions.

7-204.12 Chemicals for Washing Fruits and Vegetables, Criteria.*

Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the lye peeling of fruits and vegetables.

7-204.13 Boiler Water Additives, Criteria.*

Chemicals used as boiler water ADDITIVES shall meet the requirements specified in 21 CFR 173.310 Boiler Water Additives.

7-204.14 Drying Agents, Criteria.*

Drying agents used in conjunction with SANITIZATION shall:

(A) Contain only components that are listed as one of the following:

(1) Generally recognized as safe for use in FOOD as specified in 21 CFR 182 - Substances Generally Recognized as Safe, or 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe,

(2) Generally recognized as safe for the intended use as specified in 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe,

(3) APPROVED for use as a drying agent under a prior sanction specified in 21 CFR 181 - Prior-Sanctioned Food Ingredients,

(4) Specifically regulated as an indirect FOOD ADDITIVE for use as a drying agent as specified in 21 CFR Parts 175-178, or

(5) APPROVED for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles; and

(B) When SANITIZATION is with chemicals, the approval required under Subparagraph (A)(3) or (A)(5) of this section or the regulation as an indirect FOOD ADDITIVE required under Subparagraph (A)(4) of this section, shall be specifically for use with chemical SANITIZING solutions.

Lubricants

7-205.11 Incidental Food Contact, Criteria.*

Lubricants shall meet the requirements specified in 21 CFR 178.3570 Lubricants with incidental food contact, if they are used on FOOD-CONTACT SURFACES, on bearings and gears located on or within FOOD-CONTACT SURFACES, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into FOOD or onto FOOD-CONTACT SURFACES.

Pesticides

7-206.11 Restricted Use Pesticides, Criteria.*

RESTRICTED USE PESTICIDES specified under ¶ 7-202.12(C) shall meet the requirements specified in 40 CFR 152 Subpart I - Classification of Pesticides.

7-206.12 Rodent Bait Stations.*

Rodent bait shall be contained in a covered, tamper-resistant bait station.

7-206.13 Tracking Powders, Pest Control and Monitoring.*

(A) A tracking powder pesticide may not be used in a FOOD ESTABLISHMENT.

(B) If used, a nontoxic tracking powder such as talcum or flour may not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.[N]

Medicines

7-207.11 Restriction and Storage.*

(A) Only those medicines that are necessary for the health of EMPLOYEES shall be allowed in a FOOD ESTABLISHMENT. *This section does not apply to medicines that are stored or displayed for retail sale.*

(B) Medicines that are in a FOOD ESTABLISHMENT for the EMPLOYEES' use shall be labeled as specified under § 7-101.11 and located to prevent the contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.

7-207.12 Refrigerated Medicines, Storage.*

Medicines belonging to EMPLOYEES or to children in a day care center that require refrigeration and are stored in a FOOD refrigerator shall be:

(A) Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines; and

(B) Located so they are inaccessible to children.

First Aid Supplies

7-208.11 Storage.*

First aid supplies that are in a FOOD ESTABLISHMENT for the EMPLOYEES' use shall be:

(A) Labeled as specified under § 7-101.11;[S] and

(B) Stored in a kit or a container that is located to prevent the contamination of FOOD, EQUIPMENT, UTENSILS, and LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES.[S]

Other Personal Care Items

7-209.11 Storage.

Except as specified under §§ 7-207.12 and 7-208.11, EMPLOYEES shall store their PERSONAL CARE ITEMS in facilities as specified under ¶ 6-305.11(B).

7-3 STOCK AND RETAIL SALE

Subpart

7-301 Storage and Display

Storage and Display

7-301.11 Separation.*

POISONOUS OR TOXIC MATERIALS shall be stored and displayed for retail sale so they can not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES by:

(A) Separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning;[s] and

(B) Locating the POISONOUS OR TOXIC MATERIALS in an area that is not above FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE or SINGLE-USE ARTICLES.

Chapter

8 Compliance and Enforcement

Parts

8-1 CODE APPLICABILITY

Subparts

Use for Intended Purpose

8-101.10 Public Health Protection.

(A) The REGULATORY AUTHORITY shall apply this Code to promote its underlying purpose, as specified in § 1-102.10, of safeguarding public health and ensuring that FOOD is safe, unADULTERATED, and honestly presented when offered to the CONSUMER.

(B) In enforcing the provisions of this Code, the REGULATORY AUTHORITY shall assess existing facilities or EQUIPMENT that were in use before the effective date of this Code based on the following considerations:

(1) Whether the facilities or EQUIPMENT are in good repair and capable of being maintained in a sanitary condition;

(2) Whether FOOD-CONTACT SURFACES comply with Subpart 4-101;

(3) Whether the capacities of cooling, heating, and holding EQUIPMENT are sufficient to comply with § 4-301.11; and

(4) The existence of a documented agreement with the PERMIT HOLDER that the facilities or EQUIPMENT will be replaced as specified under ¶ 8-304.11(G) or upgraded or replaced as specified under ¶ 8-304.11(H).

Additional Requirements

8-102.10 Preventing Health Hazards, Provision for Conditions Not Addressed.

(A) If necessary to protect against public health HAZARDS or nuisances, the REGULATORY AUTHORITY may impose specific requirements in addition to the requirements contained in this Code that are authorized by LAW.

(B) The REGULATORY AUTHORITY shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation shall be provided to the PERMIT applicant or PERMIT HOLDER and a copy shall be maintained in the REGULATORY AUTHORITY'S file for the FOOD ESTABLISHMENT.

Variances

8-103.10 Modifications and Waivers.

The REGULATORY AUTHORITY may grant a VARIANCE by modifying or waiving the requirements of this Code if in the opinion of the REGULATORY AUTHORITY a health HAZARD or nuisance will not result from the VARIANCE. If a VARIANCE is granted, the REGULATORY AUTHORITY shall retain the information specified under § 8-103.11 in its records for the FOOD ESTABLISHMENT.

8-103.11 Documentation of Proposed Variance and Justification.

Before a VARIANCE from a requirement of this Code is APPROVED, the information that shall be provided by the PERSON requesting the VARIANCE and retained in the REGULATORY AUTHORITY'S file on the FOOD ESTABLISHMENT includes:

(A) A statement of the proposed VARIANCE of the Code requirement citing relevant Code section numbers;

(B) An analysis of the rationale for how the potential public health HAZARDS and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal; and

(C) A HACCP PLAN if required as specified under ¶ 8-201.13(A) that includes the information specified under § 8-201.14 as it is relevant to the VARIANCE requested.

8-103.12 Conformance with Approved Procedures.*

If the REGULATORY AUTHORITY grants a VARIANCE as specified in § 8-103.10, or a HACCP PLAN is otherwise required as specified under § 8-201.13, the PERMIT HOLDER shall:

(A) Comply with the HACCP PLANS and procedures that are submitted as specified under § 8-201.14 and APPROVED as a basis for the modification or waiver; and

(B) Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under ¶¶ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;

(1) Procedures for monitoring CRITICAL CONTROL POINTS,

(2) Monitoring of the CRITICAL CONTROL POINTS,

(3) Verification of the effectiveness of an operation or process, and

(4) Necessary corrective actions if there is failure at a CRITICAL CONTROL POINT.

8-2 PLAN SUBMISSION AND APPROVAL

Subparts

Facility and Operating Plans

8-201.11 When Plans Are Required.

A PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY properly prepared plans and specifications for review and approval before:

(A) The construction of a FOOD ESTABLISHMENT;

(B) The conversion of an existing structure for use as a FOOD ESTABLISHMENT; or

(C) The remodeling of a FOOD ESTABLISHMENT or a change of type of FOOD ESTABLISHMENT or FOOD operation as specified under ¶ 8-302.14(C) if the REGULATORY AUTHORITY determines that plans and specifications are necessary to ensure compliance with this Code.

8-201.12 Contents of the Plans and Specifications.

The plans and specifications for a FOOD ESTABLISHMENT, including a FOOD ESTABLISHMENT specified under § 8-201.13, shall include, as required by the REGULATORY AUTHORITY based on the type of operation, type of FOOD preparation, and FOODS prepared, the following information to demonstrate conformance with Code provisions:

(A) Intended menu;

(B) Anticipated volume of FOOD to be stored, prepared, and sold or served;

(C) Proposed layout, mechanical schematics, construction materials, and finish schedules;

(D) Proposed EQUIPMENT types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;

(E) Evidence that standard procedures that ensure compliance with the requirements of this Code are developed or are being developed; and

(F) Other information that may be required by the REGULATORY AUTHORITY for the proper review of the proposed construction, conversion or modification, and procedures for operating a FOOD ESTABLISHMENT.

8-201.13 When a HACCP Plan is Required.

(A) Before engaging in an activity that requires a HACCP PLAN, a PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY for approval a properly prepared HACCP PLAN as specified under § 8-201.14 and the relevant provisions of this Code if:

(1) Submission of a HACCP PLAN is required according to LAW;

(2) A VARIANCE is required as specified under § 3-502.11, ¶ 4-204.110(B), or Subparagraphs 3-203.12(B)(2)(b) or 3-401.11(D)(3); or

(3) The REGULATORY AUTHORITY determines that a FOOD preparation or processing method requires a VARIANCE based on a plan submittal specified under § 8-201.12, an inspectional finding, or a VARIANCE request.

(B) A PERMIT applicant or PERMIT HOLDER shall have a properly prepared HACCP PLAN as specified under § 3-502.12.

8-201.14 Contents of a HACCP Plan.

For a FOOD ESTABLISHMENT that is required under § 8-201.13 to have a HACCP PLAN, the plan and specifications shall indicate:

(A) A categorization of the types of POTENTIALLY HAZARDOUS FOODS that are specified in the menu such as soups and sauces, salads, and bulk, solid FOODS such as MEAT roasts, or of other FOODS that are specified by the REGULATORY AUTHORITY;

(B) A flow diagram by specific FOOD or category type identifying CRITICAL CONTROL POINTS and providing information on the following:

(1) Ingredients, materials, and EQUIPMENT used in the preparation of that FOOD, and

(2) Formulations or recipes that delineate methods and procedural control measures that address the FOOD safety concerns involved;

(C) FOOD EMPLOYEE and supervisory training plan that addresses the FOOD safety issues of concern;

(D) A statement of standard operating procedures for the plan under consideration including clearly identifying:

(1) Each CRITICAL CONTROL POINT,

(2) The CRITICAL LIMITS for each CRITICAL CONTROL POINT,

(3) The method and frequency for monitoring and controlling each CRITICAL CONTROL POINT by the FOOD EMPLOYEE designated by the PERSON IN CHARGE,

(4) The method and frequency for the PERSON IN CHARGE to routinely verify that the FOOD EMPLOYEE is following standard operating procedures and monitoring CRITICAL CONTROL POINTS,

(5) Action to be taken by the PERSON IN CHARGE if the CRITICAL LIMITS for each CRITICAL CONTROL POINT are not met, and

(6) Records to be maintained by the PERSON IN CHARGE to demonstrate that the HACCP PLAN is properly operated and managed; and

(E) Additional scientific data or other information, as required by the REGULATORY AUTHORITY, supporting the determination that FOOD safety is not compromised by the proposal.

Confidentiality

8-202.10 Trade Secrets.

The REGULATORY AUTHORITY shall treat as confidential in accordance with LAW, information that meets the criteria specified in LAW for a trade secret and is contained on inspection report forms and in the plans and specifications submitted as specified under §§ 8-201.12 and 8-201.14.

Construction Inspection and Approval

8-203.10 Preoperational Inspections.

The REGULATORY AUTHORITY shall conduct one or more preoperational inspections to verify that the FOOD ESTABLISHMENT is constructed and equipped in accordance with the APPROVED plans and APPROVED modifications of those plans, has established standard operating procedures as specified under ¶ 8-201.12(E), and is in compliance with LAW and this Code.

8-3 PERMIT TO OPERATE

Subparts

Requirement

8-301.11 Prerequisite for Operation.

A PERSON may not operate a FOOD ESTABLISHMENT without a valid PERMIT to operate issued by the REGULATORY AUTHORITY.

Application Procedure

8-302.11 Submission 30 Calendar Days Before Proposed Opening.

An applicant shall submit an application for a PERMIT at least 30 calendar days before the date planned for opening a FOOD ESTABLISHMENT or the expiration date of the current PERMIT for an existing facility.

8-302.12 Form of Submission.

A PERSON desiring to operate a FOOD ESTABLISHMENT shall submit to the REGULATORY AUTHORITY a written application for a PERMIT on a form provided by the REGULATORY AUTHORITY.

8-302.13 Qualifications and Responsibilities of Applicants.

To qualify for a PERMIT, an applicant shall:

(A) Be an owner of the FOOD ESTABLISHMENT or an officer of the legal ownership;

(B) Comply with the requirements of this Code;

(C) As specified under § 8-402.11, agree to allow access to the FOOD ESTABLISHMENT and to provide required information; and

(D) Pay the applicable PERMIT fees at the time the application is submitted.

8-302.14 Contents of the Application.

The application shall include:

(A) The name, birth date, mailing address, telephone number, and signature of the PERSON applying for the PERMIT and the name, mailing address, and location of the FOOD ESTABLISHMENT;

(B) Information specifying whether the FOOD ESTABLISHMENT is owned by an association, corporation, individual, partnership, or other legal entity;

(C) A statement specifying whether the FOOD ESTABLISHMENT:

(1) Is mobile or stationary and temporary or permanent, and

(2) Is an operation that includes one or more of the following:

(a) Prepares, offers for sale, or serves POTENTIALLY HAZARDOUS FOOD:

(i) Only to order upon a CONSUMER'S request,

(ii) In advance in quantities based on projected CONSUMER demand and discards FOOD that is not sold or served at an APPROVED frequency, or

(iii) Using time as the public health control as specified under § 3-501.19,

(b) Prepares POTENTIALLY HAZARDOUS FOOD in advance using a FOOD preparation method that involves two or more steps which may include combining POTENTIALLY HAZARDOUS ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing,

(c) Prepares FOOD as specified under Subparagraph (C)(2)(b) of this section for delivery to and consumption at a location off the PREMISES of the FOOD ESTABLISHMENT where it is prepared,

(d) Prepares FOOD as specified under Subparagraph (C)(2)(b) of this section for service to a HIGHLY SUSCEPTIBLE POPULATION,

(e) Prepares only FOOD that is not POTENTIALLY HAZARDOUS, or

(f) Does not prepare, but offers for sale only prePACKAGED FOOD that is not POTENTIALLY HAZARDOUS;

(D) The name, title, address, and telephone number of the PERSON directly responsible for the FOOD ESTABLISHMENT;

(E) The name, title, address, and telephone number of the PERSON who functions as the immediate supervisor of the PERSON specified under ¶ (D) of this section such as the zone, district, or regional supervisor;

(F) The names, titles, and addresses of:

(1) The PERSONS comprising the legal ownership as specified under ¶ (B) of this section including the owners and officers, and

(2) The local resident agent if one is required based on the type of legal ownership;

(G) A statement signed by the applicant that:

(1) Attests to the accuracy of the information provided in the application, and

(2) Affirms that the applicant will:

(a) Comply with this Code, and

(b) Allow the REGULATORY AUTHORITY access to the establishment as specified under § 8-402.11 and to the records specified under §§ 3-203.12 and 5-205.13 and Subparagraph 8-201.14(D)(6); and

(H) Other information required by the REGULATORY AUTHORITY.

Issuance

8-303.10 New, Converted, or Remodeled Establishments.

For FOOD ESTABLISHMENTS that are required to submit plans as specified under § 8-201.11 the REGULATORY AUTHORITY shall issue a PERMIT to the applicant after:

(A) A properly completed application is submitted;

(B) The required fee is submitted;

(C) The required plans, specifications, and information are reviewed and APPROVED; and

(D) A preoperational inspection as specified in § 8-203.10 shows that the establishment is built or remodeled in accordance with the APPROVED plans and specifications and that the establishment is in compliance with this Code.

8-303.20 Existing Establishments, Permit Renewal, and Change of Ownership.

The REGULATORY AUTHORITY may renew a PERMIT for an existing FOOD ESTABLISHMENT or may issue a PERMIT to a new owner of an existing FOOD ESTABLISHMENT after a properly completed application is submitted, reviewed, and APPROVED, the fees are paid, and an inspection shows that the establishment is in compliance with this Code.

8-303.30 Denial of Application for Permit, Notice.

If an application for a PERMIT to operate is denied, the REGULATORY AUTHORITY shall provide the applicant with a notice that includes:

(A) The specific reasons and Code citations for the PERMIT denial;

(B) The actions, if any, that the applicant must take to qualify for a PERMIT; and

(C) Advisement of the applicant's right of appeal and the process and time frames for appeal that are provided in LAW.

Conditions of Retention

8-304.10 Responsibilities of the Regulatory Authority.

(A) At the time a PERMIT is first issued, the REGULATORY AUTHORITY shall provide to the PERMIT HOLDER a copy of this Code so that the PERMIT HOLDER is notified of the compliance requirements and the conditions of retention, as specified under § 8-304.11, that are applicable to the PERMIT.

(B) *Failure to provide the information specified in ¶ (A) of this section does not prevent the REGULATORY AUTHORITY from taking authorized action or seeking remedies if the PERMIT HOLDER fails to comply with this Code or an order, warning, or directive of the REGULATORY AUTHORITY.*

8-304.11 Responsibilities of the Permit Holder.

Upon acceptance of the PERMIT issued by the REGULATORY AUTHORITY, the PERMIT HOLDER in order to retain the PERMIT shall:

(A) Post the PERMIT in a location in the FOOD ESTABLISHMENT that is conspicuous to CONSUMERS;

(B) Comply with the provisions of this Code including the conditions of a granted VARIANCE as specified under § 8-103.12, and APPROVED plans as specified under § 8-201.12;

(C) If a FOOD ESTABLISHMENT is required under § 8-201.13 to operate under a HACCP PLAN, comply with the plan as specified under § 8-103.12;

(D) Immediately contact the REGULATORY AUTHORITY to report an illness of an EMPLOYEE as specified under § 2-201.15;

(E) Immediately discontinue operations and notify the REGULATORY AUTHORITY if an IMMINENT HEALTH HAZARD may exist as specified under § 8-404.11;

(F) Allow representatives of the REGULATORY AUTHORITY access to the FOOD ESTABLISHMENT as specified under § 8-402.11;

(G) Except as specified under ¶ (H) of this section, replace existing facilities and EQUIPMENT specified in § 8-101.10 with facilities and EQUIPMENT that comply with this Code if:

(1) The REGULATORY AUTHORITY directs the replacement because the facilities and EQUIPMENT constitute a public health HAZARD or nuisance or no longer comply with the criteria upon which the facilities and EQUIPMENT were accepted,

(2) The REGULATORY AUTHORITY directs the replacement of the facilities and EQUIPMENT because of a change of ownership, or

(3) The facilities and EQUIPMENT are replaced in the normal course of operation;

(H) Upgrade or replace refrigeration EQUIPMENT as specified under ¶ 3-501.16(C), if the circumstances specified under Subparagraphs (G)(1)-(3) of this section do not occur first, and 5 years pass after the REGULATORY AUTHORITY adopts this Code;

(I) Comply with directives of the REGULATORY AUTHORITY including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the REGULATORY AUTHORITY in regard to the PERMIT HOLDER'S FOOD ESTABLISHMENT or in response to community emergencies;

(J) Accept notices issued and served by the REGULATORY AUTHORITY according to LAW; and

(K) Be subject to the administrative, civil, injunctive, and criminal remedies authorized in LAW for failure to comply with this Code or a directive of the REGULATORY AUTHORITY, including time

frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.

8-304.20 Permits Not Transferable.

A PERMIT may not be transferred from one PERSON to another PERSON, from one FOOD ESTABLISHMENT to another, or from one type of operation to another if the FOOD operation changes from the type of operation specified in the application as specified under ¶ 8-302.14(C) and the change in operation is not APPROVED.

8-4 INSPECTION AND CORRECTION OF VIOLATIONS

Subparts

Frequency

8-401.10 Establishing Inspection Interval.

(A) Except as specified in ¶¶ (B) and (C) of this section, the REGULATORY AUTHORITY shall inspect a FOOD ESTABLISHMENT at least once every 6 months.

(B) *The REGULATORY AUTHORITY may increase the interval between inspections beyond 6 months if:*

(1) *The FOOD ESTABLISHMENT is fully operating under an APPROVED and validated HACCP PLAN as specified under § 8-201.14 and ¶¶ 8-103.12(A) and (B);*

(2) *The FOOD ESTABLISHMENT is assigned a less frequent inspection frequency based on a written risk-based inspection schedule that is being uniformly applied throughout the jurisdiction and at least once every 6 months the establishment*

is contacted by telephone or other means by the REGULATORY AUTHORITY *to ensure that the establishment manager and the nature of* FOOD *operation are not changed; or*

(3) *The establishment's operation involves only coffee service and other un*PACKAGED *or pre*PACKAGED FOOD *that is not* POTENTIALLY HAZARDOUS *such as carbonated* BEVERAGES *and snack* FOOD *such as chips, nuts, popcorn, and pretzels.*

(C) The REGULATORY AUTHORITY shall periodically inspect throughout its PERMIT period a TEMPORARY FOOD ESTABLISHMENT that prepares, sells, or serves unPACKAGED POTENTIALLY HAZARDOUS FOOD and that:

(1) Has improvised rather than permanent facilities or EQUIPMENT for accomplishing functions such as handwashing, FOOD preparation and protection, FOOD temperature control, WAREWASHING, providing DRINKING WATER, waste retention and disposal, and insect and rodent control; or

(2) Has inexperienced FOOD EMPLOYEES.

8-401.20 Performance- and Risk-Based.

Within the parameters specified in § 8-401.10, the REGULATORY AUTHORITY shall prioritize, and conduct more frequent inspections based upon its assessment of a FOOD ESTABLISHMENT'S history of compliance with this Code and the establishment's potential as a vector of foodborne illness by evaluating:

(A) Past performance, for nonconformance with Code or HACCP PLAN requirements that are critical;

(B) Past performance, for numerous or repeat violations of Code or HACCP PLAN requirements that are noncritical;

(C) Past performance, for complaints investigated and found to be valid;

(D) The HAZARDS associated with the particular FOODS that are prepared, stored, or served;

(E) The type of operation including the methods and extent of FOOD storage, preparation, and service;

(F) The number of people served; and

(G) Whether the population served is a HIGHLY SUSCEPTIBLE POPULATION.

Access

8-402.11 Allowed at Reasonable Times after Due Notice.

After the REGULATORY AUTHORITY presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the PERSON IN CHARGE shall allow the REGULATORY AUTHORITY to determine if the FOOD ESTABLISHMENT is in compliance with this Code by allowing access to the establishment, allowing inspection, and providing information and records specified in this Code and to which the REGULATORY AUTHORITY is entitled according to LAW, during the FOOD ESTABLISHMENT'S hours of operation and other reasonable times.

8-402.20 Refusal, Notification of Right to Access, and Final Request for Access.

If a PERSON denies access to the REGULATORY AUTHORITY, the REGULATORY AUTHORITY shall:

(A) Inform the PERSON that:

(1) The PERMIT HOLDER is required to allow access to the REGULATORY AUTHORITY as specified under § 8-402.11 of this Code,

(2) Access is a condition of the acceptance and retention of a FOOD ESTABLISHMENT PERMIT to operate as specified under ¶ 8-304.11(F), and

(3) If access is denied, an order issued by the appropriate authority allowing access, hereinafter referred to as an inspection order, may be obtained according to LAW; and

(B) Make a final request for access.

8-402.30 Refusal, Reporting.

If after the REGULATORY AUTHORITY presents credentials and provides notice as specified under § 8-402.11, explains the

authority upon which access is requested, and makes a final request for access as specified in § 8-402.20, the PERSON IN CHARGE continues to REFUSE access, the REGULATORY AUTHORITY shall provide details of the denial of access on an inspection report form.

8-402.40 Inspection Order to Gain Access.

If denied access to a FOOD ESTABLISHMENT for an authorized purpose and after complying with § 8-402.20, the REGULATORY AUTHORITY may issue, or apply for the issuance of, an inspection order to gain access as provided in LAW.

Report of Findings

8-403.10 Documenting Information and Observations.

The REGULATORY AUTHORITY shall document on an inspection report form:

(A) Administrative information about the FOOD ESTABLISHMENT'S legal identity, street and mailing addresses, type of establishment and operation as specified under ¶ 8-302.14(C), inspection date, and other information such as type of water supply and SEWAGE disposal, status of the PERMIT, and personnel certificates that may be required; and

(B) Specific factual observations of violative conditions or other deviations from this Code that require correction by the PERMIT HOLDER including:

(1) Failure of the PERSON IN CHARGE to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this Code specified under § 2-102.11,

(2) Failure of FOOD EMPLOYEES and the PERSON IN CHARGE to demonstrate their knowledge of their responsibility to report a disease or medical condition as specified under §§ 2-201.14 and 2-201.15,

(3) Nonconformance with CRITICAL ITEMS of this Code,

(4) Failure of the appropriate FOOD EMPLOYEES to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and

corrective action practices required by the REGULATORY AUTHORITY as specified under § 8-103.12,

(5) Failure of the PERSON IN CHARGE to provide records required by the REGULATORY AUTHORITY for determining conformance with a HACCP PLAN as specified under Subparagraph 8-201.14(D)(6), and

(6) Nonconformance with CRITICAL LIMITS of a HACCP PLAN.

8-403.20 Specifying Time Frame for Corrections.

The REGULATORY AUTHORITY shall specify on the inspection report form the time frame for correction of the violations as specified under §§ 8-404.11, 8-405.11, and 8-406.11.

8-403.30 Issuing Report and Obtaining Acknowledgment of Receipt.

At the conclusion of the inspection and according to LAW, the REGULATORY AUTHORITY shall provide a copy of the completed inspection report and the notice to correct violations to the PERMIT HOLDER or to the PERSON IN CHARGE, and request a signed acknowledgment of receipt.

8-403.40 Refusal to Sign Acknowledgment.

The REGULATORY AUTHORITY shall:

(A) Inform a PERSON who declines to sign an acknowledgment of receipt of inspectional findings as specified in § 8-403.30 that:

(1) An acknowledgment of receipt is not an agreement with findings,

(2) Refusal to sign an acknowledgment of receipt will not affect the PERMIT HOLDER'S obligation to correct the violations noted in the inspection report within the time frames specified, and

(3) A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the REGULATORY AUTHORITY'S historical record for the FOOD ESTABLISHMENT; and

(B) Make a final request that the PERSON IN CHARGE sign an acknowledgment receipt of inspectional findings.

8-403.50 Public Information.

Except as specified in § 8-202.10, the REGULATORY AUTHORITY shall treat the inspection report as a public document and shall make it available for disclosure to a PERSON who requests it as provided in LAW.

Imminent Health Hazard

8-404.11 Ceasing Operations and Reporting.

(A) Except as specified in ¶ (B) of this section, a PERMIT HOLDER shall immediately discontinue operations and notify the REGULATORY AUTHORITY if an IMMINENT HEALTH HAZARD may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, SEWAGE backup, misuse of POISONOUS OR TOXIC MATERIALS, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health.

(B) *A PERMIT HOLDER need not discontinue operations in an area of an establishment that is unaffected by the IMMINENT HEALTH HAZARD.*

8-404.12 Resumption of Operations.

If operations are discontinued as specified under § 8-404.11 or otherwise according to LAW, the PERMIT HOLDER shall obtain approval from the REGULATORY AUTHORITY before resuming operations.

Critical Violation

8-405.11 Timely Correction.

(A) Except as specified in ¶ (B) of this section, a PERMIT HOLDER shall at the time of inspection correct a critical violation of this Code and implement corrective actions for a HACCP PLAN provision that

is not in compliance with its CRITICAL LIMIT.

(B) *Considering the nature of the potential HAZARD involved and the complexity of the corrective action needed, the REGULATORY AUTHORITY may agree to or specify a longer time frame, not to exceed 10 calendar days after the inspection, for the PERMIT HOLDER to correct critical Code violations or HACCP PLAN deviations.*

8-405.20 Verification and Documentation of Correction.

(A) After observing at the time of inspection a correction of a critical violation or deviation, the REGULATORY AUTHORITY shall enter the violation and information about the corrective action on the inspection report.

(B) As specified under ¶ 8-405.11(B), after receiving notification that the PERMIT HOLDER has corrected a critical violation or HACCP PLAN deviation, or at the end of the specified period of time, the REGULATORY AUTHORITY shall verify correction of the violation, document the information on an inspection report, and enter the report in the REGULATORY AUTHORITY'S records.

Noncritical Violation

8-406.11 Time Frame for Correction.

(A) Except as specified in ¶ (B) of this section, the PERMIT HOLDER shall correct noncritical violations by a date and time agreed to or specified by the REGULATORY AUTHORITY but no later than 90 calendar days after the inspection.

(B) *The REGULATORY AUTHORITY may approve a compliance schedule that extends beyond the time limits specified under ¶ (A) of this section if a written schedule of compliance is submitted by the PERMIT HOLDER and no health HAZARD exists or will result from allowing an extended schedule for compliance.*

8-5 PREVENTION OF FOODBORNE DISEASE TRANSMISSION BY EMPLOYEES

Subpart

8-501 Investigation and Control

Investigation and Control

8-501.10 Obtaining Information: Personal History of Illness, Medical Examination, and Specimen Analysis.

The REGULATORY AUTHORITY shall act when it has reasonable cause to believe that a FOOD EMPLOYEE has possibly transmitted disease; may be infected with a disease in a communicable form that is transmissible through FOOD; may be a carrier of infectious agents that cause a disease that is transmissible through FOOD; or is affected with a boil, an infected wound, or acute respiratory infection, by:

(A) Securing a confidential medical history of the EMPLOYEE suspected of transmitting disease or making other investigations as deemed appropriate; and

(B) Requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected EMPLOYEE and other EMPLOYEES.

8-501.20 Restriction or Exclusion of Food Employee, or Summary Suspension of Permit.

Based on the findings of an investigation related to a FOOD EMPLOYEE who is suspected of being infected or diseased, the REGULATORY AUTHORITY may issue an order to the suspected FOOD EMPLOYEE or PERMIT HOLDER instituting one or more of the following control measures:

(A) Restricting the FOOD EMPLOYEE'S services to specific areas and tasks in a FOOD ESTABLISHMENT that present no risk of transmitting the disease;

(B) Excluding the FOOD EMPLOYEE from a FOOD ESTABLISHMENT; or

(C) Closing the FOOD ESTABLISHMENT by summarily suspending a PERMIT to operate in accordance with LAW.

8-501.30 Restriction or Exclusion Order: Warning or Hearing Not Required, Information Required in Order.

Based on the findings of the investigation as specified in § 8-501.10 and to control disease transmission, the REGULATORY AUTHORITY may issue an order of restriction or exclusion to a suspected FOOD EMPLOYEE or the PERMIT HOLDER without prior warning, notice of a hearing, or a hearing if the order:

(A) States the reasons for the restriction or exclusion that is ordered;

(B) States the evidence that the FOOD EMPLOYEE or PERMIT HOLDER shall provide in order to demonstrate that the reasons for the restriction or exclusion are eliminated;

(C) States that the suspected FOOD EMPLOYEE or the PERMIT HOLDER may request an appeal hearing by submitting a timely request as provided in LAW; and

(D) Provides the name and address of the REGULATORY AUTHORITY representative to whom a request for an appeal hearing may be made.

8-501.40 Release of Food Employee from Restriction or Exclusion.

The REGULATORY AUTHORITY shall release a FOOD EMPLOYEE from restriction or exclusion according to LAW and the following conditions:

(A) A FOOD EMPLOYEE who was infected with ***Salmonella* Typhi** if the FOOD EMPLOYEE'S stools are negative for ***S*. Typhi** based on testing of at least 3 consecutive stool specimen cultures that are taken:

(1) Not earlier than 1 month after onset,

(2) At least 48 hours after discontinuance of antibiotics, and

(3) At least 24 hours apart; and

(B) If one of the cultures taken as specified in ¶ (A) of this section is positive, repeat cultures are taken at intervals of 1 month until at least 3 consecutive negative stool specimen cultures are obtained.

(C) A FOOD EMPLOYEE who was infected with ***Shigella*** spp. or ***Escherichia coli*** O157:H7 if the EMPLOYEE'S stools are negative for ***Shigella*** spp. or ***E***. ***coli*** O157:H7 based on testing of 2 consecutive stool specimen cultures that are taken:

(1) Not earlier than 48 hours after discontinuance of antibiotics; and

(2) At least 24 hours apart.

(D) A FOOD EMPLOYEE who was infected with hepatitis A virus if:

(1) Symptoms cease; or

(2) At least 2 blood tests show falling liver enzymes.

Annex

1 Compliance and Enforcement

1. PURPOSE

The purpose of this Annex is to set forth provisions, in codified form, that provide a full array of enforcement mechanisms while recognizing the diverse statutes and regulations that currently govern the operations of the thousands of state and local regulatory agencies.

2. EXPLANATION

State or local statutes, regulations, and ordinances vary in their design, specificity, and degree of comprehensiveness in that they may:

(A) Contain authorities that provide the basis for certain post-inspection compliance strategies but remain silent with respect to other enforcement mechanisms;

(B) Include specific requirements that are different from those provided in this Annex; and

(C) Be structured so that provisions such as administrative procedures are embodied in sections of the law that transcend and are separate from those governing food establishments.

Consequently, in this document a deliberate attempt is made to extract those provisions that could conceptually be adopted as an extension of Chapter 8 if they were compatible with existing, governing state and local statutes. The extracted provisions are numbered to sequentially follow Chapter 8 but are placed in this Annex so that regulatory agencies can revise them to be consistent with their statutes and their needs as discussed in the Recommendation, below.

It is anticipated that adoption of this Code will be facilitated by the fact that:

(A) The compliance provisions of Chapter 8 that should be an integral part of state or local food regulations are part of the text of the Code; and

(B) The administrative and judicial enforcement provisions that are critical to the framework of a food regulatory program, but that may be repetitive or discrepant when compared to state or local statutes, are separated in this Annex.

3. PRINCIPLE

Although the situations necessitating escalated enforcement actions comprise a small percentage of those encountered by the regulator, a full spectrum of enforcement tools must be available where immediate hazards exist, or where compliance is not obtained voluntarily. Thus, a jurisdiction must have in place both the necessary statutory framework that includes a broad-based, well-defined enforcement component and regulations that specify the requirements within those legal authorities. It is imperative that there be clearly stated and legally sound rules that include the criteria for compliance and enforcement, the responsibilities of all parties, sanctions for noncompliance, and due process guarantees.

4. RECOMMENDATION

FDA recommends that agencies assess their statutory provisions that pertain to food establishments in light of this Annex and consider proposing changes to their statutes and regulations where they determine that provisions contained within this Annex will strengthen their programs. Such an assessment may involve reviewing problems encountered in attempts to prosecute under existing state or local provisions; considering comments received by the regulatory authority about its enforcement process; consulting with staff and legal counsel to identify gaps or weaknesses in the provisions; comparing provisions with sister agencies for comprehensiveness, equity, and uniformity; and seeking input from outside sources that have experience in taking, or being the subject of, enforcement actions.

Appropriate wording and cross referencing changes to the provisions in this Annex may be necessary, based on whether they are adopted as statutes or regulations. Modifications to the adoption forms (Forms #4 and #5 in Annex 7) may also be necessary based on that decision.

Parts

8-6 CONSTITUTIONAL PROTECTION

Subparts

Procedural Safeguards

8-601.10 Preservation of Rights.

The REGULATORY AUTHORITY shall justly apply the remedies according to LAW and this Code, to preserve the rights to equal protection and due process of a PERSON to whom the remedies are applied.

Judicial Review

8-602.10 Rights of Recipients of Orders or Decisions.

A recipient of a REGULATORY AUTHORITY order or decision may file a petition for judicial review in a court of competent jurisdiction after available administrative appeal remedies are exhausted.

8-7 NOTICES

Subpart

8-701 Service of Notice

Service of Notice

8-701.10 Proper Methods.

(Note: Adoption of this section provides the basis for serving notice of inspectional findings as specified in § 8-403.30 and would be cited there.)

A notice issued in accordance with this Code shall be considered to be properly served if it is served by one of the following methods:

(A) The notice is personally served by the REGULATORY AUTHORITY, a LAW enforcement officer, or a PERSON authorized to serve a civil process to the PERMIT HOLDER, the PERSON IN CHARGE, or PERSON operating a FOOD ESTABLISHMENT without a PERMIT;

(B) The notice is sent by the REGULATORY AUTHORITY to the last known address of the PERMIT HOLDER or the PERSON operating a FOOD ESTABLISHMENT without a PERMIT, by registered or certified mail or by other public means so that a written acknowledgment of receipt may be acquired; or

(C) The notice is provided by the REGULATORY AUTHORITY in accordance with another manner of service authorized in LAW.

8-701.20 Restriction or Exclusion Order, Hold Order or Summary Suspension.

An EMPLOYEE restriction or exclusion order, an order to hold and not distribute FOOD, such as a hold, detention, embargo, or seizure order which is hereinafter referred to as a hold order, or a summary suspension order shall be:

(A) Served as specified in ¶ 8-701.10(A); or

(B) Clearly posted by the REGULATORY AUTHORITY at a public entrance to the FOOD ESTABLISHMENT and a copy of the notice sent by first class mail to the PERMIT HOLDER or to the owner or custodian of the FOOD, as appropriate.

8-701.30 When Notice is Effective.

Service is effective at the time of the notice's receipt or if service is made as specified in ¶ 8-701.20(B), at the time of the notice's posting.

8-701.40 Proof of Proper Service.

Proof of proper service may be made by affidavit of the PERSON making service or by admission of the receipt signed by the PERMIT HOLDER, the PERSON operating a FOOD ESTABLISHMENT without a PERMIT to operate, or an authorized agent.

8-8 REMEDIES

Subparts

Criteria for Seeking Remedies

8-801.10 Conditions Warranting Remedy.

The REGULATORY AUTHORITY may seek an administrative or judicial remedy to achieve compliance with the provisions of this Code if a PERSON operating a FOOD ESTABLISHMENT or EMPLOYEE:

(A) Fails to have a valid PERMIT to operate a FOOD ESTABLISHMENT as specified under § 8-301.11;

(B) Violates any term or condition of a PERMIT as specified under § 8-304.11;

(C) Allows serious or repeated code violations to remain uncorrected beyond time frames for correction APPROVED, directed, or ordered by the REGULATORY AUTHORITY under ¶¶ 8-405.11(A) and (B), and ¶¶ 8-406.11(A) and (B);

(D) Fails to comply with a REGULATORY AUTHORITY order issued as specified in § 8-501.20 concerning an EMPLOYEE suspected of having a disease transmissible through FOOD by infected PERSONS;

(E) Fails to comply with a hold order as specified in §§ 8-701.20 and 8-803.10;

(F) Fails to comply with an order issued as a result of a hearing for an administrative remedy as specified in §§ 8-806.30 or 8-806.40; or

(G) Fails to comply with a summary suspension order issued by the REGULATORY AUTHORITY as specified in §§ 8-701.20 and 8-804.10.

Administrative Inspection Orders

8-802.10 Gaining Access to Premises and Records.

(Note: Adoption of this section provides the basis for Subparagraph 8-402.20(A)(3) and § 8-402.40 and would be cited there.)

The REGULATORY AUTHORITY may order access for one or more of the following purposes, subject to LAW for gaining access:

(A) If admission to the PREMISES of a FOOD ESTABLISHMENT is denied or other circumstances exist that would justify an inspection order under LAW, to make an inspection including taking photographs;

(B) To examine and sample the FOOD; and

(C) To examine the records on the PREMISES relating to FOOD purchased, received, or used by the FOOD ESTABLISHMENT.

8-802.20 Contents of Inspection Order.

The REGULATORY AUTHORITY'S inspection order shall:

(A) Stipulate that access be allowed on or to the described PREMISES, FOOD, or records under the order's provisions;

(B) Provide a description that specifies the PREMISES, FOOD, or records subject to the order; and

(C) Specify areas to be accessed and activities to be performed.

Holding, Examination, and Destruction of Food

8-803.10 Hold Order, Justifying Conditions and Removal of Food.

(Note: Adoption of this section provides the basis for ¶ 3-202.18(B) and would be cited there.)

(A) According to time limits imposed by LAW, the REGULATORY AUTHORITY may place a hold order on a FOOD that:

(1) Originated from an unAPPROVED source;

(2) May be unsafe, ADULTERATED, or not honestly presented;

(3) Is not labeled according to LAW, or, if raw MOLLUSCAN SHELLFISH, is not tagged or labeled according to LAW; or

(4) Is otherwise not in compliance with this Code.

(B) If the REGULATORY AUTHORITY has reasonable cause to believe that the hold order will be violated, or finds that the order is violated, the REGULATORY AUTHORITY may remove the FOOD that is subject to the order to a place of safekeeping.

8-803.20 Hold Order, Warning or Hearing Not Required.

The REGULATORY AUTHORITY may issue a hold order to a PERMIT HOLDER or to a PERSON who owns or controls the FOOD, as specified in § 8-701.20, without prior warning, notice of a hearing, or a hearing on the hold order.

8-803.30 Hold Order, Contents.

The hold order notice shall:

(A) State that FOOD subject to the order may not be used, sold, moved from the FOOD ESTABLISHMENT, or destroyed without a written release of the order from the REGULATORY AUTHORITY;

(B) State the specific reasons for placing the FOOD under the hold order with reference to the applicable provisions of this Code and the HAZARD or adverse effect created by the observed condition;

(C) Completely identify the FOOD subject to the hold order by the common name, the label information, a container description, the quantity, REGULATORY AUTHORITY'S tag or identification information, and location;

(D) State that the PERMIT HOLDER has the right to an appeal hearing and may request a hearing by submitting a timely request as specified in §§ 8-805.10 and 8-805.20;

(E) State that the REGULATORY AUTHORITY may order the destruction of the FOOD if a timely request for an appeal hearing is not received; and

(F) Provide the name and address of the REGULATORY AUTHORITY representative to whom a request for an appeal hearing may be made.

8-803.40 Hold Order, Official Tagging of Food.

(A) The REGULATORY AUTHORITY shall securely place an official tag or label on the FOOD or containers or otherwise conspicuously identify FOOD subject to the hold order.

(B) The tag or other method used to identify a FOOD that is the subject of a hold order shall include a summary of the provisions specified in § 8-803.10 and shall be signed and dated by the REGULATORY AUTHORITY.

8-803.51 Hold Order, Food May Not Be Used or Moved.

(A) Except as specified in ¶ (B) of this section, a FOOD placed under a hold order may not be used, sold, served, or moved from the establishment by any PERSON.

(B) *The REGULATORY AUTHORITY may allow the PERMIT HOLDER the opportunity to store the FOOD in an area of the FOOD ESTABLISHMENT if the FOOD is protected from subsequent deterioration and the storage does not restrict operations of the establishment.*

8-803.60 Examining, Sampling, and Testing Food.

The REGULATORY AUTHORITY may examine, sample, and test FOOD in order to determine its compliance with this Code.

8-803.70 Hold Order, Removing the Official Tag.

Only the REGULATORY AUTHORITY may remove hold order tags, labels, or other identification from FOOD subject to a hold order.

8-803.80 Destroying or Denaturing Food.

If a hold order is sustained upon appeal or if a timely request for an appeal hearing is not filed, the REGULATORY AUTHORITY may order the PERMIT HOLDER or other PERSON who owns or has custody of the FOOD to bring the FOOD into compliance with this Code or to destroy or denature the FOOD under the REGULATORY AUTHORITY'S supervision.

8-803.90 Releasing Food from Hold Order.

The REGULATORY AUTHORITY shall issue a notice of release from a hold order and shall remove hold tags, labels, or other identification from the FOOD if the hold order is vacated.

Summary Permit Suspension

8-804.10 Conditions Warranting Action.

The REGULATORY AUTHORITY may summarily suspend a PERMIT to operate a FOOD ESTABLISHMENT if it determines through inspection, or examination of EMPLOYEES, FOOD, records, or other means as specified in this Code, that an IMMINENT HEALTH HAZARD exists.

8-804.20 Summary Suspension, Warning or Hearing Not Required.

The REGULATORY AUTHORITY may summarily suspend a PERSON'S PERMIT as specified in § 8-804.10 by providing written notice as specified in § 8-701.20 of the summary suspension to the PERMIT HOLDER or PERSON IN CHARGE, without prior warning, notice of a hearing, or a hearing.

8-804.30 Contents of the Notice.

A summary suspension notice shall state:

(A) That the FOOD ESTABLISHMENT PERMIT is immediately suspended and that all FOOD operations shall immediately cease;

(B) The reasons for summary suspension with reference to the provisions of this Code that are in violation;

(C) The name and address of the REGULATORY AUTHORITY representative to whom a written request for reinspection may be made and who may certify that reasons for the suspension are eliminated; and

(D) That the PERMIT HOLDER may request an appeal hearing by submitting a timely request as specified in §§ 8-805.10 and 8-805.20.

8-804.40 Time Frame for Reinspection.

After receiving a written request from the PERMIT HOLDER stating that the conditions cited in the summary suspension order no longer exist, the REGULATORY AUTHORITY shall conduct a reinspection of the FOOD ESTABLISHMENT for which the PERMIT was summarily suspended within 2 business days, which means 2 days during which the REGULATORY AUTHORITY'S office is open to the public.

8-804.50 Term of Suspension, Reinstatement of Permit.

(A) A summary suspension shall remain in effect until the conditions cited in the notice of suspension no longer exist and their elimination has been confirmed by the REGULATORY AUTHORITY through reinspection and other means as appropriate.

(B) The suspended PERMIT shall be reinstated immediately if the REGULATORY AUTHORITY determines that the public health HAZARD or nuisance no longer exists. A notice of reinstatement shall be provided to the PERMIT HOLDER or PERSON IN CHARGE.

8-805.10 Response to Notice of Hearing or Request for Hearing, Basis and Time Frame.

(Note: Adoption of this section provides the basis for ¶¶ 8-303.30(C) and 8-501.30(C). ¶¶ 8-805.10(C) and (D) would be cited there.)

(A) A PERSON who receives a notice of hearing for an administrative remedy as specified in Part 8-7, § 8-801.10, or ¶ 8-805.30(A) and elects to respond to the notice shall file a response to notice as specified in § 8-805.20 within 7 calendar days after service.

(B) A PERMIT applicant may request a hearing regarding the disposition of an application for a new or revised PERMIT if the REGULATORY AUTHORITY does not issue or deny the PERMIT within the time frame specified in LAW.

(C) A PERMIT HOLDER may request a hearing to address concerns about the REGULATORY AUTHORITY'S denial of application for a PERMIT or request for a VARIANCE, or compliance actions, except that a hearing request does not stay the REGULATORY AUTHORITY'S restriction or exclusion of EMPLOYEES specified in §§ 8-501.10 - 8-501.40, a hold order specified in § 8-803.10, or the imposition of a summary suspension specified in § 8-804.10.

(D) A PERSON desiring a hearing in response to a denial of an application for PERMIT or an adverse administrative determination shall submit a hearing request to the REGULATORY AUTHORITY within 10 calendar days of the date of the denial, inspection, or compliance action, unless the REGULATORY AUTHORITY specifies in certain situations that the request shall be submitted within a shorter period of time.

8-805.20 Response to a Notice of Hearing or Request for Hearing, Required Form and Contents.

A response to a hearing notice or a request for hearing as specified in § 8-805.10 shall be in written form and contain the following:

(A) If a response to notice of hearing,

(1) An admission or denial of each allegation of fact;

(2) A statement as to whether the respondent waives the right to a hearing; and may also contain

(3) A statement of defense, mitigation, or explanation concerning any allegation of fact; and

(4) A request to the REGULATORY AUTHORITY for a settlement of the proceeding by consent agreement, if the REGULATORY AUTHORITY will provide this opportunity.

(B) If a request for hearing,

(1) A statement of the issue of fact specified in ¶ 8-805.30(B) for which the hearing is requested; and

(2) A statement of defense, mitigation, denial, or explanation concerning each allegation of fact.

(C) If either a response to notice of hearing or a request for a hearing,

(1) A statement indicating whether the presence of witnesses for the REGULATORY AUTHORITY is required; and

(2) The name and address of the respondent's or requester's legal counsel, if any.

8-805.30 Provided Upon Request.

The REGULATORY AUTHORITY shall hold hearings according to LAW and the provisions of this Code:

(A) As determined necessary by LAW or the REGULATORY AUTHORITY to accomplish the purpose and intent of this Code specified in § 8-101.10; and

(B) As requested by a PERMIT applicant or a PERMIT HOLDER if:

(1) Requested as specified in § 8-805.10, and

(2) The request demonstrates that there is a genuine and material issue of fact that justifies that a hearing be held.

8-805.40 Provided in Accordance with Law.

Hearings shall be conducted according to LAW, administrative procedures, and this Code.

8-805.50 Timeliness, Appeal Proceeding Within 5 Business Days, Other Proceeding Within 30 Calendar Days.

(A) The REGULATORY AUTHORITY shall afford a hearing:

(1) Except as provided in ¶ (B) of this section, within 5 business days after receiving a written request for an appeal hearing from:

(a) A PERSON who is excluded by the REGULATORY AUTHORITY from working in a FOOD ESTABLISHMENT as specified in §§ 8-501.10 - 8-501.40,

(b) A PERMIT HOLDER or PERSON whose FOOD is subject to a hold order as specified in Subpart 8-803, or

(c) A PERMIT HOLDER whose PERMIT is summarily suspended as specified in Subpart 8-804; and

(2) Within 30 calendar days but no earlier than 7 calendar days after the service of a hearing notice to consider administrative remedies for other matters as specified in ¶ 8-805.10(C) or for matters as determined necessary by the REGULATORY AUTHORITY.

(B) A PERMIT HOLDER or PERSON who submits a request for a hearing as specified in Subparagraphs (A)(1)(a)-(c) of this section may waive the prompt hearing in the written request to the REGULATORY AUTHORITY.

8-805.60 Notice, Contents.

A notice of hearing shall contain the following information:

(A) Time, date, and place of the hearing;

(B) Purpose of the hearing;

(C) Facts that constitute the basis or reason for the hearing including specific details of violations or allegations;

(D) The rights of the respondent, including the right to be represented by counsel and to present witnesses and evidence on the respondent's behalf as specified in § 8-807.10;

(E) At the REGULATORY AUTHORITY'S discretion, the procedure for the respondent to request an offer from the REGULATORY AUTHORITY to settle the matter;

(F) The consequences of failing to appear at the hearing;

(G) The maximum sanctions or penalties as specified in ¶¶ 8-806.40(B)-(D) that may result from the hearing if the hearing concerns a proposed administrative remedy and if the facts are found to be as alleged;

(H) If the hearing concerns a proposed administrative remedy, a statement specifying the form and time frame for response as specified in § 8-805.10;

(I) Notification that the written response shall include the information specified in § 8-805.20; and

(J) The name and address of the PERSON to whom such written response shall be addressed.

8-805.70 Proceeding Commences Upon Notification.

A hearing proceeding commences at the time the REGULATORY AUTHORITY notifies the respondent of the hearing proceeding.

8-805.80 Procedure, Expeditious and Impartial.

Hearings shall be conducted in an expeditious and impartial manner.

8-805.90 Confidential.

(A) Hearings or portions of hearings may be closed to the public:

(1) If compelling circumstances, such as the need to discuss in the hearing a PERSON'S medical condition or a FOOD ESTABLISHMENT'S trade secrets, indicate that it would be prudent; and

(2) According to LAW, such as an open meetings LAW.

(B) A party to a hearing shall maintain confidentiality of discussions that warrant closing the hearing to the public.

8-805.100 Record of Proceeding.

A complete record of a hearing shall be prepared under the direction of the PERSON conducting the hearing and maintained as part of the REGULATORY AUTHORITY'S records for the FOOD ESTABLISHMENT. *Except as required by LAW, a verbatim transcript of the hearing need not be prepared*.

Hearing Officer, Purpose Qualifications, Appointment, and Powers

8-806.10 Appointment by Regulatory Authority and Purpose.

The REGULATORY AUTHORITY may appoint a PERSON such as an adjudicator, administrative LAW judge, or examiner, hereinafter referred to as a hearing officer, who presides over a proceeding

initiated by the REGULATORY AUTHORITY or by a PERSON contesting an action of the REGULATORY AUTHORITY, to perform one or more of the following:

(A) Hear the facts presented by an applicant or a PERMIT HOLDER;

(B) Make a decision or recommendation concerning administrative remedies to achieve compliance with this Code; or

(C) Address other concerns or allegations appropriately raised according to LAW, in the matter before the hearing officer.

8-806.20 Qualifications.

A hearing officer shall be knowledgeable of the provisions of this chapter and the LAW as they relate to hearings, and be:

(A) A REGULATORY AUTHORITY representative other than the PERSON who inspects the FOOD ESTABLISHMENT or who has any other role in making the decision that is being contested; or

(B) An individual who is not employed by the REGULATORY AUTHORITY.

8-806.30 Powers, Administration of Hearings.

(A) A hearing officer shall have the following powers in a hearing in which the hearing officer presides:

(1) Setting and conducting the course of a hearing requested in accordance with or authorized by this Code,

(2) Issuing subpoenas in the name of the REGULATORY AUTHORITY at the request of a party to a hearing, administering oaths and affirmations, examining witnesses, receiving evidence,

(3) Approving a consent agreement on the issues involved in the hearing entered into by the REGULATORY AUTHORITY and the respondent after the respondent receives a hearing notice,

(4) Sustaining, modifying, rescinding, or vacating an order or directive of the REGULATORY AUTHORITY in an appeal hearing proceeding, and if the order or directive is sustained, ordering appropriate measures to execute the REGULATORY AUTHORITY'S order or directive; and

(B) *Unless a party appeals to the head of the REGULATORY AUTHORITY within 15 days of the hearing or a lesser number of days specified by the hearing officer:*

(1) Rendering a binding decision and final order in a proceeding after conducting a hearing, if the respondent has not waived the right to a hearing, and

(2) Then notifying the respondent of the decision and the order which contains the findings and conclusions of LAW.

8-806.40 Powers, Administrative Remedies.

The hearing officer shall have the following powers in a hearing proceeding concerning an administrative remedy specified in §§ 8-801.10 and 8-805.30:

(A) Issuing orders to abate or correct violations of this Code and establishing a schedule for the abatement or correction of violations;

(B) Making a finding of fact regarding the occurrence of each violation and assessing, levying, and ordering a reasonable civil penalty, according to LAW and not to exceed the amount specified in ¶ 8-813.10(B) for each violation of this Code that is alleged and found to be committed, and calculated based on each day a violation occurs as specified in ¶ 8-813.10(C);

(C) Suspending, revoking, modifying, or imposing reasonable restrictions or conditions on a PERMIT to operate a FOOD ESTABLISHMENT, or ordering the closure of a FOOD ESTABLISHMENT that is operated without a valid PERMIT as required under § 8-301.11 of this Code;

(D) Making a finding of fact regarding the occurrence of each violation of the REGULATORY AUTHORITY'S or hearing officer's LAWful order issued in accordance with this Code and assessing, levying, and ordering a reasonable civil penalty, in accordance with LAW and not to exceed the amount specified in ¶ 8-813.10(B) for each violation of this Code that is alleged and found to be committed, and calculated based on each day a violation occurs as specified in ¶ 8-813.10(C);

(E) Deferring or suspending the imposition of a decision or execution of an order, and imposing a probationary period, upon the condition that the respondent comply with the hearing officer's reasonable terms and conditions;

(F) Dismissing the appeal if the matter is settled between the REGULATORY AUTHORITY and the respondent after a hearing notice is served;

(G) Ordering reinspection of a FOOD ESTABLISHMENT to determine compliance with a hearing officer's order;

(H) Suspending or ordering the payment of a fee established by the REGULATORY AUTHORITY for a reinspection that is required to determine compliance and for the reinstatement of a PERMIT after suspension;

(I) Retaining and exercising jurisdiction for a specific period of time not to exceed 90 calendar days after the hearing officer's

decision and final order is issued, over a respondent who receives a hearing notice; and

(J) Modifying or setting aside an order by rehearing upon the hearing officer's own motion, the motion of the REGULATORY AUTHORITY, or the motion of the respondent.

Rights of Parties and Evidence

8-807.10 Rights of Parties.

Parties to a hearing may be represented by counsel, examine and cross examine witnesses, and present evidence in support of their position.

8-807.20 Evidence to be Presented by the Regulatory Authority.

The REGULATORY AUTHORITY shall present at the hearing its evidence, orders, directives, and reports related to the proposed or appealed administrative remedy.

8-807.30 Evidence to be Excluded.

Evidence shall be excluded:

(A) If it is irrelevant, immaterial, unduly repetitious, or excludable on constitutional or statutory grounds or on the basis of evidentiary privilege recognized by the state's courts; or

(B) Otherwise according to LAW.

8-807.40 Testimony under Oath.

Testimony of parties and witnesses shall be made under oath or affirmation administered by a duly authorized official.

8-807.50 Written Evidence.

Written evidence may be received if it will expedite the hearing without substantial prejudice to a party's interests.

8-807.60 Documentary Evidence.

Documentary evidence may be received in the form of a copy or excerpt.

Settlement

8-808.10 Authorization.

The REGULATORY AUTHORITY may settle a case after a notice of hearing is served by providing a respondent with an opportunity to request a settlement before a hearing commences on the matter and by entering into a consent agreement with the respondent.

8-808.20 Respondent Acceptance of Consent Agreement Is Waiver of Right to Appeal.

Respondents accepting a consent agreement waive their right to a hearing on the matter.

Judicial

Inspection Orders

8-809.10 Gaining Access to Premises and Records.

(Note: Adoption of this section provides the basis for Subparagraph 8-402.20(A)(3) and § 8-402.40 and would be cited there.)

The REGULATORY AUTHORITY may seek access for one or more of the following purposes, according to LAW for gaining access:

(A) If admission to the PREMISES of a FOOD ESTABLISHMENT is denied or other circumstances exist that would justify an inspection order under LAW, to make an inspection including taking photographs;

(B) To examine and sample the FOOD; and

(C) To examine the records on the PREMISES relating to FOOD purchased, received, or used by the FOOD ESTABLISHMENT.

8-809.20 Contents of Court Petition.

In the absence of a specific set of requirements established by LAW, in its petition to the court to compel access the REGULATORY AUTHORITY shall:

(A) Describe in detail the PREMISES, FOOD, or records on or to which access was denied;

(B) Detail the legal authority to regulate and to have access for a specific purpose on or to the PREMISES, FOOD, or records where access was denied; and

(C) Provide information that the FOOD ESTABLISHMENT possesses a valid PERMIT from the REGULATORY AUTHORITY and that it applies to the PREMISES where access was denied; or

(D) Provide information that a PERSON is known to be or suspected of operating a FOOD ESTABLISHMENT without possessing a valid PERMIT as specified in LAW and under this Code.

8-809.30 Sworn Statement of Denied Access.

The REGULATORY AUTHORITY shall demonstrate to the court by affidavit, sworn testimony, or both that:

(A) Access on or to the PREMISES, FOOD, or records was denied after the REGULATORY AUTHORITY acted as specified in §§ 8-402.20 and 8-402.30; or

(B) There is reason to believe that a FOOD ESTABLISHMENT is being operated on the PREMISES and that access was denied or is sought under a REGULATORY AUTHORITY'S reasonable administrative plan to enforce the provisions of this Code.

8-809.40 Contents of an Order.

Upon petition of the REGULATORY AUTHORITY, the court may issue an inspection order that:

(A) Includes the information specified in ¶¶ 8-802.20(A)-(C); and

(B) Orders or authorizes any other identified agencies and persons including LAW enforcement agencies to execute, or assist with the execution of, the order.

8-809.50 Optional Contents of an Order.

Upon petition of the REGULATORY AUTHORITY, the court may further issue an inspection order that:

(A) Provides a maximum time limit for the order's execution;

(B) Authorizes LAW enforcement officers who assist in the order's execution to use necessary force against PERSONS or property to execute the order; and

(C) Requires that the agencies or PERSONS ordered or authorized to execute the order shall report to the court the date and time of the order's execution and the findings reached by the inspection, examination, or sampling conducted under the order.

Means of Instituting Judicial Enforcement Proceedings

8-810.10 Institution of Proceedings.

(A) Proceedings to enforce this Code may be instituted by the REGULATORY AUTHORITY according to LAW by issuing a citation or summons, by filing a misdemeanor complaint affidavit and request for a warrant of arrest with the court of competent jurisdiction, or by referring the complaint to a grand jury for indictment, as appropriate.

(B) The REGULATORY AUTHORITY may designate a representative to issue summons or citations or sign warrants on behalf of the agency.

Criminal Proceedings

8-811.10 Authorities, Methods, Fines, and Sentences.

(A) The REGULATORY AUTHORITY may seek to enforce the provisions of this Code and its orders by instituting criminal proceedings as provided in LAW against the PERMIT HOLDER or other PERSONS who violate its provisions.

(B) A PERSON who violates a provision of this Code shall be guilty of a misdemeanor, punishable by:

(1) A fine of not more than (designate amount) dollars, or by imprisonment not exceeding 1 year, or both the fine and imprisonment; or

(2) If the PERSON has been convicted once of violating this Code or if there is an intent to defraud or mislead, a fine not exceeding (designate amount) or imprisonment not exceeding (designate time) year(s) or both.

(C) Each day on which a violation occurs is a separate violation under this section.

Injunctive Proceeding

8-812.10 Petitions for Injunction.

The REGULATORY AUTHORITY may, according to LAW, petition a court of competent jurisdiction for temporary or permanent injunctive relief to achieve compliance with the provisions of this Code or its orders.

Civil Proceedings

8-813.10 Petitions, Penalties, and Continuing Violations.

(A) The REGULATORY AUTHORITY may petition a court of competent jurisdiction to enforce the provisions of this Code or its administrative orders and according to LAW collect penalties and fees for violations.

(B) In addition to any criminal fines and sentences imposed as specified in § 8-811.10, or to being enjoined as specified in § 8-812.10, a PERSON who violates a provision of this Code, any rule or regulation adopted in accordance with LAW related to FOOD ESTABLISHMENTS within the scope of this Code, or to any term, condition, or limitation of a PERMIT issued as specified in §§ 8-303.10 and 8-303.20 is subject to a civil penalty not exceeding (designate amount).

(C) Each day on which a violation occurs is a separate violation under this section.

Annex

2 References

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS
2. BIBLIOGRAPHY

1. UNITED STATES CODE AND CODE OF FEDERAL REGULATIONS

The *Food Code* makes frequent reference to federal statutes contained in the United States Code (USC) and the *Code of Federal Regulations* (CFR). Copies of the USC and CFR can be viewed and copied at government depository libraries or may be purchased as follows.

(A) Viewing and Copying the USC or CFR

(1) Government Depository Library

The USC and CFR are widely available for reference and viewing in some 1400 "depository libraries" located throughout the United States. *A Directory of U.S. Government Depository Libraries* is published by the Joint Committee on Printing of the United States Congress and is available through the Superintendent of Documents, U.S. Government Printing Office. This publication lists all depository libraries by state, city, and congressional district.

Persons may also obtain information about the location of the depository library nearest to them by contacting:

Library Programs Service, SL
U.S. Government Printing Office
North Capitol & H Streets, NW
Washington, DC 20401
(202) 512-1114, FAX (202) 512-1432

(2) Internet World Wide Web Information System

The CFR are available on-line in downloadable form through the Internet World Wide Web information system. The source is:

The National Archives and Records Administration
Copies of Federal Regulations - Retrieve CFR by Citation
Provided through the Government Printing Office Web Site - GPO Inet Services

http://www.access.gpo.gov/nara/cfr/cfr-table-search.html

(B) Purchasing Portions of the USC or CFR

Persons wishing to purchase relevant portions of the USC or CFR may do so by

writing:	or by calling:
Superintendent of Documents (New Orders) U.S. Government Printing Office P.O. Box 371954 Pittsburgh, PA 15250-7954;	(202)512-1800 from 7:30 a.m. to 5:00 p.m. easter time, Monday-Friday (except holidays. Orders may be charged to Discover/Novus, MasterCard or Visa.

(C) USC as it Relates to the Code Definition of "Adulterated"

This language has been retyped as accurately as possible and inserted in the Food Code Annex for informational purposes. For legal purposes, use only language taken directly from the United States Code (USC).

21 USC Sec.342
Title 21 - Food and Drugs
Chapter 9 - Federal Food, Drug and Cosmetic Act
Subchapter IV - Food

ADULTERATED FOOD

Sec. 402 [342]

A food shall be deemed to be adulterated -

(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a); or (C) if it is or if it bears or contains (*i*) any food additive that is unsafe within the meaning of section 409; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

(b) Absence, substitution, or addition of constituents

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) Color additives

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.

(d) Confectionery containing alcohol or nonnutritive substance

If it is confectionery, and -

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced and delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale;

(3) bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on a confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) Oleomargarine containing filthy, putrid, etc., matter

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(f) Dietary supplement or ingredient: safety

(1) If it is a dietary supplement or contains a dietary ingredient that -

(A) presents a significant or unreasonable risk of illness or injury under -

(i) conditions of use recommended or suggested in labeling,

or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) The Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5 to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a) (1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph (FOOTNOTE 3) (1) (A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

(FOOTNOTE 3) So in original. Probably should be “subparagraph” .

(g) Dietary supplement: manufacturing practices

(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

(2) the Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5, United States Code.

(As amended by 104th Congress, Fall, 1996.)

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Annex

3 Public Health Reasons/ Administrative Guidelines

Chapter 1 Purpose and Definitions

Applicability and *Terms Defined* **1-201.10** **Statement of Application and Listing of Terms.**

(B)(1) Accredited Program.

Food protection manager *certification* occurs when *individuals* demonstrate through a certification program that they have met specified food safety knowledge standards.

Food protection certification program *accreditation* occurs when *certification organizations* demonstrate through an accreditation program that they have met specified program standards.

Accreditation is a conformity assessment process through which organizations that certify individuals may voluntarily seek independent evaluation and listing by an accrediting agency based upon the certifying organization’s meeting program accreditation standards. Such accreditation standards typically relate to such factors as the certifying organization's structure, mission, policies, procedures, and the defensibility of its examination processes. These standards are intended to affirm or enhance the quality and credibility of the certification process, minimize the potential for conflicts of interest, ensure fairness to candidates for certification and others, and thereby increase public health protection.

Program accreditation standards known to be relevant to food protection manager certification programs include those contained in the draft *Standards for the Training, Testing, and Certification of Food Protection Managers* available from the Conference for Food Protection, 110 Tecumseh Trail, Frankfort, KY 40601. Also included are the National Commission for Certifying Agencies' *Standards for Accreditation of National Certification*

Organizations available through the National Organization for Competency Assurance, 1200 19th Street, NW, Suite 300, Washington, DC 20036-2422.

Allowing food protection managers to demonstrate their required food safety knowledge "through passing a test that is part of an accredited program" is predicated on the fact that their credentials have been issued by certifying organizations that have demonstrated conformance with rigorous and nationally recognized program standards.

Chapter 2 Management and Personnel

Responsibility **2-101.11 Assignment.***

Designation of a person in charge during all hours of operations ensures the continuous presence of someone who is responsible for monitoring and managing all food establishment operations and who is authorized to take actions to ensure that the Code's objectives are fulfilled. During the day-to-day operation of a food establishment, a person who is immediately available and knowledgeable in both operational and Code requirements is needed to respond to questions and concerns and to resolve problems.

Knowledge **2-102.11 Demonstration.***

The designated person in charge who is knowledgeable about foodborne disease prevention, Hazard Analysis and Critical Control Point (HACCP) principles, and Code requirements is prepared to recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with Code requirements, and to take appropriate preventive and corrective actions.

There are many ways in which the person in charge can demonstrate competency. Many aspects of the food operation itself will reflect the competency of that person. A dialogue with the person in charge during the inspection process will also reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.

The effectiveness of the person in charge in protecting the health of the consumer is evidenced by the person's ability to apply the required knowledge to the establishment's operations by designing and implementing procedures that ensure continued compliance with the Code.

Status of "Universal Acceptance" of Food Protection Manager Certificates

Presently there are a wide variety of industry management training and certification programs being offered by regulatory agencies, academic institutions, food companies, industry groups and "third-party" organizations. Most certification programs share a common desire to have the food manager certificate they issue universally recognized and accepted by others - especially by the increasing number of regulatory authorities that require food manager certification.

Certification programs vary significantly in focus and primary mission of sponsors, organizational structures, staff resources, revenue sources, testing mechanisms, policies toward applicants and employers of food managers, and policies pertaining to such things as public information, criteria for maintaining certification, and the need for recertification. Where courses are offered, they vary in scope, content, depth and duration, quality of instructional materials, qualifications of instructors, and instructional approach (classroom, on-the-job, PC-based, home study, etc.). Where testing is a program component, varying degrees of attention are given to test construction and test administration as they relate to nationally accepted standards (reliability, validity, job analysis, subject weighting, cut scores, test security, etc.).

Needed is a mechanism for regulatory authorities to use in determining which certificates should be considered credible based on which certificate-issuing programs meet sound organizational and certification procedures and use defensible processes in their test development and test administration.

Considerable progress has been made by the Conference for Food Protection toward providing the standards and procedures necessary for the independent evaluation and accreditation of food protection manager certification programs. The Conference is simultaneously working on two separate aspects of the program accreditation process.

The first aspect addresses the important matter of ensuring that examinations are reliable, valid, and legally defensible. The Conference has developed a process for the independent evaluation and recognition of food protection manager certification examinations that meet its standards for test development and test administration. It is projected that this aspect of the process will be announced and become available to test providers in early 1999.

The second aspect addresses the equally important organizational and operational policies and procedures of a certification program that help ensure honesty and fairness for all stakeholders and protect against conflict of interests. The Conference is working closely with national organizations that have considerable experience with the accreditation of certification programs, and is endeavoring to develop a comparable process for evaluating these aspects of a certification program.

Once the Conference completes its work on these two program components, program accreditation may become the needed mechanism for promoting the universal acceptance of certificates issued by accredited certifiers.

Duties **2-103.11 Person in Charge.**

A primary responsibility of the person in charge is to ensure compliance with Code requirements. Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service personnel, and pest control operators, comply with the Code requirements, the person in charge establishes an important barrier to food contamination.

Tours of food preparation areas serve educational and promotional purposes; however, the timing of such visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for contamination are reduced.

Disease or Medical Condition	**2-201.11**	**Responsibility of the Person in Charge to Require Reporting by Food Employees and Applicants.***

A wide range of communicable diseases and infections may be transmitted by infected food employees to consumers through food or food utensils. Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees. In order to protect the health of both consumers and employees, information concerning the health status of applicants and food employees must be disclosed to the person in charge.

Title I of the Americans with Disabilities Act of 1990 (ADA) prohibits medical examinations and inquiries as to the existence, nature, or severity of a disability before extending a conditional offer of employment. In order for the permit holder and the person in charge to be in compliance with this particular aspect of the Code and the ADA, a conditional job offer must be made before making inquiries about the applicant's health status.

Furthermore, an applicant to whom an employment offer is conditionally made or a food employee who meets the Code conditions that require restriction from certain duties or exclusion must be accommodated to the extent provided under the ADA. That is, if there is an accommodation that will not pose an undue hardship and that will prevent the transmission of the disease(s) of concern through food, such accommodation, e.g., reassignment to duties that fulfill the intent of restriction or exclusion, must be made. It should be noted that the information provided here about the ADA is intended to alert employers to the existence of ADA and related CFR requirements. For a comprehensive understanding of the ADA and its implications, consult the references listed in the References Annex that relate to this section of the Code or contact the U. S. Equal Employment Opportunity Commission.

The information required from applicants and food employees is designed to identify employees who may be suffering from a disease which can be transmitted through food. It is the responsibility of the permit holder to convey to applicants and employees the importance of notifying the person in charge of changes in their health status. Once notified, the person in charge can take action to prevent the likelihood of the transmission of foodborne illness.

Applicants, to whom a conditional offer of employment is extended, and food employees are required to report specific high-risk conditions, medical symptoms, and previous illnesses. The symptoms listed may be indicative of a disease that is transmitted through the food supply by infected food employees.

As required by the ADA, on August 15, 1996, the Centers for Disease Control and Prevention (CDC) published a list of infectious and communicable diseases that are transmitted through

food. CDC updates the list annually. The list is divided into two parts: pathogens often transmitted (List I) and pathogens occasionally transmitted (List II) through food by infected food employees.

The Lists below summarize the CDC list by comparing the common symptoms of each pathogen. Symptoms may include diarrhea, fever, vomiting, jaundice, and sore throat with fever. CDC has no evidence that the HIV virus is transmissible via food. Therefore, a food employee positive for the HIV virus is not of concern unless suffering secondary illness listed below.

LIST I. Pathogens Often Transmitted by Food Contaminated by Infected Employees.

	D	**F**	**V**	**J**	**S**
1. Hepatitis A virus	-	F	-	J	-
2. ***Salmonella* Typhi**	-	F	-	-	-
3. ***Shigella*** species	D	F	V	-	-
4. Norwalk and Norwalk-like viruses	D	F	V	-	-
5. ***Staphylococcus aureus***	D	-	V	-	-
6. ***Streptococcus pyogenes***	-	F	-	-	S

LIST II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Employees

	D	**F**	**V**	**J**	**S**
1. ***Campylobacter jejuni***	D	F	V	-	-
2. ***Entamoeba histolytica***	D	F	-	-	-
3. Enterohemorrhagic ***Escherichia coli***	D	-	-	-	-
4. Enterotoxigenic ***Escherichia coli***	D	-	V	-	-
5. ***Giardia lamblia***	D	-	-	-	-
6. Non-typhoidal ***Salmonella***	D	F	V	-	-
7. Rotavirus	D	F	V	-	-
8. ***Taenia solium***	-	-	-	-	-
9. ***Vibrio cholerae*** 01	D	-	V	-	-
10. ***Yersinia enterocolitica***	D	F	V	-	-

KEY: D = Diarrhea V = Vomiting S = Sore throat with fever
F = Fever J = Jaundice

The symptoms listed in the Code cover the common symptoms experienced by persons suffering from the pathogens identified by CDC as transmissible through food by infected food employees. An employee suffering from any of the symptoms listed presents an increased risk of transmitting foodborne illness.

The high-risk conditions that require reporting are designed to be used with the symptoms listed to identify employees who may be suffering from an illness due to the following pathogens: ***Salmonella* Typhi**, ***Shigella*** spp., ***Escherichia coli*** O157:H7, and hepatitis A virus. The specific conditions requiring reporting were identified by CDC as significant contributing factors to the incidence of foodborne illness.

The 4 organisms listed have been designated by CDC as having high infectivity. This designation is based on the number of confirmed cases reported that involved food employees infected with one of these organisms and the severity of the medical consequences to those who become ill.

Lesions containing pus that may occur on a food employee's hands, as opposed to such wounds on other parts of the body, represent a direct threat for introducing ***Staphylococcus aureus*** into food. Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other parts of the body need to be covered; but, an impermeable bandage is not considered necessary for food safety purposes. Food employees should be aware that hands and fingers that contact pustular lesions on other parts of the body or with the mucous membrane of the nose also pose a direct threat for introducing ***Staphylococcus aureus*** into food.

2-201.12 Exclusions and Restrictions.*

Restriction or exclusion of food employees suffering from a disease or medical symptom listed in the Code is necessary due to the increased risk that the food being prepared will be contaminated with a pathogenic organism transmissible through food. A person suffering from any of the symptoms or medical conditions listed may be suffering from a disease transmissible through food.

Because of the high infectivity (ability to invade and multiply) and virulence (ability to produce severe disease) of ***Salmonella* Typhi**, ***Shigella*** spp., ***Escherichia coli*** O157:H7, and hepatitis A virus, a food employee diagnosed with an active case of illness caused by any of these four pathogens must be excluded from food establishments. The exclusion is based on the severe medical consequences to individuals infected with these organisms, i.e., hospitalization and even death.

Restrictions and exclusions vary according to the population served because highly susceptible populations have increased vulnerability to foodborne illness. For example, foodborne illness in a healthy individual may be manifested by mild flu-like symptoms. The same foodborne illness may have serious medical consequences in immunocompromised individuals. This point is reinforced by statistics pertaining to deaths associated with foodborne illness caused by ***Salmonella* Enteritidis**. Over 70% of the deaths attributed to this organism occurred among individuals who for one reason or another were immunocompromised. This is why the restrictions and exclusions listed in the Code are especially stringent for food employees serving highly susceptible populations.

The symptoms experienced by individuals infected with ***Salmonella* Typhi, Shigella** spp., ***Escherichia coli*** O157:H7, or hepatitis A virus are often severe and of sufficient duration that most employees will seek medical assistance. The Code provisions related to individuals who encounter any of the high-risk conditions listed and also suffer from any of the symptoms listed in the Code are designed to identify individuals who are likely to be suffering from an illness caused by 1 of the 4 organisms that requires exclusion.

Periodic testing of food employees for the presence of diseases transmissible through food is not cost effective or reliable. Therefore, restriction and exclusion provisions are triggered by the active symptoms and high-risk conditions listed. A high-risk condition alone does not trigger restriction or exclusion. The employee must also suffer from one of the symptoms listed.

The use of high-risk conditions alone as the sole basis for restricting or excluding food employees is difficult to justify. The high-risk conditions that must be reported apply only to the 4 organisms listed. Of the 4 organisms listed, hepatitis A presents a different twist to this rationale. Food employees who meet a high-risk condition involving hepatitis A may shed the virus before becoming symptomatic. In fact, the infected employee could be shedding hepatitis A virus for up to a week before experiencing symptoms of the infection. However, even in light of this fact, blanket exclusion or restriction of a food employee solely because of a high-risk condition involving hepatitis A is not justified.

The following summarize the rationale for not restricting or excluding an asymptomatic food employee simply because the employee meets a high-risk condition involving hepatitis A:

1. Because hepatitis A virus infection can occur without clinical illness (i.e., without symptoms), or because a person may shed hepatitis A virus in the stool for up to a week before becoming symptomatic, it is possible that a person unknowingly may have been exposed to an asymptomatic hepatitis A virus shedder or to an infected person who is in the incubation stage. No restriction/exclusion routinely occurs under these -- presumably much more common -- circumstances.

2. Even though the asymptomatic food employee may be infected with hepatitis A virus and may in fact be shedding virus in the stool, foodborne transmission of hepatitis A virus is unlikely if the employee practices good personal hygiene, such as washing hands after going to the bathroom.

3. Exclusions from work for prolonged periods of time may involve economic hardship for the food employee excluded.

Based on the information presented, exclusion or restriction solely on a high-risk condition would be potentially controversial and of questionable merit.

Because of the high infectivity of hepatitis A, the person in charge or regulatory authority should handle employees and applicants who meet a high-risk condition involving hepatitis A on a case-by-case basis. With this approach in mind, the following criteria are offered as a guide. First, the following information should be collected and analyzed:

1. Clarify the type of contact the individual had with another person diagnosed with hepatitis A virus infection. Keep in mind that the closer the contact (i.e., living in the same household as the infected person), the more likely it is that a susceptible person may become infected.

2. What job does the food employee perform at the food establishment, e.g., is the employee involved in food preparation?

3. When did the employee begin work at the establishment?

4. What level of personal hygiene does the individual exhibit? For example, does the individual adhere to the handwashing requirements specified in the Code?

5. Has the individual suffered from hepatitis A in the past? If the answer to this question is yes, was blood testing done? If the individual did have hepatitis A in the past, the individual is immune from re-infection.

6. In terms of the current high-risk condition, has the individual received immune globin (IG)? When?

In addition, upon being notified of the high-risk condition, the person in charge should immediately:

1. Discuss the traditional modes of transmission of hepatitis A virus infection with the food employee involved.

2. Advise the food employee to observe good hygienic practices both at home and at work. This includes a discussion of proper handwashing, as described in the Code, after going to the bathroom, changing diapers, or handling stool-soiled material.

3. Review the symptoms listed in the Code that are caused by hepatitis A infection.

4. Remind the employee of the employee's responsibility as specified in the Code to inform the person in charge immediately upon the onset of any of the symptoms listed in the Code.

5. In light of the high infectivity of hepatitis A, ensure that the employee stops work immediately if any of the symptoms described in the Code develop and reports to the person in charge.

If after consideration of all the information gathered, the person in charge feels that the employee in question is likely to develop hepatitis A, restriction or exclusion of the individual's activities should be considered.

2-201.13 Removal of Exclusions and Restrictions.

Chapter 2 provisions related to employee health are structured to recognize certain characteristics of each of the four infectious agents, the risk of illness presented by asymptomatic shedders, the increased risk to highly susceptible populations, and the need to provide extra protection to those high-risk populations.

Asymptomatic shedders are food employees who do not exhibit the symptoms of foodborne illness but who are identified through laboratory analysis of their stools to have any one of the three bacterial pathogens identified in Chapter 2 in their gastrointestinal system.

The duties that an asymptomatic shedder performs in a food establishment are restricted if the establishment serves a general population or, if a highly susceptible population is involved, the shedder is excluded. Several considerations factor into the need to preclude asymptomatic shedders from food establishment functions that may result in the transmission of foodborne disease.

- Outbreaks of foodborne illness involving ***Salmonella* Typhi** have been traced to asymptomatic food employees who have transmitted the pathogen to food, causing illness.

- There is some epidemiological evidence of transmission of food via food employees infected with ***Shigella*** spp.

- Healthy consumers are at risk due to a low infectious dose of ***Shigella*** spp.

- Despite lacking epidemiological evidence of transmission of food via food employees infected with ***E. coli*** O157:H7, the documented ease of transmitting it from person-to-person in a day care setting, suggests a low infectious dose and the potential for the organism to be transmitted through food.

- The severity and consequences of one of the illnesses, Hemolytic Uremic Syndrome (HUS), associated with ***E. coli*** O157:H7 warrant the institution of disease interventions.

- Restriction in a food establishment that does not serve a highly susceptible populaiton affords protection for the general population and the immune-suppressed subset of the general population.

The risk that a communicable disease will be transmitted by food employees who are asymptomatic shedders varies depending upon the hygienic habits of the worker, the food itself and how it is prepared, the susceptibility of the population served, and the infectivity of the organism.

To minimize the risk in all food establishments of the transmission of foodborne disease by an asymptomatic shedder and based on the factors listed above, all known asymptomatic shedders of the three bacterial pathogens are either restricted or excluded, depending on the

population served. Requiring restriction for asymptomatic shedders of all three of the bacterial pathogens results in a uniform criterion and is consistent with APHA-published recommendations in the "Control of Communicable Diseases in Man."

The Code requires medical clearance, based on criteria designed to detect the shedder state, before a person who had a recent illness from, or is identified as a shedder of any of the three bacterial infectious agents is allowed to resume the duties from which that person was restricted or, in the case of an establishment that serves a highly susceptible population, before the person may return to work.

With respect to a food employee in an establishment that serves an immunocompromised population, the Code provisions are more stringent in that exclusion is required in 3 situations in which it is not required for food employees in other food establishments. Those 3 situations involve an employee who:

(A) Meets a high-risk condition specified in ¶ 2-201.11(D) and has a symptom of acute gastrointestinal illness;

(B) Is diagnosed as an asymptomatic shedder of ***S*. Typhi**, ***Shigella*** spp. or ***Escherichia coli*** O157:H7; or

(C) Had a recent illness caused by ***S*. Typhi, *Shigella*** spp., or ***E. coli*** O157:H7. The exclusion is in effect until a physician licensed to practice medicine or, if allowed by law, a nurse practitioner or physician assistant, provides the medical clearance specifically outlined in § 8-501.40 of the Code, indicating that the infectious agent is not detected.

2-201.14 Responsibility of a Food Employee or an Applicant to Report to the Person in Charge.*

This reporting requirement is an important component of any food safety program. A food employee who suffers from any of the illnesses or medical symptoms or meets any of the high-risk conditions in this Code may transmit disease through the food being prepared. The person in charge must first be aware that an employee or prospective employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

Some of the symptoms that must be reported may be observed by the person in charge. However, food employees and applicants share a responsibility for preventing foodborne illness and are obligated to inform the person in charge if they are suffering from any of the symptoms, high-risk conditions, or medical diagnoses listed in the Code and food employees must comply with restrictions or exclusions imposed upon them.

2-201.15 Reporting by the Person in Charge.*

Notification of the regulatory authority by the person in charge that an employee is suffering illness caused by ***Salmonella* Typhi, Shigella** spp., ***Escherichia coli*** O157:H7, or hepatitis A virus allows the regulatory authority to monitor for any associated cases of foodborne illness. The person in charge should be aware of the confidentiality provisions of the

Americans with Disabilities Act (ADA). For information about the ADA, call 800-669-EEOC or for telecommunications device for the deaf (TDD) 800-800-3302.

Hands and Arms **2-301.11 Clean Condition.***

The hands are particularly important in transmitting foodborne pathogens. Food employees with dirty hands and/or fingernails may contaminate the food being prepared. Therefore, any activity which may contaminate the hands must be followed by thorough handwashing in accordance with the procedures outlined in the Code.

Even seemingly healthy employees may serve as reservoirs for pathogenic microorganisms that are transmissible through food. Staphylococci, for example, can be found on the skin and in the mouth, throat, and nose of many employees. The hands of employees can be contaminated by touching their nose or other body parts.

2-301.12 Cleaning Procedure.*

Many employees fail to wash their hands as often as necessary and even those who do may use a flawed technique. It takes more than just the use of soap and running water to remove the transient pathogens that may be present. It is the abrasive action obtained by vigorously rubbing the surfaces being cleaned that loosens the dirt or soil present.

Many of the diseases that are transmissible through food may be harbored in the employee's intestinal tract and shed in the feces. Proper handwashing by employees after defecation establishes a protective barrier against the transmission of pathogens that may be present in the feces.

Pathogens transmissible through food may also be present in other body fluids. Therefore, precautions would be appropriate whenever an employee handles body fluids or body wastes directly or indirectly, because of the increased risk of the presence of disease. Fecal material and other contaminants routinely accumulate under the fingernails; therefore, particular attention must be given to the fingernails, fingertips, and areas between the fingers. Once the material and soil are loosened, they can be washed away in the rinsing step of proper handwashing.

2-301.13 Special Handwash Procedures.*

This section is reserved.

In earlier editions of the Code, FDA's model contained a provision for a Special Procedure in certain situations. Pursuant to a 1996 Conference for Food Protection (CFP) Recommendation, the text of this Code provision is removed and the section is reserved. It is FDA's intent to further research the matter and to submit the findings to the CFP for reconsideration of the matter.

2-301.14 When to Wash.*

The hands may become contaminated when the food employee engages in specific activities. The increased risk of contamination requires handwashing immediately after the activities listed. The specific examples listed in this Code section are not intended to be all inclusive. Employees must wash their hands after any activity which may result in contamination of the hands.

2-301.15 Where to Wash.

Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross contamination. It is important that handwashing be done only at a properly equipped handwashing facility in order to help ensure that food employees effectively clean their hands. Handwashing facilities are to be conveniently located, always accessible for handwashing, maintained so they provide proper water temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since this may result in avoidable contamination of the sink and the food prepared therein. Service sinks may not be used for food employee handwashing since this practice may introduce additional hand contaminants because these sinks may be used for the disposal of mop water, toxic chemicals, and a variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food preparation areas and toilet rooms and discharges from ill persons.

2-301.16 Hand Sanitizers.

This provision is intended to ensure that an antimicrobial product applied to the hands is both, 1) safe and effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will come into direct contact with food. The prohibition against bare hand contact contained in ¶ 3-301.11(B) applies only to an exposed ready-to-eat food.

<u>As a Drug Product</u>

There are three means by which a hand sanitizer is considered to be safe and effective when applied to human skin:

1. A hand sanitizer may be approved by FDA under a new drug application based on data showing safety and effectiveness and may be listed in the publication **Approved Drug Products with Therapeutic Equivalence Evaluations**. Also known as the “Orange Book,” this document provides “product-specifiic” listings rather than listings by compound. It is published annually with monthly supplements. These publications are available on the Internet via the FDA Web Site and Center for Drug Evaluation and Research Home Page, from the Superintendent of Documents/Government Printing Office, and from the National Technical Information Service. However, as of the end of 1998, no hand sanitizers are listed in this publication since no new drug applications have been submitted and approved for these products.

2. A hand sanitizer active ingredient may be identified by FDA in the monograph for OTC (over-the-counter) Health-Care Antiseptic Drug Products under the antiseptic handwash category. Since hand sanitizing products are intended and labeled for topical antimicrobial use by food employees in the prevention of disease in humans, these products are "drugs" under the Federal Food, Drug, and Cosmetic Act § 201(g). As drugs, hand sanitizers and dips must be manufactured by an establishment that is duly registered with the FDA as a drug manufacturer; their manufacturing, processing, packaging, and labeling must be performed in conformance with drug Good Manufacturing Practices (GMP's); and the product must be listed with FDA as a drug product.

   Products having the same formulation, labeling, and dosage form as those that existed in the marketplace on or before December 4, 1975 or that are authorized by USDA are being evaluated under the OTC (over-the-counter) Drug Review by FDA's Center for Drug Evaluation and Research. Otherwise, the far more extensive FDA review process for a new drug application (NDA) is required before marketing.

   However, as of the end of 1998, no hand sanitizers have been shown to be acceptable through this process since the monograph has not been finalized. FDA's Center for Drug Evaluation and Research is not presently objecting to the use of "instant hand sanitizers" based on ethyl alcohol or isopropyl alcohol, or certain chlorine "hand sanitizing dips" since these compounds are included in the OTC Drug Review. The ultimate status of these products will not be known until the final monograph publishes.

   Acceptable antimicrobial ingredients for hand sanitizers will be identified in a future final monograph issued under the OTC Drug Review for OTC Antiseptic Handwashes. Information about whether a specific product has been accepted and included in the proposed monograph may be obtained from the manufacturer. You may also refer to ***Federal Register*** (59) No. 116, June 17, 1994, Tentative Final Monograph (TFM) for Health Care Antiseptic Drug Products; Proposed Rule. This TFM describes the inclusion of hand sanitizers in this Review, on page 31440 under Comment 28 of Part II.

3. A hand sanitizer may be previously authorized and listed for such use in the **USDA List of Proprietary Substances and Nonfood Compounds**, Miscellaneous Publication No. 1419. In this publication, Category Code Letter "E" covers Employee Hand Care products.

   - E-1 products are hand cleaners that require a potable water rinse.
   - E-2 products are hand cleaners that provide an antimicrobial equivalency of 50 ppm chlorine that require a potable water rinse.
   - E-3 products are hand sanitizers and hand sanitizer dips with 50 ppm chlorine equivalency that specify prior handwashing/rinsing. Hands need not be rinsed with potable water following use.
   - E-4 products include products such as creams, lotions, or aerosol foams. Any such products intended to leave a film/shield on the skin to protect against contamination by chemicals, allergens, or microorganisms have been restricted by USDA to dressing

and toilet rooms for use only when the food employee is leaving the plant. Since 1992, USDA has deferred to FDA with respect to E-4 barrier-type products and requires that manufacturers obtain FDA approval prior to any new USDA listing.

This USDA publication lists acceptable employee hand-care products in all four categories. The USDA review is based only on the intended uses specified for the product by the manufacturer in a written application. However, during the second half of 1998, USDA discontinued this review program and listing. It is unknown at this time whether another organization will assume some or all of these review and listing responsibilities.

Products in all four of these USDA listed hand-care product categories are regulated by FDA's Center for Drug Evaluation and Research. Questions regarding acceptability of a hand sanitizer with respect to OTC compliance may be directed to the OTC Compliance Team, HFD-312, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, Center for Drug Evaluation and Research, 7520 Standish Place, Rockville, MD 20855-2737. Specific product label/promotional information and the formulation are required for determining a product's regulatory status.

<u>As a Food Additive</u>

To be regulated under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the components of a hand-care product must *reasonably* be expected to become a component of food based upon the product's intended use. E-3 formulations in USDA's E-Classification system meet this criterion.

Where the components of a product are reasonably expected to become a component of food based upon the product's intended use, there are three means by which they are considered by FDA to be safe:

1. A substance may be exempted from the requirement of being listed in the federal food additive regulations as specified in 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles. A review by FDA's Center for Food Safety and Applied Nutrition is required for such an exemption to be issued. The Center's Indirect Additives Team has exempted ethyl alcohol and isopropyl alcohol from the requirement of being listed in the federal food additive regulations. Therefore, there is no food additive prohibition against using these substances as components of an instant hand sanitizer.

2. A substance may be regulated for the intended use as a food additive as specified in 21 CFR 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers, and listed thereunder with conditions of safe use. However, as of 1998, no petitions have been received for the review and approval of substances for use as hand sanitizers, and therefore none are listed.

3. A substance may be "generally recognized as safe (GRAS)" for the intended use in contact with food within the meaning of the Federal Food, Drug, and Cosmetic Act

§ 201(s). Substances affirmed by FDA to be GRAS are listed in one of the following: 21 CFR 182 - Substances Generally Recognized as Safe, 21 CFR 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe. The law also provides for independent GRAS determinations.

Only USDA's E-3 category products are regulated by FDA's Center for Food Safety and Applied Nutrition. The Indirect Additives Team does not certify or provide approvals for specific products. However, if the use of a product meets the regulations of 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles, FDA may provide a letter to a firm stating that the use of this product is exempt from the requirement of a food additive listing regulation. However, the product must be the subject of a new drug application or under FDA's OTC Drug Review to be legally marketed.

Questions regarding the regulatory status of hand sanitizer components as food additives may be directed to the Indirect Additives Team, HFS-215, Office of Premarket Approval, Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, DC 20204. It may be helpful or necessary to provide label/promotional information when inquiring about a specific component.

Fingernails **2-302.11** **Maintenance.**

The requirement for fingernails to be trimmed, filed, and maintained is designed to address both the cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability concerns and may harbor pathogenic organisms.

Jewelry **2-303.11** **Prohibition.**

Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms transmissible through food.

An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for consumers, such as chipped and/or broken teeth and internal cuts and lesions.

Outer Clothing **2-304.11** **Clean Condition.**

Dirty clothing may harbor diseases that are transmissible through food. Food employees who inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In addition, employees wearing dirty clothes send a negative message to consumers about the level of sanitation in the establishment.

Food Contamination Prevention **2-401.11 Eating, Drinking, or Using Tobacco.***

Proper hygienic practices must be followed by food employees in performing assigned duties to ensure the safety of the food, prevent the introduction of foreign objects into the food, and minimize the possibility of transmitting disease through food. Smoking or eating by employees in food preparation areas is prohibited because of the potential that the hands, food, and food-contact surfaces may become contaminated. Insanitary personal practices such as scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered sneezing or coughing may result in food contamination. Poor hygienic practices by employees may also adversely affect consumer confidence in the establishment.

Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas food employees are allowed to drink from closed containers that are carefully handled.

2-401.12 Discharges from the Eyes, Nose, and Mouth.*

Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by food employees can directly contaminate exposed food, equipment, utensils, linens, and single-service and single-use articles. When these poor hygienic practices cannot be controlled, the employee must be assigned to duties that minimize the potential for contaminating food and surrounding surfaces and objects.

Hair Restraints **2-402.11 Effectiveness.**

Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect vehicle of contamination. Food employees may contaminate their hands when they touch their hair. A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching their hair.

Animals **2-403.11 Handling Prohibition.***

Dogs and other animals, like humans, may harbor pathogens that are transmissible through food. Handling or caring for animals that may be legally present is prohibited because of the risk of contamination of food employee hands and clothing.

Chapter 3 Food

Condition **3-101.11 Safe, Unadulterated, and Honestly Presented.***
Sources **3-201.11 Compliance with Food Law.***

Refer to the public health reason for § 3-401.11.

Source

A primary line of defense in ensuring that food meets the requirements of § 3-101.11 is to obtain food from approved sources, the implications of which are discussed below. However, it is also critical to monitor food products to ensure that, after harvesting and processing, they do not fall victim to conditions that endanger their safety, make them adulterated, or compromise their honest presentation. The regulatory community, industry, and consmers should exercise vigilance in controlling the conditions to which foods are subjected and be alert to signs of abuse. FDA considers food in hermetically sealed containers that are swelled or leaking to be adulterated and actionable under the Federal Food, Drug, and Cosmetic Act. Depending on the circumstances, rusted and pitted or dented cans may also present a serious potential hazard.

Food, at all stages of production, is susceptible to contamination. The source of food is important because pathogenic microorganisms may be present in the breeding stock of farm animals, in feeds, in the farm environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which plant crops are grown. Chemical contaminants that may be present in field soils, fertilizers, irrigation water, and fishing waters can be incorporated into food plants and animals.

Sources of molluscan shellfish are a particular concern because shellfish are frequently consumed raw or in an undercooked state and thus receive neither heat nor any other process that would destroy or inactivate microbial pathogens. For safety, these foods must be accompanied by certification that documents that they have been harvested from waters that meet the water quality standards contained in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. Certification also provides confidence that processing, packaging, and shipping have been conducted under sanitary conditions.

Food should be purchased from commercial supplies under regulatory control. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food. Because commercial items seldom are eaten right away, the home kitchen's limited capacity for maintaining food at proper temperatures may result in considerable microbial growth and toxin production by microorganisms introduced through the diverse sources of contamination. Controlled processing is required for the safe preparation of food entering commerce.

Labeling - General

Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows consumers to make informed decisions about what they eat. Many consumers, as a result of an existing medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In addition, consumers have a basic right to be protected from misbranding and fraud.

On July 8, 1998, FDA announced in the Federal Register a final rule that revised its food labeling regulations to require a warning statement on fruit and vegetable juice products that

have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. FDA took this action to inform consumers, particularly those at greatest risk, of the hazard posed by such juice products. FDA expects that providing this information to consumers will allow them to make informed decisions on whether to purchase and consume such juice products, thereby reducing the incidence of foodborne illnesses and deaths caused by the consumption of these juices. At the time of publication of the 1999 Food Code, rulemaking had not been finalized regarding a mandatory Hazard Analysis Critical Control Point (HACCP) program for juice products.

Refer to Chapter 1 for the definition of juice. It is important to note that the definition of "juice" includes puréed fruits and vegetables, which are commonly prepared for service to highly susceptible populations. Untreated juices or beverages containing untreated juices that are offered to consumers as prepackaged foods must bear a warning statement as specified in 21 CFR Section 101.17(g). That statement is: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." Additional information is available in the document, "Guidance for Industry. Warning and Notice Statement: Labeling of Juice Products, Small Entity Compliance Guide" which can be found on the FDA Web Page http://www.cfsan.fda.gov/~dms/juicguid.html or obtained from the FDA Office of Food Labeling.

Except for certain species of large tuna and raw molluscan shellfish, if fish are intended for raw consumption, they must be properly frozen before they are served. If this process is done off-premises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Meat and Poultry

Retail food establishments that process and package meat or poultry in a form that is not ready-to-eat, are obligated by federal regulation to label the product with safe food handling instructions. The intent of this requirement is to ensure that all consumers are alerted to the fact that such products may contain bacteria and that food safety hinges upon their thoroughly cooking the product, regardless of where they obtain the products. That is, the labeling would exist if they obtain their meat and poultry at an establishment that handles only prepackaged and prelabeled products or if they obtain their meat or poultry at an operation such as a supermarket with a meat processing operation or from a small neighborhood butcher.

Labeling for Whole-muscle, Intact Beef Steaks

In order for a food establishment operator to know that a steak is a whole-muscle, intact cut of beef that can therefore be undercooked and served without a consumer advisory, the incoming product must be labeled. Processors can accommodate this need at the retail level

by developing proposed labels, obtaining the necessary USDA Food Safety Inspection Service review and approval, and appropriately affixing the labels to their products.

3-201.12 Food in a Hermetically Sealed Container.*

Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern is the lethal toxin of ***Clostridium botulinum***, an organism whose spores (i.e., survival stages for non-growth conditions) are found throughout the environment. Even slight underprocessing of low acid food which is canned can be dangerous, because spoilage microbes are killed and there are no signs to warn consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these foods are not processed to be commercially sterile, they must be received frozen or under proper refrigeration.

Refer also to the public health reason for §§ 3-101.11 and 3-201.11.

3-201.13 Fluid Milk and Milk Products.*

Milk, which is a staple for infants and very young children with incomplete immunity to infectious diseases, is susceptible to contamination with a variety of microbial pathogens such as ***Escherichia coli*** O157:H7, ***Salmonella*** spp., and ***Listeria monocytogenes***, and provides a rich medium for their growth. This is also true of milk products. Pasteurization is required to eliminate pathogen contamination in milk and products derived from milk. Dairy products are normally perishable and must be received under proper refrigeration conditions.

3-201.14 Fish.*

After December 18, 1997, all processors of fish are required by 21 CFR 123 to have conducted a hazard analysis of their operation, identify each hazard that is reasonably likely to occur, and implement a HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have complied with this requirement. Hazards known to be associated with specific fish species are discussed in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and drugs.

The seafood implicated in histamine poisoning are the scombroid toxin-forming species, defined in 21 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family **Scrombridae**, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that allow the growth of mesophilic bacteria.

Ciguatera toxin is carried to humans by contaminated fin fish from the extreme southeastern U.S., Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel, large groupers, and snappers are particularly likely to contain ciguatoxin. Many other species of large predatory fishes may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack, and snapper are frequently ciguatoxic,

and many other species both large and small are suspect. Mackerel and barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

3-201.15 Molluscan Shellfish.*

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses.

Pathogens from the harvest area are of particular concern in molluscan shellfish because: 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

To minimize the risk of molluscan shellfish containing pathogens of sewage origin, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times or under certain restrictions from others. Shellfish Control Authorities then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been allowed.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a requirement that mollluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the name, address, and certification number of the shucker-packer or repacker.

Pathogens, such as ***Vibrio vulnificus***, ***Vibrio parahaemolyticus***, ***Vibrio cholerae***, and ***Listeria monocytogenes*** that may be present in low numbers at the time that molluscan shellfish are harvested, may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. The length of time is dependant upon either the month of the year or the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

Paralytic shellfish poisoning (PSP) results from shellfish feeding upon toxic microorganisms such as dinoflagellates. In the U.S., PSP is generally associated with the consumption of mulluscan shellfish from the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the U.S., PSP toxin has recently

been reported from the viscera of mackerel, lobster, dungeness crabs, tanner crabs, and red rock crabs.

Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

For diarrhetic shellfish poisoning there has been no documented occurrence to date in the U.S. However, instances have been documented in Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada.

Amnesic shellfish poisoning (ASP) is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of Mexico, although the algae that produce the toxin have been found there. ASP toxin has recently been identified as a problem in the viscera of dungeness crab, tanner crab, red rock crab, and anchovies along the west coast of the United States.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite, cooperative action plan involving federal and state public health officials and the shellfish industry. Those groups work together to improve shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the states' classification of shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

3-201.16 Wild Mushrooms.*

Over 5000 species of fleshy mushrooms grow naturally in North America. The vast majority have never been tested for toxicity. It is known that about 15 species are deadly and another 60 are toxic to humans whether they are consumed raw or cooked. An additional 36 species are suspected of being poisonous, whether raw or cooked. At least 40 other species are poisonous if eaten raw, but are safe after proper cooking.

Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species. In most parts of the country there is at least one organization that include individuals who can provide assistance with both identification and program design. Governmental agencies, universities, and mycological societies are examples of such groups. If a food establishment chooses to sell wild mushrooms, management must recognize and address the need for a sound identification program for providing safe wild mushrooms.

Refer also to the public health reason for §§ 3-101.11 and 3-201.11.

3-201.17 Game Animals.*

The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the human host. In addition to the risk posed to consumers of game that is not subject to an inspection program, there is risk to those who harvest and prepare wild game because they may contract infectious diseases such as rabies or tularemia.

Specifications for Receiving **3-202.11 Temperature.***

Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all, types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant levels in properly refrigerated foods that are not out of date. Effective August 27, 1999, federal regulations 7 CFR Part 59, Refrigeration and Labeling Requirements for Shell Eggs, (currently printed in the *Federal Register, 63(166): 45663-45675)* require shell eggs to be stored and transported in an ambient air temperature of no greater than 7°C (45°F).

High temperatures for a long enough time, such as those associated with thorough cooking, kill or inactivate many types of microorganisms. However, cooking does not always destroy the toxins produced in foods by certain bacteria (such as the enterotoxins of ***Staphylococcus aureus***). Cooking or hot holding that follows temperature abuse may not make the food safe. Keeping cooked foods hot as required in the Code prevents significant regrowth of heat-injured microorganisms and prevents recontamination with bacteria that are newly introduced.

3-202.12 Additives.*

It is imperative for safety that food supplies come from sources that are in compliance with laws regarding chemical additives and contaminants.

Food additives are substances which, by their intended use, become components of food, either directly or indirectly. They must be strictly regulated. In excessive amounts or as a result of unapproved application, additives may be harmful to the consumer. Unintentional contaminants or residues also find their way into the food supply. The tolerances or safe limits designated for these chemicals are determined by risk assessment evaluations based on toxicity studies and consumption estimates.

3-202.13 Shell Eggs.*

Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good growth medium for many types of bacteria. Damaged eggs must not be used as food.

3-202.14 Eggs and Milk Products, Pasteurized.*

Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other harmful microorganisms likely to be in these potentially hazardous foods. Freezing and drying of unpasteurized products will stop microbial growth and may reduce their bacterial populations; however, some organisms will survive because neither process invariably kills bacteria. Under certain conditions, freezing and drying may preserve microbes. An alternative to pasteurization may be applicable to certain cheese varieties cured or aged for a specified amount of time prior to marketing for consumption.

3-202.15 Package Integrity.*

Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the contained food. If the integrity of the packaging has been compromised, contaminants such as ***Clostridium botulinum*** may find their way into the food. In anaerobic conditions (lack of oxygen), botulism toxin may be formed. Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods. Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many cases, suspect packaging may have to be inspected by trained persons using magnifying equipment. Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate can damage or imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate that not enough heat was applied during processing (underprocessing). Suspect cans must be returned and not offered for sale.

3-202.16 Ice.*

Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice that comes into contact with food to cool it or that is used directly for consumption must be as safe as drinking water that is periodically tested and approved for consumption.

3-202.17 Shucked Shellfish, Packaging and Identification.

Plastic containers commonly used throughout the shellfish industry for shucked product bear specific information regarding the source of the shellfish as required by the NSSP Guide for the Control of Molluscan Shellfish. These containers must be nonreturnable so that there is no potential for their subsequent reuse by shellfish packers which could result in shucked product that is inaccurately identified by the label. The reuse of these containers within the food establishment must be assessed on the basis of the Food Code's criteria for multi-use containers and the likelihood that they will be properly relabeled to reflect their new contents.

3-202.18 Shellstock Identification.*

Accurate source identification of the harvesting area, harvester, and dealers must be contained on molluscan shellstock identification tags so that if a shellfish-borne disease outbreak occurs, the information is available to expedite the epidemiological investigation and regulatory action.

3-202.19 Shellstock, Condition.

Dirty, damaged, or dead shellstock can contaminate and degrade live and healthy shellstock and lead to foodborne illness. Harvesters have the primary responsibility for culling shellstock, but this responsibility continues throughout the distribution chain.

Original Containers and Records

3-203.11 Molluscan Shellfish, Original Container.

Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their source. Proper identification is needed for tracing the origin and determining conditions of shellfish processing and shipment. If the lots are commingled at retail, traceability is undermined and the root of the problem may remain undetected. If no causative factors are identified in the food establishment, tracing the incriminated lot helps in identifying products that need to be recalled or growing waters that may need to be closed to harvesting.

3-203.12 Shellstock, Maintaining Identification.*

Accurate records that are maintained in a manner that allows them to be readily matched to each lot of shellstock provide the principal mechanism for tracing shellstock to its original source. If an outbreak occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus infections, which have an incubation period that is significantly longer than other shellfish-borne diseases, to come to light. The 90 day requirement is based on the following considerations:

Shelf-life of the product	14	days
Incubation period	56	days
Medical diagnosis and confirmation	5	days
Reporting	5	days
Epidemiological investigation	10	days
Total	90	days

Preventing Contamination by Employees **3-301.11 Preventing Contamination from Hands.***

Refer to the public health reasons for §§ 2-301.11, 2-301.12, and 2-301.13.

Even though bare hands should never contact exposed, ready-to-eat food, thorough handwashing is important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the food.

Clarification of ¶ 3-301.11(B) of the FDA Food Code with Respect to the Phrase "*Except...when otherwise APPROVED*"...

Background:

Infected food employees are the source of contamination in approximately one in five foodborne disease outbreaks reported in the United States with a bacterial or viral cause.[1] Most of these outbreaks involve enteric, i.e., fecal-oral agents. These are organisms that employees were shedding in their stools at the time the food was prepared. Because of poor or nonexistent handwashing procedures, workers spread these organisms to the food. In addition, infected cuts, burns, or boils on hands can also result in contamination of food. Viral, bacterial, and parasitic agents can be involved.

Traditionally, food regulations have required two methods of preventing the spread of foodborne disease by this mode of transfer, i.e., they have prohibited food workers from preparing food when they are infectious and have required thorough and frequent handwashing. In order to strengthen fecal-oral transmission interventions, the Food Code provides focused and specific guidance about ill workers and when handwashing must occur. As a final barrier, bare-hand contact with ready-to-eat food (i.e., food that is edible without washing or is not subsequently subjected to a pathogen kill step) is prohibited and suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment are required to be used. Any alternative to this requirement must convincingly address how food employees will be managed to preclude food contamination and how management will ensure that thorough handwashing occurs after employees use the toilet.

Objective:

The objective of this guidance is to provide clarification to ¶ 3-301.11(B) of the Food Code regarding the statement "except when otherwise approved." This guidance is provided to assist the regulatory authority in evaluating conformity with the principle of no bare-hand contact through alternative practices and procedures. In this guidance, “hazard” means infected food workers spreading pathogens to food via the hands.

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[1]Based on CDC Summary Surveillance for Foodborne-Disease Outbreaks - United States, 1988-1992 and New York State Department of Health data 1980-1991 published: Weingold, Guzewich, Fudala, 1994, Use of Foodborne Disease Data for HACCP Risk Assessment. J. Food Prot. 53: 820-830.

Guidance:

I. **Requirements prerequisite** to consideration of alternatives include compliance with all Food Code provisions, particularly those related to:

(A) **Demonstration of Knowledge** - specifically ¶¶ 2-102.11(A), (B), (C), and (H);

(B) **Duties of the Person in Charge** - specifically ¶ 2-103.11(D);

(C) **Employee Health** regarding:

(1) **Reporting of diseases and medical conditions**, and

(2) **Exclusions and restrictions**, i.e., that food employees (including applicants to whom a conditional offer of employment has been made) report their health status as specified in Section 2-201.11; ill food employees are restricted or excluded as specified in Section 2-201.12; and the exclusions and restrictions are removed as specified in Section 2-201.13;

(D) **Personal Cleanliness, i.e., handwashing** procedures, including frequency and methodology of handwashing that ensure food employees keep their hands and fingertips clean and handwashing occurs at the times specified in Section 2-301.14 - including after using the toilet and between tasks that may recontaminate the hands; and

(E) **Hygienic Practices** as specified in Part 2-4.

II. FDA recommends that the **acceptability of an alternative** to no bare-hand contact **should be based on** evidence that at least the following are addressed:

(A) **Why the operator of the food establishment is unable to comply** with the Code requirement in ¶ 3-301.11(B);

(B) **How the alternative practices and procedures will control the hazard through an active managerial control program**. Such a program includes monitoring and verifying the institution of the prerequisite requirements described in Part I above and satisfies the following:

(1) **The public health hazard** associated with bare-hand contact specific to the food establishment operation **is identified and understood**. The regulatory authority needs assurance that the permit holder recognizes that the hazard being addressed is the possible contamination of ready-to-eat food by viral and parasitic as well as bacterial pathogens that are transferred from employees' hands.

(2) The ready-to-eat foods that will be contacted with bare hands are identified and both **procedures and practices** are in place so that **food employees wash their**

hands before returning to their work station and **cross-contamination** from touching raw and ready-to-eat food **is precluded**.

For example, identifying the specific type of food to be prepared, such as tacos, and the specific location, such as a situation where a food employee is assigned solely to the designated taco work station. The work station is located immediately adjacent to the taco assembly unit and the employee will be preparing only the specified ready-to-eat food using bare hands.

Another example could be a food employee who is responsible solely for assembling a variety of ready-to-eat foods.

(3) Institution of an **effective training program for food employees** which emphasizes **not working when ill** with any of the symptoms of foodborne illness, and explains **good hygienic practices, proper handwashing** procedures, and **safe food preparation** procedures. This should include a documented training plan that specifies how **management responsibility for training** has been designated, training program content, and the frequency of administration including periodic refresher sessions.

(C) The alternative should clearly include **monitoring, documentation, and verification** to ensure that the practices and procedures are followed. **Corrective actions need to be predetermined** for situations where the practices and procedures are not followed, e.g., an ill employee is found preparing foods.

III. **Documentation of the practices, procedures, and corrective actions** related to an alternative to no bare-hand contact with ready-to-eat food needs to be maintained and readily available at the food establishment at all times for use by the person-in-charge and for review by the regulatory authority.

IV. The regulatory authority should also consider industry's *elective* use, managerial control, and monitoring and verification of additional preventive measures used in tandem with the aforementioned interventions which could include one or more of the following:

(A) Vaccination against hepatitis A for food employees including initial and booster shots or medical evidence that a food employee has had a previous illness from hepatitis A virus;

(B) Double handwashing;

(C) Use of nail brushes;

(D) Use of an FDA-accepted hand sanitizer after handwashing, i.e., approved as safe for application to human skin and safe as an indirect food additive, or exempted as a food additive under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food Contact Articles; and

(E) Motivation for food employees not to work when they are ill.

Preventing Food and Ingredient Contamination

3-302.11 Packaged and Unpackaged Food - Protection, Separation, Packaging, and Segregation.*

Cross contamination can be avoided by separating raw animal foods from ready-to-eat foods. Cross contamination may also occur when raw unprepared vegetables contact ready-to-eat potentially hazardous foods. Raw animal foods must also be separated from each other because required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters vary with different types of raw animal foods.

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons delivering, stocking, or opening packages or overwraps.

Packaging must be appropriate for preventing the entry of microbes and other contaminants such as chemicals. These contaminants may be present on the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when the packaging is opened. The removal of food product overwraps may also damage the package integrity of foods under the overwraps if proper care is not taken.

3-302.12 Food Storage Containers, Identified with Common Name of Food.

Certain foods may be difficult to identify after they are removed from their original packaging. Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the consumer has specifically requested that it not be used, may result in severe medical consequences.

The mistaken use of food from unlabeled containers could result in chemical poisoning. For example, foodborne illness and death have resulted from the use of unlabeled salt, instead of sugar, in infant formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble cleaning compounds are also of particular concern.

3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.*

Raw or undercooked eggs that are used in certain dressings or sauces are particularly hazardous because the virulent organism ***Salmonella*** **Enteritidis** may be present in raw shell eggs. Pasteurized eggs provide an egg product that is free of pathogens and is a ready-to-eat food. The pasteurized product should be substituted in a recipe that requires raw or undercooked eggs.

3-302.14 Protection from Unapproved Additives.*

Refer to the public health reason for § 3-202.12.

Use of unapproved additives, or the use of approved additives in amounts exceeding those allowed by food additive regulations could result in foodborne illness, including allergic reactions. For example, many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning" of fruits and vegetables or to cause ground meat to look "redder" or fresher.

The concern for misuse of additives also applies to food establishments operating under a variance and to Annex 6 Food Processing Criteria which addresses the use of sodium nitrite or other curing agents in smoking and curing operations. However, if this process is done incorrectly, it could cause illness or death because of excessive nitrite or because the food is insufficiently preserved.

3-302.15 Washing Fruits and Vegetables.

Pathogenic organisms and chemicals may be present on the exterior surfaces of raw fruits and vegetables. Washing removes the majority of organisms and/or chemicals present. If nondrinking water is used, the fruits and vegetables could become contaminated.

Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations.

On October 26, 1998 a voluntary guidance document which addresses practices commonly used by fresh fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance contains useful information related to washing fruits and vegetables as well as the application of antimicrobial agents. The “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” is available from FDA’s Food Safety Initiative staff and also on the Internet at http://www.fda.gov.

Preventing Contamination from Ice Used as a Coolant

3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient.

Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and other contaminants. For example, ice used to store or display fish or packaged foods could become contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient, it could contaminate the final product.

3-303.12 Storage or Display of Food in Contact with Ice and Water.

Packages that are not watertight may allow entry of water that has been exposed to unsanitary exterior surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water to the food that is unclaimed in the food's formulation and label.

Unpackaged foods such as fresh fish are often stored and/or displayed on ice. A potential for increasing the microbial load of a food exists because, as the ice melts, pathogens from one food may be carried by water to other foods. The potential for contamination is reduced by continuous draining of melting ice.

Preventing Contamination From Equipment, Utensils, and Linens

3-304.11 Food Contact with Equipment and Utensils.*

Pathogens can be transferred to food from utensils that have been stored on surfaces which have not been cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly from used tableware or food containers.

Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such contamination. The handles of utensils, even if manipulated with gloved hands, are particularly susceptible to contamination.

Probe-type price or identification tags are defined as a utensil. This means that if such tags are for multiuse, they must meet the criteria listed in Parts 4-1 Materials for Construction and Repair, and 4-2 Design and Construction. Probe-type price or product identification tags can cause microbial, chemical, or physical contamination if not properly designed, constructed, and maintained.

3-304.12 In-Use Utensils, Between-Use Storage.

Refer to the public health reason for § 3-304.11.

Once a food employee begins to use a utensil such as a ladle, spatula, or knife, that has been previously cleaned and sanitized, it is then considered an in-use utensil. In-use utensils, used on a continuous or intermittent basis during preparation or dispensing, must be cleaned and sanitized on a schedule that precludes the growth of pathogens that may have been introduced onto utensil surfaces. In-use utensils may be safely stored in hot water maintained at 140°F or above during intermittent use because microbial growth is controlled at such temperatures.

3-304.13 Linens and Napkins, Use Limitation.

Refer to the public health reason for § 3-304.11.

Because of their absorbency, linens and napkins used as liners that contact food must be replaced whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to become fomites.

3-304.14 Wiping Cloths, Use Limitation.

Refer to the public health reason for § 3-304.11.

Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must be stored in a sanitizer solution at all times, with the proper sanitizer concentration in the solution. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper sanitizer concentration should be ensured by checking the solution periodically with an appropriate chemical test kit.

3-304.15 Gloves, Use Limitation.

Refer to the public health reason for § 3-304.11.

Gloves used in handling ready-to-eat food are defined as a “utensil.” This means that gloves used for food contact must meet the criteria listed in Parts 4-1 Materials for Construction and Repair, and 4-2 Design and Construction.

All gloves used in direct contact with food must meet FDA criteria for indirect food additives. The FDA, Office of Premarket Approval, Indirect Additives, reviews gloves submitted for food-contact use in the food industry on the basis of the glove’s formulation or components.

Multiuse gloves, especially when used repeatedly and soiled, can become breeding grounds for pathogens that could be transferred to food. Soiled gloves can directly contaminate food if stored with ready-to-eat food or may indirectly contaminate food if stored with articles that will be used in contact with food.

Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves (refer to Annex 2 for this section). This information should be taken into consideration when deciding whether single-use gloves made of latex will be used during food preparation.

Slash-resistant gloves are not easily cleaned and sanitized. Their use with ready-to-eat foods could contaminate the food.

3-304.16 Using Clean Tableware for Second Portions and Refills.

Refer to the public health reason for § 3-304.11.

3-304.17 Refilling Returnables.

Refer to the public health reason for § 3-304.11.

Preventing Contamination from the Premises

3-305.11 Food Storage.
3-305.12 Food Storage, Prohibited Areas.

Pathogens can contaminate and/or grow in food that is not stored properly. Drips of condensate and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

3-305.13 Vended Potentially Hazardous Food, Original Container.

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended potentially hazardous food allows microbes that may be present an opportunity to contaminate the food. Pathogens could be present on the hands of the individual packaging the food, the equipment used, or the exterior of the original packaging. In addition, many potentially hazardous foods are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

3-305.14 Food Preparation.

Food preparation activities may expose food to an environment that may lead to the food's contamination. Just as food must be protected during storage, it must also be protected during preparation. Sources of environmental contamination may include splash from cleaning operations, drips form overhead air conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing food in a building that is not constructed according to Food Code requirements.

Preventing Contamination by Consumers

3-306.11 Food Display.

During display, food can be contaminated even when there is no direct hand contact. Many microbes can be conveyed considerable distances on air currents through fine sprays or

aerosols. These may originate from people breathing or sneezing, water sprays directed at drains, or condensate from air conditioners. Even wind gusts across sewage deposits and fertilized fields have been known to contaminate food in adjacent establishments where food was unprotected.

3-306.12 Condiments, Protection.

Unpackaged condiments are exposed to contamination by consumers who could be suffering from a disease transmissible through food. Once the condiments are contaminated, subsequent consumers using the condiments may be exposed to pathogens. Condiments in individual packages are protected from consumer contamination.

On- or off-site facilities for refilling condiment dispensers must be adequately equipped to ensure that the filling operation does not introduce contaminants.

3-306.13 Consumer Self-Service Operations.*

Raw foods of animal origin usually contain pathogens. In addition, these foods, if offered for consumer self-service, could cross contaminate other foods stored in the same display. Because raw foods of animal origin are assumed to be contaminated and do provide an ideal medium for the growth of pathogenic organisms, they should not be available for consumer self-service. Self-service operations of ready-to-eat foods also provide an opportunity for contamination by consumers. The risk of contamination can be reduced by supplying clean utensils and dispensers and by employee monitoring of these operations to ensure that the utensils and dispensers are properly used.

Bean sprouts that are displayed in produce areas for consumer self-service are potentially hazardous foods and appropriate refrigeration must be maintained. However, they are not considered ready-to-eat since they are intended to be washed by the consumer before consumption.

3-306.14 Returned Food and Reservice or Sale.*

Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus. Any unpackaged foods, even bakery goods in a bread basket that are not potentially hazardous and that have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic microorganisms from the initial consumer to the next if the food is served again.

Preventing Contamination from Other Sources	**3-307.11**	**Miscellaneous Sources of Contamination.**

This Code section provides a category in which to capture sources of contamination not specifically delineated in Subparts 3-301 through 306. Codes prior to 1993 had such a provision for addressing food contamination for reasons other than those elsewhere specified. Regardless of its specificity, a Code can not anticipate all the diverse means by which food can become contaminated after receipt.

Cooking	**3-401.11**	**Raw Animal Foods.***
	3-401.12	**Microwave Cooking.***
	3-401.13	**Plant Food Cooking for Hot Holding.**

Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the food, and the food's bulk which affects the time to achieve the needed internal product temperature. Other factors to be considered include post-cooking heat rise and the time the food must be held at a specified internal temperature.

Greater numbers and varieties of pathogens generally are found on poultry than on other raw animal foods. Therefore, a higher temperature, in combination with the appropriate time is needed to cook these products.

To kill microorganisms, food must be held at a sufficient temperature for the specified time. Cooking is a scheduled process in which each of a series of continuous time/temperature combinations can be equally effective. For example, in cooking a beef roast, the microbial lethality achieved at 121 minutes after it has reached 54°C (130°F) is the same lethality attained as if it were cooked for 3 minutes after it has reached 63°C (145°F).

Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. Different species of microorganisms have different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of bacteria, the trophozoite of protozoa, or the larval form of worms) is less resistant than the same organism's survival form (the bacterial spore, protozoan cyst, or worm egg).

Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the cooking vessel and the moisture content of food aid thermal destruction.

Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food, cooking must bring *all* parts of the food up to the required temperatures for the correct length of time.

The temperature and time combination criteria specified in Part 3-4 of this Code are based on the destruction of *Salmonellae*. This Part includes temperature and time parameters that provide "D" values (decimal log reduction values) that may surpass 7D. For example, at 63°C(145°F), a time span of 15 seconds will provide a 3D reduction of ***Salmonella* Enteritidis** in eggs. This organism, if present in raw shell eggs, is generally found in relatively low numbers. Other foods, uncomminuted fish and meats including commercially raised game animal meat, specified as acceptable for cooking at this temperature and time parameter are expected to have a low level of internal contamination. The parameters are expected to provide destruction of the surface contaminants on these foods.

Seared Steak

The provision for allowing seared steaks was reviewed by the National Advisory Committee for Microbiological Criteria for Foods (NACMCF) and USDA. Paragraph 3-401.11(C) includes their recommendations.

USDA comments included, “For the purposes of this discussion, steak is a whole beef muscle. It does not include whole beef muscle that has been pinned, injected, or chopped and formed. It may be cut cross grain, such as sirloin, chuck, or porterhouse; or it may be cut with the grain, such as flank, skirt, or Chateaubriand. Other species, such as poultry, pork and lamb, are not included.”

NACMCF comments included, “Due to the low probability of pathogenic organisms being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces. Grill or char marks may be applied to the complete surface searing. The meat should be seared on both top and bottom surfaces utilizing a heating environment (e.g., grill or broiling oven) that imparts a temperature at the surface of the intact steak of at least 145°F to achieve a cooked color change on all external surfaces. The searing of all surfaces should be continuous until the desired degree of doneness and appearance are attained. This is considered a ready to eat food.”

As reflected in the definition of “whole-muscle, intact beef steak,” marination is a food safety concern when the fascia (exterior surface) of the steak is broken by scoring or other means which allows the marinade to penetrate, and potentially contaminate, the interior of the steak. In such cases, the Code allowance for undercooking without a consumer advisory is negated.

Pork

In pork, ***Trichinella spiralis***, ***Toxoplasma gondii***, and ***Taenia solium***, parasites causing foodborne illness, are inactivated at temperatures below 145°F. Therefore, pork roasts can be cooked like beef roasts (e.g., 145°F for 3 minutes) and pork chops cooked like steaks to achieve an internal temperature of 145°F for 15 seconds.

Based on the Goodfellow and Brown study, a 5D reduction of organisms is achieved at 68°C (155°F) for 15 seconds for the following foods: ratites and injected meats and comminuted: fish, meat, game animals commercially raised for food, and game animals that come under a USDA voluntary inspection program. Ratites such as ostrich, emu, and rhea are included in this list of raw animals foods because when cooked to a temperature greater than 68°C (155°F), ratites exhibit a (metallic) "off" taste.

When USDA established the time and temperature parameters for 9 CFR 318.23 (known as the "patty rule"), the Agency based the 5D for Salmonella on extrapolations applied to the research done by Goodfellow and Brown to account for the lack of a "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear relationship between the patty rule and roast beef time and temperature parameters. The patty rule also provided for an 8D reduction in the number of ***E. coli***. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements.

Temperature for Comminuted Meat at Less Than 1 Second

In the "Report of the Task Force on Technical Issues Arising from the National Advisory Committee for Microbiological Criteria for Foods' (NACMCF) Review of the Meat Patty Proposal" (undated), it is stated on page 7, in Option (A), that:

> "Based on the 1998 research data ... and an assumption that instantaneous is defined as eight seconds, manufacturers would be required to process fully-cooked meat patties at a temperature of 157°F. Given the lack of any significant margin of safety in this process, there should be no deviation below the 158°F requirement."

In November, 1997, the NACMCF Meat and Poultry Subcommittee revisited the time and temperatures for cooking hamburger and advised FDA that cooking hamburger to 158°F for less than one second is an adequate cook based on the following:

1. The cooking recommendations contained in the Food Code and in USDA guidance provide a large margin of safety for killing vegetable enteric pathogens;

2. The concept of integrated lethality (the kill imparted during the entire heating and cooling process) adds to the margin of safety; and

3. The time component of the time and temperature requirement will be exceeded before the temperature can be determined.

The parameters for cooking poultry, wild game animal meats, stuffed food products, etc., of 74°C(165°F) or above for 15 seconds yield greater than a 7D reduction.

3-401.12 Microwave Cooking.*

The rapid increase in food temperature resulting from microwave heating does not provide the same cumulative time and temperature relationship necessary for the destruction of microorganisms as do conventional cooking methods. In order to achieve comparable lethality, the food must attain a temperature of 74°C (165°F) in all parts of the food. Since cold spots may exist in food cooking in a microwave oven, it is critical to measure the food temperature at multiple sites when the food is removed from the oven and then allow the food to stand covered for two minutes post microwave heating to allow thermal equalization and exposure. Although some microwave ovens are designed and engineered to deliver energy more evenly to the food than others, the important factor is to measure and ensure that the final temperature reaches 74°C (165°F) throughout the food.

"The factors that influence microwave thermal processes include many of the same factors that are important in conventional processes (mass of objects, shape of objects, specific heat and thermal conductivity, etc.). However, other factors are unique in affecting microwave heating, due to the nature of the electric field involved in causing molecular friction. These factors are exemplified by moisture and salt contents of foods, which play a far more important role in microwave than conventional heating." (Reference: Heddelson and Doores, see Annex 2)

3-401.13 Plant Food Cooking for Hot Holding.

Fruits and vegetables that are fresh, frozen, or canned and that are heated for hot holding need only to be cooked to the temperature required for hot holding. These foods do not require the same level of microorganism destruction as do raw animal foods since these fruits and vegetables are ready-to-eat at any temperature. Cooking to the hot holding temperature of 60°C (140°F) prevents the growth of pathogenic bacteria that may be present in or on these foods. In fact, the level of bacteria will be reduced over time at the specified hot holding temperature.

Freezing 3-402.11 Parasite Destruction.*

Refer to the public health reason for § 3-201.11.

Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service as an alternative public health control to that which is provided by adequate cooking. Candling or other visual inspection techniques are not adequate to avoid the risk of parasites from fish which have not been frozen.

In response to information provided to the FDA Office of Seafood, the Fish and Fishery Hazards and Controls Guide lists certain species of tuna as not being susceptible to parasites of concern and therefore are exempted from the freezing requirements for other fish species that are consumed raw.

3-402.12 Records, Creation and Retention.

Records must be maintained to verify that the critical limits required for food safety are being met. Records provide a check for both the operator and the regulator in determining that monitoring and corrective actions have taken place.

Reheating **3-403.11** **Reheating for Hot Holding.***

When food is held, cooled, and reheated in a food establishment, there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective in reducing the numbers of ***Clostridium perfringens*** that may grow in meat, poultry, or gravy if these products were improperly held. Vegetative cells of ***C. perfringens*** can cause foodborne illness when they grow to high numbers. Although it takes as many as 1 million cells to cause foodborne illness, the generation time for ***C. perfringens*** is very short at temperatures just below adequate hot holding. Highly resistant ***C. perfringens*** spores will survive cooking and hot holding. If food is abused by being held below adequate hot holding temperatures, spores can germinate to become rapidly multiplying vegetative cells.

Although proper reheating will kill most organisms of concern, some toxins such as that produced by ***Staphylococcus aureus***, cannot be inactivated through reheating of the food. It is imperative that food contamination be minimized to avoid this risk.

The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods. This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product, are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition if temperature abuse occurs.

Refer also to the public health reason for § 3-401.12.

Temperature and Time Control **3-501.11** **Frozen Food.**

3-501.12 **Potentially Hazardous Food, Slacking.**

3-501.13 **Thawing.**

Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are preserved.

3-501.14 **Cooling.***

Proper cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive time for cooling of potentially hazardous foods has been consistently identified as one of the leading contributing factors to foodborne illness. During extended cooling, potentially hazardous foods are subject to the growth of a variety of pathogenic

microorganisms. A longer time near ideal bacterial incubation temperatures, 21°C - 49°C (70°F - 120°F), is to be avoided. If the food is not cooled in accordance with this Code requirement, pathogens may grow to sufficient numbers to cause foodborne illness.

If the cooking step prior to cooling is adequate and no recontamination occurs, all but the spore-forming organisms such as ***Clostridium perfringens*** or ***Bacillus cereus*** should be killed or inactivated. However, under poorly monitored conditions, other pathogens such as ***Salmonella*** may be reintroduced. Thus, cooling requirements have been based on growth characteristics of organisms that grow rapidly under temperature abuse conditions.

A separate method for cooling shell eggs is allowed in food establishments because of the cumulative information that has been gathered about the specific dynamics of the particular pathogen of concern in intact shell eggs. Aside from the recognized need for an integrated approach to the cooling of eggs from farm to table, there are several germane facts that support unique provisions for cooling eggs at retail.

- There is only one type of microorganism, pathogenic to humans, which appears to be passed transovarially, i.e., ***Salmonella*** spp.

- ***Salmonella*** **Enteritidis** has been shown to have an extended lag phase in shell eggs due to inhibitory characteristics of the albumen. Research indicates that the organisms are physically located near the exterior of the yolk membrane, in contact with the bacteriostatic components. Growth does not appear until the yolk membrane is weakened by age or physically breached and the yolk nutrients, such as iron, become available to the organisms.

- Traditional methods of rapidly cooling eggs after washing by the producer or packer can cause damage to the eggs. The eggs may develop cracks and/or checks because of temperature gradients which could lead to migration through the shell of microorganisms on the surface.

Federal regulations effective August 27, 1999, require shell eggs to be transported and distributed under refrigeration at an ambient temperature not to exceed 45°F. Packed shell eggs must be labeled indicating that refrigeration is required. Imported shell eggs packed for consumer use are required to include a certification that the eggs, at all times after packing, have been stored and transported at an ambient temperature of no greater than 45°F.

Shell eggs are allowed longer than 4 hours to cool to the temperature required under the Code provided they are placed immediately after receipt in refrigerated equipment that is capable of maintaining food temperatures as required by the Code. With the newly established federal requirement for eggs to be in an ambient storage and transportation temperature of 45°F, and with refrigeration of eggs at retail as described above, the overall time that eggs are stored at temperatures that allow the growth of ***Salmonella*** spp. should be shortened. Upon receiving shell eggs, food establishment operators should maximize the circulation of cooled air in refrigeration units by separating flats, cases, and multiple cartons of eggs.

3-501.15 Cooling Methods.

Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool because of the mass and volume from which heat must be removed. By reducing the volume of the food in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e., the time required for cooling and the time the food is exposed to optimal temperatures for bacterial multiplication or toxin production are increased.

Alternatives to conventional methods include avoiding the need to cool larger masses by preparing smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice water bath. Commercial refrigeration equipment is designed to hold cold food temperatures, not cool large masses of food. Rapid chilling equipment is designed to cool the food to acceptable temperatures quickly by using very low temperatures and high rates of air circulation.

3-501.16 Potentially Hazardous Food, Hot and Cold Holding.*

Bacterial growth and/or toxin production can occur if potentially hazardous food remains in the temperature "Danger Zone" of 5°C to 60°C (41°F to 140°F) too long. Up to a point, the rate of growth increases with an increase in temperature within this zone. Beyond the upper limit of the optimal temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

3-501.17 Ready-to-Eat, Potentially Hazardous Food, Date Marking.*
3-501.18 Ready-to-Eat, Potentially Hazardous Food, Disposition.*
3-501.19 Time as a Public Health Control.*

Refer to Annex 7, Chart 3.

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as ***Listeria monocytogenes***, is significantly slowed but not stopped by refrigeration. Over a period of time, this and like organisms may increase to hazardous levels in ready-to-eat foods.

The date by which the food must be consumed takes into consideration the differences in growth of ***Listeria monocytogenes*** at 5°C (41°F) and 7°C (45°F). Based on a predictive growth curve modeling program for ***Listeria monocytogenes***, ready-to-eat, potentially hazardous food may be kept at 5°C (41°F) a total of 7 days or at 7°C (45°F) a total of 4 days. Therefore, the period of time allowed before consumption is shortened for food in refrigerators incapable of maintaining food at 5°C (41°F) but capable of maintaining it at 7°C

(45°F) or below. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by date marking to ensure its safety based on the total amount of time it was held at refrigeration temperature, and the opportunity for ***Listeria monocytogenes*** to multiply, before freezing and after thawing. Potentially hazardous refrigerated foods must be consumed or discarded by the expiration date.

Potentially hazardous food may be held without temperature control for short time periods not exceeding four hours because there will be no significant growth or toxin production possible in that limited time.

Recipes in which more than one egg is combined carry an increased risk of illness and possible serious consequences for certain people. It is due to this increased risk, and documented occurrences of foodborne illness and death among highly susceptible populations from temperature-abused raw shell eggs contaminated with ***Salmonella* Enteritidis**, that the use of time as a public health control in institutional settings is not allowed.

Specialized Processing Methods

3-502.11 Variance Requirement.*

Specific food processes that require a variance have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.

3-502.12 Reduced Oxygen Packaging, Criteria.*

A Hazard Analysis Critical Control Point (HACCP) plan is necessary when using reduced oxygen packaging (ROP) processing procedures. A reduced oxygen packaged food that has at least two barriers to the growth and toxin production of ***C. botulinum*** may be packaged in accordance with the provisions of a HACCP plan. The FDA recommends two barriers be used to ensure the safety of foods when ***C. botulinum*** is a known hazard in the final packaged form.

An ROP food that has only one barrier to the growth and toxin production of ***C. botulinum*** may be produced only if the food establishment obtains a variance and produces the food in accordance with the provisions of a HACCP plan. An example of a single barrier would be a food with a natural pH of 4.6 or less. Regardless of whether a variance is required, the primary safety barrier that must be monitored for control is adequate refrigeration. Variance requests related to packaging food using reduced levels of oxygen and having only one barrier to control the growth of ***C. botulinum*** must be considered with particular caution and scrutiny.

This section does not apply to low acid canned foods produced under 21 CFR Part 108 (Emergency Permit Control) and 21 CFR Part 113 (Thermally Processed Low-Acid Foods) or 21 CFR Part 114 (Acidified Foods) because ***C. botulinum*** is not a hazard in the final packaged form.

FDA strongly recommends that garlic garlic-in-oil mixtures that are produced in a food establishment have two barriers in place. It is not possible to acidify the oil although the crushed cloves can be acidified. An example of two effective barriers is acidification of crushed garlic cloves and refrigeration of the garlic-in-oil mixture. Acidification means a finished equilibrium pH of 4.6 or less. Garlic-in-water mixtures can be acidified and refrigerated, using a HACCP plan without the necessity of a variance.

Unfrozen raw fish is specifically excluded from ROP because of this product's natural association with ***Clostridium botulinum***, Type E, which grows at or above 3°C (38°F). To be adequate, a HACCP plan must identify critical control points that are to be monitored to minimize microbial growth during product packaging and storage.

Earlier FDA guidance regarding the reduced oxygen packaging of cured meat products specified a combination of nitrites, nitrates, and salt that at the time of processing consisted of a concentration of at least 120 mg/L of sodium nitrite and a minimum brine concentration of 3.50%. The Code reflects the fact that various substances, combinations of substances, and resultant concentrations are allowed in CFR administered by USDA. The Code provision also includes the requirement for cured poultry products to meet the CFR.

Shelf-life must be determined considering holding temperatures because some pathogens, including ***Listeria monocytogenes***, may be a hazard at refrigeration temperatures. Safe food that remains frozen from the time it is packaged until prepared for service is considered adequately protected.

Accurate	**3-601.11**	**Standards of Identity.**
Representation	**3-601.12**	**Honestly Presented.**
Labeling	**3-602.11**	**Food Labels.**
	3-602.12	**Other Forms of Information.**

The identity of a food in terms of origin and composition is important for instances when a food may be implicated in a foodborne illness and for nutritional information requirements. Ingredient information is needed by consumers who have allergies to certain food or ingredients. The appearance of a food should not be altered or disguised because it is a cue to the consumer of the food's identity and condition.

Recent illnesses and deaths from ***Escherichia coli*** O157:H7 have occurred across the United States as a result of people eating hamburgers that were contaminated and then undercooked. USDA issued final rules on August 8, 1994 requiring all raw meat or poultry products have a safe-handling label or sticker or be accompanied by a leaflet that contains information on proper handling and cooking procedures.

Certain requirements in the CFR relating to aspects of nutrition labeling became effective in May, 1997. The following attempts to provide guidance regarding those requirements and exemptions as they relate to the retail environment and to alert regulators to authority that has been given to them by the Nutrition Labeling and Education Act (NLEA) of 1990. The statute and the CFR should be reviewed to ensure a comprehensive understanding of the labeling requirements.

I. The following foods need not comply with nutrition labeling in the CFR referenced in Subparagraph 3-602.11(B)(5) if they do not bear a nutrient claim, health claim, or other nutrition information:

(A) Foods packaged in a food establishment if:

(1) The food establishment has total annual sales to consumers of no more than $500,000 (or no more than $50,000 in food sales alone), and

(2) The label of the food does not bear a reference to the manufacturer or processor other than the food establishment;

(B) Low-volume food products if:

(1) The annual sales are less than 100,000 units for which a notification claiming exemption has been filed with FDA's Office of Food Labeling by a small business with less than 100 full-time equivalent employees, or

(2) The annual sales are less than 10,000 units by a small business with less than 10 full-time equivalent employees;

(C) Foods served in food establishments with facilities for immediate consumption such as restaurants, cafeterias, and mobile food establishments, and foods sold only in those establishments;

(D) Foods similar to those specified in the perceding bullet but that are sold by food establishments without facilities for immediate consumption such as bakeries and grocery stores if the food is:

(1) Ready-to-eat but not necessarily for immediate consumption,

(2) Prepared primarily in the food establishment from which it is sold, and

(3) Not offered for sale outside the food establishment;

(E) Foods of no nutritional significance such as coffee;

(F) Bulk food for further manufacturing or repacking; and

(G) Raw fruits, vegetables, and fish.

II. Game animal meats shall provide nutrition information which may be provided by labeling displayed at the point of purchase such as on a counter card, sign, tag affixed to the food, or some other appropriate device.

III. Food packaged in a food processing plant or another food establishment, shall meet the requirements specified in § 3-602.11 and enforcement by the regulatory authority is authorized in the NLEA, Section 4. State Enforcement.

Consumer Advisory	**3-603.11**	**Consumption of Raw or Undercooked Animal Foods.***

Refer to the public health reason for § 3-401.11.

Purpose:

At issue is the role of government agencies, the regulated industry, and others in providing notice to consumers that animal-derived foods that are not subjected to adequate heat treatment pose a risk because they may contain biological agents that cause foodborne disease. The deliverance of a balanced message that communicates fairly to all consumers and, where epidemiologically supported, attempts to place risk in perspective based on the consumer's health status and the food being consumed is part of the challenge. Notification of risk must be achieved via a meaningful message and in a manner that is likely to affect behavior.

Background:

Although no specific advisory language was recommended, beginning with the 1993 Food Code, FDA included a codified provision for a point-of-purchase consumer advisory and stated in Annex 3:

> "FDA has requested comments and will consider the responses as well as other information that is available related to the risks involved and methods of risk communication to determine what action may be necessary by FDA to effectively inform consumers."

Consumer Focus Groups:

During 1996 - 1998, FDA conducted two different consumer focus group studies. Because the first set of focus groups (conducted before the 1997 Code) were not receptive to the language recommended at the 1996 CFP meeting, that language was not included in the 1997 Code. Before the 1998 CFP meeting, the Agency convened a second set of focus groups with a modified approach. The latter set expressed similar thoughts as those in the earlier set and a pattern for consumer acceptance and receptiveness to menu-based advisories emerged.

It became apparent that there is a general appreciation for **“disclosure”** of what consumers view as “hidden ingredients,” for example, whether a particular menu item contains raw egg. In addition to disclosure being viewed as helpful, consumers are accepting, if not appreciative, of a **“reminder”** that consuming raw or undercooked animal-derived foods

carries an increased risk of foodborne illness. In the food establishment venue, consumers are less willing to accept a message that extends beyond a reminder and becomes a lesson or an educational message.

Satisfactory Compliance:

FDA submitted to the 1998 CFP meeting an Issue that asked the Conference to discuss an approach that incorporated the knowledge obtained from the consumer testing. It was the consensus of the CFP that **satisfactory compliance with the Code's consumer advisory provision is fulfilled when both a disclosure and reminder are provided**, as described in the insert page with § 3-603.11 of the Code. **Disclosure is** achieved when there is clear identification of animal-derived foods that are sold or served raw or undercooked, and of items that either contain or may contain (to allow for ingredient substitution) such raw or undercooked ingredients. The **reminder is** a notice about the relationship between thorough cooking and food safety.

Two options were endorsed for disclosure and two for the reminder. One of the reminder options is a menu statement that advises consumers that food safety information about the disclosed items is available upon request. The other option is a short notice alerting consumers to the increased risk of consuming the disclosed menu items.

In response to concerns raised by the Interstate Shellfish Sanitation Conference (ISSC) in an October 8, 1998 letter to FDA, a third option has been added to allow for a statement that links an increased risk of illness to consumption of raw or undercooked animal foods by persons with certain medical conditions.

Locating the Advisory:

Disclosure of raw or undercooked animal-derived foods or ingredients and reminders about the risk of consuming such foods belong at the point where the food is selected by the consumer. Both the disclosure and the reminder need to accompany the information from which the consumer makes a selection. That information could appear in many forms such as a menu, a placarded listing of available choices, or a table tent.

Educational Messages:

Educational messages are usually longer, more didactic in nature, and targeted to consumers who have been alerted to the food safety concern and take the initiative to obtain more detailed information. It is expected that, in most cases, educational messages that are provided pursuant to § 3-603.11 (i.e., in situations where the option for referring the consumer to additional information is chosen), will be embodied in brochures that will not be read at the site where the immediate food choice is being made. Nonetheless, such messages are viewed as an important facet of arming consumers with the information needed to make informed decisions and, because the information is being requested by the consumer, it would be expected to play a role in subsequent choices.

Applicability:

Food Establishments:

The consumer advisory is intended to apply to all food establishments where raw or undercooked animal foods or ingredients are sold or served for human consumption in a raw or undercooked form. This includes all types of food establishments whenever there is a reasonable likelihood that the food will be consumed without subsequent, thorough cooking - such as restaurants, raw bars, quick-service operations, carry-outs, and sites where groceries are obtained that have operations such as delicatessens or seafood departments.

"... Otherwise Processed to Eliminate Pathogens...":

This phrase is included in § 3-603.11 to encompass new technologies and pathogen control/reduction regimens as they are developed and validated as fulfilling a specific performance standard for pathogens of concern. Pasteurization of milk is an example of a long-standing validated process. For purposes of the Food Code, the level of pathogen reduction that is required before a raw or undercooked animal food is allowed to be offered without a consumer advisory must be equivalent to the levels provided by § 3-401.11 for the type of food being prepared.

The absorbed dose levels of radiation approved by FDA on December 3, 1997 for red meat are insufficient to reduce the level of most vegetative pathogens to a point that is equivalent to the reductions achieved in ¶¶ 3-401.11(A) and (B). Irradiated poultry provides a 3D kill which does not provide the level of protection of the 7D kill that results from the cooking regimen in the Food Code. Therefore, irradiated meat and poultry are not allowed to be offered in a ready-to-eat form without a consumer advisory. It is intended that future Food Code revisions will address time/temperature requirements that take into consideration the pathogen reduction that occurs with irradiated foods.

Recognition of Other Processes:

Animal-derived foods may undergo validated processes that target a specific pathogen. In such instances, along with the required consumer advisory may appear additional language that accurately describes the process and what it achieves. For example, a technology for reducing ***Vibrio vulnificus*** in oysters to nondetectable levels has been validated. FDA concurs that shellfish subjected to that process can be labeled with a truthful claim that appropriately describes the product. That is, a statement could be made such as, "pasteurized to reduce ***Vibrio vulnificus***" or "temperature treated to reduce ***Vibrio vulnificus***." Such a claim must be in accordance with labeling laws and regulations, accurate, and not misleading. The claim would not, however, negate the need for a consumer advisory because the treatment only reduces the level of one pathogenic organism.

Product-specific Advisories:

Consumer advisories may be tailored to be product-specific if a food establishment either has a limited menu or offers only certain animal-derived foods in a raw or undercooked

ready-to-eat form. For example, a raw bar serving mollluscan shellfish on the half shell, but no other raw or undercooked animal food, could elect to confine its consumer advisory to shellfish. The raw bar could also choose reminder, option #3, which would highlight the increased risk incurred when persons with certain medical conditions ingest shellfish that has not been adequately heat treated.

Terminology:

It should be noted that the actual on-site (e.g., on-the-menu) advisory language differs from the language in the codified provision, § 3-603.11. In the insert page for § 3-603.11, the **Reminder** options 2 and 3 use terms for foods that are less specific than the terms used in the actual code section. That is, the words “meat” rather than “beef, lamb, and pork” and “seafood” rather than “fish” are used. Categorical terms like “meat” are simpler and may be more likely used in conversation, making them suitable for purposes of a menu notice.

Milk:

In addition, “milk” is not mentioned in the actual on-site advisory language. The sale or service of unpasteurized milk is not allowed in interstate commerce and its consumption is not recommended by FDA. Nonetheless, approximately 25 states allow unpasteurized milk in intrastate commerce which usually involves direct dairy farm-to-consumer procurement.

In the event that a food establishment governed by § 3-603.11 of this Code operates in conjunction with a dairy farm in a state that allows the in-state sale or service of unpasteurized milk, or in the case where a state allows unpasteurized milk to be marketed via retail-level food establishments, consumers need to be advised of the risk associated with drinking unpasteurized milk. In these situations, the actual advisory language needs to be amended to include milk (refer to reminder, options 2 or 3).

Molluscan Shellstock:

In addition to areas of retail food stores such as delis in supermarkets, the consumer advisory is to be provided when a seafood department or seafood market offers raw molluscan shellstock for sale or service. There is a risk of death from ***Vibrio*** infections from consuming raw molluscan shellstock for persons who have certain medical conditions.

Disposition	**3-701.11**	**Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.***

Pathogens may be transmitted from person to person through contaminated food. The potential spread of illness is limited when food is discarded if it may have been contaminated by employees who are infected, or are suspected of being infected, or by any person who otherwise contaminates it.

Additional Safeguards	**3-801.11**	**Pasteurized Foods, Prohibited Reservice, and Prohibited Food.***

Refer to the public health reason for § 3-201.11.

The Code provisions that relate to highly susceptible populations are combined in this section for ease of reference and to add emphasis to special food safety precautions that are necessary to protect those who are particularly vulnerable to foodborne illness and for whom the implications of such illness can be dire.

As a safeguard for highly susceptible populations from the risk of contracting foodborne illness from juice, prepackaged juice is required to be obtained pasteurized or in a commercially sterile, shelf-stable form in a hermetically sealed container. It is important to note that the definition of "juice" includes puréed fruits and vegetables, which is commonly prepared for service to highly susceptible populations. There are documented cases of foodborne illness throughout the United States that were associated with the consumption of various juice products contaminated with microorganisms such as ***Cryptosporidium***, ***E. coli*** O157:H7, ***Salmonella*** spp., and ***Vibrio cholera***. As new information becomes available, the Food Code will be modified or interim interpretive guidance will be issued regarding foodborne illness interventions for on-site juicing and puréeing.

Salmonella often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. In 1986 there was a large multistate outbreak of ***Salmonella* Enteritidis** traced to stuffed pasta made with raw eggs and labeled "fully cooked." Eggs remain a major source of these infections, causing large outbreaks when they are combined and undercooked as was the case in the 1986 outbreak linked to stuffed pasta. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

Operators of food establishments serving highly susceptible populations may wish to discuss buyer specifications with their suppliers. Such specifications could stipulate eggs that are produced only by flocks managed under a ***Salmonella* Enteritidis** control program that is recognized by a regulatory agency that has animal health jurisdiction. Such programs are designed to reduce the presence of ***Salmonella* Enteritidis** in raw shell eggs. In any case, the food establishment operator must use adequate time and temperature controls within the establishment to minimize the risk of a foodborne illness outbreak relating to ***Salmonella* Enteritidis**.

Since 1995, raw seed sprouts have emerged as a recognized source of foodborne illness in the United States. The FDA and CDC have issued health advisories that persons who are at a greater risk for foodborne disease should avoid eating raw alfalfa sprouts until such time as intervention methods are in place to improve the safety of these products. For further information, see the FDA Talk Paper entitled, "Interim Advisory on Alfalfa Sprouts" issued on August 31, 1998 and available on the FDA web site (www.fda.gov). Since this issue continues to be under investigation, FDA recommends that interested persons check the FDA web site periodically for more recent, updated information.

Although the Code's allowance for the Regulatory Authority to grant a variance (refer to §§ 8-103.10 - .12, 8-201.14, and 8-304.11) is applicable to all Code provisions, variance requests related to the preparation of food for highly susceptible populations must be considered with particular caution and scrutiny. With all variances, the hazard(s) must be clearly identified and controlled by a HACCP plan that is instituted in conjunction with a standard operational plan that implements good retail practices. Variances that will impact a

highly susceptible population must be considered in light of the fact that such a population is at a significantly higher risk of contracting foodborne illnesses and suffering serious consequences including death from those illnesses, than is the general population.

Subparagraph 3-801.11(E)(3) requires a HACCP plan for the use of raw shell eggs when eggs are combined in food establishments serving highly susceptible populations. A variance is not required since the HACCP plan criteria are specific, prescriptive, and conservative and require a cooking temperature and time to ensure destruction of ***Salmonella* Enteritidis**.

Chapter 4 Equipment, Utensils, and Linens

Multiuse 4-101.11 Characteristics.*

Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared which could lead to foodborne illness. In addition, some materials can affect the taste of the food being prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes contaminated.

Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

4-101.12 Cast Iron, Use Limitation.

Cast iron is an alloy of iron and heavy metals which may leach into food if left in contact with acidic foods for extended periods of time. Heavy metal poisoning has resulted from such situations. The temporary or incidental contact that results from using cast iron as a cooking surface and for dispensing utensils used as part of an uninterrupted, short-term process is acceptable because of the brief contact time involved.

4-101.13 Lead in Ceramic, China, and Crystal Utensils, Use Limitation.

Historically, lead has been used in the formulation and/or decoration of these types of utensils. Specifically, lead-based paints that were used to decorate the utensils such as color glazes have caused high concentrations of lead to leach into the food they contain.

Lead poisoning continues to be an important public health concern due to the seriousness of associated medical problems. Lead poisoning is particularly harmful to the young and has caused learning disabilities and medical problems among individuals who have consumed

high levels. The allowable levels of lead are specific to the type of utensil, based on the average contact time and properties of the foods routinely stored in each item listed.

4-101.14 Copper, Use Limitation.*

High concentrations of copper are poisonous and have caused foodborne illness. When copper and copper alloy surfaces contact acidic foods, copper may be leached into the food. Carbon dioxide may be released into a water supply because of an ineffective or nonexistent backflow prevention device between a carbonator and copper plumbing components. The acid that results from mixing water and carbon dioxide leaches copper from the plumbing components and the leachate is then transferred to beverages, causing copper poisoning. Backflow prevention devices constructed of copper and copper alloys can cause, and have resulted in, the leaching of both copper and lead into carbonated beverages.

Brass is an alloy of copper and zinc and contains lead which is used to combine the two elements. Historically, brass has been used for items such as pumps, pipe fitting, and goblets. All 3 constituents are subject to leaching when they contact acidic foods, and food poisoning has resulted from such contact.

The steps in beer brewing include malting, mashing, fermentation, separation of the alcoholic beverage from the mash, and rectification. During mashing, it is essential to lower the pH from its normal 5.8 in order to optimize enzymatic activity. The pH is commonly lowered to 5.1-5.2, but may be adjusted to as low as 3.2. The soluble extract of the mash (wort) is boiled with hops for 1 to 2½ hours or more. After boiling, the wort is cooled, inoculated with brewers yeast, and fermented. The use of copper equipment during the prefermentation and fermentation steps typically result in some leaching of copper.

Because copper is an essential nutrient for yeast growth, low levels of copper are metabolized by the yeast during fermentation. However, studies have shown that copper levels above 0.2 mg/L are toxic or lethal to the yeast. In addition, copper levels as low as 3.5 mg/L have been reported to cause symptoms of copper poisoning in humans. Therefore, the levels of copper necessary for successful beer fermentation (i.e., below 0.2 mg/L) do not reach a level that would be toxic to humans.

Today, domestic beer brewers typically endeavor to use only stainless steel or stainless steel-lined copper equipment (piping, fermenters, filters, holding tanks, bottling machines, keys, etc.) in contact with beer following the hot brewing steps in the beer making process. Some also use pitch-coated oak vats or glass-lined steel vats following the hot brewing steps. Where copper equipment is not used in beer brewing, it is common practice to add copper (along with zinc) to provide the nutrients essential to the yeast for successful fermentation.

4-101.15 Galvanized Metal, Use Limitation.*

Galvanized means iron or steel coated with zinc, a heavy metal that may be leached from galvanized containers into foods that are high in water content. The risk of leaching increases with increased acidity of foods contacting the galvanized container.

4-101.16 Sponges, Use Limitation.

Sponges are difficult, if not impossible, to clean once they have been in contact with food particles and contaminants that are found in the use environment. Because of their construction, sponges provide harborage for any number and variety of microbiological organisms, many of which may be pathogenic. Therefore, sponges are to be used only where they will not contaminate cleaned and sanitized or in-use, food-contact surfaces such as for cleaning equipment and utensils before rinsing and sanitizing.

4-101.17 Lead in Pewter Alloys, Use Limitation.

Pewter refers to a number of silver-gray alloys of tin containing various amounts of antimony, copper, and lead. The same concerns about the leaching of heavy metals and lead that apply to brass, galvanized metals, copper, cast iron, ceramics, and crystal also apply to pewter. As previously stated, the storage of acidic moist foods in pewter containers could result in food poisoning (heavy metal poisoning).

4-101.18 Lead in Solder and Flux, Use Limitation.

Solder is a material that is used to join metallic parts and is applied in the melted state to solid metals. Solder may be composed of tin and lead alloys. As mentioned in the public health reasons for §§4-101.12 and 4-101.13, lead has been linked to many health problems especially among the young. Consequently, the amount of lead allowed in food equipment is subject to limitation.

4-101.19 Wood, Use Limitation.

The limited acceptance of the use of wood as a food-contact surface is determined by the nature of the food and the type of wood used. Moist foods may cause the wood surface to deteriorate and the surface may become difficult to clean. In addition, wood that is treated with preservatives may result in illness due to the migration of the preservative chemicals to the food; therefore, only specific preservatives are allowed.

4-101.110 Nonstick Coatings, Use Limitation.

Perfluorocarbon resin is a tough, nonporous and stable plastic material that gives cookware and bakeware a surface to which foods will not stick and that cleans easily and quickly. FDA has approved the use of this material as safe for food-contact surfaces. The Agency has determined that neither the particles that may chip off nor the fumes given off at high temperatures pose a health hazard. However, because this nonstick finish may be scratched by sharp or rough-edged kitchen tools, the manufacturer's recommendations should be consulted and the use of utensils that may scratch, abrasive scouring pads, or cleaners avoided.

4-101.111 Nonfood-Contact Surfaces.

Nonfood-contact surfaces of equipment routinely exposed to splash or food debris are required to be constructed of nonabsorbent materials to facilitate cleaning. Equipment that is

easily cleaned minimizes the presence of pathogenic organisms, moisture, and debris and deters the attraction of rodents and insects.

Single-Service and Single-Use **4-102.11 Characteristics.***

The safety and quality of food can be adversely affected through single service and single use articles that are not constructed of acceptable materials. The migration of components of those materials to food they contact could result in chemical contamination and illness to the consumer. In addition, the use of unacceptable materials could adversely affect the quality of the food because of odors, tastes, and colors transferred to the food.

Durability and Strength **4-201.11 Equipment and Utensils.**

Equipment and utensils must be designed and constructed to be durable and capable of retaining their original characteristics so that such items can continue to fulfill their intended purpose for the duration of their life expectancy and to maintain their easy cleanability. If they can not maintain their original characteristics, they may become difficult to clean, allowing for the harborage of pathogenic microorganisms, insects, and rodents. Equipment and utensils must be designed and constructed so that parts do not break and end up in food as foreign objects or present injury hazards to consumers. A common example of presenting an injury hazard is the tendency for tines of poorly designed single service forks to break during use.

4-201.12 Food Temperature Measuring Devices.*

Food temperature measuring devices that have glass sensors or stems present a likelihood that glass will end up in food as a foreign object and create an injury hazard to the consumer. In addition, the contents of the temperature measuring device, e.g., mercury, may contaminate food or utensils.

Cleanability **4-202.11 Food-Contact Surfaces.***

The purpose of the requirements for multiuse food-contact surfaces is to ensure that such surfaces are capable of being easily cleaned and accessible for cleaning. Food-contact surfaces that do not meet these requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces which have imperfections such as cracks, chips, or pits allow microorganisms to attach and form biofilms. Once established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and sanitizing efforts. The requirement for easy disassembly recognizes the reluctance of food employees to disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.

4-202.12 CIP Equipment.

Certain types of equipment are designed to be cleaned in place (CIP) where it is difficult or impractical to disassemble the equipment for cleaning. Because of the closed nature of the system, CIP cleaning must be monitored via access points to ensure that cleaning has been effective throughout the system.

The CIP design must ensure that all food-contact surfaces of the equipment are contacted by the circulating cleaning and sanitizing solutions. Dead spots in the system, i.e., areas which are not contacted by the cleaning and sanitizing solutions, could result in the buildup of food debris and growth of pathogenic microorganisms. There is equal concern that cleaning and sanitizing solutions might be retained in the system, which may result in the inadvertent adulteration of food. Therefore, the CIP system must be self-draining.

4-202.13 "V" Threads, Use Limitation.

V-type threads present a surface which is difficult to clean routinely; therefore, they are not allowed on food-contact surfaces. The exception provided for hot oil cooking fryers and filtering systems is based on the high temperatures that are used in this equipment. The high temperature in effect sterilizes the equipment, including debris in the "V" threads.

4-202.14 Hot Oil Filtering Equipment.

To facilitate and ensure effective cleaning of this equipment, Code requirements, §§ 4-202.11 and 4-202.12 must be followed. The filter is designed to keep the oil free of undesired materials and therefore must be readily accessible for replacement. Filtering the oil reduces the likelihood that off-odors, tastes, and possibly toxic compounds may be imparted to food as a result of debris buildup. To ensure that filtering occurs, it is necessary for the filter to be accessible for replacement.

4-202.15 Can Openers.

Once can openers become pitted or the surface in any way becomes uncleanable, they must be replaced because they can no longer be adequately cleaned and sanitized. Can openers must be designed to facilitate replacement.

4-202.16 Nonfood-Contact Surfaces.

Hard-to-clean areas could result in the attraction and harborage of insects and rodents and allow the growth of foodborne pathogenic microorganisms. Well-designed equipment enhances the ability to keep nonfood-contact surfaces clean.

4-202.17 Kick Plates, Removable.

The use of kick plates is required to allow access for proper cleaning. If kick plate design and installation does not meet Code requirements, debris could accumulate and create a situation that may attract insects and rodents.

Accuracy **4-203.11 Temperature Measuring Devices, Food.**

The Metric Conversion Act of 1975 (amended 1988) requires that all federal government regulations use the Celsius scale for temperature measurement. The Fahrenheit scale is included in the Code for those jurisdictions using the Fahrenheit scale for temperature measurement.

The small margin of error specified for thermometer accuracy is due to the lack of a large safety margin in the temperature requirements themselves. The accuracy specified for a particular food temperature measuring device is applicable to its entire range of use, that is, from refrigeration through cooking temperatures if the device is intended for such use.

4-203.12 Temperature Measuring Devices, Ambient Air and Water.

A temperature measuring device used to measure the air temperature in a refrigeration unit is not required to be as accurate as a food thermometer because the unit's temperature fluctuates with repeated opening and closing of the door and because accuracy in measuring internal food temperatures is of more significance.

The Celsius scale is the federally recognized scale based on The Metric Conversion Act of 1975 (amended 1988) which requires the use of metric values. The ± 1.5^{o}C requirement is more stringent than the 3°F previously required since ± 1.5^{o}C is equivalent to ± 2.7^{o}F. The more rigid accuracy results from the practical application of metric equivalents to the temperature gradations of Celsius thermometers.

If Fahrenheit thermometers are used, the 3°F requirement applies because of the calibrated intervals of Fahrenheit thermometers.

The accuracy specified for a particular air or water temperature measuring device is applicable to its intended range of use. For example, a cold holding unit may have a temperature measuring device that measures from a specified frozen temperature to 20°C (68°F). The device must be accurate to specifications within that use range.

4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment.

Flow pressure is a very important factor with respect to the efficacy of sanitization. A pressure below the design pressure results in inadequate spray patterns and incomplete coverage of the utensil surfaces to be sanitized. Excessive flow pressure will tend to atomize the water droplets needed to convey heat into a vapor mist that cools before reaching the surfaces to be sanitized.

Functionality **4-204.11 Ventilation Hood Systems, Drip Prevention.**

The dripping of grease or condensation onto food constitutes adulteration and may involve contamination of the food with pathogenic organisms. Equipment, utensils, linens, and single service and single use articles that are subjected to such drippage are no longer clean.

4-204.12 Equipment Openings, Closures and Deflectors.

Equipment openings and covers must be designed to protect stored or prepared food from contaminants and foreign matter that may fall into the food. The requirement for an opening to be flanged upward and for the cover to overlap the opening and be sloped to drain prevents contaminants, especially liquids, from entering the food-contact area.

Some equipment may have parts that extend into the food-contact areas. If these parts are not provided with a watertight joint at the point of entry into the food-contact area, liquids may contaminate the food by adhering to shafts or other parts and running or dripping into the food.

An apron on parts extending into the food-contact area is an acceptable alternative to the watertight seal. If the apron is not properly designed and installed, condensation, drips, and dust may gain access to the food.

4-204.13 Dispensing Equipment, Protection of Equipment and Food.

This requirement is intended to protect both the machine-dispensed, unpackaged, liquid foods and the machine components from contamination. Barriers need to be provided so that the only liquid entering the food container is the liquid intended to be dispensed when the machine's mechanism is activated. Recessing of the machine's components and self-closing doors prevent contamination of machine ports by people, dust, insects, or rodents. If the equipment components become contaminated, the product itself will be exposed to possible contamination.

A direct opening into the food being dispensed allows dust, vermin, and other contaminants access to the food.

4-204.14 Vending Machine, Vending Stage Closure.

Since packaged foods dispensed from vending machines could attract insects and rodents, a self-closing door is required as a barrier to their entrance.

4-204.15 Bearings and Gear Boxes, Leakproof.

It is not unusual for food equipment to contain bearings and gears. Lubricants necessary for the operation of these types of equipment could contaminate food or food-contact surfaces if the equipment is not properly designed and constructed.

4-204.16 Beverage Tubing, Separation.

Beverage tubing and coldplate cooling devices may result in contamination if they are installed in direct contact with stored ice. Beverage tubing installed in contact with ice may result in condensate and drippage contaminating the ice as the condensate moves down the beverage tubing and ends up in the ice.

The presence of beverage tubing and/or coldplate cooling devices also presents cleaning problems. It may be difficult to adequately clean the ice bin if they are present. Because of the high moisture environment, mold and algae may form on the surface of the ice bins and any tubing or equipment stored in the bins.

4-204.17 Ice Units, Separation of Drains.

Liquid waste drain lines passing through ice machines and storage bins present a risk of contamination due to potential leakage of the waste lines and the possibility that contaminants will gain access to the ice through condensate migrating along the exterior of the lines.

Liquid drain lines passing through the ice bin are, themselves, difficult to clean and create other areas that are difficult to clean where they enter the unit as well as where they abut other surfaces. The potential for mold and algal growth in this area is very likely due to the high moisture environment. Molds and algae that form on the drain lines are difficult to remove and present a risk of contamination to the ice stored in the bin.

4-204.18 Condenser Unit, Separation.

A dust-proof barrier between a condenser and food storage areas of equipment protects food and food-contact areas from contamination by dust that is accumulated and blown about as a result of the condenser's operation.

4-204.19 Can Openers on Vending Machines.

Since the cutting or piercing surfaces of a can opener directly contact food in the container being opened, these surfaces must be protected from contamination.

4-204.110 Molluscan Shellfish Tanks.

Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria.

Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of pathogenic microorganisms in shellfish held in display tanks is of concern.
If shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination must be controlled or eliminated. Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

4-204.111 Vending Machines, Automatic Shutoff.*

Failure to store potentially hazardous food at safe temperatures in a vending machine could result in the growth of pathogenic microorganisms that may result in foodborne illness. The presence of an automatic control that prevents the vending of food if the temperature of the unit exceeds Code requirements precludes the vending of foods that may not be safe.

It is possible and indeed very likely that the temperature of the storage area of a vending machine may exceed Code requirements during the stocking and servicing of the machine. The automatic shut off, commonly referred to as the "public health control", provides a limited amount of time that the ambient temperature of a machine may exceed Code requirements. Strict adherence to the time requirements can limit the growth of pathogenic microorganisms.

4-204.112 Temperature Measuring Devices.

The placement of the temperature measuring device is important. If the device is placed in the coldest location in the storage unit, it may not be representative of the temperature of the unit. Food could be stored in areas of the unit that exceed Code requirements. Therefore, the temperature measuring device must be placed in a location that is representative of the actual storage temperature of the unit to ensure that all potentially hazardous foods are stored at least at the minimum temperature required in Chapter 3.

A permanent temperature measuring device is required in any unit storing potentially hazardous food because of the potential growth of pathogenic microorganisms should the temperature of the unit exceed Code requirements. In order to facilitate routine monitoring of the unit, the device must be clearly visible.

The exception to requiring a temperature measuring device for the types of equipment listed is primarily due to equipment design and function. It would be difficult and impractical to permanently mount a temperature measuring device on the equipment listed. The futility of attempting to measure the temperature of unconfined air such as with heat lamps and, in some cases, the brief period of time the equipment is used for a given food negate the usefulness of ambient temperature monitoring at that point. In such cases, it would be more practical and accurate to measure the internal temperature of the food.

The importance of maintaining potentially hazardous foods at the specified temperatures requires that temperature measuring devices be easily readable. The inability to accurately read a thermometer could result in food being held at unsafe temperatures.

Temperature measuring devices must be appropriately scaled per Code requirements to ensure accurate readings.

The required incremental gradations are more precise for food measuring devices than for those used to measure ambient temperature because of the significance at a given point in time, i.e., the potential for pathogenic growth, versus the unit's temperature. The food temperature will not necessarily match the ambient temperature of the storage unit; it will

depend on many variables including the temperature of the food when it is placed in the unit, the temperature at which the unit is maintained, and the length of time the food is stored in the unit.

4-204.113 Warewashing Machine, Data Plate Operating Specifications.

The data plate provides the operator with the fundamental information needed to ensure that the machine is effectively washing, rinsing, and sanitizing equipment and utensils. The warewashing machine has been tested, and the information on the data plate represents the parameters that ensure effective operation and sanitization and that need to be monitored.

4-204.114 Warewashing Machines, Internal Baffles.

The presence of baffles or curtains separating the various operational cycles of a warewashing machine such as washing, rinsing, and sanitizing are designed to reduce the possibility that solutions from one cycle may contaminate solutions in another. The baffles or curtains also prevent food debris from being splashed onto the surface of equipment that has moved to another cycle in the procedure.

4-204.115 Warewashing Machines, Temperature Measuring Devices.

The requirement for the presence of a temperature measuring device in each tank of the warewashing machine is based on the importance of temperature in the sanitization step. In hot water machines, it is critical that minimum temperatures be met at the various cycles so that the cumulative effect of successively rising temperatures causes the surface of the item being washed to reach the required temperature for sanitization. When chemical sanitizers are used, specific minimum temperatures must be met because the effectiveness of chemical sanitizers is directly affected by the temperature of the solution.

4-204.116 Manual Warewashing Equipment, Heaters and Baskets.

Hot water sanitization is accomplished in water of not less than 77°C (170°F) and an integral heating device is necessary to ensure that the minimum temperature is reached.

The rack or basket is required in order to safely handle the equipment and utensils being washed and to ensure immersion. Water at this temperature could result in severe burns to employees operating the equipment.

4-204.118 Warewashing Machines, Flow Pressure Device.

Flow pressure is a very important factor impacting the efficacy of sanitization in machines that use fresh hot water at line-pressure as a final sanitization rinse. (See discussion in Public Health Reason for Section 4-203.13.) It is important that the operator be able to monitor, and the food inspector be able to check, final sanitization rinse pressure as well as machine water temperatures. ANSI/NSF Standard #3, a national voluntary consensus

standard for Commercial Spray-Type Dishwashing Machines, specifies that a pressure gauge or similar device be provided on this type machine and such devices are shipped with machines by the manufacturer. Flow pressure devices installed on the upstream side of the control (solenoid) valve are subject to damage and failure due to the water hammer effect caused throughout the dishwashing period each time the control valve closes. The IPS valve provides a ready means for checking line-pressure with an alternative pressure measuring device. A flow pressure device is not required on machines that use only a pumped or recirculated sanitizing rinse since an appropriate pressure is ensured by a pump and is not dependent upon line-pressure.

4-204.119 Warewashing Sinks and Drainboards, Self-Draining.
4-204.120 Equipment Compartments, Drainage.

The draining requirement in equipment components is needed to prevent the pooling of water. Pooled water whether from drainage, condensate, drippage, or melting ice could contain or provide a favorable environment for pathogens and other contaminants.

4-204.121 Vending Machines, Liquid Waste Products.

The presence of internal waste containers allows for the collection of liquids that spill within the vending machine. Absence of a waste container or, where required, a shutoff valve which controls the incoming liquids could result in wastes spilling within the machine, causing a condition that attracts insects and rodents and compounds cleaning and maintenance problems.

4-204.122 Case Lot Handling Equipment, Moveability.

Proper design of case lot handling equipment facilitates moving case lots for cleaning and for surveillance of insect or rodent activity.

4-204.123 Vending Machine Doors and Openings.

The objective of this requirement is to provide a barrier against the entrance into vending machines of insects, rodents, and dust. The maximum size of the openings deters the entrance of common pests.

Acceptability **4-205.10 Food Equipment, Certification and Classification.**

Under ANSI document CA-1 ANSI Policy and Criteria for Accreditation of Certification Programs, it has been stipulated that:

"For food equipment programs, standards that establish sanitation requirements shall be specified government standards or standards that have been ratified by a public health approval step. ANSI shall verify that this requirement has been met by communicating with appropriate standards developing organizations and governmental public health bodies."

The term certified is used when an item of food equipment has been evaluated against an

organization's own standard. The term classified is used when one organization evaluates an item of food equipment against a standard developed by another organization.

Equipment **4-301.11 Cooling, Heating, and Holding Capacities.**

The ability of equipment to cool, heat, and maintain potentially hazardous foods at Code-required temperatures is critical to food safety. Improper holding and cooking temperatures continue to be major contributing factors to foodborne illness. Therefore, it is very important to have adequate hot or cold holding equipment with enough capacity to meet the heating and cooling demands of the operation.

4-301.12 Manual Warewashing, Sink Compartment Requirements.

The 3 compartment requirement allows for proper execution of the 3-step manual warewashing procedure. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water and therefore diluting the strength and efficacy of the chemical sanitizer that may be used.

Alternative manual warewashing equipment, allowed under certain circumstances and conditions, must provide for accomplishment of the same 3 steps:

1. Application of cleaners and the removal of soil;

2. Removal of any abrasive and removal or dilution of cleaning chemicals; and

3. Sanitization.

Refer also to the public health reason for § 4-603.16.

4-301.13 Drainboards.

Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other and from the food preparation area in order to preclude contamination of cleaned items and of food.

Drainboards allow for the control of water running off equipment and utensils that have been washed and also allow the operator to properly store washed equipment and utensils while they air-dry.

4-301.14 Ventilation Hood Systems, Adequacy.

If a ventilation system is inadequate, grease and condensate may build up on the floors, walls and ceilings of the food establishment, causing an insanitary condition and possible deterioration of the surfaces of walls and ceilings. The accumulation of grease and condensate may contaminate food and food-contact surfaces as well as present a possible fire hazard.

Refer also to the public health reason for § 4-204.11.

4-301.15 Clothes Washers and Dryers.

To protect food, soiled work clothes or linens must be efficiently laundered. The only practical way of efficiently laundering work clothes on the premises is with the use of a mechanical washer and dryer.

Refer also to the public health reason for § 4-401.11.

Utensils, Temperature Measuring Devices, and Testing Devices

4-302.11 Utensils, Consumer Self-Service.

Appropriate serving utensils provided at each container will, among other things, reduce the likelihood of food tasting, use of fingers to serve food, use of fingers to remove the remains of one food on the utensil so that it may be used for another, use of soiled tableware to transfer food, and cross contamination between foods, including a raw food to a cooked potentially hazardous food.

4-302.12 Food Temperature Measuring Devices.

The presence and accessibility of food temperature measuring devices is critical to the effective monitoring of food temperatures. Proper use of such devices provides the operator or person in charge with important information with which to determine if temperatures should be adjusted or if foods should be discarded.

4-302.13 Temperature Measuring Devices, Manual Warewashing.

Water temperature is critical to sanitization in warewashing operations. This is particularly true if the sanitizer being used is hot water. The effectiveness of cleaners and chemical sanitizers is also determined by the temperature of the water used. A temperature measuring device is essential to monitor manual warewashing and ensure sanitization.

4-302.14 Sanitizing Solutions, Testing Devices.

Testing devices to measure the concentration of sanitizing solutions are required for 2 reasons:

1. The use of chemical sanitizers requires minimum concentrations of the sanitizer during the final rinse step to ensure sanitization; and

2. Too much sanitizer in the final rinse water could be toxic.

Location **4-401.11** **Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.**

Food equipment and the food that contacts the equipment must be protected from sources of overhead contamination such as leaking or ruptured water or sewer pipes, dripping condensate, and falling objects. When equipment is installed, it must be situated with consideration of the potential for contamination from such overhead sources.

If a clothes washer and dryer are installed adjacent to exposed food, clean equipment, utensils, linens, and unwrapped single-service and single-use articles, it could result in those items becoming contaminated from soiled laundry. The reverse is also true, i.e., items being laundered could become contaminated from the surrounding area if the washer and dryer are not properly located.

Installation **4-402.11** **Fixed Equipment, Spacing or Sealing.**

This section is designed to ensure that fixed equipment is installed in a way that:

1. Allows accessibility for cleaning on all sides, above, and underneath the units or minimizes the need for cleaning due to closely abutted surfaces;

2. Ensures that equipment that is subject to moisture is sealed;

3. Prevents the harborage of insects and rodents; and

4. Provides accessibility for the monitoring of pests.

4-402.12 **Fixed Equipment, Elevation or Sealing.**

The inability to adequately or effectively clean areas under equipment could create a situation that may attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food.

The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed equipment. It may be necessary to elevate the equipment. When elevating equipment is not feasible or prohibitively expensive, sealing to prevent contamination is required.

The economic impact of the requirement to elevate display units in retail food stores, coupled with the fact that the design, weight, and size of such units are not conducive to casters or legs, led to the exception for certain units located in consumer shopping areas, provided the floor under the units is kept clean. This exception for retail food store display equipment including shelving, refrigeration, and freezer units in the consumer shopping areas requires a rigorous cleaning schedule.

Equipment **4-501.11** **Good Repair and Proper Adjustment.**

Proper maintenance of equipment to manufacturer specifications helps ensure that it will continue to operate as designed. Failure to properly maintain equipment could lead to

violations of the associated requirements of the Code that place the health of the consumer at risk. For example, refrigeration units in disrepair may no longer be capable of properly cooling or holding potentially hazardous foods at safe temperatures.

The cutting or piercing parts of can openers may accumulate metal fragments that could lead to food containing foreign objects and, possibly, result in consumer injury.

Adequate cleaning and sanitization of dishes and utensils using a warewashing machine is directly dependent on the exposure time during the wash, rinse, and sanitizing cycles. Failure to meet manufacturer and Code requirements for cycle times could result in failure to clean and sanitize. For example, high temperature machines depend on the buildup of heat on the surface of dishes to accomplish sanitization. If the exposure time during any of the cycles is not met, the surface of the items may not reach the time-temperature parameter required for sanitization. Exposure time is also important in warewashing machines that use a chemical sanitizer since the sanitizer must contact the items long enough for sanitization to occur. In addition, a chemical sanitizer will not sanitize a dirty dish; therefore, the cycle times during the wash and rinse phases are critical to sanitization.

4-501.12 Cutting Surfaces.

Cutting surfaces such as cutting boards and blocks that become scratched and scored may be difficult to clean and sanitize. As a result, pathogenic microorganisms transmissible through food may build up or accumulate. These microorganisms may be transferred to foods that are prepared on such surfaces.

4-501.13 Microwave Ovens.

Failure of microwave ovens to meet the CFR standards could result in human exposure to radiation leakage, resulting in possible medical problems to consumers and employees using the machines.

4-501.14 Warewashing Equipment, Cleaning Frequency.

During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.

4-501.15 Warewashing Machines, Manufacturers' Operating Instructions.

To ensure properly cleaned and sanitized equipment and utensils, warewashing machines must be operated properly. The manufacturer affixes a data plate to the machine providing vital, detailed instructions about the proper operation of the machine including wash, rinse, and sanitizing cycle times and temperatures which must be achieved.

4-501.16 Warewashing Sinks, Use Limitation.

If the wash sink is used for functions other than warewashing, such as washing wiping cloths or washing and thawing foods, contamination of equipment and utensils could occur.

4-501.17 Warewashing Equipment, Cleaning Agents.

Failure to use detergents or cleaners in accordance with the manufacturer's label instructions could create safety concerns for the employee and consumer. For example, employees could suffer chemical burns, and chemical residues could find their way into food if detergents or cleaners are used carelessly.

Equipment or utensils may not be cleaned if inappropriate or insufficient amounts of cleaners or detergents are used.

4-501.18 Warewashing Equipment, Clean Solutions.

Failure to maintain clean wash, rinse, and sanitizing solutions adversely affects the warewashing operation. Equipment and utensils may not be sanitized, resulting in subsequent contamination of food.

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature required in the Code is essential for removing organic matter. If the temperature is below 110°F, the performance of the detergent may be adversely affected, e.g., animal fats that may be present on the dirty dishes would not be dissolved.

4-501.110 Mechanical Warewashing Equipment, Wash Solution Temperature.

The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The chemicals used may not adequately perform their function if the temperature is too low. Therefore, the manufacturer's instructions must be followed. The temperatures vary according to the specific equipment being used.

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures.*

If the temperature during the hot water sanitizing step is less than 75°C (170°F), sanitization will not be achieved. As a result, pathogenic organisms may survive and be subsequently transferred from utensils to food.

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

If the temperature of the hot water delivered to the warewasher manifold is inadequate to effect sanitization, surviving pathogenic organisms could contaminate equipment and utensils.

4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure.

If the flow pressure of the final sanitizing rinse is less than that required, dispersion of the sanitizing solution may be inadequate to reach all surfaces of equipment or utensils.

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.*

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 21 CFR 178.1010 must be used under water conditions stated on the label to ensure efficacy. Therefore, it is critical to sanitization that the sanitizers are used properly and the solutions meet the minimum standards required in the Code.

4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers.

Some chemical sanitizers are not compatible with detergents when a 2 compartment operation is used. When using a sanitizer that is different from the detergent-sanitizer of the wash compartment, the sanitizer may be inhibited by carry-over, resulting in inadequate sanitization.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer solution.

Utensils and Temperature and Pressure Measuring Devices

4-502.11 Good Repair and Calibration.

A utensil or food temperature measuring device can act as a source of contamination to the food it contacts if it is not maintained in good repair. Also, if temperature or pressure measuring devices are not maintained in good repair, the accuracy of the readings is questionable. Consequently, a temperature problem may not be detected, or conversely, a corrective action may be needlessly taken.

4-502.12 Single-Service and Single-Use Articles, Required Use.*

In situations in which the reuse of multiuse items could result in foodborne illness to consumers, single-service and single-use articles must be used to ensure safety.

4-502.13 Single-Service and Single-Use Articles, Use Limitation.

Articles that are not constructed of multiuse materials may not be reused as they are unable to withstand the rigors of multiple uses, including the ability to be subjected to repeated washing, rinsing, and sanitizing.

4-502.14 Shells, Use Limitation.

Mollusk and crustacea shells do not meet the Code requirements for multiuse utensils. Therefore, such shells may be used only once as serving containers.

Refer also to the public health reason for § 4-502.13.

Objective **4-601.11 Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.***

The objective of cleaning focuses on the need to remove organic matter from food-contact surfaces so that sanitization can occur and to remove soil from nonfood contact surfaces so that pathogenic microorganisms will not be allowed to accumulate and insects and rodents will not be attracted.

Frequency **4-602.11 Equipment Food-Contact Surfaces and Utensils.***

Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers, or other food-contact surfaces. Food-contact surfaces and equipment used for potentially hazardous foods should be cleaned as needed throughout the day but must be cleaned no less than every 4 hours to prevent the growth of microorganisms on those surfaces.

Refrigeration temperatures slow down the generation time of bacterial pathogens, making it unnecessary to clean every four hours. However, the time period between cleaning equipment and utensils may not exceed 24 hours. A time-temperature chart is provided in Subparagraph 4-602.11(D)(2) to accommodate operations that use equipment and utensils in a refrigerated room or area that maintains a temperature between 41°F or less and 55°F.

Surfaces of utensils and equipment contacting food that is not potentially hazardous such as iced tea dispensers, carbonated beverage dispenser nozzles, beverage dispensing circuits or lines, water vending equipment, coffee bean grinders, ice makers, and ice bins must be cleaned on a routine basis to prevent the development of slime, mold, or soil residues that may contribute to an accumulation of microorganisms. Some equipment manufacturers and industry associations, e.g., within the tea industry, develop guidelines for regular cleaning

and sanitizing of equipment. If the manufacturer does not provide cleaning specifications for food-contact surfaces of equipment that are not readily visible, the person in charge should develop a cleaning regimen that is based on the soil that may accumulate in those particular items of equipment.

4-602.12 Cooking and Baking Equipment.

Food-contact surfaces of cooking equipment must be cleaned to prevent encrustations that may impede heat transfer necessary to adequately cook food. Encrusted equipment may also serve as an insect attractant when not in use. Because of the nature of the equipment, it may not be necessary to clean cooking equipment as frequently as the equipment specified in § 4-602.11.

4-602.13 Nonfood-Contact Surfaces.

The presence of food debris or dirt on nonfood contact surfaces may provide a suitable environment for the growth of microorganisms which employees may inadvertently transfer to food. If these areas are not kept clean, they may also provide harborage for insects, rodents, and other pests.

Methods **4-603.11 Dry Cleaning.**

Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not potentially hazardous. Under some circumstances, attempts at wet cleaning may create microbiological concerns.

4-603.12 Precleaning.

Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be cleaned, detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be presoaked or scrubbed with an abrasive.

4-603.13 Loading of Soiled Items, Warewashing Machines.

Items to be washed in a warewashing machine must receive unobstructed exposure to the spray to ensure adequate cleaning. Items which are stacked or trays which are heavily loaded with silverware cannot receive complete distribution of detergent, water, or sanitizer and cannot be considered to be clean.

4-603.14 Wet Cleaning.

Because of the variety of cleaning agents available and the many different types of soil to be removed it is not possible to recommend one cleaning agent to fit all situations. Each of the different types of cleaners works best under different conditions (i.e., some work best on grease, some work best in warm water, others work best in hot water). The specific chemical

selected should be compatible with any other chemicals to be used in the operation such as a sanitizer or drying agent.

4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment.

Some pieces of equipment are too large (or fixed) to be cleaned in a sink. Nonetheless, cleaning of such equipment requires the application of cleaners for the removal of soil and rinsing for the removal of abrasive and cleaning chemicals, followed by sanitization.

4-603.16 Rinsing Procedures.

It is important to rinse off detergents, abrasive, and food debris after the wash step to avoid diluting or inactivating the sanitizer.

4-603.17 Returnables, Cleaning for Refilling.*

The refilling of consumer-owned beverage containers introduces the possibility of contamination of the filling equipment or product by improperly cleaned containers or the improper operation of the equipment. To prevent this contamination and possible health hazards to the consumer, the refilling of consumer-owned containers is limited to beverages that are not potentially hazardous. Equipment must be designed to prevent the contamination of the equipment and means must be provided to clean the containers at the facility.

Objective **4-701.10 Food-Contact Surfaces and Utensils.**

Effective sanitization procedures destroy organisms of public health importance that may be present on wiping cloths, food equipment, or utensils after cleaning, or which have been introduced into the rinse solution. It is important that surfaces be clean before being sanitized to allow the sanitizer to achieve its maximum benefit.

Frequency **4-702.11 Before Use After Cleaning.***

Sanitization is accomplished after the warewashing steps of cleaning and rinsing so that utensils and food-contact surfaces are sanitized before coming in contact with food and before use.

Methods **4-703.11 Hot Water and Chemical.***

Efficacious sanitization is dependent upon warewashing being conducted within certain parameters. Time is a parameter applicable to both chemical and hot water sanitization. The time that hot water or chemicals contact utensils or food-contact surfaces must be sufficient to destroy pathogens that may remain on surfaces after cleaning. Other parameters, such as temperature or chemical concentration, are used in combination with time to deliver effective sanitization.

Objective **4-801.11** **Clean Linens.**

Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness.

Frequency **4-802.11** **Specifications.**

Linens, cloth gloves, and cloth napkins are to be laundered between uses to prevent the transfer of pathogenic microorganisms between foods or to food-contact surfaces. The laundering of wet wiping cloths before being used with a fresh solution of cleanser or sanitizer is designed to reduce the microbiological load in the cleanser and sanitizer and thereby reduce the possible transfer of microorganisms to food and nonfood-contact surfaces.

Methods **4-803.11** **Storage of Soiled Linens**.

Soiled linens may directly or indirectly contaminate food. Proper storage will reduce the possibility of contamination of food, equipment, utensils, and single-service and single-use articles.

4-803.12 **Mechanical Washing**.

Proper laundering of wiping cloths will significantly reduce the possibility that pathogenic microorganisms will be transferred to food, equipment, or utensils.

4-803.13 **Use of Laundry Facilities**.

Washing and drying items used in the operation of the establishment on the premises will help prevent the introduction of pathogenic microorganisms into the environment of the food establishment.

Drying **4-901.11** **Equipment and Utensils, Air-Drying Required.**

Items must be allowed to drain and to air-dry before being stacked or stored. Stacking wet items such as pans prevents them from drying and may allow an environment where microorganisms can begin to grow. Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to equipment or utensils.

4-901.12 **Wiping Cloths, Air-Drying Locations.**

Cloths that are air-dried must be dried so that they do not drip on food or utensils and so that the cloths are not contaminated while air-drying.

Lubricating and Reassembling **4-902.11** **Food-Contact Surfaces.**

Food-contact surfaces must be lubricated in a manner that does not introduce contaminants to those surfaces.

4-902.12 Equipment.

Equipment must be reassembled in a way that food-contact surfaces are not contaminated.

Storing **4-903.11 Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.**

Clean equipment and multiuse utensils which have been cleaned and sanitized, laundered linens, and single-service and single-use articles can become contaminated before their intended use in a variety of ways such as through water leakage, pest infestation, or other insanitary condition.

4-903.12 Prohibitions.

The improper storage of clean and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may allow contamination before their intended use. Contamination can be caused by moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic materials, litter, dust, and other materials. The contamination is often related to unhygienic employee practices, unacceptable high-risk storage locations, or improper construction of storage facilities.

Handling **4-904.11 Kitchenware and Tableware.**
4-904.12 Soiled and Clean Tableware.
4-904.13 Preset Tableware.

The presentation and/or setting of single-service and single-use articles and cleaned and sanitized utensils shall be done in a manner designed to prevent the contamination of food- and lip-contact surfaces.

Chapter 5 Water, Plumbing, and Waste

Source **5-101.11 Approved System.***

Water, unless it comes from a safe supply, may serve as a source of contamination for food, equipment, utensils, and hands. The major concern is that water may become a vehicle for transmission of disease organisms. Water can also become contaminated with natural or man-made chemicals. Therefore, for the protection of consumers and employees, water must be obtained from a source regulated by law and must be used, transported, and dispensed in a sanitary manner.

5-101.12 System Flushing and Disinfection.*

During construction, repair, or modification, water systems may become contaminated with microbes from soil because pipes are installed underground or by chemicals resulting from soldering and welding. Floods and other incidents may also cause water to become contaminated. Chemical contaminants such as oils may also be present on or in the components of the system. To render the water safe, the system must be properly flushed and disinfected before being placed into service.

5-101.13 Bottled Drinking Water.*

Bottled water is obtained from a public water system or from a private source such as a spring or well. Either means of production must be controlled by public health law to protect the consumer from contaminated water.

Quality **5-102.11 Standards.***

Bacteriological and chemical standards have been developed for public drinking water supplies to protect public health. All drinking water supplies must meet standards required by law.

5-102.12 Nondrinking Water.*

Food establishments may use nondrinking water for purposes such as air-conditioning or fire protection. Nondrinking water is not monitored for bacteriological or chemical quality or safety as is drinking water. Consequently, certain safety precautions must be observed to prevent the contamination of food, drinking water, or food-contact surfaces. Identifying the piping designated as nondrinking waterlines and inspection for cross connections are examples of safety precautions.

5-102.13 Sampling.

Wells and other types of individual water supplies may become contaminated through faulty equipment or environmental contamination of ground water. Periodic sampling is required by law to monitor the safety of the water and to detect any change in quality. The controlling agency must be able to ascertain that this sampling program is active and that the safety of the water is in conformance with the appropriate standards. Laboratory results are only as accurate as the sample submitted. Care must be taken not to contaminate samples. Proper sample collection and timely transportation to the laboratory are necessary to ensure the safety of drinking water used in the establishment.

5-102.14 Sample Report.

The most recent water sampling report must be kept on file to document a safe water supply.

Quantity and Availability **5-103.11 Capacity.***

Availability of sufficient water is a basic requirement for proper sanitation within a food establishment. An insufficient supply of safe water will prevent the proper cleaning of items such as equipment and utensils and of food employees' hands.

Hot water required for washing items such as equipment and utensils and employees' hands, must be available in sufficient quantities to meet demand during peak water usage periods. Booster heaters for warewashers that use hot water for sanitizing are designed to raise the temperature of hot water to a level that ensures sanitization. If the volume of water reaching the booster heater is not sufficient or hot enough, the required temperature for sanitization

can not be reached. Manual washing of food equipment and utensils is most effective when hot water is used. Unless utensils are clean to sight and touch, they cannot be effectively sanitized.

5-103.12 Pressure.

Inadequate water pressure could lead to situations that place the public health at risk. For example, inadequate pressure could result in improper handwashing or equipment operation. Sufficient water pressure ensures that equipment such as mechanical warewashers operate according to manufacturer's specifications.

Distribution, Delivery, and Retention **5-104.11 System.**

Inadequate water systems may serve as vehicles for contamination of food or food- contact surfaces. This requirement is intended to ensure that sufficient volumes of water are provided from supplies shown to be safe, through a distribution system which is protected.

5-104.12 Alternative Water Supply.

Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport vehicles and containers, may result in contamination of safe water and render it hazardous to human health.

Materials **5-201.11 Approved.***

Plumbing systems and hoses conveying water must be made of approved materials and be smooth, durable, nonabsorbent, and corrosion-resistant. If not, the system may constitute a health hazard because unsuitable surfaces may harbor disease organisms or it may be constructed of materials that may, themselves, contaminate the water supply.

Design, Construction, and Installation **5-202.11 Approved System and Cleanable Fixtures.***

Water within a system will leach minute quantities of materials out of the components of the system. To make sure none of the leached matter is toxic or in a form that may produce detrimental effects, even through long-term use, all materials and components used in water systems must be of an approved type. New or replacement items must be tested and approved based on current standards.

Improperly designed, installed, or repaired water systems can have inherent deficiencies such as improper access openings, dead spaces, and areas difficult or impossible to clean and disinfect. Dead spaces allow water quality to degrade since they are out of the constant circulation of the system. Fixtures such as warewashing sinks that are not easily cleanable may lead to the contamination of food products.

5-202.12 Handwashing Facility, Installation.

Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands. An inadequate flow or temperature of water may lead to poor handwashing practices by food employees. A mixing valve or combination faucet is needed to provide properly tempered water for handwashing. Steam mixing valves are not allowed for this use because they are hard to control and injury by scalding is a possible hazard.

5-202.13 Backflow Prevention, Air Gap.*

During periods of extraordinary demand, drinking water systems may develop negative pressure in portions of the system. If a connection exists between the system and a source of contaminated water during times of negative pressure, contaminated water may be drawn into and foul the entire system. Standing water in sinks, dipper wells, steam kettles, and other equipment may become contaminated with cleaning chemicals or food residue. To prevent the introduction of this liquid into the water supply through back siphonage, various means may be used.

The water outlet of a drinking water system must not be installed so that it contacts water in sinks, equipment, or other fixtures that use water. Providing an air gap between the water supply outlet and the flood level rim of a plumbing fixture or equipment prevents contamination that may be caused by backflow.

5-202.14 Backflow Prevention Device, Design Standard.

In some instances an air gap is not practical such as is the case on the lower rinse arm for the final rinse of warewashers. This arm may become submerged if the machine drain becomes clogged. If this failure occurs, the machine tank would fill to the flood level rim, which is above the rinse arm. A backflow prevention device is used to avoid potential backflow of contaminated water when an air gap is not practical. The device provides a break to the atmosphere in the event of a negative pressure within the system.

Minerals contained in water and solid particulate matter carried in water may coat moving parts of the device or become lodged between them over time. This may render the device inoperative. To minimize such an occurrence, only devices meeting certain standards of construction, installation, maintenance, inspection, and testing for that application may be used. The necessary maintenance can be facilitated by installing these devices in accessible locations.

5-202.15 Conditioning Device, Design.

Water conditioning devices must be designed for easy disassembly for servicing so that they can be maintained in a condition that allows them to perform the function for which they were designed.

Numbers and Capacities

5-203.11 Handwashing Facilities.*

Because handwashing is such an important factor in the prevention of foodborne illness, sufficient facilities must be available to make handwashing not only possible, but likely.

5-203.12 Toilets and Urinals.*

Adequate, sanitary toilet facilities are necessary for the proper disposal of human waste, which carries pathogenic microorganisms, and for preventing the spread of disease by flies and other insects.

Toilet facilities must be of sanitary design and kept clean and in good repair to prevent food contamination and to motivate employees to use sanitary practices in the establishment.

5-203.13 Service Sink.

Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Waste water must be disposed of in a sanitary manner that will not contaminate food or food equipment. A service sink or curbed cleaning facility with a drain allows for such disposal.

5-203.14 Backflow Prevention Device, When Required.*

The delivery end of hoses attached to hose bibbs on a drinking water line may be dropped into containers filled with contaminated water or left in puddles on the floor or in other possible sources of contamination. A backflow prevention device must be installed on the hose bibb to prevent the back siphonage of contaminated liquid into the drinking water system during occasional periods of negative pressure in the water line.

5-203.15 Backflow Prevention Device, Carbonator.*

This section is reserved.

The text of this section was deleted in response to a 1996 Conference for Food Protection (CFP) Recommendation. FDA intends to further review the information that is available related to alternative methods of protecting the consumer from this potential cause of copper poisoning and to report its findings to the CFP for reconsideration of the matter.

When carbon dioxide is mixed with water, carbonic acid, a weak acid, is formed. Carbonators on soft drink dispensers form such acids as they carbonate the water to be mixed with the syrups to produce the soft drinks. If, for some reason, a negative pressure develops in the water line to the carbonator, some acidic water will be drawn into the water line. If this line is made of copper, carbonic acid will dissolve some of the copper. When pressure is restored, the trapped water containing dissolved copper will return to the carbonator and be mixed into the first few drinks. This may result in copper poisoning.

Location and Placement **5-204.11 Handwashing Facilities.***

Hands are probably the most common vehicle for the transmission of pathogens to foods in an establishment. Hands can become soiled with a variety of contaminants during routine operations. Some employees are unlikely to wash their hands unless properly equipped handwashing facilities are accessible in the immediate work area. Facilities which are improperly located may be blocked by portable equipment or stacked full of soiled utensils and other items, rendering the facility unavailable for regular employee use. Nothing must block the approach to a handwashing facility thereby discouraging its use, and the facility must be kept clean and well stocked with soap and sanitary towels to encourage frequent use.

5-204.12 Backflow Prevention Device, Location.

Backflow prevention devices are meant to protect the drinking water system from contamination caused by backflow. If improperly placed, backflow prevention devices will not work. If inconveniently located, these devices may not be accessed when systems are extended, altered, serviced, or replaced. Over a period of time, unserviced devices may fail and system contamination may occur.

5-204.13 Conditioning Device, Location.

When not located for easy maintenance, conditioning devices will be inconvenient to access and devices such as filters, screens, and water softeners will become clogged because they are not properly serviced.

Operation and Maintenance **5-205.11 Using a Handwashing Facility.**

Facilities must be maintained in a condition that promotes handwashing and restricted for that use. Convenient accessibility of a handwashing facility encourages timely handwashing which provides a break in the chain of contamination from the hands of food employees to food or food-contact surfaces. Sinks used for food preparation and warewashing can become sources of contamination if used as handwashing facilities by employees returning from the toilet or from duties which have contaminated their hands.

5-205.12 Prohibiting a Cross Connection.*

Nondrinking water may be of unknown or questionable origin. Waste water is either known or suspected to be contaminated. Neither of these sources can be allowed to contact and contaminate the drinking water system.

5-205.13 Scheduling Inspection and Service for a Water System Device.

Water system devices, such as filters and backflow preventers, are affected by the water in the system. How devices are affected depends on water quality, especially pH, hardness,

and suspended particulate matter in the water. Complexity of the device is also a factor. Manufacturer recommendations, as well as inspection and maintenance schedules for these devices, must be strictly followed to prevent failure during operation.

Cleaning **5-205.14** **Water Reservoir of Fogging Devices, Cleaning.***

Water reservoirs that have poor water exchange rates, such as reservoirs for some humidifiers or aerosol or fogging devices, and that are directly or indirectly open to the atmosphere, may be contaminated with respiratory pathogens such as ***Legionella pneumophila***. This organism is extremely infectious and can be transmitted through very small droplets of a fogger or humidifier. It is important that the manufacturer's cleaning and maintenance schedule be scrupulously followed to prevent a reservoir from colonization by this bacterium.

5-205.15 **System Maintained in Good Repair.***

Improper repair or maintenance of any portion of the plumbing system may result in potential health hazards such as cross connections, backflow, or leakage. These conditions may result in the contamination of food, equipment, utensils, linens, or single-service or single-use articles. Improper repair or maintenance may result in the creation of obnoxious odors or nuisances, and may also adversely affect the operation of warewashing equipment or other equipment which depends on sufficient volume and pressure to perform its intended functions.

Materials **5-301.11** **Approved.**

Materials used in the construction of a mobile water tank are affected by the water they contact. Tank liners may deteriorate and flake. Metals or platings can be toxic. To prevent the degradation of the quality of the water, it is important that the materials used in the construction of the tank are suitable for such use.

Design and Construction **5-302.11** **Enclosed System, Sloped to Drain.**
5-302.12 **Inspection and Cleaning Port, Protected and Secured.**

The tank must be a closed system from the filling inlet to the outlet to prevent contamination of water. It is important that the bottom of the tank be sloped to the outlet to allow the tank to drain completely, to facilitate the proper cleaning and disinfection of the tank, and to prevent the retention of water or solutions after cleaning.

Some tanks are designed with an access opening to facilitate the cleaning and servicing of the water tank. The access must be constructed to prevent the opening from becoming a source of contamination of the water.

5-302.13 "V" Type Threads, Use Limitation.

V-type threads are difficult to clean if contaminated with food or waste. To prevent the contamination of the drinking water, this type of thread should only be used on water tank inlets and outlets if the connection is permanent which eliminates exposed, difficult-to-clean threads.

5-302.14 Tank Vent, Protected.

Water tanks are equipped with a vent to preclude distortion during filling or draining. The vent should be equipped with a suitable screen or filter to protect the tank against the entry of insects or other vermin that may contaminate the water supply.

5-302.15 Inlet and Outlet, Sloped to Drain.

Both the inlet and outlet must be sloped to drain to prevent the pooling of possibly contaminated water or sanitizing solution.

5-302.16 Hose, Construction and Identification.

Hoses used to fill potable water tanks should be dedicated for that one task and should be identified for that use only to prevent contaminating the water. Hoses must be made of a material that will not leach detrimental substances into the water.

Numbers and Capacities

5-303.11 Filter, Compressed Air.

Compressor pistons are lubricated with oil to minimize wear. Some of the oil is carried into the air lines and if not intercepted may contaminate the tank and water lines.

5-303.12 Protective Cover or Device.

Protective equipment provided for openings of the water supply must be in use to prevent contamination which may be present where the supply is exposed to the environment, i.e., at water inlets or outlets or the ends of transfer hoses.

5-303.13 Mobile Food Establishment Tank Inlet.

Mobile units may be particularly vulnerable to environmental contamination if soiled hose connections are coupled to the tank inlet.

Operation and Maintenance

5-304.11 System Flushing and Disinfection.*

Contaminants of various types may be introduced into a water system during construction or repair or other incidents. The system must be flushed and sanitized after maintenance and before it is placed into service to prevent contamination of the water introduced into the tank.

5-304.12 Using a Pump and Hoses, Backflow Prevention.

When a water system includes a pump, or a pump is used in filling a water tank, care must be taken during hookup to prevent negative pressure on the supplying water system. Backflow prevention to protect the water supply is especially necessary during cleaning and sanitizing operations on a mobile system.

5-304.13 Protecting Inlet, Outlet, and Hose Fitting.

When not connected for use, water inlets, outlets, and hose fittings should be closed to the environment. Unless capped or otherwise protected, filling inlets, outlets, and hoses may become contaminated by dust or vermin.

5-304.14 Tank, Pump, and Hoses, Dedication.

Hoses, pumps, and tanks used for food or water may not be used for other liquids because this may contaminate the water supply. If a hose, tank, or pump has been used to transfer liquid food, the equipment must be cleaned and sanitized before using it for water delivery. Failure to properly clean and sanitize the equipment would introduce nutrients, and possibly bacteria, into the water as well as inactivate residual chlorine from public water supplies.

Mobile Holding Tank

5-401.11 Capacity and Drainage.

Liquid waste from a mobile or temporary food establishment must be stored in a properly constructed waste tank to discourage the attraction of flies and other vermin. The waste tank must be 15% larger than the water storage tank to allow for storage of wastes and used water from the drinking water supply tank. The drain from the waste tank must be larger than the filling hose to prevent the use of the drinking water filling hose to drain the waste tank.

Retention, Drainage, and Delivery

5-402.10 Establishment Drainage System.

The drainage system must be designed and installed properly to prevent the backup of sewage and the possible contamination of foods or food-contact surfaces in the establishment.

5-402.11 Backflow Prevention.*

Improper plumbing installation or maintenance may result in potential health hazards such as cross connections, back siphonage or backflow. These conditions may result in the contamination of food, utensils, equipment, or other food-contact surfaces. It may also adversely affect the operation of equipment such as warewashing machines.

5-402.12 Grease Trap.

Failure to locate a grease trap so that it can be properly maintained and cleaned could result in the harborage of vermin and/or the failure of the sewage system.

5-402.13 Conveying Sewage.*
5-402.14 Removing Mobile Food Establishment Waste.

Improper disposal of waste provides a potential for contamination of food, utensils, and equipment and, therefore, may cause serious illness or disease outbreaks. Proper removal is required to prevent contamination of ground surfaces and water supplies, or creation of other insanitary conditions that may attract insects and other vermin.

5-402.15 Flushing a Waste Retention Tank.

Thoroughly flushing the liquid waste retention tank will prevent the buildup of deposits within the tank which could affect the proper operation of the tank.

Disposal Facility **5-403.11 Approved Sewage Disposal System.***

Many diseases can be transmitted from one person to another through fecal contamination of food and water. This transmission can be indirect. Proper disposal of human wastes greatly reduces the risk of fecal contamination. This Code provision is intended to ensure that wastes will not contaminate ground surfaces or water supplies; pollute surface waters; be accessible to children or pets; or allow rodents or insects to serve as vectors of disease from this source.

5-403.12 Other Liquid Waste and Rainwater.

Liquid food wastes and rainwater can provide a source of bacterial contamination and support populations of pests. Proper storage and disposal of wastes and drainage of rainwater eliminate these conditions.

Facilities on the Premises	**5-501.10**	**Indoor Storage Area.**
	5-501.11	**Outdoor Storage Surface.**
	5-501.12	**Outdoor Enclosure.**
	5-501.13	**Receptacles.**
	5-501.14	**Receptacles in Vending Machines.**
	5-501.15	**Outside Receptacles.**
	5-501.16	**Storage Areas, Rooms, and Receptacles, Capacity and Availability.**
	5-501.17	**Toilet Room Receptacle, Covered.**
	5-501.18	**Cleaning Implements and Supplies.**
	5-501.19	**Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.**
	5-501.110	**Storage Refuse, Recyclables, and Returnables**
	5-501.111	**Areas, Enclosures, and Receptacles, Good Repair.**
	5-501.112	**Outside Storage Prohibitions.**
	5-501.113	**Covering Receptacles.**
	5-501.114	**Using Drain Plugs.**
	5-501.115	**Maintaining Refuse Areas and Enclosures.**
	5-501.116	**Cleaning Receptacles.**

Proper storage and disposal of garbage and refuse are necessary to minimize the development of odors, prevent such waste from becoming an attractant and harborage or breeding place for insects and rodents, and prevent the soiling of food preparation and food service areas. Improperly handled garbage creates nuisance conditions, makes housekeeping difficult, and may be a possible source of contamination of food, equipment, and utensils.

Storage areas for garbage and refuse containers must be constructed so that they can be thoroughly cleaned in order to avoid creating an attractant or harborage for insects or rodents. In addition, such storage areas must be large enough to accommodate all the containers necessitated by the operation in order to prevent scattering of the garbage and refuse.

All containers must be maintained in good repair and cleaned as necessary in order to store garbage and refuse under sanitary conditions as well as to prevent the breeding of flies.

Garbage containers should be available wherever garbage is generated to aid in the proper disposal of refuse.

Outside receptacles must be constructed with tight-fitting lids or covers to prevent the scattering of the garbage or refuse by birds, the breeding of flies, or the entry of rodents. Proper equipment and supplies must be made available to accomplish thorough and proper cleaning of garbage storage areas and receptacles so that unsanitary conditions can be eliminated.

Removal **5-502.11** **Frequency.**
5-502.12 **Receptacles or Vehicles.**

Refuse, recyclables, and returnable items, such as beverage cans and bottles, usually contain a residue of the original contents. Spillage from these containers soils receptacles and storage areas and becomes an attractant for insects, rodents, and other pests. The handling of these materials entails some of the same problems and solutions as the handling of garbage and refuse. Problems are minimized when all of these materials are removed from the premises at a reasonable frequency.

Facilities for Disposal and Recycling **5-503.11** **Community or Individual Facility.**

Alternative means of solid waste disposal must be conducted properly to prevent environmental consequences and the attraction of insects, rodents, and other pests.

Chapter 6 Physical Facilities

Indoor Areas **6-101.11** **Surface Characteristics.**

Floors, walls, and ceilings that are constructed of smooth and durable surface materials are more easily cleaned.

Floor surfaces that are graded to drain and consist of effectively treated materials will prevent contamination of foods from dust and organisms from pooled moisture.

The special requirements for carpeting materials and nonabsorbent materials in areas subject to moisture are intended to ensure that the cleanability of these surfaces is retained.

Although food served from temporary food establishments is subject to the same potential for contamination as food served in permanent establishments, the limited capabilities and short duration of operation are recognized by less stringent requirements for surface characteristics.

Outdoor Areas **6-102.11** **Surface Characteristics.**

The requirements concerning surface characteristics of outdoor areas are intended to facilitate maintenance and minimize the accumulation of dust and mud on walking and driving areas, provide durable exterior building surfaces, and prevent the attracting, harboring, or breeding of insects, rodents, and other pests where refuse, recyclables, or returnables are stored.

Cleanability **6-201.11 Floors, Walls, and Ceilings.**
6-201.12 Floors, Walls, and Ceilings, Utility Lines.

Floors that are of smooth, durable construction and that are nonabsorbent are more easily cleaned. Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.

6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed.

When cleaning is accomplished by spraying or flushing, coving and sealing of the floor/wall junctures is required to provide a surface that is conducive to water flushing. Grading of the floor to drain allows liquid wastes to be quickly carried away, therebypreventing pooling which could attract pests such as insects and rodents or contribute to problems with certain pathogens such as ***Listeria monocytogenes***.

6-201.14 Floor Carpeting, Restrictions and Installation.

Requirements and restrictions regarding floor carpeting are intended to ensure that regular and effective cleaning is possible and that insect harborage is minimized. The restrictions for areas not suited for carpeting materials are designed to ensure cleanability of surfaces where accumulation of moisture or waste is likely.

6-201.15 Floor Covering, Mats and Duckboards.

Requirements regarding mats and duckboards are intended to ensure that regular and effective cleaning is possible and that accumulation of dirt and waste is prevented.

6-201.16 Wall and Ceiling Coverings and Coatings.
6-201.17 Walls and Ceilings, Attachments.
6-201.18 Walls and Ceilings, Studs, Joists, and Rafters.

Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and effectively cleaned. Special requirements related to the attachment of accessories and exposure of wall and ceiling studs, joists, and rafters are intended to ensure the cleanability of these surfaces.

Functionality **6-202.11 Light Bulbs, Protective Shielding.**

Shielding of light bulbs helps prevent breakage. Light bulbs that are shielded, coated, or otherwise shatter-resistant are necessary to protect exposed food, clean equipment, utensils and linens, and unwrapped single-service and single-use articles from glass fragments should the bulb break.

6-202.12 Heating, Ventilating, Air Conditioning System Vents.

Heating and air conditioning system vents that are not properly designed and located may be difficult to clean and result in the contamination of food, food preparation surfaces, equipment, or utensils by dust or other accumulated soil from the exhaust vents.

6-202.13 Insect Control Devices, Design and Installation.

Insect electrocution devices are considered supplemental to good sanitation practices in meeting the Code requirement for controlling the presence of flies and other insects in a food establishment.

Improper design of the device and dead insect collection tray could allow dead insect parts and injured insects to escape, rendering the device itself a source of contamination.

Exposed food and food-contact surfaces must be protected from contamination by insects or insect parts. Installation of the device over food preparation areas or in close proximity to exposed food and/or food-contact surfaces could allow dead insects and/or insect parts to be impelled by the electric charge, fall, or be blown from the device onto food or food-contact surfaces.

6-202.14 Toilet Rooms, Enclosed.

Completely enclosed toilet facilities minimize the potential for the spread of disease by the movement of flies and other insects between the toilet facility and food preparation areas.

6-202.15 Outer Openings, Protected.

Insects and rodents are vectors of disease-causing microorganisms which may be transmitted to humans by contamination of food and food-contact surfaces. The presence of insects and rodents is minimized by protecting outer openings to the food establishment.

In the National Fire Protection Association's NFPA 101, Life Safety Code®, 1994 Edition, doors to exit enclosures such as stairs, horizontal exits, or exit passageways are required to be self closing. The Life Safety Code does not require exterior doors used as exits to be self closing, but they can be.

The intent of Subparagraph 6-202.15(A)(3) is to protect food establishments from the entry of insects and rodents by keeping doors closed when not in use. Self-closing devices allow a door to return to its closed position after use. If an exterior door is not routinely used for entry or exit because its use is restricted by the fire protection authority for emergency use only, it is not a portal for the entry of pests and does not need a self-closing device. Doors not requiring a self-closing device include exterior emergency exit doors that open into a public way from a fire and that meet the criteria in ¶ 6-202.15(C).

6-202.16 Exterior Walls and Roofs, Protective Barrier.

Walls and roofs provide a barrier to protect the interior and foods from the weather, windblown dirt and debris, and flying insects.

6-202.17 Outdoor Food Vending Areas, Overhead Protection.

The potential for contamination from airborne dust and particulates or inclement weather is present in outside areas. Overhead protection minimizes the potential for contamination of food under such conditions.

6-202.18 Outdoor Servicing Areas, Overhead Protection.

Pooled water, which may result if overhead protection is not provided for outdoor servicing areas, attracts wild animals and birds and creates a condition suitable for the breeding of insects.

6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain.

If foot traffic is allowed to occur from undrained areas, contamination will be tracked into the establishment. Surfaces graded to drain minimize these conditions. Pooled water on exterior walking and driving surfaces may also attract rodents and breed insects.

6-202.110 Outdoor Refuse Areas, Curbed and Graded to Drain.

If refuse areas are not graded properly, waste water will pool and attract insects and rodents.

6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibited.
6-202.112 Living or Sleeping Quarters, Separation.

Areas or facilities that are not compatible with sanitary food establishment operations must be located and/or separated from other areas of the establishment to preclude potential contamination of food and food-contact surfaces from poisonous or toxic materials, dust or debris, the presence of improperly designed facilities and equipment, and the traffic of unauthorized and/or unnecessary persons or pets.

Further, Article IV of the Amendments to the U.S. Constitution ensures the right of persons to be secure in their homes against unreasonable search and seizure. This provision could hinder the regulatory authority's access to conduct routine inspections of a food establishment operated in the living area of a private home. A search warrant may be the only mechanism by which to gain entry; yet, it may be difficult to obtain and might not authorize the necessary inspectional activities.

Handwashing Facilities **6-301.10 Minimum Number.**

Refer to the public health reason for § 5-203.11.

6-301.11 Handwashing Cleanser, Availability.

Hand cleanser must always be present to aid in reducing microorganisms and particulate matter found on hands.

6-301.12 Hand Drying Provision.

Provisions must be provided for hand drying so that employees will not dry their hands on their clothing or other unclean materials.

6-301.14 Handwashing Signage.

A sign or poster is required to remind food employees to wash their hands.

6-301.20 Disposable Towels, Waste Receptacle.

Waste receptacles at handwashing lavatories are required for the collection of disposable towels so that the paper waste will be contained, will not contact food directly or indirectly, and will not become an attractant for insects or rodents.

Toilets and Urinals **6-302.10 Minimum Number.**

Refer to the public health reason for § 5-203.12.

6-302.11 Toilet Tissue, Availability.

To minimize hand contact with fecal waste, toilet tissue is necessary for hygienic cleaning following use of toilet facilities. Toilet tissue must be supplied to meet the demand.

Lighting **6-303.11 Intensity.**

Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as reading labels; discerning the color of substances; identifying toxic materials; recognizing the condition of food, utensils, and supplies; and safely conducting general food establishment operations and clean-up. Properly distributed light makes the need for cleaning apparent by making accumulations of soil conspicuous.

Ventilation **6-304.11 Mechanical.**

When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls, ceilings, and other equipment is minimized; obnoxious odors or toxic fumes

are effectively removed; and no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.

Balancing of the exhaust and make-up air must be ensured so that the system can operate efficiently.

Dressing Areas and Lockers **6-305.11** **Designation.**

Street clothing and personal belongings can contaminate food, food equipment, and food-contact surfaces. Proper storage facilities are required for articles such as purses, coats, shoes, and personal medications.

Service Sinks **6-306.10** **Availability.**

A service sink or curbed facility is required so that the cleanliness of the food establishment can be maintained, attractants for insects and rodents minimized, and contamination of food and equipment by accumulated soil prevented. Liquid wastes generated during cleaning must be disposed of in a sanitary manner to preclude contamination of food and food equipment. A service sink is provided to prevent the improper disposal of wastes into other sinks such as food preparation and handwashing sinks.

Handwashing Facilities **6-401.10** **Conveniently Located.**

Facilities must be located in or adjacent to toilet rooms and convenient to the different work stations of the food employee for proper and routine handwashing to prevent contamination of the food and food-contact surfaces.

Toilet Rooms **6-402.11** **Convenience and Accessibility.**

Toilet rooms must be conveniently accessible to food employees at all times to encourage employee use of appropriate facilities for the disposing of human wastes as needed followed by the washing of hands.

Employee Accommodations **6-403.11** **Designated Areas**.

Because employees could introduce pathogens to food by hand-to-mouth-to-food contact and because street clothing and personal belongings carry contaminants, areas designated to accommodate employees' personal needs must be carefully located. Food, food equipment and utensils, clean linens, and single-service and single-use articles must not be in jeopardy of contamination from these areas.

Distressed Merchandise **6-404.11** **Segregation and Location.**

Products which are damaged, spoiled, or otherwise unfit for sale or use in a food establishment may become mistaken for safe and wholesome products and/or cause contamination of other foods, equipment, utensils, linens, or single-service or single-use articles. To preclude this, separate and segregated areas must be designated for storing unsalable goods.

Refuse, Recyclables, and Returnables **6-405.10** **Receptacles, Waste Handling Units, and Designated Storage Areas.**

Waste materials and empty product containers are unclean and can be an attractant to insects and rodents. Food, equipment, utensils, linens, and single-service and single-use articles must be protected from exposure to filth and unclean conditions and other contaminants. This Code provision addresses these concerns by requiring the facility to be segregated, to be located to allow cleaning of adjacent areas, and to preclude creation of a nuisance.

Premises, Structures, Attachments, **and** ***Fixtures, - Methods*** **6-501.11** **Repairing.**

Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is intended to ensure that the physical facilities are properly maintained in order to serve their intended purpose.

6-501.12 **Cleaning, Frequency and Restrictions.**

Cleaning of the physical facilities is an important measure in ensuring the protection and sanitary preparation of food. A regular cleaning schedule should be established and followed to maintain the facility in a clean and sanitary manner. Primary cleaning should be done at times when foods are in protected storage and when food is not being served or prepared.

6-501.13 **Cleaning Floors, Dustless Methods.**

Dustless floor cleaning methods must be used so that food; equipment, utensils, and linens; and single-service and single-use articles are not contaminated.

6-501.14 **Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.**

Both intake and exhaust ducts can be a source of contamination and must be cleaned regularly. Filters that collect particulate matter must be cleaned or changed frequently to prevent overloading of the filter. Outside areas under or adjacent to exhaust duct outlets at

the exterior of the building must be maintained in a clean and sanitary manner to prevent pest attraction.

6-501.15 Cleaning Maintenance Tools, Preventing Contamination.*

Maintenance tools used to repair the physical facilities must be cleaned in a separate area to prevent contamination of food and food preparation and warewashing areas.

6-501.16 Drying Mops.

Mops can contaminate food and food preparation areas if not properly cleaned and stored after use. Mops should be cleaned and dried in a sanitary manner away from food flow areas.

6-501.17 Absorbent Materials on Floors, Use Limitation.

Cleanliness of the food establishment is important to minimize attractants for insects and rodents, aid in preventing the contamination of food and equipment, and prevent nuisance conditions. A clean and orderly food establishment is also conducive to positive employee attitudes which can lead to increased attention to personal hygiene and improved food preparation practices. Use of specified cleaning procedures is important in precluding avoidable contamination of food and equipment and nuisance conditions.

Temporary floor coverings such as sawdust can contaminate food, attract insects and rodents, and become a nuisance to the food operation.

6-501.18 Maintaining and Using Handwashing Facilities.

Handwashing facilities are critical to food protection and must be maintained in operating order at all times so they will be used.

Refer also to the public health reason for § 5-205.11.

6-501.19 Closing Toilet Room Doors.

Toilet room doors must remain closed except during cleaning operations to prevent insect and rodent entrance and the associated potential for the spread of disease.

6-501.110 Using Dressing Rooms and Lockers.

Street clothing and personal belongings can contaminate food, food equipment, and food preparation surfaces and consequently must be stored in properly designated areas or rooms.

6-501.111 Controlling Pests.*

Insects and other pests are capable of transmitting disease to man by contaminating food and food-contact surfaces. Effective measures must be taken to control their presence in food establishments.

6-501.112 Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests.

Dead rodents, birds, and insects must be removed promptly from the facilities to ensure clean and sanitary facilities and to preclude exacerbating the situation by allowing carcasses to attract other pests.

6-501.113 Storing Maintenance Tools.

Brooms, mops, vacuum cleaners, and other maintenance equipment can contribute contamination to food and food-contact surfaces. These items must be stored in a manner that precludes such contamination.

To prevent harborage and breeding conditions for rodents and insects, maintenance equipment must be stored in an orderly fashion to permit cleaning of the area.

6-501.114 Maintaining Premises, Unnecessary Items and Litter.

The presence of unnecessary articles, including equipment which is no longer used, makes regular and effective cleaning more difficult and less likely. It can also provide harborage for insects and rodents.

Areas designated as equipment storage areas and closets must be maintained in a neat, clean, and sanitary manner. They must be routinely cleaned to avoid attractive or harborage conditions for rodents and insects.

6-501.115 Prohibiting Animals.*

Animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food-contact surfaces. The restrictions apply to live animals with limited access allowed only in specific situations and under controlled conditions and to the storage of live and dead fish bait. Employees with support animals are required under § 2-301.14 to wash their hands after each contact with animals to remove bacteria and soil.

Animals shed hair continuously and may deposit liquid or fecal waste, creating the need for vigilance and more frequent and rigorous cleaning efforts.

The definition for “service animal” is adapted from 28 CFR 36.104 adopted pursuant to the Americans with Disabilities Act (ADA) of 1990 (42 U.S.C. 12101 et seq.). A service animal performs some of the functions that persons with a disability cannot perform for themselves,

such as those provided by “seeing eye dogs”; alerting persons with hearing impairments to sounds; pulling wheelchairs or carrying and picking up things for persons with mobility impairments; and assisting persons with mobility impairments with balance. A service animal is not considered to be a pet.

Under Title III of the ADA, privately owned businesses that serve the public are prohibited from discriminating against individuals with diabilities. The ADA requires these businesses to allow people with disabilities to bring their service animals onto business premises in whatever areas customers are generally allowed. Some, but not all, service animals wear special collars or harnesses. Some, but not all, are licensed or certified and have identification papers.

Decisions regarding a food employee or applicant with a disability who needs to use a service animal should be made on a case-by-case basis. An employer must comply with health and safety requirements, but is obligated to consider whether there is a reasonable accommodation that can be made. Guidance is available from the U.S. Department of Justice, Civil Rights Division, Disability Rights Section or the U.S. Equal Employment Opportunity Commission, the federal agency which has the lead in these matters, in documents such as, “Commonly Asked Questions About Service Animals in Places of Business”; “The Americans with Disabilities Act Questions and Answers”; “A Guide to Disability Rights Laws”; and “Americans with Disabilities Act Title III Technical Assistance Manual, 1994 Supplement.” The ADA Information Line is 800-514-0301 (voice) or 800-514-0383 (TDD) and the Internet Home Page address is http://www.usdoj.gov/crt/ada/adahom1.htm.

Chapter 7 Poisonous or Toxic Materials

Original Containers **7-101.11** **Identifying Information, Prominence.***

The accidental contamination of food or food-contact surfaces can cause serious illness. Prominent and distinct labeling helps ensure that poisonous and toxic materials including personal care items are properly used.

Working Containers **7-102.11** **Common Name.***

It is common practice in food establishments to purchase many poisonous or toxic materials including cleaners and sanitizers in bulk containers. Working containers are frequently used to convey these materials to areas where they will be used, resulting in working containers being stored in different locations in the establishment. Identification of these containers with the common name of the material helps prevent the dangerous misuse of the contents.

Storage **7-201.11 Separation.***

Separation of poisonous and toxic materials in accordance with the requirements of this section ensures that food, equipment, utensils, linens, and single-service and single-use articles are properly protected from contamination. For example, the storage of these types of materials directly above or adjacent to food could result in contamination of the food from spillage.

Presence and Use **7-202.11 Restriction.***

The presence in the establishment of poisonous or toxic materials that are not required for the maintenance and operation of the establishment represents an unnecessary risk to both employees and consumers.

Preserving food safety depends in part on the appropriate and proper storage and use of poisonous or toxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the manufacturer on the material's label. If additional poisonous or toxic materials are present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

7-202.12 Conditions of Use.*

Failure to properly use poisonous or toxic materials can be dangerous. Many poisonous or toxic materials have general use directions on their label. Failure to follow the stated instructions could result in injury to employees and consumers through direct contact or the contamination of food.

Particular precautions must be taken during the application of poisonous or toxic materials to prevent the contamination of food and other food-contact surfaces. Residues of certain materials are not discernible to the naked eye and present an additional risk to the employee and consumer.

Because of the toxicity of restricted-use pesticides, they can only be applied by certified operators. A certified operator would be aware of the dangers involved in the contamination of food and food-contact surfaces during the application of these materials. Improperly applied pesticides present health risks to employees as well as consumers and special precautions must be taken when restricted-use pesticides are applied.

Container Prohibitions **7-203.11 Poisonous or Toxic Material Containers.***

Use of poisonous or toxic material containers to store, transport, or dispense food is prohibited because of the potential for contamination of the food. The risk of serious medical

consequences to anyone consuming food stored in these containers coupled with the lack of confidence that all of the material could or would be removed in the wash and sanitizing procedures are reasons for prohibiting this practice.

Chemicals **7-204.11** **Sanitizers, Criteria.***

Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.

7-204.12 **Chemicals for Washing Fruits and Vegetables, Criteria.***
7-204.13 **Boiler Water Additives, Criteria.***
7-204.14 **Drying Agents, Criteria.***

If the sanitizer, chemical wash, boiler water additive, or drying agent used is not made up of components that are approved as food additives or generally recognized as safe, illness may result. This could be due to residues that may remain from the use of compounds such as unrecognized drying agents. This is why only those chemicals that are listed in the CFR can be used.

Chemicals that are not listed for these uses may be submitted for review by filing a Food Additive Petition. Sanitizers, wash chemicals, and drying agents are classified as food additives because of the possibility that they may end up in food. Therefore, they are subject to review before being used or listed in the CFR.

21 CFR section 173.315 specifically identifies chemicals that may be used in washing fruits and vegetables, but it **does not specify any maximum level** (2000 ppm or otherwise) of chemical usage for sodium hypochlorite. FDA acknowledges the use of sodium hypochlorite on fruits and vegetables and also allows calcium hypochlorite to be used interchangeably with sodium hypochlorite under 21 CFR 173.315.

Lubricants **7-205.11** **Incidental Food Contact, Criteria.***

Lubricants used on food equipment may directly or indirectly end up in the food. Therefore, the lubricants used must be approved as food additives or generally recognized as safe and listed in the CFR. Lubricants that are not safe present the possibility of foodborne illness if they find their way into the food.

Pesticides **7-206.12** **Rodent Bait Stations.***

Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on food-contact surfaces and ultimately in the food being prepared or served.

7-206.13 Tracking Powders, Pest Control and Monitoring.*

The use of tracking powder pesticides presents the potential for the powder to be dispersed throughout the establishment. Consequently, the powder could directly or indirectly contaminate food being prepared. This contamination could adversely affect both the safety and quality of the food and, therefore, tracking powder pesticides are not allowed.

Medicines **7-207.11 Restriction and Storage.***

Medicines that are not necessary for the health of employees present an unjustified risk to the health of other employees and consumers due to misuse and/or improper storage. There are circumstances that require employees or children in a day care center to have personal medications on hand in the establishment. To prevent misuse, personal medications must be labeled and stored in accordance with the requirements stated for poisonous or toxic materials. Proper labeling and storage of medicines to ensure that they are not accidentally misused or otherwise contaminate food or food-contact surfaces.

7-207.12 Refrigerated Medicines, Storage.*

Some employee medications may require refrigerated storage. If employee medications are stored in a food refrigerator, precautions must be taken to prevent the contamination of other items stored in the same refrigerator.

First Aid Supplies **7-208.11 Storage.***

First aid supplies for employee use must be identified and stored in accordance with the requirements of this Code in order to preclude the accidental contamination of food, food equipment, and other food-contact surfaces.

Personal Care Items **7-209.11 Storage.**

Employee personal care items may serve as a source of contamination and may contaminate food, food equipment, and food-contact surfaces if they are not properly labeled and stored.

Storage and Display **7-301.11 Separation.***

Poisonous or toxic materials held for sale on store shelves or stored in stock rooms present a risk of contamination of food, equipment, utensils, linens, and single-service and single-use articles if not stored properly.

8-201.12 Contents of the Plans and Specifications.
8-203.10 Preoperational Inspections.

In conjunction with the Conference for Food Protection Plan Review committee, FDA has participated in developing a document that is intended to assist regulators in reviewing food establishment plans, and industry in understanding what is expected in the plan review process. For several years, this Plan Review Manual has been used in the FDA State Training Branch Plan Review courses. It was endorsed by the CFP at the Conference's 1998 meeting and continues to undergo expansion to address temporary food events. It can be accessed through http://www.fda.gov/~dms/prev-toc.html.

At the plan review stage, the regulatory authority may be dealing with an agent of the permit applicant who is seeking a building permit and who is not in a position to discuss plans for safely conducting the food operation. Nonetheless, the plan review step presents a unique opportunity to lay a foundation that enables the proposed operation to proactively sustain compliance with the Code over time. Standard operational procedures (SOPs) are a part of that foundation and ideally are developed in tandem with designing the facility. Consequently, as an integral part of the plan review process, discussion needs to occur about such procedures and their scope.

SOPs need to be developed by the time of the preoperational inspection and put into effect when the food operation begins. It is recommended that such procedures be written, available for reference by the person in charge, conveyed to the appropriate employees, and available for review by the regulatory authority during inspections. Operating procedures should include definitive practices and expectations that ensure that:

(1) The transmission of foodborne disease is prevented by managing job applicants and food employees as specified under Subpart 2-201,

(2) Food is received from approved sources as specified under § 3-201.11,

(3) Food is managed so that the safety and integrity of the food from the time of delivery to the establishment throughout its storage, preparation, and transportation to the point of sale or service to the consumer is protected,

(4) Potentially hazardous food is maintained, including freezing, cold holding, cooking, hot holding, cooling, reheating, and serving in conformance with the temperature and time requirements specified under Parts 3-4 and 3-5,

(5) Warewashing is effective, including assurance that the chemical solutions and exposure times necessary for cleaning and sanitizing utensils and food-contact surfaces of equipment are provided as specified under Parts 4-6 and 4-7, and

(6) Records that are specified under §§ 3-203.11, 3-203.12, and 5-205.13 are retained for inspection.

During the plan review stage, the regulatory authority and a management representative of the proposed food establishment should discuss available training options that may be used to train food employees and the person in charge regarding food safety as it relates to their assigned duties. By the time of the preoperational inspection, operating procedures for training should include definitive practices and expectations of how the management of the proposed food establishment plans to comply with ¶ 2-103.11(L) of this Code which requires the person in charge to assure that food employees are properly trained in food safety as it relates to their assigned duties.

Annex

4 Food Establishment Inspection

1. INTRODUCTION

(A) Purpose

A principal goal to be achieved by a food establishment inspection is to prevent foodborne disease. Inspection is the primary tool a regulatory agency has for detecting procedures and practices which may be hazardous and taking actions to correct deficiencies. Food Code-based laws and ordinances provide inspectors scientifically based rules for food safety.

This Annex provides regulatory agencies with guidance on planning, scheduling, conducting, and evaluating inspections. It also supports programs by providing recommendations for training and equipping the inspection staff, and attempts to enhance the effectiveness of inspections by stressing the importance of communication and information exchange during regulatory visits. Inspections aid the industry by:

(1) *Serving as educational sessions on specific Code requirements as they apply to an establishment and its operation;*

(2) *Conveying new food safety information to establishment management and providing an opportunity for management to ask questions about general food safety matters; and*

(3) *Providing a written report to the establishment's permit holder or person in charge so that the responsible person can bring the establishment into conformance with the Code.*

(B) Background and Current Applications of HACCP

Inspections have been a part of food safety regulatory activities since the earliest days of public health. Traditionally, inspections have focused primarily on sanitation. Each inspection is unique in terms of the establishment's management, personnel, menu, recipes, operations, size, population served, and many other considerations.

Changes to the traditional inspection process were first suggested in the 1970's. The terms "traditional" or "routine" inspection have been used to describe periodic inspections conducted as part of an on-going regulatory scheme. A full range of approaches was tried and many were successful in managing a transition to a new inspection philosophy and format. During the 1980's, many progressive jurisdictions started employing the HACCP approach to refocus their inspections. The term "HACCP approach" inspection is used to describe an inspection using the "Hazard Analysis and Critical Control Point" concepts. Food safety is the primary focus of a HACCP approach inspection. One lesson learned was that good communication skills on the part of the person conducting an inspection are essential.

The HACCP Annex to the Code provides a full background on the origin, principles, and applications of HACCP and explains the concepts used during inspections in greater detail than found in this Annex. It should be reviewed in connection with the material found here to better prepare for performing a HACCP approach inspection. The HACCP Annex also provides an extensive list of references.

FDA has taught thousands of state and local inspectors the principles and applications of HACCP since the 1980's. The State Training Branch and the FDA Regional Food Specialists have provided 2-day to week-long courses comprising the scientific principles on which HACCP is based, practical application of these principles including field exercises, and review of case studies. States and local jurisdictions have also offered many training opportunities for HACCP.

A recent review of state and local retail food protection agencies shows that HACCP is being applied in the following ways:

(1) *Formal Studies* - Inspector is trained in HACCP and is using the concepts to study food hazards in establishments. These studies actually follow foods from delivery to service and involve the write-up of data obtained (flow charts, cooling curves, etc.).

(2) *Routine Use* - State has personnel trained in HACCP and is using the hazard analysis concepts to more effectively discover hazards during routine inspections.

(3) *Consultation* - HACCP-trained personnel are consulting with industry and assisting them in designing and implementing internal HACCP systems and plans.

(4) *Alternative Use* - Jurisdiction used HACCP to change inspection forms or regulations.

(5) *Risk-Based* - Jurisdiction prioritized inventory of establishments and set inspection frequency using a hazard assessment.

(6) *Training* - Jurisdiction is in the active process of training inspectors in the HACCP concepts.

2. PROGRAM PLANNING

(A) Resources

The primary resource available to a jurisdiction is the number of hours to perform inspections and related administrative activities. Total hours required will vary somewhat depending on such things as the type of establishments and geographical distribution.

As a suggested target, it is recommended that approximately 8 to 10 hours be allocated per establishment per year. This includes time for inspection, follow-up inspections, complaint investigations, and administrative work, such as plan review, enforcement documentation preparation, hearings, and court actions. The suggested time is based on a typical mix of establishments and average travel times. Simpler food operations in establishments or smaller areas will mean that fewer hours are needed, whereas more complex operations and larger areas will add additional time requirements.

Other factors which affect the use of planned resources are:

(1) *Inspection frequency for each category of establishment (refer to Section **2.** (C));*

(2) *Establishment operations' variation over time; and*

(3) *Training provided to the inspection staff (refer to Section **3.**).*

Establishment variation results from turnover of management and employees or changes in menu and procedures. Initial and continuing staff development are important activities which

support quality regulatory programs and should be factored into the overall allocation of available time.

(B) Equipment

Inspectors must be properly equipped to perform the inspections in their assigned territory. Recommended equipment and supplies include:

(1) *Necessary forms and administrative materials;*

(2) *Lab coat or equivalent protection to cover street clothes;*

(3) *Head cover: baseball cap, hair net, or equivalent;*

(4) *Alcohol swabs;*

(5) *Thermocouple or thermistor temperature measuring device for food and ambient air;*

(6) *Maximum registering thermometer or temperature-sensitive tapes for verifying hot water warewasher final rinse temperature, 73°C (160°F);*

(7) *Pressure gauge for determining in-line pressure of hot water at injection point of warewasher (15-25 psi) - (inspector should have access to a gauge);*

(8) *Chemical test kits for different chemical sanitizer types;*

(9) *Flashlight;*

(10) *Light meter;*

(11) *Measuring device for measuring distances;*

(12) *Time/temperature data logger (optional);*

(13) *pH meter (optional);*

(14) *Water activity meter (optional);*

(15) *Camera (optional); and*

(16) *Electronic Inspection System (recommended).*

If the establishment is performing complex operations, the inspector must also have pH meters, water activity (a_w) meters, and time-temperature data loggers.

Programs require a fully equipped kit for investigating foodborne illness complaints. Kits should include necessary forms, sterile collection utensils and sample containers, indelible marking pens, labels, sealing tape, and an insulated sample shipping case. Sterile containers are also needed for collection of appropriate specimens from victims. Current recommendations from the laboratory for maintaining food samples and patient specimens should be maintained with the kit.

Personal computers are very useful for managing inspection and program data both in the office and the field. If equipped with modems, they also enable the program to keep current with the latest in food safety technical information through the FDA CFSAN Home Page (http://www.cfsan.fda.gov) Internet service. Computer software packages are also useful for modeling the growth of pathogenic bacteria, calculating refrigeration requirements, and investigating foodborne illness reports.

(C) Risk Categorization of Food Establishments

(Refer to Subpart 8-401, Food Code)

Studies have shown that the types of food served, the preparation steps these foods require, the volume of food, the population served, and previous compliance history can have a bearing on the opportunity for the occurrence of foodborne illness.

The rational allocation of inspection resources to target the highest risk establishments with more inspection time and the lowest risk establishments with the least is a HACCP approach concept. Risk categorization allows establishments to be ranked by considering risk factors and creating a variable inspection frequency for each category. An example of risk categorization and frequency of inspection is shown in Table 1.

Table 1. Risk Categorization of Food Establishments

RISK TYPE	RISK TYPE CATEGORY DESCRIPTION	FREQUENCY #/YR
1	Pre-packaged nonpotentially hazardous foods only. Limited preparation of nonpotentially hazardous foods only.	1
2	Limited menu (1 or 2 main items). Pre-packaged raw ingredients are cooked or prepared to order. Retail food operations exclude deli or seafood departments. Raw ingredients require minimal assembly. Most products are cooked/prepared and served immediately. Hot and cold holding of potentially hazardous foods is restricted to single meal service. Preparation processes requiring cooking, cooling, and reheating are limited to 1 or 2 potentially hazardous foods.	2
3	Extensive handling of raw ingredients. Preparation process includes the cooking, cooling, and reheating of potentially hazardous foods. A variety of processes require hot and cold holding of potentially hazardous food. Advance preparation for next day-service is limited to 2 or 3 items. Retail food operations include deli and seafood departments. Establishments doing food processing at retail.	3
4	Extensive handling of raw ingredients. Preparation processes include the cooking, cooling, and reheating of potentially hazardous foods. A variety of processes require hot and cold holding of potentially hazardous foods. Food processes include advanced preparation for next-day service. Category would also include those facilities whose primary service population is immunocompromised.	4
5	Extensive handling of raw ingredients. Food processing at the retail level, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.	4

Previous compliance history should also be considered when establishing inspection frequency. Non-conformance with critical Code items or HACCP plan requirements may move an establishment up into the next higher frequency range until a record of more consistent compliance is achieved.

There are a wide variety of ways to assign establishments to categories. The simplest method for that jurisdiction is usually the best.

Resources need to be allocated for seasonal and temporary food establishment operations. Frequently, this involves scheduling inspections on weekends and during evening hours. Some jurisdictions have also found it useful to schedule a number of inspections during the evening hours to get a more balanced view of certain food operations.

Some agencies replace one or more of their routine inspections with such alternatives as a full-scale HACCP study, or a staff training session. If a manager certified in food safety is on duty at all times, some agencies may discontinue routine inspection. Care must be exercised in using these alternatives to maintain sufficient regulatory oversight.

(D) Types of Inspections

The Food Code specifies that access to a retail establishment for inspection is a condition of the acceptance and retention of the food establishment permit. Inspections are generally unannounced to obtain a more accurate assessment of normal operating practices and conditions. Exceptions can be made during construction and preoperational inspections where an appointment is needed to ensure that all parties are available for discussion or where work is intermittent and access to a new establishment is limited; or during follow-up inspections which may require the presence of specific personnel or management from the establishment. Full documentation should be maintained on each inspection as a part of the establishment's official agency record.

Inspections determine the food establishment's compliance with the Food Code. These inspections may be categorized by purpose such as:

(1) *Preoperational Inspection*
(Refer to Subpart 8-203, Food Code)

The Food Code specifies that a preoperational inspection shall be conducted to ensure that the establishment is built or remodeled in accordance with the approved plans and specifications. It is helpful to have these documents available during the inspection.

(2) *Routine Inspection*
(Refer to Part 8-4 and Subpart 8-403, Food Code)

Routine inspections should be scheduled on an interval based on risk. These inspections are full reviews of the food establishment operations and facilities and their impact on food safety. They include assessment of food employee and management health, practices, and knowledge of food safety; food flows, source, storage, thawing, preparation (including cooking temperatures and times) and post-preparation processes; equipment and facility construction; cleaning and sanitizing processes; water sources; sewage disposal; and vermin control.

Detailed reports are prepared at the conclusion of each inspection and presented to the person in charge. Items found not to be in compliance are categorized as critical or noncritical. Items found to be repetitive from the previous inspection are also noted. The Code section in violation is included in the report citation section.

(3) *Follow-up Inspection*
(Refer to Subpart 8-405, Food Code)

The Food Code specifies that the agency shall verify that critical violations have been corrected within 10 days of the initial routine inspection that detected them. Follow-up inspections should be briefer than the routine inspection, since they concentrate on the critical violations previously reported.

Corrections and continued violations should be noted on an inspection report. Continued violations should be used to initiate further compliance actions.

Time available for follow-up inspections will vary between jurisdictions. The compliance strategy is more effective if those follow-ups are mandated in a realistic fashion which takes available resources into account. It is a sign of a weak program when required 10-day follow-ups never occur or are late. It is better to consistently follow-up on the worst 5% than to schedule follow-ups on the worst 25% of the establishments and only perform a few of these. Refer to Section 13., Establishment Scoring, for further information.

(4) *HACCP Inspection*
(Refer to Subpart 8-403, Food Code)

Establishments operating under a variance requiring a HACCP plan need to be inspected differently. HACCP plans have critical limits which must be routinely monitored and recorded by the establishment, and monitoring and other elements of the plan must be verified by the inspector.

Copies of the firm's approved HACCP plan are useful during these inspections. Additional time may be necessary to fully assess the establishment's compliance with the HACCP plan. Verifying the maintenance of the required records is an important element of the HACCP inspection. Notation in the records of process deviations that occurred and corrective actions taken in response to those deviations should not be cited as adverse findings.

(5) *Complaint Inspection*
(Refer to Subpart 8-404, Food Code)

Consumer complaints received about a food establishment should be investigated in accordance with the agency's policies. Quick response is required for those related to foodborne illnesses. Speed is essential to preserve both memories of events and possible food or environmental samples. The regulatory agency's medical staff could be used to coordinate, with the complainant's physician or hospital staff, the collection of appropriate specimens.

HACCP principles can be used to supplement traditional procedures for investigation of foodborne illness complaints to help the inspector focus on possible causes and gather better data. Hazard analysis is a useful tool when evaluating implicated menus or foods. It helps focus the investigation on foods which have been epidemiologically linked with illness. Other foods should not be completely dismissed because as more becomes known about the causes of foodborne illness, foods which may not have been historically linked to illnesses are being implicated.

The charting of food product flows and the designation of critical control points can help delineate potential problems. If a hazard seems evident, the suspect product or process can be recreated with the cooperation of the establishment and the critical limits monitored.

Other consumer complaints about food establishments should be evaluated in terms of public health significance before scheduling inspections. For example, allegations about an establishment purchasing shellfish from an illegal source should receive a higher priority than complaints about a littered parking lot.

3. STAFF TRAINING

Basic staff training is very important to staff development and should be a well-defined process. Initial training is usually provided within the local regulatory agency and more advanced training is available through a state agency's program. National training is available from FDA's State Training Branch and from the Centers for Disease Control and Prevention's Distance Learning Program. These programs range from basic to advanced subject-specific seminars offered regionally, to homestudy courses including video, slide, or textbook-based programs, and finally to direct satellite broadcast seminars and courses as a part of the Public Health Training Network. An FDA regional food specialist may be requested to work with a trainee who is employed by a state or large local regulatory program, early in the trainee's career.

(A) Basic Training

The training process can be divided into three phases. The first provides an orientation to the program. This initial phase includes a review of program history, structure, and relationships to other food programs. Specific emphasis should be on the program's goals and objectives. A structured approach is beneficial to familiarize the inspector with the FDA Food Code, as well as state and local food protection codes. This phase can also include interim quizzes to assess knowledge retention and reveal areas which need further work. Development of good communication skills should also be emphasized.

The study of epidemiology of foodborne illness, including the organisms, foods, and contributing factors and case studies, is an important part of the early technical training. Basic food microbiology, including the effects of temperature, pH, water activity, and other hurdles and barriers to the survival and growth of foodborne pathogens, are appropriate subjects. Scientific journal articles in the fields of food microbiology, food technology, and HACCP should be provided. A review of access procedures to on-line databases such as the FDA CFSAN Home Page (http://www.fda.gov) is also important.

(B) Field Training

The next phase of training moves the new inspector into the field with the training officer. On-site training should focus on specific inspection tasks such as interviewing, making observations, and measuring conditions such as temperatures and sanitizer strength. Time should be spent practicing completion of the inspection forms to conform to the regulatory agency's standard of description of the violation. If the FDA Electronic Inspection System is used by the agency, training in its use could be included in this phase.

The field orientation should also include at least one full HACCP inspection to acquaint the inspector with food operations and flows in establishments. The pre-HACCP review discussions should be guided by the new inspector and include a review of the establishment's menu, operations, and the recipes and standard operating procedures. A full food or operational cycle should be included in this HACCP training exercise, but is not normally expected to be a part of a routine HACCP-based food protection program.

The inspector should be able to demonstrate proficiency with gathering information about the process, including accurate charting of the food flows and determination of the critical control points and their critical limits. The HACCP training exercise should include defining the practical monitoring alternatives for the critical limits, reasonable record maintenance, and a review of acceptable options when critical limits are not met. All of these steps should be conducted in conjunction with the management of the establishment. Observations and measurements should be recorded in an unobtrusive manner during the entire food cycle or operation.

The trainee should prepare a comprehensive report on the HACCP field exercise and the training officer should critique the report. In assessing the success of this important part of the training program, the training officer should include a review of the thoroughness of the information gathering and the observation phases of the exercise.

Evaluation of HACCP skills such as selection of appropriate critical control points should be performed. The training officer should comment on the proficiency of the trainee's communication skills and plans should be made for working on any areas found to need improvement.

(C) Standardization and Certification

The following describes a model for applying the concept of standardizing regulatory personnel and confirming that they are standardized in the understanding, interpretation, and application of the Food Code. The first paragraph addresses the training period during which the person becomes standardized and the second paragraph addresses a formal verification process leading to certification of the standardized person. FDA is in the process of seeking comment regarding a revised, Interim Procedure for the process of certifying retail food regulatory personnel. As those Procedures are finalized, this description will be modified in future editions of the Code.

The future regulatory responsibilities of the trainee should be emphasized during the next phase of field training. This part of the orientation begins as the trainee observes the training officer making inspections, where there is extensive discussion of the inspection process. The points of violation are fully discussed and differentiated from similar conditions which are not violations. The time involved in this phase of training depends on the capabilities of the trainee to grasp and apply the important concepts of translating the words to regulatory

actions including the differentiation of the relative significance of the violations. At the end of this phase, the trainee should be proficient in the application of the Food Code and state/local food protection regulations.

The next period should proceed with the reversal of roles in which the trainee determines the violations, explains the reasons, and cites the proper regulation section. The training officer should be standardized by the appropriate FDA retail food specialist. The testing phase should follow the FDA-recommended protocol for certification. Independent simultaneous inspections are made of the establishment, and violations are recorded on inspection reports. After 8 inspections, there should be agreement between the trainee and the training officer on at least 90% of the violations recorded by the training officer that relate to foodborne illness risk factors. If this is not accomplished, remedial training should be given and the certification procedure repeated.

(D) Continuing Education

The final phase of training is never finished. The standardization procedure should be repeated with the training officer on an annual basis. The agency should establish continuing education programs to keep the staff current with the changing food safety concerns and the latest information. Six regional FDA seminars are held each year by the regional food specialists to acquaint state and local agency personnel with new information concerning important changes in the interpretation and application of the Food Code.

Professional association meetings and state agency-sponsored courses also can serve to keep staff development progressing. FDA and other federal agencies offer a series of training opportunities and a lending library of training materials to assist the state and local food regulatory programs. The FDA Web Page (http://www.fda.gov/ora/training/course_ora.html) regularly includes listing of these sessions and materials.

Industry-sponsored training sessions should not be overlooked as an educational resource. In addition to providing technical materials, they can foster a better understanding of the concerns of regulators and the industry. The food manager certification training and testing programs offer excellent opportunities for acquiring basic food safety knowledge. Testing inspectors in training may prove helpful in evaluating their knowledge of the material.

4. CONDUCTING THE INSPECTION

The HACCP approach inspection examines an operation as a total process by identifying "critical control points" in an attempt to prevent food safety hazards from occurring (i.e., conditions at the establishment which could lead to foodborne illness).

Individual differences in programs, personnel, establishments, and jurisdictions need to be taken into account in establishing agency procedures for assigning establishments and

preparing for and executing inspections. The following discussion is provided as a guideline for developing those procedures.

(A) Assignment

There is no single best way to assign inspections. Regulatory agencies frequently use geographical location, trying to balance hours required to inspect the total number of establishments within each territory. Many times other environmental health functions are also performed in addition to the food protection program, and these functions are accounted for in the work planning. Often agencies periodically rotate areas among inspectors or redivide the areas based on changes in the establishment inspection inventory.

Other agencies may choose to specifically or categorically assign establishments to the inspectors. Institutional-type food operations may be in the inventory of one inspector while those establishments doing food processing at retail under HACCP plans may be under another's. Specialization sometimes has advantages with the more complex types of inspections.

Under certain circumstances, some agencies find it more efficient to maintain all plan review, preoperational, and remodeling inspections under an inspector who specializes in those functions. Others may have all follow-up and other compliance inspections performed by one group of inspectors.

(B) Preparing for the Inspection

The establishment file should be reviewed before the inspection is conducted. This is particularly important if the last inspection was conducted by a different inspector. Notation of previous violations should be made to ensure that these violations will be reviewed.

Inspections of establishments operating under variances and HACCP plans should include a review of specifics of the plan. Pertinent parts of the plan and the establishment's monitoring procedure may need to be copied and taken on the inspection to confirm that the plan is being followed.

The regulatory agencies using the FDA Electronic Inspection System's Field Module will automatically have the previous inspections and the HACCP plan elements loaded onto the notebook computer for reference in the field. Previous violations or HACCP plans may be retrieved during the inspection.

(C) Entering the Establishment

(Refer to Subpart 8-402, Food Code)

Inspectors should enter the establishment during the hours of operation or at other reasonable times. The inspector must provide the permit holder or person in charge with a notice of the purpose of, and intent to conduct, the inspection. According to agency policy, this may be a verbal or a written notice at the time of inspection.

Procedures outlined in the Food Code and in the agency procedures should be followed if access to conduct an inspection is denied. Refusal should be documented on the inspection report and an administrative or judicial inspection order obtained.

(D) Introductions

The tone of the inspection is often set during the first few minutes of the inspection. The professional but personable approach is the balance which should be maintained. Genuine interest in the establishment and the staff translates into good relations which may be helpful in conveying the agency's goal of promoting public health.

Near the outset, particularly if the visit is a follow-up inspection, questions should be directed to corrections made since the last inspection. This is also the time to explain the nature of the visit, such as an investigation of a complaint or a follow-up.

A preliminary walk-through may be beneficial in acquainting the inspector with the layout and facilities.

(E) Menu/Operations Review

The inspection should always start with discussions of the menu and food preparation operations being performed in the establishment. It may be more helpful to involve the chef or departmental supervisor in discussions than rely on the memory of the permit holder. Even though the inspector may be knowledgeable about an operation or establishment, conditions change. A few minutes spent early in the inspection may reveal some faulty assumptions or items of public health significance.

Questions should be phrased to elicit the actual process rather than the answer the establishment employee thinks the inspector wants to hear. For example, "What happens to the gumbo next?" may work better than "Please tell me how you rapidly cool that 50 gallons of gumbo." Brief notes taken at this point, with later verification, keep the process of information gathering moving forward.

Full food flow cycles should be reviewed even though only a portion of them will be taking place during the inspection.

(F) Set the Example

The inspector can begin teaching food safety by the example set when entering the food areas of the establishment. Clothing, including shoes, should be clean. Some jurisdictions provide laboratory coats to their staff to set a more professional image. The inspector should also wear a proper hair restraint to comply with the jurisdiction's requirements for food employees.

Handwashing is the important first step when entering a food area. Not only is a good example set by the inspector but a more accurate assessment of the adequacy of the handwashing facility can be determined. The handwashing procedures of accompanying management can also be observed at this time while discussions are continued about its importance.

(G) Initial Observations

A few minutes should be spent getting the larger view of the operation from a corner of the food area. After the layout and general areas of concern have been determined, the inspector should start on a route through the facility which will include the points determined to be significant during the pre-inspection discussions.

(H) Focus During the Inspection

The primary focus of the inspection should be the food employees and the food. The inspector should observe the sources, storage practices, preparation steps, and post-preparation operations as foodborne illness is primarily attributed to these areas of an operation. The specifics of conditions which are violations should be noted during the inspection.

Information regarding known risks associated with certain food preparation practices and menu items should guide the allocation of time and focus during the inspection. Concentration should be on the complex food processes which involve multiple ingredients being assembled or mixed, cooking of potentially hazardous food, foods which are prepared and held for several hours before service, foods which must be cooled, and steps involving reheating. Foods that have been more frequently implicated in foodborne illness should receive higher priority. Foods prepared in large volumes are definite indicators of a process which should be checked. Foods requiring manual assembly prior to service should also be closely watched during inspections.

(I) Questions About the Establishment's Operations

General questions about food flow and operations are covered in the opening discussions with the permit holder or person in charge. Specific questions about particular parts of the operation are best addressed to the employee performing the operation. Some establishments may have a strict policy about individual employees talking to regulatory personnel which needs to be respected and accommodated. Questions should be asked in an open-ended format and in a nonthreatening manner.

(J) Inspectional Observations

(Refer to Subpart 8-403, Food Code)

Accurate measurements of conditions in the establishment are integral to a thorough inspection. The Food Code or the establishment's accepted HACCP plan provides the critical limits for operations being conducted. Some of the critical limits to be measured may

include food product temperatures, pH, water activity (a_w), food additive concentrations, and sanitizer concentrations. The following sections of this Annex provide discussion on specific measurement considerations.

(1) *Food Product Temperature Measurements*
(Refer to Subpart 2-103, Food Code)

Food cooking temperatures and times and holding temperatures should be routinely monitored by the food establishment management and by the inspector during each inspection. The temperature measuring device and technique are essential in accurately determining the temperatures of potentially hazardous foods.

The geometric center of a product is often chosen as the point of measurement of product temperature, particularly in measuring critical limits of cooking, cooling, and cold holding processes. Hot holding critical limits may need additional measurements taken at points farthest from the heat source, e.g., near the product surface on steam tables.

Ambient temperature monitoring devices should be used as indicators of where further temperature investigations are warranted. Questionable practices such as improper product cooling methods are other indicators. Temperatures monitored between packages of food, such as cartons of milk or packages of meat, also indicate the need for further examination. However, the temperature of a potentially hazardous food itself, rather than the temperature between packages, is necessary for regulatory citations.

(a) *Cooking Temperature Measurements*
(Refer to Part 3-4, Food Code)

The three dimensions of bacterial load, temperature, and time need to be considered when inspecting the cooking process. Poultry and leftovers are examples of foods that require higher terminal temperatures than beef products.

Critical limits for cooking potentially hazardous foods in the Food Code include specifications that all parts of the food be heated to a certain temperature. Temperature measurement should take into account post-cooking heat rise which allows the temperature to reach equilibrium throughout the food.

The critical limit of time at the terminal temperature must also be measured during inspections. For example, a roast beef cooked at 55°C (130°F) is required to be held at this temperature for 120 minutes to ensure destruction of pathogens. Notation should be made of cooking times as well as temperature.

(b) *Cooling and Holding Temperature Measurements*
(Refer to Part 3-5, Food Code)

Cold and hot holding temperatures should be thoroughly checked during the inspection. This includes the temperature of potentially hazardous food during transport, e.g., hot holding

carts being taken to patient areas in an institution or cold food being taken to an off-premise event by a caterer.

Product cooling temperatures and times need to be closely evaluated during inspection. Temperature profiles throughout the product may show proper temperatures at outer edges and hot spots at the core of the product. Improper cooling practices, such as tightly packing hot pans together, shrouding rolling racks, or closing the doors on rolling cabinets are factors that warrant further temperature and time investigation.

The time dimension is also important in citing holding temperatures. For example, a casserole which was cooked before noon and measured at 43°C (110°F) at 4:30 PM is far more hazardous than a hamburger properly cooked at 3:30 PM being found at 43°C (110°F) at 4:30 PM. The violation citation should note time when citing the casserole temperatures.

(c) *Methods for Temperature Measurements*

The temperature measurement is only as accurate as the device used. Regular calibration of the device is an important practice and a provision of the Food Code. Thermometers should have calibration instructions from the manufacturer and suggested calibration intervals. The regulatory agency should maintain a log identifying each piece of its inspection equipment that requires calibration. It is also helpful for the agency to have a person assigned the duty of monitoring calibration maintenance cycles. Certificates of calibration may be useful in legal proceedings when the accuracy of instrumentation is questioned.

Modern thermometers which measure temperature electrically, rather than the older bimetal types which rely on thermal expansion of two different metals, are recommended. In these instruments, a sensor is used to detect the temperature and the signal is amplified and processed electronically. This device generally yields a faster response and provides greater overall accuracy because it does not drift out of calibration and is less likely to give variable readings.

A number of different sensor technologies are available, most of which are satisfactory for the temperature range needed in food temperatures. However, there are considerations other than temperature range which should be taken into account when selecting the best and most appropriate device for the specific application.

Refer to item **8. TEMPERATURE MEASURING DEVICES,** which summarizes the different types of temperature measurement equipment, and item **9. CALIBRATION PROCEDURES,** which discusses procedures that could be used.

(d) *Cleaning and Sanitizing the Temperature Probe*

Before internal food temperatures are taken, the probe must be cleaned and sanitized. When taking a series of temperatures, it is particularly important to thoroughly clean and sanitize the probe between uses to prevent cross contamination. Boiling water, sanitizers, or

alcohol swabs can be used to destroy any remaining pathogens on the probe before it is used.

(e) *Monitoring Procedures for Temperature Measurements (Refer to Subpart 4-502, Food Code)*

Some of the most important critical limits in a food operation involve the temperatures and times at which pathogen growth is limited or pathogens are destroyed. Establishments should monitor critical control points at a frequency which ensures that they are under control. Inspections should verify that monitoring is occurring by involving the person in charge of these activities during the regulatory inspection. The presence of required thermometers and their proper use can be assessed.

Comparisons should also be made between a calibrated instrument from the inspecting agency and those used by the establishment. Notation of deviations should be made on the inspection report.

(2) *pH Measurements*

The pH measurement becomes important in determining if a food is potentially hazardous. The determination can be done in a regulatory agency's laboratory or can be assessed in the field with a portable pH meter. The closer the food approaches the critical pH limit of 4.6, the more precise the measurement should be. If pH adjustment is being used by the food establishment as a part of its HACCP plan for protecting certain food products, regular monitoring of pH should be a requirement. The agency should carefully verify that the instrumentation is suitable, calibration procedures are regularly and properly performed, and sampling procedure and analysis meet scientific standards. The establishment HACCP plan should show the above procedures and the HACCP records should include the results from the calibration and sample measurements. Refer to item **9. CALIBRATION PROCEDURES** for a discussion on the calibration of equipment.

When measuring the pH of a food, the measurement must be representative of the whole. Care must be exercised in the selection of collection containers and procedures to eliminate their influence on the sample's pH. It is recommended that multiple samples of the food product be checked to increase the reliability of the measurement.

The pH measurement checks the hydrogen ion concentration of the food. A pH measurement instrument consists of a meter and a suitable electrode probe. The probe may be of a flat type which can directly measure the pH of the sample or a regular pH probe used in laboratories. The latter may be used if the food is made into a slurry with recently boiled and cooled distilled water with a pH of 7.0. Boiling removes any CO_2 residual in the water.

Care must be taken to maintain the electrode in a clean condition. It should be thoroughly rinsed with distilled water between measurements. Oils from foods can frequently contaminate the sensitive electrodes and cause erroneous measurements. If oily foods are checked, extra cleaning is required.

(3) *Water Activity Measurements*

Water activity (a_w) is another factor in determining if a food is considered potentially hazardous under the Food Code. The relative humidity of the food influences the ability of bacteria to grow and multiply. Water activity is the ratio of water vapor pressure in a food to the vapor pressure of pure water at the same temperature. Most potentially hazardous foods have an a_w of >0.95 with all pathogenic bacterial growth stopped at an a_w of 0.85.

A laboratory or a field water activity meter may be used to determine the food sample's a_w. Because the measurement is somewhat temperature-dependent, temperature control cabinets are usually used in the laboratory. The measurement also takes up to several hours after the sample is placed in a sealed sample cavity. Multiple samples of the same food product will provide more reliable information on the actual value of the a_w. Refer to item 9. for a discussion on the calibration of equipment.

(4) *Food Additives Concentrations*
(Refer to Subpart 3-302, Food Code)

If food additives such as sodium nitrite are added as a part of a food processing operation at retail, the regulatory agency should be prepared to analyze food product samples to verify that the additive is being added at the appropriate concentration. Samples usually are collected and returned to a laboratory for the analysis. Recognized methods for sample collection and testing such as those published in the most recent edition of the Association of Official Analytical Chemists (AOAC) Official Methods of Analysis should be used.

Portable analysis systems are sometimes available to conduct the measurement in the field. These systems should be cross checked with the acceptable laboratory methods to verify their accuracy before regulatory reliance is placed on them. They should be maintained with proper field calibration and the replacement of reagents as required in the manufacturer's instructions.

Food establishments using additives as a part of their accepted HACCP plan should regularly monitor the resulting levels. The sampling plan should be readily maintained in the processing area and the results logged in the appropriate records being available by the establishment.

(5) *Warewashing Process Evaluation*
(Refer to Subpart 4-501, Food Code)

Because proper cleaning of food-contact surfaces is an important safeguard of public health, the wash, rinse, and sanitizing processes must be verified to ensure that they meet Food Code provisions. This is more effective than attempting to recover organisms from food-contact surfaces.

Mechanical warewashers are required to have data plates which indicate acceptable parameters for temperatures and cycle times for that model of machine. The operational

parameters, in conjunction with the Food Code provisions, should be used as the basis for the machine's evaluation.

(a) *Wash/Rinse/Heat Sanitization Measurement*

The devices used for measuring food product temperatures can also be used for determining the critical limits of washing, rinsing, and sanitizing. Manual operations are easier to assess, but this should not deter the inspector from verifying mechanical warewashers.

Both the three-compartment sink and many mechanical warewashers have vats for wash and sometimes rinse water that can be checked with a probe-type thermometer and compared to the installed thermometer readings. The machine must be briefly turned off before these measurements are taken. Hot water sanitizing warewashers require indirect measurement of the sanitizing rinse temperature. This can be done by exposing a securely tied remote probe of a thermocouple or the sensor of a well-shielded maximum registering thermometer to the spray. The temperature should be noted after the sanitizing rinse phase of the cycle is triggered. A temperature exceeding 71°C (160°F) in the spray pattern verifies that the temperature in the manifold is at least 82°C (180°F).

Maximum registering temperature indicators can also be attached to a clean utensil and sent through the machine's cycle. The effect of the wash and rinse temperatures on the indicator need to be considered. If these temperatures approach 71°C (160°F), they may trigger the response of the maximum registering temperature indicator so that the sanitizing rinse can not be accurately determined. The heating elements in these compartments may need to be turned off temporarily in order to verify the sanitizing rinse temperature.

(b) *Sanitizer Concentration*

The chemical sanitizer concentrations in both manual and mechanical warewashing operations need to be monitored. The Food Code specifies that the establishment shall have a device to measure the sanitizer concentration for the type of sanitizer being used. This device may be used during the inspection, but the inspector should have an independent means of verifying concentrations.

Sanitizer test kits commonly use colorimetric comparisons of a color chart to a strip of treated paper which is immersed in the sanitizing solution. The chart provides approximate solution strength in mg/L (ppm) for the various colors shown. The kits are sanitizer-specific; therefore it is important to use the one designed for the sanitizer in question.

The sensitivity of the test strips may be affected by age, heat, and humidity. Manufacturer's instructions should be followed with regard to their proper storage, use, and replacement. It is helpful to conspicuously date these sanitizer kits when they are received or opened to ensure that they are replaced when expired.

Test kits require various procedures for immersion into sanitizer solutions and subsequent readings. Some types require a quick immersion; others require holding in the solution for a period of time. The time required for color comparison also varies.

Mechanical warewashing machines using a chemical sanitizing cycle may require slightly different verification that the proper concentration has been applied. When supplied, manufacturer's instructions for measurement should be followed. A reliable indication can be found in the residual sanitizer on the utensil surface.

(c) *Pressure Measurements*

The hot water sanitizing rinse pressure of mechanical warewashing machines is an important factor. The Food Code specifies that the water supply line shall have a 6.4 mm (1/4 inch) Iron Pipe Size (IPS) valve installed immediately upstream from the automatic sanitizing rinse control valve. To measure the line pressure, it is prudent to request that establishment personnel connect the pressure gauge.

Use of a standard gauge made for measuring the pressure of liquids is recommended. It should read in a range of 100 to 350 kilopascals (15 psi to 50 psi) to accommodate the minimum required pressure and 100% overage of the maximum acceptable pressure. This high upper limit helps protect the proper functioning of the gauge in cases in which extremely high pressure is encountered.

(d) *Time Measurements*

Time, as well as temperature and concentration, is significant in the evaluation of warewashing operations. A watch with a second readout or hand is needed to make sure that immersion times or cycle segments meet Food Code provisions.

The conveyor speed for mechanical warewashing machines is important in achieving an adequate wash, rinse, and sanitizing cycle. The machine's data plate is required to state the maximum speed for the conveyor. The actual speed is usually adjustable and should be measured during the inspection. This may be done by measuring the length of the machine and dividing this figure by the time that a utensil takes to travel this distance.

(6) *Light Distribution*
(Refer to Subpart 6-303, Food Code)

Portable light meters reading in the desired range are necessary to measure the level of illumination in food areas of an establishment. The instrument should be routinely calibrated against a standard. Care should be taken that the meter is correctly used by avoiding shadows and reflecting surfaces which will bias measurements.

Measurements should be taken systematically to be representative of the actual light levels. These measurements should be taken 76 cm (30 inches) above the floor. Although it is an impractical and unnecessary method of measurement for the purposes of most inspections,

the most accurate measurement of illumination in a given area involves dividing the area into 0.6 m (2 foot) squares and taking readings in each of these squares, recording the readings, and averaging them.

(7) *Insect and Rodent Infestation*
(Refer to Subpart 6-501, Food Code)

Physical evidence of insect and rodent infestation is usually easy to discover. Live and dead vermin, droppings, nesting, gnawings, grease marks on the walls, and other signs are often readily apparent. A bright flashlight, a magnifying lens, and an ultraviolet light to detect rodent urine stains can be used to reveal these infestations.

5. INSPECTION DOCUMENTATION

Accurate notes of the inspector's observations and recordings are essential. These can be as informal as the inspector's "scratch notes" and may contain liberal use of abbreviations. These notes are usually maintained in the inspector's daily log and are not usually provided as a part of the inspection report. Such notes may serve to refresh the inspector's memory should the violations noted in the inspection report result in administrative or judicial proceedings.

(A) HACCP Inspection Data Form

The HACCP Inspection Data form contained in Annex 7 is one suggested format for recording the observations and measurements collected during an inspection. It consists of an administrative section, a food flow section, a section for recording temperatures which are spot-checked, and categorical sections to record other data. Refer to item **10. HACCP INSPECTION DATA FORM** for a discussion on the use of the form.

(B) Corrections During Inspection
(Refer to Subpart 8-405, Food Code)

Many items found during the inspection can be corrected immediately, if the permit holder or person in charge is accompanying the inspector. Such responsiveness should be encouraged, particularly for critical violations, because immediate actions best protect public health.

Detailed notes should be kept on the HACCP Inspection Data form for these violations and corrections. Immediate correction does not negate the original violation, but should be recognized as a part of the documentation of the inspection. Violations and corrections should be noted on the official inspection report.

Information on the original occurrence of the violation becomes significant if it recurs. During subsequent inspections, recurrence becomes a repeat violation which has additional compliance consequences.

6. INSPECTION REPORT

(Refer to Subpart 8-403, Food Code)

(A) Purpose

The inspection report is the official agency document regarding compliance of the food establishment with agency requirements.

The goal of the report is to clearly, concisely, and fairly present the compliance status of the establishment and to convey compliance information to the permit holder or person in charge at the conclusion of the inspection. Such a report should be completed for routine, follow-up, and investigative inspections.

The inspection report should be kept in the food establishment's files for subsequent compliance actions and review before the next inspection. Individual inspection reports are to be made available for public inspection in accordance with the agency's Freedom of Information policies, while every precaution is taken to protect trade secrets. *(Refer to Subpart 8-202, Food Code)*

(B) Preparation/Completion of the Inspection Report

The inspection report can be prepared by using either the:

(1) Food Establishment Inspection Report (refer to item 11 for discussion and to Annex 7 for the form); or

(2) FDA Electronic Inspection System (refer to item 12 for discussion).

The inspection report is usually completed at the end of the inspection by reviewing the field notes recorded on the HACCP Inspection Data form (refer to Annex 7). This transfer of information usually provides a more legible and complete report than one completed while each violation is being observed.

Not every item recorded on the HACCP Inspection Data form will be included in the inspection report. The HACCP Inspection Data form may contain some information such as documentation of acceptable holding temperatures that are not necessary for the final report.

Inspection findings are recorded on the Food Establishment Inspection Report form to detail the violations found in the establishment. FDA's studies of programs which have the most effective compliance programs found a relationship between the completeness of data provided and the success of the compliance program. The form is designed to maximize the opportunity for capturing relevant information about the violations found at the time of the inspection.

(C) Establishment Scoring

(Refer to Subpart 8-403, Food Code)

Establishment scoring provides an indication of how well an establishment is complying with the food safety rules of the agency. It is also a method for designating those establishments which require follow-up inspections or other forms of regulatory sanctions when they fall too far from the accepted levels. These establishments represent a potential public health problem for the community. The specific purpose of the follow-up inspection is to determine if critical violations detected during the initial inspection have been corrected. It may also be the basis for further compliance actions if the remedial actions by the permit holder are not effective.

Some agencies use a system of compliance tools as provided in Chapter 8 of the Food Code to protect public health. The inspection score may serve as the basis for triggering these penalties. Violations which are classified as imminent health hazards in the Food Code warrant immediate actions such as a permit suspension.

Compliance with the provisions of the Code is the basis for retaining the food establishment's permit. The establishment should be in jeopardy of losing its permit if it has a history of noncompliance at a level predetermined by the jurisdiction or if the number of critical items violated warrants a regulatory action based on the jurisdiction's enforcement protocol (refer to item **13. ESTABLISHMENT SCORING**). A history of noncompliance at a level set by the jurisdiction or a single inspection's score of critical items in the highest category of noncompliance would signal the need for strong regulatory response to protect public health. Item **13. ESTABLISHMENT SCORING** provides information on critical and noncritical violation scores.

(D) Closing Conference

The closing conference requires a high level of effective communication. During the conference, the inspector clearly and firmly conveys the compliance status of the establishment. The public health reasons for citing the violations and preventing future occurrences are covered. Acceptable alternatives and time frames for compliance are established during this conference.

The person in charge at the time of the inspection should be the principal establishment representative at the closing conference. It may be beneficial to include other members of the supervisory team in the presentation of findings and subsequent discussions. Ideally, this conference should be held in a quiet location conducive to concentration on the findings and discussion. The length is dependent on a number of factors, but should be kept as brief as possible.

(E) Report Review

The written report is the focus of the closing conference, since it is the record of findings. The listing of the results with the critical violations listed first helps focus the

closing conference on the violations which could directly lead to foodborne illness. The notations of repeated violations highlight the areas which may lead to further compliance actions. The organization of violations in the report by operational areas within the establishment often clarifies the information for the review.

The written report includes a notice to correct the identified violations. The permit holder or person in charge must be requested to acknowledge receipt of the report with the required signature. Appropriate procedures are specified in the Code should a signature be refused.

Discussion of the results promotes public health compliance in the establishment by giving the permit holder or person in charge an opportunity to ask questions and provide additional information about the establishment's operation. The inspector needs to be well versed in the Food Code and its public health reasons, and have knowledge of the industry in order to competently discuss the concerns of the establishment.

Discussions should focus on the critical violations found during the inspection. The time allocated during the closing conference should be on a risk-to-public-health basis. Noncritical items found to be in violation of the Food Code and actions needed to bring them into compliance should be addressed, but their discussion should not overshadow the significance of the critical violations.

Pamphlets or other educational materials may be useful in reinforcing an understanding of the public health issues involved. Questions which need further research and follow-up response may arise during the inspection, so notes should be taken and follow-up information provided.

Disputes of facts should be resolved in a courteous and professional manner. The permit holder or person in charge should be informed of the responsibilities and rights under the Food Code and of the agency's administrative and judicial procedures.

(F) Compliance Plans

(Refer to Subparts 8-405 and 8-406, Food Code)

The closing conference must include a detailed discussion of the establishment's plans for correcting violations found during the inspection. The violation facts and the alternatives available for compliance should be emphasized but no recommendations should be made about a particular product or service.

Corrections observed during the inspection must be noted, and reinforcing such responsiveness with encouraging remarks may be to everyone's benefit. However, these violations did occur and therefore they do count as an item of noncompliance.

The compliance plan should address changes in establishment procedures which will prevent the recurrence of noted violations. The best alternatives for compliance usually come from the permit holder or person in charge. One jurisdiction terms this the "table top HACCP" phase of the inspection. The violative process or condition is diagramed and

alternatives for correction are explored. For example, the best solution for cooling the gumbo may be to avoid the need for cooling at all by making daily batches.

The establishment's compliance plans should be formally documented on the inspection report form. Follow-up letters may be necessary to elicit fulfillment of these agreements.

(G) Notice of Corrections Completed

(Refer to Subpart 8-405, Food Code)

Timely follow-ups are mandated under the Food Code. These follow-ups verify that the critical items cited during the original inspection have been corrected or determine the course for further compliance actions.

Some jurisdictions use procedures which require establishments to return a notice to the agency that violations cited during the inspection have been corrected. These may be form letters or postcards that are preprinted with the agency's mailing address. Such notifications may be helpful, but they do not substitute for an official follow-up inspection. Consistent follow-up on violations is the agency's commitment to public health protection and equitable enforcement.

7. ADMINISTRATIVE PROCEDURES BY THE STATE/LOCAL AUTHORITIES

Administrative organization is a key to effective program management. It must encompass the proper office procedures for establishing administrative files and maintaining the inspection reports and other data pertinent to the establishment.

A comprehensive and detailed record maintenance system supports the program and tracks potential compliance actions. The records maintained usually include documents including ledgers regarding plan review submissions and approvals; permits; inspections; training; complaints; foodborne illness investigations; laboratory sample analyses; and compliance actions, including legal proceedings.

Computerization of the administrative and inspection procedures of the agency has been developing at a rapid rate across the country. The FDA Electronic Inspection System provides a comprehensive basis for the inspection and complaint investigation procedures. Other software may be integrated with it to maintain other aspects of agency records.

(A) Files

The following documents should be included in the active files: records related to initial plan review, permit application and issuance, inspection reports, complaints, investigations, management training and certification, correspondence, and compliance actions. Variance requests including complete HACCP plans and agency actions on the request must be maintained in the establishment's file.

Files must be retained in accordance with the agency's policies, but for those agencies without an established policy, 3 or 4 years in the active file should be sufficient. Closed establishments should be purged from active files, but the files should not be discarded, since these establishments often reopen under different management. The old records may be helpful in advising new, or prospective new, owners about the establishment. Documents related to administrative matters should be kept in an orderly manner to assist in program management. This includes local and state procedures, correspondence and policies, FDA recommendations, references, and source listings such as the Interstate Milk Shippers List and Interstate Certified Shellfish Shippers List.

(B) Follow-up Letters

As an intermediate measure between follow-up inspections and administrative hearings, regulatory agencies often send letters concerning inspection results to the establishments which have continuing problems. These letters to the permit holder specify instances in which deviations from the Food Code were identified during the previous inspection. Letters can cover single establishments or several establishments under the control of the permit holder. Such letters may further strengthen an agency's position in subsequent compliance proceedings.

Follow-up letters can be easily compiled and generated by the FDA Electronic Inspection System. The establishment's records can be quickly reviewed for significant non-compliance. Descriptions of specific violations can be prepared for export to a computer file in word processing software. These data can be quickly merged with the permit holder's name and address and a letter produced. Statewide chain reports can be generated in a similar manner to bring corporate compliance problems to the attention of top management.

(C) Management Reports

Agency managers should constantly review program performance to ensure that it is sufficient for the public health needs of the community. The timeliness of the program's accomplishment of initial, follow-up, and complaint inspections should be reviewed. Violation statistics should be examined for inconsistencies in the inspections. Statistics on the performance of various sectors of the industry can better focus inspection and educational efforts. Recent foodborne illness data from the community or state should be used to target program resources.

Computerized systems, such as the FDA Electronic Inspection System, should be used for record keeping and reporting to expedite the generation of management reports. These reports keep agency management informed of program performance. Community and political support for food protection programs are engendered through routine and special focus reports on program activities.

(D) Quality Assurance Programs

Continuous program improvement efforts maintain program priorities focused on protecting public health. Regular assessments of the program and individual elements of the program's status determine the direction of program movement.

One of the basics of quality assurance is the design of meaningful and measurable goals. A few well-chosen indicators such as the reduction of overdue follow-ups is desirable. Too many goals make the monitoring system too complex.

Program management is also responsible for ensuring quality inspections through a quality improvement program. Some jurisdictions have members of a quality team or supervisors who monitor a small percentage of inspections through an announced program of reinspection soon after the initial inspection is completed. Conditions will vary somewhat, but general trends can be determined.

From the information gathered, continuing staff education efforts can be directed to needed areas, or program policies can be clarified. Inconsistencies between inspections and application of the rules are a constant complaint of the industry that can be reduced through on-going quality improvement programs.

Retail food protection program evaluations are available from the state-level food regulatory agencies. FDA program evaluations of general program or particular program elements may be requested through the FDA regional retail food specialist and are recommended every 3 years. The program elements are evaluated according to FDA-suggested protocol. A statistically significant random selection of establishments is inspected by FDA-certified inspection or evaluation officers to determine the sanitation level in the state program's jurisdiction. State programs have comparable evaluation services for local programs.

8. TEMPERATURE MEASURING DEVICES

(A) Sensor-Type Temperature Measuring Devices

(1) *Bimetal Bayonet Style*

A bimetal bayonet style thermometer with a dial face scale with a range of -18 to 105°C (0 to 220°F) may be used for certain applications in food temperature measurement. The scale must be in 1°C (2°F) increments. The dial face should be a minimum of about 1 inch in diameter and is usually available in larger sizes. The stem length should be a minimum of 127 mm (5 inches) and may need to be much longer to measure thicker foods.

Specific measurement instructions from the manufacturer of the instrument should be followed. The temperature measured is an approximate average of the temperature between the immersion point, which is approximately 2 inches up the stem, and the stem tip.

The bimetal bayonet style thermometer can accurately measure the temperature of relatively thick or deep foods such as beef roasts and stock pots. However, this instrument does not accurately measure the temperature of food less than 2 inches thick. The thermistor and the thermocouple discussed below do not have these limitations. The recent foodborne illness outbreaks associated with inadequate cooking of eggs and hamburger patties have shown that it is very important to be able to accurately determine the temperatures associated with these products as well.

(2) *Thermistor*

This device uses the temperature sensitivity of a semiconductor junction as the sensor. Advantages are high output and fast response at a very low cost. Disadvantages include nonlinearity and a limited upper temperature range, typically 300°C (572°F). The accuracy and response time of a thermistor lend themselves very well to food temperature measurement.

(3) *Thermocouple*

This device relies on the voltage generated by the junction of two dissimilar metals. The voltage output is proportional to the temperature of the junction. The advantages are a relatively rugged construction and a wide temperature range. Disadvantages include higher cost, lower sensitivity, and non-linear output, which requires a built-in reference. This technology has been used in food preparation for a number of years and has performed very well.

(4) *Infrared Thermometers*

The infrared thermometer quickly registers surface temperatures which facilitates general food safety system surveillance by allowing the scanning of numerous food temperatures over a short period of time. It operates much like a radar gun and requires the user only to aim at the target food, pull the trigger, and read the displayed temperature. ***This type of thermometer is intended only for measuring surface temperatures of food products and should not be used to measure and verify critical internal temperatures such as cooking temperatures.***

Infrared thermometers are usually constructed of a high-strength, solvent-resistant plastic and measure invisible infrared energy being emitted from a target object. All objects emit infrared energy. The hotter the object is, the more active its molecules are and the more infrared energy it emits. An infrared thermometer houses optics that collect the radiant infrared energy from the object and focus it onto a detector. The detector converts the energy into an electrical signal which is amplified and displayed as a temperature reading.

(B) Performance - Thermocouples, Thermistors, and Infrared Thermometers

The major applicable sensor types for thermocouples and thermistors have an appropriate temperature range for food product measurement. In addition, response time is more than adequate (<1 second) for all the sensors. A bare sensor, however, is not recommended for food use because of fragility and difficulty of cleaning.

Sensors used for food temperature measurement should be encased in a metal sheath. Unfortunately, the disadvantage of a sheath is that it increases response time. As the thickness and length of the probe increase, response time increases dramatically. A food probe with a maximum diameter of 4 mm (0.150 inch) is the best compromise.

Smaller diameters show similar response times for a wide variety of probe materials, including stainless steel. A usable response time for food measurement should be less than 6 seconds TC (time constant). Probes thicker than 4 mm (0.150 inch) show a response TC of 8 to 10 seconds and should be used only for hot grease and surface measurements.

The TC of any sensor is defined as the time required for that sensor to respond to 63.2% of its total output signal when subject to steep change, for example, rapid immersion into a stirred hot oil bath. The step changes can be either an increase or a decrease in the parameter being measured. Five constants are required for a sensor to reach 99% of its total change.

A second factor in response time is placement of the sensor within the probe. The actual sensor element should be placed no more than 1 mm (0.04 inch) (±10%) from the tip of the sheath. If the sensor is not firmly against the end of the probe, response time increases dramatically. As an example, if the sensor is placed 1 mm (0.5 inch) from the tip, the response time can be as high as 20 seconds.

The sensor should be held in place by thermally conductive epoxy with a thermal coefficient of at least 7.0. Standard epoxies can act as a heat barrier and should be used in stationary applications only where temperature is relatively constant over a long period of time.

Most types of electrical-based thermometers are capable of effectively measuring the internal temperature of thin foods. Depending on construction, basically all are capable of at least ±0.5°C (±2°F) accuracy over the required temperature range. The limiting factor for effective temperature measurement is the physical characteristics of the probe that is inserted into the food. Thick metal walls and improper placement of the sensor can lead to erroneous readings. The bimetal bayonet-style thermometer may be suitable for measuring internal temperatures of thick foods.

As stated earlier, infrared thermometers do not measure internal temperature, but register surface temperature only, from a variety of distances based on their field of view. Typical applications are at a salad bar where surface temperatures will likely be higher than internal product temperatures or a hot buffet line where surface temperatures will likely be cooler

than internal product temperatures. ***Because it only measures surface temperatures, use of an infrared thermometer should be followed by a closer analysis using an internal temperature measuring device that measures internal food temperature, such as a thermocouple, if problems are suspected.***

(C) Dataloggers

Dataloggers are devices which record temperature over time. The measurements may be stored on a circular chart, printed out, or stored electronically for later reporting or downloading to a computer. These devices are primarily used for ambient or product-specific cold holding or cooling, but may also be used for cooking or smoking operations, hot holding, or special applications such as CIP systems.

Some dataloggers allow multiple sensors to simultaneously report data to the recorder. The frequency of recording may be adjustable from continuous to once every 24 hours depending on the application. Portable dataloggers can be useful in HACCP verification work.

The instrument may be either an analog or digital type. The remote sensing probes are subject to the same parameters discussed in connection with other temperature measuring devices. Proper calibration procedures should also be followed.

The records generated from these devices should indicate date, time, and source of reading and should be signed by the individual responsible for the device at that time.

(D) Time/Temperature Integrators/Indicators

Time/Temperature Indicators or Integrators (TTI) are simple label-like devices that continuously monitor cumulative time and temperature of food products. Some of these devices are threshold-sensitive or change in appearance when a certain threshold for temperature or time is reached. The appearance changes only if the threshold has been breached.

Other devices will record the full history of the temperature and time profile. Some are coupled with bar code-like readers which download information to computers. These devices and the computer software are calibrated to mimic actual changes in the product over the range of temperatures and times encountered.

TTIs are not widely used now, but industry and public health officials agree that there are widespread potential benefits. Applications would include Reduced Oxygen Packaging (ROP) products such as sous vide or vacuum-packaged foods and some fresh products which are temperature-sensitive, such as milk and seafood.

9. CALIBRATION PROCEDURES

(A) Calibration of Sensor Thermometers

(Refer to Subpart 4-502, Food Code)

Thermometers used for regulatory inspections should be calibrated initially, and then regularly thereafter, to ensure that accuracy of measurement is maintained. This calibration should be in the range of normal regulatory concern, 5°C (41°F) to 74°C (165°F). Calibrations should include both the instrument and any interchangeable probes used with that instrument. Each piece should be separately identified in the calibration records with serial numbers or agency equipment numbers.

The thermometer should be calibrated against a thermometer which has been certified by the National Institute of Standards and Technology (NIST). Standard laboratory calibration protocol such as American Public Health Association (APHA) Standards for the Examination of Dairy Products should be followed. Proper calibration documentation is essential.

A wet ice and boiling water procedure may be used for field checks of the thermometer and sensor. The ice should be broken into very small pieces, packed into an insulated container, and stirred with cold water into a very thick slurry. The sensor should be placed at the very center of the container to a depth of at least 50 mm (2 inches) and should be frequently agitated. The temperature should be noted when the temperature has stabilized after 3 minutes and should be ±0.5°C (±2°F) from 0°C (32°F).

The field check for higher temperatures may be conducted with boiling water. Consideration should be given to altitude above sea level in using this method. A 25 cm (>10 inch) deep container of water should be brought to a rolling boil on a stove or other source of constant heat. The probe should be carefully inserted in the boiling water until the sensor is located in the approximate center of the container with at least 76 mm (3 inches) of water below it. The temperature should be noted when the temperature has stabilized after 3 minutes and should be ±0.5°C (±2°F) from 100°C (212°F).

Adjustments to some of the instruments are possible to bring them back into calibration. Others should be returned to the manufacturer since field adjustments are not possible. Some instruments are not adjustable and should be replaced.

(B) Calibration of pH Meters

The manufacturer's calibration instructions should be followed for both laboratory and portable pH meters. The calibration procedure must take into consideration the expected pH range of food. This factor is extremely important if a pH of 4.6 is used as a critical limit. A 2-point calibration using standard buffers of 4.0 and 7.0 is most common for working with potentially hazardous foods. Calibrations are usually performed immediately before the pH of the food samples is measured. Compensation for the temperature of the sample is required if the pH meter does not automatically address this variable.

(C) Calibration of Water Activity Equipment

The manufacturer's calibration instructions should be followed for both laboratory and portable a_w instruments. The expected food moisture should be taken into consideration during the calibration procedure. The critical limit of 0.85 is the crucial point at which the instrument should be calibrated if the question is whether or not the food is potentially hazardous.

10. HACCP INSPECTION DATA FORM

(A) Purpose

(Refer to Subpart 8-403, Food Code)

The HACCP Inspection Data form in Annex 7 is one suggested format for recording the observations and measurements collected during an inspection. It consists of an administrative section, a food flow section, a section for recording other temperatures which are spot-checked, and categorical sections to record other data.

(B) Form Completion

(1) *Administrative Section*

This section contains the minimum information to link the form to the particular establishment. It identifies the date and time of the inspection. This information may be important later to substantiate findings in relation to a particular food preparation process.

(2) *Food Flow Section*

This section allows for space for the inspector to record detailed information about as many as four food items identified as having the most potential for presenting problems. Additional sheets can be used if more than four foods are tracked. The foods are listed horizontally across the top, and steps from source to reheating are included down the left side of the form.

Under each food listed, space is provided for recording information observed such as times and temperatures for each of the steps. A shaded column is provided for each of the foods to identify the critical limit, if any, for each of the steps. As an example, if the baking of chickens is being observed, the internal temperature and cooking time would be noted in the observation (unshaded) column, e.g., indicating that the food was baked to a temperature of 63 - 86°C (145 - 187°F) for 2 minutes. The critical limits column at this step would specify 74°C (165°F) for 15 seconds unless the establishment is preparing chickens under a variance regarding time and temperature, in which case the time and temperature conditions of the variance would be listed in this column.

The entire preparation and service cycle may not occur during the inspection. It should be clearly delineated on the form at which point the observations began and ended. The additional parts of the process can be discussed with the permit holder or person in charge to determine any potential problem areas where critical limits may not have been met.

(3) *Food Temperature Recording*

This section allows for the recording of food temperatures which are not being tracked above. The index letters indicating the food steps above can be used in conjunction with the recording of these measurements. Both acceptable and violative temperatures may be recorded here, but only the violative temperatures are later cited on the inspection report.

(4) *Other Data*

This section is located on the back of the form and can be used to record observations and measurements related to other areas of the operation. These include the following areas: management/personnel; other food; equipment, utensils, and linens; water, plumbing, and waste; physical facilities; and poisonous or toxic materials. Notes can be recorded under each of these categories. Additional forms can be used for the same establishment, if needed.

11. FOOD ESTABLISHMENT INSPECTION REPORT

(A) Introduction

(Refer to Subpart 8-403, Food Code)

When using the manual method of preparing the Food Establishment Inspection Report, enter the data on the report form (refer to Annex 7 for the form) in the appropriate field. Use continuation pages to give a full description of the conditions found in the establishment.

(B) Administrative Data

Enter the administrative data to clearly identify the food establishment and update the information when necessary. Use abbreviations where they do not interfere with reliable identification of the establishment.

Use the Inspection Type (**Insp. Type**) when recording the reason for the inspection. Use the Time blank for recording the time the establishment inspection takes or the time of day the inspection was made. Each agency should develop models for standardizing the way this form is completed.

(C) Debiting Methodology

It is critical to standardize the inspection process within the agency. Standardization using state-level and federal-level standardization procedures and certified inspection personnel is important for a program. The standardization procedure is explained in more detail in the staff training section.

The following process delineates the specifics of what constitutes a violation of the Food Code. It limits the possible shades of gray but does not totally eliminate them.

Items are marked as violations on the inspection report when they clearly exist in the food establishment. A violation represents a deviation from a Food Code provision. Slight violations, such as one dirty utensil among thousands of clean ones, does not indicate that the establishment is significantly deviating from the requirement to use clean utensils.

Each violation of a Food Code provision is reported as a separate item on the inspection report. This does not mean, however, that each instance should be considered a distinctly separate reportable violation. Some discretion is warranted when preparing the inspection report, but this discretion should have a firm basis within the standardization process.

For example, a cooler with mechanical problems may result in a dozen or more potentially hazardous food items being at a violative temperature. It may categorically be considered a malfunctioning refrigeration device under § 4-301.11, Cooling, Heating, and Holding Capacities, because repairs are needed to bring the unit into compliance. The food temperature violation is also cited only one time under ¶ 3-501.16(B) or (C), Potentially Hazardous Food, Hot and Cold Holding. Additionally, if the time the food is out of temperature warrants, each of the violative foods should be discarded by the permit holder or person in charge and disposition noted on the report.

Alternatively, the unit may be properly functioning, but improper cooling practices were used, resulting in the high temperatures being found in the potentially hazardous food. This would be a violation of ¶ 3-501.15(A), Cooling Methods, and ¶ 3-501.16(B) or (C), Potentially Hazardous Food, Hot and Cold Holding.

If 12 separate coolers were found with items out of temperature as the result of 12 separate instances of improper practices by employees, each instance should be individually cited as a critical violation. The details included in each citation should clearly delineate the conditions found in each instance.

Failure to clean floors is another example which can be easily visualized. A large meat cutting room may have numerous separate areas requiring cleaning. If there is a build-up of old food debris and other filth on the floor of the room in five separate areas, then one violation would exist. However, if the cleaning problem existed in this room, the produce area, bakery, and two restrooms, one violation of ¶ 6-501.12(A) is cited with each of the incidences listed.

(D) Violation Data

Record inspectional findings on the report form to detail the violations found during the inspection of the establishment. As mentioned elsewhere in this Annex, FDA's studies of programs which have the most effective compliance programs found a relationship between the completeness of data provided and the success of the compliance program. The form is designed to maximize the opportunity for capturing relevant information about the violations found at the time of the inspection. Use as many of the rows of the Violation Description section as are needed to describe the violation.

Indicate critical violations in the first column, **Category,** using an **X**. Always list the critical violations first for emphasis. Leave a blank line between individual violations cited.

Note repeat violations with an **X** in the second column, **Repeat**. Repeat items are those that were in violation on the last inspection. Indicating in this column when the original violation occurred may also be helpful.

Record specific Food Code section references in the third column, **Code References**. The Inspectional Guide (refer to Annex 7) may be used to quickly find the appropriate Code section numbers. The Code reference provides information about the legal basis for the noted violation and helps the person in charge to find the actual Code requirement. It is important to standardize inspectors in accurately citing the Code. Succinctly provide the specifics of the observed violation in the fourth column, **Violation Description/Remarks/ Corrections**. Record any explanations or other data, including the fact that a correction was made during the inspection. Use as many lines as necessary to explain the details of the violation. Legibility is important.

12. FDA ELECTRONIC INSPECTION SYSTEM

(A) Introduction

(Refer to Subpart 8-403, Food Code)

The FDA Electronic Inspection System (FDA EIS) is a powerful tool for regulatory agencies to use in managing important program data. It can provide the regulated establishments with a comprehensive, legible, and understandable report of the agency's evaluation of the establishment.

The FDA EIS software is being provided to state and local regulatory agencies as a part of the Food and Drug Administration's mandate under the Public Health Service Act to assist these agencies in their important roles of protection of the consumer's food, seafood, and milk supplies. Federal agencies are receiving this support under the Economy Act. A complete package is available at a nominal cost from National Technical Information Service.

FDA EIS may be used to integrate data management between existing agency database management systems and the food protection program. It can also consolidate inspection data collection and reporting between different levels of food protection programs within a state.

There are two components to the integrated FDA EIS software package, the *Office System* and the *Field System*.

(B) Office System

Features of the EIS that expedite and enhance office-based functions include:

(1) *Flexibility* - Agencies can customize definitions to match the way their programs currently operate.

(2) *Easy to Use* - FDA EIS is menu-driven to allow quick implementation of powerful program features.

(3) *Ad Hoc Reports* - Menus are used to easily format and save management reports routinely needed and to generate spontaneous, unique reports for immediate management decisions.

(4) *Complaint Management* - FDA EIS provides integrated input, ledger, assignment, and tracking for routine establishment complaints.

(5) *Epi-Tracker* - A sophisticated relational database program is included to input foodborne illness complaints, track environmental samples and patient specimens, and look for similarities between previously reported complaints.

(6) *HACCP Support* - Program provides a risk-based inspection frequency and accommodates thousands of Hazard Analysis Critical Control Point (HACCP) plans allowing an individual establishment's plan to be incorporated into that firm's inspection.

(7) *Data Export* - Reports are formatted by FDA EIS for direct export as a .WK1 file, a .DBF file or as an ASCII file which can be used by a wide variety of other software packages for further statistical analysis, graphical portrayal of management data, or incorporation into word processing applications.

(C) Field System

EIS features that support and enhance inspections include:

(1) *Previous Inspections* - Agencies can choose how many previous inspections are automatically loaded on the Field System for ready reference during the current inspection.

(2) *Automatic Repeat* - Possible repeat violations are automatically flagged for inspector concurrence, and the previous violation statement can be automatically repeated and prepared for editing.

(3) *Code Citation* - Definitive Code section citation is possible to provide for clear and defensible inspection reports.

(4) *Violation Look-Up* - Possible violations can be searched by keyword, chapter, or database for easy Code citation.

(5) *Violation Reporting* - Specific description of findings during inspection to increase management understanding of violations and aid in possible enforcement actions.

(6) *Departmental Reporting* - Findings may be allocated to specific operational areas of an establishment, in effect creating sub-reports for departmental managers which cite only violations occurring in their area of responsibility.

(7) *Realistic Results* - Violations are summarized by number of critical and noncritical items to produce establishment score.

(8) *Reference Library* - An FDA reference library including Code interpretations, Milk Shippers and Shellfish Shippers lists, and Food Recall List may be kept up to date by downloading from the FDA CFSAN Web Page at http://www.cfsan.fda.gov/list.html . FDA's *Foodborne Pathogenic Microorganism and Natural Toxins Reference Book* is also available for inclusion. State and local SOPs and inspection manuals can be easily added by the user.

(9) *System Support and Future Enhancements* - Consistent with available resources FDA will endeavor to provide technical support and system updates and enhancements.

(D) Basic Implementation Level

The FDA EIS provides two approaches for implementation. The basic plan is achievable by those regulatory agencies with access to an IBM-compatible personal computer. The inspection data is entered in a batch process into the office computer, and the full power of the database management and reporting systems can be immediately used.

Inspection Reports can be preprinted with most of the administrative information inserted through a word processor merge file. The permit generation process can be facilitated with the FDA EIS Office System. Complaint and foodborne illness data tracking are enhanced with the implementation of the basic plan.

(E) Advanced Implementation Level

Moving up the technological ramp, the full power and benefits of FDA EIS can be used when the Field System is installed on notebook computers. Inspection results are entered at the conclusion of each inspection and the report is generated within the establishment with a portable printer.

Data accuracy will be more ensured with this method. Timeliness will also be enhanced in generating the agency's management reports. The cost savings should quickly justify the purchase of the modest field computer and printer required to run the FDA EIS Field System.

13. ESTABLISHMENT SCORING

(A) Introduction

(Refer to Subpart 8-404, Food Code)

Certain Food Code violations are imminent health hazards and require immediate action or closure of the affected part of the food establishment. Sewage backing up in a food preparation area is an example of an imminent health hazard. Imminent health hazards require immediate intervention and may result in a summary suspension of the permit as specified in the Food Code.

Critical items are Food Code violations which are more likely to contribute to food contamination, illness, or environmental degradation and represent substantial public health hazards. The Food Code delineates critical items by the use of asterisks ***** after the tag line. All provisions within an asterisked section are critical unless they are otherwise marked by a superscripted ^{N}, which means that the item is noncritical, or a superscripted ^{S}, which means criticality is dependent upon the circumstances.

In previous codes, violations have been always considered critical or noncritical. The Food Code allows the inspector to use professional judgement regarding some of the violations to determine their seriousness based on the likelihood of food contamination, illness, or environmental degradation occurring as a result of the violation.

(B) Scoring Methods

The Food Code is based on citing violations in two categories, critical and noncritical. Each of the violations is expected to be corrected within given time frames. The number of violations is the basis for applying the compliance action provisions of the Food Code. The score, which is the number of items in violation, is significant as an indicator of the overall

control of the causes of foodborne illness; however, there is no defined point at which a score translates into a significant health hazard. In fact, it is possible to have only one critical violation which has the potential for causing a foodborne illness outbreak.

Regulatory agencies which have categorized their establishments based on risk, as reviewed earlier, may choose to score their establishments by using these same categories. Others may choose to score their establishments by a simpler method which does not reflect the complexity of relative risk for foodborne illness causation.

A basic premise of the first two methods discussed below is that it is easier for simpler operations to achieve compliance with the Food Code. More complex operations have more opportunity for missing the targets. In no case should a significant level of noncompliance which will affect public health be tolerated.

Each jurisdiction has variations in conditions which need to be considered in establishing the compliance strategies which will work best for it. Some jurisdictions, even within the same state, have significantly higher or lower levels of compliance when measured with a standardized inspection. An establishment's critical violation score that requires a follow-up inspection will be much different between jurisdictions. Guidance regarding the rational allocation of the available regulatory resources is the purpose of the following discussion.

(1) *Total Quality Management Method*

A total quality management (TQM) methodology employs statistical process control to keep the organization's efforts focused on continuous quality improvement. By using measurable factors, such as the number of critical items in violation, an organization can continually monitor its results and make adjustments in process (follow-up inspections) to derive the most food safety benefits.

This method uses the industry norms to set the levels for precipitating the follow-up inspection. With the TQM method, regulatory resources are always focused on the establishments within a given category that require further regulatory compliance actions. (Refer to item **2. PROGRAM PLANNING**, (C) *Risk Categorization of Food Establishments,* for information about possible categories.) An industry norm can usually be reliably established for the jurisdiction after the first 50 inspections of establishments in that particular category. This norm is not static and will change with improvement in compliance and other influences. A regulatory agency would be well advised to conduct a semiannual or annual review of the categorical industry norms.

The TQM method uses the simple but effective statistical tool of percentile rank to judge the compliance of an establishment against the range of compliance levels of similar establishments within that category. The establishment percentile rank is expressed as the percentage of the scores, in the collection of scores, below its score.

The raw scores of critical violations are arrayed to show a frequency distribution to derive the percentile rank. Then the level established is compared with this frequency distribution. A point below the selected level of compliance is chosen as the number of critical items to initiate a follow-up inspection.

Table 2 shows an example summary of the frequency information for critical item violations for Type 4 establishments which have extensive menus and prepare large quantities of food that require many preparation steps. Portrayed are the raw scores and the frequency of occurrence of each critical violation. These calculations may be routinely done through manual computation or use of simple software packages. In this hypothetical jurisdiction and within this category, the highest 20% of violators of critical items in the Code has been established as the point at which follow-up inspections will be made. The frequency distribution is counted down from the highest number of violations to determine that for this period of time the establishments with more than eight critical violations would have follow-ups. This is three more critical violations than the average establishment in this category would have for the same period of time.

Table 2.
Example of Percentile Ranking
of Risk Type 4 Establishments

Est. = Establishment Identification
No. = No. of Critical Violations on an Initial Inspection
Sum Critical Violations = 581.00
Mean No. of Critical Violations = 5.81

Est.	No.	Est.	No.	Est.	No.	Est.	No.
1	1	26	8	51	20	76	5
2	2	27	5	52	4	77	7
3	4	28	7	53	5	78	4
4	5	29	6	54	3	79	4
5	6	30	1	55	2	80	3
6	10	31	3	56	4	81	3
7	13	32	6	57	4	82	4
8	2	33	7	58	12	83	5
9	3	34	5	59	11	84	5
10	4	35	4	60	12	85	4
11	2	36	8	61	3	86	3
12	6	37	10	62	4	87	3
13	5	38	12	63	12	88	5
14	4	39	3	64	2	89	15
15	14	40	3	65	3	90	1
16	2	41	5	66	4	91	2
17	3	42	4	67	5	92	4
18	6	43	5	68	5	93	9
19	4	44	5	69	11	94	4
20	3	45	7	70	10	95	3
21	7	46	6	71	3	96	11
22	8	47	2	72	3	97	2
23	4	48	3	73	5	98	14
24	14	49	8	74	6	99	12
25	4	50	12	75	8	100	7

No.	Freq.	%
1	3	3
2	9	9
3	17	17
4	19	19
5	15	15
6	7	7
7	6	6
8	5	5

Follow-ups for highest 20% of category

No.	Freq.	%
9	1	1
10	3	3
11	3	3
12	6	6
13	1	1
14	3	3
15	1	1
20	1	1

(2) *Fixed Categorization*

In this method, a fixed number of critical violations is selected for each category of establishment. Table 3 illustrates one application of this method using this type of categorization.

Table 3. Critical Violations

Type	Critical
1	2
2	3
3	5
4	5

The number of violations used may be adjusted to accommodate current levels of resources in the agency and varying levels of compliance in the industry.

(3) *Fixed without Categorization*

The simplest method of establishing follow-up is to set a single level of compliance for all types and complexities of establishments. This figure should accommodate more realistic levels of compliance in the more complex operations, e.g., five critical violations in a full-service cafeteria would be the criterion before a follow-up inspection is triggered. This may mean that few, if any, follow-ups will be conducted in the quick service or simple retail food store operations.

As with the other methods, the number of critical items for causing follow-ups may be altered to conform to resource realities in the agency and changing levels of conformance in the industry.

Annex

5 HACCP Guidelines

1. INTRODUCTION

The acronym HACCP stands for Hazard Analysis and Critical Control Point, which is a prevention-based food safety system. HACCP systems are designed to prevent the occurrence of potential food safety problems. This is achieved by assessing the inherent risks attributable to a product or a process and then determining the necessary steps that will control the identified risks.

Essentially, HACCP is a system that identifies and monitors specific foodborne hazards -- biological, chemical, or physical properties -- that can adversely affect the safety of the food product. This hazard analysis serves as the basis for establishing critical control points (CCPs). CCPs identify those points in the process that must be controlled to ensure the safety of the food. Further, critical limits are established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system, again, to ensure that potential risks are controlled. The hazard analysis, critical control points, critical limits, and monitoring and verification steps are documented in a HACCP plan. Seven principles have been developed which provide guidance on the development of an effective HACCP plan.

HACCP represents an important food protection tool. HACCP is not something limited to food franchises or chains. The concept can be applied by small independents as well as national or regional companies and can be integrated into the recipes and standard operating procedures of any size establishment. Employee training is key to successful implementation. Employees must learn which control points are critical in an operation and what the critical limits are at these points, for each preparation step they perform.

Establishment management must also follow through by routinely monitoring the food operation to verify that employees are keeping the process under control by complying with the critical limits.

As is the case with industry, mastering and applying regulatory aspects of HACCP is not limited to large state programs. Local jurisdictions can effectively promote HACCP and apply the concept during inspections. The implementation of HACCP continues to evolve and to be further refined as new products and procedures are developed and as hazards and their control measures are more clearly defined. To meet the challenges presented by advances in food research, product development, and their impact at retail, regulatory personnel must keep themselves informed. Food protection publications issued by the food industry, professional organizations, and other groups and continuing education programs can be particularly helpful in providing an understanding of food operations and how the application of HACCP can bring a focus to food safety that traditional inspection methods have lacked.

(A) Definitions

Many terms are used in discussion of HACCP that must be clearly understood to effectively develop and implement a plan. The following definitions are provided for clarity:

(1) *Acceptable level* means the presence of a hazard which does not pose the likelihood of causing an unacceptable health risk.

(2) *Control point* means any point in a specific food system at which loss of control does not lead to an unacceptable health risk.

(3) *Critical control point*, as defined in the Food Code, means a point at which loss of control may result in an unacceptable health risk.

(4) *Critical limit,* as defined in the Food Code, means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.

(5) *Deviation* means failure to meet a required critical limit for a critical control point.

(6) *HACCP plan,* as defined in the Food Code, means a written document that delineates the formal procedures for following the HACCP principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

(7) *Hazard,* as defined in the Food Code, means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

(8) *Monitoring* means a planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensurethat the critical limit maintains product safety. Continuous monitoring means an uninterrupted record of data.

(9) *Preventive measure* means an action to exclude, destroy, eliminate, or reduce a hazard and prevent recontamination through effective means.

(10) *Risk* means an estimate of the likely occurrence of a hazard.

(11) *Sensitive ingredient* means any ingredient historically associated with a known microbiological hazard that causes or contributes to production of a potentially hazardous food as defined in the Food Code.

(12) *Verification* means methods, procedures, and tests used to determine if the HACCP system in use is in compliance with the HACCP plan.

(B) History

The application of HACCP to food production was pioneered by the Pillsbury Company with the cooperation and participation of the National Aeronautic and Space Administration (NASA), Natick Laboratories of the U.S. Army, and the U.S. Air Force Space Laboratory Project Group. Application of the system in the early 1960's created food for the United State's space program that approached 100% assurance against contamination by bacterial and viral pathogens, toxins, and chemical or physical hazards that could cause illness or injury to astronauts. HACCP replaced end-product testing to provide food safety assurance and provided a preventive system for producing safe food that had universal application.

In the succeeding years, the HACCP system has been recognized worldwide as an effective system of controls. The system has undergone considerable analysis, refinement, and testing and is widely accepted in the United States and internationally.

(C) Advantages of HACCP

FDA is recommending the implementation of HACCP in food establishments because it is a system of preventive controls that is the most effective and efficient way to ensure that food products are safe. A HACCP system will emphasize the industry's role in continuous problem solving and prevention rather than relying solely on periodic facility inspections by regulatory agencies.

HACCP offers two additional benefits over conventional inspection techniques. First, it clearly identifies the food establishment as the final party responsible for ensuring the safety of the food it produces. HACCP requires the food establishment to analyze its preparation methods in a rational, scientific manner in order to identify critical control points and to establish critical limits and monitoring procedures. A vital aspect of the establishment's responsibility is to establish and maintain records that document

adherence to the critical limits that relate to the identified critical control points, thus resulting in continuous self-inspection. Secondly, a HACCP system allows the regulatory agency to more comprehensively determine an establishment's level of compliance. A food establishment's use of HACCP requires development of a plan to prepare safe food. This plan must be shared with the regulatory agency because it must have access to CCP monitoring records and other data necessary to verify that the HACCP plan is working. Using conventional inspection techniques, an agency can only determine conditions during the time of inspection which provide a "snapshot" of conditions at the moment of the inspection. However, by adopting a HACCP approach, both current and past conditions can be determined. When regulatory agencies review HACCP records, they have, in effect, a look back through time. Therefore, the regulatory agency can better ensure that processes are under control.

Traditional inspection is relatively resource-intensive and inefficient and is reactive rather than preventive compared to the HACCP approach for ensuring food safety. Regulatory agencies are challenged to find new approaches to food safety that enable them to become more focused and efficient and to minimize costs wherever possible. Thus, the advantages of HACCP-based inspections are becoming increasingly acknowledged by the regulatory community.

Examples of the successful implementation of HACCP by food establishments may be found throughout the food industry. During the past several years, FDA and a number of state and local jurisdictions have worked with two national voluntary pilot projects for retail food stores and restaurants. These projects involved more than 20 food establishments and demonstrated that HACCP is a viable and practical option to improve food safety. FDA believes that HACCP concepts have matured to the point at which they can be formally implemented for all food products on an industry-wide basis.

2. HACCP PRINCIPLES

(A) Background

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which developed HACCP principles, was established in 1988 and has as members officials from several federal agencies which include the Food and Drug Administration, the Centers for Disease Control and Prevention, the Food Safety Inspection Service, the Agricultural Research Service, the National Marine Fisheries Service, and the U.S. Army. The NACMCF also has national experts from academia, state government, consumer groups, and the food industry.

(B) Principles

The NACMCF has developed seven widely accepted HACCP principles that explain this process in great detail. To prepare an effective HACCP plan these principles must be

followed. Further, a comprehensive review of a HACCP plan must include consideration of these principles. These HACCP principles are discussed below.

PRINCIPLE #1: HAZARD ANALYSIS

(a) *Purposes*

The hazard analysis process accomplishes three purposes:

(i) Hazards of significance are identified;

(ii) The hazard analysis provides a risk basis for selecting likely hazards;

(iii) Identified hazards can be used to develop preventive measures for a process or product to ensure or improve food safety.

Before beginning to develop a HACCP plan, a team should be assembled that is familiar with the overall food operation and the specific production processes to be included in the plan. The team's goal and each member's responsibilities in reaching that goal must be clearly defined.

The first step in the development of a HACCP plan for a food operation is identification of hazards associated with the product. A hazard may be a biological, chemical, or physical property that can cause a food to be unsafe. The analysis of hazards requires the assessment of two factors with respect to any identified hazard, i.e., the likelihood that the hazard will occur and the severity if it does occur. Hazard analysis also involves establishment of preventive measures for control. Hazards that involve low risk and that are not likely to occur need not be considered for the purposes of HACCP.

To be effectively addressed, hazards must be such that their prevention, elimination, or reduction to acceptable levels is attained.

Numerous issues have to be considered during hazard analysis. These relate to factors such as ingredients, processing, distribution, and the intended use of the product. These issues include whether a food contains sensitive ingredients that can create microbiological, chemical, or physical hazards; or whether sanitation practices that are used can introduce these hazards to the food that is being prepared or processed. An example is whether the finished food will be heated by the consumer, if it is consumed off the premises. Even factors beyond the immediate control of the food establishment, such as how the food will be treated if taken out by the consumer and how it will be consumed, must be considered because these factors could influence how food should be prepared or processed in the establishment.

(b) *Flow Diagram*

Consequently, a flow diagram that delineates the steps in the process from receipt to sale or service forms the foundation for applying the seven principles. The significant

hazards associated with each step in the flow diagram should be listed along with preventative measures proposed to control the hazards. This tabulation will be used under Principle 2 to determine the CCPs. The flow diagram should be constructed by a **HACCP** team that has knowledge and expertise on the product, process, and the likely hazards. Each step in a proces should be identified and observed to accurately construct the flow diagram. Some examples of flow diagrams are found at the end of this Annex.

(c) *Biological Hazards*

Foodborne biological hazards include bacterial, viral, and parasitic organisms. These organisms are commonly associated with humans and with raw products entering the food establishment. Many of these pathogens occur naturally in the environment where foods are grown. Most are killed or inactivated by adequate cooking and numbers are kept to a minimum by adequate cooling during distribution and storage.

Bacterial pathogens comprise the majority of reported foodborne disease outbreaks and cases. A certain level of the pathogens can be expected with some raw foods. Temperature abuse, such as improper hot or cold holding temperatures, can significantly magnify this number. Cooked food which has been subject to cross-contamination with pathogens often provides a fertile medium for their rapid and progressive growth.

Enteric viruses can be foodborne, waterborne, or transmitted from a person or from animals. Unlike bacteria, a virus cannot multiply outside of a living cell. Hepatitis A and Norwalk viruses are examples of viral hazards associated with ready-to-eat foods.

Parasites are most often animal host-specific and can include humans in their life cycles. Parasitic infections are commonly associated with undercooking meat products or cross contamination of ready-to-eat food. Fishborne parasites in products that are intended to be eaten raw, marinated, or partially cooked can be killed by effective freezing techniques.

The following table provides an assessment of severity of the biological hazards which may be associated with food being prepared, served, or sold in food establishments.

TABLE 1. Hazardous Microorganisms and Parasites Grouped on the Basis of Risk Severity[a]

Severe Hazards

Clostridium botulinum types A, B, E, and F
Shigella dysenteriae
***Salmonella* Typhi; paratyphi** A, B
Hepatitis A and E
Brucella abortus; ***B. suis***
Vibrio cholerae 01
Vibrio vulnificus
Taenia solium
Trichinella spiralis

Moderate Hazards: Potentially Extensive Spread[b]

Listeria monocytogenes
Salmonella spp.
Shigella spp.
Enterovirulent ***Escherichia coli*** (EEC)
Streptococcus pyogenes
Rotavirus
Norwalk virus group
Entamoeba histolytica
Diphyllobothrium latum
Ascaris lumbricoides
Cryptosporidium parvum

Moderate Hazards: Limited Spread

Bacillus cereus
Campylobacter jejuni
Clostridium perfringens
Staphylococcus aureus
Vibrio cholerae, non-01
Vibrio parahaemolyticus
Yersinia enterocolitica
Giardia lamblia
Taenia saginata

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[a] Adapted from International Commission on Microbiological Specifications for Food (ICMSF) (1986). Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

[b] Although classified as moderate hazards, complications and sequelae may be severe in certain susceptible populations.

(d) *Chemical Hazards*

Chemical hazards in foods should be considered during a hazard analysis. Chemical contaminants may be naturally occurring or may be added during the processing of food. Harmful chemicals at very high levels have been associated with acute cases of foodborne illnesses and can be responsible for chronic illness at lower levels.

The following table provides some examples of chemical hazards found within the naturally occurring and added chemical categories. The Code of Federal Regulations, Title 21, provides guidance on naturally occurring toxic substances and allowable limits for many of the chemicals added during processing (food additives). The FDA Compliance Policy Guidelines also provide information on other naturally occurring chemicals.

Table 2. Types of Chemical Hazards and Examples[a]

Naturally Occurring Chemicals

Mycotoxins (e.g., aflatoxin) from mold
Scombrotoxin (histamine) from protein decomposition
Ciguatoxin from marine dinoflagellates
Toxic mushroom species
Shellfish toxins (from marine dinoflagellates)
  Paralytic shellfish poisoning (PSP)
  Diarrhetic shellfish poisoning (DSP)
  Neurotoxic shellfish poisoning (NSP)
  Amnesic shellfish poisoning (ASP)
Plant toxins
Pyrrolizidine alkaloids
Phytohemagglutinin

Added Chemicals

Agricultural chemicals:
  Pesticides, fungicides, fertilizers, insecticides,
  antibiotics and growth hormones
Polychlorinated biphenyls (PCBs)
Industrial chemicals
Prohibited substances (21 CFR 189)
  Direct
  Indirect
Toxic elements and compounds:
  Lead, zinc, arsenic, mercury, and cyanide
Food additives:
  Direct - allowable limits under GMPs
    Preservatives (nitrite and sulfiting agents)
    Flavor enhancers (monosodium glutamate)
    Nutritional additives (niacin)
    Color additives
  Secondary direct and indirect
    Chemicals used in establishments (e.g., lubricants, cleaners, sanitizers,
    cleaning compounds, coatings, and paints)
Poisonous or toxic chemicals intentionally added (sabotage)

[a]Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY and adapted.

(e) *Physical Hazards*

Illness and injury can result from hard foreign objects in food. These physical hazards can result from contamination and/or poor procedures at many points in the food chain from harvest to consumer, including those within the food establishment.

As establishments develop their HACCP programs, the following table can be used to further identify sources of potential physical risks to the food being prepared, served, or sold.

Table 3. Main Materials of Concern as Physical Hazards and Common Sources[a,b]

Material	Injury Potential	Sources
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, light, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth Cuts, infection; may require surgery to remove	Fields, buildings, machinery, fields, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

[a] Adapted from Corlett (1991).
[b] Used with permission, "HACCP Principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

(f) *Determining Level of Risk*

The potential significance or risk of each hazard should be assessed by considering its likelihood of occurrence and severity. The estimate of risk for a hazard occurring is based upon a combination of experience, epidemiological data, and information in the technical literature. Severity is the degree of seriousness of the consequences of a hazard if it were to become an actuality.

Hazard identification in conjunction with risk estimation provides a rational basis for determining which hazards are significant and must be addressed in the HACCP plan. To

determine risk during the hazard analysis, safety concerns must be differentiated from quality concerns. A food safety hazard is a biological, chemical, or physical property that may cause a food to be unsafe. There may be differences of opinion, even among experts, as to the risk of a hazard. The food establishment must rely upon the expert opinion published in peer reviewed literature or experts who actively assist in the development of the HACCP plan. The hazards must at least include those that are commonly associated with a specific product. If a hazard that is commonly associated is dismissed from the plan, the basis for rejecting it must be clearly stated in the hazard analysis so that it is understood and agreed to by the regulatory authority reviewing the HACCP plan.

(g) *Hazard Analysis Process*

This point in hazard analysis consists of asking a series of questions which are appropriate to each step in the flow diagram. The hazard analysis should question the effect of a variety of factors upon the safety of the food.

(i) *Ingredients*

• Does the food contain any sensitive ingredients that are likely to present microbiological hazards (e.g., ***Salmonella***, ***Staphylococcus aureus***), chemical hazards (e.g., aflatoxin, antibiotic, or pesticide residues) or physical hazards (stones, glass, bone, metal)?

(ii) *Intrinsic factors of food*

Physical characteristics and composition (e.g., pH, type of acids, fermentable carbohydrate, water activity, preservatives) of the food during and after preparation can cause or prevent a hazard.

• Which intrinsic factors of the food must be controlled in order to ensure food safety?

• Does the food permit survival or multiplication of pathogens and/or toxin formation in the food before or during preparation?

• Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps of preparation, storage, or consumer possession?

• Are there other similar products in the market place? What has been the safety record for these products?

(iii) *Procedures used for preparation/processing*

• Does the preparation procedure or process include a controllable step

that destroys pathogens or their toxins? Consider both vegetative cells and spores.

• Is the product subject to recontamination between the preparation step (e.g., cooking) and packaging?

(iv) *Microbial Content of the Food*

• Is the food commercially sterile (i.e., low acid canned food)?

• Is it likely that the food will contain viable sporeforming or nonsporeforming pathogens?

• What is the normal microbial content of the food stored under proper conditions?

• Does the microbial population change during the time the food is stored before consumption?

• Does that change in microbial population alter the safety of the food?

(v) *Facility design*

• Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat foods?

• Is positive air pressure maintained in product packaging areas? Is this essential for product safety?

• Is the traffic pattern for people and moving equipment a potentially significant source of contamination?

(vi) *Equipment design*

• Will the equipment provide the time/temperature control that is necessary for safe food?

• Is the equipment properly sized for the volume of food that will be prepared?

• Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?

• Is the equipment reliable or is it prone to frequent breakdowns?

• Is the equipment designed so that it can be cleaned and sanitized?

• Is there a chance for product contamination with hazardous substances, e.g., glass?

• What product safety devices such as time/temperature integrators are used to enhance consumer safety?

(vii) *Packaging*

• Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?

• Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?

• Is the package clearly labeled "Keep Refrigerated" if this is required for safety?

• Does the package include instructions for the safe handling and preparation of the food by the consumer?

• Are tamper-evident packaging features used?

• Is each package legibly and accurately coded to indicate production lot?

• Does each package contain the proper label?

(viii) *Sanitation*

• Can the sanitation practices that are employed impact upon the safety of the food that is being prepared?

• Can the facility be cleaned and sanitized to permit the safe handling of food?

• Is it possible to provide sanitary conditions consistently and adequately to ensure safe foods?

(ix) *Employee health, hygiene, and education*

• Can employee health or personal hygiene practices impact the safety of the food being prepared?

• Do the employees understand the food preparation process and the factors they must control to ensure safe foods?

• Will the employees inform management of a problem which could impact food safety?

(x) *Conditions of storage between packaging and the consumer*

• What is the likelihood that the food will be improperly stored at the wrong temperature?

• Would storage at improper temperatures lead to a microbiologically unsafe food?

(xi) *Intended use*

• Will the food be heated by the consumer?

• Will there likely be leftovers?

(xii) *Intended consumer*

• Is the food intended for the general public, i.e., a population that does not have an increased risk of becoming ill.

• Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the elderly, the infirm, and immunocompromised individuals)?

(h) *Developing Preventive Measures*

The preventive measures procedure identifies the steps in the process at which hazards can be controlled.

After identifying the hazards the food establishment must then consider what preventive measures, if any, can be applied for each hazard. Preventive measures are physical, chemical, or other factors that can be used to control an identified health hazard. More than one preventive measure may be required to control a specific hazard and more than one hazard may be controlled by a specified preventive measure.

For example, if a HACCP team were to conduct a hazard analysis for the preparation of hamburgers from frozen beef patties, enteric pathogens on the incoming raw meat would be identified as a potential hazard. Cooking is a preventive measure which can be used to eliminate this hazard. Thus, cooking, the preventive measure, would be listed along with the hazard (i.e., enteric pathogens) as follows:

Step	Identified Hazard	Preventive Measures
Cooking	Enteric pathogens	Cooking sufficiently to kill enteric pathogens

PRINCIPLE #2: IDENTIFY THE CRITICAL CONTROL POINTS (CCP) IN FOOD PREPARATION

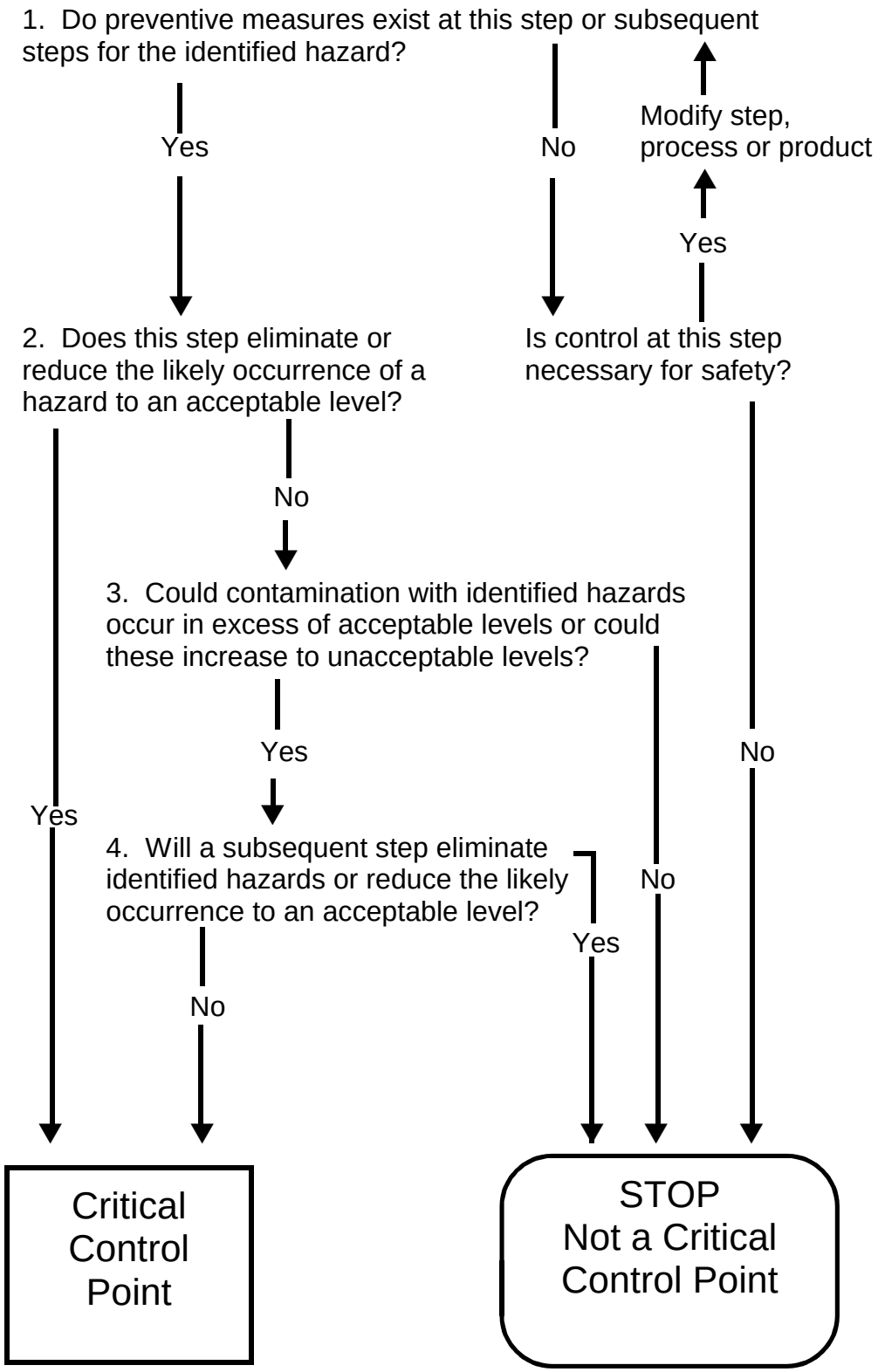
A CCP is a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. Points in food preparation that may be CCPs include cooking, chilling, specific sanitation procedures, product formulation control, prevention of cross contamination, and certain aspects of employee and environmental hygiene. For example, cooking that must occur at a specific temperature and for a specified time in order to destroy microbiological pathogens is a critical control point. Likewise, refrigeration or the adjustment of a food's pH to a level required to prevent hazardous microorganisms from multiplying or toxins from forming are also CCPs.

Many points in food preparation may be considered control points, but very few are actually critical control points. A control point is any point, step, or procedure at which biological, physical, or chemical factors can be controlled. Concerns that do not impact food safety may be addressed at control points; however, since these control points do not relate to food safety, they are not included in the HACCP plan.

Different facilities preparing the same food can differ in the risk of hazards and the points, steps, or procedures which are CCPs. This can be due to differences in each facility such as layout, equipment, selection of ingredients, or the process that is used. Generic HACCP plans can serve as useful guides; however, it is essential that the unique conditions within each facility be considered during the development of a HACCP plan.

CCPs must be carefully developed and documented. In addition, they must be used only for purposes of product safety. The following decision tree is helpful in verifying which of the food preparation steps should be designated as CCPs.

CCP Decision Tree Table



Decision Tree adapted from NACMCF.

PRINCIPLE #3: ESTABLISH CRITICAL LIMITS FOR PREVENTIVE MEASURES

Associated with Each Identified Critical Control Point

This step involves establishing a criterion that must be met for each preventive measure associated with a CCP. Critical limits can be thought of as boundaries of safety for each CCP and may be set for preventive measures such as temperature, time, physical dimensions, a_w, pH, and available chlorine. Critical limits may be derived from sources such as regulatory standards and guidelines, scientific literature, experimental studies, and consultation with experts.

Criteria Most Frequently Used for Critical Limits

Time
Temperature
Humidity
a_w
pH
Titratable acidity
Preservatives
Salt concentration
Available chlorine
Viscosity

(a) *Critical Limit*

A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Each CCP will have one or more preventive measures that must be properly controlled to ensure prevention, elimination, or reduction of hazards to acceptable levels. The food establishment is responsible for using competent authorities to validate that the critical limits chosen will control the identified hazard.

(b) *Target Level*

In some cases, variables involved in food preparation may require certain target levels to ensure that critical limits are not exceeded. For example, a preventive measure and critical limit may be an internal product temperature of 71°C (160°F) during one stage of a process. The oven temperature, however, may be 71 ±3°C (160±°F); thus an oven target temperature would have to be greater than 74°C (165°F) so that no product receives a cook of less than 71°C (160°F).

(c) *Application Example*

An example for Principle 3 is the cooking of beef patties. The process should be designed to eliminate the most heat-resistant vegetative pathogen which could reasonably be expected to

be in the product. Criteria may be required for factors such as temperature, time, and meat patty thickness. Technical development of the appropriate critical limits requires accurate information on the probable maximum numbers of these microorganisms in the meat and their heat resistance. The relationship between the CCP and its critical limits for the meat patty example is shown below:

Process Step	CCP	Critical Limits
Cooking	YES	Minimum internal temperature of patty: 68°C / 155°F Broiler temperature: _____°C / _____°F Time; rate of heating/cooling (e.g., conveyer belt speed in): cm/min: _____ ft/min ____ Patty thickness: _____ cm / ____in Patty composition: e.g., % Fat, % Filler Oven humidity: _____% RH

PRINCIPLE #4: ESTABLISH PROCEDURES TO MONITOR CCPS

(a) *Observations and Measurements*

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for use in future verification procedures. There are three main purposes for monitoring:

(i) It tracks the system's operation so that a trend toward a loss of control can be recognized and corrective action can be taken to bring the process back into control before a deviation occurs;

(ii) It indicates when loss of control and a deviation have actually occurred, and corrective action must be taken; and

(iii) It provides written documentation for use in verification of the HACCP plan.

Examples of Measurements for Monitoring

Visual observations
Temperature
Time
pH
a_w

(b) *Continuous Monitoring*

An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a critical defect, monitoring procedures must be effective.

Continuous monitoring is always preferred when feasible and continuous monitoring is possible with many types of physical and chemical methods. For example, the temperature and time for an institutional cook-chill operation can be recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the batch must be recorded as a process deviation and reprocessed or discarded.

Instrumentation used by the food establishment for measuring critical limits must be carefully calibrated for accuracy. Records of calibrations must be maintained as a part of the HACCP plan documentation.

(c) *Monitoring Procedures*

When it is not possible to monitor a critical limit on a continuous basis, it is necessary to establish that the monitoring interval will be reliable enough to indicate that the hazard is under control. Statistically designed data collection or sampling systems lend themselves to this purpose. When statistical process control is used, it is important to recognize that violations of critical limits must not occur. For example, when a temperature of 68°C (155°F) or higher is required for product safety, the minimum temperature of the product may be set at a target that is above this temperature to compensate for variation.

Most monitoring procedures for CCPs will need to be done rapidly because the time frame between food preparation and consumption does not allow for lengthy analytical testing. Microbiological testing is seldom effective for monitoring CCPs because of its time-consuming nature. Therefore, physical and chemical measurements are preferred because they may be done rapidly and can indicate whether microbiological control is occurring.

Assignment of responsibility for monitoring is an important consideration for each CCP within the operation. Specific assignments will depend on the number of CCPs, preventive measures, and the complexity of monitoring. The most appropriate employees for such assignments are often directly associated with the operation, such as the person in charge of the food establishment, chefs, and departmental supervisors.

Individuals monitoring CCPs must be trained in the monitoring technique, completely understand the purpose and importance of monitoring, and be unbiased in monitoring and reporting so that monitoring is accurately recorded. The designated individuals must have ready access to the CCP being monitored and to the calibrated instrumentation designated in the HACCP plan.

The person responsible for monitoring must also record a food operation or product that does not meet critical limits and ensure that immediate corrective action can be taken. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring.

Random checks may be useful in supplementing the monitoring of certain CCPs. They may be used to check incoming ingredients, serve as a check for compliance where ingredients are recertified as meeting certain standards, and assess factors such as equipment. Random checks are also advisable for monitoring environmental factors such as airborne contamination, and cleaning and sanitizing gloves.

With some foods containing microbiologically sensitive ingredients, there may not be an alternative to microbiological testing. However, it is important to recognize that a sampling frequency which is adequate for reliable detection of low levels of pathogens is seldom possible because of the large number of samples needed. For this reason, microbiological testing has limitations in a HACCP system, but is valuable as a means of establishing and verifying the effectiveness of control at CCPs (such as through challenge tests, random testing, or testing that focuses on isolating the source of a problem).

PRINCIPLE #5: ESTABLISH THE CORRECTIVE ACTION TO BE TAKEN WHEN MONITORING SHOWS THAT A CRITICAL LIMIT HAD BEEN EXCEEDED

(a) *Purpose of Corrective Action Plan*

Although the HACCP system is intended to prevent deviations from occurring, perfection is rarely, if ever, achievable. Thus, there must be a corrective action plan in place to:

(i) Determine the disposition of any food that was produced when a deviation was occurring;

(ii) Correct the cause of the deviation and ensure that the critical control point is under control; and

(iii) Maintain records of corrective actions.

(b) *Aspects of Corrective Action Plan*

Because of the variations in CCPs for different food operations and the diversity of possible deviations, specific corrective action plans must be developed for each CCP. The actions must demonstrate that the CCP has been brought under control. Individuals who have a thorough understanding of the operation, product, and HACCP plan must be assigned responsibility for taking corrective action. Corrective action procedures must be documented in the HACCP plan.

Food establishments covered by the Food Code will usually be concerned with food which has a limited shelf-life and distribution. Primary focus for the application of this HACCP principle will be on the correction of the procedure or condition which led to the noncompliance. More frequent monitoring may be temporarily required to ensure that the deviation from the established critical limit is not continuing when the operation is resumed.

If a deviation should occur in food operations that are traditionally considered food processing operations, such as cook-chill, curing and smoking, or reduced oxygen packaging, the food establishment must place the product on hold pending completion of appropriate corrective actions and analyses. As appropriate, scientific experts and regulatory agencies must be consulted regarding additional testing or disposition of the product. Identification of deviant lots and corrective actions taken to ensure safety of these lots must be noted in the HACCP record. This record must remain on file for a reasonable period after the expiration date or expected shelf life of the product.

HACCP PRINCIPLE #6: ESTABLISH EFFECTIVE RECORD KEEPING SYSTEMS THAT DOCUMENT THE HACCP SYSTEM

(a) *Written HACCP Plan*

This principle requires the preparation and maintenance of a written HACCP plan by the food establishment. The plan must detail the hazards of each individual or categorical product covered by the plan. It must clearly identify the CCPs and critical limits for each CCP. CCP monitoring and record keeping procedures must be shown in the establishment's HACCP plan. HACCP plan implementation strategy should be provided as a part of the food establishment's documentation.

(b) *Record Keeping*

The principle requires the maintenance of records generated during the operation of the plan. The record keeping associated with HACCP procedures ultimately makes the system work. One conclusion of a study of HACCP performed by the U.S. Department of Commerce is that correcting problems without record keeping almost guarantees that problems will recur. The requirement to record events at CCPs on a regular basis ensures that preventive monitoring is occurring in a systematic way. Unusual occurrences that are discovered as CCPs are monitored or that otherwise come to light must be corrected and recorded immediately with notation of the corrective action taken.

The level of sophistication of the record keeping necessary for the food establishment is dependent on the complexity of the food preparation operation. A sous vidé process or cook-chill operation for a large institution would require more record keeping than a limited menu cook-serve operation. The simplest effective record keeping system that lends itself well to integration within the existing operation is best.

(c) *Contents of the Plan and Records*

The approved HACCP plan and associated records must be on file at the food establishment. Generally, the following are examples of documents that can be included in the total HACCP system:

(i) Listing of the HACCP team and assigned responsibilities;
(ii) Description of the product and its intended use;
(iii) Flow diagram food preparation indicating CCPs;
(iv) Hazards associated with each CCP and preventive measures;
(v) Critical limits;
(vi) Monitoring system;
(vii) Corrective action plans for deviations from critical limits;
(viii) Record keeping procedures; and
(ix) Procedures for verification of HACCP system.

(d) *Format for HACCP Information*

In addition to listing the HACCP team, product description and uses, and providing a flow diagram, other information in the HACCP plan can be tabulated as follows:

Process Step	CCP	Chemical Physical Biological Hazards	Critical Limit	Monitoring Procedures Frequency Person(s) Responsible	Corrective Action(s) Person(s) Responsible	HACCP Records	Verification Procedures/ Person(s) Responsible

The following chart is an example of a HACCP plan documentation for a product cooling step in a retail level food establishment.

PROCESS STEP	**COOLING**
CCP	**Critical Control Point #8**
Criteria or Critical Limit	Cool Foods Rapidly in Small Quantities to 5°C(41°F)
Establish Monitoring	Department Personnel Break Down Food into Small Quantities and Monitor The Cooling Process
Corrective/Preventive Action	Modify Cooling Procedures/ Discard
HACCP Records	Deli Cooking/Cooling Log
HACCP System Verification	Deli Safety Audit by Store Manager

(e) *Examples of Records obtained during the operation of the plan:*

(i) *Ingredients*

• Supplier certification documenting compliance with establishment's specifications.

• Establishment audit records verifying supplier compliance.

• Storage temperature record for temperature-sensitive ingredients.

• Storage time records of limited shelf-life ingredients.

(ii) *Preparation*

• Records from all monitored CCPs.

• Records verifying the continued adequacy of the food preparation procedures.

(iii) *Packaging*

• Records indicating compliance with specifications of packaging materials.

• Records indicating compliance with sealing specifications.

(iv) *Finished product*

• Sufficient data and records to establish the efficacy of barriers in maintaining product safety.

• Sufficient data and records establishing the safe shelf-life of the product; if age of product can affect safety.

• Documentation of the adequacy of the HACCP procedures from an authority knowledgeable of the hazards involved and necessary controls.

(v) *Storage and distribution*

• Temperature records.

• Records showing no product shipped after shelf life date on temperature-sensitive products.

(vi) *Deviation and corrective action*

• Validation records and modification to the HACCP plan indicating approved revisions and changes in ingredients, formulations, preparation, packaging, and distribution control, as needed.

(vii) *Employee training*

• Records indicating that food employees responsible for implementation of the HACCP plan understand the hazards, controls, and procedures. Refer to the discussion regarding Training and Knowledge under Principle #7.

PRINCIPLE #7: ESTABLISH PROCEDURES TO VERIFY THAT THE HACCP SYSTEM IS WORKING

(a) *Establishing Verification Procedures*

(i) The first phase of the process is the scientific or technical verification that critical limits at CCPs are satisfactory. This can be complex and may require intensive involvement of highly skilled professionals from a variety of disciplines capable of doing focused studies and analyses. A review of the critical limits is necessary to verify that the limits are adequate to control the hazards that are likely to occur.

(ii) The second phase of verification ensures that the facility's HACCP plan is functioning effectively. A functioning HACCP system requires little end-product sampling, since appropriate safeguards are built in early in the food preparation. Therefore, rather than relying on end-product sampling, food establishments must rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, review of CCP records, and determinations that appropriate risk management decisions and product dispositions are made when preparation deviations occur.

(iii) The third phase consists of documented periodic revalidations, independent of audits or other verification procedures, that must be performed to ensure the accuracy of the HACCP plan. Revalidations are performed by a HACCP team on a regular basis and/or whenever significant product, preparation, or packaging changes require modification of the HACCP plan. The revalidation includes a documented on-site review and verification of all flow diagrams and CCPs in the HACCP plan. The HACCP team modifies the HACCP plan as necessary.

(iv) The fourth phase of verification deals with the regulatory agency's responsibility and actions to ensure that the establishment's HACCP system is functioning satisfactorily.

(b) *The following are some examples of HACCP plan verification activities which should be used as a part of a HACCP program:*

(i) Verification procedures may include:

• Establishment of appropriate verification inspection schedules;

• Review of the HACCP plan;

• Review of CCP records;

• Review of deviations and their resolution, including the disposition of food;

• Visual inspections of operations to observe if CCPs are under control;

• Random sample collection and analysis;

• Review of critical limits to verify that they are adequate to control hazards;

• Review of written record of verification inspections which certifies compliance with the HACCP plan or deviations from the plan and the corrective actions taken;

• Validation of HACCP plan, including on-site review and verification of flow diagrams and CCPs; and

• Review of modifications of the HACCP plan.

(ii) *Verification inspections should be conducted:*

• Routinely or on an unannounced basis, to ensure that selected CCPs are under control;

• When it is determined that intensive coverage of a specific food is needed because of new information concerning food safety;

• When foods prepared at the establishment have been implicated as a vehicle of foodborne disease;

• When requested on a consultative basis and resources allow accommodating the request;

• When established criteria have not been met; and

• To verify that changes have been implemented correctly after a HACCP plan has been modified.

(iii) *Verification reports should include information about:*

• Existence of a HACCP plan and the person(s) responsible for administering and updating the HACCP plan;

• The status of records associated with CCP monitoring;

• Direct monitoring data of the CCP while in operation; Certification that monitoring equipment is properly calibrated and in working order;

• Deviations and corrective actions;

• Any samples analyzed to verify that CCPs are under control. Analyses may involve physical, chemical, microbiological, or organoleptic methods;

• Modifications to the HACCP plan; and

• Training and knowledge of individuals responsible for monitoring CCPs.

(c) *Training and Knowledge*

(i) *Focus and Objective*

Training and knowledge are very important in making HACCP successful in any food establishment. HACCP works best when it is integrated into each employee's normal duties rather than added as something extra.

The depth and breadth of training will depend on the particular employee's responsibilities within the establishment. Management or supervisory individuals will need a deeper understanding of the HACCP process because they are responsible for proper plan implementation and routine monitoring of CCPs such as product cooking temperatures and cooling times. The training plan should be specific to the establishment's operation rather than attempt to develop HACCP expertise for broad application.

The food employee's training should provide an overview of HACCP's prevention philosophy while focusing on the specifics of the employee's normal functions. The CCPs such as proper handwashing and use of utensils or gloves for working with ready-to-eat food should be stressed. The use of recipes or Standard Operating Procedures (SOPs) which include the critical limits of cooking times and temperatures, with a final cooking time and temperature measurement step, should be included.

For all employees, the fundamental training goal should be to make them proficient in the specific tasks which the HACCP plan requires them to perform. This includes the development of a level of competency in their decision making about the implementation of proper corrective actions when monitoring reveals violation of the critical limit. The training should also include the proper completion and maintenance of any records specified in the establishment's plan.

(ii) *Reinforcement*

Training reinforcement is also needed for continued motivation of the food establishment employees. Some examples might include:

• A HACCP video training program such as the Pennsylvania Department of Environmental Regulation's Foodborne Illness: It's Your Business;

• Changing reminders about HACCP critical limits such as "HANDWASHING PAYS BIG DIVIDENDS" printed on employee's time cards or checks; and

• Work station reminders such as pictorials on how and when to take food temperatures.

Every time there is a change in a product or food operation within the establishment, the HACCP training needs should be evaluated. For example, when a food establishment substitutes a frozen seafood product for a fresh one, proper thawing critical limits should be taught and then monitored for implementation. The employees should be made sensitive to how the changes will affect food safety

The HACCP plan should include a feedback loop for employees to suggest what additional training is needed. All employees should be made a part of the continuous food safety improvement cycle because the old statement is very true, "The customer's health is in their hands". This helps maintain their active awareness and involvement in the importance of each job to the safety of the food provided by their establishment.

3. SUMMARY

HACCP is a systematic approach to food safety which will dramatically improve the level of food safety. The NACMCF has developed the seven HACCP principles discussed within this Annex. The FDA recommends the implementation of a HACCP system throughout the food industry using these NACMCF recommendations.

An effective national food safety program from food production to consumer is enhanced by the implementation of HACCP. The statistics from foodborne surveillance reveal that retail level food establishments can have a significant impact on the health of consumers.

Implementation of HACCP programs by the establishments will profoundly enhance their role in the protection of public health beyond the traditional emphasis on facility and equipment design and maintenance and adherence to the principles of sanitation, good manufacturing, and food preparation practices. The education and training of all personnel are critical to the success and effectiveness of any HACCP program. The Food Code stresses the application to HACCP principles and the knowledge and responsibilities of establishment management and employees.

Specific HACCP plans for the products prepared and sold by the retail food establishment should be developed and implemented for optimal food safety management. HACCP systems are recommended for use as a tool for regulatory inspections. The regulatory official should incorporate procedures in the inspection process that ensure record reviews and active monitoring.

Because the retail food establishment industry is composed of large, small, chain, and independent establishments, the level of food safety expertise varies widely and is not necessarily linked to size or affiliation. Regardless of the size and sophistication of the establishment, a HACCP plan for safe food preparation and sales needs to be designed, implemented, and verified.

Studies have shown that a significant level of illness and mortality from foodborne disease in institutional feeding operations such as hospitals, nursing homes, and prisons is related to preventable causes. For populations that may be more vulnerable to foodborne disease, FDA and the NACMCF recommend that HACCP systems be immediately implemented by establishments and institutions preparing foods for these susceptible individuals.

Food processing operations at retail food establishments such as reduced oxygen packaging and curing and smoking under the Food Code are required to develop and implement a HACCP plan for that part of the operation. Additionally, any establishment seeking a variance from the requirements of the Code must submit a HACCP plan. The HACCP Annex can serve to guide these establishments in this process.

Food establishments have the primary responsibility for food safety. The development and implementation of HACCP programs is a reliable and responsible step to help ensure the safety of food offered for consumption.

4. ACKNOWLEDGMENTS

Much of this HACCP Annex material is adapted from National Advisory Committee on Microbiological Criteria for Foods, Hazard Analysis and Critical Control Point System, adopted March 20, 1992.

Some of the charts were provided courtesy of "Overview of Biological, Chemical, and Physical Hazards" in "HACCP Principles and Applications, Merle Pierson and Donald A. Corlett, Jr. (Eds.), 1992 p 8-28. Chapman and Hall, New York.

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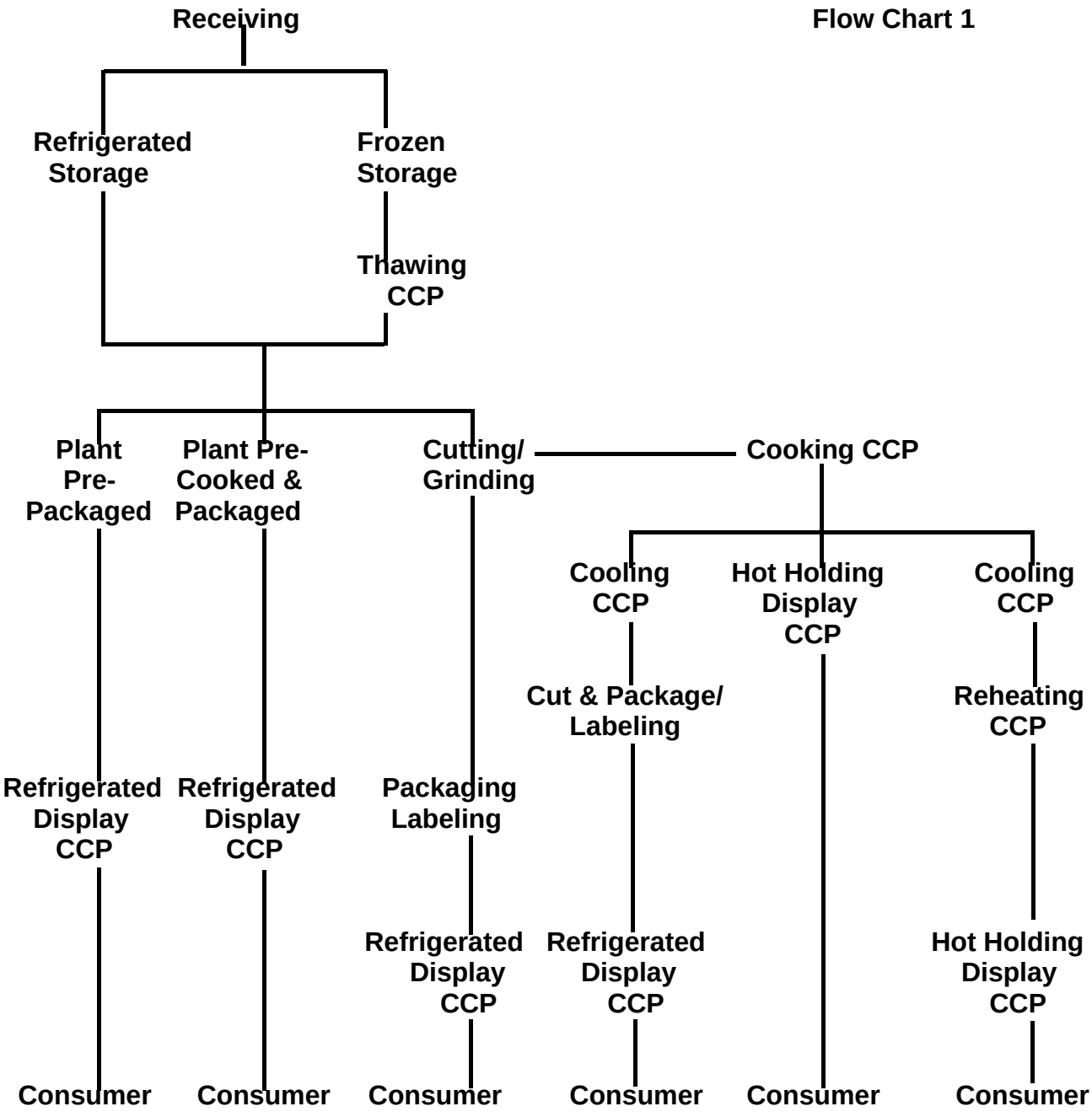
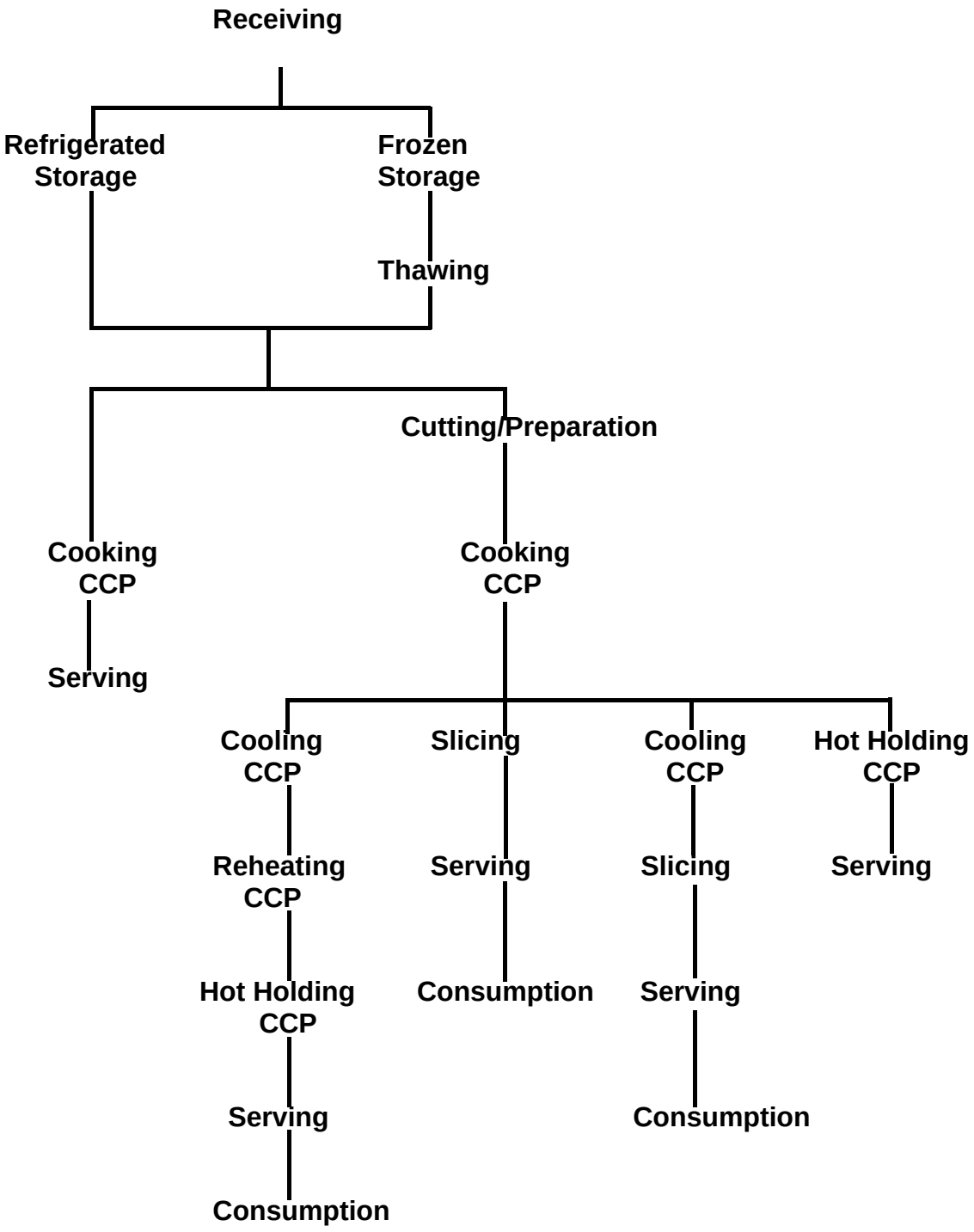
Two Typical Flow Diagrams



Flow Chart 2


Receiving
Refrigerated Storage
Frozen Storage
Thawing
Cutting/Preparation
Cooking CCP
Serving
Cooking CCP
Cooling CCP
Slicing
Cooling CCP
Hot Holding CCP
Reheating CCP
Serving
Slicing
Serving
Hot Holding CCP
Consumption
Serving
Serving
Consumption
Consumption

Annex

6 Food Processing

1. INTRODUCTION

From its inception, the retail segment of the food industry has prepared foods in consumer-sized portions, using commercially available equipment for cutting, grinding, slicing, cooking, and refrigeration, and applying herbs and spices readily available to consumers at their local grocery.

During the past decade, retail segment operators have expanded into food manufacturing/processing-type operations, often using sophisticated new technologies and equipment that are sometimes microprocessor-controlled. Many now desire to alter the atmospheres within food packages, or apply federally regulated chemical food additives as a method of food preservation. Food processing operations now being conducted or proposed include cook-chill; vacuum packaging; sous vide; smoking and curing; brewing, processing, and bottling alcoholic beverages, carbonated beverages, or drinking water; and custom processing of animals.

The Food Code specifies that a HACCP plan acceptable to the regulatory authority be the basis for approving food manufacturing/processing operations at retail. The HACCP plans are to be provided and accepted in two ways as follows.

(A) Reduced Oxygen Packaging

Section 3-502.12 of the Food Code provides the criteria that are to be met in the HACCP plans of those operators who are conducting reduced oxygen packaging (ROP) operations. Unless prior approval of the HACCP plan is required by the regulatory authority, the HACCP plan covering this operation along with the related records documenting monitoring and corrective actions *need only be available and acceptable to the regulatory authority at the time of inspection.*

(B) Other Food Manufacturing/Processing Operations

Except for ROP as discussed in (A) above, the Food Code specifies under §§ 3-502.11, 8-103.10, 8-103.11 and 8-201.13 that the food establishment operator must obtain a variance from the regulatory authority for all food manufacturing/processing operations *based on the prior approval of a HACCP plan*.

The purpose of this Annex is to provide processing criteria for different types of food manufacturing/processing operations for use by those preparing and reviewing HACCP plans and proposals. Criteria for additional processes will be provided as they are developed, reviewed, and accepted.

2. REDUCED OXYGEN PACKAGING

(A) Introduction

ROP which provides an environment that contains little or no oxygen, offers unique advantages and opportunities for the food industry but also raises many microbiological concerns. Products packaged using ROP may be produced safely if proper controls are in effect. Producing and distributing these products with a HACCP approach offer an effective, rational, and systematic method for the assurance of food safety. The purpose of this Annex is to provide guidelines for effective food safety controls for retail food establishments covering the receipt, processing, packaging, holding, displaying, and labeling of food in reduced oxygen packages.

(B) Definitions

The term ROP is defined as any packaging procedure that results in a reduced oxygen level in a sealed package. The term is often used because it is an inclusive term and can include other packaging options such as:

(1) *Cook-chill* is a process that uses a plastic bag filled with hot cooked food from which air has been expelled and which is closed with a plastic or metal crimp.

(2) *Controlled Atmosphere Packaging (CAP)* is an active system which continuously maintains the desired atmosphere within a package throughout the shelf-life of a product by the use of agents to bind or scavenge oxygen or a sachet containing compounds to emit a gas. Controlled Atmosphere Packaging (CAP) is defined as packaging of a product in a modified atmosphere followed by maintaining subsequent control of that atmosphere.

(3) *Modified Atmosphere Packaging (MAP)* is a process that employs a gas flushing and sealing process or reduction of oxygen through respiration of vegetables or microbial action. Modified Atmosphere Packaging (MAP) is defined as packaging

of a product in an atmosphere which has had a one-time modification of gaseous composition so that it is different from that of air, which normally contains 78.08% nitrogen, 20.96% oxygen, 0.03% carbon dioxide.

(4) *Sous Vide* is a specialized process of ROP for partially cooked ingredients alone or combined with raw foods that require refrigeration or frozen storage until the package is thoroughly heated immediately before service. The sous vide process is a pasteurization step that reduces bacterial load but is not sufficient to make the food shelf-stable. The process involves the following steps:

(a) Preparation of the raw materials (this step may include partial cooking of some or all ingredients);

(b) Packaging of the product, application of vacuum, and sealing of the package;

(c) Pasteurization of the product for a specified and monitored time/temperature;

(d) Rapid and monitored cooling of the product at or below 3°C(38°F) or frozen; and

(e) Reheating of the packages to a specified temperature before opening and service.

(5) *Vacuum Packaging* reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.

(C) Benefits of ROP

ROP can create a significantly anaerobic environment that prevents the growth of aerobic spoilage organisms, which generally are Gram negative bacteria such as Pseudomonads or aerobic yeast and molds. These organisms are responsible for off-odors, slime, and texture changes, which are signs of spoilage.

ROP can be used to prevent degradation or oxidative processes in food products. Reducing the oxygen in and around a food retards the amount of oxidative rancidity in fats and oils. ROP also prevents color deterioration in raw meats caused by oxygen. An additional effect of sealing food in ROP is the reduction of product shrinkage by preventing water loss.

These benefits of ROP allow an extended shelf-life for foods in the distribution chain, providing additional time to reach new geographic markets or longer display at retail. Providing an extended shelf-life for ready-to-eat convenience foods and advertising foods as "Fresh-Never Frozen" are examples of economic and quality advantages.

(D) Safety Concerns

Use of ROP with some foods can markedly increase safety concerns. Unless potentially hazardous foods are protected inherently, simply placing them in ROP without regard to microbial growth will increase the risk of foodborne illnesses. ROP processors and regulators must assume that during distribution of foods or while they are held by retailers or consumers, refrigerated temperatures may not be consistently maintained. In fact, a serious concern is that the increased use of vacuum packaging at retail supermarket deli-type operations may be followed by temperature abuse in the establishment or by the consumer. Consequently, at least one barrier or multiple hurdles resulting in a barrier need to be incorporated into the production process for products packaged using ROP. The incorporation of several sub-inhibitory barriers, none of which could individually inhibit microbial growth but which in combination provide a full barrier to growth, is necessary to ensure food safety.

Some products in ROP contain no preservatives and frequently do not possess any intrinsic inhibitory barriers (such as, pH, a_w, or salt concentrations) that either alone or in combination will inhibit microbial growth. Thus, product safety is not provided by natural or formulated characteristics.

An anaerobic environment, usually created by ROP, provides the potential for growth of several important pathogens. Some of these are psychrotrophic and grow slowly at temperatures near the freezing point of foods. Additionally, the inhibition of the spoilage bacteria is significant because without these competing organisms, tell-tale signs signaling that the product is no longer fit for consumption will not occur.

The use of one form of ROP, vacuum packaging, is not new. Many food products have a long and safe history of being vacuum packaged in ROP. However, the early use of vacuum packaging for smoked fish had disastrous results, causing a long-standing moratorium on certain uses of this technology.

(1) *Refrigerated Holding Requirements for Foods in ROP*

Safe use of ROP technology demands that adequate refrigeration be maintained during the entire shelf-life of potentially hazardous foods to ensure product safety.

Bacteria, with the exception of those that can form spores, are eliminated by pasteurization. However, pathogens may survive in the final product if pasteurization is inadequate, poor quality raw materials or poor handling practices are used, or post-processing contamination

occurs. Even if foods that are in ROP receive adequate thermal processing, a particular concern is present at retail when employees open manufactured products and repackage them. This operation presents the potential for post-processing contamination by pathogens.

If products in ROP are subjected to mild temperature abuse, i.e., 5°-12°C (41°-53°F), at any stage during storage or distribution, foodborne pathogens, including ***Bacillus cereus***, ***Salmonella*** spp., ***Staphylococcus aureus***, and ***Vibrio parahaemolyticus*** can grow slowly. Marginal refrigeration that does not facilitate growth may still allow ***Salmonella*** spp., ***Campylobacter*** spp., and ***Brucella*** spp. to survive for long periods of time.

Recent published surveys indicate that refrigeration practices at retail need improvement. Some refrigerated products offered in convenience stores were found at or above 7.2°C (45°F) 50% of the time; in several cases temperatures as high as 10°C (50°F) were observed. Delicatessen display cases have been shown to demonstrate poor temperature control. Foods have been observed above 10°C (50°F) and above 12.8°C (55°F) in several instances. Supermarket fresh meat cases appear to have a relatively good record of temperature control. However, even these foods can occasionally be found above 10°C (50°F).

Temperature abuse is common throughout distribution and retail markets. Strict adherence to temperature control and shelf-life must be observed and documented by the establishment using ROP. Information on temperature control should also be provided to the consumer. Currently these controls are not extensively used. Additionally, some commercial equipment is incapable of maintaining foods below 7.2°C (45°F) because of refrigeration capacity, insufficient refrigerating medium, or poor maintenance.

Most warehouses and transport vehicles in U.S. distribution chains maintain temperatures in the 0°-3.3°C (32°-38°F) range. It must be assumed, however, for purposes of assessing risk, that occasionally temperatures of 10°C (50°F) or higher may occur for extended periods. At retail, further temperature abuse must also be assumed. For instance, retail display cases can be as high as 13.3°C (56°F) for short periods and some refrigerated foods are provided no refrigeration for short periods of time. These realities point to the need for establishments to implement controls, such as buyer specifications, over refrigerated distribution systems so that better temperature control can be ensured.

(2) *Control of **Clostridium botulinum** and **Listeria monocytogenes** in Reduced Oxygen Packaged Foods*

Recently, there has been an increased interest in vacuum packaging or MAP at retail using conventional refrigeration for holding. Refrigerated foods packaged at retail may be chilled either after they are physically prepared and repackaged, or packaged after a cooking step. In either case but primarily the latter, germination of ***Clostridium botulinum*** spores must be inhibited because spores are not destroyed by a heating step. Sanitary safeguards must be employed to prevent reintroduction of pathogens. Chief among these is ***Listeria monocytogenes***.

Clostridum botulinum is the causative agent of botulism, a severe food poisoning characterized by double vision, paralysis, and occasionally death. The organism is an anaerobic spore-forming bacteria that produces a potent neurotoxin. The spores are ubiquitous in nature, relatively heat-resistant, and can survive most minimal heat treatments that destroy vegetative cells. Certain strains of ***C***. ***botulinum*** (type E and non-proteolytic types B and F), which have been primarily associated with fish, are psychrotrophic and can grow and produce toxin at temperatures as low as 3.3°C (38°F). Other strains of ***C***. ***botulinum*** (type A and proteolytic types B and F) can grow and produce toxin at temperatures slightly above 10°C (50°F). If present, ***C. botulinum*** could potentially grow and render toxigenic a food packaged and held in ROP because most other competing organisms are inhibited by ROP. Therefore, the food could be toxic yet appear organoleptically acceptable. This is particularly true of psychrotrophic strains of ***C. botulinum*** that do not produce tell-tale proteolytic enzymes. Because botulism is potentially deadly, foods held in anaerobic conditions merit regulatory concern and vigilance.

The potential for botulism toxin to develop also exists when ROP is used after heat treatments such as pasteurization, or sous vide, processing of foods which will not destroy the spores of ***C. botulinum***. Mild heat treatments in combination with ROP may actually select for ***C. botulinum*** by killing off its competitors. If the applied heat treatment does not produce commercial sterility, the food requires refrigeration to prevent spoilage and ensure product safety. For this reason, sous vide products are frequently flash frozen in liquid nitrogen and held in frozen storage until use.

There is a further microbial concern with ROP at retail. Processed products such as meats and cheeses which have undergone an adequate cooking step to kill ***L. monocytogenes*** can be contaminated when opened, sliced, and repackaged at retail. Thus, a simple packaging or repackaging operation can present an opportunity for recontamination with pathogens if strict sanitary safeguards are not in place.

Processors of products using ROP should be cautious if they plan to rely on refrigeration as the sole barrier that ensures product safety. This approach requires very rigorous temperature controls and monitored refrigeration equipment. If extended shelf-life is sought, a temperature of 3.3°C (38°F) or lower must be maintained at all times to prevent outgrowth of ***C. botulinum*** and the subsequent production of toxin. ***Listeria monocytogenes*** can grow at even lower temperatures; consequently, appropriate use-by dates must be established and readily apparent to the consumer. Since refrigeration alone does not guarantee safety from pathogenic microorganisms, additional growth barriers must be provided. Growth barriers are provided by hurdles such as low pH, a_w, or short shelf life, and constant monitoring of the temperature. Any one hurdle, or a combination of several, may be used with refrigeration to control pathogenic outgrowth.

(3) *Design of Heat Processes for Foods in Reduced Oxygen Packages*

Heat processes for sous vide or cook-chill operations should be designed so that, at a minimum, all vegetative pathogens are destroyed by a pasteurization process. Special

labeling of these products is necessary to ensure adequate warning to consumers that these foods must be refrigerated at 5°C (41°F) and consumed by the date required by the Code for that particular product.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) chartered by the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) recently commented on the microbial safety of refrigerated foods containing cooked, uncured meat or poultry products that are packaged for extended refrigerated shelf-life and are ready-to-eat or prepared with little or no additional heat treatment. The Committee recommended guidelines for evaluating the ability of thermal processes to inactivate ***L. monocytogenes*** in extended shelf-life refrigerated foods. Specifically, it recommended a proposed requirement for demonstrating that an ROP process provides a heat treatment sufficient to achieve a 4 decimal log reduction (4D) of ***L. monocytogenes***.

Other scientific reports recommend more extensive thermal processing. Thermal processes for sous vide practiced in Europe are designed to achieve a 12-13 log reduction (12-13D) of the target organism ***Streptococcus faecalis***. It is reasoned that thermal inactivation of this organism would ensure destruction of all other vegetative pathogens.

Food manufacturers with adequate in-house research and development programs may have the ability to design their own thermal processes. However, small retailers and supermarkets may not be able to perform the microbiological challenge studies necessary to provide the same level of food safety. If a retail establishment wishes to use an ROP process, microbiological studies should be performed by, or in conjunction with, an appropriate process authority or person knowledgeable in food microbiology who is acceptable to the regulatory authority.

Finally, if foods are held long enough, even under proper refrigeration, extended shelf-life may be a problem. A recent study on fresh vegetables inoculated with ***L. monocytogenes*** was conducted to determine the effect of CAP on shelf life. The study found that CAP lengthened the time that all vegetables were considered acceptable, but that populations of ***L. monocytogenes*** increased during that extended storage.

(4) *Consumer Handling Practices and In-Home Refrigeration Temperatures*

Extended shelf-life provided by ROP is cause for concern because of the potential for abuse by the consumer. Consumers often can not, or do not, maintain adequate refrigeration of potentially hazardous foods at home. Foods in ROP that are taken home may not be eaten until enough time/temperature abuse has occurred to allow any pathogens present to increase to levels which can increase the chance of illness. Under the best of circumstances home refrigerators can be expected to range between 5° and 10°C (41°-50°F). One study reported that home refrigerator temperatures in 21% of the households surveyed were 10°C

(50°F). Another study reported more than 1 of 4 home refrigerators are above 7.2°C (45°F) and almost 1 of 10 are above 10°C (50°F). Thus, refrigeration alone cannot be relied on for ensuring microbiological safety after foods in ROP leave the establishment.

Consumers have come to expect that certain packages of foods would be safe without refrigeration. Low-acid canned foods have been thermally processed, which renders the food shelf-stable. Retort heating ensures the destruction of ***C. botulinum*** spores as well as all other foodborne pathogens. Yet consumers may not understand that most products that are packaged in ROP are not commercially sterile or shelf-stable and must be refrigerated. A clear label statement to keep the product refrigerated must be provided to consumers.

The use of ROP has been extensively studied by regulators and the food industry over the past several years. Recommendations have been adapted from the Association of Food and Drug Officials "Retail Guidelines - Refrigerated Foods in Reduced Oxygen Packages" and New York State Department of Agriculture and Markets "Proposed Reduced Oxygen Packaging Regulations." As provided in the Food Code, some ROP operations may be conducted under provision 3-502.12 Reduced Oxygen Packaging, Criteria. Food that is packaged by an ROP method under these provisions is considered safe while it is under the control of the establishment and, if the labeling instructions are followed, while under the control of the consumer.

(E) Safety Barrier Verification

The safety barriers for all processed foods held in ROP at retail must be verified in writing. This can be accomplished through written certification from the product manufacturer. Independent laboratory analysis using methodology approved by the regulatory authority can also be used to verify incoming product and should be used to verify the barriers in a product that is packaged within the establishment by an ROP method. It should be noted that the Association of Food and Drug Officials (AFDO) guidelines recommend that laboratory analysis be conducted by official methods of the Association of Official Analytical Chemists (AOAC).

The multiple barrier or hurdle efficacy should be validated by inoculated pack or challenge studies. A product should be tested under abuse temperatures to demonstrate product safety during the food's shelf life.

Any changes in product formulation or processing procedures are cause for notification of the regulatory authority and a required approval of the revised ROP process. A record of all safety barrier verifications should be updated every 12 months. This record must be available to the regulatory authority for review at the time of inspection.

(F) USDA Process Exemption

Meat and poultry products cured at a food processing plant regulated by the U.S. Department of Agriculture using substances specified in 9 CFR 318.7 Approval of substances for use in the preparation of products and 9 CFR 381.147 Restrictions on the use

of substances in poultry products are exempt from the safety barrier verification requirements. Other ROP operations may be developed that do not meet the provisions of Section 3-502.12 of the Code and that will require a variance and prior approval by the regulatory authority under Section 3-502.11.

(G) Recommendations for ROP Without Multiple Barriers

(1) *Employee Training*

If ROP is used, employees assigned to packaging of the foods must have documented proof that demonstrates familiarity with ROP guidelines in this Annex and the potential hazards associated with these foods. At the discretion of the regulatory authority, a description of the training and course content provided to the employees must either be available for review or have prior approval by the regulatory authority.

(2) *Refrigeration Requirements*

Foods in ROP that have only one barrier, i.e., refrigeration, to ***C. botulinum***, must be refrigerated to 5°C (41°F) or below and marked with a use-by date within either the manufacturer's labeled use-by date or 14 days after preparation at retail, whichever comes first. Alternatively, foods packaged by ROP may be kept frozen if freezing is used as the declared primary safety barrier. Any extension of shelf life past 14 days will require a further variance that considers lower refrigeration temperatures. Foods that are intended for refrigerated storage beyond 14 days must be maintained at or below 3°C (38°F).

(3) *Labeling - Refrigeration Statements*

All foods in ROP which rely on refrigeration as a barrier to microbial growth must bear the statement "Important - Must be kept refrigerated at 5°C (41°F)" or "Important - Must be kept frozen," in the case of foods which rely on freezing as a primary safety barrier. The statement must appear on the principal display panel in bold type on a contrasting background. Foods held under ROP which have lower refrigeration requirements as a condition of safe shelf life must be monitored for temperature history and must not be offered for retail sale if the temperature and time specified in the variance are exceeded.

(4) *Labeling - "Use-by date"*

Each container of food in ROP must bear a "use-by" date. This date cannot exceed 14 days from retail packaging or repackaging without a further variance granted by the regulatory authority. The date assigned by a repacker cannot extend beyond the manufacturer's recommended "pull date" for the food. The "use-by" date must be listed on the principal display panel in bold type on a contrasting background. Any label must contain a combination of a "sell-by" date and use-by instructions which makes it clear that the product must be consumed within 14 days of retail packaging or repackaging, as an acceptable alternative to a 14 day "use-by" date, i.e., for product packaged on November 1,

1999 - "Sell by November 10, 1999" - use within 4 days of sell-by date. Foods that are frozen before or immediately after packaging and remain frozen until use should bear a "Keep frozen, use within 4 days after thawing" statement.

(H) Foods Which Require a Variance Under Code Section 3-502.11 if Packaged in Reduced Oxygen Atmosphere

(1) Processed fish and smoked fish may not be packed by ROP unless establishments are approved for the activity and inspected by the regulatory authority. Establishments packaging such fish products, and smoking and packing establishments, must be licensed in accordance with applicable law. Caviar may be packed on the premises by ROP if the establishment is approved by the regulatory authority and has an approved scheduled process established by a processing authority acceptable to the regulatory authority.

(2) Soft cheeses such as ricotta, cottage cheese, cheese spreads, and combinations of cheese and other ingredients such as vegetables, meat, or fish at retail must be approved for ROP and inspected by the regulatory authority.

(3) Meat or poultry products which are smoked or cured at retail, except that raw food of animal origin which is cured in a USDA-regulated processing plant, or establishment approved by the regulatory authority to cure these foods may be smoked in accordance with approved time/temperature requirements and packaged in ROP at retail if approved by the regulatory authority.

(I) Hazard Analysis and Critical Control Point (HACCP) Operation

All food establishments packaging food in a reduced oxygen atmosphere must develop a HACCP plan and maintain the plan at the processing site for review by the regulatory authority. For ROP operations the plan must include:

(1) A complete description of the processing, packaging, and storage procedures designated as critical control points, with attendant critical limits, corrective action plans, monitoring and verification schemes, and records required;

(2) A list of equipment and food-contact packaging supplies used, including compliance standards required by the regulatory authority, i.e., USDA or a recognized third party equipment by the evaluation organization such as NSF International;

(3) A description of the lot identification system acceptable to the regulatory authority;

(4) A description of the employee training program acceptable to the regulatory authority;

(5) A listing and proportion of food-grade gasses used; and

(6) A standard operating procedure for method and frequency of cleaning and sanitizing food-contact surfaces in the designated processing area.

(J) Precautions Against Contamination at Retail

Only unopened packages of food products obtained from sources that comply with the applicable laws relating to food safety can be used to package at retail in a reduced oxygen atmosphere. If it is necessary to stop packaging for a period in excess of one-half hour, the remainder of that product must be diverted for another use in the retail establishment.

(K) Disposition of Expired Product at Retail

Processed reduced oxygen foods that exceed the "use-by" date or manufacturer's "pull date" cannot be sold in any form and must be disposed of in a proper manner.

(L) Dedicated Area/Restricted Access

All aspects of reduced oxygen packaging shall be conducted in an area specifically designated for this purpose. There shall be an effective separation to prevent cross contamination between raw and cooked foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in food packaged by an ROP method. Some ROP procedures such as sous vide may require a "sanitary zone" or dedicated room with restricted access to prevent contamination.

(M) References

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3. SMOKING AND CURING

(A) Introduction

Meat and poultry are cured by the addition of salt alone or in combination with one or more ingredients such as sodium nitrite, sugar, curing accelerators, and spices. These are used for partial preservation, flavoring, color enhancement, tenderizing and improving yield of meat. The process may include dry curing, immersion curing, direct addition, or injection of the curing ingredients. Curing mixtures are typically composed of salt (sodium chloride), sodium nitrite, and seasonings. The preparation of curing mixtures must be carefully controlled. A number of proprietary mixtures which are uniform in composition are available. The maximum residual sodium nitrite in the finished product is limited to 200 ppm by the USDA Food Safety and Inspection Service (FSIS). A sodium nitrite concentration of 120 ppm is usually sufficient for most purposes. Specific requirements for added nitrite may be found in USDA regulations, 9 CFR 318 and 381. It is important to use curing methods which achieve uniform distribution of the curing mixture in the meat or poultry product.

(B) Definitions

Cured meat and poultry can be divided into three basic categories: (1) uncomminuted smoked products; (2) sausages; and (3) uncomminuted unsmoked processed meats.

(1) *Uncomminuted smoked products* - include bacon, beef jerky, hams, pork shoulders, turkey breasts, turkey drumsticks.

(2) *Sausages* - include both finely ground and coarse ground products. Finely ground sausages include bologna, frankfurters, luncheon meats and loaves, sandwich spreads, and viennas. Coarse ground sausages include chorizos, kielbasa, pepperoni, salami, and summer sausages.

(3) *Cured sausages* - may be categorized as: (1) raw, cured; (2) cooked, smoked; (3) cooked, unsmoked; and (4) dry, semidry, or fermented.

(4) *Uncomminuted, unsmoked processed products* - include corned beef, pastrami, pig's feet, corned tongues. This category of products may be sold as either raw ready-to-cook or ready-to-eat.

(C) Incorporation of Cure Ingredients

Regardless of preparation method, cure ingredients must be distributed throughout the product. Cure ingredients may be introduced into sausage products during mixing or comminution. Proper and thorough mixing is necessary whether the cure is added to the formulation in dry or solution form. Muscle cuts may be cured by immersion into a curing (pickle) solution. These methods are slow to diffuse curing agents through the product. Products must be properly refrigerated during immersion curing.

Several methods may be used to shorten curing times. These include hot immersion curing greater than 49°C (>120°F), injection by arterial pumping (e.g., hams), and stitch pumping by a series of hollow needles. If the injection method is used, injection needles must be frequently monitored during processing to ensure that they are not fouled or plugged.

Tumbling or massaging may also be used as an aid to hasten curing. Proper sanitation must be observed to prevent contamination during this operation.

The dry curing method, a similar process, may also be used. In this case, curing ingredients are rubbed over cuts and surfaces of meat held under refrigeration. Precautions must include wearing sanitary gloves when meat is handled. Product temperature maintenance is critical.

(D) Smoking

Smoking is the process of exposing meat products to wood smoke. Depending on the method, some products may be cooked and smoked simultaneously, smoked and dried without cooking, or cooked without smoking. Smoke may be produced by burning wood chips or using an approved liquid smoke preparation. Liquid smoke preparations may also be substituted for smoke by addition directly onto the product during formulation in lieu of using a smokehouse or another type of smoking vessel. As with curing operations, a standard operating procedure must be established to prevent contamination during the smoking process.

(E) Fermentation and Dehydration

Meat may be fermented or dehydrated for preservation. The purpose of fermentation is to reduce the pH to below 4.6 and inhibit bacteria harmful to health as well as bacteria which can cause spoilage. Meat products may also be cured and then dehydrated to prevent germination and growth of bacterial spores. Many fermented and dehydrated meats are made without a cooking step. Sanitary practices in the production of these products are extremely important because ***Staphylococcus aureus*** can be introduced. ***Staphylococcus aureus*** produces an enterotoxin that is heat stable and thus will not be inactivated by subsequent cooking.

Processed pork products require treatment to destroy ***Trichinella spirilla***. At retail, products which contain raw pork and which are not subsequently cooked must be produced from trichina-free certified pork or treated to destroy trichina. USDA regulations, 9 CFR 318.10(c)(3), establish various requirements for destroying trichina in pork by heating, freezing, drying, or smoking.

Some fermented and dry cured products are processed without cooking. The labeling for these products should include instructions to the consumer to cook thoroughly before consumption.

(F) Recommendations for Safe Curing of Meat and Poultry

(1) *Posting of Acceptable Products*

A list of products approved by the regulatory authority, or by an approved knowledgeable authority on curing acceptable to the regulatory authority, must be posted in the processing area of the establishment.

(2) *Employee Training*

Employees assigned to cure meat or poultry must demonstrate familiarity with these guidelines and the potential hazards associated with curing foods. A description of the training and course content provided to the employees must be available for review by the regulatory authority.

(3) *HACCP*

A HACCP plan is needed for all curing operations. The following recommendations must be met to cure meat and poultry products in the establishment. References are available from local USDA extension offices, public libraries, and college or university food or meat science departments to develop HACCP plans for curing meat and poultry.

(a) *Critical Control Points*

The following are critical control points to be addressed:

(i) Purchase of prepared cure mixes; or

(ii) If cure mixes are blended on the premises instead of acquired pre-mixed, mixing must be carefully controlled by using calibrated weighing devices.

(iii) Cure ingredients must be stored in a dry location. Cure must be discarded if the package is wet or appears to have been wetted.

(b) *Raw Material Handling*

(i) Thawing must be monitored and controlled to ensure thoroughness and to prevent temperature abuse. Improperly thawed meat could cause insufficient cure penetration. Temperature abuse can cause spoilage or growth of pathogens.

(ii) Meat must be fresh. Curing may not be used to salvage meat that has excessive bacterial growth or spoilage.

(c) Formulating, Preparation and Curing

(i) A formulation and preparation procedure must be documented.

(ii) All equipment and utensils must be cleaned and sanitized.

(iii) Pieces must be prepared to uniform sizes to ensure uniform cure penetration. This is extremely critical for dry and immersion curing.

(iv) Calibrated scales must be used to weigh ingredients.

(v) A schedule or recipe must be established for determining the exact amount of curing formulation to be used for a specified weight of meat or meat mixture.

(vi) Methods and procedures must be strictly controlled to ensure uniform cure.

(vii) Mixing of curing formulation with comminuted ingredients must be controlled and monitored.

(viii) All surfaces of meat must be rotated and rubbed at intervals of sufficient frequency to ensure cure penetration when a dry curing method is used.

(ix) Immersion curing requires periodic mixing of the batch to facilitate uniform curing.

(x) The application of salt during dry curing of muscle cuts requires that the temperature of the product be strictly controlled between 35° and 45°F. The lower temperature is set for the purpose of ensuring cure penetration and the upper temperature is set to limit microbial growth. Refer to USDA regulations 9 CFR 318.10(c)(3)(iv) for specific details on dry curing.

(xi) Curing solutions must be discarded daily unless they remain with the same batch of product during its entire curing process.

(xii) Injection needles must be inspected for plugging when stitch pumping or artery pumping of muscle cuts is performed.

(xiii) Sanitary casings must be provided for sausage, chub or loaf forming.

(xiv) Casings may not be stripped for reuse in forming additional chubs or sausages from batch to batch.

(xv) Hot curing of bacon bellies, hams, or any other products must be performed at >120°F as specified in 9 CFR 318.

(d) *Cooking and/or Smoking*

(i) When smokehouses are initially installed or structurally modified, calibration of product heating characteristics must be ascertained by competent food technologists. Tests should be run with full range of anticipated product loading. Verification of even air flow and moisture should be recorded in operational records of the smokehouse for these various loads. Procedures should be documented for opening and closing combinations of vents and drains which are required during each specific smokehouse operation.

(ii) Procedures for delivering the appropriate thermal treatment of cooked meats in conformance with the Food Code must be developed and used. (Also see 9 CFR 318.17 and 318.23 for USDA requirements for meat products.) A minimum of 165°F should be used for cured poultry products.

(iii) Cooking equipment that provides even temperature control of the heating medium must be used.

(iv) Products must be adequately separated to prevent overlap in the cooking media whether immersed in hot water, sprayed with hot water, steamed, or oven heated.

(v) Calibrated temperature measuring devices must be used for determining internal product temperatures.

(vi) Temperature measuring device probes must be sanitized to prevent contaminating products when internal temperatures are measured.

(vii) Calibrated temperature measuring devices must be used for measuring temperatures of the heating medium.

(viii) Raw products must be separated from cooked products.

(ix) Time/temperature parameters of the cooking process must be monitored and recorded. In some processes, the heating medium temperature should also monitored.

(e) *Cooling*

(i) Cooling must be done in accordance with recommendations in the Food Code or under a variance. USDA Cooling Guideline, FSIS Directive 7110.3 for special procedures for cured products, provides specific guidance.

(ii) Written cooling procedures must be established.

(iii) Chill water used in water sprays or immersion chilling which is in direct contact with products in casings or products cooked in an impervious package must be properly chlorinated.

(iv) Chill water temperature must be monitored and controlled.

(v) Chill water may not be reused until properly chlorinated. Reclaimed chill water must be discarded daily.

(vi) Product must be placed in a manner that allows chilled water or air to uniformly contact the product for assurance of uniform cooling.

(vii) Internal temperatures must be monitored during cooling by using calibrated temperature measuring devices.

(viii) Adequate cooling medium circulation must be maintained and monitored.

(ix) Temperatures of the cooling medium must be monitored and recorded in accordance with a written procedure.

(x) Handling of product must be minimized during cooling, peeling of casing, and packaging. Sanitary gloves must be used in these procedures.

(f) *Fermentation and Drying*

(i) Temperature and time must be controlled and logs must be maintained that record the monitoring of this process.

(ii) Humidity must be controlled by use of a humidistat. Monitoring of the process must be recorded in a written log.

(iii) Product must be kept separated to allow adequate air circulation during the process.

(iv) Use of an active and pure culture must be ensured to effect a rapid pH drop of the product. Use of commercially produced culture is necessary and the culture must be used according to the manufacturer's instructions.

(v) Determination of the pH of fermented sausages at the end of the fermentation cycle must be recorded.

(vi) Handling of products must be minimized and only done with sanitary gloves or sanitized utensils.

(vii) Dry (unfermented) products may not be hot smoked until the curing and drying procedures are completed.

(viii) Semi-dry fermented sausage must be heated after fermentation to a time/temperature sufficient to control growth of pathogenic and spoilage organisms of concern.

(4) *Dedicated Area/Restricted Access*

All aspects of curing operations must be conducted in an area specifically designated for this purpose. There must be an effective separation to prevent cross contamination between raw and cooked foods or cured and uncured foods. Access to processing equipment shall be restricted to responsible trained personnel who are familiar with the potential hazards inherent in curing foods.

(5) *Equipment Cleaning and Sanitizing*

The procedures for cleaning and sanitization must be accomplished according to parts 4-6 and 4-7 of the Food Code.

(G) References

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Annex

7 Model Forms, Guides, and Other Aids

1. **Form 1** **APPLICANT AND FOOD EMPLOYEE INTERVIEW**
2. **Form 2** **FOOD EMPLOYEE REPORTING AGREEMENT**
3. **Form 3** **APPLICANT AND FOOD EMPLOYEE MEDICAL REFERRAL**
4. **Form 4** **ADOPTION BY REFERENCE**
5. **Form 5** **ADOPTION BY SECTION-BY-SECTION REFERENCE**
6. **Form 6** **HACCP INSPECTION DATA**
7. **Form 7** **FOOD ESTABLISHMENT INSPECTION REPORT**
8. **Guide 1** **EXCLUSIONS AND RESTRICTIONS**
9. **Guide 2** **REMOVAL OF EXCLUSIONS AND RESTRICTIONS**
10. **Guide 3** **INSPECTIONAL GUIDE**
11. **List** **WORLDWIDE STATUS OF *SALMONELLA* TYPHI, *SHIGELLA* SPP., *ESCHERICHIA COLI* O157:H7, AND HEPATITIS A VIRUS BY GEOGRAPHICAL AREA**
12. **Chart 1** **SUMMARY CHART FOR MINIMUM COOKING FOOD TEMPERATURES AND HOLDING TIMES REQUIRED BY CHAPTER 3**
13. **Chart 2** **SUMMARY CHART FOR MINIMUM FOOD TEMPERATURES AND HOLDING TIMES REQUIRED BY CHAPTER 3 FOR REHEATING FOODS FOR HOT HOLDING**
14. **Chart 3** **SUMMARY CHART - DATE MARKING AND DISPOSING READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD**
15. **Chart 4** **FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX**
16. **Summary** **SUMMARY OF CHANGES IN THE FDA FOOD CODE**

The documents provided in this Annex are intended to facilitate adoption of the Food Code and the application of its provisions as they relate to applicants' and food employees' health and to food establishment inspections.

Forms 1-3, Guides 1 and 2, and the List are designed to assist those responsible for preventing foodborne disease. The Food Code specifies that the **permit holder is responsible** for requiring applicants and food employees to report certain symptoms, diagnoses, past illnesses, high-risk conditions, and foreign travel as they relate to diseases transmitted through food by infected workers. The **food employee is personally responsible** for reporting this information to the person in charge.

Forms 4 and 5 can be used for the Code adoption process and Forms 6 and 7 are provided for use in recording HACCP information and inspectional observations. Guide 3 is a compressed outline of the Code to use as a tool in locating and citing Code provisions.

FORM 1

Applicant and Food Employee Interview

Preventing Transmission of Diseases through Food by Infected Food Employees with Emphasis on illness due to ***Salmonella* Typhi, *Shigella*** spp., ***Escherichia coli*** O157:H7, and Hepatitis A Virus

The purpose of this form is to ensure that Applicants to whom a conditional offer of employment has been made and Food Employees advise the Person in Charge of past and current conditions described so that the Person in Charge can take appropriate steps to preclude the transmission of foodborne illness.

Applicant or Employee name (print) _____
Address _____
_____
Telephone *Daytime:*_____ *Evening:*_____

TODAY:

Are you suffering from any of the following:

1. Symptoms

Diarrhea?	**YES/NO**
Fever?	**YES/NO**
Vomiting?	**YES/NO**
Jaundice?	**YES/NO**
Sore throat with fever?	**YES/NO**

2. Lesions containing pus on the hand, wrist or an exposed body part?
(*such as boils and infected wounds, however small)* **YES/NO**

PAST:

Have you ever been diagnosed as being ill with typhoid fever (*Salmonella* Typhi), **shigellosis *(Shigella*** spp.), ***Escherichia coli* O157:H7 infection (*E. coli* O157:H7),** or **hepatitis A** (hepatitis A virus)?
YES/NO
If you have, what was the date of the diagnosis? _____

HIGH-RISK CONDITIONS

1. Have you been exposed to or suspected of causing a confirmed outbreak of typhoid fever, shigellosis, *E. coli* O157:H7 infection, or hepatitis A?
YES/NO
2. Do you live in the same household as a person diagnosed with typhoid fever, shigellosis, hepatitis A, or illness due to *E. coli* O157:H7? **YES/NO**
3. Do you have a household member attending or working in a setting where there is a confirmed outbreak of typhoid fever, shigellosis, *E. coli* O157:H7 infection, or hepatitis A? **YES/NO**

Name, Address, and Telephone Number of your Doctor:
Name _____
Address _____
_____
Telephone - *Daytime* _____ *Evening* _____

Signature of Applicant or Food Employee _____ **Date** _____

Signature of Permit Holder's Representative _____ Date _____

FORM 2

Food Employee Reporting Agreement

Preventing Transmission of Diseases through Food by Infected Food Employees with Emphasis on illness due to ***Salmonella* Typhi, *Shigella*** spp.***,*** ***Escherichia coli*** O157:H7, and Hepatitis A Virus

The purpose of this agreement is to ensure that Food Employees notify the Person in Charge when they experience any of the conditions listed so that the Person in Charge can take appropriate steps to preclude the transmission of foodborne illness.

I AGREE TO REPORT TO THE PERSON IN CHARGE:

FUTURE SYMPTOMS and PUSTULAR LESIONS:

1. **Diarrhea**
2. **Fever**
3. **Vomiting**
4. **Jaundice**
5. **Sore throat with fever**
6. **Lesions containing pus on the hand, wrist, or an exposed body part** (*such as boils and infected wounds, however small)*

FUTURE MEDICAL DIAGNOSIS:

Whenever diagnosed as being ill with typhoid fever (***Salmonella* Typhi**), **shigellosis** (***Shigella*** spp.), ***Escherichia coli* O157:H7 infection (E. coli O157:H7), or hepatitis A** (hepatitis A virus)

FUTURE HIGH-RISK CONDITIONS:

1. Exposure to or suspicion of causing any confirmed outbreak of typhoid fever, shigellosis, *E. coli* O157:H7 infection, or hepatitis A
2. A household member diagnosed with typhoid fever, shigellosis, illness due to *E. coli* O157:H7, or hepatitis A
3. A household member attending or working in a setting experiencing a confirmed outbreak of typhoid fever, shigellosis, *E. coli* O157:H7 infection, or hepatitis A

I have read (or had explained to me) and understand the requirements concerning my responsibilities under the **Food Code** and this agreement to comply with:

1. Reporting requirements specified above involving symptoms, diagnoses, and high-risk conditions specified;
2. Work restrictions or exclusions that are imposed upon me; and
3. Good hygienic practices.

I understand that failure to comply with the terms of this agreement could lead to action by the food establishment or the food regulatory authority that may jeopardize my employment and may involve legal action against me.

Applicant or Food Employee Name (please print) _____

Signature of Applicant or Food Employee _____**Date** _____

Signature of Permit Holder's Representative _____**Date** _____

FORM 3

Applicant and Food Employee Medical Referral

Preventing Transmission of Diseases through Food by Infected Food Employees with Emphasis on Illness due to ***Salmonella* Typhi, *Shigella*** spp.**,** ***Escherichia coli*** O157:H7, and Hepatitis A Virus

The Food Code specifies, under ***Part 2-2 Employee Health Subpart 2-201 Disease or Medical Condition***, that Applicants to whom a conditional offer of employment has been made and Food Employees obtain medical clearance from a physician licensed to practice medicine whenever the individual:

1. Is chronically suffering from a symptom such as **diarrhea;** *or*
2. Meets one of the high-risk conditions specified under Paragraph 2-201.11(D) and is suffering from any symptom specified under Subparagraph 2-201.11(B)(1).
3. Has a **current illness** involving ***Salmonella* Typhi** (typhoid fever), ***Shigella*** spp. (shigellosis), ***Escherichia coli*** O157:H7 (***E. coli*** O157:H7 infection), or hepatitis A virus (hepatitis A), *or*
4. Reports ***past illness*** involving ***S.* Typhi** (typhoid fever), ***Shigella*** spp. (shigellosis), ***E. coli*** O157:H7, or hepatitis A virus (hepatitis A), if the establishment is a facility serving a highly susceptible population such as preschool age children, immunocompromised persons, or older adults.

Applicant or Food Employee being referred:(_____ (Name, please print)_____)
Serving a highly susceptible population YES G NO G

REASON FOR MEDICAL REFERRAL: The reason for this referral is checked below:

G Chronic diarrhea or other chronic symptom _____(specify)_____ .
G Meets a high-risk condition specified under Paragraph 2-201.11(D) _____(specify)_____ and suffers from a symptom specified under Subparagraph 2-201.11(B)(1). _____(specify)_____ .
G Diagnosed or suspected typhoid fever, shigellosis, ***E. coli*** O157:H7 infection, or hepatitis A.
G Reported past illness from typhoid fever, shigellosis, ***E. coli*** O157:H7 infection, or hepatitis A.
G Other medical condition of concern per the following description:_____

PHYSICIAN'S CONCLUSION:

G Applicant or food employee is free of ***S.* Typhi*, Shigella*** spp., ***E. coli*** O157:H7, or hepatitis A virus and may work as a food employee without restrictions.
G Applicant or food employee is an asymptomatic shedder of ____(pathogen) ___ and is restricted from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles in establishments that do not serve highly susceptible populations.
G Applicant or food employee is not ill but continues as an asymptomatic shedder of ____(pathogen) ___ and should be excluded from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles in food establishments that serve highly susceptible populations such as those who are preschool age, immunocompromised, or older adults and in a facility that provides preschool custodial care, health care, or assisted living.
G Applicant or food employee is suffering from typhoid fever, Shigellosis, ***E. coli*** O157:H7 infection, or hepatitis A and should be excluded from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

COMMENTS: (In accordance with Title I of the Americans with Disabilities Act (ADA) and to provide only the information necessary to assist the food establishment operator in preventing foodborne disease transmission, please confine comments to explaining your conclusion and estimating when the employee may be reinstated.)

_____

Signature of Physician_____ **Date**_____

Paraphrased from the FDA Food Code for Physician's Reference

From §2-201.11(A) <u>Organisms of Concern:</u>

Any foodborne pathogen, with special emphasis on these 4 organisms:

S.* Typhi** ***Shigella spp. ***E. coli*** O157:H7 **Hepatitis A** virus

From §2-201.11(B)(1) <u>Symptoms:</u>

Symptoms associated with an acute gastrointestinal illness such as:

Diarrhea **Fever** **Vomiting** **Jaundice** **Sore throat with fever**

From §2-201.11(D) <u>High-Risk Conditions Related to a Person's Activities:</u>

(1) Suspected of causing a foodborne outbreak or being exposed to an outbreak caused by 1 of the 4 organisms above, at an event such as a family meal, church supper, or festival because the person:
Prepared or consumed an implicated food; or
Consumed food prepared by a person who is infected or ill with the organism that caused the outbreak or who is suspected of being a carrier;
(2) Lives with a person who is diagnosed with illness caused by 1 of the 4 organisms; or
(3) Lives with a person who works where there is an outbreak caused by 1 of the 4 organisms.

From §2-201.12 <u>Exclusion and Restriction:</u>

Decisions to exclude or restrict a food employee are made considering the available evidence about the person's role in actual or potential foodborne illness transmission. Evidence includes:

Symptoms **Diagnosis** **High-risk conditions** **Past illnesses** **Stool/blood tests**

- **!** In facilities serving highly susceptible populations such as day care centers and health care facilities, a person for whom there is evidence of foodborne illness is almost always <u>excluded</u> from the food establishment.
- **!** In other establishments that offer food to typically healthy consumers, a person might only be <u>restricted</u> from certain duties, based on the evidence of foodborne illness.
- **!** Exclusion from any food establishment is required when the person is:
  Diagnosed with illness caused by 1 of the 4 organisms of concern; or
  Jaundiced within the last 7 days.

From §8-501.40 <u>Release of Employee from Exclusion or Restriction:</u>

In addition to local law, these requirements must be met in the situations specified:

- **!** For infection with ***S.* Typhi**, the person's stools must be negative for 3 consecutive cultures taken at least 1 month after onset, no earlier than 48 hours after antibiotics are discontinued, and at least 24 hours apart.
- **!** For ***Shigella*** spp. or ***E. coli*** O157:H7 infections, the person's stools must be negative for 2 consecutive cultures taken no earlier than 48 hours after antibiotics are discontinued and at least 24 hours apart.
- **!** For hepatitis A virus infection, the symptoms must cease or at least 2 blood tests must show falling liver enzymes.

FORM
4

Adoption by Reference

This "short form" may be used by governmental bodies adopting the Food Code where authorized by law. Use of the adoption by reference form may substantially reduce the cost of publishing and printing.

The description of the Food Code, below, includes Chapter 8 and the Chapter 8 annex (Annex 1). Modifications to the description may be necessary, based on what provisions are being adopted and whether they are being adopted as law or regulation.

Section 2 lists provisions that may require modifications to be consistent with existing law or that require insertion of dollar amounts.

(JURISDICTION) FOOD CODE

(**statute/regulation/ordinance**) Number _____

ADOPTING THE 1999 EDITION OF THE "FOOD CODE" REGULATING THE RETAIL SALE, COMMERCIAL AND INSTITUTIONAL SERVICE, AND VENDING OF FOOD; DEFINING PERMIT HOLDER, PERSON IN CHARGE, EMPLOYEE, FOOD, POTENTIALLY HAZARDOUS FOOD, FOOD ESTABLISHMENT, SAFE MATERIAL, SANITIZATION, AND OTHER TERMS; AND PROVIDING STANDARDS FOR EMPLOYEE FOOD SAFETY KNOWLEDGE, HEALTH, AND PRACTICES; FOOD SOURCES, PREPARATION, HOLDING TEMPERATURES, AND PROTECTION; EQUIPMENT DESIGN, CONSTRUCTION, INSTALLATION, CLEANING, AND SANITIZATION; WATER, AND LIQUID AND SOLID WASTES; FACILITIES CONSTRUCTION AND MAINTENANCE, AND STORAGE AND USE OF POISONOUS AND TOXIC MATERIALS; REQUIRING A PERMIT TO OPERATE A FOOD ESTABLISHMENT; AND PROVIDING FOR THE RESTRICTION OR EXCLUSION OF EMPLOYEES, THE EXAMINATION AND CONDEMNATION OF FOOD, AND THE ENFORCEMENT OF THIS CODE INCLUDING THE SETTING OF PENALTIES.

The **(governing body)** of the **(jurisdiction)** does ordain as follows:

SECTION 1. ADOPTION OF FOOD CODE

That a certain document, three copies of which are on file in the office of the **(jurisdiction's keeper of records)** of the **(type of jurisdiction)** of **(name of jurisdiction)** being marked and designated as the *Food Code, 1999 Recommendations of the United States Public Health Service/Food and Drug Administration* as published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration be, and is hereby adopted as, the Food Code of **(type of jurisdiction)** of **(name of jurisdiction)** in the State of **(state name)**; for regulating the design, construction, management and operation of food establishments, and providing for plans submission and approval and the issuance of permits and collection of fees therefore.

SECTION 2. INSERTIONS AND CHANGES

That the following provisions are hereby revised as follows:

Paragraph 8-811.10(B) Insert **(Dollar Amount)**

Paragraph 8-813.10(B) Insert **(Dollar Amounts)**
Subparagraph 8-811.10(B)(2) Insert **(Number of Year(s))**

SECTION 3. INCONSISTENT CODES REPEALED

That **(statute/regulation/ordinance)** number **(present code number)** of the **(jurisdiction)** titled, **(complete title of the food code[s] in effect at the present time so they will be repealed by definite mention)** and all other codes or portions of codes in conflict herewith are hereby repealed in that respect only.

SECTION 4. CERTIFICATION OF ADOPTION AND PUBLISHING

That the **(jurisdiction's keeper of records)** shall certify the adoption of this **(statute/regulation/ordinance** and cause the same to be published as required by law.

SECTION 5. EFFECTIVE DATE

That this Code and the rules, regulations, provisions, requirements, orders, and matters established and adopted hereby shall take effect and be in full force and effect **(time period)** from and after the date of its final passage and approval.

PASSED AND APPROVED BY **(name of adopting authority)** on this **(day)** of **(month, year)** **.**

BY: _____

Examples of how some jurisdictions have set fines, sentences, and penalties:

California law provides:

A. For Food Manufacturing Violations:

Criminal fines and sentence for violations of up to **$10,000** and **one** year imprisonment if there is shown an intent to defraud or mislead, and

Civil penalties of up to **$5,000** per day for certain violations.

B. For Retail Food Violations:

Criminal fines and sentence for violations of not less than twenty-five dollars ($25) or more than one thousand dollars ($1000) for each offense, or by imprisonment in the county jail for a term not exceeding six months, or by both such fine and imprisonment.

Maryland law provides:

Criminal fines and sentence for certain violations of up to **$10,000** and **one** year imprisonment, and in the case of repeat code violation convictions, up to **$25,000** and **three** years imprisonment; and

Civil penalties of up to **$5,000** for each violation and for each day the violation continues.

Texas law provides:

Criminal fines and sentence for certain violations of up to **$10,000** and **two** years imprisonment; and

Assessment of five "severity" levels of administrative or civil penalties with base amounts ranging from **$1,250** through **$10,000.** Base amounts can be decreased or increased by as much as 50% considering factors such as past performance, good faith, direct impact on health and safety, high-risk populations involved, etc.

Federal law provides under the *Criminal Fine Enforcement Act of 1984* for a fine up to **$100,000** for a misdemeanor by a corporation or individual not resulting in death and, for misdemeanors resulting in death, a

fine of up to **$250,000** for individuals and **$500,000** for corporations.

FORM 5

Adoption by Section-by-Section Reference

This "long form" may be used by governmental bodies adopting the Food Code section-by-section.

The description of the "Food Code," below, includes Chapter 8 and the Chapter 8 annex (Annex 1). Modifications to the description may be necessary, based on what provisions are being adopted and whether they are being adopted as law or regulation.

Section 2 lists provisions that may require modifications to be consistent with existing law or that require insertion of dollar amounts.

(JURISDICTION) FOOD CODE

(statute/regulation/ordinance) Number _____

ADOPTING A CODE REGULATING THE RETAIL SALE, COMMERCIAL AND INSTITUTIONAL SERVICE, AND VENDING OF FOOD; DEFINING PERMIT HOLDER, PERSON IN CHARGE, EMPLOYEE, FOOD, POTENTIALLY HAZARDOUS FOOD, FOOD ESTABLISHMENT, SAFE MATERIAL, SANITIZATION, AND OTHER TERMS; AND PROVIDING STANDARDS FOR EMPLOYEE FOOD SAFETY KNOWLEDGE, HEALTH, AND PRACTICES; FOOD SOURCES, PREPARATION, HOLDING TEMPERATURES, AND PROTECTION; EQUIPMENT DESIGN, CONSTRUCTION, INSTALLATION, CLEANING AND SANITIZATION; WATER, AND LIQUID AND SOLID WASTES; FACILITIES CONSTRUCTION AND MAINTENANCE, AND STORAGE AND USE OF POISONOUS AND TOXIC MATERIALS; REQUIRING A PERMIT TO OPERATE A FOOD ESTABLISHMENT; AND PROVIDING FOR THE RESTRICTION OR EXCLUSION OF EMPLOYEES, THE EXAMINATION AND CONDEMNATION OF FOOD, AND THE ENFORCEMENT OF THIS CODE INCLUDING THE SETTING OF PENALTIES.

The **_(governing body)_** of the **_(jurisdiction)_** does ordain as follows:

(REPRINT THE *FOOD CODE, 1999 RECOMMENDATIONS OF THE UNITED STATES PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION,* SECTION-BY-SECTION)

SECTION 2. INSERTIONS AND CHANGES

That the following provisions may need to be completed as follows:

Paragraph 8-811.10(B) Insert (**Dollar Amount**)
Paragraph 8-813.10(B) Insert **(Dollar Amounts)**
Subparagraph 8-811.10(B)(2) Insert **(Number of Year(s))**

SECTION 3. INCONSISTENT CODES REPEALED

That **_(statute/regulation/ordinance)_** number **_(present code number)_** of the **_(jurisdiction)_** titled, **(complete title of the food code[s] in effect at the present time so they will be repealed by definite mention)** and all other codes or portions of codes in conflict herewith are hereby repealed in that respect only.

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PASSED AND APPROVED BY **(name of adopting authority)** on this **(day)** of **(month, year)**.

BY: _____

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Federal law provides under the *Criminal Fine Enforcement Act of 1984* for a fine up to **$100,000** for a misdemeanor by a corporation or individual not resulting in death and, for misdemeanors resulting in death, a fine of up to **$250,000** for individuals and **$500,000** for corporations.

FORM
6

HACCP Inspection Data

The HACCP Inspection Data form is designed to accommodate the recording of observations during an inspection. The design of the form focuses on information related to the flow of potentially hazardous foods being prepared, displayed, sold, and served within the establishment. The form is intended as a worksheet for use in noting food temperatures/times at each step and other pertinent data as they compare to the established critical limits. This juxtaposition of the observations and the critical limits highlights the violative steps. The information then is transferred to the Establishment Inspection Report form.

Refer to Annex 4, Food Establishment Inspection, Sections 5 and 10, for further discussion regarding the use of the form.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

HACCP INSPECTION DATA

EST. NAME:	**PERMIT NO.**	**INSPECTOR:**	
DATE:	**TIME IN:**	**:AM / PM**	**TIME OUT:** **:AM/ PM**

Record all observations below - transfer violations to Inspection Report

FOOD TEMPERATURES / TIMES / OTHER CRITICAL LIMITS

Use Additional Forms If Necessary

FOOD STEP	1.	CRITICAL LIMIT	2	CRITICAL LIMIT	3	CRITICAL LIMIT	4	CRITICAL LIMIT
A. SOURCE								
B. STORAGE								
C. PREP BEFORE COOK								
D. COOK								
E. PREP AFTER COOK								
F. HOT/COLD HOLD								
G. DISPLAY/ SERVICE								
H. COOL								
I. REHEAT								

OTHER FOOD TEMPERATURES OBSERVED **Use steps from above for location**

FOOD	TEMP. $^0C/^0F$	STEP	FOOD	TEMP. $^0C/^0F$	STEP	FOOD	TEMP. $^0C/^0F$	STEP

MANAGEMENT / PERSONNEL OBSERVATIONS

OTHER FOOD OBSERVATIONS

EQUIPMENT, UTENSILS, AND LINEN OBSERVATIONS

WATER, PLUMBING, AND WASTE OBSERVATIONS

PHYSICAL FACILITIES

POISONOUS OR TOXIC MATERIALS OBSERVATIONS

FORM
7

Food Establishment Inspection Report

The food establishment inspection report is the official agency document regarding compliance of the establishment with agency requirements. The goal of the report is to clearly, concisely, and fairly present the compliance status of the establishment and to convey compliance information to the permit holder or person in charge at the conclusion of the inspection. The Food Establishment Inspection Report form is provided as a model for use during routine, follow-up, and investigative inspections.

Refer to Annex 4, Food Establishment Inspection, Sections 6, 11, and 12, for further discussion.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

FOOD ESTABLISHMENT INSPECTION REPORT

Violations cited in this report shall be corrected within the time frames specified below, but within a period not to exceed 10 calendar days for critical items (§ 8-405.11) or 90 days for noncritical items (§ 8-406.11).

VIOLATIONS: CRITICAL _____ NONCRITICAL_____

ESTABLISHMENT:	**PERMIT NUMBER:**	**DATE:**	
ADDRESS:	**CITY:**	**STATE:**	**ZIP:**
PERSON IN CHARGE / TITLE:	**TELEPHONE:**		
INSPECTOR / TITLE:			
INSPECTION TYPE: ROUTINE FOLLOW-UP COMPLAINT OTHER:	**TIME:**		

Critical **(X)**	Repeat **(X)**	Code Reference	Violation Description / Remarks / Corrections

FOOD ESTABLISHMENT INSPECTION REPORT

ESTABLISHMENT: **PERMIT NUMBER:** **DATE:**

Critical **(X)**	Repeat **(X)**	Code Reference	Violation Description / Remarks / Corrections

GUIDE 1

Exclusions and Restrictions for Food Employees and Applicants

Health Status	Facilities Serving Highly Susceptible Population	Facilities Not Serving Highly Susceptible Population
1. Diagnosed with illness due to ***Salmonella* Typhi, *Shigella*** spp., ***Escherichia coli*** O157:H7, or hepatitis A virus	Exclude 2-201.12(A)	Exclude 2-201.12(A)
2. Experiencing a symptom listed in 2-201.11(B)	Restrict 2-201.12(B)	Restrict 2-201.12(B)
3. Experiencing a symptom listed in 2-201.11(B)(1) and meets a high-risk condition* of 2-201.11(D)(1)-(3)	Exclude 2-201.12(C)(1)*	Restrict 2-201.12(B)(1)
4. Asymptomatic but stools positive for ***S.* Typhi**, ***Shigella*** spp., or ***E. coli*** O157:H7	Exclude 2-201.12(C)(2)	Restrict 2-201.12(B)(2)
5. Past illness from ***Salmonella* Typhi** within the last 3 months	Exclude 2-201.12(C)(3)	No Restrictions
6. Past illness from ***Shigella*** spp. or ***E. coli*** O157:H7 within the last month	Exclude 2-201.12(C)(4)	No Restrictions
7. Onset of jaundice within the last 7 days	Exclude 2-201.12(D)(1)	Exclude 2-201.12(D)(1)
8. Onset of jaundice more than 7 days ago	Exclude 2-201.12(D)(2)(a)	Restrict 2-201.12(D)(2)(b)

***** High-risk conditions apply only to exclusions under this Subparagraph.

GUIDE
2

Removal of Exclusions & Restrictions for Food Employees and Applicants

HEALTH STATUS 2-201.11 and .12	FACILITIES SERVING HIGHLY SUSCEPTIBLE POPULATION 2-201.13	FACILITIES NOT SERVING HIGHLY SUSCEPTIBLE POPULATION 2-201.13
1. Diagnosed with illness due to ***Salmonella* Typhi, *Shigella*** spp., ***Escherichia coli*** O157:H7, or hepatitis A virus 2-201.11(A)	1. RA Approval + 2. Doctor*: Stool free or Blood free or symptom-free (A)(1)	1. RA Approval + 2. Doctor*: Stool free or Blood free or symptom-free (A)(2)
2. Experiencing a symptom listed in 2-201.11(B)	1. No illness results + no symptoms or 2. Suspect cause of illness + no symptoms + Doctor*: stool or blood free or 3. Doctor*: Noninfectious condition (B)(1)	1. No illness results + no symptoms or 2. Suspect cause of illness + no symptoms + Doctor*: stool or blood free or 3. Doctor*: Noninfectious condition (B)(1)
3. Experiencing a symptom listed in 2-201.11(B)(1) and meets a high-risk condition 2-201.11(D)(1)-(3) 2-201.12(C)(1)	Doctor*: 1. Stools or blood free or 2. No jaundice per .13(D) 3..12 (C)(1) Noninfectious condition (C)	1. No illness results + no symptoms or 2. Suspect cause of illness + no symptoms + Doctor*: stool or blood free or 3. Doctor*: Noninfectious condition (B)(1)
4. Asymptomatic but stools positive for ***S.* Typhi**, ***Shigella*** spp., or ***E. coli*** O157:H7 2-201.12(B)(2) & (C)(2)	Doctor* - stools free (C)	Doctor* - stools free (B)(2)
5. Past illness from ***Salmonella* Typhi** within the last 3 months 2-201.11(C)	Doctor* - stools free (C)	NA
6. Past illness from ***Shigella*** spp., or ***E. coli*** O157:H7 within last month 2-201.11(C)	Doctor* - stools free (C)	NA
7. Onset of jaundice within last 7 days 2-201.12(D)(1)	1. No illness results + Doctor* - blood free or Doctor* - no jaundice or 2. Suspect cause of illness + both satisfied (D)	1. No illness results + Doctor* - blood free or Doctor* - no jaundice or 2. Suspect cause of illness + both satisfied (D)
8. Onset of jaundice more than 7 days ago 2-201.12(D)(2)	1. No illness results + Doctor* - blood free or Doctor* - no jaundice or 2. Suspect cause of illness + both satisfied (D)	1. No illness results + Doctor* - blood free or Doctor* - no jaundice or 2. Suspect cause of illness + both satisfied (D)

*Where “doctor” is indicated, nurse practitioner or physician assistant, if allowed by law, may provide documentation.

GUIDE
3

Inspectional Guide

The major headings from each of the Code chapters have been extracted and condensed in this Guide to key word phrases to assist the person conducting inspections in locating the Code citation that corresponds to a given violation. The Guide is intended to be used during inspections as an aid in referencing Code provisions, ensuring that provisions of the Code are not overlooked during the inspection, and accurately completing the Food Establishment Inspection Report form.

INSPECTIONAL GUIDE

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2-102.11 Demonstration of **Knowledge***
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2-301.12 Cleaning Procedure*
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2-301.14 When to Wash*
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5-202.12 Handwashing Facility, Installation
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5-202.14 Backflow Prevention Device, Design
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Numbers and Capacities
5-203.11 Handwashing Facilities*****
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5-203.13 Service Sink
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5-205.13 Scheduling Device Inspect./Service
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5-303.11 Filter, Compressed Air
5-303.12 Protective Equipment or Device
5-303.13 Mobile Food Est. Water Tank Inlet
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5-304.11 Flushing and Disinfecting System*****
5-304.12 Using Pump and Hoses/Backflow Prev.
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5-402.12 Grease Trap
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5-402.14 Removing Mobile Food Est. Wastes
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5-501.17 Toilet Room Receptacle, Covered
5-501.18 Cleaning Implements and Supplies
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5-501.110 Storing Refuse/Recyclables/Return.
5-501.111 Areas/Enclosures/Receptacles, Repair
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5-501.113 Covering Receptacles
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6-201.12 Floors/Walls/Ceilings,Utility Lines
6-201.13 Junctures, Coved/Enclosed/Sealed
6-201.14 Carpeting,Restriction/Installation
6-201.15 Floor Covering, Mats and Duckboards
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6-202.11 Light Bulbs, Protective Shielding
6-202.12 Ventilation System, Exhaust Vents
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6-202.14 Toilet Rooms, Enclosed
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7-102.11 **Working Containers**, Common Name*****
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7-202.11 Restriction*****
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7-203.11 Poisonous/Toxic Material Containers*****
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7-204.12 Washing Fruits and Vegetables*****
7-204.13 Boiler Water Additives*****
7-204.14 Drying Agents*****
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Pesticides
7-206.11 Restricted-Use, Criteria*
7-206.12 Bait Stations*
7-206.13 Tracking Powders*****
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7-207.11 Restriction and Storage*****
7-207.12 Medicines, Refrigerated Storage*****
7-208.11 **First Aid Supplies**, Storage*****
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LIST

Worldwide Status of *Salmonella* Typhi, *Shigella,*
***Escherichia coli* O157:H7, and Hepatitis A Virus by Geographical Area.**

Preventing Transmission of Diseases through Food by Infected Food Employees with Emphasis on ***Salmonella*** **Typhi**, ***Shigella*** spp., ***Escherichia coli*** *O157:H7, and Hepatitis A Virus.*

The following list of countries shows where typhoid fever, hepatitis A, and various diarrheal diseases commonly occur or are epidemic as reported to the Centers for Disease Control and Prevention (CDC) by the World Health Organization (WHO). CDC publishes this information annually in what is referred to as the "Yellow Book," ***Health Information for International Travel****. Statistics cited were adapted from CDC's 1996-97 edition in the section entitled "Geographical Distribution of Potential Health Hazards to Travelers." The list is not comprehensive. Reporting to WHO is voluntary and is based on mortality, not morbidity. Where the Yellow Book refers to nonspecific "diarrheal disease,"* ***E. coli*** *O157:H7 has been denoted as a possible cause.*

This list is intended to be used as an aid to increase awareness of the person in charge that travel to some points outside the U.S. may increase the risk for acquiring foodborne illness. The person in charge can use the list to educate food employees about the need to be vigilant in the protection of their health during travel and the importance of informing the person in charge if symptoms occur or if there is a diagnosis of an illness (due to one of the four pathogens listed above) during or following travel.

AFRICA

Northern Africa

Typhoid	Shigellosis	*E. coli* O157:H7	Hepatitis A

Algeria, Egypt, Libyan Arab Jamahiriya, Morocco, and Tunisia

Sub-Saharan Africa

Typhoid	Shigellosis	*E. coli* O157:H7	Hepatitis A

Angola, Benin, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad,

Comoros, Congo, Côte D'Ivoire, Djiouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Niger, Nigeria, Réunion, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, Sudan, Togo, Uganda, United Republic of Tanzania, Zaire, Zambia, and Zimbabwe.

Southern Africa

Typhoid	Shigellosis	*E. coli* O157:H7	Hepatitis A

Botswana, Lesotho, Namibia, St. Helena, South Africa, and Swaziland.

The AMERICAS

North America

G Typhoid	**G** Shigellosis	**G** *E. coli* O157:H7	**G** Hepatitis A

Bermuda, Canada, Greenland, St. Pierre and Miquelon and the United States of America.

Mainland Middle America

Typhoid	Shigellosis	*E. coli* O157:H7	Hepatitis A

Belize, Costa Rica, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, and Panama.

Caribbean Middle America

G Typhoid	Shigellosis	*E. coli* O157:H7	Hepatitis A

Antigua and Barbuda, Aruba, Bahamas, Barbados, British Virgin Islands, Cayman Islands, Cuba, Dominica, Dominican Republic, Grenada, Guadeloupe, Haiti, Jamaica, Martinique, Montserrat, Netherlands Antilles, Puerto Rico, St. Christopher and Nevis, Saint Lucia, Saint Vincent, and the Grenadines, Trinidad and Tobago, Turks and Caicos Islands, and the Virgin Islands (USA).

Tropical South America

G Typhoid	Shigellosis	*E. coli* O157:H7	Hepatitis A

Bolivia, Brazil, Colombia, Ecuador, French Guiana, Guyana, Paraguay, Peru, Suriname, and Venezuela.

Temperate South America

Typhoid	Shigellosis	*E. coli* O157:H7	Hepatitis A

Argentina, Chile, Falkland Islands (Malvinas), and Uruguay.

ASIA

East Asia

G Typhoid | G Shigellosis | G *E. coli* O157:H7 | G Hepatitis A

China, the Democratic People’s Republic of Korea, Hong Kong, Japan, Macao, Mongolia, and the Republic of Korea.

Eastern South Asia

G Typhoid | G Shigellosis | G *E. coli* O157:H7 | G Hepatitis A

Brunei Darussalam, Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar (formerly Burma), the Philippines, Singapore, Thailand, and Viet Nam.

Middle South Asia

~~G~~ Typhoid	~~G~~ Shigellosis	~~G~~ *E. coli* O157:H7	~~G~~ Hepatitis A

Afghanistan, Armenia, Azerbaijan, Bangladesh, Bhutan, India, Islamic Republic of Iran, Kazakhstan, Kyrgyzstan, Maldives, Nepal, Pakistan, Sri Lanka, Tajikistan, Turkmenistan, and Uzbekistan.

Western South Asia

~~G~~ Typhoid	~~G~~ Shigellosis	~~G~~ *E. coli* O157:H7	~~G~~ Hepatitis A

Bahrain, Cyprus, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Syrian Arab Republic, Turkey, the United Arab Emirates, and Yemen.

EUROPE

Northern Europe

G Typhoid	**G** Shigellosis	**G** *E. coli* O157:H7	**G** Hepatitis A

Belarus, Belgium, Czech Republic, Denmark (with the Faroe Islands), Estonia, Finland, Germany, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Republic of Moldova, Russian Federation, Slovakia, Sweden, Ukraine, and the United Kingdom (with the Channel Islands and the Isle of Man).

Southern Europe

~~G~~ Typhoid	~~G~~ Shigellosis	~~G~~ *E. coli* O157:H7	**G** Hepatitis A

Albania, Andorra, Austria, Bosnia, and Herzegovina, Bulgaria, Croatia, France, Gibraltar, Greece, Hungary, Italy, Liechtenstein, Malta, Monaco, Portugal (with the Azores and Madeira), Romania, San Marino, Slovenia, Spain (with the Canary Islands), Switzerland, and the former Yugoslav Republic of Macedonia, and Yugoslavia.

OCEANIA

Australia, New Zealand & Antarctic

G Typhoid	**G** Shigellosis	**G** *E. coli* O157:H7	**G** Hepatitis A

Melanesia & Micronesia (Polynesia)

~~G~~ Typhoid	~~G~~ Shigellosis	~~G~~ *E. coli* O157:H7	**G** Hepatitis A

American Samoa, Cook Islands, Easter Island, Federated States of Micronesia, Fiji, French Polynesia, Guam, Kiribati, Marshall Islands, Nauru, New Caledonia, Niue, Palau, Papua New Guinea, Pitcairn, Samoa, Solomon Islands, Tokelau, Tonga, Trust Territory of the Pacific Islands, Tuvalu, Vanuata, Wake Island (U.S.) and the Wallis and Futuna Islands.

Chart 1

Summary Chart for Minimum Cooking Food Temperatures and Holding Times Required by Chapter 3

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature
Unpasteurized Shell Eggs prepared for immediate service **Commercially Raised Game Animals** **Fish, Pork, and Meat** Not Otherwise Specified in this Chart or in ¶ 3-401.11(B)	**63°C (145°F)**	**15 seconds**
Unpasteurized Shell Eggs not prepared for immediate service **Exotic Species of Game Animals** **Comminuted Fish and Meats** **Injected Meats**	70°C (158°F) **68°C (155°F)** 66°C (150°F) 63°C (145°F)	< 1 second **15 seconds** 1 minute 3 minutes
Poultry **Stuffed Fish; Stuffed Meat; Stuffed Pasta;** **Stuffed Poultry** **Stuffing Containing Fish, Meat, or Poultry** **Wild Game Animals**	**74°C (165°F)**	**15 seconds**
Food Cooked in A Microwave Oven	**74°C (165°F)**	**and hold for 2 minutes after removing from microwave oven**

Chart 2

Summary Chart for Minimum Food Temperatures and Holding Times Required by Chapter 3 for Reheating Foods for Hot Holding

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature	Maximum Time to Reach Minimum Temperature
¶ 3-403.11(A) Food that is cooked, cooled, and reheated	74°C (165°F)	15 seconds	2 hours
¶ 3-403.11(B) Food that is reheated in a microwave oven	74°C (165°F)	and hold for 2 minutes after removing from microwave oven	2 hours
¶ 3-403.11(C) Food that is taken from a commercially processed, hermetically sealed container or intact package	60°C (140°F)	No time specified	2 hours
¶ 3-403.11(E) Unsliced portions of roasts of beef and roasts of pork cooked as specified under Subparagraph 3-401.11(B)	Same oven parameters and minimum time and temperature conditions as specified under Subparagraph 3-401.11(B)		Not applicable
	OR		
	Minimum time and temperature conditions listed in this chart for ¶ 3-403.11(A) or ¶ 3-403.11(B).		

Chart 3 **Summary Chart**
Ready-to-Eat, Potentially Hazardous Food,
Date Marking § 3-501.17 and Disposition § 3-501.18

"IF" → **"THEN"**

(A) or (C) On site preparation and held > 24 hours, or Commercial container is opened →
- (1) @ ≤ 41°F for ≤ 7 days
- or
- (2) @ > 41 - 45°F for ≤ 4 days

(B) or (D) Freeze →
- (1) For consumption within 24 hours of thawing
- or
- (2) Time from preparation, or opening commercial container, to freezing

(B3) or (D3) Remove from freezer →
- (a) @ ≤ 41°F 7 days minus ✷
- or
- (b) @ >41 - 45°F 4 days minus ✷

✷ Time from preparation, or opening commercial container, to freezing.

Formula for Consume- or Dispose-by Date
C = T - F

C = consume- or dispose-by date
T = days allowed based on storage temperature
F = days before freezing

Example: The morning of October 1, a chicken was cooked, then cooled, refrigerated for 2 days at 41°F and then frozen. If the chicken is thawed October 10, the food must be consumed or discarded no later than midnight of October 15.

Chart 4

FDA Food Code Mobile Food Establishment Matrix

This table is a plan review and inspectional guide for mobile food establishments based on the mobile unit's menu and operation. Mobile units range in type from push carts to food preparation catering vehicles.

To use the table, read down the columns based on the menu and operation in use. For example, if only prepackaged potentially hazardous food is served, then requirements listed in the **Potentially Hazardous Menu - *Prepackaged*** column apply. Likewise, if only food that is not potentially hazardous is prepared on board, then requirements listed in the **Not Potentially Hazardous Menu - *Food Preparation*** column apply. Note that if a mobile food establishment has available for sale to the consumer both prepackaged potentially hazardous food and potentially hazardous food prepared on board, then the more stringent requirements of the **Potentially Hazardous Menu - *Food Preparation*** column apply.

It is important to remember that mobile units may also be subject to all Food Code provisions that apply to food establishments. Consult the local regulatory authority for specific local requirements.

The local regulatory authority's decision to require auxiliary support services such as a commissary or servicing area should be based on the menu, type of operation and availability of on-board or on-site equipment.

NOTE: The Food Code definition of "Food Establishment" does not include an establishment that offers only prepackaged foods that are not potentially hazardous.

FDA FOOD CODE MOBILE FOOD ESTABLISHMENT MATRIX			
Food Code	***Potentially Hazardous Menu***		***Not Potentially Hazardous Menu***
Areas/Chapter	*Food Preparation*	*Prepackaged*	*Food Preparation*
Personnel	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (B)	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (B)	Applicable Sections of Parts 2-2 - 2-4 5-203.11 (B)
Food	3-101.11 3-201.11-.16 3-202.16; Applicable Sections of Part 3-3; 3-501.16 3-501.18(A) &(C)	3-101.11 3-201.11-.16 3-303.12(A) 3-305.11; 3-305.12 (Applicable to Service Area or Commissary)	3-101.11; 3-201.11 3-202.16; Applicable Sections of Part 3-3
Temperature Requirements	3-202.11; Applicable Sections of Parts 3-4 & 3-5	3-202.11 3-501.16	NONE
Equipment Requirements	Applicable Sections of Parts 4-1- 4-9 and 5-5	Applicable Sections of Parts 4-1 - 4-2; 4-6 and 5-5	Applicable Sections of Parts 4-1 - 4-2; 4-5 - 4-6 and 5-5
Water & Sewage	5-104.12 5-203.11(A) & (B) Part 5-3; 5-401.11 5-402.13-.15	5-203.11(B)	5-104.12 5-203.11(A) & (B) Part 5-3; 5-401.11 5-402.13-.15
Physical Facility	6-101.11; 6-201.11 6-102.11(A) & (B) 6-202.15; 6-501.11 6-501.12; 6-501.111	6-101.11 6-102.11(A) & (B) 6-202.15 6-501.111	6-101.11; 6-201.11 6-102.11(A) & (B) 6-202.15; 6-501.11 6-501.12; 6-501.111
Toxic Materials	Applicable Sections of Chapter 7	Applicable Sections of Chapter 7	Applicable Sections of Chapter 7
Servicing	6-202.18 / As necessary to comply with the Food Code	6-202.18 / As necessary to comply with the Food Code	6-202.18 / As necessary to comply with the Food Code
Compliance and Enforcement	Applicable Sections of Chapter 8 and Annex 1	Applicable Sections of Chapter 8 and Annex 1	Applicable Sections of Chapter 8 and Annex 1

Summary of Changes in the FDA Food Code

This Summary provides a synopsis of the textual changes from the 1997 FDA Food Code Chapters and Annexes to the 1999 edition. The primary intent of this record is to capture the nature of the changes rather than to identify every word or editing change. This record should not be relied upon as an absolute comparison that identifies each and every change.

General:

- Numerous editing changes were made throughout the document for internal consistency, to correct some errors in the '97 Code and for clarification.

- Italics and capitalization of *Salmonellae* are modified throughout the document, with the exception of Annex 2 where titles of published documents remain unchanged. The modifications reflect current, commonly recognized conventions used in the scientific community. Species of *Salmonellae* are not italicized and begin with a capital letter.

- Defined words and terms are in small capital letters throughout the Chapters and Annex 1 to highlight that they have a specific meaning within the context of the Code. Refer to the Preface, Information to Assist the Reader, for a discussion of this feature.

- Section numbers listed refer to the 1997 Code unless otherwise noted. Definition numbers listed refer to the 1999 Code. Renumbering occurred in the 1999 edition, based on the changes made.

Chapter 1:

1-201.10 - Definitions
(1) added "Accredited program" (CFP 98-02-06)
(21) revised "Easily movable" for consistency with NSF International's use of terms
(28) modified "Foodborne disease outbreak" for consistency with CDC (CFP 98-01-11)
(43) added "Juice"
(61) amended "Potentially hazardous food" regarding garlic-in-oil mixtures
(67) amended "Reduced oxygen packaging" to more fully explain the ROP processes
(74) deleted existing (81) "Support animal" and replaced it with new definition, "Service animal", for consistency with the ADA
(75) modified "Servicing area" to include vehicle and equipment cleaning
(81) modified "Single-service articles" to specify the intent for them to be discarded
(87) added "probe-type price and identification tags" to the definition of a "Utensil"
(90) added the definition of "Variance" from § 8-103.10 in § 1-201.10
(91) modified "Vending machine" to include optional manual operation
(94) added "Whole-muscle, intact beef"

Chapter 2:

2-103.11 added ¶¶ (K) and (L) (CFP 96-01-07)
2-201.11(D)(4) deleted (CFP 98-01-42)
2-201.13 added recognition of nurse practitioners, and physician assistants, if allowed by law, for purpose of medical documentation
2-201.15 deleted “or a person who applies for a job as a food employee” and “or is suspected of having” (CFP 98-01-41); changed language to “... shall notify ... that an employee...”
2-301.12 updated to include approved automatic handwashing facility (CFP 98-03-10); other related provisions in Chapters 2, 5, and 6 were changed to be consistent
2-301.14(D) amended to clarify that a person may drink from a closed container without washing hands each time (CP 98-01-40)
2-301.16 revised to clarify approval methods for hand sanitizers
2-302.11 formed a new ¶ (A) and added a new ¶ (B) to prohibit the wearing of fingernail polish or artificial fingernails (CFP 98-01-35)

Chapter 3:

3-201.11 added ¶ (E) to address labeling of whole-muscle, intact beef by a food processor and ¶ (F) to address labeling meat and poultry with safe handling instructions (CFP 98-01-29)
3-202.11(C) changed reference to § 3-401.16 to § 3-401.13
3-301.11 added an insert page to alert readers that Annex 3 contains a full discussion clarifying ¶ (B) and to provide a brief synopsis of that discussion
3-301.11(C) is identified as a swing item to allow for judgment regarding the significance of bare hand contact with food that is not ready-to-eat
3-304.11 ¶ (A) deleted and combined with ¶ (B) (CFP 98-03-16) to allow the use of probe-type price identification tags
3-304.12 ¶ (C) amended to clarify that both the in-use utensil and the food-contact surfaces must be cleaned and sanitized; added a new ¶ (F) to allow in-use utensils to be stored in water that is maintained at a temperature of at least 140°F (CFP 98-01-07)
3-304.14 changed the tagline; changed the word “moist” to “wet” in ¶¶ (B) and (C); added specificity about the concentration of the sanitizing solution; and added ¶ (D) to clarify that each time the sanitizing solution is changed, the wiping cloth needs to be evaluated to determine that it is clean (CFP 98-03-18)
3-304.16(A) amended to allow refilling by food employees under certain circumstances (CFP 98-01-19)
3-306.13(A) amended to include consumer self-service of raw, frozen, shell-on shrimp and lobster (CFP 98-01-26)
3-306.14 changed tagline and amended to allow transfer of certain food containers from one consumer to another (CFP 98-01-20)
3-401.11(A)(1)(b) added “pork” to be cooked to 145°F (CFP 98-03-03); (A)(2) deleted “pork” to be cooked at 155°F;(A)(2) amended the chart to include the temperature at which certain foods, e.g., hamburger can be cooked if the time is less than one second (CFP 98-03-23); (B) added “pork roasts” and “cured pork roasts” to beef roast cooking parameters
(CFP 98-03-03); added new ¶ C to allow the surface searing of a whole-muscle, intact beef steak without fully cooking the steak (CFP 98-03-25); (D) added to exempt seared steaks from a consumer advisory (CFP 98-03-20)
3-501.18 added new ¶ (G) to address the date marking of an existing portion of food to which new portions of food are added (CFP 98-01-18)

3-501.19 amended so that former ¶¶ (A)-(D) are now contained in ¶ A and added new ¶ B stating time may not be used as the public health control for raw eggs for a highly susceptible population
3-502.11 amended to clarify that a variance is not required if smoking food is done solely for flavor enhancement
3-502.12 amended to clarify that a HACCP plan is needed for ROP foods with two barriers to ***C. botulinum***
3-603.11 amended to exempt from the consumer advisory requirement, animal foods that are "otherwise processed to eliminate pathogens"; added a new insert page to alert the reader to what constitutes satisfactory compliance with the provision and direct the reader to Annex 3 for more discussion
3-801.11 expanded ¶ (A) to include all fruit and vegetable juice and prohibit prepackaged unpasteurized juice; amended ¶ (B) to require pasteurized eggs whenever raw eggs are combined, except for 3 specific situations; ¶ (D) expanded to prohibit raw seed sprouts (CFP 98-03-22); added new ¶ (E) to describe the restricted conditions under which raw eggs may be used

Chapter 4:

4-501.16(A) deleted the end statement "or dumping mop water" (CFP 98-01-05). This leaves the prohibition of dumping mop water in a warewashing sink as a critical item in § 6-501.15.
4-602.11(B) revised to clarify intent of cleaning frequency when equipment is contacting raw animal food that requires a higher cooking temperature than the previous food contacting the same equipment
4-602.11 ¶ (D) amended with time/temperature chart to allow cleaning frequency greater than 4 hours with refrigerated food-contact utensils and equipment (CFP 98-03-05)
4-602.11(D)(7) added new subparagraph to specify the cleaning frequency for the water container used to hold the 140°F water and the in-use utensil
4-802.11 amended ¶ (D) to clarify the cleaning frequency of wiping cloths (CFP 98-03-18)

Chapter 5

5-103.11 added requirement for hot water capacity as a critical item. Split provision into ¶¶ (A) and (B).
5-103.13 deleted and combined with 5-103.11

Chapter 6:

6-202.15(A) amended to refer to the paragraphs as they were redesignated; new ¶ (C) allows an exception to the use of self-closing devices on emergency doors used as exits under certain conditions (CFP 98-01-46); ¶ (C) ➜ ¶ (D); ¶ (D) ➜ ¶ (E)
6-301.14 added a new section requiring a handwashing sign to be posted (CFP 98-01-36)
6-501.115 added clarifying language in Subparagraph (B)(3) regarding service animals to be consistent with the ADA; added language in Subparagraph (B)(5) allowing certain animals on the premises

Chapter 8:

8-201.12 ¶ (E) redrafted to ease the paperwork burden on industry during plan review; relocated requirement for standard operating procedures to § 8-203.10; moved Subparagraphs (1)-(6) from ¶ (E); deleted ¶ (F) because the new ¶ 2-103.11(L) addresses training; ¶ (G) ➜ ¶ (F)

8-203.10 amended this section to require standard operating procedures by the time of the preopening inspection and to cross reference ¶ 8-201.12(E)
8-501.20, 8-501.30, and 8-501.40 added the word “Food” before “employee” where it was missing, for internal consistency

Annex 2:

References added for many code provisions

Annex 3:

1-201.10 added a discussion about accredited programs
2-201.11 modified language, including adding language about hands in contact with pustular lesions on parts of the body other than hands also posing a threat for introducing ***Staphylococcus aureus*** into food
3-201.11 added information regarding labeling for safe handling instructions on packages of meat and poultry; labeling juices that have not been pasteurized; and identifying whole-muscle, intact beef steaks (CFP 98-01-29)
3-202.11 added new federal regulation requiring shell eggs to be stored and transported in ambient air temperature of 45°F or below
3-301.11 added a discussion that clarifies the phrase in ¶ (B), “except when otherwise approved”
3-302.15 added reference to a guidance document regarding the washing of fruits and vegetables (CFP 98-03-14)
3-304.12 - 3-304.17 separated the public health reasons and added new language
3-401.11 added discussion regarding seared steak and hamburger cooking temperature and pork cooking
3-401.13 clarified that the hot holding temperature applies to fruits and vegetables that are fresh, frozen, or canned
3-501.14 modified in concert with current CFR regarding shell eggs
3-603.11 expanded with a current discussion of the purpose, background, satisfactory compliance with and applicability of the consumer advisory provision; explained that irradiated meat and poultry can not be offered in a ready-to-eat form without a consumer advisory
3-801.11 updated the discussion regarding the importance of using pasteurized juices in highly susceptible populations; added a discussion regarding federal juice labeling requirements, ***Salmonella* Enteritidis** in raw shell eggs, and raw seed sprouts
6-202.15 expanded to discuss how the National Fire Protection Association’s guidance is related to this section
6-501.115 discussed that new Code language allows a food establishment to have both a snack bar and a pet sales area or to sell food adjacent to animal displays; added discussion regarding compliance with ADA requirements for allowing service animals on the premises
7-204.12 clarified that the CFR has no maximum limit on the concentration of chlorine applied to fruits and vegetables
8-201.12 and 8-203.10 added new language regarding using the plan review process for discussion between the regulatory authority and the operator about long-term compliance with the Food Code; including operating procedures that address training

Annex 4:

Item 8 Temperature Measuring Devices (A) Sensor-Type Temperature Measuring Devices (4) Infrared Thermometers: added infrared thermometers to the listing of types of temperature measuring devices and provided a brief discussion of them

Annexes 5 and 6:

Made changes consistent with changes elsewhere in the document

Annex 7:

Form 1 in the purpose statement, after the word "Applicant," added the phrase "to whom a conditional offer of employment has been made" for consistency with the ADA and under the topic High-Risk Conditions, deleted the question concerning travel
Form 3 added "to whom a conditional offer of employment has been made" for consistency with the ADA; **Paraphrased From the FDA Food Code for Physician's Reference**, High-Risk Conditions Related to a Person's Activities, deleted (4) concerning travel
Guide 1 deleted reference to Subparagraph 2-201.11(D)(4) concerning travel
Guide 2 under Health Status # 3, deleted reference to Subparagraph 2-201.11(D)(4); recognized nurse practitioners and physician assistants for medical documentation
List deleted the word "endemic;" replaced reference to the 1995 version of CDC's Yellow Book with 1996-97 edition; stated criterion for denoting ***E. coli*** O157:H7 in some geographical areas; added language to clarify intended use of the list since travel is deleted from the Chapter 2 high-risk conditions
Charts 1 & 2 updated to reflect new temperatures for pork and instant kill at 158°F for certain foods
Chart 3 added new chart on "Ready-to-Eat, Potentially Hazardous Food, Date Marking and Disposition"

ADA = Americans with Disabilities Act
CFP = Conference for Food Protection
CFR = Code of Federal Regulations
ROP = Reduced Oxygen Packaging

FDA Food Code 2013

Why do we inspect food establishments?

- Most common causes of outbreak in 2012:
  - Norovirus: 41% of reported outbreaks
  - Salmonella: 25% of reported outbreaks
- In 2012, in the food preparation setting, outbreaks originated at
  - Restaurants (60%)
  - Caterers or banquet facilities (13%)
  - Homes (13%)

Foodborne Disease Outbreaks, 2011-2012*

Outbreak reported:	1,632
Cases of illness:	29,112
Hospitalizations:	1,750
Deaths:	68

*Source: Foodborne Disease Outbreak Surveillance System, 2011-2012 are the most recent years for which outbreak data are finalized.

Major Changes in 2013 Food Code

- Cut leafy greens and cut tomatoes require refrigeration for safety.
- Packaged food labels must include a major food allergen statement.
- Holding temperature for hot food drops from 140°F to 135°F.
- Egg pooling requirements change.
- Egg cooking temperature requirements change.

Major Changes in 2013 Food Code

- Raw or undercooked animal products are prohibited on a children's menu.
- Partial cooking now requires plan review and approval.
- Grill marking provisions are added.
- Glove change/hand washing requirements have changed.

Major Changes in 2013 Food Code

- Unattended cooking and hot holding is prohibited.
- Variance and HACCP plan required for sous vide cooking.

Cut Leafy Greens and Tomatoes

- What are "cut leafy greens"?
  - Leaves removed from head, cut, shredded, sliced, chopped, torn.
  - Doesn't include harvest cut whole leaves that were only cut once on the farm, or whole heads from which leaves were removed and discarded.
  - Doesn't include fresh herbs (parsley, cilantro…).
- Responsible for numerous outbreaks of salmonella and e. coli.
- Now considered potentially hazardous foods.
- Need refrigeration for safety.

Cut Tomatoes

- Whole tomatoes may still be stored/ripened at room temperature.
- Must refrigerate once tomato is sliced or cut.
- Recipes using cut tomatoes must be refrigerated.
- Processed food containing cut tomatoes must be refrigerated unless the manufacturer doesn't require refrigeration (sun dried tomatoes, will be marked on container).

Washing Produce

- Running water rinse required.
- If soaked or “crisped” a running water rinse must follow.

Major Food Allergens

- Can cause life-threatening allergic reactions.
- Packaged foods offered for sale must be labeled.
- Foods wrapped on a per order basis does NOT require labeling.
- Most customer self-service items must be labeled.
- Must educate food workers about major food allergen ingredients and risks.

Labeling must also include

- Name of food
- Ingredients
- Name/address of manufacturer or distributor
- Quantity of contents

- Recommended: Packaging date code for freshness and in case of recall.

Hot Food Holding Temperatures

- Research has shown upper limit of pathogen growth is around 125 ° F.
- Prior requirements was 140° F.
- Now is 135 °F.

Egg Pooling Changes

- Egg pooling are four or more eggs together and is prohibited unless pooled together immediately before cooking.
- Raw eggs must be cooked within 30 minutes after breaking, unless used in batters.
- Must use pasteurized eggs are required if recipes contain four or more eggs and is not cooking within 30 minutes after pooling.

More Eggs!

- Eggs cooked immediately after breaking for a single consumer order must be cooked to 145 °F.
- Eggs broken for multiple consumer orders must be cooked to 155 °F and must be cooked within 30 minutes after breaking. Includes quiche, flan, buffet and line scrambled eggs.
- For establishments ONLY serving highly susceptible populations (pre-school, elder care), undercooking eggs is prohibited.

Children's Menus

- Raw or undercooked eggs, meat, and seafood are prohibited.
- Raw or undercooked eggs, meat, seafood, and raw seed sprouts are prohibited in pre-schools and elder care facilities.

Partial Cooking (AKA Non-Continuous Cooking)

- Cooking food in which the heating of the food is intentionally halted so that it may be cooking and held for complete cooking at a later time.
- Requires a plan review/approval from the Health Dept
  - How to ensure thorough final cooking temperatures.
  - How to prevent cross contamination.

Grill Marking

- Heating not more than one minute per side.
- Not considered partial cooking as long as the food is:
  - Cooled immediately
  - Labeled and stored as raw animal product
  - Cooked to appropriate final temperature/time
  - Disposed if left over cooking/hot holding

Glove Changing & Hand Washing

- Prior: Hand wash required prior to putting on gloves.
- Now: No hand washing required when changing gloves if they are still at the same station doing the same task.
- Still requires gloves or utensil use for ready-to-eat foods.

Unattended cooking

- Prohibits unattended cooking unless monitoring is provided for cooking temperature or oven temperatures.
- Purpose is to prevent undercooking.

Sous Vide

- Method of cooking food sealed in airtight plastic bags in water baths for longer than normal cooking times.
- Must be included in HACCP plans to prevent bacterial growth, botulism in particular.

Sources

- Centers for Disease Control and Prevention (CDC). 2014. New CDC data on foodborne disease outbreaks. Retrieved on June 12, 2014 from http://www.cdc.gov/features/foodborne-diseases-data/.
- U.S. Food and Drug Administration (FDA). 2013. Food Code 2013. College Park, MD.

Gila County
Health & Emergency Services
Prevent. Promote. Protect.

GILA COUNTY DIVISION of HEALTH and EMERGENCY SERVICES

5515 South Apache Ave., Suite 100, Globe, AZ 85501
PHONE: (928) 402-8811 FAX: (928) 425-0794

Summary of Changes to Food Code

Chapter 2 Management and Personnel

Reportable illness sections were amended to add non-typhoidal *Salmonella* (NTS) as one of the reportable illnesses:

> The Food Code has added non-typhoidal *Salmonella* (NTS) as one of the now six designated organisms listed in the as having high infectivity via contamination of food by infected food employees. The new changes require food employees to report a diagnosis of non-typhoidal *Salmonella* (NTS), prompts the person in charge to exclude food employees with diagnosis of NTS, and provides conditions for reinstatement of a food employee who has been diagnosed with NTS. This change may require an update to the food establishment's written health policies and training.

Employees must report to person in charge about their health relating to diseases that are transmissible through food.

> Having been exposed to, including living in the same household, suspected source of a confirmed disease outbreak, ill or infected with any of:
>
> > Norovirus within 48 hours of last exposure
> > Shiga Toxin-Producing Escherichia Coli or Shigella within past 3 days of last exposure
> > Salmonella Typhi within past 14 days of last exposure
> > Hepatitis A virus within past 30 days of last exposure
>
> Has been exposed by attending/working in a setting where there is a confirmed disease outbreak, living in the same household where there is a confirmed disease outbreak.

Person in charge shall notify the Gila County Division of Health & Emergency Services when an employee is:

- Jaundiced and/or
- Diagnosed with a pathogen:
  - Norovirus
  - Hepatitis A virus
  - Shigella spp.
  - Shiga Toxin-Producing Escherichia Coli
  - Salmonella Typhi
  - Nontyphoidal Salmonella

Person in charge needs to explain how all employees need to comply with reporting responsibilities and the exclusion/restriction of foods (in particular food allergens).

Person in charge must verify foods delivered during non-operating hours are from approved sources and are placed in appropriate storage locations and maintained at required temperatures, protected from contamination, are unadulterated, and accurately present

Employees must be trained in food safety, including food allergy awareness.

Specified Cleaning Procedure for Hand Washing

Employees shall use the following cleaning procedure, for at least 20 seconds, in the order stated to clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands and arms:

1. Rinse under clean, running warm water.
2. Apply an amount of cleaning compound recommended by the cleaning compound manufacturer.
3. Rub together vigorously for at least 10 to 15 seconds while paying particular attention to removing soil from underneath the fingernails during the cleaning procedure, and creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, finger tips, and areas between the fingers.
4. Thoroughly rinse under clean, running warm water.
5. Immediately follow the cleaning procedure with thorough drying method (disposable paper towels or similar clean barriers when touching surfaces such as manually operated faucet handles or handle of restroom door).

Addition When to Wash:

- Before donning gloves to initiate a task that involves working with food.

New addition of section: Responding to Contamination Events

Food establishment shall have procedures to follow when responding to vomiting or diarrheal events that will minimize the spread of contamination and the exposure of employees, consumers, food, and surfaces.

Chapter 3 Food

A new provision allows bare hand contact with ready to eat foods that are subsequently going to be added to a product containing raw animal foods that will be fully cooked OR any other food product that will be subsequently cooked to a minimum of 145°F prior to consumption.

Amended to clarify that prior to sale or service, raw animal foods cooked using a non-continuous cooking process shall be cooked to a temperature and for a time as specified under ¶¶3-401.11 (A)-(C). Previous versions had required all products cooked under non-continuous conditions to be cooked to 165F.

Amended to add three new paragraphs to address the removal of reduced oxygen packaged (e.g. vacuum packed) frozen fish labeled that it should be kept frozen until use must be removed from its packaging before thawing to prevent *C. botulinum* toxin formation.

Amended ¶3-602.11(B)(2),(3),(5), and (7) to clarify the information that a label should include. The term “sub ingredients” was added to this subparagraph to clarify that individual component ingredients of a main ingredient must be disclosed in the statement of ingredients. This clarification helps to make clear that all individual ingredients in a packaged food will be disclosed in the statement of ingredients.

Chapter 4 Equipment, Utensils, and Linens

4-602.11 Equipment Food Contact Surfaces and Utensils
Amended to change the cleaning and sanitizing frequency for food contact surfaces or utensils that are in contact with a raw animal food that is a major food allergen such as fish, followed by other types of raw animal foods. With this change, in addition to evaluating the cooking temperature a concessioner will need to determine if the product is a major food allergen.

Amended to change the minimum temperature requirement for an iodine solution from "24°C (75°F)" to "20°C (68°F) to be consistent with EPA iodophor registration protocols (CFP 2008-III-010).

Chapter 7 Poisonous or Toxic Materials

Allows the use of ozone on fruits and vegetables according to 21 CFR 173.368.

Chapter 8 Compliance and Enforcement

Adds a requirement for the permit holder to post a sign or placard notifying the public that inspectional information is available for review upon request.

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ARF-2808 **Regular Agenda Item 3. C.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For: Jeffrey Hessenius, Finance Director

Submitted By: Jeannie Sgroi, Contracts Administrator, Finance Division

Department: Finance Division

Information

Request/Subject

Intergovernmental Agreement No. 062014 - Animal Control between Gila County and the City of Globe.

Background Information

The Gila County Health and Emergency Services Division Director, Michael O'Driscoll, received a request from the City of Globe Manager, Brent Billingsley, to initiate an Intergovernmental Agreement (IGA) between Gila County and the City of Globe for animal control services.

While Gila County has been providing animal control services to the City of Globe for a fee, there has not been a formal written agreement in place for those services.

Evaluation

By entering into Intergovernmental Agreement No. 062014 with the City of Globe, set fees for services outlined within the IGA are hereby defined.

Rabies and animal control is a statutory requirement of Gila County; therefore, the IGA term will commence upon the date first signed and shall terminate one year after signing. The IGA shall be renewed from year to year automatically at each termination date unless either party at any time terminates the IGA by giving the other party thirty (30) days' prior written notice.

Conclusion

Staff feels it is in the best interest of Gila County to establish an IGA with the City of Globe, for animal control services, in order to clearly define the animal control services that Gila County will provide to the City of Globe and at the fees, as described for those services, identified in IGA No. 062014.

Recommendation

Staff recommends approval of Intergovernmental Agreement No. 062014 with the City of Globe, to establish a formal written agreement of various animal control services Gila County will provide to the City of Globe, at specified rates for said services.

Suggested Motion

Information/Discussion/Action to approve Intergovernmental Agreement No. 062014 between Gila County and the City of Globe to establish services and fees provided by Gila County to the City of Globe for animal control services commencing on October 21, 2014, for a one-year term, with automatic renewals at the end of each term, at a cost of $40,000 per year, and either party may terminate the Agreement by giving the other party thirty days' prior written notice. **(Jeff Hessenius)**

Attachments

Intergovernmental Agreement No. 062014 with City of Globe for Animal Control

Legal Explanation

INTERGOVERNMENTAL AGREEMENT NO. 062014
BETWEEN
GILA COUNTY
AND
THE CITY OF GLOBE

THIS AGREEMENT is made and entered into effective this _____ day of _____ ___, 2014, by and between Gila County, a Political subdivision of the State of Arizona, hereinafter referred to as "County" and the City of Globe, an Arizona Municipal Corporation, hereinafter referred to as the "City".

RECITALS

WHEREAS, County is authorized, pursuant to A.R.S. §11-952 to contract for services or jointly exercise common powers for joint cooperative action; and

WHEREAS, City is authorized, pursuant to the Globe City Code to contract for services or jointly exercise common powers for joint cooperative action; and

WHEREAS, the City operates an animal enforcement program but is without the facilities to properly impound, care for, vaccinate, license and dispose of animals; and

WHEREAS, the County operates a County pound which includes impound, maintenance, vaccination, licensing and disposition of animals pursuant to A.R.S. § 11-1001, et seq.; and

WHEREAS, it is in the best interest of both parties to enter into this agreement whereby the County and the City cooperate with each other for the impoundment, licensing, vaccination, maintenance, and disposition of animals.

SCOPE

NOW, THEREFORE, in consideration of the mutual promises contained in this agreement, and of the mutual benefits to result therefrom, the parties agree as follows:

SECTION 1

All terms in this Intergovernmental Agreement (IGA) shall be given their definitions as stated in A.R.S. § 11-1001 through 11-1029.

SECTION 2

1. If City law enforcement personnel, in the performance of their duties, come into the custody of any cats or dogs, or if private citizens bring cats or dogs to the County pound, the County must accept all cats or dogs brought to the County Pound in Globe, Arizona by the City law enforcement personnel or private citizens.

2. County hours of operations are 8 A.M. to 5 P.M. for calls and patrol, during which time they will respond to all calls within the Globe city limits. After 5 P.M. and before 8:00 A.M., the globe Police Department will handle all calls unless the calls involve an animal bite or a vicious animal. An officer cannot handle animal bites or a vicious animal.

SECTION 3

The County will bring dogs and cats to the Pound under the following circumstances:

a. Unlicensed animals found running at large.

b. Animals exposed to animal cruelty, pursuant to Globe City Code.

c. Animals subject to quarantine after it has bitten a person or other animal.

d. Licensed animals impounded pursuant to the Gila County Animal Control Ordinance No.'s 01-3 and 01-4.

e. Suffering animals.

f. Unwanted animals.

The City may also bring dogs and cats to the Pound under the above-listed circumstances, provided the officer(s) can do so without exposure to undue risk. The City shall abide by the Gila County Animal Control Ordinance No.'s 01-3 and 01-4 when performing activities pursuant to this Section.

SECTION 4

The County will perform the following services for animals brought into the pound:

a. All cats and dogs impounded shall be given proper care and maintenance.

b. Each unlicensed cat or dog impounded shall be kept and maintained at the Pound for a minimum of seventy-two (72) hours unless earlier claimed by its owner.

c. Each animal exposed to animal cruelty impounded shall be kept and maintained at the Pound for a minimum of seventy-two (72) hours.

d. Each licensed animal impounded shall be kept and maintained at the Pound for a minimum of seven (7) days unless earlier claimed by its owner. The City and the County will attempt to notify or contact the owner within the seven (7) day period so the owner may reclaim the animal.

e. Unlicensed suffering animals impounded may be destroyed if destruction is necessary to prevent the dog or cat from suffering or to prevent the spread of disease.

f. Unvaccinated dogs or cats impounded shall be confined and quarantined for not less than ten (10) days to determine if the animal has rabies. The quarantine period shall start on the date of the bite incident. If the date of the bite is not known, the quarantine period shall start on the first day of impoundment.

The County may destroy any animal confined and quarantined for rabies observation prior to the termination of the minimum ten (10) day confinement period if:

1. The animal shows clear clinical signs of rabies, or
2. The animal's owner consents to its destruction for rabies testing.

If destruction does not occur, the animal shall be returned to its owner provided all applicable fees established by this IGA are paid.

g. Unwanted animals impounded, if healthy, may immediately be placed for adoption by the County but shall not be destroyed until after seventy-two (72) hours of impound.

SECTION 5

PURCHASE OF ANIMALS OR RECLAMATION OF ANIMALS BY THE OWNER:

a. Any impounded licensed animal may be reclaimed by its owner or such owner's agent provided that the person reclaiming the animal furnishes proof of his right to do so and pays all applicable fees set by state statute or the County. The current fees are as follows: An owner reclaiming an animal shall be charged $10.00 per day. The owner shall also pay a $20.00 impound fee (first offense), $45.00 impound fee (second offense), $85.00 impound fee (third offense and recurring) and the following fees as applicable:

1. If the license is expired, $30.00 if the animal is not spayed or neutered; $10.00 if the animal is spayed or neutered.
2. If rabies vaccination has expired, $25.00.
3. If the animal is reclaimed after a 10 day aggressive/quarantine, $200.00.

b. Any impounded unlicensed dog or cat may be purchased after the seventy-two (72) hour period.

SECTION 6

Persons adopting or reclaiming an animal must pay the applicable fees which currently are:

a. Dog – four (4) months or older:
Adoption fee $20.00; Rabies vaccination $25.00; License fee $30.00 for unspayed or unneutered dog, License fee for spayed or neutered, $10.00; Spay Deposit $40.00, Neuter Deposit $30.00 and Micro Chip $40.00.

b. Dog-under the age of four(4) months:
Adoption fee $20.00; Spay Deposit $40.00, Neuter Deposit $30.00 and Micro Chip $40.00.

c. Cat:
Adoption fee $20.00; Spay Deposit $30.00, Neuter Deposit $25.00.

SECTION 7

PAYMENT BY THE CITY OF GLOBE TO THE COUNTY:

The City shall pay the County an amount of $40,000.00 in eleven monthly payments in the amount of $3.333.33 due on the thirtieth day after the execution of the contract and the same day of each succeeding month thereafter except the last payment of each contract year will be $3,333.37 for the term of this Intergovernmental Agreement, for the scope of services as provided for in Sections 1 through 6.

SECTION 8

TERM:

This Agreement shall commence upon the date first signed and shall terminate one year after signing. This Agreement shall be renewed from year to year, automatically at each termination date, unless either party at any time, terminates this agreement by giving the other party thirty (30) days prior written notice of its intention to terminate the Agreement.

SECTION 9

Notices
All notices or demands upon any party to this agreement shall be in writing, unless other forms are designated elsewhere, and shall be delivered in person or sent by mail addressed as follows:

City of Globe
Attn: Terence O. Wheeler
150 N. Pine Street
Globe, Arizona 85501

Gila County Board of Supervisors
Attn: Don McDaniel, Jr.
1400 E. Ash Street
Globe, Arizona 85501

GENERAL TERMS

1. Indemnification: To the extent permitted by law, the CITY shall indemnify, defend and hold harmless, County, its officers, employees and agents, from and against any and all suits, actions, legal administrative proceedings, claims or demands and costs attendant thereto, arising out of any act, omission, fault of negligence by the CITY, its agents, employees or anyone under its direction or control or on its behalf in connection with performance of this Agreement, but only to the extent that such claims which result in vicarious/derivative liability to the County, are caused by the act, omission, negligence, misconduct or other fault of the City, its officers, officials, agents, employees or volunteers, provided, however, that the City shall have no obligation to indemnify the County for the County's passive negligence.

2. To the extent permitted by law the County shall indemnify, defend and hold harmless, CITY, its officers, employees and agents from and against any and all suits, actions, legal administrative proceedings, claims or demands and costs attendant thereto, arising out of any act, omission, fault of negligence by the County, its agents, employees or anyone under its direction or control or on its behalf in connections with performance of this Agreement, but only to the extent that such claims which result in vicarious/derivative liability to the City, are caused by the act, omission, negligence, misconduct or other fault of the County, its officers, officials, agents, employees or volunteers, provided, however, that the County shall have no obligation to indemnify the City for the City's passive negligence.

3. Termination: Either party may, at any time and without cause, cancel this Agreement by providing 30 days written notice to the other party.

4. Cancellation: This Agreement may be canceled pursuant to the provisions of A.R.S. §38-511. The parties hereby acknowledge notice of A.R.S. §38-511 which provides for cancellation of contracts for violation of the conflict of interest statute.

5. Compliance with All Laws: The parties shall comply with all federal, state and local laws, rules, regulations, standards and Executive Orders, without limitation to those designated within this Agreement. Any changes in the governing laws, rules and regulations during the term of this agreement shall apply but do not require an amendment.

6. Entire Agreement: This document constitutes the entire agreement between the parties pertaining to the subject matter hereof, and all prior or contemporaneous agreements and understandings, oral or written, are hereby superseded and merged herein. This Agreement may be modified, amended, altered or extended only by a written amendment signed by the parties.

6. The County and the CITY shall each maintain a budget to fulfill their obligations under this Intergovernmental Agreement.

7. The County shall furnish to the City a semi-annual listing of all animals brought to the Pound by the City. The listing shall include the date the animal was impounded and the amount of days the animal was maintained and final disposition of the animal.

IN WITNESS THEREOF, the parties to this Intergovernmental Agreement No 062014, have caused their names to be affixed hereto by their proper offices on the date indicated above.

GILA COUNTY BOARD OF SUPERVISORS

Michael A. Pastor, Chairman of the Board

ATTEST

Marian Sheppard, Clerk of the Board

APPROVED AS TO FORM

Deputy County Attorney/Civil Bureau Chief
for Bradley D. Beauchamp, County Attorney

CITY OF GLOBE

Terence O. Wheeler
Mayor

ATTEST

Shelly Salazar, City Clerk

APPROVED AS TO FORM

William J. Sims, City Attorney

GILA COUNTY ATTORNEY

Bradley D. Beauchamp

Re: County Attorney's Office approval of IGA pursuant to A.R.S. § 11-952(D).

To whom it may concern:

The County Attorney's Office has reviewed the Intergovernmental Agreement attached to this agenda item and has determined that it is in its "proper form" and "is within the powers and authority granted under the laws of this state to such public agency or public procurement unit" pursuant to A.R.S. § 11-952(D).

Explanation of the Gila County Attorney's Office Intergovernmental Agreement (IGA) Review

A.R.S. § 11-952(D) requires that

> every agreement or contract involving any public agency or public procurement unit of this state . . . before its execution, shall be submitted to the attorney for each such public agency or public procurement unit, who shall determine whether the agreement is in proper form and is within the powers and authority granted under the laws of this state to such public agency or public procurement unit.

In performing this review, the County Attorney's Office reviews IGAs to see that they are in "proper form" prior to their execution. "Proper form" means that the contract conforms to fundamental contract law, conforms to specific legislative requirements, and is within the powers and authority granted to the public agency. It does not mean that the County Attorney's Office approves of or supports the policy objectives contained in the IGA. That approval is solely the province of the public agency through its elected body.

Likewise, this approval is not a certification that the IGA has been properly executed. Proper execution can only be determined after all the entities entering into the IGA have taken legal action to approve the IGA. There is no statutory requirement for the County Attorney's Office to certify that IGAs are properly executed.

Nonetheless, it is imperative for each public agency to ensure that each IGA is properly executed because A.R.S. § 11-952(F) requires that "[a]ppropriate action … applicable to the governing bodies of the participating agencies approving or extending the duration of the … contract shall be necessary before any such agreement, contract or extension may be filed or become effective." This can be done by ensuring that the governing body gives the public proper notice of the meeting wherein action will be taken to approve the IGA, that the item is adequately described in the agenda accompanying the notice, and that the governing body takes such action. Any questions regarding whether the IGA has been properly executed may be directed to the County Attorney's Office.

Proper execution of IGAs is important because A.R.S. § 11-952(H) provides that "[p]ayment for services under this section shall not be made unless pursuant to a fully approved written contract." Additionally, A.R.S. § 11-952(I) provides that "[a] person who authorizes payment of any monies in violation of this section is liable for the monies paid plus twenty per cent of such amount and legal interest from the date of payment."

The public agency or department submitting the IGA for review has the responsibility to read and understand the IGA in order to completely understand its obligations under the IGA if it is ultimately approved by the public entity's board. This is because while the County Attorney's Office can approve the IGA as to form, the office may not have any idea whether the public agency has the capacity to actually comply with its contractual obligations. Also, the County Attorney's Office does not monitor IGA compliance. Hence the public entity or submitting department will need to be prepared to monitor their own compliance. A thorough knowledge of the provisions of the IGA will be necessary to monitor compliance.

Before determining whether an IGA contract "is in proper form," the County Attorney's Office will answer any questions or concerns the public agency has about the contract. It is the responsibility of the public agency or department submitting the IGA for review to ask any specific questions or address any concerns it has about the IGA to the County Attorney's Office at the same time they submit the IGA for review. Making such an inquiry also helps improve the County Attorney's Office review of the IGA because it will help focus the review on specific issues that are of greatest concern to the public agency. Failing to make such an inquiry when the agency does have issues or concerns will decrease the ability of the County Attorney's Office to meaningfully review the IGA.

ARF-2803 **Regular Agenda Item 3. D.**

Regular BOS Meeting

Meeting Date:	10/21/2014		
Submitted For:	Jacque Griffin, Asst. County Manager/Librarian	Submitted By:	Pam Beerens, Public Services Librarian, Asst County Manager/Library District
Department:	Asst County Manager/Library District	Division:	Library District
Fiscal Year:	2014-2015	Budgeted?:	Yes
Contract Dates Begin & End:	July 1, 2014 - June 30, 2015	Grant?:	No
Matching Requirement?:	No	Fund?:	Renewal

Information

Request/Subject

Library Service Agreements with Globe, San Carlos, and Young Libraries.

Background Information

The Gila County Library District contracts yearly with the eight affiliate public libraries to cooperate in the provision of library services to the citizens of the District. These Library Service Agreements serve as contracts for facilitating funding and resource sharing. Five Library Service Agreements were approved by the Board on August 5, 2014. These are the remaining three Library Service Agreements.

Evaluation

Library funding is based on the aggregate percentages of the four library service measures, from the baseline FY 2012 year along with a base amount for each of the community libraries. Due to the five percent decrease in revenue from the secondary tax for library assistance, the funding amounts to each of the eight affiliate libraries has been decreased by five percent. This year's funding totals are as follows: Globe Public Library - $107,920.00; San Carlos Public Library - $31,920.00; and Young Public Library - $52,820.00. The Library District distributes these funds in two installments; November 2014 and May 2015.

Conclusion

Approval of the Library Service Agreements facilitates funding and resource sharing with the affiliate libraries.

Recommendation

The Gila County District Librarian recommends the approval of the Library Service Agreements between the Gila County Library District and Globe Public Library, San Carlos Public Library, and Young Public Library for fiscal year 2014-2015.

Suggested Motion

(Motion to adjourn as the Board of Supervisors and convene as the Gila County Library District Board of Directors.) Information/Discussion/Action to approve Library Service Agreements between the Gila County Library District and the following three libraries to cooperate in the provision of library services to the citizens of the District for the period July 1, 2014, through June 30, 2015: Globe Public Library - $107,920; San Carlos Public Library - $31,920; and Young Public Library - $52,820. **(Jacque Griffin) (Motion to adjourn as the Library District Board of Directors and reconvene as the Board of Supervisors.)**

Attachments

Globe LSA

San Carlos LSA

Young LSA

Legal Explanation (Young LSA)

Legal Explanation (Globe, San Carlos)

GILA COUNTY LIBRARY DISTRICT
LIBRARY SERVICE AGREEMENT
JULY 1, 2014 TO JUNE 30, 2015

This Library Service Agreement ("Agreement") is entered into between the GILA COUNTY LIBRARY DISTRICT, hereinafter referred to as the "District," and the City of Globe, hereinafter referred to as the "CITY," and shall be for a period commencing July 1, 2014 to June 30, 2015.

WHEREAS, the Gila County Board of Supervisors has established a County Library District, pursuant to A.R.S. 11-901 et seq. and 48-3901 et seq.; and

WHEREAS, the District and the CITY recognize the need to cooperate in the provision of library services to the citizens of the District; and

WHEREAS, the CITY operates and maintains a library and it is the desire of the CITY to continue as a participating member of the District; and

WHEREAS, the parties wish to establish terms and conditions prior to distribution of District tax levied funds to participating CITIES.

NOW THEREFORE IT IS AGREED by and between the District and the CITY as follows:

1. All citizens of the District shall have full use of the library facilities and services.

2. All library materials purchased with District funds by the CITY, are the property of the CITY.

3. It is understood by both parties that officials, employees and agents of the District remain the sole responsibility of the District. It is further understood that the officials, employees and agents of the CITY remain the sole responsibility of the CITY.

4. Each party (as "indemnitor") agrees to indemnify, defend and hold harmless the other party (as "indemnitee") from and against any and all claims, losses, liability, costs or other expenses including reasonable attorney's fees (hereinafter collectively referred to as "claims") arising out of bodily injury of any person (including death) or property damage, but only to the extent that such claims which result in vicarious/derivative liability to the indemnitee, are caused by the act, omission, negligence, misconduct or other fault of the indemnitor, its officers, official agents, employees or volunteers provided, however, that the indemnitor shall have no obligation to indemnify the indemnitee for the indemnitor's passive negligence Insurance provisions set forth in this Agreement are separate and independent from the indemnity provisions of this Agreement, and neither the insurance provisions nor the indemnity provisions shall be construed in any way to limit the scope, magnitude, or enforcement of the other provisions, The indemnity provisions of this Agreement shall survive the termination of this Agreement.

For purposes of workers' compensation, an employee of a party to this Agreement, who works under the jurisdiction or control of, or who works within the jurisdictional boundaries of another party pursuant to this specific intergovernmental agreement, is deemed to be an employee of both the party who is his primary employer and the party under whose jurisdiction or control or within whose jurisdictional boundaries he is then working, as provided in A.R.S. §23-1022(D). The primary employer party of such employee shall be solely liable for payment of workers' compensation benefits for the purposes of this section, Each party herein shall comply with the provisions of A.R.S. § 23-1022(E) by posting the public notice required.

5. The CITY agrees to the following conditions:

   A. The CITY shall use the District funds to insure the payments of salaries, routine maintenance and upkeep and other necessary expenses of the CITY's library, pursuant to ARS 48 - 3901 et seq. Funds will not be used for capital improvement projects or major building repairs without prior approval from the Board of Directors of the Gila County Library District.

   B. The CITY shall annually submit to the Arizona State Library the Arizona Public Library Statistical Report as required by the State Library.

   C. The CITY shall support resource sharing among libraries by participating in intra-library and inter-library loan services as a borrower and lender of library materials.

   D. The CITY shall comply with any reasonable conditions or restrictions which the District or another participating library imposes with respect to loans of books, materials, or equipment to the CITY library.

   E. The CITY agrees to reimburse any other participating library for any losses and/or damage to books, materials, or equipment belonging to another participating library or the District, which occur while these items are in the possession and control of the CITY.

   F. The CITY's decision to participate in a countywide online system is evidenced by the authorized signature(s) on this Agreement. The CITY agrees to utilize the online system for: cataloging, circulation, online shared public access catalog, long-term loan of supplementary Library District materials, if applicable, and other online functions as may be implemented.

   G. The CITY shall insure that the Library Manager (Librarian) and staff understand and are proficient in all functions of the online system that they are responsible for by providing reasonable time for staff to attend training on the online system at the District's recommendation. Training will be overseen by, and coordinated through the District.

   H. CITY library staff agrees to attend and participate in at least three of the four quarterly countywide librarians meetings each year.

I. Legal Arizona Workers Act Compliance

The CITY hereby warrants that it will at all times during the term of this Contract comply with all federal immigration laws applicable to City's employment of its employees, and with the requirements of A.R.S. § 23-214 (A) (together the "State and Federal Immigration Laws"). The City shall further ensure that each subcontractor who performs any work for City under this contract likewise complies with the State and Federal Immigration Laws.

The District shall have the right at any time to inspect the books and records of the City and any subcontractor in order to verify such party's compliance with the State and Federal Immigration Laws.

Any breach of the City's or any subcontractor's warranty of compliance with the State and Federal Immigration Laws, or of any other provision of this section, shall be deemed to be a material breach of this Contract subjecting the City to penalties up to and including suspension or termination of this Contract. If the breach is by a subcontractor, and the subcontract is suspended or terminated as a result, the City shall be required to take such steps as may be necessary to either self-perform the services that would have been provided under the subcontract or retain a replacement subcontractor as soon as possible so as not to delay project completion.

The City shall advise each subcontractor of District's rights, and the subcontractor's obligations, under this Section 5.I by including a provision in each subcontract substantially in the following form: "Subcontractor hereby warrants that it will at all times during the term of this contract comply with all federal immigration laws applicable to Subcontractor's employees, and with the requirements of A.R.S. § 23-214 (A). Subcontractor further agrees that District may inspect the Subcontractor's books and records to insure that Subcontractor is in compliance with these requirements. Any breach of this paragraph by Subcontractor will be deemed to be a material breach of this contract subjecting Subcontractor to penalties up to and including suspension or termination of this contract."

Any additional costs attributable directly or indirectly to remedial action under this Section 5.I shall be the responsibility of the City.

6. The District will provide the following benefits and support services to the library:

   A. Opportunity to participate in a countywide online system subject to conditions specified in this Agreement. Operation of the countywide online system is a Library District function subject to oversight by the Board of Directors of the Library District, who will make final decisions regarding this system.

   B. Operate the online system continuously, notifying the participating library in advance of any scheduled shutdowns, should any be necessary for maintenance and backup routines.

   C. Provide internet access (connectivity) for both library staff and public computers

D. Coordination of countywide library development.

E. Continuing education opportunities for staff and volunteers.

F. Offer regular orientation training on the online system for all new staff at the affiliate libraries, as well as coordinate and oversee special update training for veteran staff.

G. Professional assistance and consultation services.

7. The CITY and the District acknowledge that the services performed have a value to the District and the CITY. In consideration of that value, the District agrees:

   A. To fund the CITY for library services, in the total amount of **$107,920.00** for fiscal year 2015.

   B. To distribute this amount in two installments Fifty-Three Thousand Nine Hundred Sixty Dollars ($53,960) on, November1, 2014 and Fifty-Three Thousand Nine Hundred Sixty Dollars ($53,960) May 1, 2015.

8. This Agreement may be renewed from year to year by mutual agreement of the parties involved.

9. This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and, it may be amended, modified or waived only by an instrument in writing signed by both parties.

10. This Agreement may be canceled pursuant to A.R.S. 38-511, the pertinent provisions of which are fully incorporated herein by reference.

11. Either party may terminate this Agreement by giving 30 days' notice to the other. Upon termination of this Agreement by either party, the CITY agrees to return to the owner, by the date of termination, any books, materials and equipment belonging to the Library District or other participating library, which had been entrusted to the possession or control of the CITY. Conversely, the Library District agrees to deliver to the CITY library, by the date of termination, any books, materials, and equipment belonging to the CITY library which had been entrusted to the possession or control of the Library District and to make reasonable, good faith efforts to return to the CITY library any books, materials and equipment belonging to the CITY library which had been entrusted to the possession or control of another participating library.

    Any dispute, controversy, claim, or cause of action arising out of or related to this Agreement shall be governed by Arizona law and may, but in no event need, be settled by submission with the consent of both parties to binding arbitration in accordance with the rules of the American Arbitration Association and the Arizona Uniform Arbitration Act, ARS 12 - 1501, et seq., and judgment

upon any award rendered by the arbitrators may be entered in the Superior Court of Gila County, or any such dispute, controversy, claim, or cause of action may be litigated in a court. The venue for any such dispute shall be Gila County, Arizona. Each party waives the right to object to venue in Gila County for any reason. Neither party shall be entitled to recover any of its attorneys' fees or other costs from the other party incurred in any such dispute, controversy, claim or cause of action, but each party shall bear its own attorneys' fees and costs, whether the same is resolved through arbitration, litigation in a court, or otherwise.

IN WITNESS THEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

CITY	GILA COUNTY LIBRARY DISTRICT
Mayor	Chairman, Board of Directors
ATTEST:	ATTEST:
CITY Clerk	Clerk of the Board
Date 8/12/14	Date

Pursuant to A.R.S. 11-952(D) the foregoing Agreement has been reviewed by the undersigned attorney for the CITY, who has determined that the Agreement is in proper form and is within the powers and authority granted under the laws of the State to the CITY.

CITY Attorney

Pursuant to A.R.S. 11-952(D) the foregoing Agreement has been reviewed by the undersigned attorney for the Gila County Library District, who has determined that the Agreement is in proper form and is within the powers and authority granted under the laws of the State to Gila County.

Deputy County Attorney

LIBRARY SERVICE AGREEMENT
BETWEEN
GILA COUNTY LIBRARY DISTRICT
AND
SAN CARLOS APACHE TRIBE

JULY 1, 2014 TO JUNE 30, 2015

This Library Service Agreement (the "Agreement") is entered into between the GILA COUNTY BOARD OF SUPERVISORS acting as the GILA COUNTY LIBRARY DISTRICT, hereinafter referred to as the "District," and the SAN CARLOS APACHE TRIBE, hereinafter referred to as the "Tribe," and shall be for a period commencing July 1, 2014 to June 30, 2015.

WHEREAS, the San Carlos Apache Tribe is a federally recognized tribe organized pursuant to the Indian Reorganization Act of June 18, 1934 (48 Stat. 984), as amended by the Act of June 15, 1935 (49 Stat. 378);

WHEREAS, the Gila County Board of Supervisors has established a County Library District, pursuant to A.R.S. 11-901 et seq. and 48-3901 et seq.; and

WHEREAS, the District and the Tribe recognize the need to cooperate in the provision of library services to the citizens of the District; and

WHEREAS, the Tribe operates and maintains a public library (the "Tribe's Library") and it is the desire of the Tribe to continue as a participating member of the District; and

WHEREAS, the parties wish to establish terms and conditions prior to distribution of District tax levied funds to participating Tribes.

NOW, THEREFORE, IT IS AGREED by and between the District and the Tribe as follows:

1. In consideration of District funds received by the Tribe, all citizens of the District shall have full use of the Tribe's library facilities and services.

2. All library materials purchased with District funds by the Tribe shall be the property of the Tribe.

3. It is understood by both parties that officials, employees and agents of the District remain the sole responsibility of the District. It is further understood that the officials, employees and agents of the Tribe remain the sole responsibility of the Tribe.

4. Each party (as "indemnitor") agrees to indemnify, defend and hold harmless the other party (as "indemnitee") from and against any and all claims, losses, liability, costs or other expenses including reasonable attorney's fees (hereinafter collectively referred to as "claims") arising out of bodily injury of any person (including death) or property damage, but only to the extent that such claims which result in vicarious/derivative liability to the indemnitee, are caused by the act, omission, negligence, misconduct or other fault of the indemnitor, its officers, official agents, employees or volunteers.

5. The Tribe agrees to the following conditions:

   A. The Tribe shall use the District's funds to insure the payments of salaries, routine maintenance and upkeep and other necessary expenses of the Tribe's library, pursuant to A.R.S. §48 - 3901 *et seq.* Tribe agrees not to use District's funds for capital improvement projects or major building repairs without prior approval from the Board of Directors of the Gila County Library District.
   B. The Tribe, by and through its Library Program, shall annually submit to the Arizona State Library, the Arizona Public Library Statistical Report as required by the State Library.

   C. The Tribe shall support resource sharing among libraries by participating in intra-library and inter-library as a borrower and lender of library materials.

   D. The Tribe shall comply with any reasonable conditions or restrictions that the District or another participating library imposes with respect to loans of books, materials, or equipment to the Tribe's Library.

   E. The Tribe agrees to reimburse any other participating library for any losses and/or damage to books, materials, or equipment belonging to another participating library or the District, which occur while these items are in the possession and control of the Tribe.

   F. The Tribe's decision to participate in the countywide online system is evidenced by the authorized signature(s) on this Agreement and the resolution of the Tribal Council of the Tribe providing such authorization, as attached and incorporated by this reference. This Agreement shall not be valid without the authorization of the Tribal Council in the form of its resolution. The Tribe agrees to utilize the online system for: cataloging, circulation, online shared public access catalog, long-term loan of

supplementary Library District materials, if applicable, and other online functions as may be implemented.

G. The Tribe shall ensure that the Tribe's Library Manager (Librarian) and staff understand and are proficient in all functions of the online system that they are responsible for by providing reasonable time for staff to attend training on the online system at the District's recommendation. Training will be provided by, and coordinated through the District.

H. Tribe agrees that its library staff shall attend and participate in at least three of the four quarterly countywide librarians meetings each year.

I. **Arizona Workers Act Compliance**
The Tribe hereby warrants that it will at all times during the term of this Contract comply with all federal immigration laws if applicable to Tribe's employment of its employees, and with the requirements of A.R.S. 23-214 (A), if applicable (together the "State and Federal Immigration Laws"). The Tribe further agrees not to subcontract any of the services provided by the Tribe's Library.

6. The District will provide the following benefits and support services to the Tribe's library:

A. The Tribe may participate in the countywide online system, subject to conditions specified in this Agreement. Operation of the countywide online system is a Library District function subject to oversight by the Board of Directors of the Library District, who will make final decisions regarding this system.

B. The District shall ensure continuous operation of and access to the online system, notifying the Tribe's library in advance of any scheduled shutdowns, should any be necessary for maintenance and backup routines.

C. The District shall further provide the Tribe's library with:

(1) Coordination of countywide library development;

(2) Continuing education opportunities for staff and volunteers;

(3) Regular orientation training on the online system for all new staff at the affiliate libraries, as well as coordinate and oversee special update training for veteran staff; and

(4) Professional assistance and consultation services.

7. The Tribe and the District acknowledge that the library services performed have a value to the District and the Tribe. In consideration of that value, the District agrees to:

   A. Fund library services, in the amount of **$31,920.00** for Fiscal Year 2015;

   B. Distribute this amount to the Tribe in two installments, in November 2014 and May 2015;

8. This Agreement may be renewed from year to year by mutual agreement of the parties involved.

9. Upon reasonable notice, the District shall have the right at any time to inspect the books and records of Tribe' and any subcontractor.

10. Any breach of Tribe's warranty of compliance with the State and Federal Immigration Laws, or of any other provision of this section, shall be deemed to be a material breach of this Agreement subjecting Tribe to penalties up to and including suspension or termination of this Agreement.

11. Any additional costs attributable directly or indirectly to remedial action under this Article shall be the responsibility of the Tribe.

12. This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and, it may be amended, modified or waived only by an instrument in writing signed by both parties.

13. This Agreement may be canceled pursuant to A.R.S. §38-511, the pertinent provisions of which are fully incorporated herein by reference.

14. Either party may terminate this Agreement by giving 30 days' notice to the other. Upon termination of this Agreement by either party, the Tribe agrees to return to the owner, by the date of termination, any books, materials and equipment belonging to the Library District or other participating library, which had been entrusted to the possession or control of the Tribe. Conversely, the Library District agrees to deliver to the Tribe's Library, by the date of termination, any books, materials, and equipment belonging to the Tribe's Library which had been entrusted to the possession or control of the Library District and to make reasonable, good faith efforts to return to the Tribe library any books, materials and equipment belonging to the Tribe's Library which had been entrusted to the possession or control of another participating library.

15. In the event of a dispute under this Agreement, the parties agree to make a good faith attempt to resolve the dispute prior to taking formal. In the event that such dispute, controversy, claim, or cause of action ("Dispute") arising out of or related to this Agreement cannot be settled, the Dispute may, but in no event need, be settled by submission with the consent of both parties to binding arbitration. Judgment upon any award rendered by the arbitrators may be entered in any court of competent jurisdiction. Neither party shall be entitled to recover any of its attorneys' fees or other costs from the other party incurred in any such dispute, controversy, claim or cause of action, but each party shall bear its own attorneys' fees and costs, whether the same is resolved through arbitration, litigation in a court, or otherwise. The Tribe does not agree to any arbitration by persons or parties or their assignees which are not a party to this Agreement, nor to any arbitration proceeding or other proceeding based on alleged tortious conduct, or for the imposition of incidental, consequential, exemplary or punitive damages or lost profits.

16. The provisions of this section shall govern and control this Agreement where such provisions are in conflict with any other provision of the Agreement.

17. Nothing in this Agreement shall be construed as a waiver of sovereign immunity by the San Carlos Apache Tribe, its consent to be sued, or its consent to the jurisdiction of any federal or state court.

IN WITNESS THEREOF, the parties have caused this agreement to be executed by their duly authorized representatives.

SAN CARLOS APACHE TRIBE

Terry Rambler
Chairman

ATTEST:

Tribal Council Secretary

9-16-14
Date

GILA COUNTY BOARD OF SUPERVISORS
As the: GILA COUNTY LIBRARY DISTRICT

Tommie C. Martin
Chairman

ATTEST:

Clerk of the Board

Date

The foregoing Agreement has been reviewed by the undersigned attorney for the Tribe, who has determined that the agreement is in proper form and is within the powers and authority of the Tribe.

Attorney for San Carlos Apache Tribe

Pursuant to A.R.S. 11-952(D) the foregoing agreement has been reviewed by the undersigned attorney for the Gila County Library District, who has determined that the agreement is in proper form and is within the powers and authority granted under the laws of the State to Gila County.

Deputy County Attorney, Gila County

GILA COUNTY LIBRARY DISTRICT
LIBRARY SERVICE AGREEMENT
JULY 1, 2014 TO JUNE 30, 2015

This agreement is entered into between the GILA COUNTY LIBRARY DISTRICT, hereinafter referred to as the "District," and the PLEASANT VALLEY COMMUNITY LIBRARY BOARD OF THE YOUNG PUBLIC LIBRARY, hereinafter referred to as the "Board" and shall be for a period commencing July 1, 2014 to June 30, 2015.

WHEREAS, the Gila County Board of Supervisors has established a County Library District, pursuant to A.R.S. 11-901 et seq. and 48-3901 et seq.; and

WHEREAS, the District and the Board recognize the need to cooperate in the provision of library services to the citizens of the District; and

WHEREAS, the Board operates and maintains a library and it is the desire of the Board to join the District and to continue as an established station of the District; and

WHEREAS, the parties wish to establish terms and conditions prior to distribution of District tax levied funds to participating boards.

NOW THEREFORE IT IS AGREED by and between the District and the Board as follows:

1. All citizens of the District shall have full use of the library facilities and services.

2. All library materials purchased with District funds by the Board, are the property of the Board.

3. It is understood by both parties that officials, employees and agents of the District remain the sole responsibility of the District. It is further understood that the officials, employees and agents of the Board remain the sole responsibility of the Board.

4. Each party (as "indemnitor") agrees to indemnify, defend and hold harmless the other party (as "indemnitee") from and against any and all claims, losses, liability, costs or other expenses including reasonable attorney's fees (hereinafter collectively referred to as "claims") arising out of bodily injury of any person (including death) or property damage, but only to the extent that such claims which result in vicarious/derivative liability to the indemnitee, are

caused by the act, omission, negligence, misconduct or other fault of the indemnitor, its officers, official agents, employees or volunteers.

5. The Board agrees to the following conditions:

   A. The Board shall use the District funds to insure the payments of salaries, routine maintenance and upkeep and other necessary expenses of the library, pursuant to ARS 48 - 3901 et seq. Funds will not be used for capital improvement projects or major building repairs without prior approval from the Board of Directors of the Gila County Library District. District funds may not be accumulated from year to year for capital projects. An annual written accounting shall be made to the District describing the manner and use of funds as required by the District.

   B. Because the Board receives public monies from the District, the Board shall conduct all business meetings in accordance with Arizona Open Meeting Laws, A.R.S. 38-431 et seq.

   C. The Board shall require that the library maintain a minimum of 24 public service hours each week. These hours may be inclusive of official holidays observed by Gila County.

   D. The Board shall annually submit to the Arizona State Library, the Arizona Public Library Statistical Report as required by the State Library.

   E. The Board shall support resource sharing among libraries by participating in intra-library and inter-library services as a borrower and lender of library materials.

   F. The Board shall comply with any reasonable conditions or restrictions which the District or another participating library imposes with respect to loans of books, materials, or equipment to the station library.

   G. The Board agrees to reimburse any other participating library for any losses and/or damage to books, materials, or equipment belonging to another participating library or the District, which occur while these items are in the possession and control of the station library.

   H. The Board's decision to participate in a countywide online system is evidenced by the authorized signature(s) on this Agreement. The Board agrees to utilize the online system for: cataloging, circulation, online shared public access catalog, long-term loan of supplementary Library District materials, if applicable, and other online functions as may be implemented.

   I. The Board shall insure that the Library Manager (Librarian) and staff understand and are proficient in all functions of the online system that they

are responsible for by providing reasonable time for staff to attend training on the online system at the District's recommendation. Training will be overseen by, and coordinated through the District.

J. The Board shall require library staff or a representative to attend and participate in at least three of the four quarterly countywide librarians meetings each year.

K. Legal Arizona Workers Act Compliance

The Board hereby warrants that it will at all times during the term of this Contract comply with all federal immigration laws applicable to Board's employment of its employees, and with the requirements of A.R.S. § 23-214 (A) (together the "State and Federal Immigration Laws"). Board shall further ensure that each subcontractor who performs any work for Board under this contract likewise complies with the State and Federal Immigration Laws.

The District shall have the right at any time to inspect the books and records of Board and any subcontractor in order to verify such party's compliance with the State and Federal Immigration Laws.

Any breach of Board's or any subcontractor's warranty of compliance with the State and Federal Immigration Laws, or of any other provision of this section, shall be deemed to be a material breach of this Contract subjecting Board to penalties up to and including suspension or termination of this Contract. If the breach is by a subcontractor, and the subcontract is suspended or terminated as a result, Board shall be required to take such steps as may be necessary to either self-perform the services that would have been provided under the subcontract or retain a replacement subcontractor as soon as possible so as not to delay project completion.

The Board shall advise each subcontractor of District's rights, and the subcontractor's obligations, under this Article by including a provision in each subcontract substantially in the following form: "Subcontractor hereby warrants that it will at all times during the term of this contract comply with all federal immigration laws applicable to Subcontractor's employees, and with the requirements of A.R.S. § 23-214 (A). Subcontractor further agrees that District may inspect the Subcontractor's books and records to insure that Subcontractor is in compliance with these requirements. Any breach of this paragraph by Subcontractor will be deemed to be a material breach of this contract subjecting Subcontractor to penalties up to and including suspension or termination of this contract."

Any additional costs attributable directly or indirectly to remedial action under this Article shall be the responsibility of the Board.

6. The District will provide the following benefits and support services to the library:

A. Opportunity to participate in a countywide online system subject to conditions specified in this agreement. Operation of the countywide

online system is a Library District function subject to oversight by the Board of Directors of the Library District, who will make final decisions regarding this system.

B. Operate the online system continuously, notifying the participating library in advance of any scheduled shutdowns, should any be necessary for maintenance and backup routines.

C. Provide internet access (connectivity) for both library staff and public computers

D. Coordination of countywide library development.

E. Continuing education opportunities for staff and volunteers.

F. Offer regular orientation training on the online system for all new staff at the affiliate libraries, as well as coordinate and oversee special update training for veteran staff.

G. Professional assistance and consultation services.

7. The Board and the District acknowledge that the services to be performed have a value to the District and to the Board. In consideration of that value, the District agrees:

   A. To pay the Board an amount not to exceed **$52,820.00** for library services, for fiscal year 2015.

   B. To distribute this amount in two installments, November 2014, and May 2015.

8. This agreement may be renewed from year to year by mutual agreement of the parties involved.

9. This agreement contains the entire agreement of the parties with respect to the subject matter hereof and, it may be amended, modified or waived only by an instrument in writing signed by both parties.

10. This agreement may be canceled pursuant to A.R.S. 38-511, the pertinent provisions of which are fully incorporated herein by reference.

11. Either party may terminate this Agreement by giving 30 days' notice to the other. Upon termination of this Agreement by either party, the Board agrees to return to the owner, by the date of termination, any books, materials and equipment belonging to the Library District or other participating library, which had been entrusted to the possession or control of the Board. Conversely, the Library District agrees to deliver to the station library, by the date of termination, any books, materials, and equipment belonging to the

station library which had been entrusted to the possession or control of the Library District and to make reasonable, good faith efforts to return to the Board any books, materials and equipment belonging to the library which had been entrusted to the possession or control of another participating library.

IN WITNESS THEREOF, the parties have caused this agreement to be executed by their duly authorized representatives.

PLEASANT VALLEY COMMUNITY LIBRARY BOARD	GILA COUNTY LIBRARY DISTRICT
Polly A. Hageman	
Chairman of the Board	Chairman, Board of Directors
ATTEST:	ATTEST:
Secretary of the Board	Clerk of the Board
Date	Date

The foregoing agreement has been reviewed by the undersigned attorney for the Gila County Library District, who has determined that the agreement is in proper form and is within the powers and authority granted under the laws of the State to Gila County.

Deputy County Attorney, Gila County

GILA COUNTY ATTORNEY

Bradley D. Beauchamp

Re: County Attorney's Office "approval as to form" of contract or agreement.

To whom it may concern:

The County Attorney's Office has reviewed the contract or agreement attached to this agenda item and has determined that it is in its proper form and is within the powers and authority granted under the laws of this state to the public agency requesting the County Attorney's Office review.

Explanation of the Gila County Attorney's Office "Approval as to Form" Review

The Gila County Attorney's Office is often called upon to review contracts and other agreements between public entities represented by the County Attorney and private vendors, contractors, and individuals.

In performing this review, the County Attorney's Office reviews these contracts to see that they are in "proper form" prior to their execution. "Proper form" means that the contract conforms to fundamental contract law, conforms to specific legislative requirements, and is within the powers and authority granted to the public agency. It does not mean that the County Attorney's Office approves of or supports the policy objectives contained in the contract. That approval is solely the province of the public agency through its elected body.

The public agency or department submitting the contract for review has the responsibility to read and understand the contract in order to completely understand its obligations under the contract if it is ultimately approved by the public entity's board. This is because while the County Attorney's Office can approve the contract as to form, the office may not have any idea whether the public agency has the capacity to actually comply with its contractual obligations. Also, the County Attorney's Office does not monitor contract compliance. Hence the public entity or

submitting department will need to be prepared to monitor their own compliance. A thorough knowledge of the provisions of the contract will be necessary to monitor compliance.

Before signing a contract "approved as to form," the County Attorney's Office will answer any questions or concerns the public agency has about the contract. It is the responsibility of the public agency or department submitting the contract for review to ask any specific questions or address any concerns it has about the contract to the County Attorney's Office at the same time they submit the contract for review. Making such an inquiry also helps improve the County Attorney's Office review of the contract because it will help focus the review on specific issues that are of greatest concern to the public agency. Failing to make such an inquiry when the agency does have issues or concerns will decrease the ability of the County Attorney's Office to meaningfully review the agreement.

GILA COUNTY ATTORNEY

Bradley D. Beauchamp

Re: County Attorney's Office approval of IGA pursuant to A.R.S. § 11-952(D).

To whom it may concern:

The County Attorney's Office has reviewed the Intergovernmental Agreement attached to this agenda item and has determined that it is in its "proper form" and "is within the powers and authority granted under the laws of this state to such public agency or public procurement unit" pursuant to A.R.S. § 11-952(D).

Explanation of the Gila County Attorney's Office Intergovernmental Agreement (IGA) Review

A.R.S. § 11-952(D) requires that

> every agreement or contract involving any public agency or public procurement unit of this state . . . before its execution, shall be submitted to the attorney for each such public agency or public procurement unit, who shall determine whether the agreement is in proper form and is within the powers and authority granted under the laws of this state to such public agency or public procurement unit.

In performing this review, the County Attorney's Office reviews IGAs to see that they are in "proper form" prior to their execution. "Proper form" means that the contract conforms to fundamental contract law, conforms to specific legislative requirements, and is within the powers and authority granted to the public agency. It does not mean that the County Attorney's Office approves of or supports the policy objectives contained in the IGA. That approval is solely the province of the public agency through its elected body.

Likewise, this approval is not a certification that the IGA has been properly executed. Proper execution can only be determined after all the entities entering into the IGA have taken legal action to approve the IGA. There is no statutory requirement for the County Attorney's Office to certify that IGAs are properly executed.

Nonetheless, it is imperative for each public agency to ensure that each IGA is properly executed because A.R.S. § 11-952(F) requires that "[a]ppropriate action … applicable to the governing bodies of the participating agencies approving or extending the duration of the … contract shall be necessary before any such agreement, contract or extension may be filed or become effective." This can be done by ensuring that the governing body gives the public proper notice of the meeting wherein action will be taken to approve the IGA, that the item is adequately described in the agenda accompanying the notice, and that the governing body takes such action. Any questions regarding whether the IGA has been properly executed may be directed to the County Attorney's Office.

Proper execution of IGAs is important because A.R.S. § 11-952(H) provides that "[p]ayment for services under this section shall not be made unless pursuant to a fully approved written contract." Additionally, A.R.S. § 11-952(I) provides that "[a] person who authorizes payment of any monies in violation of this section is liable for the monies paid plus twenty per cent of such amount and legal interest from the date of payment."

The public agency or department submitting the IGA for review has the responsibility to read and understand the IGA in order to completely understand its obligations under the IGA if it is ultimately approved by the public entity's board. This is because while the County Attorney's Office can approve the IGA as to form, the office may not have any idea whether the public agency has the capacity to actually comply with its contractual obligations. Also, the County Attorney's Office does not monitor IGA compliance. Hence the public entity or submitting department will need to be prepared to monitor their own compliance. A thorough knowledge of the provisions of the IGA will be necessary to monitor compliance.

Before determining whether an IGA contract "is in proper form," the County Attorney's Office will answer any questions or concerns the public agency has about the contract. It is the responsibility of the public agency or department submitting the IGA for review to ask any specific questions or address any concerns it has about the IGA to the County Attorney's Office at the same time they submit the IGA for review. Making such an inquiry also helps improve the County Attorney's Office review of the IGA because it will help focus the review on specific issues that are of greatest concern to the public agency. Failing to make such an inquiry when the agency does have issues or concerns will decrease the ability of the County Attorney's Office to meaningfully review the IGA.

ARF-2829 **Regular Agenda Item 3. E.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Reporting Period: September 30, 2014

Submitted For: Marian Sheppard, Clerk

Submitted By: Marian Sheppard, Clerk, Clerk of the Board of Supervisors

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Information

Subject

September 30, 2014, Board of Equalization Meeting Minutes

Suggested Motion

(Motion to adjourn as the Gila County Board of Supervisors and convene as the Gila County Board of Equalization.) Information/Discussion/Action to approve the September 30, 2014, Board of Equalization's meeting minutes. **(Motion to adjourn as the Gila County Board of Equalization and reconvene as the Gila County Board of Supervisors.)**

Attachments

9-30-14 BOE Minutes

BOARD OF EQUALIZATION MINUTES
GILA COUNTY, ARIZONA

Date: September 30, 2014

MICHAEL A. PASTOR Chairman	**MARIAN E. SHEPPARD** Clerk of the Board
TOMMIE C. MARTIN Vice-Chairman	By: Marian E. Sheppard Clerk of the Board
JOHN D. MARCANTI Member	Gila County Courthouse Globe, Arizona

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PRESENT: Michael A. Pastor, Chairman; Tommie C. Martin, Vice-Chairman (via ITV); John D. Marcanti, Member; Marian E. Sheppard, Clerk of the Board; Laurie J. Kline, Deputy Clerk; Deborah Hughes, Assessor; Lisa Romo, Chief Deputy Assessor

Item 1 – CALL TO ORDER

Chairman Pastor called this hearing to order at 1:30 p.m.

Item 2 – AGENDA ITEMS:

A. Information/Discussion/Action to consider an appeal by Nicholas Brotcke for the Nicholas and Maureen Brotcke Family Trust regarding the Assessor's valuation of tax parcel number 302-41-001A, as shown on the Assessor's Notice of Value filed for tax year 2015.

Chairman Pastor called on the petitioners, Nicholas and Maureen Brotcke, to present their appeal; however, Mr. Brotcke asked that the Assessor's Office first present their findings.

Lisa Romo, Chief Deputy Assessor, stated that Nicholas Brotcke, on behalf of the Nicholas and Maureen Brotcke Trust, is appealing the Assessor's valuation of the subject property based on a cost approach, income approach and "other" as stated on line #7 of the Petition for Review of Real Property Valuation that was submitted to the Board of Equalization. She advised that the petitioner provided an Income and Expense Statement and three Federal Tax Form 1040 Schedule Cs titled "Profit or Loss from Business" for tax years 2011, 2012, and 2013 to support their appeal to the Board of Equalization. The Assessor has set the full cash value (FCV) of the subject property at $250,772 and the limited property value (LPV) at $151,869. The petitioners have set the FCV and the LCV at $143,638.

Mr. Brotcke's initial appeal to the Assessor was denied because: 1) commercial income was not provided per Arizona law, 2) interior access to the property was not granted at the field inspection, and 3) cost data to support the valuation amount of $143,638 was not provided. Ms. Romo proceeded to review the Assessor's packet of information that was provided to each Board member and she explained the method used to value this particular commercial property which is an antique store and recreational vehicle (RV) storage facility with Commercial Three District (C3) zoning. It is .91 of an acre in size, and located on a corner of a busy highway. Ms. Romo noted that the Schedule Cs are not inclusive of all business income as they do not contain 1040s or signatures. Additionally, appealing the property valuation on the "income approach" is typically not valid for owner occupants, as is the case with the Brotckes. In this case, the petitioner would be asked to provide income relevant to similar type antique or retail stores and RV storage businesses. No information was provided to correlate the loss of income as shown on the Schedule Cs with a value amount of $143,638. There is further disclosure under the income approach by the petitioner regarding family health issues; however, the Assessor chose to not address those issues. The petitioner has stated to the Assessor that the business is a "hobby" business and is operated approximately 12 hours per week. Ms. Romo advised that this property is open two days per week, so it is not typical of a commercial business. A property value of $42,000 was listed on the Income and Expense Statement. Ms. Romo noted that amount was the initial purchase price in the 1970s; however, the petitioner did not provide information to show the replacement cost of the buildings at today's cost, nor was an explanation provided by the petitioner as to their opinion of the property's current value of $143,638. The Assessor has accounted for both age and condition of the improvements by listing them as poor condition and low quality. The petitioner disclosed that the improvements have not been maintained; however, the Assessor has documentation from past years' appeals that the parcel has remained in an unkempt state for over 10 years. The parcel is surrounded by a barbed wire, chain link fence with a gate, which is atypical for a retail establishment. The Assessor further chose to analyze land sales despite the parcel having a unitary valuation. Ms. Romo continued reviewing the packet of information page by page.

Ms. Romo reviewed sales of comparable properties and she noted that they are properties of a similar size, but are not zoned for commercial use. As a result, the Assessor has made a zoning adjustment to come up with a median value for land. The improvement cost value at low quality, poor condition of the improvements was also considered and a median land value was added to arrive at a lowest, supportable value of $206,061 for the property of which that amount is being recommended to the Board of Equalization.

Mr. Brotcke argued that there was no justification for the increase in the property value for the following reasons: The RV storage business continues to

diminish and it generates at the most $300-$400 per year. This antique business, known as the Pioneer Village Trading Post, has been operating for 43 years at the same location; however, it generates little revenue because it is operated as "an old fashioned store", unlike other similar local businesses. There is a lot of customer traffic but not a lot of sales. Due to personal circumstances of the Brotckes, "no profit can be produced" from this business. It should not be compared to other local, similar-type businesses, but rather the value should be based upon "business income profit" as outlined in the documentation that was submitted to the Board of Equalization for this hearing. If the Board upholds the Assessor's opinion of value, the Brotckes will be forced to close their business, which they believe has been a long-term asset to the community of Payson.

Mr. Brotcke advised the Board that he has appealed his property valuations to federal tax court on two separate occasions, and he may consider doing it again. Supervisor Marcanti asked Mr. Brotcke if there is a pending lawsuit against Gila County, to which Mr. Brotcke replied there is not a pending lawsuit. He then read aloud a letter he wrote in support of his appeal.

Assessor Deborah Hughes advised that this particular property received an "override" on its value for the past 10 plus years. The override basically froze the property value; however, that override has been removed which has caused the value amount to increase from last year to this year. Vice-Chairman Martin expressed a concern with the situation of the Brotcke's property value almost doubling. Ms. Hughes replied that it is her opinion that the Brotckes received a "discount for some 10 years." She recently has removed the "override" status on many other commercial properties. There have been land sales that will be applied next year which will cause the values of other commercial properties to be increased. Chairman Pastor questioned the reason overrides were placed on so many properties. Ms. Hughes replied that it was the previous Assessor's decision to apply the override status.

Vice-Chairman Martin concluded by stating that the Board's decision must be based on whether or not the Brotckes have been treated equally and fairly; it is not the Board's decision to decide on the "right" value as that is the purpose of tax court.

Upon motion by Vice-Chairman Martin, seconded by Supervisor Marcanti, the Board unanimously upheld the Assessor's recommended value of $206,061 for parcel number 302-41-001A for tax year 2015.

Item 3 – CALL TO THE PUBLIC: **Call to the Public is held for public benefit to allow individuals to address the Board of Equalization on any issue within the jurisdiction of the Board of Equalization. Board members may not discuss items that are not specifically identified on the agenda. Therefore, pursuant to Arizona Revised Statute §38-431.01(H), at the**

conclusion of an open call to the public, individual members of the Board of Equalization may respond to criticism made by those who have addressed the Board, may ask staff to review a matter or may ask that a matter be put on a future agenda for further discussion and decision at a future date.

There were no comments from the public.

There being no further business to come before the Board of Equalization, Chairman Pastor adjourned the hearing at 2:30 p.m.

APPROVED:

_____

Michael A. Pastor, Chairman

ATTEST:

_____

Marian Sheppard, Clerk of the Board

ARF-2811 **Consent Agenda Item 4. A.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For:	Jeffrey Hessenius, Finance Director	Submitted By:	Jeannie Sgroi, Contracts Administrator, Finance Division
Department:	Finance Division		
Fiscal Year:	2013/2014 and 2014/2015	Budgeted?:	Yes
Contract Dates Begin & End:	January 7, 2014 to January 6, 2015	Grant?:	No
Matching Requirement?:	No	Fund?:	Renewal

Information

Request/Subject

Amendment No. 2 to Professional Services Agreement No. 062813-Medical Examiner Services for Gila County.

Background Information

On January 7, 2014, Gila County entered into Professional Services Agreement No. 062813 with Dr. Mark Fischione for Medical Examiner Services for Gila County. The contract was issued for a period of one year in a not to exceed amount of $30,000 without prior written approval from Gila County. Additionally, the contract allows for the option to renew the contract term for three additional one-year periods. During the first four months of the contract term, an amount of $26,320 had been expended.

On June 24, 2014, the Board of Supervisors approved Amendment No. 1 to increase the total contract by an additional $40,000 for a new total contract amount of $70,000.

Evaluation

As of October 2014, there is an available balance of $13,450 on Professional Services Agreement No. 062813. In order to cover the remainder of the contract term, which expires on January 6, 2015, Amendment No. 2 has been prepared to increase the total contract amount by an additional $30,000 for a new total contract amount of $100,000.

Conclusion

As there is no way to predict the costs that will be incurred during the course of the contract term, Amendment No. 2 has been issued to increase the contract amount from $70,000 to $100,000 for the remainder of the contract term, which expires on January 6, 2015.

Recommendation

Staff recommends the approval of Amendment No. 2 to increase the contract amount of Professional Services Agreement No. 062813 with Dr. Mark Fischione for Medical Examiner Services for Gila County.

Suggested Motion

Approval of Amendment No. 2 to Professional Services Contract No. 062813-Medical Examiner Services between Gila County and Mark A. Fischione, M.D., PLC to increase the contract amount from $70,000 to $100,000 to cover the remainder of the original contract term which expires on January 6, 2015.

Attachments

Amendment No. 2 to Professional Services Agreement No. 062831 with Mark Fischione

Amendment No. 1 to Professional Services Agreement No. 062831 with Mark Fischione

Professional Services Agreement No. 062831-Medical Examiner Services with Dr. Fischione

Legal Explanation

Tommie C. Martin, District I Supervisor
610 E. Highway 260, Payson, AZ 85541
(928) 474-2029 Ext. 7100

Michael A. Pastor, District II Supervisor
1400 E. Ash St. Globe, AZ. 85501
(928) 425-3231 Ext. 8753

John D. Marcanti, District III Supervisor
1400 E. Ash St., Globe, AZ 85501
(928)425-3231 Ext. 8511

GILA COUNTY
www.gilacountyaz.gov

Don E. McDaniel Jr., County Manager,
1400 E. Ash St., Globe, AZ 85501
Phone (928) 425-3231 Ext.8761

Jeff Hessenius, Finance Director
1400 E. Ash St., Globe, AZ 85501
(928)425-3231 Ext. 8743

FAX (928) 425-8104
TTY: 7-1-1

PROFESSIONAL SERVICES CONTRACT NO. 062813
MEDICAL EXAMINER SERVICES
BETWEEN
GILA COUNTY AND MARK A. FISCHIONE, M.D., PLC

AMENDMENT NO. 2

Effective January 07, 2014, Gila County and Mark A. Fischione, M.D., PLC, entered into a contract whereby Dr. Fischione would provide medical examiner services for the Gila County Health and Emergency Services Department.

The contract was executed for a not to exceed without written authorization amount of $30,000.

Amendment No. 1 was approved and executed, on June 24, 2014, by the Gila County Board of Supervisors, to increase the contract amount by Forty-Thousand dollars ($40,000), for a new, not to exceed without written authorization, contract amount of Seventy Thousand dollars ($70,000).

The cost to date for the first eight months of the contract term is $56,550, which leaves an available balance on the current contract term of $13,450.00. There are four months remaining on the existing contract term.

Amendment No. 2 will serve to increase the contract amount by Thirty Thousand dollars ($30,000), for a new, not to exceed without written authorization, contract amount of One Hundred Thousand dollars ($100,000), for the contract term from January 07, 2014, to January 06, 2015.

All other terms, conditions and provisions of the original Contract shall remain in full force and effect during the term of the contract.

IN WITNESS WHEREOF, three (3) identical counterparts of this amendment, each which shall include original signatures and for all purposes be deemed an original thereof, have been duly executed by the parties hereinabove named, on this _____ day of _____, 2014.

GILA COUNTY BOARD OF SUPERVISORS:

_____

Michael A. Pastor, Chairman of the Board

MEDICAL EXAMINER:

Mark A. Fischione MD, PLC

Mark A. Fischione, M.D., PLC.

ATTEST:

_____

Marian Sheppard, Clerk of the Board of Supervisors

APPROVED AS TO FORM:

_____

Bryan B. Chambers, Deputy County Attorney/Civil Bureau Chief
for Bradley D. Beauchamp, County Attorney

Tommie C. Martin, District I Supervisor
610 E. Highway 260, Payson, AZ 85541
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TTY: 7-1-1

PROFESSIONAL SERVICES CONTRACT NO. 062813
MEDICAL EXAMINER SERVICES
BETWEEN
GILA COUNTY AND MARK A. FISCHIONE, M.D., PLC

AMENDMENT NO. 1

Effective January 07, 2014, Gila County and Mark A. Fischione, M.D., PLC, entered into a contract whereby Dr. Fischione would provide medical examiner services for the Gila County Health and Emergency Services Department.

The contract was executed for a not to exceed without written authorization amount of $30,000. The cost to date for the first five months of the contract term is approximately $27,000.00. Amendment No. 1 will serve to increase the contract amount by Forty-Thousand dollars ($40,000), for a new not to exceed without written authorization contract amount of Seventy Thousand dollars ($70,000).

Amendment No. 1 will increase the contract amount by ~~$30,000~~ $40,000 for a new total contract amount of $70,000 for the contract term from January 07, 2014, to January 06, 2015.

All other terms, conditions and provisions of the original Contract shall remain in full force and effect during the term of the contract.

IN WITNESS WHEREOF, three (3) identical counterparts of this amendment, each which shall include original signatures and for all purposes be deemed an original thereof, have been duly executed by the parties hereinabove named, on this 24th day of June, 2014.

GILA COUNTY BOARD OF SUPERVISORS:

Michael A. Pastor, Chairman of the Board

MEDICAL EXAMINER:

Mark A. Fischione, M.D., PLC.

ATTEST:

Marian Sheppard, Clerk of the Board of Supervisors

APPROVED AS TO FORM:

Bryan B. Chambers, Deputy Attorney Principal
for Bradley D. Beauchamp, County Attorney

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TTY: 7-1-1

GILA COUNTY
www.gilacountyaz.gov

GILA COUNTY ATTORNEY
1400 E. ASH STREET, GLOBE, ARIZONA, 85501

PROFESSIONAL SERVICES AGREEMENT NO. 062813
GILA COUNTY MEDICAL EXAMINER

THIS AGREEMENT, made and entered into this 7TH day of January, 2014 by and between Gila County a political subdivision of the State of Arizona, hereinafter designated the **County,** and **Mark A. Fischione, M.D.,PLC**, of the City of Scottsdale, County of Maricopa, State of Arizona, hereinafter designated the ***Medical Examiner***.

WITNESSETH: That the Medical Examiner, for and in consideration of the sum to be paid him by the County, in the manner and at the time hereinafter provided, and of the other covenants and agreements herein contained, hereby agrees, for himself, his heirs, administrators, successors, and assigns as follows:

That he is licensed and otherwise legally and professionally qualified to be appointed as Gila County Medical Examiner and Forensic Pathologist for Gila County, Arizona.

ARTICLE 1 – SCOPE OF SERVICES: The Medical Examiner agrees to provide Medical Examiner Services and **Forensic Pathologist Services** to Gila County pursuant to A.R.S. § 11-594, A.R.S. § 11-600, and A.R.S. § 36-861.

Duties of County Medical Examiner

A. The county medical examiner or alternate medical examiner shall direct a death investigation, shall determine whether an external examination or autopsy is required and shall:

1. Take charge of the dead body.
2. Certify to the cause and manner of death following completion of the death investigation, unless the medical examiner or alternate medical examiner determines there is no jurisdiction pursuant to section A.R.S. § 11-593, reduce the findings to writing and promptly make a full report on forms prescribed for that purpose.
3. Have subpoena authority for all documents, records and papers deemed useful in the death investigation.
4. Execute a death certificate provided by the state registrar of vital statistics indicating the cause and the manner of death for those bodies for which a death investigation has been conducted and jurisdiction is assumed.

5. Give approval for cremation of a dead body after a death investigation and record the approval on the death certificate.

6. Notify the county attorney or other law enforcement authority when death is found to be from other than natural causes.

7. Carry out the duties specified under Section 28-668.

8. Carry out the duties specified under Title 36, Chapter 7, Article 3.

9. Observe all policies adopted by the board of supervisors regarding conflicts of interest and disclosure of non-county employment.

B. The county medical examiner or alternate medical examiner may:

1. Assign to a medical death investigator or other qualified personnel all aspects of a death investigation except the performance of autopsies.

2. Authorize forensic pathologists to perform examinations and autopsies. The medical examiner or alternate medical examiner may authorize medical students or residents and fellows in pathology training to perform autopsies under the supervision of a licensed physician who is board certified in anatomic pathology, pursuant to procedures adopted by the county medical examiner or alternate medical examiner. Authorization and the amount to be paid by the county for pathology services are subject to approval of the board of supervisors.

3. Delegate any power, duty or function whether ministerial or discretionary vested by this chapter in the medical examiner or alternate medical examiner to a person meeting the qualifications prescribed in this chapter who is employed by or who has contracted with the county to provide death investigation services. The medical examiner or alternate medical examiner shall be responsible for the official acts of the person designated pursuant to this section and shall act under the name and authority of the medical examiner or alternate medical examiner.

4. Authorize the taking of organs and tissues as they prove to be usable for transplants, other treatment, therapy, education or research if all of the requirements of Title 36, Chapter 7, Article 3 are met. The medical examiner or alternate medical examiner shall give this authorization within a time period that permits a medically viable donation.

5. Authorize licensed physicians, surgeons or trained technicians to remove parts of bodies provided they follow an established protocol approved by the medical examiner or alternate medical examiner.

6. Limit the removal of organs or tissues for transplants or other therapy or treatment if, based on a review of available medical and investigative information within a time that permits a medically viable donation, the medical examiner or alternate medical examiner makes an initial determination that their removal would interfere with a medical examination, autopsy or certification of death. Before making a final decision to limit the removal of organs, the medical examiner or alternate medical examiner shall consult with the organ procurement organization. After the consultation and when the organ procurement organization provides information that the organ procurement organization reasonably believes could alter the initial decision and at the request of the organ procurement organization, the medical examiner or alternate medical examiner shall conduct a physical examination of the body. If the medical examiner or alternate medical examiner limits the removal of organs, the medical examiner or alternate medical examiner shall maintain documentation of this decision and shall make the documentation available to the organ procurement organization.

C. A county medical examiner or alternate medical examiner shall not be held civilly or criminally liable for any acts performed in good faith pursuant to subsection B, paragraphs 4, 5 and 6 of this section.

D. If a dispute arises over the findings of the medical examiner's report, the medical examiner, on an order of the superior court, shall make available all evidence and documentation to a court-designated licensed forensic pathologist for review, and the results of the review shall be reported to the superior court in the county issuing the order.

E. For providing external examinations and autopsies pursuant to this section, the medical examiner may charge a fee established by the board of supervisors pursuant to Section A.R.S. § 11-251.08.

F. The county medical examiner or alternate medical examiner is entitled to all medical records and related records of a person for whom the medical examiner is required to certify cause of death.

Burial of Indigent Deceased

A. When a death investigation has been completed by the county medical examiner and no other person takes charge of the body of the deceased, the examiner shall cause the body to be delivered to a funeral establishment. If there is not sufficient property in the estate of the deceased to pay the necessary expenses of the burial, the expenses shall be a legal charge against the county. Upon determination of indigency the funeral establishment shall perform the normal county indigent burial, in the manner and for the fee then being paid by the county, or release the body, upon county request, without fee, to the funeral establishment designated by the county for other indigent burials.

B. Within thirty days after the examination, the medical examiner shall deliver to the public fiduciary of the county or the legal representative of the deceased any money or property found upon the body.

Release of Information

A. The county medical examiner shall release the name, contact information and available medical and social history of a decedent whose body is under the jurisdiction of the medical examiner to:
   1. The designated procurement organization, hospital, accredited medical school, dental school, college or university of an anatomical gift executed pursuant to section A.R.S. § 36-844.
   2. Any procurement organization under procedures adopted by the medical examiner for coordination of the procurement of anatomical gifts.

ARTICLE 2 – FEES: For the services provided by the Medical Examiner under this agreement, financial compensation from the County will be as follows:

$2,200.00 per complete autopsy
$ 170.00 per external examination, cause of death
$ 65.00 per cremation
$ 250.00 per month Malpractice Insurance – not to exceed $3,000.00 without prior written approval from the County

ARTICLE 3 – TERMINATION: Contract shall terminate thirty (30) days after written notice is received by either party to the other. Upon receipt of the notice, work in progress will be completed and any summaries and/or status reports shall be prepared and submitted, all within thirty (30) days. The County's financial obligation shall cover only the work performed up to the notice to terminate plus thirty (30) days, and not work completed thereafter.

In the event that the County has reasonable cause to believe that the Medical Examiner alleged violations of applicable statutes, rules or regulations, alleged breach of contract or alleged misconduct of any nature whatsoever, presents, or may present a threat to the interest of the County or its citizens in receiving competent medical examiner or other related services pursuant to this agreement, County may terminate this Agreement immediately upon written or oral notice to Medical Examiner. Upon such notice, Medical Examiner shall immediately cease to perform the duties customarily performed by a medical examiner except as specifically directed by the County. As of the date of such notice, County shall not be liable for any further payment or performance pursuant to this Agreement.

ARTICLE 4 – INSPECTION OF RECORDS AND PREMISES: Upon reasonable notice, authorized County representatives may inspect Medical Examiner's records related to services provided pursuant to this Agreement except to the extent that any specific records may be deemed confidential pursuant to specific statutory authority. County representatives may enter upon and inspect any facility used by Medical Examiner to perform services as provided in this contract in order to determine Medical Examiner's compliance with the terms of the contract. Medical Examiner agrees to retain all financial records and other documents relating to the services performed pursuant to this contract for five (5) years after final payment of all amounts owed to Medical Examiner or until after resolution of any audits, investigations or other inquiries which may require access to the subject records or documents, whichever is later. County, state or federal officials or other persons duly authorized by the County shall have full access to, and the right to examine, copy and use any such materials.

ARTICLE 5 - INDEMNIFICATION CLAUSE: The Medical Examiner agrees to defend, indemnify, and hold harmless Gila County from all losses, liability, claims or expenses (including reasonable attorney's fees) arising from bodily injury, including death or property damage, to any person or persons caused in whole or in part by the negligence or misconduct of the Medical Examiner, except to the extent same are caused by the negligence or willful misconduct of the County. It is the intent of this section to require the Medical Examiner to indemnify the County to the extent permitted under Arizona Law.

ARTICLE 6 – INSURANCE REQUIREMENTS: The Medical Examiner agrees to take out and keep in force during the term of this agreement at his expense, professional liability insurance, general liability insurance and other insurance(s) as requested by the County with reputable insurance companies acceptable to the County under this agreement.

ARTICLE 7 – ASSIGNMENTS AND SUBCONTRACTS: No rights or obligations of the Medical Examiner under this agreement shall be assigned. No rights or obligations of the Medical Examiner under this agreement shall be subcontracted by the Medical Examiner without approval of the County. All subcontracts shall incorporate the laws, rules, and regulations governing this agreement. The approved subcontracts shall forward copies of such to the County Office of Health and shall retain originals on file.

ARTICLE 8 – LEGAL ARIZONA WORKERS ACT COMPLIANCE: Medical Examiner hereby warrants that it will at all times during the term of this Contract comply with all federal immigration laws applicable to Medical Examiner's employment of its employees, and with the requirements of A.R.S. § 23-214 (A) (together the "State and Federal Immigration Laws"). Medical Examiner shall further ensure that each subcontractor who performs any work for the Medical Examiner under this contract likewise complies with the State and Federal Immigration Laws. County shall have the right at any time to inspect the books and records of the Medical Examiner and any subcontractor in order to verify such party's compliance with the State and Federal Immigration Laws.

Any breach of Medical Examiner's or any subcontractor's warranty of compliance with the State and Federal Immigration Laws, or of any other provision of this section, shall be deemed to be a material breach of this Contract subjecting the Medical Examiner to penalties up to and including suspension or termination of this Contract. If the breach is by a subcontractor, and the subcontract is suspended or terminated as a result, the Medical Examiner shall be required to take such steps as may be necessary to either self-perform the services that would have been provided under the subcontract or retain a replacement subcontractor as soon as possible so as not to delay project completion.

The Medical Examiner shall advise each subcontractor of County's rights, and the subcontractor's obligations, under this Article by including a provision in each subcontract substantially in the following form:

"Subcontractor hereby warrants that it will at all times during the term of this contract comply with all federal immigration laws applicable to Subcontractor's employees, and with the requirements of A.R.S. § 23-214 (A). Subcontractor further agrees that County may inspect the Subcontractor's books and records to insure that Subcontractor is in compliance with these requirements. Any breach of this paragraph by Subcontractor will be deemed to be a material breach of this contract subjecting Subcontractor to penalties up to and including suspension or termination of this contract."

ARTICLE 9 – LAWS AND ORDINANCES: This agreement shall be enforced under the laws of the State of Arizona. The Medical Examiner shall maintain in current status all Federal, State and Local licenses and permits required for the operation of the business conducted by the Medical Examiner. The Medical Examiner shall comply with the applicable provisions of the Americans with Disabilities Act (Public Law 101-336, 42 U.S.C. 12101-12213) and applicable federal regulations under the Act.

ARTICLE 10 – CANCELLATION: This agreement is subject to cancellation pursuant to A.R.S. § 38-511, the pertinent provisions of which are incorporated herein by reference. If the Agreement is terminated, the county shall be liable only for payment for services rendered by the County before the effective date of termination.

ARTICLE 11 – TERM: The term of the contract shall commence on the date the contract is approved by the Board of Supervisors, and continue in full force and effect for one year, unless terminated, canceled or extended as otherwise provided herein. The Medical Examiner agrees that Gila County shall have the right, at its sole option, to renew the contract for three (3) additional one (1) year periods. In the event the County exercises such a right, all terms, conditions and provisions of the original contract shall remain the same and apply during the renewal period.

ARTICLE 12 – PAYMENT: The Medical Examiner shall be paid pursuant to the fees stated in Article 2 of this agreement, but in no event shall payment exceed $30,000.00 for each of the one year contract terms, without prior written approval from the County.

Gila County employs a "Net 15" payment term for professional services meaning the payment will be issued fifteen (15) days from the date the County receives the invoice from the Medical Examiner. Purchase orders sent to the Medical Examiner reflect these terms and conditions and they apply to all invoices received by the County.

The Medical Examiner shall have a current I.R.S. W-9 form on file with the County unless not required by law. The County shall not remit payment if the Medical Examiner does not have a current W-9

Invoices
All invoices shall be submitted to Gila County Accounts Payable at 1400 E. Ash St., Globe, Arizona 85501, and contain the purchase order number, contract number, and description of services performed. Invoices may be emailed to accountspayable@co.gila.az.us .

IN WITNESS WHEREOF, *three (3) identical counterparts of this contract, each which shall include original signatures and for all purposes be deemed an original thereof, have been duly executed by the parties hereinabove named, on the date and year first above written.*

GILA COUNTY BOARD OF SUPERVISORS

Michael A. Pastor, Chairman Board of Supervisors

MEDICAL EXAMINER

Mark A. Fischione, M.D., PLC

ATTEST:

Marian Sheppard, Clerk of the Board of Supervisors

APPROVED AS TO FORM

Bryan B. Chambers, Deputy Attorney Principal
For Bradley D. Beauchamp, County Attorney

GILA COUNTY ATTORNEY

Bradley D. Beauchamp

Re: County Attorney's Office "approval as to form" of contract or agreement.

To whom it may concern:

The County Attorney's Office has reviewed the contract or agreement attached to this agenda item and has determined that it is in its proper form and is within the powers and authority granted under the laws of this state to the public agency requesting the County Attorney's Office review.

Explanation of the Gila County Attorney's Office "Approval as to Form" Review

The Gila County Attorney's Office is often called upon to review contracts and other agreements between public entities represented by the County Attorney and private vendors, contractors, and individuals.

In performing this review, the County Attorney's Office reviews these contracts to see that they are in "proper form" prior to their execution. "Proper form" means that the contract conforms to fundamental contract law, conforms to specific legislative requirements, and is within the powers and authority granted to the public agency. It does not mean that the County Attorney's Office approves of or supports the policy objectives contained in the contract. That approval is solely the province of the public agency through its elected body.

The public agency or department submitting the contract for review has the responsibility to read and understand the contract in order to completely understand its obligations under the contract if it is ultimately approved by the public entity's board. This is because while the County Attorney's Office can approve the contract as to form, the office may not have any idea whether the public agency has the capacity to actually comply with its contractual obligations. Also, the County Attorney's Office does not monitor contract compliance. Hence the public entity or

submitting department will need to be prepared to monitor their own compliance. A thorough knowledge of the provisions of the contract will be necessary to monitor compliance.

Before signing a contract "approved as to form," the County Attorney's Office will answer any questions or concerns the public agency has about the contract. It is the responsibility of the public agency or department submitting the contract for review to ask any specific questions or address any concerns it has about the contract to the County Attorney's Office at the same time they submit the contract for review. Making such an inquiry also helps improve the County Attorney's Office review of the contract because it will help focus the review on specific issues that are of greatest concern to the public agency. Failing to make such an inquiry when the agency does have issues or concerns will decrease the ability of the County Attorney's Office to meaningfully review the agreement.

ARF-2809 **Consent Agenda Item 4. B.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For:	Jeffrey Hessenius, Finance Director	Submitted By:	Jeannie Sgroi, Contracts Administrator, Finance Division
Department:	Finance Division		
Fiscal Year:	FY 2014-2015	Budgeted?:	Yes
Contract Dates Begin & End:	4-27-2014 to 4-26-2018	Grant?:	No
Matching Requirement?:	No	Fund?:	Renewal

Information

Request/Subject

Amendment No. 2 to Electric Drive Lease Agreement with Arizona Public Service Company.

Background Information

On April 27, 2006, Gila County entered into a lease agreement with Arizona Public Service (APS) to lease a portion of property owned by APS, located at State Route 188 and Electric Drive in Globe, AZ. The property was leased for the purpose of a parking/impound lot for the Sheriff's Office. The term of the contract was for a five-year period and it expired on April 26, 2011. Per the **Special Terms** included in the "BASIC LEASE INFORMATION", Gila County agreed, at the County's expense, to crack seal the parking lot, followed up by chip sealing the parking lot. The work was to be completed no later than December 31, 2006.

On April 5, 2011, the Board of Supervisors approved Amendment No. 1 to the Lease Agreement, which served to extend the lease term from April 27, 2011 to April 26, 2014.

Evaluation

Amendment No. 2 to the Lease Agreement between APS and Gila County will allow for the agreement term to be extended for four years, from April 27, 2014, to April 26, 2018. The lease shall remain in full force and effect according to its terms.

Pursuant to Item C. 2 in Amendment No. 2, issued by APS, the County shall remove, replace and seal coat all parking lot asphalt on leased property. Parking lot replacement shall be completed no later than July 1, 2015. Parking lot seal coat shall be completed no later than July 1, 2016.

The County shall continue to pay Arizona Public Service the amount of $1 per month for lease of the property.

Conclusion

The lease extension will allow the Sheriff's Office to continue to use the property for another four years as an impound/parking lot, through April 26, 2018.

Recommendation

The Public Works Division Director recommends that the Board of Supervisors approve Amendment No. 2 to the Lease Agreement between Arizona Public Service Company and Gila County to extend the lease term for four more years.

Suggested Motion

Approval of Amendment No. 2 to a Lease Agreement between Arizona Public Service Company and Gila County to extend the term of the lease for an additional four years, from April 27, 2014, to April 26, 2018, in the amount of one dollar per month; and replace all parking lot asphalt on leased property by July 1, 2015, and seal coat parking lot by July 1, 2016.

Attachments

Amendment No. 2 to Lease

Amendment No. 1 to Lease

2006 Lease Agreement with APS for SR188 and Electric Drive

Legal Explanation

SECOND AMENDMENT TO LEASE

THIS SECOND AMENDMENT TO LEASE ("Amendment") is made and entered into as of this 27th day of August, by and between **ARIZONA PUBLIC SERVICE COMAPANY** ("Lessor") and **GILA COUNTY** ("Lessee").

RECITALS:

A. Lessor and Lessee entered into that certain Lease commencing April 27, 2006, and First Amendment dated April 8, 2011, for certain real property located in the Town of Globe, County of Gila, State of Arizona, consisting of approximately .30 acres as defined in Appendix A of the Lease and referred as the "Property" and;

B. Lessee has requested from Lessor to extend the Lease Term, as more particularly described hereinafter; and,

C. Lessor has agreed to extend the Lease Term upon the terms and conditions set forth in the Lease, as hereby modified and amended;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Lessor and Lessee do hereby amend the Lease and agree as follows:

1. The Term of the Lease is hereby extended for an additional Term commencing April 27, 2014 and terminating as of April 26, 2018.

2. Lessee shall remove, replace and seal coat all parking lot asphalt on leased property. Parking lot replacement shall be completed no later than July 1, 2015. Parking lot seal coat shall be completed no later than July 1, 2016.

3. Lessee shall keep the premises clean, neat and orderly, free of weeds and debris.

4. Capitalized terms not otherwise defined in this SECOND Amendment shall have the meanings set forth in the Lease.

Except as herein modified and amended, the Lease shall remain in full force and effect according to its terms.

IN WITNESS WHEREOF, the parties have executed this SECOND Amendment as of the date written above.

LESSOR:
Arizona Public Service Company

By: [signature]

Title: Manager, Facilities

Date: 9/29/2014

LESSEE:
Gila County

By: _____
Michael A. Pastor, Chairman, Board of Supervisors

Date: _____

Attest: _____
Marian Sheppard, Clerk of the Board

Approved as to Form: _____
Bryan B. Chambers, Deputy County Attorney/Civil Bureau Chief
for Bradley Beauchamp, County Attorney

FIRST AMENDMENT TO LEASE
ARIZONA PUBLIC SERIVCE COMPANY
AND GILA COUNTY
SR 188 & ELECTRIC DRIVE, GLOBE, AZ

THIS FIRST AMENDMENT TO LEASE ("Amendment") is made and entered into as of this 8th day of April, 2011, by and between **ARIZONA PUBLIC SERVICE COMPANY** ("Lessor") and **GILA COUNTY** ("Lessee").

RECITALS:

A. Lessor and Lessee entered into that certain Lease commencing April 27, 2006, for certain real property located in the Town of Globe, County of Gila, State of Arizona, consisting of approximately .30 acres as defined in Appendix A of the Lease and referred as the "Property" and;

B. Lessee has requested from Lessor to extend the Lease Term, as more particularly described hereinafter; and,

C. Lessor has agreed to extend the Lease Term upon the terms and conditions set forth in the Lease, as hereby modified and amended;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Lessor and Lessee do hereby amend the Lease and agree as follows:

1. The Term of the Lease is hereby extended for an additional Term commencing April 27, 2011 and terminating as of April 26, 2014.

2. Capitalized terms not otherwise defined in this First Amendment shall have the meanings set forth in the Lease.

Except as herein modified and amended, the Lease shall remain in full force and effect according to its terms.

IN WITNESS WHEREOF, the parties have executed this First Amendment as of the date first above written.

LESSOR:
ARIZONA PUBLIC SERVICE COMPANY

By: Nancy Lutey

Title: Real Property Administrator

Date: 4/8/11

LESSEE:
GILA COUNTY

By: Michael A. Pastor

Title: Michael A. Pastor, Chairman, Board of Supervisors

Date: 4/5/11

Attest: Marian Sheppard
Marian Sheppard, Chief Deputy Clerk of the Board

Approved as to Form: Bryan B. Chambers
Bryan B. Chambers, Chief Deputy County Attorney
for Daisy Flores, County Attorney

When recorded,
return to:
Marian Sheppard, BOS
(6/27/06 #8)

Gila County, AZ
Linda Haught Ortega, Recorder
06/29/2006
04:45PM
Doc Code: L

Doc Id: 2006-011148
Receipt #: 46259
Rec Fee: 0.00

GILA CO BOS MARIAN SHEPPARD

2006-011148
Page: 1 of 11
06/29/2006 04:45P
Gila County, AZ L 0.00

LEASE

BETWEEN

ARIZONA PUBLIC SERVICE COMPANY

AND

GILA COUNTY

FOR LAND GENERALLY LOCATED AT

SR 188 AND ELECTRIC DRIVE, GLOBE, ARIZONA

Re-record —
No property
description,
exhibit "A" Not
Legible - Cant be
read & will NOT
reproduce from
fiche.

BASIC LEASE INFORMATION

LEASE DATE:	March 29, 2006
LESSOR:	Arizona Public Service Company PO Box 53999 Station 2178 Phoenix, Arizona 85072-3999 Attn: Real Estate Leasing Administrator
LESSEE:	Gila County PO Box 1400 East Ash Street Globe, Arizona 85501
COMMENCEMENT:	April 27, 2006
TERM:	Five (5) years
RENEWAL OPTIONS:	One (1) three year option to renew
SITE:	.30 acres, listed as Parcel B in the legal description of which is attached as Appendix A
RENT:	One (1) dollar per month
PERMITTED USE:	Parking / impound lot
SPECIAL TERMS:	**Lessee expressly acknowledges and agrees to, at Lessee's sole cost and expense, do a crack seal and then a chip seal of the parking lot described as Parcel B, in Appendix A. The work shall be completed no later than December 31, 2006.**

The foregoing Lease Information is a part of the Lease. Each reference in the Lease to any of the Lease Information shall mean the respective information set forth above. Lessor and Lessee acknowledge that they have read and understand all of the provisions contained in the entire Lease and all Appendices which are a part thereof and agree that the Lease, including the Lease Information and all Appendices, reflects the entire understanding and reasonable expectations of Lessor and Lessee regarding the Property.

Lessor's Initials: nl
Lessee's Initials: _____

LEASE BETWEEN ARIZONA PUBLIC SERVICE COMPANY AND GILA COUNTY FOR LAND LOCATED AT SR 188 AND ELECTRIC DRIVE, GLOBE, ARIZONA

TABLE OF CONTENTS

LEASE BETWEEN

ARIZONA PUBLIC SERVICE COMPANY

AND

GILA COUNTY

FOR LAND LOCATED AT

SR 188 AND ELECTRIC DRIVE, GLOBE, ARIZONA

1. PARTIES

The parties to this Lease are ARIZONA PUBLIC SERVICE COMPANY, hereinafter called "Lessor", and GILA COUNTY, hereinafter called "Lessee".

2. ENTIRE AGREEMENT

This Lease embodies the entire agreement between Lessor and Lessee. The parties shall not be bound by or be liable for any statement or representation of any nature not set forth in this Lease. Changes of any of the provisions of this Lease shall not be valid unless reduced to writing and signed by both parties.

3. PROPERTY

Subject to the terms and conditions of this Lease, Lessor agrees to lease to Lessee that certain property located in the Town of Globe, County of Gila, State of Arizona, consisting of approximately .30 acres, hereinafter referred to as the "Property" described in Appendix A, attached hereto.

4. TERM

The term of this Lease shall commence on April 27, 2006, and shall continue in effect until April 26, 2011.

5. RENEWAL OPTIONS

The renewal term shall be for a period of three years.

Upon mutual agreement of the Lessor and Lessee, Lessee may exercise such option to renew by notifying Lessor in writing at least 90 days prior to the term of the existing lease. The renewal term shall be subject to all of the terms and conditions of the lease.

6. RATE AND PAYMENT

Lessee agrees to pay Lessor a monthly rental for the Property of One (1) DOLLAR ($1).

Rent shall be paid on or before the first day or each month during the term of this Lease.

Lessee shall pay by check, without notice, demand or any setoff whatsoever, mailed to the following address:

Arizona Public Service Company
PO Box 53920
Phoenix, Arizona 85072-3920
Attn: Financial Services

7. USE OF PROPERTY

Lessee shall use the Property for the sole purpose of a parking/impound lot for vehicles, except upon prior written consent of Lessor.

Lessee shall comply with all laws and regulations applicable to the use or occupancy of the Property.

8. GOOD HUSBANDRY

Lessee shall, at Lessee's sole cost and expense, properly and promptly comply with any and all laws, permits, ordinances, rules, regulations, requirements, and orders whatsoever, present or future (collectively "Laws"), of the national, state, county or municipal government which may in any way apply to the use, maintenance or occupation, environmental or physical condition of, or operations on the Property.

Lessee shall not store, use or dispose of any Hazardous Substances, except for fuel contained in the tank used to operate the vehicle being stored. The term "Hazardous Substance" means any substance which has the characteristics of ignitability, corrosivity, toxicity, reactivity or radioactivity or has other characteristics determined to render the substance dangerous to health, safety or the environment pursuant to any existing or subsequently enacted federal, state or local law, regulation or ordinance. The term, "Hazardous Substance" includes, without limitation, substances defined as "hazardous material", "toxic substances", "hazardous waste", or "hazardous substances" in and federal, state or local law, regulation or ordinance.

Lessee shall immediately notify Lessor of any inquiry, test, investigation, enforcement proceeding by or against Lessee or the Property containing Hazardous Substances. If Lessee shall be required to submit information or written reports to any agency on or relating to any of the foregoing, Lessee shall concurrently provide Lessor with copies thereof. If Lessee fails to comply with any laws, then Lessor, without obligation to do so, may take all necessary steps to ensure compliance. In such event, Lessee shall reimburse Lessor, upon demand, for all costs and expenses which Lessor incurs, including any additional charges, assessments or penalties levied or charged against Lessor by reason of Lessee's failure to comply with such laws. Lessee will clean up all properties and maintain them in like manner during the term of the Lease.

9. LIENS

Lessee hereby agrees that Lessee will not permit or suffer any liens of any kind to be filed against the Property as a result of any obligation, malfeasance, negligence or mission of the Lessee, and that Lessee shall diligently take all necessary and proper steps to remove and discharge any liens which are filed.

10. INDEMNITY

Lessee shall indemnify, defend, and save harmless Lessor and all of its employees, agents, and representatives, from any and all claims demands, suits, actions, proceedings, loss, cost, and damages of every kind and description, including any attorneys' fees and/or litigation expenses, which may be brought, made against, or incurred by Lessor on account of loss or damage to any property and for injury to or death of any person, caused by, arising out of, or contributed to, in whole or in part, by reason of any alleged act, omission, fault, mistake, or to the rental of the Property under this Lease or by reason of any use, non-use, or condition of the Property created by or attributable to Lessee or Lessee's use or manner of use of the Property.

11. INSURANCE

Personal Property – It shall be the Lessee's responsibility to carry and maintain, at Lessee's sole expense, all insurance to cover Lessee's personal property.

Liability – Lessee shall, at all times during the term if this Lease, maintain and keep in force a policy or policies of insurance with reputable insurance companies which will adequately insure Lessor and Lessee against public liability and property damage in, on or about the Property. Minimum requirements for an "Owners, Landlords, and Tenants" policy or a "comprehensive general liability" policy shall provide coverage in the amount of at least $300,000 bodily injury per individual, per occurrence and

$1,000,000 property damage. The policy shall name Lessor as additional insured.

Lessee shall, within thirty (30) days from and after the execution of this Lease, cause to be issued to Lessor proper certificates of insurance evidencing that the foregoing covenant of Lessee has been complied with, and said certificate shall provide that if the underlying insurance is canceled or changed during the term of the policy, the insurance company shall notify Lessor in writing, and that no such cancellation or change shall become effective until ten (10) days from and after the date of receipt of such notice by Lessor.

12. IMPROVEMENTS AND ALTERATIONS

Lessee may not make improvements and/or alterations in and to the Property without first obtaining the written authorization of Lessor except as listed under section "Special Terms" in the Basic Lease Information.

Any improvements or alterations commenced by Lessee shall be completed expeditiously, subject to any delays beyond Lessee's control, and shall be in compliance with all laws, ordinances, rules, and regulations of any and all governmental authorities having jurisdiction over the Property. All such alterations and improvements, other than those constituting trade fixtures, shall become the property of Lessor upon the termination of this Lease at no cost to Lessor. Upon Lessor's approval or request for Lessee's removal of any of said alterations and improvements, Lessee shall repair any damage incurred to the Property by said removal, at Lessee's sole expense.

13. ASSIGNMENT/SUBLETTING

Lessee shall not assign this Lease or sublease any portion of the Property without the prior written consent of Lessor, and accordingly, any such assignment or subletting without such prior written consent of Lessor shall be void. Lessor shall have the right to assign or transfer this Lease, or any rights to it. In the even all or any portion of the lease is assigned or sublet to an entity by the Lessee as a result of Lessor's prior approval, said assignment or sublease shall not relieve Lessee from the obligations outlined herein.

14. TERMINATION FOR LESSEE'S DEFAULT

Lessor may terminate this Lease at its own option, without notice of termination to Lessee, and without any obligation to refund any rent or reimburse any expense; and reenter the Property without being guilty of trespass; and/or may exercise any other right or remedy provided by law should Lessee:

Default in the performance of any other provision of this Lease and continue in such default for a period of thirty (30) days after Lessor has made written demand to Lessee to cure such default.

In the case of Lessee's default or breach other than failure to pay rent, followed by notice thereof from Lessor, Lessee shall proceed with reasonable diligence and in good faith to cure any default specified in such notice within thirty (30) days. Should Lessee's curing of such default require more than a thirty (30) day period due to acts of God, war, or any other cause beyond Lessee's control, Lessee shall not be deemed to be in default for failure to cure said default, and Lessor will allow a reasonable additional time for the diligent curing of such default.

The rights and remedies of Lessor shall include, but not be limited to, enforcement of any rights or privileges hereunder, or of any promises or covenants hereunder by mandatory injunction, restraining order, or other equitable relief.

15. CONDITION OF PROPERTY ON TERMINATION

At the expiration or sooner termination of this Lease, upon vacating the Property, Lessee shall leave the property in good condition or better than the condition of the Property at the commencement of this Lease and free of Hazardous Substances.

16. INSOLVENCY AND BANKRUPTCY

In addition to any other rights or remedies of Lessor hereunder or at law, should Lessee be, or become, insolvent at any time during the term of this Lease; or should Lessee compound Lessee's debts or sign over Lessee's estate or effects for payments thereof; or, if Lessee causes any legal, or any other, officer to take possession of the Property by virtue of any execution or attachment; or, if any receiver or trustee is appointed of Lessee's property, or should Lessee be adjudged a bankrupt; then Lessor may, upon Lessor's election, enter the Property or any part thereof, to have, hold, possess, and this Lease shall be termination notwithstanding anything contained herein to the contrary.

17. LEGAL EXPENSES

Should any suit be instituted by Lessor or Lessee against the other in connection with this Lease, or for the recovery of rent or possession of the Property, the successful party to any such action shall recover from the other, reasonable attorney's fees and court costs in connection with said suit.

18. RIGHT OF ENTRY

Lessor, employees, agents or representatives may enter upon the Property at any time for the purpose of inspecting the Property and determining Lessee's compliance with the provisions of this Lease.

Lessor's employees, agents, or representatives may enter upon the Property at any time to construct, operate, or maintain its electric facilities on, over, or through the Property.

19. SURRENDER

Upon any termination of this Lease, Lessee shall peaceably surrender possession of the Property and all alterations and improvements, excluding Lessee's fixtures and equipment, and said Property shall become the property of Lessor.

20. NOTICES

All notices to be given hereunder by either party shall be in writing and shall be mailed, postage prepaid, first class, certified, or registered, return receipt requested.

The date of any notice by certified or registered mail shall be deemed to be the date of certification or registration thereof.

All notice shall be delivered or addressed to the parties as shown:

To Lessor: Arizona Public Service Company
PO Box 53999 Station 2178
Phoenix, Arizona 85072-3999
Attn: Real Estate and Leasing Administrator

To Lessee: Gila County
1400 East Ash Street
Globe, Arizona 85501
Attn: Gila County Board of Supervisors

21. NO WAIVER

Any waiver by any of the parties hereto of any breach of this Lease, or of any right of any party, shall not constitute a waiver of nay other breach or of any other right.

22. INUREMENT

The terms, covenants, and conditions of this Lease shall inure to the benefit of and be binding upon the parties hereto and their respective heirs, executors, administrators, legal representatives, successors, and assigns.

23. SECTION HEADINGS

The section headings contained herein are inserted only for convenience of reference and are in no way to be construed as a part of this Lease or as a limitation on the scope or the particular sections to which they refer.

24. CANCELLATION

This lease is subject to the cancellation provisions of ARS Section 38-511.

LESSOR:

Arizona Public Service Co.

By: Nancy Lutey
Nancy Lutey

Date: 6-1-06

Title: Real Estate & Facility Services, Section Leader

LESSEE:

Gila County Board of Supervisors

By: Jose M. Sanchez
Jose M. Sanchez, Chairman

Date: June 27, 2006

Title: Chairman

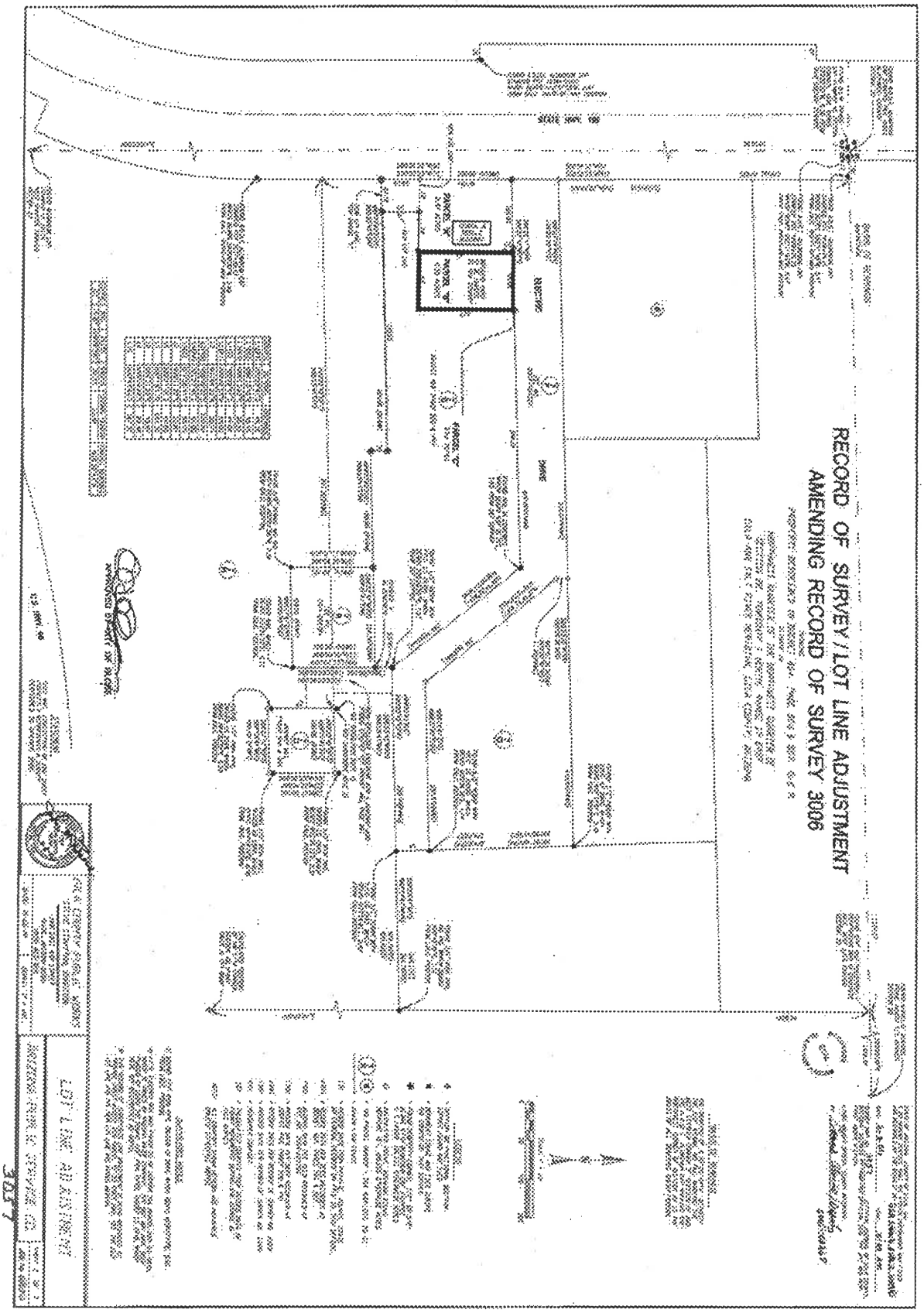
ATTEST:

Steven L. Besich
Clerk of the Gila County Board of Supervisors

APPROVED AS TO FORM:

Bryan Chambers
2nd Chief Deputy
Gila County Attorney's Office

APPENDIX A



GILA COUNTY ATTORNEY

Bradley D. Beauchamp

Re: County Attorney's Office "approval as to form" of contract or agreement.

To whom it may concern:

The County Attorney's Office has reviewed the contract or agreement attached to this agenda item and has determined that it is in its proper form and is within the powers and authority granted under the laws of this state to the public agency requesting the County Attorney's Office review.

Explanation of the Gila County Attorney's Office "Approval as to Form" Review

The Gila County Attorney's Office is often called upon to review contracts and other agreements between public entities represented by the County Attorney and private vendors, contractors, and individuals.

In performing this review, the County Attorney's Office reviews these contracts to see that they are in "proper form" prior to their execution. "Proper form" means that the contract conforms to fundamental contract law, conforms to specific legislative requirements, and is within the powers and authority granted to the public agency. It does not mean that the County Attorney's Office approves of or supports the policy objectives contained in the contract. That approval is solely the province of the public agency through its elected body.

The public agency or department submitting the contract for review has the responsibility to read and understand the contract in order to completely understand its obligations under the contract if it is ultimately approved by the public entity's board. This is because while the County Attorney's Office can approve the contract as to form, the office may not have any idea whether the public agency has the capacity to actually comply with its contractual obligations. Also, the County Attorney's Office does not monitor contract compliance. Hence the public entity or

submitting department will need to be prepared to monitor their own compliance. A thorough knowledge of the provisions of the contract will be necessary to monitor compliance.

Before signing a contract "approved as to form," the County Attorney's Office will answer any questions or concerns the public agency has about the contract. It is the responsibility of the public agency or department submitting the contract for review to ask any specific questions or address any concerns it has about the contract to the County Attorney's Office at the same time they submit the contract for review. Making such an inquiry also helps improve the County Attorney's Office review of the contract because it will help focus the review on specific issues that are of greatest concern to the public agency. Failing to make such an inquiry when the agency does have issues or concerns will decrease the ability of the County Attorney's Office to meaningfully review the agreement.

ARF-2797 **Consent Agenda Item 4. C.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For: Jeffrey Hessenius, Finance Director

Submitted By: Jeannie Sgroi, Contracts Administrator, Finance Division

Department: Finance Division

Information

Request/Subject

Intergovernmental Agreement No. 061014-1 with the Town of Hayden for Use of Various Types of Equipment and/or Services.

Background Information

On occasion, the Town of Hayden has a need to use various types of equipment and/or services that the County owns or is able to provide. On January 7, 2014, the Board of Supervisors approved Intergovernmental Agreement (IGA) No. 101113-1 with the Town of Hayden for the use of various types of equipment and/or services. IGA No. 101113-1 expired on June 30, 2014.

Evaluation

In the past, the Town of Hayden has requested to use various pieces of County-owned equipment. On January 7, 2014, the Board of Supervisors approved IGA No. 101113-1 to enable the County to respond timely when the Town of Hayden requests equipment and/or services, provided, the equipment and/or services is available at the time of the request.

IGA No. 101113-1 expired on June 30, 2014. IGA No. 061014-1 will provide the necessary documentation to be in place should the Town of Hayden need to request equipment and/or services between July 1, 2014, and June 30, 2015.

Conclusion

By having an active IGA in place, it will allow for the County to provide, when available and upon request by the Town of Hayden, various types of equipment and/or services to the Town of Hayden for various functions as they arise between July 1, 2014, and June 30 2015.

Recommendation

Staff recommends that the Board approve Intergovernmental Agreement No. 061014-1 between Gila County and the Town of Hayden for use of various types of equipment and/or services, on occasion and, when available and upon request, for safety needs and/or efforts by the Town of Hayden to increase revenue within the Town of Hayden by the Town of Hayden sponsoring various activities and events.

Suggested Motion

Approval of Intergovernmental Agreement No. 061014-1 between Gila County and the Town of Hayden whereby upon request from the Town of Hayden, the County will provide various types of equipment and/or services on occasion and when available for safety needs and/or efforts by the Town of Hayden beginning July 1, 2014, through June 30, 2015.

Attachments

Intergovernmental Agreement No. 061014-1 with the Town of Hayden

Expired Intergovernmental Agreement No. 101113-1 with the Town of Hayden

Legal Explanation

INTERGOVERNMENTAL AGREEMENT NO. 061014-1
BETWEEN
GILA COUNTY
AND
TOWN OF HAYDEN

THIS AGREEMENT is made and entered into effective this _____ day of _____, 2014, by and between Gila County, hereinafter referred to as "County" and the Town of Hayden, hereinafter referred to as "the Town".

RECITALS

WHEREAS, the Gila County Board of Supervisors desires to grant permission to the Town to use various types of equipment and/or services of Gila County in order to further the economic development potentials of the Town; and

WHEREAS, the Town has requested to use various types of equipment and/or services on occasion, for safety needs and/or efforts to increase revenue within the Town by sponsoring various activities and events; and

WHEREAS, the County has determined that the purpose of this funding request is public and that the expenditure of these funds will improve or enhance the economic welfare of the inhabitants of the County.

SCOPE

It is the intent of the County pursuant to A.R.S. §11-254 to provide, when available, and upon request by the Town, various types of equipment and/or services to the Town, for various functions as they arise between July 1, 2014 and June 30, 2015, to further the economic development of the County.

NOW, THEREFORE, in consideration of the mutual promises contained in this agreement, and of the mutual benefits to result therefrom, the parties agree as follows:

1. The County may provide, when available, and upon request by the Town, various types of equipment and/or services to the Town, for various functions, as they arise between July 1, 2014 and June 30, 2015.

2. Notices
All notices or demands upon any party to this agreement shall be in writing, unless other forms are designated elsewhere, and shall be delivered in person or sent by mail addressed as follows:

Town of Hayden
Attn: Mayor/Vice Mayor
520 Velasco Avenue
Hayden, Arizona 85135

Gila County Board of Supervisors
Attn: Don McDaniel, Jr.
1400 E. Ash Street
Globe, Arizona 85501

GENERAL TERMS

1. Indemnification: The Town shall indemnify, defend and hold harmless, County, its officers, employees agents from and against any and all suits, actions, legal administrative proceedings, claims or demands and costs attendant thereto, arising out of any act, omission, fault of negligence by the Town, its agents, employees or anyone under its direction or control or on its behalf in connection with performance of this Agreement.

2. Termination: Either party may, at any time and without cause, cancel this Agreement by providing 30 days written notice to the other party.

3. County Discretion: The County maintains discretion to accept or decline any request from the Town to use any equipment or service under this Agreement. Additionally, County may impose additional conditions upon the Town in order to use any equipment or service under this Agreement.

4. Cancellation: This Agreement may be canceled pursuant to the provisions of A.R.S. §38-511. The parties hereby acknowledge notice of A.R.S. §38-511 which provides for cancellation of contracts for violation of the conflict of interest statute.

5. Compliance with All Laws: The parties shall comply with all federal, state and local laws, rules, regulations, standards and Executive Orders, without limitation to those designated within this Agreement. Any changes in the governing laws, rules and regulations during the term of this agreement shall apply but do not require an amendment.

6. Entire Agreement: This document constitutes the entire agreement between the parties pertaining to the subject matter hereof, and all prior or contemporaneous agreements and understandings, oral or written, are hereby superseded and merged herein. This Agreement may be modified, amended, altered or extended only by a written amendment signed by the parties.

7. Non-Appropriation: Notwithstanding any other provision in this Agreement, this Agreement may be terminated if, for any reason, the County or the Town does not appropriate sufficient monies for the purpose of maintaining this Agreement.

IN WITNESS THEREOF, the parties to this Intergovernmental Agreement No. 061014-1, have caused their names to be affixed hereto by their proper offices on the date indicated above.

GILA COUNTY

_____

Michael A. Pastor, Chairman
Gila County Board of Supervisors

ATTEST

_____

Marian Sheppard, Clerk of the Board of Supervisors

APPROVED AS TO FORM:

_____

Bryan B. Chambers, Deputy Attorney Principal
for Bradley D. Beauchamp, County Attorney

TOWN OF HAYDEN

_____

Mayor/Vice Mayor
Town of Hayden

ATTEST

_____

Laura E. Romero, Town Clerk

APPROVED AS TO FORM:

_____

Stephen R. Cooper, Town Attorney

INTERGOVERNMENTAL AGREEMENT NO. 101113-1
BETWEEN
GILA COUNTY
AND
TOWN OF HAYDEN

THIS AGREEMENT is made and entered into effective this 7TH day of January 2014, by and between Gila County, hereinafter referred to as "County" and the Town of Hayden, hereinafter referred to as "the Town".

RECITALS

WHEREAS, the Gila County Board of Supervisors desires to grant permission to the Town to use various types of equipment and/or services of Gila County in order to further the economic development potentials of the Town; and

WHEREAS, the Town has requested to use various types of equipment and/or services on occasion, for safety needs and/or efforts to increase revenue within the Town by sponsoring various activities and events; and

WHEREAS, the County has determined that the purpose of this funding request is public and that the expenditure of these funds will improve or enhance the economic welfare of the inhabitants of the County.

SCOPE

It is the intent of the County pursuant to A.R.S. §11-254 to provide, when available, and upon request by the Town, various types of equipment and/or services to the Town, for various functions as they arise between July 1, 2013 and June 30, 2014, to further the economic development of the County.

NOW, THEREFORE, in consideration of the mutual promises contained in this agreement, and of the mutual benefits to result therefrom, the parties agree as follows:

1. The County may provide, when available, and upon request by the Town, various types of equipment and/or services to the Town, for various functions, as they arise between July 1, 2013 and June 30, 2014.

2. Notices
All notices or demands upon any party to this agreement shall be in writing, unless other forms are designated elsewhere, and shall be delivered in person or sent by mail addressed as follows:

Town of Hayden
Attn: Charles Vega
520 Velasco Avenue
Hayden, Arizona 85135

Gila County Board of Supervisors
Attn: Don McDaniel, Jr.
1400 E. Ash Street
Globe, Arizona 85501

GENERAL TERMS

1. Indemnification: The Town shall indemnify, defend and hold harmless, County, its officers, employees agents from and against any and all suits, actions, legal administrative proceedings, claims or demands and costs attendant thereto, arising out of any act, omission, fault of negligence by the Town, its agents, employees or anyone under its direction or control or on its behalf in connection with performance of this Agreement.

2. Termination: Either party may, at any time and without cause, cancel this Agreement by providing 30 days written notice to the other party.

3. County Discretion: The County maintains discretion to accept or decline any request from the Town to use any equipment or service under this Agreement. Additionally, County may impose additional conditions upon the Town in order to use any equipment or service under this Agreement.

4. Cancellation: This Agreement may be canceled pursuant to the provisions of A.R.S. §38-511. The parties hereby acknowledge notice of A.R.S. §38-511 which provides for cancellation of contracts for violation of the conflict of interest statute.

5. Compliance with All Laws: The parties shall comply with all federal, state and local laws, rules, regulations, standards and Executive Orders, without limitation to those designated within this Agreement. Any changes in the governing laws, rules and regulations during the term of this agreement shall apply but do not require an amendment.

6. Entire Agreement: This document constitutes the entire agreement between the parties pertaining to the subject matter hereof, and all prior or contemporaneous agreements and understandings, oral or written, are hereby superseded and merged herein. This Agreement may be modified, amended, altered or extended only by a written amendment signed by the parties.

7. Non-Appropriation: Notwithstanding any other provision in this Agreement, this Agreement may be terminated if, for any reason, the County or the Town does not appropriate sufficient monies for the purpose of maintaining this Agreement.

IN WITNESS THEREOF, the parties to this Intergovernmental Agreement No. 101113-1, have caused their names to be affixed hereto by their proper offices on the date indicated above.

GILA COUNTY

Michael A. Pastor, Chairman
Gila County Board of Supervisors

TOWN OF HAYDEN

11-18-13

Charles Vega
Town of Hayden, Mayor

ATTEST

Marian Sheppard, Clerk of the Board of Supervisors

ATTEST

11-18-13

Laura E. Romero, Town Clerk

APPROVED AS TO FORM:

Bryan B. Chambers, Deputy Attorney Principal
for Bradley D. Beauchamp, County Attorney

APPROVED AS TO FORM:

11-18-13

Stephen R. Cooper, Town Attorney

GILA COUNTY ATTORNEY

Bradley D. Beauchamp

Re: County Attorney's Office approval of IGA pursuant to A.R.S. § 11-952(D).

To whom it may concern:

The County Attorney's Office has reviewed the Intergovernmental Agreement attached to this agenda item and has determined that it is in its "proper form" and "is within the powers and authority granted under the laws of this state to such public agency or public procurement unit" pursuant to A.R.S. § 11-952(D).

Explanation of the Gila County Attorney's Office Intergovernmental Agreement (IGA) Review

A.R.S. § 11-952(D) requires that

> every agreement or contract involving any public agency or public procurement unit of this state . . . before its execution, shall be submitted to the attorney for each such public agency or public procurement unit, who shall determine whether the agreement is in proper form and is within the powers and authority granted under the laws of this state to such public agency or public procurement unit.

In performing this review, the County Attorney's Office reviews IGAs to see that they are in "proper form" prior to their execution. "Proper form" means that the contract conforms to fundamental contract law, conforms to specific legislative requirements, and is within the powers and authority granted to the public agency. It does not mean that the County Attorney's Office approves of or supports the policy objectives contained in the IGA. That approval is solely the province of the public agency through its elected body.

Likewise, this approval is not a certification that the IGA has been properly executed. Proper execution can only be determined after all the entities entering into the IGA have taken legal action to approve the IGA. There is no statutory requirement for the County Attorney's Office to certify that IGAs are properly executed.

Nonetheless, it is imperative for each public agency to ensure that each IGA is properly executed because A.R.S. § 11-952(F) requires that "[a]ppropriate action … applicable to the governing bodies of the participating agencies approving or extending the duration of the … contract shall be necessary before any such agreement, contract or extension may be filed or become effective." This can be done by ensuring that the governing body gives the public proper notice of the meeting wherein action will be taken to approve the IGA, that the item is adequately described in the agenda accompanying the notice, and that the governing body takes such action. Any questions regarding whether the IGA has been properly executed may be directed to the County Attorney's Office.

Proper execution of IGAs is important because A.R.S. § 11-952(H) provides that "[p]ayment for services under this section shall not be made unless pursuant to a fully approved written contract." Additionally, A.R.S. § 11-952(I) provides that "[a] person who authorizes payment of any monies in violation of this section is liable for the monies paid plus twenty per cent of such amount and legal interest from the date of payment."

The public agency or department submitting the IGA for review has the responsibility to read and understand the IGA in order to completely understand its obligations under the IGA if it is ultimately approved by the public entity's board. This is because while the County Attorney's Office can approve the IGA as to form, the office may not have any idea whether the public agency has the capacity to actually comply with its contractual obligations. Also, the County Attorney's Office does not monitor IGA compliance. Hence the public entity or submitting department will need to be prepared to monitor their own compliance. A thorough knowledge of the provisions of the IGA will be necessary to monitor compliance.

Before determining whether an IGA contract "is in proper form," the County Attorney's Office will answer any questions or concerns the public agency has about the contract. It is the responsibility of the public agency or department submitting the IGA for review to ask any specific questions or address any concerns it has about the IGA to the County Attorney's Office at the same time they submit the IGA for review. Making such an inquiry also helps improve the County Attorney's Office review of the IGA because it will help focus the review on specific issues that are of greatest concern to the public agency. Failing to make such an inquiry when the agency does have issues or concerns will decrease the ability of the County Attorney's Office to meaningfully review the IGA.

ARF-2820 **Consent Agenda Item 4. D.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For: Malissa Buzan, Director Submitted By: Christine Lopez, Administrative Clerk Specialist, Community Services Division

Department: Community Services Division Division: GEST Department

Information

Request/Subject

Amendment No. 1 to Request for Qualified Vendor Agreement (RFQVA) No. DDD 710000 between the Arizona Department of Economic Security, Division of Developmental Disabilities (DDD), and the Gila County Board of Supervisors d/b/a Gila Employment and Special Training (GEST).

Background Information

On September 16, 2014, the Board of Supervisors approved Amendment No. 1 to RFQVA No. DDD 71000. Upon receipt of Amendment No. 1, the Arizona Department of Economic Security (ADES) notified the Gila County GEST Department that the amendment needed to be corrected and returned to ADES as soon as possible. Chairman Pastor signed the corrected Amendment No. 1 on October 6, 2014, and it was then resubmitted to ADES.

Evaluation

The Amendment contains updated Assurances and Submittals and Data Sharing Agreement documents in order to continue to provide and be reimbursed for services. The submittal of said documents will allow the GEST Department to maintain a Qualified Vendor Agreement with the DDD. The Board of Supervisors needs to approve the corrected Amendment No. 1 that was signed by Chairman Pastor on October 6, 2014, and submitted to ADES immediately thereafter.

The Amendment No. 1 approved by the Gila County Board of Supervisors on September 16, 2014, contained an incorrect date on page 1.

The RFQVA is amended as follows:

This amendment extends the Agreement Term of all Qualified Vendor Agreements to 12/31/2010. This amendment supersedes both the Agreement Term stated in §1, NOTICE OF REQUEST FOR QUALIFIED VENDOR APPLICATIONS (RFQVA) and §6.3.8-9 of the Standard Terms and Conditions. The agreement can be terminated as specified in Section 6, DES/DDD Terms and Conditions.

The correct Amendment No. 1 does not include the above statement on Page 1, in its place, is "Amendments have been made to the identified portions of the specific Sections listed below:"

It is dated September 1, 2014 on page 7.

Conclusion

The corrected Amendment No. 1 to the RFQVA No. DDD 710000, will allow the GEST Department to continue to provide DDD services to residents of Gila County, and remain in compliance with federal and state regulations and provisions of the RFQVA.

Recommendation

The Community Services Division Director recommends that the Board of Supervisors approve the corrected Amendment No. 1 to the RFQVA No. DDD 710000, in order for the GEST Department to continue to provide services to eligible residents of Gila County.

Suggested Motion

Approval of the corrected Amendment No. 1 to Request for Qualified Vendor Agreement No. DDD 710000 between the Arizona Department of Economic Security, Division of Developmental Disabilities (DDD), and the Gila County Board of Supervisors d/b/a Gila County Employment and Special Training Department to allow for the continued provision of DDD services to eligible residents of Gila County, and remain in compliance with federal and state regulations and provisions of the Qualified Vendor Agreement.

Attachments

DDD Approved Amendment Application 10-21-14

DDD Amendment Application 10-6-14

DDD Approved Application 9-16-14

Approved Data Sharing Request

Legal Explanation

ASSURANCES AND SUBMITTALS

INSTRUCTIONS:
The Applicant must respond to each of the following items, then print and sign the document and attach hardcopies of the applicable submittals. The submittals shall indicate the item number to which it corresponds and also include the Applicant's Federal Employer Identification Number (FEIN).

1	Does the Applicant/Qualified Vendor agree to maintain and comply with any license(s), certification(s), and/or registration(s) set forth under federal or Arizona law, rules, or policy for the provision of each developmental disability service applied for?	Yes
2	Does the Applicant/Qualified Vendor understand that payment will not be made for services delivered prior to the effective date of any licensure, certification(s), and/or registration(s) required by federal or Arizona law, rules, or policy?	Yes
3	Has the Applicant/Qualified Vendor or any of its Key Personnel had a community developmental disability service or similar service license(s), certification(s) and/or registration(s) revoked, denied, or suspended in Arizona or in any other state within the past five (5) years? *(For the purposes of these Assurances and Submittals, "Key Personnel" shall include the Applicant/Qualified Vendor if an individual, or if the Applicant/Qualified Vendor is a corporation or other entity, any partner, manager, director, officer, or person directly or indirectly controlling 10% or more of the outstanding voting shares or other ownership interest of the Applicant/Qualified Vendor)*	No
3.1	If "yes", submit an explanation and current status.	
4	Has the Applicant/Qualified Vendor or any of its Key Personnel been a party to any contract terminated for cause relating to community developmental disability services or similar services in Arizona or in any other state within the past five (5) years?	No
4.1	If "yes", submit a detailed description of such terminations.	
5	Has the Applicant/Qualified Vendor or any of its Key Personnel been a party to any litigation relating to community developmental disability services or similar services in Arizona or in any other state within the past five (5) years?	No
5.1	If "yes", submit a detailed description of such terminations.	
6	Are there any court actions or judgments pending or entered within the last five (5) years against the Applicant/Qualified Vendor or any of its Key Personnel related to the provision of community developmental disability services or similar services in Arizona or in any other state?	No
6.1	If "yes", submit a summary of those suits or judgments and describe actions the Applicant/Qualified Vendor has taken to prevent future suits or judgments.	

ASSURANCES AND SUBMITTALS

7 Has the Applicant/Qualified Vendor or any of its Key Personnel been convicted of a criminal offense related to Medicare, Medicaid, or the State Children's Health Insurance Program? **No**

7.1 If "yes", submit a summary of those suits or judgments and describe actions the Applicant/Qualified Vendor has taken to prevent future suits or judgments.

8 Has the Applicant/Qualified Vendor or any of its Key Personnel been convicted of a felony? **No**

8.1 If "yes", submit information on the Key Personnel and the conviction.

9 Has any federal or state agency ever made a finding of noncompliance with any civil rights requirements with respect to the Applicant/Qualified Vendor or any of its Key Personnel? **No**

9.1 If "yes", submit an explanation.

10 Has the Applicant/Qualified Vendor or any of its Key Personnel been debarred, suspended, or otherwise lawfully prohibited from any public procurement activity, or does the Applicant/Qualified Vendor employ, consult, subcontract with, or otherwise reimburse for services any person substantially involved in the management of another entity that is now debarred, suspended, or otherwise lawfully prohibited from any public procurement activity? **No**

10.1 If "yes", submit an explanation.

10.2 Is a suspension or debarment currently pending? **No**

10.2.1 If "yes" to Assurance 10.2, submit an explanation.

11 Are there any judgments, tax deficiencies or claims pending or entered against the Applicant/Qualified Vendor or against any entity affiliated by common ownership or directorship with the Applicant/Qualified Vendor that would require disclosure in an audited financial statement or that would affect the financial stability of the Applicant/ Qualified Vendor? *(For purposes of these Assurances and Submittals, "common ownership" means that persons owning over 25% of the Applicant/Qualified Vendor's outstanding voting shares or other ownership interests also own over 25% of another corporation or entity's outstanding voting shares or other ownership interests; "common directorship" means that a majority of the persons comprising the directors or Applicant/ Qualified Vendor, or performing similar management and oversight functions if the Applicant/Qualified Vendor is limited liability company or other non-corporate entity, also comprise the majority of the directors of another corporation or persons performing similar management and oversight functions with respect to a limited liability company or other non-corporate entity.)* **No**

11.1 If "yes", submit a disclosure statement.

12 Has the Applicant/Qualified Vendor or any of its Key Personnel declared bankruptcy within the last seven (7) years? **No**

12.1 If "yes", submit the most recent or the final court-approved order disposing of the case, including any court-approved plans.

ASSURANCES AND SUBMITTALS

13	Is the Applicant/Qualified Vendor a corporation or other entity that is affiliated with another corporation or entity?	No
13.1	If "yes", submit an organizational chart that demonstrates ownership and/or corporate affiliations.	
14	Does the Applicant/Qualified Vendor or any of its Key Personnel or administrative staff have a relative, as defined in Arizona Revised Statutes ("A.R.S.") § 38-502, who is an employee of the Division with direct or indirect responsibility for the purchasing, authorizing, monitoring, or evaluating of community developmental disability services or vendors?	No
14.1	If "yes", submit a statement disclosing the conflict or potential conflict of interest.	
15	Is the Applicant/Qualified Vendor required to make a full written disclosure pursuant to the provision of Section 6.4.9 (Substantial Interest Disclosure) of the *DES/DDD Standard Terms and Conditions for Qualified Vendors?*	No
15.1	If "yes", submit a full written disclosure of the proposed payments and amount.	
16	Does the Applicant/Qualified Vendor certify that it did not engage in collusion or other anti-competitive practices in connection with the preparation or submission of the Application or any Amendment to the QVA?	Yes
17	Does the Applicant/Qualified Vendor certify that it will comply with Section 6.3.3 (Audit) of the *DES/DDD Standard Terms and Conditions for Qualified Vendors* and prepare and submit to the Division the required financial reports according to the timeframe specified?	Yes
18	Does the Applicant/Qualified Vendor certify that it will submit the Certificates of Insurance, required by Section 6.7.6 (Indemnification and Insurance) of the DES/DDD Standard Terms and Conditions for Qualified Vendors, prior to accepting a referral or providing a service?	Yes
18.1	Does the Applicant/Qualified Vendor understand that service authorizations and payments may be withheld unless the Applicant/Qualified Vendor has provided acceptable proof of insurance coverage as required by Section 6.7.6 (Indemnification and Insurance) of the DES/DDD Standard Terms and Conditions for Qualified Vendors?	Yes
18.2	Does the Applicant/Qualified Vendor certify that it will submit any renewal or change to the Certificates of Insurance to the Division's Contract Management Unit within ten (10) business days of renewal or change?	Yes
18.3	Does the Applicant/Qualified Vendor certify that the Applicant's/Qualified Vendor's Insurer or the Applicant/Qualified Vendor will provide the Division's Contract Management Unit with a copy of all notices of insurance cancellation (including, but not limited to, notices issued prior to the effective date of cancellation) immediately upon issuance or receipt?	Yes

ASSURANCES AND SUBMITTALS

19	Will the Applicant/Qualified Vendor use a subcontractor(s) to provide QVA services?	No
19.1	If "yes" to Assurance 19, submit information about each subcontract as required in Section 6.6.3 (Subcontracts) of the DES/DDD Standard Terms and Conditions for Qualified Vendors.	
19.2	If "yes" to Assurance 19, will the Applicant/Qualified Vendor provide all the required insurance for the subcontractor(s)?	No
19.3	If "no" to Assurance 19.2, does the Applicant/Qualified Vendor certify that it will obtain the required Certificates of Insurance from the subcontractor(s) and submit the certificates to the Division's Contract Management Unit?	Yes
19.4	If "yes" to Assurance 19, does the Applicant/Qualified Vendor certify that its subcontracts incorporate by reference the entirety of the QVA and the Arizona Health Care Cost Containment System's ("AHCCCS") Minimum Subcontract Provisions?	No
20	Does the Applicant/Qualified Vendor warrant compliance with the Federal Immigration and Nationality Act (FINA) and all other federal immigration laws and regulations related to the immigration status of its employees and Key Personnel?	Yes
20.1	Is the Applicant/Qualified Vendor providing services through subcontractors?	No
20.1.1	If "yes" to Assurance 20.1, does the Applicant/Qualified Vendor agree to obtain statements from its subcontractors certifying compliance and furnish the statements to the Division upon request? These warranties shall remain in effect through the term of the QVA. The Applicant/ Qualified Vendor and its subcontractors shall also maintain Employment Eligibility Verification forms (I-9) as required by the U.S. Department of Labor's Immigration and Control Act for all employees performing work under the QVA. I-9 forms are available at www.USCIS.gov.	No
20.1.2	The State may request verification of compliance for any Qualified Vendor or subcontractor performing work under the QVA. All costs necessary to verify compliance are the responsibility of the Qualified Vendor. Does the Applicant/Qualified Vendor understand this potential provision?	Yes
21	Does the Applicant/Qualified Vendor warrant compliance with all Federal immigration laws and regulations relating to employees and warrant its compliance with A.R.S. § 23-214, subsection A? (That subsection reads: "After December 31, 2007, every employer, after hiring an employee, shall verify the employment eligibility of the employee through the E-Verify program and shall keep a record of the verification for the duration of the employee's employment or at least three years, whichever is longer.")	Yes

ASSURANCES AND SUBMITTALS

22	Does the Applicant/Qualified Vendor certify that background checks for employment through the ADES Child Protective Services ("CPS") Central Registry shall be conducted for each existing employee and subcontractors, including volunteers, who provide direct services to children or vulnerable adults? By answering "yes", the Applicant/ Qualified Vendor certifies that background checks for each subsequent employee, subcontractor, and volunteer will be done as required by law, regulation, and contract. The Applicant/Qualified Vendor may utilize Section 9, Attachment G, Request for Search of Central Registry for Background Check, of the RFQVA # DDD 710000 for this purpose.	Yes
22.1	Does the Applicant/Qualified Vendor certify that before being employed or volunteering in a position that provides direct service to children or vulnerable adults, (1) persons shall certify on forms that are provided by the ADES whether an allegation of abuse or neglect was made against them and was substantiated, and (2), the completed forms shall be maintained as confidential?	Yes
22.2	Does the Applicant/Qualified Vendor certify that a person awaiting receipt of the CPS Central Registry Background Check will be permitted to provide direct service to ADES clients only if the person has first completed and submitted the Direct Service Position certification and: (1) the person is not currently the subject of an investigation of child abuse or neglect in Arizona or any other state or jurisdiction, and (2) the person has not been the subject of an investigation of child abuse or neglect in Arizona, or another state or jurisdiction, which resulted in a substantiated finding?	Yes
22.3	Does the Applicant/Qualified Vendor certify that if the Central Registry Background Check specifies any disqualifying act and the person does not have a Central Registry exception, the person shall be prohibited from providing direct services to ADES clients?	Yes
23	As a registered provider with the Arizona Health Care Cost Containment System Administration ("AHCCCSA"), does the Applicant/Qualified Vendor certify that it will screen all employees, contractors, and/or subcontractors no less frequently than monthly to determine whether any of them have been excluded from participation in federally-funded health care programs by checking the following databases and any other such databases that may be prescribed?	Yes
23.1	The List of Excluded Individuals and Entities ("LEIE"), which may be accessed at http://www.oig.hhs.gov/fraud/exclusions.asp?	Yes
23.2	The System for Award Management ("SAM"), which may be accessed at https://www.sam.gov/portal/public/SAM/?	Yes
24	Will all solicitation amendments to RFQVA # DDD 710000 issued by the Division be acknowledged by an authorized signature and will the signature page(s) of the Amendment(s) be submitted with the hardcopy Application?	Yes
25	Did a consultant assist the Applicant in completing the Application or assist the Qualified Vendor in preparing an amendment to the awarded QVA?	No

ASSURANCES AND SUBMITTALS

25.1 If "yes", submit a list of the name(s) and affiliation(s) (i.e., company/business name) of each consultant.

26 Did the Applicant/Qualified Vendor use another Application for a QVA and/or an awarded QVA as a resource in preparing this Application or an amendment to the QVA? No

26.1 If "yes", submit a list of the name(s) of each Applicant that submitted an Application and/or the name(s) of each awarded QVA that was used as a resource.

27 Is the hardcopy of the Qualified Vendor Application package or the QVA Amendment a true copy of the information submitted in electronic form in the QVADS and does it contain all required attachments and submittals? Yes

I have the authority and responsibility to submit this Application and to act as a representative of the Applicant in all phases of the Application process or the Qualified Vendor in all phases of amending as awarded QVA.

The information provided in the Application or any subsequent Amendment, including information entered into the QVADS and any attachments and submittals, is true, correct, and accurate to the best of my knowledge. I understand that any false statements may disqualify this Application from further consideration or be cause for termination of the QVA.

I agree to notify the Division within ten (10) business days of any changes to the information provided in this Application or in any subsequent amendment Amendment of an awarded QVA.

Authorized Signature

10-21-2014
Date

86-6000444
Federal Employer Identification Number

FAILURE TO COMPLETE, SIGN, SUBMIT, AND UPDATE AS NECESSARY THIS FORM MAY BE CAUSE FOR REJECTION OF THE APPLICATION OR TERMINATION OF AN AWARDED QVA.

The Division may contact any source available to verify the information submitted in the Application or any subsequent Amendment proposed to an awarded QVA and may use this information and any additional information obtained from the source(s) in evaluating the Application or any subsequent Amendment to an awarded QVA.

RFQVA AMENDMENT	DEPARTMENT OF ECONOMIC SECURITY
RFQVA No: DDD 710000	**Agency: Division of Developmental Disabilities**
Amendment No: 1	**Address: 1789 W. Jefferson, Site Code 791A** **Phoenix, Arizona 85007**
Page 1 of 7	**Phone: (602) 542-6874**

A signed copy of the signature page (page 7) of this amendment must be submitted with the hardcopy of the Application, or, if a Qualified Vendor Agreement has been awarded as of the date of issue of this amendment, the Qualified Vendor must return a signed copy of this amendment within 30 days of the date of issue to:

Contract Management Section
Business Operations – Site Code 791A
Arizona Department of Economic Security
Division of Developmental Disabilities
P.O. Box 6123
Phoenix, Arizona 85005

Please read the portions of each Section of your Agreement identified below for the changes made by this Amendment.

The full text of the amended Agreement is located at https://www.azdes.gov/ddd/

Amendments have been made to the identified portions of the specific Sections listed below:

RFQVA Application Submittal Checklist

Section 1: Notice of Request for Qualified Vendor Applications (RFQVA)
RFQVA Number: DDD 710000
Submittal Locations

Section 2: Table of Contents

Section 3: Instructions to Applicants
3.1 Inquiries
3.2 Application Preparation
3.3 RFQVA Schedule
3.4 Individual Independent Providers and Professional Independent Providers
3.6 Protests
3.7 Evaluation

Day Treatment and Training, Adult
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Utilization Information
- Rate Basis
- Recordkeeping and Reporting Requirements

Day Treatment and Training, Child (After School)
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Utilization Information
- Rate Basis
- Recordkeeping and Reporting Requirements

Day Treatment and Training, Child (Summer)
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Utilization Information
- Rate Basis
- Recordkeeping and Reporting Requirements

Employment Support Aide
- Service Description
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Utilization Information
- Direct Service Staff Qualifications
- Recordkeeping and Reporting Requirements

Group Supported Employment
- Service Description
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Outcomes
- Service Utilization Information
- Rate Basis
- Direct Service Staff Qualifications
- Recordkeeping and Reporting Requirements

Habilitation Communication
- Service Description
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Utilization Information
- Direct Service Staff Qualifications
- Recordkeeping and Reporting Requirements

Habilitation, Community Protection and Treatment Hourly
- Service Description
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Utilization Information
- Direct Service Staff Qualifications
- Recordkeeping and Reporting Requirements

Habitation, Consultation (New Service)

Habilitation, Early Childhood Autism Specialized (New)
Replaces Habilitation, Specialized Behavior

Habilitation, Group Home
Additional Service Description for Community Protection and Treatment
Service Requirements and Limitations (All Group Homes)
Service Goals and Objectives
Service Utilization Information
Rate Basis
Direct Service Staff Qualifications
Recordkeeping and Reporting Requirements (All Group Homes)

Habilitation, Hourly Support
Service Description
Service Requirements and Limitations
Service Goals and Objectives
Service Utilization Information
Direct Service Staff Qualifications
Recordkeeping and Reporting Requirements

Habilitation, Individually Designed Living Arrangement
Service Requirements and Limitations
Service Goals and Objectives
Service Utilization Information
Rate Basis
Direct Service Staff Qualifications
Recordkeeping and Reporting Requirements

Habilitation, Music Therapy
Service Description
Service Requirements and Limitations
Service Goals and Objectives
Service Utilization Information
Rate Basis
Direct Service Staff Qualifications
Recordkeeping and Reporting Requirements

Habilitation, Nursing Supported Group Home
Service Description
Service Requirements and Limitations
Service Goals and Objectives
Service Utilization Information
Direct Service Staff Qualifications
Recordkeeping and Reporting Requirements

Habilitation, Vendor Supported Developmental Home (Child and Adult)
Service Description
Service Requirements and Limitations
Service Goals and Objectives
Service Utilization Information
Direct Service Staff Qualifications
Recordkeeping and Reporting Requirements

Home Health Aide
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Utilization Information
- Direct Service Staff and Agency Qualifications
- Recordkeeping and Reporting Requirements

Homemaker (formally Housekeeping)
- Service Description
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Utilization Information
- Direct Service Staff Qualifications
- Direct Service Staff Training Requirements
- Recordkeeping and Reporting Requirements

Individual Supported Employment
- Service Description
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Utilization Information
- Rate Basis
- Direct Service Staff Qualifications
- Recordkeeping and Reporting Requirements

Nursing
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Utilization Information
- Direct Service Staff and Agency Qualifications
- Recordkeeping and Reporting Requirements

Occupational Therapy
- Service Description
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Utilization Information
- Direct Service Staff Qualifications
- Recordkeeping and Reporting Requirements

Person-Centered Planning Facilitation
- *Service Not Being Solicited*

Physical Therapy
- Service Description
- Service Requirements and Limitations
- Service Goals and Objectives
- Service Utilization Information
- Direct Service Staff Qualifications
- Recordkeeping and Reporting Requirements

Respiratory Therapy
- Service Requirements and Limitations
- Service Goals and Objectives

Service Utilization Information
Direct Service Staff and Agency Qualifications
Recordkeeping and Reporting Requirements

Respite
Service Description
Service Requirements and Limitations
Service Goals and Objectives
Service Utilization Information
Direct Service Staff Qualifications
Direct Service Training Requirements
Recordkeeping and Reporting Requirements

Room and Board, All Group Homes
Service Requirements and Limitations
Service Goals and Objectives
Service Utilization Information
Recordkeeping and Reporting Requirements

Room and Board, Vendor Supported Developmental Home (Child and Adult)
Service Requirements and Limitations
Service Goals and Objectives
Service Utilization Information
Direct Service Staff Qualifications
Recordkeeping and Reporting Requirements

Speech Therapy
Service Description
Service Requirements and Limitations
Service Goals and Objectives
Service Utilization Information
Direct Service Staff Qualifications
Recordkeeping and Reporting Requirements

Support Coordination
Service Not Being Solicited

Transition to Employment (New Service)

Transportation
Service Description
Service Requirements and Limitations
Service Goals and Objectives
Service Utilization Information
Direct Service Staff Qualifications
Recordkeeping and Reporting Requirements

Section 8: Arizona Geographic Map

Section 9: Attachment A – Application and Agreement Award

Section 9: Attachment E – ADES Data Sharing Request and Agreement
Replaces Hardcopy Version of Assurances and Submittals

Section 9: Attachment G – Central Registry Search Request

Section 9: Attachment H – Business Plan

Section 9: Attachment I – Contingency Plan
Replaces Contractors Pandemic Planning Checklist

Throughout the Request for Qualified Vendor Application ("RFQVA") and the Qualified Vendor Agreement ("QVA" or "Agreement"), the following changes have been made uniformly:

References to "consumer" have been changed to "member".

References to "Individual Support Plan" and "Individualized Family Service Plan" have been changed to "planning document".

References to "Individual Support Plan Team" and "Individualized Family Service Plan Team" have been changed to "planning team".

The "Hardcopy Version of Assurances and Submittals" is removed from the solicitation.

BY SIGNING BELOW, THE QUALIFIED VENDOR AGREES TO AND ACCEPTS THE REVISED PROVISIONS OF RFQVA # DDD 71000, AS AMENDED BY THIS AMENDMENT NUMBER 1.

TO THE EXTENT THAT ANY PROVISION OF RFQVA # DDD 710000 IS NOT INCLUDED IN THIS AMENDMENT, SUCH PROVISION SHALL REMAIN IN EFFECT.

Applicant hereby acknowledges receipt and understanding of the above RFQVA amendment. Michael A Pastor 10-6-14 Signature Date Michael A. Pastor, Chairman, Gila County Board of Supervisors Typed Name and Title of Authorized Signatory Gila County dba Gila Employment and Special Training Name of Qualified Vendor (on W-9) 86-6000444 Qualified Vendor FEIN (on W-9) 05785 Qualified Vendor Agreement Number on QVA	The above referenced RFQVA Amendment is hereby Executed this 1st day of September, 2014 at Phoenix Arizona Signature Leah D. Gibbs, DDD Contracts Administrator Types Name and Title of Authorized Signatory

ASSURANCES AND SUBMITTALS

INSTRUCTIONS:
The Applicant must respond to each of the following items, then print and sign the document and attach hardcopies of the applicable submittals. The submittals shall indicate the item number to which it corresponds and also include the Applicant's Federal Employer Identification Number (FEIN).

▲ 1 Does the Applicant/Qualified Vendor agree to maintain and comply with any license(s), certification(s), and/or registration(s) set forth under federal or Arizona law, rules, or policy for the provision of each developmental disability service applied for? Yes

▲ 2 Does the Applicant/Qualified Vendor understand that payment will not be made for services delivered prior to the effective date of any licensure, certification(s), and/or registration(s) required by federal or Arizona law, rules, or policy? Yes

▲ 3 Has the Applicant/Qualified Vendor or any of its Key Personnel had a community developmental disability service or similar service license(s), certification(s) and/or registration(s) revoked, denied, or suspended in Arizona or in any other state within the past five (5) years? *(For the purposes of these Assurances and Submittals, "Key Personnel" shall include the Applicant/Qualified Vendor if an individual, or if the Applicant/Qualified Vendor is a corporation or other entity, any partner, manager, director, officer, or person directly or indirectly controlling 10% or more of the outstanding voting shares or other ownership interest of the Applicant/Qualified Vendor)* No

3.1 If "yes", submit an explanation and current status.

▲ 4 Has the Applicant/Qualified Vendor or any of its Key Personnel been a party to any contract terminated for cause relating to community developmental disability services or similar services in Arizona or in any other state within the past five (5) years? No

4.1 If "yes", submit a detailed description of such terminations.

▲ 5 Has the Applicant/Qualified Vendor or any of its Key Personnel been a party to any litigation relating to community developmental disability services or similar services in Arizona or in any other state within the past five (5) years? No

5.1 If "yes", submit a detailed description of such terminations.

▲ 6 Are there any court actions or judgments pending or entered within the last five (5) years against the Applicant/Qualified Vendor or any of its Key Personnel related to the provision of community developmental disability services or similar services in Arizona or in any other state? No

6.1 If "yes", submit a summary of those suits or judgments and describe actions the Applicant/Qualified Vendor has taken to prevent future suits or judgments.

ASSURANCES AND SUBMITTALS

▲ 7 Has the Applicant/Qualified Vendor or any of its Key Personnel been convicted of a criminal offense related to Medicare, Medicaid, or the State Children's Health Insurance Program? **No**

7.1 If "yes", submit a summary of those suits or judgments and describe actions the Applicant/Qualified Vendor has taken to prevent future suits or judgments.

▲ 8 Has the Applicant/Qualified Vendor or any of its Key Personnel been convicted of a felony? **No**

8.1 If "yes", submit information on the Key Personnel and the conviction.

▲ 9 Has any federal or state agency ever made a finding of noncompliance with any civil rights requirements with respect to the Applicant/Qualified Vendor or any of its Key Personnel? **No**

9.1 If "yes", submit an explanation.

▲ 10 Has the Applicant/Qualified Vendor or any of its Key Personnel been debarred, suspended, or otherwise lawfully prohibited from any public procurement activity, or does the Applicant/Qualified Vendor employ, consult, subcontract with, or otherwise reimburse for services any person substantially involved in the management of another entity that is now debarred, suspended, or otherwise lawfully prohibited from any public procurement activity? **No**

10.1 If "yes", submit an explanation.

10.2 Is a suspension or debarment currently pending?

10.2.1 If "yes" to Assurance 10.2, submit an explanation.

▲ 11 Are there any judgments, tax deficiencies or claims pending or entered against the Applicant/Qualified Vendor or against any entity affiliated by common ownership or directorship with the Applicant/Qualified Vendor that would require disclosure in an audited financial statement or that would affect the financial stability of the Applicant/ Qualified Vendor? *(For purposes of these Assurances and Submittals, "common ownership" means that persons owning over 25% of the Applicant/Qualified Vendor's outstanding voting shares or other ownership interests also own over 25% of another corporation or entity's outstanding voting shares or other ownership interests; "common directorship" means that a majority of the persons comprising the directors or Applicant/ Qualified Vendor, or performing similar management and oversight functions if the Applicant/Qualified Vendor is limited liability company or other non-corporate entity, also comprise the majority of the directors of another corporation or persons performing similar management and oversight functions with respect to a limited liability company or other non-corporate entity.)* **No**

11.1 If "yes", submit a disclosure statement.

▲ 12 Has the Applicant/Qualified Vendor or any of its Key Personnel declared bankruptcy within the last seven (7) years? **No**

12.1 If "yes", submit the most recent or the final court-approved order disposing of the case, including any court-approved plans.

ASSURANCES AND SUBMITTALS

▲ 13	Is the Applicant/Qualified Vendor a corporation or other entity that is affiliated with another corporation or entity?	No
13.1	If "yes", submit an organizational chart that demonstrates ownership and/or corporate affiliations.	
▲ 14	Does the Applicant/Qualified Vendor or any of its Key Personnel or administrative staff have a relative, as defined in Arizona Revised Statutes ("A.R.S.") § 38-502, who is an employee of the Division with direct or indirect responsibility for the purchasing, authorizing, monitoring, or evaluating of community developmental disability services or vendors?	No
14.1	If "yes", submit a statement disclosing the conflict or potential conflict of interest.	
▲ 15	Is the Applicant/Qualified Vendor required to make a full written disclosure pursuant to the provision of Section 6.4.9 (Substantial Interest Disclosure) of the *DES/DDD Standard Terms and Conditions for Qualified Vendors?*	No
15.1	If "yes", submit a full written disclosure of the proposed payments and amount.	
▲ 16	Does the Applicant/Qualified Vendor certify that it did not engage in collusion or other anti-competitive practices in connection with the preparation or submission of the Application or any Amendment to the QVA?	Yes
▲ 17	Does the Applicant/Qualified Vendor certify that it will comply with Section 6.3.3 (Audit) of the *DES/DDD Standard Terms and Conditions for Qualified Vendors* and prepare and submit to the Division the required financial reports according to the timeframe specified?	Yes
▲ 18	Does the Applicant/Qualified Vendor certify that it will submit the Certificates of Insurance, required by Section 6.7.6 (Indemnification and Insurance) of the DES/DDD Standard Terms and Conditions for Qualified Vendors, prior to accepting a referral or providing a service?	Yes
▲ 18.1	Does the Applicant/Qualified Vendor understand that service authorizations and payments may be withheld unless the Applicant/Qualified Vendor has provided acceptable proof of insurance coverage as required by Section 6.7.6 (Indemnification and Insurance) of the DES/DDD Standard Terms and Conditions for Qualified Vendors?	Yes
▲ 18.2	Does the Applicant/Qualified Vendor certify that it will submit any renewal or change to the Certificates of Insurance to the Division's Contract Management Unit within ten (10) business days of renewal or change?	Yes
▲ 18.3	Does the Applicant/Qualified Vendor certify that the Applicant's/Qualified Vendor's Insurer or the Applicant/Qualified Vendor will provide the Division's Contract Management Unit with a copy of all notices of insurance cancellation (including, but not limited to, notices issued prior to the effective date of cancellation) immediately upon issuance or receipt?	Yes

ASSURANCES AND SUBMITTALS

▲ 19 Will the Applicant/Qualified Vendor use a subcontractor(s) to provide QVA services? No

19.1 If "yes" to Assurance 19, submit information about each subcontract as required in Section 6.6.3 (Subcontracts) of the DES/DDD Standard Terms and Conditions for Qualified Vendors.

19.2 If "yes" to Assurance 19, will the Applicant/Qualified Vendor provide all the required insurance for the subcontractor(s)?

19.3 If "no" to Assurance 19.2, does the Applicant/Qualified Vendor certify that it will obtain the required Certificates of Insurance from the subcontractor(s) and submit the certificates to the Division's Contract Management Unit?

19.4 If "yes" to Assurance 19, does the Applicant/Qualified Vendor certify that its subcontracts incorporate by reference the entirety of the QVA and the Arizona Health Care Cost Containment System's ("AHCCCS") Minimum Subcontract Provisions?

▲ 20 Does the Applicant/Qualified Vendor warrant compliance with the Federal Immigration and Nationality Act (FINA) and all other federal immigration laws and regulations related to the immigration status of its employees and Key Personnel? Yes

▲ 20.1 Is the Applicant/Qualified Vendor providing services through subcontractors? No

20.1.1 If "yes" to Assurance 20.1, does the Applicant/Qualified Vendor agree to obtain statements from its subcontractors certifying compliance and furnish the statements to the Division upon request? These warranties shall remain in effect through the term of the QVA. The Applicant/ Qualified Vendor and its subcontractors shall also maintain Employment Eligibility Verification forms (I-9) as required by the U.S. Department of Labor's Immigration and Control Act for all employees performing work under the QVA. I-9 forms are available at www.USCIS.gov.

20.1.2 The State may request verification of compliance for any Qualified Vendor or subcontractor performing work under the QVA. All costs necessary to verify compliance are the responsibility of the Qualified Vendor. Does the Applicant/Qualified Vendor understand this potential provision?

▲ 21 Does the Applicant/Qualified Vendor warrant compliance with all Federal immigration laws and regulations relating to employees and warrant its compliance with A.R.S. § 23-214, subsection A? (That subsection reads: "After December 31, 2007, every employer, after hiring an employee, shall verify the employment eligibility of the employee through the E-Verify program and shall keep a record of the verification for the duration of the employee's employment or at least three years, whichever is longer.") Yes

ASSURANCES AND SUBMITTALS

▲ 22	Does the Applicant/Qualified Vendor certify that background checks for employment through the ADES Child Protective Services ("CPS") Central Registry shall be conducted for each existing employee and subcontractors, including volunteers, who provide direct services to children or vulnerable adults? By answering "yes", the Applicant/ Qualified Vendor certifies that background checks for each subsequent employee, subcontractor, and volunteer will be done as required by law, regulation, and contract. The Applicant/Qualified Vendor may utilize Section 9, Attachment G, Request for Search of Central Registry for Background Check, of the RFQVA # DDD 710000 for this purpose.	Yes
▲ 22.1	Does the Applicant/Qualified Vendor certify that before being employed or volunteering in a position that provides direct service to children or vulnerable adults, (1) persons shall certify on forms that are provided by the ADES whether an allegation of abuse or neglect was made against them and was substantiated, and (2), the completed forms shall be maintained as confidential?	Yes
▲ 22.2	Does the Applicant/Qualified Vendor certify that a person awaiting receipt of the CPS Central Registry Background Check will be permitted to provide direct service to ADES clients only if the person has first completed and submitted the Direct Service Position certification and: (1) the person is not currently the subject of an investigation of child abuse or neglect in Arizona or any other state or jurisdiction, and (2) the person has not been the subject of an investigation of child abuse or neglect in Arizona, or another state or jurisdiction, which resulted in a substantiated finding?	Yes
▲ 22.3	Does the Applicant/Qualified Vendor certify that if the Central Registry Background Check specifies any disqualifying act and the person does not have a Central Registry exception, the person shall be prohibited from providing direct services to ADES clients?	Yes
▲ 23	As a registered provider with the Arizona Health Care Cost Containment System Administration ("AHCCCSA"), does the Applicant/Qualified Vendor certify that it will screen all employees, contractors, and/or subcontractors no less frequently than monthly to determine whether any of them have been excluded from participation in federally-funded health care programs by checking the following databases and any other such databases that may be prescribed?	Yes
▲ 23.1	The List of Excluded Individuals and Entities ("LEIE"), which may be accessed at http://www.oig.hhs.gov/fraud/exclusions.asp?	Yes
▲ 23.2	The System for Award Management ("SAM"), which may be accessed at https://www.sam.gov/portal/public/SAM/?	Yes
▲ 24	Will all solicitation amendments to RFQVA # DDD 710000 issued by the Division be acknowledged by an authorized signature and will the signature page(s) of the Amendment(s) be submitted with the hardcopy Application?	Yes
▲ 25	Did a consultant assist the Applicant in completing the Application or assist the Qualified Vendor in preparing an amendment to the awarded QVA?	No

ASSURANCES AND SUBMITTALS

25.1 If "yes", submit a list of the name(s) and affiliation(s) (i.e., company/business name) of each consultant.

▲ 26 Did the Applicant/Qualified Vendor use another Application for a QVA and/or an awarded QVA as a resource in preparing this Application or an amendment to the QVA? No

26.1 If "yes", submit a list of the name(s) of each Applicant that submitted an Application and/or the name(s) of each awarded QVA that was used as a resource.

▲ 27 Is the hardcopy of the Qualified Vendor Application package or the QVA Amendment a true copy of the information submitted in electronic form in the QVADS and does it contain all required attachments and submittals? Yes

I have the authority and responsibility to submit this Application and to act as a representative of the Applicant in all phases of the Application process or the Qualified Vendor in all phases of amending as awarded QVA.

The information provided in the Application or any subsequent Amendment, including information entered into the QVADS and any attachments and submittals, is true, correct, and accurate to the best of my knowledge. I understand that any false statements may disqualify this Application from further consideration or be cause for termination of the QVA.

I agree to notify the Division within ten (10) business days of any changes to the information provided in this Application or in any subsequent amendment Amendment of an awarded QVA.

Michael A. Pastor

Authorized Signature Michael A. Pastor, Chairman
Gila County Board of Supervisors

9-16-14

Date

86-6000444

Federal Employer Identification Number

FAILURE TO COMPLETE, SIGN, SUBMIT, AND UPDATE AS NECESSARY THIS FORM MAY BE CAUSE FOR REJECTION OF THE APPLICATION OR TERMINATION OF AN AWARDED QVA.

The Division may contact any source available to verify the information submitted in the Application or any subsequent Amendment proposed to an awarded QVA and may use this information and any additional information obtained from the source(s) in evaluating the Application or any subsequent Amendment to an awarded QVA.

GILA COUNTY ATTORNEY

Bradley D. Beauchamp

Re: County Attorney's Office approval of IGA pursuant to A.R.S. § 11-952(D).

To whom it may concern:

The County Attorney's Office has reviewed the Intergovernmental Agreement attached to this agenda item and has determined that it is in its "proper form" and "is within the powers and authority granted under the laws of this state to such public agency or public procurement unit" pursuant to A.R.S. § 11-952(D).

Explanation of the Gila County Attorney's Office Intergovernmental Agreement (IGA) Review

A.R.S. § 11-952(D) requires that

> every agreement or contract involving any public agency or public procurement unit of this state . . . before its execution, shall be submitted to the attorney for each such public agency or public procurement unit, who shall determine whether the agreement is in proper form and is within the powers and authority granted under the laws of this state to such public agency or public procurement unit.

In performing this review, the County Attorney's Office reviews IGAs to see that they are in "proper form" prior to their execution. "Proper form" means that the contract conforms to fundamental contract law, conforms to specific legislative requirements, and is within the powers and authority granted to the public agency. It does not mean that the County Attorney's Office approves of or supports the policy objectives contained in the IGA. That approval is solely the province of the public agency through its elected body.

Likewise, this approval is not a certification that the IGA has been properly executed. Proper execution can only be determined after all the entities entering into the IGA have taken legal action to approve the IGA. There is no statutory requirement for the County Attorney's Office to certify that IGAs are properly executed.

Nonetheless, it is imperative for each public agency to ensure that each IGA is properly executed because A.R.S. § 11-952(F) requires that "[a]ppropriate action … applicable to the governing bodies of the participating agencies approving or extending the duration of the … contract shall be necessary before any such agreement, contract or extension may be filed or become effective." This can be done by ensuring that the governing body gives the public proper notice of the meeting wherein action will be taken to approve the IGA, that the item is adequately described in the agenda accompanying the notice, and that the governing body takes such action. Any questions regarding whether the IGA has been properly executed may be directed to the County Attorney's Office.

Proper execution of IGAs is important because A.R.S. § 11-952(H) provides that "[p]ayment for services under this section shall not be made unless pursuant to a fully approved written contract." Additionally, A.R.S. § 11-952(I) provides that "[a] person who authorizes payment of any monies in violation of this section is liable for the monies paid plus twenty per cent of such amount and legal interest from the date of payment."

The public agency or department submitting the IGA for review has the responsibility to read and understand the IGA in order to completely understand its obligations under the IGA if it is ultimately approved by the public entity's board. This is because while the County Attorney's Office can approve the IGA as to form, the office may not have any idea whether the public agency has the capacity to actually comply with its contractual obligations. Also, the County Attorney's Office does not monitor IGA compliance. Hence the public entity or submitting department will need to be prepared to monitor their own compliance. A thorough knowledge of the provisions of the IGA will be necessary to monitor compliance.

Before determining whether an IGA contract "is in proper form," the County Attorney's Office will answer any questions or concerns the public agency has about the contract. It is the responsibility of the public agency or department submitting the IGA for review to ask any specific questions or address any concerns it has about the IGA to the County Attorney's Office at the same time they submit the IGA for review. Making such an inquiry also helps improve the County Attorney's Office review of the IGA because it will help focus the review on specific issues that are of greatest concern to the public agency. Failing to make such an inquiry when the agency does have issues or concerns will decrease the ability of the County Attorney's Office to meaningfully review the IGA.

ARF-2814 **Consent Agenda Item 4. E.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For: Malissa Buzan, Director Submitted By: Leitha Griffin, Administrative Assistant, Community Services Division

Department: Community Services Division Division: Administration

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Information

Request/Subject

Intergovernmental Agreement Renewal between Gila County and the City of Coolidge.

Background Information

Access Points are employment information centers which were launched by the Department of Labor under the Workforce Investment Act. The initiative was part of an effort to create local outreach centers where job seekers could access workforce development services in their local communities. This concept created a unique opportunity for community agencies and the One-Stop System to engage and partner to promote access to the workforce system.

An incentive grant from the Arizona Department of Economic Security shall fund this initiative.

Evaluation

While each Access Point offers a unique set of resources (depending on the participating partners), all Access Points offer free computer and Internet access for the purpose of job searching. Access Points connect job seekers to both employment and community resources in a convenient location and close to home.

Gila County agrees to provide:

- access to employment resources;
- training to help job seekers with job search;
- personal contacts in and connections to the One-Stop Centers, staff and key partners;
- inspection of the locations and signage for location;
- training of staff to help job seekers with job search activities;
- equipment maintenance;
- supplies, Access Point signage; and
- desktop computers (Microsoft Program with Internet access), printer, computer desk and chair

(Access Point) agrees to:

- host a publicly accessible Access point consisting of a computer with Internet access and Point of Contact trained by workforce system staff;
- help job seekers as needed and staff availability;
- publicize job seeker services to the Access Point's community;
- send staff to initial training;
- submit sign-in sheets monthly to document activities;
- assure that it will take reasonable precautions to ensure hardware, software, and/or other equipment remain secure and in good repair;
- abide by all applicable federal, state and local laws; and
- refer customers to the One-Stop and supportive services as needed.

Conclusion

The purpose of this Intergovernmental Agreement is to continue to provide a local Access Point at the City of Coolidge Library. Under the Workforce Investment Act, the "Access Point" model consists of local entities/organizations and/or businesses where job services can be provided, assisted by trained individuals.

Recommendation

The Gila County Community Services Division Director recommends that the Board of Supervisors approve this Intergovernmental Agreement Renewal for the period of July 1, 2014, through June 30, 2015.

Suggested Motion

Approval of an Intergovernmental Agreement renewal between Gila County and the City of Coolidge, whereby the City of Coolidge Library will continue to be a designated "Access Point" under the Workforce Investment Act for the period of July 1, 2014, through June 30, 2015.

Attachments

Renewal of IGA-Coolidge

Legal Explanation

RENEWAL OF INTERGOVERNMENTAL AGREEMENT

THIS RENEWAL OF INTERGOVERNMENTAL AGREEMENT ("Renewal Agreement") is made and entered by and between the CITY OF COOLIDGE, an Arizona municipal corporation ("City") and GILA COUNTY dba GILA/PINAL WORKFORCE INVESTMENT BOARD ("Gila County").

RECITALS

A. On August 12, 2013, the City and Gila County entered into an Intergovernmental Agreement ("Agreement") to establish a local Access Point in the City of Coolidge and set forth the obligations of each party in connection therewith.

B. The term of the Agreement expired on June 30, 2014. Pursuant to Section 2.1 of the Agreement, the Agreement is renewable annually by mutual agreement of the parties. The City and Gila County desire to renew the Agreement for one (1) year, through June 30, 2015, on the same terms and conditions in the Agreement.

C. City and Gila County renew the Agreement in accordance with the terms and conditions of this Renewal Agreement.

NOW, THEREFORE, in consideration of the promises and covenants contained herein, and for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. The term of the Agreement shall be renewed for one (1) year commencing July 1, 2014 and ending June 30, 2015 (the "Renewal Term").

2. All terms and conditions of the Agreement shall remain in full force and effect during the Renewal Term.

3. This Renewal Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same Renewal Agreement.

IN WITNESS WHEREOF, the parties have executed and delivered this Renewal Agreement effective as of the date set forth below.

CITY OF COOLIDGE

Thomas R. Shope
Mayor

GILA COUNTY (dba GILA/PINAL WORKFORCE INVESTMENT BOARD)

Michael A. Pastor
Chairman, Gila County Board of Supervisors

9-8-14

Date

Date

APPROVED AS TO FORM

Denis M. Fitzgibbons, City Attorney

APPROVED AS TO FORM

Bryan B. Chambers, Deputy Gila County Attorney

ATTEST

Norma Ortiz, City Clerk

ATTEST

Marian Sheppard, Clerk of the Court

GILA COUNTY ATTORNEY

Bradley D. Beauchamp

Re: County Attorney's Office approval of IGA pursuant to A.R.S. § 11-952(D).

To whom it may concern:

The County Attorney's Office has reviewed the Intergovernmental Agreement attached to this agenda item and has determined that it is in its "proper form" and "is within the powers and authority granted under the laws of this state to such public agency or public procurement unit" pursuant to A.R.S. § 11-952(D).

Explanation of the Gila County Attorney's Office Intergovernmental Agreement (IGA) Review

A.R.S. § 11-952(D) requires that

> every agreement or contract involving any public agency or public procurement unit of this state . . . before its execution, shall be submitted to the attorney for each such public agency or public procurement unit, who shall determine whether the agreement is in proper form and is within the powers and authority granted under the laws of this state to such public agency or public procurement unit.

In performing this review, the County Attorney's Office reviews IGAs to see that they are in "proper form" prior to their execution. "Proper form" means that the contract conforms to fundamental contract law, conforms to specific legislative requirements, and is within the powers and authority granted to the public agency. It does not mean that the County Attorney's Office approves of or supports the policy objectives contained in the IGA. That approval is solely the province of the public agency through its elected body.

Likewise, this approval is not a certification that the IGA has been properly executed. Proper execution can only be determined after all the entities entering into the IGA have taken legal action to approve the IGA. There is no statutory requirement for the County Attorney's Office to certify that IGAs are properly executed.

Nonetheless, it is imperative for each public agency to ensure that each IGA is properly executed because A.R.S. § 11-952(F) requires that "[a]ppropriate action … applicable to the governing bodies of the participating agencies approving or extending the duration of the … contract shall be necessary before any such agreement, contract or extension may be filed or become effective." This can be done by ensuring that the governing body gives the public proper notice of the meeting wherein action will be taken to approve the IGA, that the item is adequately described in the agenda accompanying the notice, and that the governing body takes such action. Any questions regarding whether the IGA has been properly executed may be directed to the County Attorney's Office.

Proper execution of IGAs is important because A.R.S. § 11-952(H) provides that "[p]ayment for services under this section shall not be made unless pursuant to a fully approved written contract." Additionally, A.R.S. § 11-952(I) provides that "[a] person who authorizes payment of any monies in violation of this section is liable for the monies paid plus twenty per cent of such amount and legal interest from the date of payment."

The public agency or department submitting the IGA for review has the responsibility to read and understand the IGA in order to completely understand its obligations under the IGA if it is ultimately approved by the public entity's board. This is because while the County Attorney's Office can approve the IGA as to form, the office may not have any idea whether the public agency has the capacity to actually comply with its contractual obligations. Also, the County Attorney's Office does not monitor IGA compliance. Hence the public entity or submitting department will need to be prepared to monitor their own compliance. A thorough knowledge of the provisions of the IGA will be necessary to monitor compliance.

Before determining whether an IGA contract "is in proper form," the County Attorney's Office will answer any questions or concerns the public agency has about the contract. It is the responsibility of the public agency or department submitting the IGA for review to ask any specific questions or address any concerns it has about the IGA to the County Attorney's Office at the same time they submit the IGA for review. Making such an inquiry also helps improve the County Attorney's Office review of the IGA because it will help focus the review on specific issues that are of greatest concern to the public agency. Failing to make such an inquiry when the agency does have issues or concerns will decrease the ability of the County Attorney's Office to meaningfully review the IGA.

ARF-2816 **Consent Agenda Item 4. F.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For:	Michael O'Driscoll, Director	Submitted By:	Celena Cates, Executive Administrative Assistant, Health & Emergency Services Division
Department:	Health & Emergency Services Division	Division:	Health Services
Fiscal Year:	2014-2015	Budgeted?:	Yes
Contract Dates Begin & End:	October 1, 2014 to September 30, 2015	Grant?:	Yes
Matching Requirement?:	No	Fund?:	New

Information

Request/Subject

Amendment No. 1 to an Intergovernmental Agreement (Contract No. ADHS14-063025) with the Arizona Department of Health Services.

Background Information

The Gila County Division of Health and Emergency Services in agreement with the Arizona Department of Health Services (ADHS) is committed to achieving accreditation through the Public Health Accreditation Board (PHAB).

On February 18, 2014, the Board of Supervisors approved an Intergovernmental Agreement (Contract No. ADHS14-063025) with the Arizona Department of Health Services in a not to exceed amount of $45,000 for the contract period January 6, 2014, through September 30, 2014. The funds were used to continue preparing for national accreditation.

Amendment No. 1 extends the contract for the period of October 1, 2014, through September 30, 2015, in the amount of $47,968.

Evaluation

This funding will allow Gila County to provide infrastructure to the Health and Emergency Services Division for public health accreditation preparation activities.

Conclusion

This funding will allow the Gila County Division of Health and Emergency Services to continue focusing on improving public health services and outcomes by implementing Quality Improvement practices. This funding also allows the Gila County Division of Health and Emergency Services to focus on workforce development by taking a strategic approach to the development of a trained and competent workforce in order to address the population's public health issues in Gila County.

Recommendation

It is the recommendation of the Director of Health and Emergency Services that the Board of Supervisors approve Amendment No. 1 to Contract No. ADHS14-063025 with Arizona Department of Health Services in the amount of $47,968 for the period of October 1, 2014, to September 30, 2015, to continue preparing for national accreditation.

Suggested Motion

Approval of Amendment No. 1 to an Intergovernmental Agreement (Contract No. ADHS14-063025) with the Arizona Department of Health Services in the amount of $47,968 to provide work force development infrastructure to the Health and Emergency Services Division to prepare for national accreditation for the period of October 1, 2014, through September 30, 2015.

Attachments

ADHS14-063025-Amendment #1

ADHS14-063025-Executed IGA

Legal Explanation

	INTERGOVERNMENTAL AGREEMENT (IGA) AMENDMENT	**ARIZONA DEPARTMENT OF HEALTH SERVICES** 1740 West Adams, Room 303 Phoenix, Arizona 85007 **(602) 542-1040** **(602) 542-1741 FAX**
	Contract No.: **ADHS14-063025** — Amendment No.: **1**	Procurement Officer: **Delilah Gonzalez**

PUBLIC HEALTH ACCREDITATION PREPARATION ACTIVITIES

Effective October 1, 2014, it is mutually agreed that the Intergovernmental Agreement referenced is amended as follows:

1. Pursuant to Terms and Conditions, Provision Six (6), **Contract Changes**, Item 6.1, Amendments, Purchase Orders and Change Orders the Agreement is hereby amended as defined by this Amendment One (1).
2. The Price Sheet is revised and replaced with the Price Sheet on Page Three (3) of this Amendment.
3. Pursuant to, Terms and Conditions, Provision Four (4), **Contract Administration and Operation**, 4.2, Contract Renewal, this Agreement is hereby extended through September 30, 2015.
4. Exhibit 1 is hereby added to the Contract.

ALL OTHER PROVISIONS OF THIS AGREEMENT REMAIN UNCHANGED.

Michael A. Pastor, Chairman, Board of Supervisors

Contractor Name: **GILA COUNTY HEALTH SERVICES**

Authorized Signature

1400 EAST ASH

Address:

Print Name

GLOBE — City
ARIZONA — State
85501 — Zip

Title

Pursuant to A.R.S. § 11-952, the undersigned public agency attorney has determined that this Intergovernmental Agreement is in proper form and is within the powers and authority granted under the laws of Arizona

Signature — Date

Bryan Chambers, Deputy County Attorney/Civil Bureau Chief

Print Name — Title

This Intergovernmental Agreement Amendment shall be effective the date indicated. The Public Agency is hereby cautioned not to commence any billable work or provide any material, service or construction under this IGA until the IGA has been executed by an authorized ADHS signatory.

State of Arizona

Signed this _____ day of _____ 2014.

Procurement Officer

Attorney General Contract No.: **P0012014000078**, which is an Agreement between public agencies, has been reviewed pursuant to A.R.S. § 11-952 by the undersigned Assistant Attorney, who has determined that it is in proper form and is within the powers and authority granted under the laws of the State of Arizona.

Signature — Date

Assistant Attorney General

Print Name — Title

RESERVED FOR USE BY THE SECRETARY OF STATE

Under House Bill 2011, A.R.S. § 11-952 was amended to remove the requirement that Intergovernmental Agreements be filed with the Secretary of State.

5. Scope of Work, Provision 2, Categories Selected, is revised and replaced with the following:

2. CATEGORIES SELECTED - The following Categories have been selected from Exhibit 1 and are incorporated as outlined below:

2.3 Category 3: **Building a Culture of Quality Improvement** (related PHAB Domain:9)

Quality improvement (QI) is the result of leadership support and requires staff commitment at all levels to build a culture of quality and ensure it is fully integrated into organizational structures, processes, services, operations, and more. Counties selecting this category may use this award to conduct activities that will show progress towards building a culture of Quality Improvement (QI) that will fulfill one (1) or more of the outlined deliverables (e.g., assessment of current QI culture and description of desired future state, plan for regularly communicating about QI activities, etc.).

2.4 Category 4: **Workforce Development** (related PHAB Domain: 8)

A multi-disciplinary workforce that is matched to the specific community being served facilitates the interdisciplinary approaches required to address the population's public health issues. PHAB Standards and Measures (v1.0) focus on the need for LHDs to take as strategic approach to the development of a trained and competent workforce to effectively perform duties. Counties selecting this category may use this award to conduct activities that will show progress towards training and development of the LHD workforce that will fulfill one (1) or more of the outlined deliverables (e.g., job descriptions that include core competencies, a workforce development plan, etc.).

6. Scope of Work, Provision 6, Deliverables is revised and replaced with the following:

6. DELIVERABLES - The following Deliverables have been selected from Exhibit 1 and are incorporated as outlined below:

6.3 Category 3: **Building a Culture of Quality Improvement**

6.3.1 Detailed written description of process and criteria for identifying and initiating appropriate QI projects.

6.3.8 QI staff training including training goals and objectives, and documentation of training content such as PowerPoint presentations, a curriculum, evaluation results, etc.

6.4 Category 4: **Workforce Development**

6.4.1 Detailed written plan for ensuring adoption of relevant public health core competencies among staff.

6.4.3 Staff training plan based upon results of assessment, including training schedules and description of curricula topics, and how identified gaps in staff competencies will be addressed.

REVISED PRICE SHEET

Effective October 1, 2014

ADHS will pay for completed Tasks monthly upon receipt of an Invoice from the County

Deliverable Description	Budget Amount
Category 3, Deliverable 6.3.3: Detailed written description of process and criteria for identifying and initiating appropriate QI projects.	**$11,992.14**
Category 3, Deliverable 6.3.8: QI staff training including training goals and objectives, and documentation of training content such as PowerPoint presentations, a curriculum, evaluation results, etc.	**$11,992.14**
Category 4 , Deliverable 6.4.1: Detailed written plan for ensuring adoption of relevant public health core competencies among staff.	**$11,992.14**
Category 4 , Deliverable 6.4.3: Staff training plan based upon results of assessment, including training schedules and description of curricula topics, and how identified gaps in staff competencies will be addressed,	**$11,992.14**
Total Contract Amount Not to Exceed	**$47,968.56**

1. DELIVERABLES AVAILABLE FOR EACH CATEGORY IDENTIFIED ABOVE: The applicable Deliverable/s is/are identified in the Scope of Work, Provision 6 and any changes or updates to this Provision will be made and applied via an Amendment to the Contract.

6.1 Category 1: **Progress Towards Preparing or Applying for Accreditation**

6.1.1 A written self-study by the Accreditation Team against the PHAB Standards, Measures, and Required Documentation that details the LHD's strengths, opportunities for improvement, and plans for addressing gaps,

6.1.2 Materials from staff and governing entity training(s) on the value of and LHD's process for achieving accreditation,

6.1.3 Detailed written description of process to systematically review and revise department policies and procedures as needed, and evidence of implementation of this process,

6.1.4 Detailed written description of process for identifying and reviewing documentation for PHAB, and evidence of implementation of this process,

6.1.5 List of possible documentation for each of the PHAB measures, using PHAB's Documentation Selection Spreadsheet or like tool.

6.1.6 Other deliverable related to Category 1.

6.2 Category 2: **Establishing and Monitoring a System of Performance Management**

6.2.1 Completed performance management self-assessment.

6.2.2 Detailed written performance management plan including: leadership and staff roles and responsibilities; objectives and standards for measuring progress toward milestones; methods, tools, and processes for measuring, tracking, and reporting performance; and timelines for completion.

6.2.3 Performance management staff training including training goals and objectives, and documentation of training content such as PowerPoint presentation, a curriculum, evaluation results, etc.

6.2.4 Evidence of an adopted system of performance management including the agency's selected performance goals, standards, objectives, targets, and indicators. This should include an established mechanism for data collection, analysis, and reporting of performance progress such as performance dashboards, spreadsheets and narrative text.

6.2.5 Detailed written description of a formal process used to select and implement an information system to support performance management efforts, such as a requirements gathering process, and evidence of implementation of process. The process should detail how the agency examined its needs related to performance management; explored various information system options; considered various stakeholders; and accounted for financial considerations.

6.2.6 Other Deliverable/s related to Category 2.

6.3 Category 3: **Building a Culture of Quality Improvement**

6.3.1 Detailed written description of assessment results for current QI culture and desired future state of quality in organization,

6.3.2 Detailed written description and documentation of the LHD's QI governance structure,

6.3.3 Detailed written description of process and criteria for identifying and initiating appropriate QI projects,

6.3.4 Detailed written description of process for identifying performance goals, objectives, and measures with time-framed targets

6.3.5 Detailed written plan for collecting, analyzing, and tracking progress toward performance goals and making improvements as needed,

6.3.6 Detailed written description of the LHD's plan for regularly communicating about QI activities in the department, and evidence of at least 3 of those mechanisms implemented,

6.3.7 Completed QI plan with all required components including descriptions of the following: 1) Key quality terms; 2) Desired future state of quality; 3) Key elements of the QI governance structure; 4) Types of internal QI trainings available and conducted; 5) How projects are identified and initiated and aligned with agency strategic plan; 6) QI goals, objectives, measures with time-framed targets, and responsible parties; 7) Plan for collecting, analyzing, and tracking progress toward performance goals and making improvements as needed; and 8) Plan for regularly communicating about QI activities.

6.3.8 QI staff training including training goals and objectives, and documentation of training content such as PowerPoint presentations, a curriculum, evaluation results, etc.,

6.3.9 Written or visual example of a completed QI project(s) in a program and/or administrative area, and

6.3.10 Other Deliverable/s related to Category 3.

6.4 Category 4: **Workforce Development**

6.4.1 Detailed written plan for ensuring adoption of relevant public health core competencies among staff,

6.4.2 Assessment(s) used to assess staff competencies against the adopted core competencies and detailed description of process for implementing assessment,

6.4.3 Staff training plan based upon results of assessment, including training schedules and description of curricula topics, and how identified gaps in staff competencies will be addressed,

6.4.4 Workforce development plan that includes all required components including the following: 1) Adopted public health core competencies for staff; 2) Assessment of staff competencies against adopted core competencies; 3) Curricula and training schedules; and 5) Identification of barriers and strategies for addressing them.

6.4.5 Other Deliverable/s related to Category 4.

6.5 Category 5: **Using Award Funds for PHAB Fees**

6.5.1 Provide evidence to ADHS that the LHD has applied to PHAB within the project timeframe.

INTERGOVERNMENTAL AGREEMENT (IGA)

Contract No. ADHS14-063025

ARIZONA DEPARTMENT OF HEALTH SERVICES
1740 West Adams. Room 303
Phoenix, Arizona 85007
(602) 542-1040
(602) 542-1741 FAX

Project Title: Accreditation

Begin Date: January 6, 2014

Geographic Service Area: Gila County

Termination Date: September 30, 2014

1 1 1.1
1 1 1.2 Arizona Department of Health Services has authority to contract for services specified herein in accordance with A R S §§ 11-951, 11-952, 36-104 and 36-132 The Contractor represents that it has authority to contract for the performance of the services provided herein pursuant to:

- [X] Counties: A.R.S. §§ 11-201, 11-951, 11-952 and 36-182.
- [ ] Indian Tribes: A.R.S. §§ 11-951, 11-952 and the rules and sovereign authority of the contracting Indian Nation.
- [ ] School Districts: A.R.S. §§ 11-951, 11-952, and 15-342.
- [ ] City of Phoenix: Chapter II, §§ 1 & 2, Charter, City of Phoenix.
- [ ] City of Tempe: Chapter 1, Article 1, §§ 1.01 & 1.03, Charter, City of Tempe.
- [ ] Other: Federal Agency

Amendments signed by each of the parties and attached hereto are hereby adopted by reference as a part of this Contract. from the effective date of the Amendment, as if fully set out herein.

Arizona Transaction (Sales) Privilege: _____

Federal Employer Identification No : _____

Tax License No.: _____

Contractor Name: Gila County Health Services

Address: 1400 East Ash
Globe. Arizona 85501

FOR CLARIFICATION, CONTACT:

Name: Michael O'Driscoll, Director

Phone: (928) 402-8761

Email: modriscoll@co.gila.az.us

CONTRACTOR SIGNATURE:

The Contractor agrees to perform all the services set forth in the Agreement and Work Statement

Michael A. Pastor 2-18-14

Michael A. Pastor, Chairman, Board of Supervisors

Print Name and Title

This Contract shall henceforth be referred to as Contract

No. ADHS14-063025 The Contractor is hereby cautioned not to commence any billable work or provide any material, service or construction under this Contract until Contractor receives a fully executed copy of the Contract.

State of Arizona

Signed this 13th day of March, 2014

Christie Ruth

Procurement Officer

CONTRACTOR ATTORNEY SIGNATURE:

Pursuant to A R S § 11-952. the undersigned Contractor's Attorney has determined that this Intergovernmental Agreement is in proper form and is within the powers and authority granted under the laws of Arizona

2-18-14

Bryan B. Chambers, Deputy Attorney Principal

Print Name and Title

Attorney General Contract, No. P0012012000033. which is an Agreement between public agencies. has been reviewed pursuant to A R S § 11-952 by the undersigned Assistant Attorney General. who has determined that it is in the proper form and is within the powers granted under the laws of the State of Arizona to those parties to the Agreement represented by the Attorney General

The Attorney General, BY:

3-10-14

Signature Date

Assistant Attorney General: Patricia Lattagna

RESERVED FOR USE BY THE SECRETARY OF STATE

Under House Bill 2011, A.R.S. § 11-952 was amended to remove the requirement that Intergovernmental Agreements be filed with the Secretary of State.

1 **Definition of Terms.** As used in this Contract, the terms listed below are defined as follows:

1.1 *"Attachment"* means any document attached to the Contract and incorporated into the Contract

1 2 *"ADHS"* means Arizona Department of Health Services

1.3 *"Budget Term"* means the period of time for which the contract budget has been created and during which funds should be expended

1 4 *"Change Order"* means a written order that is signed by a Procurement Officer and that directs the Contractor to make changes authorized by the Uniform Terms and Conditions of the Contract

1 5 *"Contract"* means the combination of the Uniform and Special Terms and Conditions, the Specifications and Statement or Scope of Work, Attachments, Referenced Documents, any Contract Amendments and any terms applied by law

1 6 *"Contract Amendment"* means a written document signed by the Procurement Officer and the Contractor that is issued for the purpose of making changes in the Contract

1 7 *"Contractor"* means any person who has a Contract with the Arizona Department of Health Services

1 8 *"Cost Reimbursement"* means a contract under which a contractor is reimbursed for costs, which are reasonable, allowable and allocable in accordance with the contract terms and approved by ADHS.

1 9 *"Days"* means calendar days unless otherwise specified

1 10 *"Fixed Price"* establishes a set price per unit of service The set price shall be based on costs, which are reasonable, allowable and allocable

1.11 *"Gratuity"* means a payment, loan, subscription, advance, deposit of money, services, or anything of more than nominal value, present or promised, unless consideration of substantially equal or greater value is received.

1 12 *"Materials"* unless otherwise stated herein, means all property, including but not limited to equipments, supplies, printing, insurance and leases of property

1 13 *"Procurement Officer"* means the person duly authorized by the State to enter into and administer Contracts and make written determinations with respect to the Contract

1.14 *"Purchase Order"* means a written document that is signed by a Procurement Officer, that requests a vendor to deliver described goods or services at a specific price and that, on delivery and acceptance of the goods or services by ADHS, becomes an obligation of the State

1 15 *"Services"* means the furnishing of labor, time or effort by a Contractor or Subcontractor

1 16 *"Subcontract"* means any contract, express or implied, between the Contractor and another party or between a subcontractor and another party delegating or assigning, in whole or in part, the making or furnishing of any material or any service required for the performance of this Contract

1.17 *"State"* means the State of Arizona and/or the ADHS. For purposes of this Contract, the term "State" shall not include the Contractor

2 **Contract Type.**

This Contract shall be: Fixed Price

3 **Contract Interpretation.**

3 1 Arizona Law. The law of Arizona applies to this Contract including, where applicable, the Uniform Commercial Code as adopted by the State of Arizona.

3 2 Implied Contract Terms. Each provision of law and any terms required by law to be in this Contract are a part of this Contract as if fully stated in it

3 3 Contract Order of Precedence In the event of a conflict in the provisions of the Contract, as accepted by the State and as they may be amended, the following shall prevail in the order set forth below:

3 3 1 Terms and Conditions;

3 3 2 Statement or Scope of Work;

3 3 3 Attachments;

3.3 4 Referenced Documents.

3.4 Relationship of Parties The Contractor under this Contract is an independent Contractor Neither party to this Contract shall be deemed to be the employee or agent of the other party to the Contract.

3 5 Severability. The provisions of this Contract are severable Any term or condition deemed illegal or invalid shall not affect any other term or condition of the Contract

3 6 No Parole Evidence. This Contract is intended by the parties as a final and complete expression of their agreement. No course of prior dealings between the parties and no usage of the trade shall supplement or explain any terms used in this document

3 7 No Waiver Either party's failure to insist on strict performance of any term or condition of the Contract shall not be deemed a waiver of that term or condition even if the party accepting or acquiescing in the nonconforming performance knows of the nature of the performance and fails to object to it.

3.8 Headings. Headings are for organizational purposes only and shall not be interpreted as having legal significance or meaning

4 **Contract Administration and Operation.**

4 1 Term As indicated on the signature page of the Contract, the Contract shall be effective as of the Begin Date and shall remain effective until the Termination Date

4 2 Contract Renewal This Contract shall not bind, nor purport to bind, the State for any contractual commitment in excess of the original Contract period. The term of the Contract shall not exceed five years. However, if the original Contract period is for less than five years, the State shall have the right, at its sole option, to renew the Contract, so long as the original Contract period together with the renewal periods does not exceed five years If the State exercises such rights, all terms, conditions and provisions of the original Contract shall remain the same and apply during the renewal period with the exception of price and Scope of Work, which may be renegotiated

4 3 New Budget Term. If a budget term has been completed in a multi-term Contract, the parties may agree to change the amount and type of funding to accommodate new circumstances in the next budget term. Any increase or decrease in funding at the time of the new budget term shall coincide with a change in the

Scope of Work or change in cost of services as approved by the Arizona Department of Health Services

4 4 Non-Discrimination. The Contractor shall comply with State Executive Order No 2009-09 and all other applicable Federal and State laws, rules and regulations, including the Americans with Disabilities Act

4 5 Records and Audit Under A R S § 35-214 and A.R S § 35-215, the Contractor shall retain and shall contractually require each subcontractor to retain all data and other records ("records") relating to the acquisition and performance of the Contract for a period of five years after the completion of the Contract All records shall be subject to inspection and audit by the State and where applicable the Federal Government at reasonable times Upon request, the Contractor shall produce a legible copy of any or all such records

4 6 Financial Management For all contracts, the practices, procedures, and standards specified in and required by the Accounting and Auditing Procedures Manual for the ADHS funded programs shall be used by the Contractor in the management of Contract funds and by the State when performing a Contract audit. Funds collected by the Contractor in the form of fees, donations and/or charges for the delivery of these Contract services shall be accounted for in a separate fund

4 6.1 *Federal Funding* Contractors receiving federal funds under this Contract shall comply with the certified finance and compliance audit provision of the Office of Management and Budget (OMB) Circular A-133, if applicable. The federal financial assistance information shall be stated in a Change Order or Purchase Order

4 6.2 *State Funding* Contractors receiving state funds under this Contract shall comply with the certified compliance provisions of A R S. § 35-181.03

4.7 Inspection and Testing The Contractor agrees to permit access, at reasonable times, to its facilities

4 8 Notices Notices to the Contractor required by this Contract shall be made by the State to the person indicated on the signature page by the Contractor, unless otherwise stated in the Contract Notices to the State required by the Contract shall be made by the Contractor to an ADHS Procurement Officer, unless otherwise stated in the Contract An authorized ADHS Procurement Officer and an authorized Contractor representative may change their respective person to whom notice shall be given by written notice, and an amendment to the Contract shall not be necessary

4 9 Advertising and Promotion of Contract The Contractor shall not advertise or publish information for commercial benefit concerning this Contract without the prior written approval of an ADHS Procurement Officer

4.10 Property of the State

4 10.1 *Equipment* Except as provided below or otherwise agreed to by the parties, the title to any and all equipment acquired through the expenditure of funds received from the State shall remain the property of the State by and through the ADHS and, as such, shall remain under the sole direction, management and control of the ADHS When this Contract is terminated, the disposition of all such property shall be determined by the ADHS For Fixed Price contracts, when the Contractor provides the services/materials required by the Contract, any and all equipment purchased by the Contractor remains the property of the Contractor All purchases of equipment need to be reported to the ADHS Office of Inventory Control

4 10 2 *Title and Rights to Materials.* As used in this section, the term "Materials" means all products created or produced by the Contractor under this Contract, including, but not limited to: written and electronic information, recordings, reports, research, research findings, conclusions, abstracts, results, software, data and any other intellectual property or deliverables created, prepared, or received by the Contractor in performance of this Contract Contractor acknowledges that all Materials are the property of the State by and through the ADHS and, as such, shall remain under the sole direction, management and control of the ADHS. The Contractor is not entitled to a patent

or copyright on these Materials and may not transfer a patent or copyright on them to any other person or entity To the extent any copyright in any Materials may originally vest in the Contractor, the Contractor hereby irrevocably transfers to the ADHS, for and on behalf of the State, all copyright ownership The ADHS shall have full, complete and exclusive rights to reproduce, duplicate, adapt, distribute, display, disclose, publish, release and otherwise use all Materials The Contractor shall not use or release these Materials without the prior written consent of the ADHS When this Contract is terminated, the disposition of all such Materials shall be determined by the ADHS Further, the Contractor agrees to give recognition to the ADHS for its support of any program when releasing or publishing program Materials.

Notwithstanding the above, if the Contractor is a State agency, the following shall apply instead It is the intention of ADHS and Contractor that all material and intellectual property developed under this Agreement be used and controlled in ways to produce the greatest benefit to the parties to this Contract and the citizens of the State of Arizona As used in this paragraph, "Material" means all written and electronic information, recordings, reports, findings, research information, abstracts, results, software, data, discoveries, inventions, procedures and processes of services developed by the Contractor and any other materials created, prepared or received by the Contractor and subcontractors in performance of this Agreement "Material" as used herein shall not include any pre-existing data, information, materials, discoveries, inventions or any form of intellectual property invented, created, developed or devised by Contractor (or its employees, subcontractors or agents) prior to the commencement of the services funded by this Agreement or that may result from Contractor's involvement in other service activities that are not funded by the Agreement

Title and exclusive copyright to all Material shall vest in the State of Arizona, subject to any rights reserved on behalf of the federal government As State agencies and instrumentalities, both ADHS and Contractor shall have full, complete, perpetual, irrevocable and non-transferable rights to reproduce, duplicate, adapt, make derivative works, distribute, display, disclose, publish and otherwise use any and all Material The Contractor's right to use Material shall include the following rights: the right to use the Material in connection with its internal, non-profit research and educational activities, the right to present at academic or professional meetings or symposia and the right to publish in journals, theses, dissertations or otherwise of Contractor's own choosing Contractor agrees to provide ADHS with a right of review prior to any publication or public presentation of the Material, and ADHS shall be entitled to request the removal of its confidential information or any other content the disclosure of which would be contrary to the best interest of the State of Arizona Neither party shall release confidential information to the public without the prior expressly written permission of the other, unless required by the State public records statutes or other law, including a court order Each party agrees to give recognition to the other party in all public presentations or publications of any Material, when releasing or publishing them

In addition, ADHS and Contractor agree that any and all Material shall be made freely available to the public to the extent it is in the best interest of the State However, if either party wants to license or assign an intellectual property interest in the material to a third-party for monetary compensation, ADHS and Contractor agree to convene to determine the relevant issues of title, copyright, patent and distribution of revenue In the event of a controversy as to whether the Material is being used for monetary compensation or in a way that interferes with the best interest of the state or ADHS, then the Arizona Department of Administration shall make the final decision Notwithstanding the above, "monetary compensation' does not include compensation paid to an individual creator for traditional publications in academia (the copyrights to which are Employee-Excluded Works under ABOR Intellectual Property Policy Section 6-908C.4), an honorarium or other reimbursement of expenses for an academic or professional presentation, or an unprofitable distribution of Material.

4 11 E-Verify Requirements In accordance with A.R S § 41-4401, Contractor warrants compliance with all Federal immigration laws and regulations relating to employees and warrants its compliance with Section A R S. § 23-214, Subsection A

4.12 Federal Immigration and Nationality Act The Contractor shall comply with all federal, state and local

immigration laws and regulations relating to the immigration status of their employees during the term of the Contract. Further, the Contractor shall flow down this requirement to all subcontractors utilized during the term of the Contract The State shall retain the right to perform random audits of Contractor and subcontractor records or to inspect papers of any employee thereof to ensure compliance Should the State determine that the Contractor and/or any subcontractors be found noncompliant, the State may pursue all remedies allowed by law, including, but not limited to; suspension of work, termination of the Contract for default and suspension and/or debarment of the Contractor

5 **Costs and Payments**

5 1 Payments. Payments shall comply with the requirements of A.R S Titles 35 and 41, net 30 days Upon receipt and acceptance of goods or services, the Contractor shall submit a complete and accurate Contractor's Expenditure Report for payment from the State within thirty (30) days, as provided in the Accounting and Auditing Procedures Manual for the ADHS

5 2 Recoupment of Contract Payments

5 2 1 *Unearned Advanced Funds* Any unearned State funds that have been advanced to the Contractor and remain in its possession at the end of each budget term, or at the time of termination of the Contract, shall be refunded to the ADHS within forty-five (45) days of the end of a budget term or of the time of termination

5.2.2 *Contracted Services.* In a fixed price contract, if the number of services provided is less than the number of services for which the Contractor received compensation, funds to be returned to the ADHS shall be determined by the Contract price Where the price is determined by cost per unit of service or material, the funds to be returned shall be determined by multiplying the unit of service cost by the number of services the Contractor did not provide during the Contract term. Where the price for a deliverable is fixed, but the deliverable has not been completed, the Contractor shall be paid a pro rata portion of the completed deliverable. In a cost reimbursement contract, the ADHS shall pay for any costs that the Contractor can document as having been paid by the Contractor and approved by ADHS In addition, the Contractor will be paid its reasonable actual costs for work in progress as determined by Generally Accepted Accounting Procedures up to the date of contract termination

5.2.3 *Refunds.* Within forty-five (45) days after the end of each budget term or of the time of termination of the Contract, the Contractor shall refund the greater of: i) the amount refundable in accordance with paragraph 5.2.1, Unearned Advanced Funds; or ii) the amount refundable in accordance with paragraph 5 2 2, Contracted Services

5 2 4 *Unacceptable Expenditures.* The Contractor agrees to reimburse the ADHS for all Contract funds expended, which are determined by the ADHS not to have been disbursed by the Contractor in accordance with the terms of this Contract The Contractor shall reimburse ADHS within forty-five (45) days of the determination of unacceptability

5 3 Unit Costs/Rates or Fees. Unit costs/rates or fees shall be based on costs, which are determined by ADHS to be reasonable, allowable and allocable as outlined in the Accounting and Auditing Procedures Manual for the ADHS.

5 4 Applicable Taxes.

5.4.1 *State and Local Transaction Privilege Taxes* The State of Arizona is subject to all applicable state and local transaction privilege taxes Transaction privilege taxes apply to the sale and are the responsibility of the seller to remit Failure to collect taxes from the buyer does not relieve the seller from its obligation to remit taxes.

5 4 2 *Tax Indemnification* The Contractor and all subcontractors shall pay all federal, state and local taxes applicable to its operation and any persons employed by the Contractor Contractor shall

require all subcontractors to hold the State harmless from any responsibility for taxes, damages and interest, if applicable, contributions required under Federal, and/or state and local laws and regulations and any other costs, including transaction privilege taxes, unemployment compensation insurance, Social Security and Worker's Compensation

5 4 3 *I R S W9 Form* In order to receive payment under any resulting Contract, the Contractor shall have a current I R S W9 Form on file with the State of Arizona

5 5 Availability of Funds for the Next Fiscal Year. Funds may not be presently available for performance under this Contract beyond the first year of the budget term or Contract term. The State may reduce payments or terminate this Contract without further recourse, obligation or penalty in the event that insufficient funds are appropriated in the subsequent budget term. The State shall not be liable for any purchases or Subcontracts entered into by the Contractor in anticipation of such funding. The Procurement Officer shall have the discretion in determining the availability of funds.

5 6 Availability of Funds for the Current Contract Term. Should the State Legislature enter back into session and decrease the appropriations through line item or general fund reductions, or for any other reason these goods or services are not funded as determined by ADHS, the following actions may be taken by ADHS:

5 6 1 Accept a decrease in price offered by the Contractor;

5.6 2 Reduce the number of goods or units of service and reduce the payments accordingly;

5 6 3 Offer reductions in funding as an alternative to Contract termination; or

5 6 4 Cancel the Contract.

5.7 Authorization for Provision of Services: Authorization for purchase of services under this contract shall be made only upon ADHS issuance of a Purchase Order that is signed by an authorized agent. The Purchase Order will indicate the contract number and the dollar amount of funds authorized. The Contractor shall only be authorized to perform services up to the amount on the Purchase Order. ADHS shall not have any legal obligation to pay for services in excess of the amount indicated on the Purchase Order. No further obligation for payment shall exist on behalf of ADHS unless a) the Purchase Order is changed or modified with an official ADHS Procurement Change Order, and/or b) an additional Purchase Order is issued for purchase of services under this contract

6 Contract Changes

6.1 Amendments, Purchase Orders and Change Orders. This Contract is issued under the authority of the Procurement Officer who signed this Contract. The Contract may be modified only through a Contract Amendment, Purchase Order and/or Change Order within the scope of the Contract, unless the change is administrative or otherwise permitted by the Special Terms and Conditions. Changes to the Contract, including the addition of work or materials, the revision of payment terms, or the substitution of work or materials, directed by an unauthorized State employee or made unilaterally by the Contractor are violations of the Contract and of applicable law. Such changes, including unauthorized Contract Amendments, Purchase Orders and/or Change Orders, shall be void and without effect, and the Contractor shall not be entitled to any claim under this Contract based on those changes

6 2 Subcontracts. The Contractor shall not enter into any subcontract under this Contract without the advance written approval of the Procurement Officer. The subcontract shall incorporate by reference all material and applicable terms and conditions of this Contract

6.3 Assignments and Delegation. The Contractor shall not assign any right nor delegate any duty under this Contract without the prior written approval of the Procurement Officer. The State shall not unreasonably withhold approval

7. **Risk and Liability**

7 1 Risk of Loss The Contractor shall bear all loss of conforming material covered under this Contract until received and accepted by authorized personnel at the location designated in the Purchase Order, Change Order or Contract Mere receipt does not constitute final acceptance. The risk of loss for nonconforming materials shall remain with the Contractor regardless of receipt

7 2 Mutual Indemnification Each party (as "indemnitor") agrees to indemnify, defend and hold harmless the other party (as "indemnitee") from and against any and all claims, losses, liability, costs or expenses (including reasonable attorney's fees) (hereinafter collectively referred to as "claims") arising out of bodily injury of any person (including death) or property damage, but only to the extent that such claims, which result in vicarious/derivative liability to the indemnitee, are caused by the act, omission, negligence, misconduct, or other fault of the indemnitor, its officers, officials, agents, employees or volunteers

7 3 Indemnification - Patent and Copyright. To the extent permitted by A R.S § 41-621 and A R.S. § 35-154, the Contractor shall indemnify and hold harmless the State against any liability, including costs and expenses, for infringement of any patent, trademark or copyright arising out of performance of the Contract or use by the State of materials furnished by or work performed under this Contract The State shall reasonably notify the Contractor of any claim for which it may be liable under this paragraph.

7 4 Force Majeure.

7 4 1 *Liability and Definition* Except for payment of sums due, neither party shall be liable to the other nor deemed in default under this Contract if and to the extent that such party's performance of this Contract is prevented by reason of force majeure The term "*force majeure*" means an occurrence that is beyond the control of the party affected and occurs without its fault or negligence Without limiting the foregoing, force majeure includes acts of God; acts of the public enemy, acts of terrorism; war; riots; strikes; mobilization; labor disputes; civil disorders; fire; flood; lockouts; injunctions-interventions not caused by or resulting from the act or failure to act of the parties; failures or refusals to act by government authority not caused by or resulting from the act or failure to act of the parties, and other similar occurrences beyond the control of the party declaring force majeure, which such party is unable to prevent by exercising reasonable diligence

7 4 2 *Exclusions* Force Majeure shall not include the following occurrences:

7 4 2 1 Late delivery of Materials caused by congestion at a manufacturer's plant or elsewhere, or an oversold condition of the market;

7 4 2 2 Late performance by a subcontractor unless the delay arises out of a force majeure occurrence in accordance with this force majeure term and condition; or

7 4 2 3 Inability of either the Contractor or any subcontractor to acquire or maintain any required insurance, bonds, licenses or permits

7 4 3 *Notice* If either party is delayed at any time in the progress of the work by force majeure, the delayed party shall notify the other party in writing of such delay, as soon as is practicable and no later than the following working day of the commencement thereof, and shall specify the causes of such delay in such notice Such notice shall be delivered or mailed certified-return receipt and shall make a specific reference to this article, thereby invoking its provisions The delayed party shall cause such delay to cease as soon as practicable and shall notify the other party in writing when it has done so The time of completion shall be extended by Contract Amendment for a period of time equal to the time that the results or effects of such delay prevent the delayed party from performing in accordance with this Contract

7 4 4 *Default* Any delay or failure in performance by either party hereto shall not constitute default hereunder or give rise to any claim for damages or loss of anticipated profits if, and to the extent that, such delay or failure is caused by force majeure

7 5 Third Party Antitrust Violations The Contractor assigns to the State any claim for overcharges resulting from antitrust violations to the extent that those violations concern materials or services supplied by third parties to the Contractor for or toward the fulfillment of this Contract.

8 **Description of Materials** The following provisions shall apply to Materials only:

8 1 Liens. The Contractor agrees that the Materials supplied under this Contract are free of liens. In the event the Materials are not free of liens, Contractor shall pay to remove the lien and any associated damages or replace the Materials with Materials free of liens

8 2 Quality Unless otherwise modified elsewhere in these terms and conditions, the Contractor agrees that, for one year after acceptance by the State of the Materials, they shall be:

8 2 1 Of a quality to pass without objection in the Contract description;

8 2 2 Fit for the intended purposes for which the Materials are used;

8 2 3 Within the variations permitted by the Contract and are of even kind, quantity, and quality within each unit and among all units;

8 2 4 Adequately contained, packaged and marked as the Contract may require; and

8.2.5 Conform to the written promises or affirmations of fact made by the Contractor

8.3 Inspection/Testing. Subparagraphs 8 1 through 8 2 of this paragraph are not affected by inspection or testing of or payment for the Materials by the State

8 4 Compliance With Applicable Laws The Materials and services supplied under this Contract shall comply with all applicable federal, state and local laws, and the Contractor shall maintain all applicable license and permit requirements

8 5 Survival of Rights and Obligations After Contract Expiration and Termination.

8 5 1 *Contractor's Representations* All representations and warranties made by the Contractor under this Contract in paragraphs Seven (7) and Eight (8) shall survive the expiration or termination hereof In addition, the parties hereto acknowledge that pursuant to A R S. § 12.510, except as provided in A R S § 12-529, the State is not subject to or barred by any limitations of actions prescribed in A.R S Title 12, Chapter Five (5)

8 5 2 *Purchase Orders and Change Orders* Unless otherwise directed in writing by the Procurement Officer, the Contractor shall fully perform and shall be obligated to comply with all Purchase Orders and Change Orders received by the Contractor prior to the expiration or termination hereof, including, without limitation, all Purchase Orders and Change Orders received prior to but not fully performed and satisfied at the expiration or termination of this Contract

9. **State's Contractual Remedies**

9 1 Right to Assurance. If the State, in good faith, has reason to believe that the Contractor does not intend to, or is unable to, perform or continue performing under this Contract, the Procurement Officer may demand in writing that the Contractor give a written assurance of intent to perform. Failure by the Contractor to provide written assurance within the number of Days specified in the demand may, at the State's option, be the basis for terminating the Contract

9.2 Stop Work Order.

9.2.1 *Terms* The State may, at any time, by written order to the Contractor, require the Contractor to

stop all or any part of the work called for by this Contract for a period up to ninety (90) Days after the order is delivered to the Contractor, and for any further period to which the parties may agree The order shall be specifically identified as a stop work order issued under this clause Upon receipt of the order, the Contractor shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage

9 2 2 *Cancellation or Expiration* If a stop work order issued under this clause is canceled or the period of the order or any extension expires, the Contractor shall resume work The Procurement Officer shall make an equitable adjustment in the delivery schedule or Contract price, or both, and the Contract shall be amended in writing accordingly

9 3 Non-exclusive Remedies The rights and remedies of ADHS under this Contract are not exclusive, and ADHS is entitled to all rights and remedies available to it, including those under the Arizona Uniform Commercial Code and Arizona common law

9 4 Right of Offset The State shall be entitled to offset against any sums due the Contractor in any Contract with the State or damages assessed by the State because of the Contractor's non-conforming performance or failure to perform this Contract. The right to offset may include, but is not limited to, a deduction from an unpaid balance and a collection against the bid and/or performance bonds. Any offset taken for damages assessed by the State shall represent a fair and reasonable amount for the actual damages and shall not be a penalty for non-performance.

10. **Contract Termination**

10 1 Cancellation for Conflict of Interest Pursuant to A R S. § 38-511, the State may cancel this Contract within three (3) years after Contract execution without penalty or further obligation if any person significantly involved in initiating, negotiating, securing, drafting or creating the Contract on behalf of the State is, or becomes at any time while the Contract or an extension of the Contract is in effect, an employee of or a consultant to any other party to this Contract with respect to the subject matter of the Contract The cancellation shall be effective when the Contractor receives written notice of the cancellation, unless the notice specifies a later time. If the Contractor is a political subdivision of the State, it may also cancel this Contract as provided in A R S. § 38-511.

10 2 Gratuities The State may, by written notice, terminate this Contract, in whole or in part, if the State determines that employment or a Gratuity was offered or made by the Contractor or a representative of the Contractor to any officer or employee of the State for the purpose of influencing the outcome of the procurement, securing the Contract or an Amendment to the Contract, or receiving favorable treatment concerning the Contract, including the making of any determination or decision about Contract performance. The State, in addition to any other rights or remedies, shall be entitled to recover exemplary damages in the amount of three times the value of the Gratuity offered by the Contractor

10 3 Suspension or Debarment. The State may, by written notice to the Contractor, immediately terminate this Contract if the State determines that the Contractor or its subcontractor has been debarred, suspended or otherwise lawfully prohibited from participating in any public procurement activity, including but not limited to, being disapproved as a subcontractor of any public procurement unit or other governmental body.

10.4 Termination Without Cause.

10 4 1 Both the State and the Contractor may terminate this Contract at any time with thirty (30) days notice in writing specifying the termination date Such notices shall be given by personal delivery or by certified mail, return receipt requested

10 4 2 If the Contractor terminates this Contract, any monies prepaid by the State, for which no service or benefit was received by the State, shall be refunded to the State within five (5) days of the termination notice In addition, if the Contractor terminates the Contract, the Contractor shall indemnify the State for any sanctions imposed by the funding source as a result of the

Contractor's failure to complete the Contract

10 4 3 If the State terminates this Contact pursuant to this Section, the State shall pay the Contractor the Contract price for all Services and Materials completed up to the date of termination. In a fixed price contract, the State shall pay the amount owed for the Services or Materials by multiplying the unit of service or item cost by the number of unpaid service units or items. In a cost reimbursement contract, the ADHS shall pay for any costs that the Contractor can document as having been paid by the Contractor and approved by ADHS In addition, the Contractor will be paid its reasonable actual costs for work in progress as determined by GAAP up to the date of termination Upon such termination, the Contractor shall deliver to the ADHS all deliverables completed ADHS may require Contractor to negotiate the terms of any remaining deliverables still due

10 5 Mutual Termination. This Contract may be terminated by mutual written agreement of the parties specifying the termination date and the terms for disposition of property and, as necessary, submission of required deliverables and payment therein

10 6 Termination for Default The State reserves the right to terminate the Contract in whole or in part due to the failure of the Contractor to comply with any material obligation, term or condition of the Contract, to acquire and maintain all required insurance policies, bonds, licenses and permits, or to make satisfactory progress in performing the Contract In the event the ADHS terminates the Contract in whole or in part as provided in this paragraph, the ADHS may procure, upon such terms and in such manner as deemed appropriate, Services or Materials, similar to those terminated, and Contractor shall be liable to the ADHS for any excess costs incurred by the ADHS in obtaining such similar Services or Materials

10 7 Continuation of Performance Through Termination Upon receipt of the notice of termination and until the effective date of the notice of termination, the Contractor shall perform work consistent with the requirements of the Contract and, if applicable, in accordance with a written transition plan approved by the ADHS If the Contract is terminated in part, the Contractor shall continue to perform the Contract to the extent not terminated. After receiving the notice of termination, the Contractor shall immediately notify all subcontractors, in writing, to stop work on the effective date of termination, and on the effective date of termination, the Contractor and subcontractors shall stop all work

10 8 Disposition of Property. Upon termination of this Contract, all property of the State, as defined herein, shall be delivered to the ADHS upon demand.

11 **Arbitration** Pursuant to A R S. § 12-1518, disputes under this Contract shall be resolved through the use of arbitration when the case or lawsuit is subject to mandatory arbitration pursuant to rules adopted under A R S § 12 -133

12 **Communication**

12 1 Program Report. When reports are required by the Contract, the Contractor shall provide them in the format approved by ADHS

12.2 Information and Coordination The State will provide information to the Contractor pertaining to activities that affect the Contractor's delivery of services, and the Contractor shall be responsible for coordinating their activities with the State's in such a manner as not to conflict or unnecessarily duplicate the State's activities As the work of the Contractor progresses, advice and information on matters covered by the Contract shall be made available by the Contractor to the State throughout the effective period of the Contract

13 **Client Grievances** If applicable, the Contractor and its subcontractors shall use a procedure through which clients may present grievances about the operation of the program that result in the denial, suspension or reduction of services provided pursuant to this Contract and which is acceptable to and approved by the State

14. **Sovereign Immunity** Pursuant to A R.S § 41-621(O), the obtaining of insurance by the State shall not be a

waiver of any sovereign immunity defense in the event of suit

15 **Administrative Changes** The Procurement Officer, or authorized designee, reserves the right to correct any obvious clerical, typographical or grammatical errors, as well as errors in party contact information (collectively, "Administrative Changes"), prior to or after the final execution of a Contract or Contract Amendment Administrative Changes subject to permissible corrections include. misspellings, grammar errors, incorrect addresses, incorrect Contract Amendment numbers, pagination and citation errors, mistakes in the labeling of the rate as either extended or unit, and calendar date errors that are illogical due to typographical error The Procurement Office shall subsequently send to the Contractor notice of corrections to administrative errors in a written confirmation letter with a copy of the corrected Administrative Change attached

16 **Survival of Terms After Termination or Cancellation of Contract** All applicable Contract terms shall survive and apply after Contract termination or cancellation to the extent necessary for Contractor to complete and for the ADHS to receive and accept any final deliverables that are due after the date of the termination or cancellation.

17. **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** The Contractor warrants that it is familiar with the requirements of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009, and accompanying regulations and will comply with all applicable HIPAA requirements in the course of this Contract Contractor warrants that it will cooperate with the Arizona Department of Health Services (ADHS) in the course of performance of the Contract so that both ADHS and Contractor will be in compliance with HIPAA, including cooperation and coordination with the Government Information Technology Agency (GITA), Statewide Information Security and Privacy Office (SISPO) Chief Privacy Officer and HIPAA Coordinator and other compliance officials required by HIPAA and its regulations Contractor will sign any documents that are reasonably necessary to keep ADHS and Contractor in compliance with HIPAA, including, but not limited to, business associate agreements

If requested by the ADHS Procurement Office, Contractor agrees to sign a "Pledge To Protect Confidential Information" and to abide by the statements addressing the creation, use and disclosure of confidential information, including information designated as protected health information and all other confidential or sensitive information as defined in policy. In addition, if requested, Contractor agrees to attend or participate in HIPAA training offered by ADHS or to provide written verification that the Contractor has attended or participated in job related HIPAA training that is: (1) intended to make the Contractor proficient in HIPAA for purposes of performing the services required and (2) presented by a HIPAA Privacy Officer or other person or program knowledgeable and experienced in HIPAA and who has been approved by the GITA/SISPO Chief Privacy Officer and HIPAA Coordinator

18 **Comments Welcome** The ADHS Procurement Office periodically reviews the Uniform Terms and Conditions and welcomes any comments you may have Please submit your comments to: ADHS Procurement Administrator, Arizona Department of Health Services, 1740 West Adams, Suite 303, Phoenix, Arizona, 85007

19. **Key Personnel** It is essential that the Contractor provide adequate experienced personnel, capable of and devoted to the successful accomplishment of work to be performed under this Contract The Contractor must agree to assign specific individuals to the key positions

1 The Contractor agrees that, once assigned to work under this Contract, key personnel shall not be removed or replaced without written notice to the State.

2 Key personnel are not available for work under this Contract for a continuous period exceeding 30 calendar days, or are expected to devote substantially less effort to the work than initially anticipated, the Contractor shall immediately notify the State, and shall, subject to the concurrence of the State, replace such personnel with personnel of substantially equal ability and qualifications

20 **Data Universal Numbering System (DUNS) Requirement** For federal funding, pursuant to 2 CFR 25 100 et seq., no entity (defined as a Governmental organization, which is a State, local government, or Indian tribe; foreign public entity; domestic or foreign nonprofit organization; domestic or foreign for-profit organization; or Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity) may receive a subaward from ADHS unless the entity provides its Data Universal Numbering System (DUNS) Number to ADHS

Public Health Accreditation Preparation Activities

1. BACKGROUND

The Arizona Department of Health Services (ADHS) is committed to achieving accreditation through the voluntary Public Health Accreditation Board (PHAB) The accreditation process focuses on improving public health services and outcomes by implementing Quality Improvement (QI) practices In response to the accreditation standards, ADHS created the Managing for Excellence Program (MEP) concentrating on the accreditation requirements In 2011 the Strategic Plan, one (1) of three (3) PHAB prerequisites, was updated In 2014 ADHS will focus on the remaining two (2) PHAB prerequisites, a comprehensive 'Statewide Community Health Assessment' and the 'State Health Improvement Plan' (SHIP). An important component of the planning process is organizing partnerships across the State, collaborating with County Health Departments, and sharing information gathered from Community Health Assessments (CHA) and Community Health Improvement Plans (CHIP)

The Preventive Health and Health Services Block funding will be aimed at supporting local public health departments (LHDs) in undertaking accreditation preparation activities Funding will be provided to LHDs to engage in activities that will demonstrate a measurable increase in their readiness to achieve Public Health Accreditation Board (PHAB) accreditation.

Each County will select two (2) or more categories of work, and two (2) or more deliverables within each category, based on an identified area of need around accreditation readiness

Opportunities for peer networking, sharing, and technical assistance (TA) will be provided by ADHS

Counties can select the deliverable(s) based on:

1 1 Feasibility for the LHD to undertake and complete within the project timeframe, and

1 2 Greatest benefit to the LHD in their accreditation readiness. Counties should only choose deliverables that that will be completed during the course of this project, and not those that have already been completed

For each deliverable(s) selected, Counties will be required to describe the activities they propose to undertake in order to accomplish that deliverable, the corresponding timeframes, and expected outcomes The County will also be required to provide an overall budget which will be used to reconcile expenditures by ADHS Local Health

For contextual purposes, categories include references to the most closely related domains within the PHAB Standards and Measures However, it is understood that work in one (1) or more of the categories may span across several PHAB domains indirectly, or in conjunction with other categories of work

2. CATEGORIES SELECTED

2 3 **Category 3: Building a Culture of Quality Improvement** (related PHAB Domain: 9)

Quality improvement (QI) is the result of leadership support and requires staff commitment at all levels to build a culture of quality and ensure it is fully integrated into organizational structures, processes, services, operations, and more Counties selecting this category may use this award to conduct activities that will show progress towards building a culture of Quality Improvement (QI) that will fulfill one (1) or more of the outlined deliverables (e g , assessment of current QI culture and description of desired future state, plan for regularly communicating about QI activities, etc.)

2.4 **Category 4: Workforce Development** (related PHAB Domain: 8)

A multi-disciplinary workforce that is matched to the specific community being served facilitates the interdisciplinary approaches required to address the population's public health issues PHAB Standards and Measures (v1 0) focus on the need for LHDs to take as strategic approach to the development of a trained and competent workforce to effectively perform duties Counties selecting this category may use this award to conduct activities that will show progress towards training and development of the LHD workforce that will fulfill one (1) or more of the outlined deliverables (e g , job descriptions that include core competencies, a workforce development plan, etc)

3. COUNTY RESPONSIBILITY

Each County funded shall:

3 1 Designate one (1) main point of contact with whom ADHS will directly communicate on all matters related to this project This Project Coordinator will be responsible for submitting all deliverables, participating in peer networking conference calls or webinars, and completing evaluation activities;

3 2 Designate at least one (1) relevant staff member to attend the ADHS training on workforce development, QI and performance management Funding for traveling to this training must be allocated from the total award amount to the county; and

3 3 Submit, per the Contract Scope of Work, all deliverables as selected in the Application and two (2) project update assessments Selected deliverables will be posted to ADHS, MEP, website

4. ADHS' RESPONSIBILTIES

ADHS will provide:

4 1 A monetary award that will be paid in installments per agreed up on deliverables and price sheet; □

4 2 Opportunities for peer-to-peer networking among all selected LHDs and those within each category of work including hosted conference calls, as appropriate;

4 3 Access to virtual TA and guidance from ADHS staff, LHD peers/mentors, and/or potentially subject-matter experts related to the category of work for which the County received the award, as appropriate. (Please note that this guidance will be limited; if significant TA is necessary for a County to complete their work, Counties should plan to contract with a consultant/SME and budget for the expense within the Application.); and

4 4 Connection to learning communities and national networks

5. APPROVALS:

5 1 The ADHS will make payment in accordance to the Terms and Conditions and Scope of Work set forth in the Contract.

6. DELIVERABLES

6.1 Category 3: **Building a Culture of Quality Improvement**

6.1 1 Detailed written description of process and criteria for identifying and initiating appropriate QI projects,

6 1.2 Detailed written description of the LHD's plan for regularly communicating about QI activities in the department, and evidence of at least three (3) of those mechanisms implemented,

6 1.3 Written or visual example of a completed QI project(s) in a program and/or administrative area, and

6.2 Category 4. **Workforce Development**

6 2 1 Detailed written plan for ensuring adoption of relevant public health core competencies among staff,

6 2.2 Assessment(s) used to assess staff competencies against the adopted core competencies and detailed description of process for implementing assessment,

6 2 3 Staff training plan based upon results of assessment, including training schedules and description of curricula topics, and how identified gaps in staff competencies will be addressed.

7. NOTICES, CORRESPONDENCE, REPORTS AND INVOICES:

7 1 Notices, Correspondence, Reports and Invoices from the Contractor to ADHS should be sent to:

Arizona Department of Health Services
Local Health
Attention: Carol Vack
150 18th Avenue, Suite # 520
Phoenix, Arizona 85007
Telephone: 602 542-7395
Email: carol.vack@azdhs.gov

7 2 Notices, correspondence, and reports from ADHS to the Contractor shall be sent to:

Gila County Health Services
Attn: Michael O'Driscoll, Director
(Site) 5515 South Apache Ave, Ste. 100
(Mailing) 1400 East Ash
Globe, Arizona 85501
Phone: (928) 402-8761
Fax: (928) 425-0794
Email: modriscoll@co.gila.az.us

PRICE SHEET
Effective January 6, 2014

ADHS will pay for completed Tasks monthly upon receipt of a Invoice from the County

Description	Budget Amount
Category 3: Building a Culture of Quality Improvement: Detailed written description of process and criteria	$7500.00
Category 3: Building a Culture of Quality Improvement: Detailed written description of the LHD's plan for regularly communicating about QI activities in the department	$7500.00
Category 3: Building a Culture of Quality Improvement. Written or visual example of a completed QI project(s)	$7500 00
Category 4: Workforce Development: Detailed written plan for ensuring adoption of relevant public health core competencies among staff	$7500 00
Category 4: Workforce Development: Assessment(s) used to assess staff competencies against the adopted core competencies	$7500.00
Category 4: Workforce Development: Staff training plan based upon results of assessment	$7500 00
Total Contract Amount Not to Exceed	$45,000 00

GILA COUNTY ATTORNEY

Bradley D. Beauchamp

Re: County Attorney's Office approval of IGA pursuant to A.R.S. § 11-952(D).

To whom it may concern:

The County Attorney's Office has reviewed the Intergovernmental Agreement attached to this agenda item and has determined that it is in its "proper form" and "is within the powers and authority granted under the laws of this state to such public agency or public procurement unit" pursuant to A.R.S. § 11-952(D).

Explanation of the Gila County Attorney's Office Intergovernmental Agreement (IGA) Review

A.R.S. § 11-952(D) requires that

> every agreement or contract involving any public agency or public procurement unit of this state . . . before its execution, shall be submitted to the attorney for each such public agency or public procurement unit, who shall determine whether the agreement is in proper form and is within the powers and authority granted under the laws of this state to such public agency or public procurement unit.

In performing this review, the County Attorney's Office reviews IGAs to see that they are in "proper form" prior to their execution. "Proper form" means that the contract conforms to fundamental contract law, conforms to specific legislative requirements, and is within the powers and authority granted to the public agency. It does not mean that the County Attorney's Office approves of or supports the policy objectives contained in the IGA. That approval is solely the province of the public agency through its elected body.

Likewise, this approval is not a certification that the IGA has been properly executed. Proper execution can only be determined after all the entities entering into the IGA have taken legal action to approve the IGA. There is no statutory requirement for the County Attorney's Office to certify that IGAs are properly executed.

Nonetheless, it is imperative for each public agency to ensure that each IGA is properly executed because A.R.S. § 11-952(F) requires that "[a]ppropriate action … applicable to the governing bodies of the participating agencies approving or extending the duration of the … contract shall be necessary before any such agreement, contract or extension may be filed or become effective." This can be done by ensuring that the governing body gives the public proper notice of the meeting wherein action will be taken to approve the IGA, that the item is adequately described in the agenda accompanying the notice, and that the governing body takes such action. Any questions regarding whether the IGA has been properly executed may be directed to the County Attorney's Office.

Proper execution of IGAs is important because A.R.S. § 11-952(H) provides that "[p]ayment for services under this section shall not be made unless pursuant to a fully approved written contract." Additionally, A.R.S. § 11-952(I) provides that "[a] person who authorizes payment of any monies in violation of this section is liable for the monies paid plus twenty per cent of such amount and legal interest from the date of payment."

The public agency or department submitting the IGA for review has the responsibility to read and understand the IGA in order to completely understand its obligations under the IGA if it is ultimately approved by the public entity's board. This is because while the County Attorney's Office can approve the IGA as to form, the office may not have any idea whether the public agency has the capacity to actually comply with its contractual obligations. Also, the County Attorney's Office does not monitor IGA compliance. Hence the public entity or submitting department will need to be prepared to monitor their own compliance. A thorough knowledge of the provisions of the IGA will be necessary to monitor compliance.

Before determining whether an IGA contract "is in proper form," the County Attorney's Office will answer any questions or concerns the public agency has about the contract. It is the responsibility of the public agency or department submitting the IGA for review to ask any specific questions or address any concerns it has about the IGA to the County Attorney's Office at the same time they submit the IGA for review. Making such an inquiry also helps improve the County Attorney's Office review of the IGA because it will help focus the review on specific issues that are of greatest concern to the public agency. Failing to make such an inquiry when the agency does have issues or concerns will decrease the ability of the County Attorney's Office to meaningfully review the IGA.

ARF-2807 **Consent Agenda Item 4. G.**

Regular BOS Meeting

Meeting Date:	10/21/2014		
Submitted For:	Paula Horn, Deputy Director of Prevention Services	Submitted By:	Paula Horn, Deputy Director of Prevention Services, Health & Emergency Services Division
Department:	Health & Emergency Services Division	Division:	Prevention Services
Fiscal Year:	2014-2015	Budgeted?:	Yes
Contract Dates Begin & End:	July 1, 2014 - June 30, 2015	Grant?:	Yes
Matching Requirement?:	No	Fund?:	Renewal

Information

Request/Subject

Amendment to an Intergovernmental Agreement (Contract No. GRA-RC004-13-0556-01-Y3) with First Things First.

Background Information

The original Intergovernmental Agreement (Contract No. GRA-RC004-13-0556-01), which allowed the Gila County Health Department to provide the Healthy Steps Program, was approved by the Board of Supervisors on September 18, 2012, in the amount of $155,000. The original contract period was from October 1, 2012, through June 30, 2013.

The renewal of the Intergovernmental Agreement (Contract No. GRA-RC004-13-0556-01) was approved by the Board of Supervisors (BOS) on May 7, 2013, for the period of July 1, 2013, through June 30, 2014, in the amount of $190,000.

The renewal packet of the Intergovernmental Agreement (Contract No. GRA-RC004-13-0556-01-Y3) was signed by the BOS on April 15, 2014.

The grant renewal amendment is for the 2015 grant award.

Evaluation

The Board of Supervisors' approval of this Intergovernmental Agreement (Contract No. GRA-RC004-13-0556-01-Y3) for the period of July 1, 2014, to June 30, 2015, in the amount of $190,000 will allow the continuation of the Healthy Steps Program which provides home visitation support, information, and education to families on the practices and community resources related to family health and child development.

Conclusion

Approval of an Intergovernmental Agreement (Contract No. GRA-RC004-13-0556-01-Y3) between Gila County and First Things First will allow the Gila County Health Department to continue the Healthy Steps Program.

Recommendation

It is the recommendation of the Director of Health and Emergency Services that the Board of Supervisors approve the Grant Renewal Amendment Contract No. GRA-RC004-13-0556-01-Y3 between Gila County and First Things First in the amount of $190,000 to continue to provide Healthy Steps Program services for the period of July 1, 2014, through June 30, 2015.

Suggested Motion

Approval of a Grant Renewal Amendment to an Intergovernmental Agreement (Contract No. GRA-RC004-13-0556-01-Y3) between Gila County and First Things First to receive the 2015 Grant Award in the amount of $190,000, which allows the Gila County Health Department to continue to provide Healthy Steps Program services for the period of July 1, 2014, through June 30, 2015.

Attachments

Grant Renewal Amendment

Notice of Grant Renewal Consideration 14-15

Grant Renewal Package 13-14

Original Agreement

Legal Explanation

Grant Renewal Amendment

FIRST THINGS FIR
Ready for School. Set for L

2015 Grant Award
GRA-RC004-13-0556-01-Y3
Gila
Care Coordination/Medical Home

Early Childhood Health and Development Board (First Things First)

4000 North Central Avenue, Suite 800
Phoenix, Arizona 85012

(602) 771-5000 (602) 265-0009 fax

CONTRACTOR:

Gila County
Divison of Health and Community Services
5515 S. Apache Ave., Ste. 100
Globe, Arizona 85501

PURPOSE OF AMENDMENT:

1. Pursuant to Special Terms and Conditions, "Contract Renewal", of the above referenced Grant Agreement/Contract Award, the State of Arizona hereby exercises its sole option to renew the Grant Agreement/Contract Award number referenced above. The renewal start date is July 1, 2014 and end date is June 30, 2015.

2. Total award amount for the contract period is $190,000.00

3. The Grantee is responsible for all updated Standards of Practice located for reference in the First Things First Grant Management System known as PGMS under Grantee Resources.

4. All other terms and conditions remain unchanged.

Contractor hereby acknowledges receipt and understanding of the contract amendment.

Signature_____

Name Michael A. Pastor

Title Board of Supervisors, Chairman

Date_____

The above referenced amendment is hereby executed effective July 1, 2014 once signed and dated below:

_____

Josh Allen CFO/COO

_____

Date

_____

Bryan Chambers, Deputy County Attorney/Civil Bureau Chief

First Things First
Notice of Renewal Consideration

DATE: March 6, 2014

TO: Gila County

FROM: Marjorie Bennett
Fiscal Specialist

RE: Renewal Information for Fiscal Year 2015

The current Fiscal Year (FY) 2014 grant awards are approaching renewal consideration from the First Things First Gila Regional Partnership Council. Receipt of this packet does not guarantee renewal of the grant award; it indicates eligibility for renewal consideration. First Things First may renew grant awards based on a number of factors including past performance and response to this renewal package.

If renewed, the responsibility for adherence to all rules, regulations and terms and conditions set forth in the original Request for Grant Application (RFGA) or grant agreement will remain in effect for the contract period. This includes compliance with the appropriate standards of practice, program implementation, as well as timely submission of data and narrative reports and financial reimbursements.

The renewal package includes instructions and the following attachments:

Attachment A - Program Implementation Questions
Attachment B - Program Implementation Plan
Attachment C - Line Item Budget and Budget Narrative
Attachment D - Key Personnel
Attachment E - Disclosure of Other Funding
Attachment F - First Things First Standard Agency Information Collection Form

The completed renewal package (Attachments A-F) must be ***received*** no later than ***3:00 PM on April 4, 2014.*** Submit via email to mbennett@azftf.gov. Electronic submission is preferred but if sending by standard mail, please send to my attention, First Things First, 4000 N. Central Avenue, Suite 800, Phoenix, AZ 85012.

Once received, responses will be reviewed and funding recommendations will be made to the Gila Regional Partnership Council and the Board of First Things First. First Things First staff may contact you for clarifications prior to making recommendations. Grant awards will be in effect from July 1, 2014 through June 30, 2015.

For questions, please contact me via email or phone, (602) 771-5084.

Thank you.

First Things First
Grant Renewal Instructions
July 1, 2014 – June 30, 2015

The following First Things First (FTF) grant is eligible for renewal by extending the current FY 2014 grant award. Programs in FY 2015 cannot be different in scope than from what was originally awarded.

Grantee Name:	Gila County
FTF Grant Number:	GRA-RC004-13-0556-01-Y2
Strategy Name:	Care Coordination/Medical Home
Data Template(s) Assigned:	Care Coordination / Medical Home Developmental and Sensory Screening Health Insurance Enrollment
Eligible Renewal Amount:	$ 190,000.00 The amount is subject to change pending legal and procurement review at First Things First. If a different amount is approved for renewal, an updated line item budget & budget narrative will be required.

The renewal package includes the completion and submission of Attachments A-F.

Program Implementation Questions (Attachment A)
Provide a narrative response to each question in Attachment A.

Program Implementation Plan (Attachment B)
Provide an updated implementation plan for FY 2015. The implementation plan should be related to the originally approved program activities, tasks, data collection, data submission, and process.

2015 Budget Forms (Attachment C – must include both the line item budget and budget narrative)

Key Personnel (Attachment D)
List all staff that will be paid from this grant program during FY 2015. The staff listed should correspond with your line item budget and budget narrative. Submit resumes for any new staff or for those that have not yet been submitted to First Things First.

Disclosure of Other Funding Sources (Attachment E)
List any other funding utilized for this program administered by your agency.

First Things First Standard Agency Information Collection Form (Attachment F)

FTF Regional Boundary Changes: Regional boundary changes that impact the North Phoenix, Central Phoenix, South Phoenix, Northeast Maricopa, Central Maricopa, Central Pima, North Pima and South Pima regions will go into effect July 1, 2014. Any grant that is approved for renewal in the affected regions will continue to serve the same geographic area they were originally awarded to serve, with the expectation of maintaining current service delivery and service numbers from FY14 into FY15, unless otherwise indicated.

Standards of Practice Updates: Utilization of the Standards of Practice are part of the requirements for all awarded grants and represent the intent for how specific strategies are to be implemented. Prior authorization is needed if the program deviates from the Standards of Practice. Grantees are responsible for reviewing and implementing the most recent versions of the Standards of Practice, located in the FTF Strategy Toolkit, http://www.azftf.gov/pages/webmain.aspx?PageID=2D427ADB35B34BB09F353B77B74AB9BA.

Model Programs that Require Certification and Accreditation: It is the responsibility of the grantee to maintain accreditation/certification with national program models. Grantees are to include staff training, program model accreditation/certification and quality assurance and evaluation costs in budgets, as needed. Programs will need to refer to their national office and/or administrative home for cost information, if applicable.

Compliance with State and Federal Law: As a reminder, all other state rules, regulations, and special terms and conditions will remain in effect for the grant period. This renewal application information becomes part of the agreement and expectations for program implementation and performance. A complete listing of the state uniform terms and conditions can be found via the State Procurement Office website at: http://spo.az.gov/Admin_Policy/SPM/Forms/default.asp.

Quality Assurance: It is the intent that each FTF grantee receives a targeted quality assurance (QA) visit within the cycle of their full grant period. The findings from targeted QA visits will also be used to assess grantee/program performance for renewal considerations. A grantee's performance is reviewed individually and not in comparison with other grantees when considerations are made.

Program Performance and Data Reporting Requirements: First Things First provides program information to the public, regional partnership councils, and the Board of First Things First. The information regularly provided includes data related to performance measures and target service units; prior program performance, including QA findings; information provided in program narrative reports; and financial/expenditure information. Regional partnership councils utilize this information in strategic planning efforts, to identify annual funding priorities, to assist with renewal decisions, to develop new or modified strategies, to review the impact of programs in the region and state, and to highlight achievements in system building.

Grantee Data Reporting Requirements are identified in each grant award and can be accessed in the FTF Strategy Toolkit, http://www.azftf.gov/pages/webmain.aspx?PageID=2D427ADB35B34BB09F353B77B74AB9BA. Please review the latest Data Reporting Requirements in preparation for implementation upon grant renewal.

Renewal Package Due Date: The renewal package must be ***received*** no later than ***3:00 PM on April 4, 2014.*** Submit via email or standard mail to:

Marjorie Bennett, Fiscal Specialist
Michael Strawther, Fiscal Specialist
First Things First
4000 N. Central
Phoenix, AZ 85012
mbennett@azftf.gov
mstrawther@azftf.gov
(602) 771-5084

Attachment A

Program Implementation Questions

1. **Provide a brief narrative description of your current approved program and your plan for continuation in SFY15, including context for the activities listed in the Program Implementation Plan. (Attachment B)**

   Gila County Healthy Steps Program will implement the National Healthy Steps model to provide care coordination to children and their families. Services will be provided in Globe and Payson with a full time staff person in each city. The model implemented will be the Community Based program that collaborates with various partners in the community to provide services to children. Initial contacts will be made with many families in the hospital. Other families' first contact with the program may be from the Family Access Developmental Screening Program or their well child care provider's referral. The program will partner with local hospitals, Payson Christian Clinic, Community Physicians, Canyonlands Clinic as well as the County Immunization Clinic and the WIC Program. The program has added additional partners including pre-schools, day care providers, mental health agencies and other early intervention programs. The program will provide the services as outlined in the National Healthy Steps model as well as meeting the components of the Scope of Work and Standards of practice included in this document. The program will provide home visits at birth and key developmental stages when appropriate to meet the needs of the families and their children. We have identified 200 as the number of children birth to five. The program will consist of a .25 Program Manager who will oversee the two full time program coordinators housed in Globe and Payson. The program will serve as the lead agency to implement the ASQ Enterprise and Family Access Program within the Healthy Steps Program. In addition the program will develop a plan to implement the Enterprise System region-wide through community partners that provide services to children birth to five. The goal of the program is to provide parent education, identification of delays and coordination of care for all children who reside in Gila County, and to assist with creating a medical home. Training for staff will utilize a combination of the National Healthy Steps training as well as on-going training and support of the Arizona Healthy Steps Program trainers. Intensive training was provided during the last grant period that will insure the success of the program and model fidelity. The target will be 200 children birth to five and their families in Gila County receiving ongoing Healthy Steps support. 200 children will receive ASQ AND ASQ-SE development screening either through the Parent Access Program or screening conducted by Healthy Steps Coordinator.

   We plan to continue with the above program objectives and we have added several new partners we are collaborating with to implement the ASQ online system and to provide referrals to the Healthy Steps program.

2. **If applicable, explain any proposed modifications for SFY15, including the change(s) to be made, how they were determined to be necessary, and how they will contribute to the success of your program. Please note that program modifications cannot deviate from the original scope of work or applicable standards of practice.**
   No modifications at this time.

3. **Describe how the program data will be utilized to improve program implementation. Include assurances that data collection and submission will be timely and ongoing.**

The Healthy Coordinators are the ASQ enterprise system program administrators and are able to compile reports to determine there is a delay in a specific developmental area. At this point the Globe Healthy Step administrator has identified communication delays and will be addressing the delays through developmental play group activities. Other individual delays are addressed on a case by case basis, giving families the support and education needed to assist the child.

Attachment B

Program Implementation Plan
2015

Activities	Task	Person Responsible	Date Task Will Be Completed/Timeline	Support Documentation
Implementation	Home visits/hospital visits/in-office visits/social group settings to families in Gila County	Program Coordinators	On-going	Case file/progress notes
	Collaboration with local pediatricians, family doctors, pre-schools, school districts, Hospitals, daycare providers, mental health agencies and other early intervention programs that provide service to children birth to five	Program Manager/Program Coordinators	On-going to build capacity	Meetings/contact information
	Provide education to parents on child development, literacy, parenting, and referral for other supporting resources	Program Manager/Program Coordinators	On-going	Case file/progress notes
Follow-up	Appropriate referrals	Program Manager/Program Coordinators	As needed	Referrals/progress notes/agency correspondence
	Review with physician to provide family with a team approach for healthy development of their child	Program Coordinators	On-going	Case file/progress notes
	Developmental screening referrals	Program Coordinators	On-going	ASQ online system
Outreach	Distribute incentives, flyers, referral forms and program information to agencies, providers and community members.	Program Coordinatos	On-going	Outreach materials
	Utilize National Healthy Steps outreach education and information brochures/pamphlets/fact sheets.	Program Coordinator	On-going	Brochures/pamphlets/fact sheets
	PSA's to local radio and newspaper.	Program Manager/Program Coordinators	On-going	Articles

Training	Continuing education on child development, parenting and all other topics related to family wellness.	Program Coordinators	On-going	Certificates/flyers/agendas
Evaluation	Ensure all reports are provided to FTF in a timely manner.	Program Manager	On-going	Quarterly Reports
	Create public awareness of the Parent Access System and provide follow-up for families entering into the developmental screening process.	Program Coordinators	On-going	ASQ online system
	Create reports from the ASQ online system to determine the areas of delays.	Program Coordinators	On-going	ASQ online system

Attachment C (Instructions)

How to Complete the Line Item Budget and Budget Narrative

Complete a 12-month budget for the period July 1, 2014 through June 30, 2015 using the template provided. Please make sure to include the provided budget narrative which describes the proposed line item budget.

Please keep in mind items described in a line item budget and in more detail in the budget narrative should describe how the costs were determined and the public purpose for the cost related successfully implementing the project. Requested funds must follow these guidelines:

- Be necessary and reasonable for proper and efficient performance and administration of First Things First funds.
- Be authorized or not prohibited under State or local laws or regulations.
- Be consistent with policies, regulations, and procedures that apply uniformly to all costs charged and expended by the agency – consistent treatment of costs.
    - For example – a cost may not be assigned to another grant award as an indirect cost if any other cost incurred for the same purposes in like circumstances has been allocated to the First Things First award as a direct cost.
    - For example – a cost for a certain type of expense is charged one rate to another source of funding and a different rate to First Things First - this would not be consistent treatment of costs.
- Be determined in accordance with generally accepted accounting principles.
- Be adequately documented.
- All travel related costs for these trainings and meetings should be included in the Applicant's budget and calculated using the State of Arizona travel rate limitations for mileage, per diem and lodging as described on the budget narrative worksheet. For more information about the state requirements, visit http://www.gao.az.gov/travel/.
- Budget modification requests must be submitted via the FTF Partner Grant Management System (PGMS) Communication Log and approval received prior to the implementation of any of the modifications.

Attachment C

Line Item Budget

While you must use this format, you may reproduce it in Word or Excel. Limit your budget line items to the budget categories listed below.

Budget period: July 1, 2014 – June 30, 2015

Budget Category	Line Item Description	Requested Funds	Total Cost
PERSONNEL SERVICES		**Personnel Services Sub Total**	**$100,000.00**
Salaries	Program Manager-Paula Horn	14,000.00	
	Program Coordinator-Sonia Yanez	40,000.00	
	Program Coordinator-Chandra Wattleworth	40,000.00	
	Sarah Chavez-Accounting Clerk	6000.00	
EMPLOYEE RELATED EXPENSES		**Employee Related Expenses Sub Total**	**$37,600.00**
Fringe Benefits or Other ERE	Program Manager-Paula Horn	5,600.00	
	Program Coordinator-Sonia Yanez	16,000.00	
	Program Coordinator-Chandra Wattleworth	16,000.00	
PROFESSIONAL AND OUTSIDE SERVICES		**Professional & Outside Services Sub Total**	**$1,336.30**
Contracted Services	ASQ contract maintenance	1,336.30	
TRAVEL		**Travel Sub Total**	**$6,740.40**
In-State Travel	Mileage fleet charges @ County rate	5540.40	
Out of State Travel	Hotel 2X6 @ 150.00	900.00	
	Perdiem 2X6@$25.00	300.00	
AID TO ORGANIZATIONS OR INDIVIDUALS		**Aid to Organizations or Individuals Sub Total**	**$0**
Subgrants or Subcontracts to organizations/agencies/entities			
OTHER OPERATING EXPENSES		**Other Operating Expenses Sub Total**	**$27,050.54**
• Telephones/Communications Services	2 cell phones	1680.00	
• Internet Access	Payson Annex Office/Mobile access	1080.00	
• General Office Supplies	2 office locations	2390.54	
• Food	Client classes/events	600.00	
• Rent/Occupancy	Payson annex office	8400.00	
• Utilities	Payson annex office	1200.00	
• Furniture		300.00	
• Postage		200.00	
• Advertising		2500.00	
• Printing/Copying		800.00	
• Equipment Maintenance		0	
• Professional Development/Staff Training	Including lease rental/usage	0	
• Conference Workshops/ Training Fees for Staff		400.00	
• Program Materials		0	
• Program Supplies		0	
• Scholarships		2500.00	
• Program Incentives		2500.00	
		0	
		2500.00	
NON-CAPITAL EQUIPMENT		**Non-Capital Sub Total**	**$**
Equipment $4,999 or less in value			
Subtotal Direct Program Costs			**$**
ADMINISTRATIVE/INDIRECT COSTS		**Total Admin/Indirect**	**$**
Indirect/Admin Costs		$17272.76	**$17,272.76**
Total		**$**	**$190,000.00**

Authorized signature Michael A. Pastor Michael A. Pastor Chairman, BOS Date April 15, 2014

Attachment C (Continued)

Gila County Healthy Steps Program

12 Month Budget Narrative

Personnel

The Program Manager position is filled by Paula Horn. She oversees all the Maternal and Child Health Programs and will be spending 25% of their time on the proposed program for the 12-month grant cycle to include attending program related meetings and training. The manager will provide assistance with purchasing, coordination and outreach of the program. The program manager will also be responsible for the quality assurance, staff supervision of the program. The manager's salary will total $14,000.00.

The two positions of Program Coordinator are filled by Chandra Wattleworth and Sonia Yanez. They will be responsible for daily oversight of program implementation for the12 month grant cycle. They will provide home visitation services, working with each of the families and providing developmental screenings and follow-up for participants. They will be responsible for outreach, media campaign and coordination with other agencies. The Program Coordinators salaries will total $80,000.00.

Sarah Chavez is the accounting clerk. She will provide all the billing and fiscal management for the program. The clerk will be spending 17% of her time on the proposed program for the 12 month grant cycle. The accounting clerk's salary will total $6,000.00.

Grand total of personnel expenses will be $100,000.00.

ERE/Fringe Benefits

The approved fringe benefits for all Gila County employees include: Arizona Retirement, Medicare, Social Security, Arizona Unemployment, Worker's Compensation, and health insurance. The program manager's portion will total $5600.00. The program coordinator's portion will total $32,000.00. Grand total of fringe benefits will be $37600.00.

Professional and Outside Services

The ASQ online enterprise system has annual cost of $996.35, a technical support cost of $139.95, and $0.50 per screen over 100 ($200 for 400 screens) to implement in Gila County. Total amount is $1,336.30.

Travel Expenses

Staff will attend Gila Regional Partnership Council meetings every three months (200 miles 2 times) fleet charges of .57 cents per mile for a total of $228.00. Staff will be required to attend monthly staff meetings (180 miles each trip) fleet charges of .57 cents per mile for a total of $1231.20. Travel for out of town training will be six trainings at 180 miles each trip fleet charges of .57 cents per mile for a total of $1231.20. Program travel for the manager and program coordinators is necessary in the successful implementation of the program including outreach, recruiting participants, coordination with local agencies and program implementation. We have estimated mileage to be 5000 miles fleet charges .57 per mile total $2850.00. Total mileage $5,540.40. Perdiem is estimated to provide $25.00 per day for two staff for six days total $300.00. Six night hotel stay for the program manager and community health assistant total $900.00. Total travel expenses $6,740.40.

Other Operating Expenses

The routine office operating expenses will consist of paper, envelopes, business cards, mailings, appointments and referral cards the total price will be $2,390.54. Communication supplies will consist of two cell phones prices at $80.00 per month(included WIFI) and internet services for the Payson office at $70.00 per month. In Payson we will rent office space in the amount of $700.00 per month plus utilities in the amount of $200.00 per month. We will provide food for social events for clients and families in the amount of $600.00 We will continue to provide a kid zone furnishings in the amount of $300.00. Advertising in local newspapers, flyers, referral cards and other outreach materials for $2,500.00. Each staff member will need to pay for coping expenses and a portion of the copy machine lease for each office for a total of $800.00. The staff will need to have continuing education and training projected amount of $400.00. Program materials, supplies and incentives will include books, educational materials, and participation incentives in the amount of $7,500.00. This results in a grand total of $26,886.84.

Indirect costs

As a Gila County employee there are indirect costs for personnel paperwork, finance, mail routing, and support staff which will be budgeted in the amount of $17,272.76 per year. This reflects approximately 10% of direct expenses.

Applicants must list either Option A or Option B and provide proper justification for expenses included:

■ **Option A - Administrative Costs**: *with proper justification, sub grantees may include an allocation for administrative costs for up to 10% of the total direct costs requested of the grant request. Administrative costs may include allocable direct charges for: costs of financial, accounting, auditing, contracting or general legal services; costs of internal evaluation, including overall organization's management improvement costs; and costs of general liability insurance that protects the organization(s) responsible for operating a project, other than insurance costs solely attributable to the project. Administrative costs may also include that portion of salaries and benefits of the project's director and other administrative staff not attributable to the time spent in support of a specific project.*

OR

☐ ***Option B - Federally Approved Indirect Costs***: *If your organization has a federally approved indirect cost rate agreement in place, grantees may include an allocation for indirect costs for up to 10% of the direct costs.* ***Applicants must provide a copy of their federally approved indirect cost rate agreement***.

Indirect costs are costs of an organization that are not readily assignable to a particular project, but are necessary to the operation of the organization and the performance of the project. The cost of operating and maintaining facilities, depreciation, and administrative salaries are examples of the types of costs that are usually treated as indirect.

Authorized signature Michael A Pastor Date April 15, 2014

Michael A. Pastor Chairman, Board of Supervisors

Date April 15, 2014

Bryan Chambers, Deputy Attorney Principal

Attachment D

Key Personnel

STAFF MEMBER	BACKGROUND AND EXPERTISE OF PERSONNEL
Name: Title: FTE on this project:	Paula Horn Program Manager .25
Name: Title: FTE on this project:	Sonia Yanez Healthy Steps Program Coordinator 1 FTE
Name: Title: FTE on this project:	Chandra Wattleworth Healthy Steps Program Coordinator 1 FTE
Name: Title: FTE on this project:	Sarah Chavez Accounting Clerk .17
Name: Title: FTE on this project:	
Name: Title: FTE on this project:	

***In addition, please attach a resume (for current personnel) or a job description (for positions to be hired) for the key personnel involved in the project and listed above. If awarded and there is a change in staff or a vacant position filled, a Staff Change Notification form and resume must be uploaded via the Communication Log in PGMS within 14 days of hire.**

KEY PERSONNEL INCLUDE ANYONE WHO WILL BE PAID FROM THE GRANT

Attachment E

DISCLOSURE OF OTHER FUNDING SOURCES

Please list all other funding that your organization currently receives from State or Public Agencies, Federal Agencies, Non-Profit Organizations, or any other source providing funding for the funded program*. Statute ARS 8-1183 provides for a prohibition on supplanting of state funds by First Things First expenditures, meaning that no First Things First monies expended are to be used to take the place of any existing state or federal funding for early childhood development and health programs.

Use a continuation sheet if necessary. The following form may be reproduced with word processing software or another form may be created that contains all the information requested.

Type of Funding (Federal, State, local, other)	Received From	Amount	✔ If used for match on this grant
N/A			
TOTAL:			

***Should include only those funds that will support the program detailed the awarded First Things First grant award**

Attachment F

First Things First Standard Agency Information Collection Form

A. Agency Information:

Program Name (if applicable) Gila County Healthy Steps Program

Agency Gila County Division of Health and Emergency Services

Contact Person Paula Horn

Address 5515 S. Apache Avenue, Suite 100

Position Deputy Director

Address

Email phorn@co.gila.az.us

City, State, Zip Globe, AZ 85501

Phone 928-402-8813 Ext

County Gila

Fax 928-425-0794

Employer Identification Number: 86-6000444

Agency Classification: ____State Agency ___X County Government ____Local Government ____Schools

____Tribal ____Faith Based ____Non Profit ____Private Organization ____Other

Have you previously conducted business with First Things First using this EIN? __X__Y ____N

If not, please go to http://www.gao.az.gov/Vendor/account_setup_home.asp, download the State of Arizona Substitute W-9 Form, and submit with your application

Congressional district (federal) in which agency provides most services: District # __1__

Legislative district (state) in which agency provides most services: District # __8__

Go to http://www.azredistricting.org and click on Final Maps to identify your Congressional and legislative district

Approximate federal funding (from a federal source) to be received in current fiscal year? $5,500,000

Agency's fiscal year-end date: 6/30/2013

Agency's accounting method: ____ Cash __X__ Accrual

Does your organization undergo an annual independent audit in accordance with OMB Circular A-133? __X__Y ____N

Contact information for firm conducting agency audit:

Audit firm: Clifton, Larson and Allen LLP

Address: 20 E. Thomas Road , Suite 2300 Phoenix, AZ 85012

Phone: 602-266-2248

:

B. Proposed Program Information/Description:

Amount requested: $190,000.00

Service area of proposed program: Gila County

Target population of proposed program: 200

Lead Strategy - Care Coordination/Medical Home

There are assigned Service units for the strategy award from First Things First. Given the Listed Service Unit, provide a contracted number for FY 14.

Number of children served: 200
Number of children receiving screening: 200
Number of developmental screenings conducted: 200-400
Number of hearing screenings conducted: _____
Number of vision screenings conducted: _____
Number of families served (HIE Assistance): _____

Important Items to note:

- **If you are providing a different contracted service number than what was contracted in FY 14, provide a brief description explaining the change.**
- **If you are not providing services for a particular service unit within a strategy that has more than one service unit, please indicate "NA."**
- **A complete listing of First Things First Target Service Unit descriptions can be found in PGMS under the Grantee Resources folder.**

Please provide a brief description (250 words or less) of the proposed program. This description will be used by First Things First for all public information regarding the grant.

Gila County Healthy Steps Program enhances the relationship between the parents of an infant and their pediatrician, through the child's fifth year. The Healthy Steps Specialist will work with parents to connect them to services in the community, conduct developmental screenings on a regular basis, introduce and support early literacy activities through the provision of developmentally appropriate books to the child, and work to be sure that parent's questions are answered. Home visits will be conducted at birth and key developmental stages to support families raise healthy successful children. The program will implement the Ages and Stages On-Line Enterprise Screening including Parent Access to ensure that all children receive timely developmental and social emotional screen. The Gila County Healthy Steps Program will serve as the leader in implementing a region-wide developmental screening process that will allow children to receive timely screenings from their first contact with the early childhood system.

Contact Information:

For each contract in the Partner and Grants Management System (PGMS), there are four contact slots available that provide a varying degree of access. The four slots are the Main Contact (all access), the Program Contact (access to narrative and data reports), the Evaluation Contact (access to only data reports) and the Finance Contact (budget and reimbursements.) The same person may be assigned to more than one slot.

Main Contact: This person has overall responsibility for ensuring the program is successfully implemented and will have access to all financial, programmatic, and data reports in PGMS.

Main Contact: Paula Horn

Position: Program Manager/Deputy Director

Address: 5515 S. Apache Avenue, Suite 100

City, State, Zip: Globe, AZ 85501

Email: phorn@gilacountyaz.gov

Phone: 928-402-8813 Ext. _____ Fax: 928-425-0794

Program Contact: This person has responsibility for the regular program operations. They will be able to access program narrative and data reports in PGMS.

Program Contact: Sonia Yanez

Position: Program Coordinator

Address: 5515 S. Apache Avenue, Suite 100

City, State, Zip: Globe, AZ 85501

Email: syanez@gilacountyaz.gov

Phone: 928-402-8810 Ext. _____ Fax: 928-425-0794

Financial Contact: This person has the responsibility for financial accounting and reporting including submitting reimbursement request through PGMS. They will be able to access financial information in PGMS.

Financial Contact: Sarah Chavez

Position: Accounting Clerk

Address: 5515 S. Apache Avenue, Suite 100

City, State, Zip: Globe, AZ 85501

Email: schavez@gilacounty.az

Phone: 928-402-4332 Ext. _____ Fax: 928-425-0794

Evaluation Contact: This contact person has responsibility for the program's evaluation and data collection activities. They will be able to access the data reports in PGMS.

Evaluation Contact: Paula Horn

Position: Program Manager/Deputy Director

Address: 5515 S. Apache Avenue, Suite 100

City, State, Zip: Globe, AZ 85501

Email: phorn@gilacountyaz.gov

Phone: 928-402-8813 Ext. _____ Fax: 928-425-0794

PGMS Training

If any of the contacts are new or in need of technical assistance with PGMS, please indicate the type of training and which contact:

- ☐ **Accessing/Navigating PGMS** **Contact(s):** _____
- ☐ **Narrative/Data Report Entry** **Contact(s):** _____
- ☐ **Reimbursements/Budget Modifications** **Contact(s):** _____
- ☐ **Other:** _____ **Contact(s):** _____

First Things First
Grant Renewal Package Instructions
July 1, 2013 – June 30, 2014

Your First Things First (FTF) grant is eligible for a program renewal by extending the previous 2013 fiscal year grant award. Programs proposed for the 2014 fiscal year cannot be different in scope than the previous grant award.

Grantee Name:	Gila County Health Department
FTF Grant Number:	GRA-RC004-13-0556-01
Strategy Name:	Care Coordination/Medical Home
Data Template(s) Assigned:	Care Coordination /Medical Home Developmental and Sensory Screening
Eligible Renewal Amount:	$190,000.00 The amount is subject to change pending legal and procurement review at First Things First. If a different amount is approved for renewal, an updated line item budget & budget narrative will be required.

The renewal package includes the completion and submission of Attachments A-F. Attachment G, Data Security Guidelines, has been revised and replaces previous versions.

Program Implementation Questions (Attachment A)
Provide a narrative response to each question in Attachment A.

Program Implementation Plan (Attachment B)
Provide an updated implementation plan for the 2014 fiscal year. The implementation plan should be related to the originally approved program activities, tasks, data collection, data submission, and process.

2014 Budget Forms (Attachment C – must include both the line item budget and budget narrative)

Key Personnel (Attachment D)
List all staff that will be paid from this grant program during the 2014 grant cycle. This should match your line item budget and budget narrative. Submit resumes and/or staff change notification forms for new staff or those that have not yet been submitted to First Things First previously. The staff change notification form is located under the Grantee Resources folder on the Partner Grant Management System (PGMS) home page.

Disclosure of Other Funding Sources (Attachment E)
List any other funding utilized for this program administered by your agency.

First Things First Standard Agency Information Collection Form (Attachment F)
Please complete all sections detailing:

- The main, program, financial and evaluation contact information for PGMS access to the 2014 grant.
- The **Target Service Number(s)** to be served/completed in 2014 for all identified strategies.
- A brief program description to be used for public descriptions of First Things First funded programs.

Standards of Practice Updates: Utilizing the standards of practice are part of the requirements for the award and implementation of your grant program. They represent FTF's intent for the implementation of a specific strategy. Prior authorization is needed if the program deviates from the standards of practice. Grantees are responsible for reviewing and implementing the most recent updates to the standards of practice, located in the FTF Strategy Toolkit.

Model Programs that Require Certification and Accreditation: It is the grantee's responsibility to maintain accreditation/certification with national program models. Grantees are to include staff training, program model accreditation/certification and quality assurance and evaluation costs in budgets, as needed. Programs will need to refer to their national office and/or administrative home for cost information, if applicable.

Compliance with State and Federal Law: As a reminder, all other state rules, regulations, and special terms and conditions will remain in effect for the grant period. This renewal application information becomes part of the agreement and expectations for program implementation and performance. A complete listing of the state uniform terms and conditions can be found via the State Procurement Office website at: http://spo.az.gov/Admin_Policy/SPM/Forms/default.asp. Additionally, First Things First will post any applicable grantee requirement and updated Communications Protocol information under the Grantee Resources folder in PGMS.

Grantees must maintain compliance with the Federal Immigration and Nationality Act (FINA) and all other federal immigration laws and regulations related to the immigration status of its employees. These warranties shall remain in effect through the term of the agreement. Grantees will also maintain Employment Eligibility Verification forms (I-9) as required by the U.S. Department of Labor's Immigration and Control Act for all employees performing work under the agreement. I-9 forms are available for download at USCIS.GOV.

First Things First may request verification for any grantee or subgrantee performing work under the agreement. Should FTF suspect or find that a grantee is not in compliance with state or federal laws, First Things First may pursue any and all remedies allowed by law, including, but not limited to: suspension of work, termination of the agreement for default and suspension and/or debarment of the grantee. All costs necessary to verify compliance are the responsibility of the grantee.

Data Security: All grantees must have a data security policy in force, which identifies how the organization ensures that data is protected in all its forms, during all phases of its life cycle, from inappropriate access, use, modification, disclosure, or destruction. All grantees subject to HIPAA, FERPA, GITA, or other data regulation, are required to submit and maintain those approvals for all data. Refer to **Attachment G,** Data Security Guidelines and Requirements for Collaborators, for more information.

Program Performance and Data Reporting Requirement Updates: First Things First provides program information to the public, Regional Partnership Councils, and the Board of First Things First. The information regularly provided to the Regional Partnership Councils and Board of First Things First include proposed renewal information; submission of data related to performance measures and target service units; prior program performance; information provided in program narrative reports; and financial/expenditure information. Regional Partnership Councils utilize this information to continue strategic planning efforts and identify annual funding priorities; to assist with renewal decisions; to develop new or modified strategies; to review the impact that programs have had in the region and state; as well as achievements in system building.

Grantee Data Reporting Requirements are identified in each grant and can be accessed in the

FTF Strategy Toolkit. Please review the latest Data Reporting Requirements in preparation for implementation upon grant renewal.

Renewal Package Due Date: The renewal package must be ***received*** by ***April 1, 2013 at 3:00pm*** and submitted via email or standard mail:

Maria A. Soto, Fiscal Specialist
First Things First
4000 N. Central
Phoenix, AZ 85012
msoto@azftf.gov
(602) 771-5083

Or

Marjorie Bennett, Fiscal Specialist
First Things First
4000 N. Central
Phoenix, AZ 85012
mbennett@azftf.gov
(602) 771-5084

Attachment A

Program Implementation Questions

Provide a narrative response to the questions below. To ensure that you are not changing the scope of work of your original grant, you must use the same programs and/or strategies as described in your original proposal, unless you have obtained prior approval.

1. **Provide a brief narrative description of your proposed program that will be implemented in SFY14. This description should match information provided in your Implementation Plan (Attachment B) and explain anything from the Implementation Plan needing additional description.**

Gila County Healthy Steps Program will implement the National Healthy Steps model to provide care coordination to children and their families. Services will be provided in Globe and Payson with a full time staff person in each city. The model implemented will be the Community Based program that collaborates with various partners in the community to provide services to children. Initial contacts will be made with many families in the hospital. Other families' first contact with the program may be from the Family Access Developmental Screening Program or their well child care providers referral. The program will partner with local hospitals, Payson Christian Clinic, Community Physicans, Canyonlands Clinic as well as the County Immunization Clinic and the WIC Program. The program will provide the services as outlined in the National Healthy Steps model as well as meeting the components of the Scope of Work and Standards of practice included in this document. The program will provide home visits at birth and key developmental stages when appropriate to meet the needs of the families and their children. We have identified 200 as the number of children birth to five. The program will consist of a .25 Program Manager who will oversee the two full time program coordinators housed in Globe and Payson. The program will serve as the lead agency to implement the ASQ Enterprise and Family Access Program within the Healthy Steps Program. In addition the program will develop a plan to implement the Enterprise System region-wide through community partners that provide services to children birth to five. The goal of the program is to provide parent education, identification of delays and coordination of care for all children who reside in Gila County, and to assist with creating a medical home. Training for staff will utilize a combination of the National Healthy Steps training as well as on-going training and support of the Arizona Healthy Steps Program trainers. Intensive training will be provided during the first grant period to insure the success of the program and model fidelity.

Consider the following for inclusion in the narrative description:

a) **If your program received approved modifications, please describe how those modifications will continue to be implemented in SFY 2014. NONE**

b) **If you have proposed modifications moving forward, please describe how they will enhance program implementation and/or why they are necessary for the program to be successful in the upcoming fiscal year. NONE**

c) **If there are no modifications or no planned modifications, please indicate no modifications necessary and provide a brief description of the existing program implementation. NONE**

2. **Please describe current and ongoing plans for data collection and submission, including how your program is using data to promote optimal service and ongoing improvement.**

We plan to capture the reporting requirements in an electronic data base which our County IT has password protected software in place to ensure confidentiality. The staff our familiar with reporting requirements of First Things First.

We plan to purchase the ASQ online enterprise system and begin implementation upon completion of the Healthy Steps training. After the staff become super-users of the on-line system, we will attempt to collaborate with other programs to use the on-line system. Healthy Steps staff will be the technical support for the ASQ online system. The Developmental Screening Program set up will meet all of the requirements outlined in the scope of work including community collaboration and reporting to the Regional Council.

3. **Describe how you anticipate being better able to achieve your proposed target service units.**

The problem we had in the first grant period was receiving qualified applicants to fill the needed staff positions. We will provide the following once all staff have been hired and appropriately trained;

- Unit of service will be 200 unduplicated children birth to five and their families in Gila County receiving ongoing Healthy Steps support.
- 200 children will receive ASQ and ASQ-SE developmental screening either through the Parent Access Program or screenings conducted by the Healthy Steps Specialist. The program will screen children at key developmental milestone with a target of 400 screens and appropriate follow-up.

4. **Please describe how you will ensure target service numbers will be met in the next SFY implementation of this First Things First grant award.**

We have been assured by the National Healthy Steps Trainer that once the appropriate staff is in place the program will be very successful.

5. **Please provide an update on the Online Developmental Screening implementation and a copy of the plan as required in the initial scope of work.**

Phase 1:

Gila County Health Department

Healthy Steps, Health Start, Home Visitation, Nursing, Gila County WIC, Gila County Well Baby Clinic, Gila County Well Baby Program

Phase 2:

Hospitals

Cobre Valley Regional Medical Center, Payson Regional Medical Center

Non-Governmental Organizations

Head Start, Early Head Start, Horizon Human Services, Arizona's Children Association, ChildHelp AZ

Phase 3:

Public Schools

Globe USD, Hayden-Winkleman SD, Miami USD, Payson USD, Pine Elementary SD, Tonto Basin SD, Young Public SD, San Carlos USD, Gila County Regional School District

6. **Please describe how you will reach 200 units of service for children served and 200 children screened using the online developmental screening program in SFY14 implementation; and how you will address barriers to ensure success.**

We have been trying to recruit two workers with the correct qualifications to apply and accept the Healthy Steps Coordinator positions. The barriers we have faced with the application process are lack of applicants possessing a bachelor's degree in a specific field which is required by "Healthy Steps" model. We have been very proactive is the recruitment process. The units of service will not be a problem once staff are fully trained and begin implementation.

The barriers we believe may arise will be the participation from one of the hospitals in the area and marketing the program to let the community know about the services that will be available. The plan to address the above barriers will be to collaborate with existing staff currently working with the hospital. Outreach and marketing will be a priority in the initial stages of the program. The personnel required for the program will be compensated at a higher level which will entrust we will get a good selection of applicants in which to pick from.

Attachment B

Program Implementation Plan
2014

Activities	Task	Person Responsible	Date Task Will Be Completed/Timeline	Support Documentation
Preparation	Continue to recruit new employees for Healthy Steps Program Coordinator	HR/Program Manager/Deputy Director	Hopefully prior to start of grant cycle-undetermined	Job Description/Job filled/Resume of new staff
	Purchase supplies	Program Coordinators	Ongoing	Purchase orders/receipts
Training	Schedule training with National Healthy Steps program	Program Manager	When training is available for out-of-state	Training certificate
	One-on-one training with Healthy Steps consultants	Program Coordinators/Program Manager	On-going	Training logs
	ASQ online system	Program Coordinators	On-going	Certification/performance
Outreach	Utilize National Healthy Steps outreach education and information brochures/pamphlets/fact sheets	Program Coordinators/Program Manager	On-going	Outreach materials
	ASQ-online system enterprise	Program Manager	On-going	On-line materials/website
	Format the program description for Divisional brochures/Websites/flyer to be distributed	Program Coordinators	On-going	Outreach materials
Implementation	Home visits/hospital visits/in-office visits/social group settings to families in Gila County	Program Coordinators	On-going	Case files
	Collaboration with local pediatricians and family doctors that provide service to children birth to five.	Program Manager/Program Coordinators	On-going to build capacity	Meetings/contact information

	Provide education to parents on child development, literacy, parenting, and referral for other supporting resources	Program Manager/Program Coordinators	On-going	Case files
Follow-up	Appropriate referrals	Program Manager/Program Coordinators	At time of visit	Referral/case note
	Review with physician to provide family with a team approach for healthy development of their child	Program Manager/Program Coordinators	On-going	Case notes
	Developmental screening referrals	Program Manager/Program Coordinator	On-going	ASQ online system
Implementation	Ensure all reports are provided to FTF in a timely manner.	Program Manager	On-going	Quarterly Reports
	Purchase and implement the ASQ-3 and ASQ-SE Online Enterprise system and parent access system.	Program Manager	June 1,2013	Financial Reports
	Set up the Parent access and Enterprise systems for use and train staff.	Program Manager/Program Coordinators	June1, 2013	Online system ready for use and children being screen.
	Collaborate with First Things First Staff and Gila Regional Council to convene community stakeholders to discuss expansion of the Enterprise system across the region.	Program Manager	May 30, 2013	Sign in Sheets from meetings held
	Prepare a report for the Region Council on the pilot implementation of the on-line system and plans for expansion to community partners.	Program Manager/Program Coordinators	August 1, 2013 On-going process	Report submitted to First Things First
	Collaborate with First Things First to provide data from the Gila Enterprise System to the First Things First Hub	Program Manager/Program Coordinators	Initial meeting April 9, 2013 and when the First Things First Hub is in place.	Case note
	Outreach the parent access system within the community and provide follow-up for families entering into the developmental screening process through the system.	Program Coordinators	On-going	ASQ online system

Attachment C

Line Item Budget

While you must use this format, you may reproduce it in Word or Excel. Limit your budget line items to the budget categories listed below.

Budget period: July 1, 2013 – June 30, 2014

Budget Category	Line Item Description	Requested Funds	Total Cost
PERSONNEL SERVICES		**Personnel Services Sub Total**	**$100,000.00**
Salaries	Vacant Program Manager Vacant-Program Coordinator Vacant-Program Coordinator Sarah Chavez-Accounting Clerk	14,000.00 40,000.00 40,000.00 6000.00	
EMPLOYEE RELATED EXPENSES		**Employee Related Expenses Sub Total**	**$36660.00**
Fringe Benefits or Other ERE	Vacant Program Manager Vacant-Program Coordinator Vacant-Program Coordinator Sarah Chavez-Accounting Clerk	5,460.00 15,600.00 15,600.00	
PROFESSIONAL AND OUTSIDE SERVICES		**Professional & Outside Services Sub Total**	**$1,500.00**
Contracted Services	ASQ contract maintenance services	1,500.00	
TRAVEL		**Travel Sub Total**	**$11,340.60**
In-State Travel Out of State Travel	Mileage x .445 Hotel 2X2 @ 100.00 Perdiem 2X2X4 Flight/taxi Hotel 2X4 Perdiem 4X3	5,108.60 400.00 200.00 2,200.00 2016.00 1416.00	
AID TO ORGANIZATIONS OR INDIVIDUALS		**Aid to Organizations or Individuals Sub Total**	**$**
Subgrants or Subcontracts to organizations/agencies/entities			
OTHER OPERATING EXPENSES		**Other Operating Expenses Sub Total**	**$23,227.00**
• Telephones/Communications Services	2 cell phones	1680.00	
• Internet Access	Payson annex office	840.00	
• General Office Supplies	3 staff members	1257.00	
• Food	Client classes	500.00	
• Rent/Occupancy	Payson office	8400.00	
• Evaluation (non-contracted & non-personnel expenses)	N/A		
• Utilities	Payson office	1200.00	
• Furniture	Kid friendly zones	300.00	
• Postage		200.00	
• Software (including IT supplies)		100.00	
• Dues/Subscriptions		0	
• Advertising		800.00	
• Printing/Copying	Including lease rental for copiers	800.00	
• Equipment Maintenance		0	
• Professional Development/Staff Training	Brazelton	900.00	
• Conference Workshops/ Training Fees for Staff		200.00	
• Insurance		0	
• Program Materials		2000.00	
• Program Supplies		2000.00	
• Scholarships		0	
• Program Incentives		2100.00	
NON-CAPITAL EQUIPMENT		**Non-Capital Sub Total**	**$**
Equipment $4,999 or less in value		0	
Subtotal Direct Program Costs:			**$**

			172727.60
ADMINISTRATIVE/INDIRECT COSTS			
Indirect/Admin Costs		Total Admin/Indirect	$17272.76
Total		$	$17272.76
		$	$190000.00

Authorized signature_____ Date 5-7-2013

Michael A. Pastor, Chairman
Gila County Board of Supervisors

Attachment C (Continued)

Gila County Healthy Steps Program

12 Month Budget Narrative

Personnel

The Program Manager position is currently vacant. They oversees all the Maternal and Child Health Programs and will be spending 25% of their time on the proposed program for the 12-month grant cycle to include attending program related meetings and training. The manager will provide assistance with purchasing, coordination and outreach of the program. The program manager will also be responsible for the quality assurance, staff supervision of the program. The manager's salary will total $14,000.00.

The position of Program Coordinator will be hired at a full-time basis. Due to the lack of interest we are requesting a higher salary for the coordinators which results in a $5,000.00 increase. There will be two Program Coordinators. They will be responsible for daily oversight of program implementation for the12 month grant cycle. They will provide home visitation services, working with each of the families and providing developmental screenings and follow-up for participants. They will be responsible for outreach, media campaign and coordination with other agencies. The Program Coordinators salaries will total $80,000.00.

Sarah Chavez is the accounting clerk. She will provide all the billing and fiscal management for the program. The clerk will be spending 17% of her time on the proposed program for the 12 month grant cycle. The accounting clerk's salary will total $6,00000.

Grand total of personnel expenses will be $100,000.00.

ERE/Fringe Benefits

The approved fringe benefits for all Gila County employees include: Arizona Retirement, Medicare, Social Security, Arizona Unemployment, Worker's Compensation, and health insurance. The program manager's portion will total $5460.00. The program coordinator's portion will total $31200.00. Grand total of fringe benefits will be $36660.00.

Professional and Outside Services

The ASQ online enterprise system has annual cost of $996.35, a technical support cost of $139.95, and $0.50 per screen over 100 ($200 for 400 screens) to implement in Gila County. Total amount is $1500.00

Travel Expenses

The program manager and two program coordinators will be required to attend one out of state training for Brazelton and the flight will be $700.00, hotel $168.00 a night for 4 nights, taxi fare of $100.00 and perdiem at $59.00 per day for four days. The total out-of –state travel costs will be $5,632.00. Staff will attend Gila Regional Partnership Council meetings every three months (200 miles 2 times) mileage .445 cents per mile for a total of $178.00. Staff will be required to attend monthly staff meetings (180 miles each trip) mileage .445 cents per mile for a total of $480.60. Program travel for the manager and community health assistant is necessary in the successful implementation of the program including outreach, recruiting participants, coordination with local agencies and program implementation. We have estimated mileage to be 5000 miles at .445 per mile total $4,450.00. Total mileage $5,108.60. Perdiem is estimated to provide $25.00 per day for two staff for four days total $200.00. Two night hotel stay for the program manager and community health assistant total $400.00. Total travel expenses $11,340.60.

Other Operating Expenses

The routine office operating expenses will consist of paper, envelopes, business cards, mailings, appointments and referral cards the total price will be $1,200.00. Communication supplies will consist of two cell phones prices at $70.00 per month and internet services for the Payson office at $70.00 per month. In Payson we will rent office space in the amount of $700.00 per month plus utilities in the amount of $200.00 per month. We will provide food for social events for clients and families in the amount of $500.00 We will continue to provide a kid zone furnishings in the amount of $300.00. This is a new program and they will need advertising in local newspapers, flyers and referral cards for $800.00. Each staff member will need to pay for coping expenses and a portion of the copy machine lease for each office for a total of $800.00. The Brazelton Institute Training will cost $300.00 for all three staff members to attend for a total of $900.00. Program materials, supplies and incentives will include books, educational materials, and participation incentives in the amount of $6,100.00. This results in a grand total of $23227.00.

Indirect costs

As a Gila County employee there are indirect costs for personnel paperwork, finance, mail routing, and support staff which will be budgeted in the amount of $16695.45 per year. This reflects approximately 10% of direct expenses.

Applicants must list either Option A or Option B and provide proper justification for expenses included:

- ■ **Option A - Administrative Costs**: *with proper justification, sub grantees may include an allocation for administrative costs for up to 10% of the total direct costs requested of the grant request. Administrative costs may include allocable direct charges for: costs of financial, accounting, auditing, contracting or general legal services; costs of internal evaluation, including overall organization's management improvement costs; and costs of general liability insurance that protects the organization(s) responsible for operating a project, other than insurance costs solely attributable to the project. Administrative costs may also include that portion of salaries and benefits of the project's director and other administrative staff not attributable to the time spent in support of a specific project.*

OR

- ☐ ***Option B - Federally Approved Indirect Costs***: *If your organization has a federally approved indirect cost rate agreement in place, grantees may include an allocation for indirect costs for up to 10% of the direct costs.* ***Applicants must provide a copy of their federally approved indirect cost rate agreement***.

Indirect costs are costs of an organization that are not readily assignable to a particular project, but are necessary to the operation of the organization and the performance of the project. The cost of operating and maintaining facilities, depreciation, and administrative salaries are examples of the types of costs that are usually treated as indirect.

Authorized signature Michael A. Pastor Date 5-7-2013

Michael A. Pastor, Chairman
Gila County Board of Supervisors

Attachment D

Key Personnel

STAFF MEMBER	BACKGROUND AND EXPERTISE OF PERSONNEL
Name: Title: FTE on this project:	Vacant Program manager .25
Name: Title: FTE on this project:	Vacant Program Coordinator 1 FTE
Name: Title: FTE on this project:	Vacant Program Coordinator 1 FTE
Name: Title: FTE on this project:	Sarah Chavez Accounting Clerk .10
Name: Title: FTE on this project:	
Name: Title: FTE on this project:	

***In addition, please attach a resume (for current personnel) or a job description (for positions to be hired) for the key personnel involved in the project and listed above. If awarded and there is a change in staff or a vacant position filled, a Staff Change Notification form and resume must be uploaded via the Communication Log in PGMS.**

KEY PERSONNEL SHOULD INCLUDE ANYONE WHO WILL BE PAID FROM THE GRANT

Attachment E

DISCLOSURE OF OTHER FUNDING SOURCES

Please list all other funding that your organization currently receives from State or Public Agencies, Federal Agencies, Non-Profit Organizations, or any other source providing funding for the funded program*. Statute ARS 8-1183 provides for a prohibition on supplanting of state funds by First Things First expenditures, meaning that no First Things First monies expended are to be used to take the place of any existing state or federal funding for early childhood development and health programs.

Use a continuation sheet if necessary. The following form may be reproduced with word processing software or another form may be created that contains all the information requested.

Type of Funding (Federal, State, local, other)	Received From	Amount	✔ If used for match on this grant
N/A			
TOTAL:			

***Should include only those funds that will support the program detailed the awarded First Things First grant award**

Attachment F

First Things First Standard Agency Information Collection Form

A. Agency Information:

Program Name (if applicable) Gila County Healthy Steps Program

Agency Gila County Division of Health and Emergency Services

Contact Person Paula Horn

Address 5515 S. Apache Avenue, Suite 100

Position Deputy Director

Address

Email phorn@co.gila.az.us

City, State, Zip Globe, AZ 85501

Phone 928-402-8813 Ext

County Gila

Fax 928-425-0794

Employer Identification Number: 86-6000444

Agency Classification: ____State Agency ___X_County Government ____Local Government ____Schools

____Tribal ____Faith Based ____Non Profit ____Private Organization ____Other

Have you previously conducted business with First Things First using this EIN? __X____Y ____N

If not, please go to http://www.gao.az.gov/Vendor/account_setup_home.asp, download the State of Arizona Substitute W-9 Form, and submit with your application

Congressional district (federal) in which agency provides most services: District # __1____

Legislative district (state) in which agency provides most services: District # __8____

Go to http://www.azredistricting.org and click on Final Maps to identify your Congressional and legislative district

Approximate federal funding (from a federal source) to be received in current fiscal year? $5,500,000

Agency's fiscal year-end date: 6/30/2012

Agency's accounting method: ____ Cash __X__ Accrual

Does your organization undergo an annual independent audit in accordance with OMB Circular A-133? __X__Y ____N

Contact information for firm conducting agency audit:

Audit firm: Clifton, Larson and Allen LLP

Address: 20 E. Thomas Road , Suite 2300 Phoenix, AZ 85012

Phone: 602-266-2248

B. Proposed Program Information / Description:

Amount requested: $190,000.00

Service area of proposed program: Gila County

Target population of proposed program: 200

Lead Strategy - Care Coordination/Medical Home

There are assigned service units for the strategy award from First Things First. Given the listed service unit, provide a contracted number for FY 14.

Number of children served: 200

Non-Lead Strategy 1 - Developmental and Sensory Screening

Number of children receiving screening: 200
Number of developmental screenings conducted: 200
Number of hearing screenings conducted: _____
Number of vision screenings conducted: _____

Important Items to NOTE:

If you are providing a Service Unit different than the FY 13 contracted number, provide a brief description explaining the change.
If you are not providing services for a particular Target Service Unit within the assigned Strategy please indicate with "NA".

IMPORTANT: Please find the full listing of First Things First Target Service Unit descriptions loaded in PGMS under Grantee Resources within a folder called Target Service Units.

C. Contact Information:

First Things First Partner and Grants Management System (PGMS) requires contact information for persons filling overall grant management, financial, programmatic, and evaluation roles. The same person may be assigned to more than one of the roles.

Main contact information: This contact person has overall responsibility for ensuring the program is successfully implemented. This person will be able to view all programmatic, financial, and evaluation information in PGMS. Correspondence from First Things First will be sent to this person.

Main contact person: Paula Horn

Position: Deputy Director

Address: 5515 S. Apache Avenue, Suite 100

City, State, Zip: Globe, AZ 85501

Email: phorn@co.gila.az.us

Phone: 928-402-8813 Ext. _____ Fax: 928-425-0794

Program contact information: This contact person has responsibility for the regular program operations. They will be able to view program and evaluation information in PGMS.

Program Contact Person: Program Manager/Vacant

Position: _____

Address: _____

City, State, Zip: _____

Email: _____

Phone: _____ Ext. _____ Fax: _____

Financial contact information: This contact person has the responsibility for financial accounting and reporting including submitting reimbursement request through PGMS. They will be able to view financial information in PGMS.

Financial contact person: Sarah Chavez

Position: Accounting Clerk

Address: 5515 S. Apache Avenue, Suite 100

City, State, Zip: Globe, AZ 85501

Email: schavez@co.gila.az.us

Phone: 928-402-4332 Ext. _____ Fax: 928-425-0794

Evaluation contact information: This contact person has responsibility for the program's evaluation and data collection activities. They will be able to view evaluation information in PGMS.

Evaluation contact person: Program Manager/Vacant

Position: _____

Address: _____

City, State, Zip: _____

Email: _____

Phone: _____ Ext. _____ Fax: _____

Your application may have included information about a collaborating partner/agency. Please provide contact information for these collaborators below.

Collaborator ☐ ☐

Agency: Gila County Nursing
Contact Person: Lorraine Dalrymple
Address: 5515 S. Apache Ave, suite 100
Position: Health Program Manager
Address:
Email: ldalrymp@co.gila.az.us
City, State, Zip: Globe, AZ 85501
County: Gila
Phone: 928-402-8811 Ext.
Fax: 928-425-0794

Collaborator ☐ ☐

Agency: Gila County WIC
Contact Person: Jamilyn Anderson
Address: 5515 S. Apache Avenue
Position: Supervisor
Address:
Email: janderson@co.gila.az.us
City, State, Zip: Globe, AZ 85501
County: Gila
Phone: 928-402-4306 Ext.
Fax: 928-425-0794

Collaborator ☐ ☐

Agency: Cobre Valley Regional Medical Center
Contact Person:
Address: 5880 S. Hospital Drive
Position: OB department
Address:
Email:
City, State, Zip: Globe, AZ 85501
County: Gila
Phone: 928-425-3261 Ext.
Fax:

Collaborator ☐ ☐

Agency:
Contact Person:
Address:
Position:
Address:
Email:
City, State, Zip:
County:
Phone: Ext.
Fax:

Attachment G

First Things First - Arizona Early Childhood Development and Health Board Data Security Guidelines and Requirements for Collaborators

BACKGROUND:
The purpose of the Arizona Early Childhood Development and Health Board (First Things First - FTF) is to aid in the creation of a system that offers opportunities and support for families and communities in the development of all children, so they can grow up healthy and ready to succeed. Our work is accountable and transparent to decision-makers and the citizens of Arizona. Collaboration and direct funding of grantees to undertake work on behalf of the children and families of Arizona is fundamental to the purpose and mission of FTF. Regular submission of data related to funded work is an important part of ensuring accountability and maximum positive impact for young children, as well as a material condition of receiving FTF grant funding.

Data Security Guidelines for Data Submission to FTF
First Things First will ensure that resources allocated have maximum impact for the benefit of children and families. To ensure this accountability, FTF has established data reporting requirements for all state and regional grantees. All funded providers shall regularly submit programmatic and financial reports as identified in the FTF reporting requirements.

FTF data submissions are classified in one of three levels:

- **Public data**
- **Limited distribution data**
- **Confidential data**

The majority of FTF reporting submissions are completed through the FTF Partner Grant Management System (PGMS). Subsequent to the award of an FTF grant, the grantee will receive general training on login and navigation within the PGMS system. With this login, the grantee will be able to manage their contract information. An additional training on strategy-specific data submission requirements will also be conducted. During that training, the grantee will be informed on submission of data reporting requirements through PGMS. All data submitted through PGMS is **public data** or **limited distribution data**. Because PGMS is located in a secure extranet environment, grantees using PGMS for data submission are not required to undertake additional security measures related to their data submission above those identified in the general and data submission orientations (password and login security, guidelines for upload of narrative and other reports).

A small group of grantees submit data requirements, with an agreement between the grantee and FTF, through an established secure web service or FTP (File Transfer Protocol) site via the internet, rather than a PGMS web-based entry form. Such data is likely to contain limited distribution data and shall adhere to the following protocols. Grantees that submit data through the secure web service must submit data within the established data structures and format; follow all login procedures; submit a formal data change request form if needed; and ensure that limited distribution data may not be intercepted or viewed at any time by parties other than the grantee and FTF. Additionally, Grantee must ensure that throughout the reporting and submission process the data is secured, and that any confidential data is de-identified and/or encrypted.

Any grantee submitting data identified as confidential must file a formal data security policy with FTF.

Data Security Guidelines for Grantee Maintenance of Data

In order to submit data to FTF in fulfillment of reporting requirements, grantees shall keep all data collected for their program(s) within their system (database) or hardcopies. Grantee data is likely to contain highly sensitive information on individuals, their education and their health. These guidelines and requirements are for the maintenance of those data.

All grantees must have a data security policy in force that identifies how the organization ensures that data is protected in all its forms, during all phases of its life cycle, from inappropriate access, use, modification, disclosure, or destruction.

All grantees subject to HIPAA, FERPA, GITA, tribal law, or other data regulation, are required to submit and maintain those approvals for all data.

Data Permission Guidelines for Grantee Data

All grantees must be prepared for FTF review of client-level data (e.g. child-level, teacher-level, or early care and education provider-level) during on-site visits. Additionally, FTF data reporting requirements may include submission of client-level data (e.g. child-level, teacher-level, or early care and education provider-level). The grantee agrees to allow FTF to access such data. Should the data be subject to HIPAA, the grantee agrees to enter into FTF's HIPAA Business Associate Agreement.

To inform clients of FTF's reporting requirements, all grantees must include in their client enrollment forms the statement: "To comply with reporting requirements of the funding source, I grant permission to [insert grantee organizational name] to release background, service, and impact related information to the Arizona Early Childhood Development and Health Board, also known as First Things First." The grantee warrants to FTF that prior to entering into the grant agreement for FTF funding, it has appropriately enquired and satisfied itself that it has the ability and authority comply with the requirements of this section.

Grantees Serving Clients on Tribal Lands

First Things First honors tribal ownership of data and recognizes communication is necessary with Arizona Tribes to determine what process/protocol is needed to obtain data. FTF further recognizes Arizona Tribes as owners of their indigenous knowledge, cultural resources and intellectual property. To this end, it is imperative that all appropriate tribal approvals for data collection and submission to FTF must be obtained and kept on-file by the grantee and FTF for granting serving clients on tribal lands.

Compliance with Data Security Guidelines

The grantee acknowledges that failure to comply with any requirement of these Data Security Guidelines shall be a material breach of the grant agreement.

Revised January 2013

GRANTEE AGREEMENT

GRA-RC004-13-0556-01

Between The
Gila Regional Partnership Council,
Arizona Early Childhood Development and Health Board
(First Things First)
And
Gila County Health Department

WHEREAS, A.R.S. Title 8, Chapter 13, Article 3 charges the Arizona Early Childhood Development and Health Board (also known as First Things First), the Gila Regional Partnership Council (hereinafter referred to as GRANTOR) with the responsibility of administering funds.

THEREFORE, it is agreed that the GRANTOR shall provide funding to Gila County Health Department (hereinafter referred to as the GRANTEE) for services under the terms of this Grant Agreement.

I. PURPOSE OF AGREEMENT

The purpose of this Agreement is to specify the responsibilities and procedures for the GRANTEE role in administering Arizona Early Childhood Development and Health Board grant funds.

II. TERM OF AGREEMENT, TERMINATION AND AMENDMENTS

This Agreement shall become effective on October 1, 2012 and shall terminate on June 30, 2013. This agreement is renewable for two (2) additional twelve (12) month extensions, based on satisfactory performance and continued available funding.

III. DESCRIPTION OF SERVICES

The GRANTEE shall provide the following services for the GRANTOR as approved and summarized below:

A. Effective care coordination begins with recognizing the needs of families and the coordination between health providers and health systems. It is based upon the relationship between the family, the health care providers and the care coordinator. It enhances access to needed services and resources, promotes optimal health and functioning of children, and supports improved quality of life. Data shows that primary care physicians struggle to fulfill the care-coordination needs of children, youth, and families. Care is coordinated and/or integrated across all elements of the complex health care and social services systems (e.g., subspecialty care, hospitals, home health agencies, home visitation services) and the patient's community (e.g., family, schools, childcare, public and private community-based services). Care coordinators enable medical practices to assure that their patients get the necessary services when and where they need it in a culturally and linguistically appropriate

manner. An important component of a Care Coordination strategy is to insure children receive regular developmental screenings at six-month intervals. Developmental screening has been a practice used in multiple settings; however, integrating the information using an online web-based system from those settings into a common database is a relatively new option.

B. There are a number of successful care coordination national models, which have demonstrated impressive health outcomes for children ages birth through five by offering high-risk families additional support to access health care and social services. Applicants are required by the Gila Regional Council to use the Healthy Steps National Model to provide care coordination services and the Ages and Stages Questionnaire (ASQ-3) online developmental screening tools and systems to be used for the trial implementation period. The Scope of work can be found in Exhibit A. The Standards of Practice for Care Coordination and Developmental Screening can be found in Exhibits B and C.

C. Adhere to the First Things First Data Collection Target Service Unit Guidance Document (Exhibit D).

D. Adhere to the First Things First Data Security Guidelines (Exhibit E).

E. Comply with the Scope of Work Narrative Responses, Implementation Plan and Submit the Grant Management Forms provided by First Things First (Attachments A – H).
NOTE: Narrative Responses, Implementation Plan, Line Item Budget, and Line Item Budget Narrative are required to be submitted prior to this agreement becomes final and is signed by First Things First. Submission is required by August 1, 2012.

F. Agencies and Departments implementing FTF programming are required to coordinate and collaborate with all First Things First grant recipients. Collaboration is critical to developing a seamless service delivery system for children and families.

IV. MANNER OF FINANCING

The GRANTOR shall:

a) Provide up to **$155,000.00** to GRANTEE for services provided under Paragraph III.

b) Payment made by the GRANTOR to the GRANTEE shall be on a reimbursement basis only and is conditioned upon receipt of applicable, accurate and complete reimbursement documents to be submitted by the GRANTEE via the First Things First on-line grants management system. Final payment will be contingent upon receipt of all fiscal and programmatic reports required of the GRANTEE under this Agreement.

c) Prior to processing payment, a review of submitted quarterly program narratives and data submission reports will be conducted as well as a review of any other required submission of programmatic information by the grantor to ensure programmatic requirements have been fulfilled. Timely submission of these reports is also required for payment.

V. FISCAL RESPONSBILITY

It is understood and agreed that the total amount of the funds used under this Agreement shall be used for the project(s) and scope of work outlined in this Agreement. Therefore, should the

project not be completed, be partially completed, or be completed at a lower cost than the original budget called for, the amount reimbursed to the GRANTEE shall be for only the amount of dollars actually spent by the GRANTEE. For any funds received under this Agreement for which expenditure is disallowed by an audit exception by the GRANTOR, the State, or Federal government, the GRANTEE shall reimburse said funds directly to the GRANTOR immediately.

VI. FINANCIAL AUDIT

GRANTEE agrees to terms specified in A.R.S. §§ 35-214 and 35-215.

In addition, in compliance with the Federal Single Audit Act (31 U.S.C. par., 7501-7507), as amended by the Single Audit Act Amendments of 1996 (P.L. 104 to 156), GRANTEE must have an annual audit conducted in accordance with Office of Management and Budget (OMB) Circular #A-133 ("Audits of States, Local Governments, and Non-profit Organizations") if GRANTEE expends more than $500,000 from federal awards/dollars, *a copy of the GRANTEE's audit report for the previous fiscal year must be submitted to the GRANTOR for review within thirty (30) days of signing this Agreement. Otherwise the annual audit review/statement must be provided to the GRANTOR within thirty (30) days.*

VII. DEBARMENT CERTIFICATION

The GRANTEE agrees to comply with the Federal Debarment and Suspension regulations as outlined in the "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion – Lower Tier Covered Transactions".

VIII. FUNDS MANAGEMENT

The GRANTEE must maintain funds received under this Agreement in separate ledger accounts and cannot mix these funds with other sources. GRANTEE must manage funds according to applicable regulations for administrative requirements, costs principles and audits.

The GRANTEE must maintain adequate business systems to comply with State of Arizona requirements. The business systems that must be maintained are:

- Financial Management
- Procurement
- Personnel
- Property
- Travel

A system is adequate if it is 1) written; 2) consistently followed – it applies in all similar circumstances; and 3) consistently applied – it applies to all sources of funds. Rates for mileage, lodging and meals are limited to the rates established by the State of Arizona Travel Policy (http://gao.az.gov/travel/default.asp).

IX. REPORTING REQUIREMENTS

Regular reports by the GRANTEE shall include:

Programmatic, Data Submission, and Financial Reports

1. The GRANTEE shall provide quarterly program narrative & evaluation data reports to the GRANTOR within twenty (20) working days of the last day of the quarter in which services are provided. Reporting is submitted via the First Things First on-line grants management system known as Partners and Grant Management System (PGMS) and shall contain such information as deemed necessary by the GRANTOR.

   a. Quarterly Programmatic Narrative & Data Submission Reports are due:

      i. Period: October 1, 2012 – December 31, 2012
         Due: January 20, 2013
      ii. January 1, 2013 – March 31, 2013
         Due: April 20, 2013
      iii. April 1, 2013 – June 30, 2013
         Due: July 20, 2013
      iv. The final programmatic report as submitted shall be marked FINAL

   b. Financial Reimbursement Reports

      i. The GRANTEE shall provide, as frequently as monthly but not less than quarterly, requests for reimbursement. Reimbursement requests shall be submitted using the First Things First online grants management system known as Partners and Grant Management System (PGMS). This submission includes a basic line item ledger to detail the type of expense relating to the approved line item budget and validates approved staffing assigned to the project, travel is within the approved state rate limitation, and other line item budget expenditure details.

      ii. The GRANTEE shall submit a final reimbursement request for expenses obligated prior to the end of the termination of this Agreement no more than forty-five (45) days after the end of the Agreement. Requests for reimbursement received later than the forty-five (45) days after the Agreement termination will not be paid. The final reimbursement request as submitted shall be marked FINAL.

All reports shall be submitted to the contact person designated in Paragraph XLII, NOTICES, of this Agreement.

X. ASSIGNMENT AND DELEGATION

GRANTEE may not assign any rights hereunder without the express, prior written consent of both parties.

XI. AMENDMENTS

Any change in this Agreement including but not limited to the Description of Services and budget described herein, whether by modification or supplementation, must be accomplished by a formal written Agreement amendment signed and approved by and between the duly authorized representative of the GRANTEE and the GRANTOR.

Any such amendment shall: 1) specify an effective date; 2) specify any increases or decreases in the amount of the GRANTEE's compensation if applicable; 3) be titled as an "Amendment"; and 4) be signed by the parties identified in the preceding sentence. The GRANTEE expressly and explicitly understands and agrees that no other method of communication, including any other document, correspondence, act, or oral communication by or from any person, shall be used or construed as an amendment or modification or supplementation to this Agreement.

XII. SUBCONTRACTORS

The GRANTEE may enter into written subcontract(s) for performance of certain of its functions under the contract in accordance with terms established in the State of Arizona procurement policy.

The GRANTEE agrees and understand that no subcontract that the GRANTEE enters into with respect to performance under this Agreement shall in any way relieve the GRANTEE of any responsibilities for performance if its duties. The GRANTEE shall give the GRANTOR immediate notice in writing by certified mail of any action or suit filed and prompt notice of any claim made against the GRANTEE by any subcontractor or vendor which in the opinion of the GRANTEE may result in litigation related in any way to the Agreement with the GRANTOR.

XIII. OFFSHORE PERFORMANCE OF WORK PROHIBITED

Due to security and identity protection concerns, all services under this Agreement shall be performed within the borders of the United States. All storage and processing of information shall be performed within the borders of the United States. This provision applies to work performed by subcontractors at all tiers.

XIV. PROHIBITION ON GOVERNMENT CONTRACTS

Pursuant to A.R.S. 35-393.06, the GRANTEE certifies that it does not have business operations in either Sudan or Iran.

XV. AGREEMENT RENEWAL

This Agreement shall not bind nor purport to bind the GRANTOR for any contractual commitment in excess of the original Agreement period.

XVI. RIGHT TO ASSURANCE

If the GRANTOR in good faith has reason to believe that the GRANTEE does not intend to, or is unable to perform or continue performing under this Agreement, the GRANTOR may demand in writing that the GRANTEE give a written assurance of intent to perform. Failure by the GRANTEE

to provide written assurance within the number of days specified in the demand may, at the GRANTOR's option, be the basis for terminating this Agreement under the terms of this Agreement or other rights and remedies available by law.

XVII. CANCELLATION FOR CONFLICT OF INTEREST

The GRANTOR or the GRANTEE may, by written notice cancel this Agreement without penalty or further obligation pursuant to A.R.S. § 38-511 if any person significantly involved in initiating, negotiating, securing, drafting or creating the Agreement on behalf of the State or its subdivisions (unit of local government) is an employee or agent of any other party in any capacity or a consultant to any other party to the Agreement with respect to the subject matter of the Agreement. Such cancellation shall be effective immediately upon receipt of written notice from the GRANTOR or the GRANTEE, unless the notice specifies a later time.

XVIII. THIRD PARTY ANTITRUST VIOLATIONS

GRANTEE assigns to the State of Arizona, GRANTOR any claim for overcharges resulting from antitrust violations to the extent that such violations concern materials or services supplied by third parties to GRANTEE toward fulfillment of this Agreement.

XIX. AVAILABILITY OF FUNDS

Every payment obligation of the GRANTOR under this Agreement is conditioned upon the availability of funds appropriated or allocated for the payment of such obligations. If the funds are not allocated and available for the continuance of this Agreement, the GRANTOR may terminate this Agreement at the end of the period for which funds are available. No liability shall accrue to the GRANTOR in the event this provision is exercised, and the GRANTOR shall not be obligated or liable for any future payments or for any damages as a result of termination under this paragraph, including purchases and/or contracts entered into by the GRANTEE in the execution of this Agreement.

XX. FORCE MAJEURE

If either party hereto is delayed or prevented from the performance of any act required in this Agreement due to acts of God, strikes, lockouts, labor disputes, civil disorder, or other causes without fault and beyond the control of the party obligated, performance of or payment for such act will be excused for the period of the delay.

XXI. ARBITRATION

This agreement is subject to arbitration to the extent required by A.R.S. § 12-1518.

XXII. GOVERNING LAW AND CONTRACT INTERPRETATION

a) This Agreement shall be governed and interpreted in accordance with the laws of the State of Arizona. First Things First follows all State of Arizona and Federal laws, State of Arizona Uniform Terms and Conditions and in particular abides by the Arizona Uniform Terms and Conditions and Uniform Instructions and are incorporated into this Agreement through reference. These laws

include Federal Immigration and Nationality Act (FINA) and all other federal immigration laws and regulations related to immigration status of its employees. First Things First may request verification for any Grantee, Contractor, or Subcontractor performing work under the agreement. Anyone entering into an Agreement with First Things First is required to follow any and all State laws around immigration and English only. Should First Things First suspect that a grantee is not in compliance with state or federal laws and First Things First may pursue any and all remedies allowed by law, including but not limited to: suspension of work, termination, and suspension and/or debarment of the grantee. All costs necessary to verify compliance are the responsibility of the grantee.

b) This Agreement is intended by the parties as a final and complete expression of their agreement. No course of prior dealings between the parties and no usage of the trade shall supplement or explain any terms in this document.

c) Either party's failure to insist on strict performance of any term or condition of the Agreement shall not be deemed a waiver of that term or condition even if the party accepting or acquiescing in the nonconforming performance knows of the nature of the performance and fails to object.

XXIII. ENTIRE AGREEMENT

This Agreement and its Attachments/Exhibits constitute the entire Agreement between the parties hereto pertaining to the subject matter hereof and may not be changed or added to except by a writing signed by all parties hereto in conformity with Section X Reporting Requirements of this Agreement; provided, however, that the GRANTOR shall have the right to immediately amend this Agreement so that it complies with any new legislation, laws, ordinances, or rules affecting this Agreement. All prior and contemporaneous agreements, representations, and understandings of the parties, oral, written, pertaining to the subject matter hereof, are herby superseded or merged herein.

XXIV. RESTRICTIONS ON LOBBYING

The GRANTEE shall not use funds made available to it under this Agreement to pay for, influence, or seek to influence any officer or employee of a State, Local or Federal government.

XXV. LICENSING

The GRANTEE, unless otherwise exempted by law, shall obtain and maintain all licenses, permits and authority necessary to perform those acts it is obligated to perform under this Agreement.

XXVI. NON-DISCRIMINATION

The GRANTEE shall comply with all state and federal equal opportunity and non-discrimination requirements and conditions of employment, including the American with Disability Act, in accordance with A.R.S. Title 41, Chapter 9, Article 4 and Executive Order 2009-09, which mandates that all persons, regardless of race, color, religion, sex, age, national origin, disability or political affiliation, shall have equal access to employment opportunities and all applicable provisions and regulations relating to Executive Order No. 13279 – Equal Protection of the Laws

for Faith-based and Community Organizations.

XXVII. SECTARIAN REQUESTS

Funds disbursed pursuant to this Agreement may not be expended for any sectarian purpose or activity, including sectarian worship or instruction in violation of the United States or Arizona Constitutions.

XXVIII. SEVERABILITY

The provisions of this Agreement are severable. Any term or condition deemed illegal or invalid shall not affect any other term or condition of the Agreement.

XXIX. ADVERTISING AND PROMOTION OF AGREEMENT

The GRANTEE shall not advertise or publish information for commercial benefit concerning this Agreement without the written approval of the GRANTOR.

XXX. OWNERSHIP OF INFORMATION, PRINTED AND PUBLISHED MATERIAL

The GRANTOR reserves the right to review and approve any publications and/or media funded or partially funded through this Agreement. All publications funded or partially funded through this Agreement shall recognize the GRANTOR, and GRANTOR shall have full and complete rights to reproduce, duplicate, disclose, perform, and otherwise use all materials prepared under this Agreement.

The GRANTEE agrees that any report, printed matter, or publication (written, visual, or sound, but excluding press releases, newsletters, and issue analyses) issued by the GRANTEE describing programs or projects funded under this agreement in whole or in part with First Things First funds and shall follow the protocol and style guide provided by First Things First and normally located in the Partners and Grant Management System (PGMS).

XXXI. INDEMNIFICATION

Indemnification Language for Public Agencies. Each party (as 'indemnitor') agrees to indemnify, defend, and hold harmless the other party (as 'indemnitee'') from and against any and all claims, losses, liability, costs, or expenses (including reasonable attorney's fees) (hereinafter collectively referred to as 'claims') arising out of bodily injury of any person (including death) or property damage but only to the extent that such claims which result in vicarious/derivative liability to the indemnitee, are caused by the act, omission, negligence, misconduct, or other fault of the indemnitor, its' officers, officials, agents, employees, or volunteers."

This indemnity shall not apply if the Grantee or sub-contractor(s) is/are an agency, board, commission or university of the State of Arizona.

XXXII. INSURANCE REQUIREMENTS

Grantee and subcontractors shall procure and maintain until all of their obligations have been discharged, including any warranty periods under this Contract, are satisfied, insurance against claims for injury to persons or damage to property which may arise from or in connection with the performance of the work hereunder by the Grantee, his agents, representatives, employees or subcontractors.

The *insurance requirements* herein are minimum requirements for this Contract and in no way limit the indemnity covenants contained in this Contract. First Things First in no way warrants that the minimum limits contained herein are sufficient to protect the Grantee from liabilities that might arise out of the performance of the work under this contract by the Grantee, its agents, representatives, employees or subcontractors, and Grantee is free to purchase additional insurance.

All certificates required by this Contract shall be sent directly to (First Things First, Grants and Contracts Procurement Specialist, 4000 N. Central, Suite 800, Phoenix, AZ 85012). The State of Arizona project/contract number and project description shall be noted on the certificate of insurance. The State of Arizona reserves the right to require complete, certified copies of all insurance policies required by this Contract at any time and shall be submitted within 15 days of the Agreement becoming final.

A. MINIMUM SCOPE AND LIMITS OF INSURANCE: Grantee shall provide coverage with limits of liability not less than those stated below.

1. **Commercial General Liability – Occurrence Form**
   Policy shall include bodily injury, property damage, personal injury and broad form contractual liability coverage.

• General Aggregate	$2,000,000
• Products – Completed Operations Aggregate	$1,000,000
• Personal and Advertising Injury	$1,000,000
• Blanket Contractual Liability – Written and Oral	$1,000,000
• Fire Legal Liability	$50,000
• Each Occurrence	$1,000,000

   a. The policy shall be endorsed to **include coverage for sexual abuse and molestation**.
   b. The policy shall be endorsed to include the following additional insured language: ***"The State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees shall be named as additional insureds with respect to liability arising out of the activities performed by or on behalf of the Grantee".***
   c. Policy shall contain a waiver of subrogation against the State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees for losses arising from work performed by or on behalf of the Grantee.

2. **Business Automobile Liability**
   Bodily Injury and Property Damage for any owned, hired, and/or non-owned vehicles used in the performance of this Contract.
   - Combined Single Limit (CSL) $1,000,000

     a. The policy shall be endorsed to include the following additional insured language: ***"The State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees shall be named as additional insureds with respect to liability arising out of the activities performed by or on behalf of the Grantee, involving automobiles owned, leased, hired or borrowed by the Grantee".***
     b. Policy shall contain a waiver of subrogation against the State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees for losses arising from work performed by or on behalf of the Grantee.

3. **Worker's Compensation and Employers' Liability**
   - Workers' Compensation Statutory
   - Employers' Liability
     - Each Accident $ 500,000
     - Disease – Each Employee $ 500,000
     - Disease – Policy Limit $1,000,000

     a. Policy shall contain a waiver of subrogation against the State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees for losses arising from work performed by or on behalf of the Grantee.
     b. This requirement shall not apply to separately, EACH Grantee or subcontractor exempt under A.R.S. §23-901, AND when such Grantee or subcontractor executes the appropriate waiver (Sole Proprietor/Independent Contractor) form.

4. **Professional Liability (Errors and Omissions Liability)**
   - Each Claim $1,000,000
   - Annual Aggregate $2,000,000

     a. In the event that the professional liability insurance required by this Contract is written on a claims-made basis, Grantee warrants that any retroactive date under the policy shall precede the effective date of this Contract; and that either continuous coverage will be maintained or an extended discovery period will be exercised for a period of two (2) years beginning at the time work under this Contract is completed.
     b. The policy shall cover professional misconduct or lack of ordinary skill for those positions defined in the Scope of Work of this contract.

B. <u>ADDITIONAL INSURANCE REQUIREMENTS:</u> The policies shall include, or be endorsed to include, the following provisions:
   1. The State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees wherever additional insured status is required such

additional insured shall be covered to the full limits of liability purchased by the Grantee, even if those limits of liability are in excess of those required by this Contract.

2. The Grantee's insurance coverage shall be primary insurance with respect to all other available sources.

2. Coverage provided by the Grantee shall not be limited to the liability assumed under the indemnification provisions of this Contract.

C. NOTICE OF CANCELLATION: Each insurance policy required by the insurance provisions of this Contract shall provide the required coverage and shall not be suspended, voided, canceled, or reduced in coverage or in limits except after thirty- (30) days prior written notice has been given to the State of Arizona. Such notice shall be sent directly to (First Things First, Grants and Contracts Procurement Specialist, 4000 N. Central, Suite 800, Phoenix, AZ 85012) and shall be sent by certified mail, return receipt requested.

D. ACCEPTABILITY OF INSURERS: Insurance is to be placed with duly licensed or approved non-admitted insurers in the state of Arizona with an "A.M. Best" rating of not less than A-VII. The State of Arizona in no way warrants that the above-required minimum insurer rating is sufficient to protect the Grantee from potential insurer insolvency.

E. VERIFICATION OF COVERAGE: Grantee shall furnish the State of Arizona with certificates of insurance (ACORD form or equivalent approved by the State of Arizona) as required by this Contract. The certificates for each insurance policy are to be signed by a person authorized by that insurer to bind coverage on its behalf.

F. All certificates and endorsements are to be received and approved by the State of Arizona before work commences. Each insurance policy required by this Contract must be in effect at or prior to commencement of work under this Contract and remain in effect for the duration of the project. Failure to maintain the insurance policies as required by this Contract, or to provide evidence of renewal, is a material breach of contract.

G. All certificates required by this Contract shall be sent directly to (First Things First, Grants and Contracts Procurement Specialist, 4000 N. Central, Suite 800, Phoenix, AZ 85012). The State of Arizona project/contract number and project description shall be noted on the certificate of insurance. The State of Arizona reserves the right to require complete, certified copies of all insurance policies required by this Contract at any time. DO NOT SEND CERTIFICATES OF INSURANCE TO THE STATE OF ARIZONA'S RISK MANAGEMENT SECTION.

H. SUBCONTRACTORS: Grantees' certificate(s) shall include all subcontractors as insureds under its policies or Grantee shall furnish to the State of Arizona separate certificates and endorsements for each subcontractor. All coverages for subcontractors shall be subject to the minimum requirements identified above.

I. APPROVAL: Any modification or variation from the *insurance requirements* in this Contract shall be made by the Department of Administration, Risk Management Section, whose decision shall be final. Such action will not require a formal Contract amendment, but may be made by administrative action.

J. EXCEPTIONS: In the event the Grantee or sub-contractor(s) is/are a public entity, then the Insurance Requirements shall not apply. Such public entity shall provide a Certificate of Self-Insurance. If the Grantee or sub-contractor(s) is/are a State of Arizona agency, board, commission, or university, none of the above shall apply.

XXXIII. CONFIDENTIALITY OF RECORDS

The GRANTEE shall establish and maintain procedures and controls that are acceptable to the GRANTOR for the purpose of assuring that no information contained in its records or obtained from the State of Arizona or from a subcontractor under this Agreement shall be used by or disclosed by it, its agents, officers, or employees, except as required, to efficiently perform duties under the Agreement. GRANTEE also agrees that any information pertaining to individual persons shall not be divulged other than to employees or officers of the GRANTEE as needed for performance of duties under this Agreement, unless otherwise agreed to in writing.

XXXIV. CONFIDENTIALITY OF GRANTEE 'S INFORMATION

GRANTEE acknowledges that confidentiality provided in A.R.S. § §41-1505.06 (D) and 41-1505.07(J) may be waived with the GRANTEE's consent, and GRANTEE consents to a total and complete waiver of confidentiality. In waiving confidentiality, GRANTEE understand and consents to disclosure of any information submitted to the GRANTOR that concerns the identify, background, financial status, marketing plans, or trade secrets or any other proprietary information related to the GRANTEE or any person or organization involved in the project(s), including the application and supporting materials, unless such information or materials are clearly marked as "confidential".

XXXV. TERMINATION

a) The GRANTOR reserves the right to terminate the Agreement in whole or in part due to the failure of the GRANTEE to comply with any term or condition of the Agreement, to acquire and maintain all required insurance policies, bonds, licenses and permits or to make satisfactory progress in performing the Agreement. The GRANTOR staff shall provide written notice of the termination to the GRANTEE.

b) The GRANTOR may, upon termination of this Agreement, procure, on terms and in the manner that it deems appropriate, materials or services to replace those under this Agreement. The GRANTEE shall be liable to the GRANTOR for any excess costs incurred by the GRANTOR in procuring materials or services in substitution for those due from the GRANTEE.

XXXVI. CONTINUATION OF PERFORMANCE THROUGH TERMINATION

The GRANTEE shall continue to perform, in accordance with the requirements of the Agreement, up to the date of termination, as directed in the termination notice.

XXXVII. PARAGRAPH HEADINGS

The paragraph headings in this Agreement are for convenience of reference only and do not define, limit, enlarge, or otherwise affect the scope, construction, or interpretation of this Agreement or any of its provisions.

XXXVIII. COUNTERPARTS

This Agreement may be executed in any number of counterparts, copies, or duplicate originals. Each such counterpart, copy, or duplicate original shall be deemed an original, and collectively they shall constitute one agreement.

XXXIX. AUTHORITY TO EXECUTE THIS AGREEMENT

Each individual executing this Agreement on behalf of the GRANTEE represents and warrants that he or she is duly authorized to execute this Agreement.

XL. COMPLIANCE WITH FEDERAL IMMIGRATION LAWS AND REGULATIONS

The GRANTEE shall comply with Executive Order 2005-30, which mandates as follows: 1) The GRANTEE shall, and by signing this agreement does, represents that it is in compliance with all federal immigration laws and regulations; 2) The GRANTEE shall take affirmative action to ensure that all subcontractors of the Contractor execute similar representation; 3) the breach of any such warranty shall be deemed a material breach of this Contract, subject to monetary penalties or other penalties up to and including termination of the Contract; and 4) the State retains the legal right to inspect the papers of any employee who works on the Contract to ensure that the employer is in compliance with its representation.

XLI. Legal Arizona Worker

GRANTEE hereby warrants that it will at all times during the term of this Contract comply with all federal immigration laws applicable to GRANTEE employment of its employees, and with the requirements of A.R.S. § 23-214 (A) (together the "State and Federal Immigration Laws"). GRANTEE shall further ensure that each subcontractor who performs any work for GRANTEE under this contract likewise complies with the State and Federal Immigration Laws.

XLII. NOTICES

Any and all notices, requests, demands or communications by either party to this Agreement, pursuant to or in connection with this Agreement shall be in writing and shall be delivered in person or shall be sent by the United States Postal Service, certified mail, return receipt requested, to the respective parties at the following addresses:

The GRANTEE shall submit notices relative to this Agreement to:

First Things First
Attention: Finance
4000 North Central, Suite 800
Phoenix, Arizona 85012

GRANTOR shall address all notices relative to this Agreement to:

Gila County Health Department
5515 S. Apache Avenue, Ste. 100
Globe, Arizona 85501

XLIII. <u>IN WITNESS WHEREOF</u>

The parties hereto agree to execute this Agreement.

FOR AND BEHALF OF
Gila County

Tommie C. Martin, Chairman,
Board of Supervisors

9/18/12
Date

FOR AND BEHALF OF THE
Arizona Early Childhood Development
And Health Board

Rhian Evans Allvin
Chief Executive Officer

10/9/12
Date

Bryan Chambers, Chief Deputy
Gila County Attorney

9 19 2017
Date

Grant Agreement Attachments & Exhibits

Attachment A	Standard Agency Information Collection Form
Attachment B	Personnel Overview
Attachment C	Narrative Questions and Responses
Attachment D	Implementation Plan
Attachment E	Line Item Budget Form
Attachment F	Budget Narrative Explanation
Attachment G	Disclosure of Other Funding Sources
Attachment H	Financial Systems Survey
Attachment I	Data Collection Form

Exhibit A	Scope of Work Reference/Information
Exhibit B	Care Coordination/Medical Home Standards of Practice
Exhibit C	Developmental and Sensory Screening Standards of Practice
Exhibit D	First Things First Care Coordination/Medical Home Target Service Unit Information
Exhibit E	First Things First Developmental and Sensory Screening Target Service Unit Information
Exhibit F	Data Security Guidelines

Attachment A

FIRST THINGS FIRST STANDARD AGENCY INFORMATION COLLECTION FORM

A. Agency Information:

Program Name (if applicable) Gila County Healthy Steps

Agency Gila County Division of Health and Emergency Services

Contact Person Paula Horn

Address 5515 S. Apache Avenue, Suite 100

Position Deputy Director of Prevention Services

Address

Email phorn@co.gila.az.us

City, State, Zip Globe, AZ 85501

Phone 928-402-8813 x Fax

County Gila

Employer Identification Number: 86-6000444

Agency Classification: _____State Agency xx County Government _____Local Government _____Schools

_____Tribal _____Faith Based _____Non Profit _____Private Organization _____Other

Have you previously conducted business with First Things First using this EIN? x **Y** ____**N**

If **NO,** please go to the following website, download the State of Arizona Substitute W-9 Form and submit with your Application: http://www.gao.az.gov/Vendor/account_setup_home.asp.

In which Congressional (Federal) District is your agency? Enter District # 1

http://www.azredistricting.org (click on Final Maps)

In which Legislative (State) District is your agency? Enter District # 8

http://www.azredistricting.org (click on Final Maps)

Approximately how much FEDERAL funding (from a Federal Source) will your organization expend in your current fiscal year? $5,500,000

What is your organization's fiscal year-end date? 06-30-2012

Accounting Method: _____Cash X Accrual

Does your organization undergo an annual independent audit in accordance with OMB Circular A-133? X **Y** _____**N**

Please provide contact information of the audit firm conducting your audit:

Agency Miller, Allen & CO., P.C.

Address 5333 N. 7th Street Phoenix, AZ 85014

Phone Number 602-264-3888

B. Proposed Program Information / Description:

Amount requested: $155,000.00

Service area of proposed program: Gila County

Target population of proposed program: 200

Number of children to be served: 200

Number of children screened for developmental delays: 200

Please provide a **BRIEF** description of the **proposed program** in one or two paragraphs and this will be the source for a public description describing the nature of the program being implemented that will be used by First Things First.

Gila County Healthy Steps Program enhances the relationship between the parents of an infant and their pediatrician, through the child's fifth year. The Healthy Steps Specialist will work with parents to connect them to services in the community, conduct developmental screenings on a regular basis, introduce and support early literacy activities through the provision of developmentally appropriate books to the child, and work to be sure that parent's questions are answered. Home visits will be conducted at birth and key developmental stages to support families raise healthy successful children. The program will implement the Ages and Stages On-Line Enterprise Screening including Parent Access to ensure that all children receive timely developmental and social emotional screen. The Gila County Healthy Steps Program will serve as the leader in implementing a region-wide developmental screening process that will allow children to receive timely screenings from their first contact with the early childhood system.

C. Contact Information

First Things First Partner and Grants Management System (PGMS) require four designated contacts for contact with First Things First related to this grant (the same person may be assigned to more than one of the roles, if appropriate).

Main Contact Information – This should be information for the person designated as the Main contact for this grant award and this person can view all information related to this grant (financial, programmatic and data collection/evaluation in nature). This person will also be the primary contact for First Things First and should be the person responsible for ensuring the program plan is implemented. Primary correspondence from First Things First will be sent to this person.

Main Contact Person Paula Horn

Position Deputy Director of Prevention Services

Address 5515 S. Apache Avenue, Suite 100

City, State, Zip Globe, AZ 85501

Email phorn@co.gila.az.us

Phone 928-402-8813 x _____ Fax 928425-0794

Program Contact Information – This should be information for the person designated as the Program contact for this grant award and this person can view information related to this grant for program or data collection purposes only.

Program Contact Person Lauren Savaglio

Position Program Manager

Address 5515 S. Apache Avenue, Suite 100

City, State, Zip Globe, AZ 85501

Email lsavaglio@gilacountyaz.gov

Phone 928-402-8811 x _____ Fax 425-0794

Financial Contact Information – This should be information for the person designated as the financial contact for this grant award and this person can view information related to this grant for financial purposes only.

Financial Contact Person Sarah Chavez

Position Accounting Clerk

Address 5515 S. Apache Avenue Suite 300

City, State, Zip Globe, AZ 85501

Email schavez@gilacountyaz.gov

Phone 928-402-4332 x _____ Fax 928-425-0794

Evaluation Contact Information – This should be information for the person designated as the Evaluation contact for this grant award and this person can view information related to this grant for data collection purposes only.

Evaluation Contact Person Lauren Savaglio

Position Program Manager

Address 5515 S. Apache Avenue, Suite 100

City, State, Zip Globe, AZ 85501

Email lsavaglio@gilacountyaz.gov

Phone 928-402-8811 x Fax 928-425-0794

In addition, your application may have included information about a collaborating partner/agency. Please replicate this information as many times as necessary to document the participation and agreement to be involved with the application as a collaborating agency/partner.

Collaborator

Agency Gila County Nursing Section

Address Globe and Payson Location

Address

City, State, Zip

County

Contact Person Lorraine Dalrymple

Position

Email

Phone x Fax

Collaborator

Agency Gila County WIC

Address 5515 S. Apache, Suite 700

Address

City, State, Zip Globe, AZ 85501

County Gila

Contact Person Jamilyn Anderson

Position Supervisor

Email janderson@co.gila.az.us

Phone 928-402-4306 x Fax 928-425-0794

Collaborator

Agency Cobre Valley Regional Medical Center

Address 5880 S. Hospital Drive

Address

City, State, Zip Globe, AZ 85501

County Gila

Contact Person Sheena Guerrero

Position OB Director

Email

Phone 928-425-3261 x Fax

Attachment B

PERSONNEL OVERVIEW

STAFF MEMBER	BACKGROUND AND EXPERTISE OF PERSONNEL
Name: Title: FTE on this project:	Lauren Savaglio Program Manager .25
Name: Title: FTE on this project:	Vacant Healthy Steps Coordinator 1 FTE
Name: Title: FTE on this project:	Vacant Healthy Steps Coordinator 1 FTE
Name: Title: FTE on this project:	Sarah Chavez Accounting Clerk .10
Name: Title: FTE on this project:	
Name: Title: FTE on this project:	

***In addition to this overview, please attach a resume (for current personnel) or a job description (for positions to be hired) for individuals involved in the project.**

Attachment C

Narrative Questions and Responses

Narrative Responses Required
To complete your Application, provide a narrative response that addresses each of the items below.

Provide a description of the program being proposed.

Gila County Healthy Steps Program will implement the National Healthy Steps model to provide care coordination to children and their families. Services will be provided in Globe and Payson with a full time staff person in each city. The model implemented will be the Community Based program that collaborates with various partners in the community to provide services to children. Initial contacts will be made with many families in the hospital. Other families' first contact with the program may be from the Family Access Developmental Screening Program or their well child care providers referral. The program will partner with local hospitals, Payson Christian Clinic, Community Physicans, Canyonlands Clinic as well as the County Immunization Clinic and the WIC Program. The program will provide the services as outlined in the National Heathly Steps model as well as meeting the components of the Scope of Work and Standards of practice included in this document. The program will provide home visits at birth and key developmental stages when appropriate to meet the needs of the families and their children. We have identified 200 as the number of children birth to five. The program will consist of a .25 Program Manager who will oversee the two full time program coordinators housed in Globe and Payson. The program will serve as the lead agency to implement the ASQ Enterprise and Family Access Program within the Healthy Steps Program. In addition the program will develop a plan to implement the Enterprise System region-wide through community partners that provide services to children birth to five. The goal of the program is to provide parent education, identification of delays and coordination of care for all children who reside in Gila County, and to assist with creating a medical home. Training for staff will utilize a combination of the National Healthy Steps training as well as on-going training and support of the Arizona Healthy Steps Program trainers. Intensive training will be provided during the first grant period to insure the success of the program and model fidelity.

Identify and describe the target population to be served by the proposed strategy, including:

- Unit of service will be 200 unduplicated children birth to five and their families in Gila County receiving ongoing Healthy Steps support.
- 200 children will receive ASQ and ASQ-SE developmental screening either through the Parent Access Program or screenings conducted by the Healthy Steps Specialist. The program will screen children at key developmental milestone with a target of 400 screens and appropriate follow-up.

How the strategy will meet the needs of the targeted population in terms of being culturally competent, linguistically appropriate, age appropriate and gender responsive.

We plan to follow the Healthy Steps curriculum which has been proven to be evidence based as well as culturally competent, linguistically appropriate and gender responsive . Gila County provides training to all staff regarding cultural competency and currently has staff to assist with linguistic barriers.

Recruitment and outreach efforts, engagement and retention practices for the targeted population.

Healthy Steps curriculum and training will provide a multi-faceted approach to retention of clientele. Outreach will consist of working with agencies who service the same target population.

Identify capacity or infrastructure building which will be needed, including agreements and partnerships with other departments and agencies, additional resources, and training and technical assistance to provide the proposed service.

The program will partner with local hospitals, Payson Christian Clinic, Community Physicans, Canyonlands Clinic as well as the County Immunization Clinic and the WIC Program. We plan to form a partnership with the home visitation program coordinator in Gila County to assist with meetings and capacity building. Training and technical assistance will be provide by the National and State Healthy Steps Program. The program will become an official Healthy Steps Site upon completion of the initial training.

Identify barriers to providing the service or program proposed and plans for addressing these barriers. Describe plans to recruit and locate personnel within the geographical region of the provided service and that are linguistically and culturally competent for the population to be served.

The barriers we believe may arise will be the participation from one of the hospitals in the area and marketing the program to let the community know about the services that will be available. The plan to address the above barriers will be to collaborate with existing staff currently working with the hospital. Outreach and marketing will be a priority in the initial stages of the program. The personnel required for the program will be compensated at a higher level which will entrust we will get a good selection of applicants in which to pick from.

Describe the plan and resources necessary to meet FTF basic reporting requirements, maintain data securely and confidentially.

We plan to capture the reporting requirements in an electronic data base which our County IT has password protected software in place to ensure confidentiality. The staff our familiar with reporting requirements of First Things First.

Describe the process of implementing the ASQ-3 online system within the community of health practitioners.

We plan to purchase the enterprise system and begin implementation upon completion of the Healthy Steps training. After the staff become super-users of the on-line system, we will attempt to collaborate with other programs to use the on-line system. Healthy Steps staff will be the technical support for the ASQ online system. The Developmental Screening Program set up will meet all of the requirements outlined in the scope of work including community collaboration and reporting to the Regional Council.

Attachment D

IMPLEMENTATION PLAN: October 1, 2012 – June 30, 2013

Activities	Task	Person Responsible	Date Task Will Be Completed/Timeline	Support Documentation
Preparation	Recruit new employees for Healthy Steps Program Coordinator	HR/Program Manager/Deputy Director	11/15/2012	Job Description/Job filled/Resume of new staff
	Purchase office equipment	Program Manager	11/15/12	Purchase orders/receipts
	Purchase supplies	Program Coordinators	12/01/12	Receipts
Training	Schedule training with National Healthy Steps program	Program Manager	10/31/12	Training certificates
	On-on-one training with Healthy Steps consultant	Program Coordinators/Program Manager	On-going	Training logs
	ASQ-3 developmental assessment training	Program Manager/Program Coordinators	12/01/12	Certificate/performance
Outreach	Introduction letters to local agencies, physicians and healthcare providers.	Program Manager/Program Coordinators	01/31/13	Letters
	Utilize National Healthy Steps outreach education and information brochures/pamphlets/fact sheets.	Program Manager/Program Coordinators	01/31/13	Outreach materials
	ASQ-online system enterprise	Program Manager	01/31/13	On-line materials
Implementation	Home visits/hospital visits/in-office visits/social group settings to families in Gila County	Program Coordinators	On-going	Case files
	Collaboration with local pediatricians and family doctors that provide service to children birth to five.	Program Manager/Program Coordinators	On-going to build capacity	Meetings/contact information
	Provide education to parents on child development, literacy, parenting, and referral for other supporting resources	Program Manager/Program Coordinators	On-going	Case files
Follow-up	Appropriate referrals	Program Manager/Program Coordinators	At time of visit	Referral/case note

	Review with physician to provide family with a team approach for healthy development of their child	Program Manager/Program Coordinators	On-going	Case note
	Developmental screening referrals	Program Coordinators	On-going	ASQ online system
Evaluation	Ensure all reports are provided to FTF in a timely manner.	Program Manager	On-going	Quarterly Reports
	Purchase and implement the ASQ-3 and ASQ-SE Online Enterprise system and parent access system.	Program Manager	October 31,2012	Financial Reports
	Set up the Parent access and Enterprise systems for use and train staff.	Program Manager/Program Coordinators	November 30, 2012	Online system ready for use and children being screen.
	Collaborate with First Things First Staff and Gila Regional Council to convene community stakeholders to discuss expansion of the Enterprise system accoss the region.	Program Manager	November 1, 2012	Sign in Sheets from meetings held
	Prepare a report for the Region Council on the pilot implementation of the on-line system and pland for expansion to community partners.	Program Manager/Program Coordinators	April 1, 2012	Report submitted to First Things First
	Collaborate with First Things First to provide data from the Gila Enterprise System to the First Things First Hub	Program Manager/Program Coordinators	Approximately April 2012 or when the First Things First Hub is in place.	Case note
	Outreach the parent access sytem withn the community and provide follow-up for families entering into thedevelopmental screening process throught the system.	Program Coordinators	On-going	ASQ online system

Attachment E

Line Item Budget

While you must use this format, you may reproduce it with Word Processing or Spreadsheet software. Limit your budget line items to the following categories: Personnel, Fringe Benefits, Professional Services, Travel, Pass-Through (i.e. Sub grants), Other Operating Expenses and Administrative/Indirect Costs.

Budget period: October 1, 2012 – June 30, 2013

Budget Category	Line Item Description	Requested Funds	Total Cost
PERSONNEL SERVICES		**Personnel Services Sub Total**	**$62,125.00**
Salaries	Lauren Savaglio-Program Manager	7,583.34	
	Vacant-Program Coordinator	26,250.00	
	Vacant-Program Coordinator	26,250.00	
	Sarah Chavez-Accounting Clerk	2,041.66	
EMPLOYEE RELATED EXPENSES		**Employee Related Expenses Sub Total**	**$23,432.50**
Fringe Benefits or Other ERE	Lauren Savaglio-Program Manager	2957.50	
	Vacant-Program Coordinator	10237.50	
	Vacant-Program Coordinator	10237.50	
PROFESSIONAL AND OUTSIDE SERVICES		**Professional & Outside Services Sub Total**	**$21,589.85**
Contracted Services	Healthy Steps	20,000.00	
	ASQ Enterprise System	1589.85	
TRAVEL		**Travel Sub Total**	**$11,340.60**
In-State Travel	Mileage x .445	5,108.60	
	Hotel 2X2 @ 100.00	400.00	
	Perdiem 2X2X4	200.00	
Out of State Travel	Flight/taxi	2,200.00	
	Hotel 2X4	2016.00	
	Perdiem 4X3	1416.00	
AID TO ORGANIZATIONS OR INDIVIDUALS		**Aid to Organizations or Individuals Sub Total**	**$**
Subgrants or Subcontracts to organizations/agencies/entities			
OTHER OPERATING EXPENSES		**Other Operating Expenses Sub Total**	**$23,551.00**
• Telephones/Communications Services	2 cell phones	840.00	
• Internet Access	Payson office	420.00	
• General Office Supplies	3 staff members	1091.00	
• Rent/Occupancy	Payson office space	4,200.00	
• Utilities	n/a	0	
• Furniture	2 staff members	6000.00	
• Postage		200.00	
• Software (including IT supplies)	2 laptop systems	4000.00	
• Dues/Subscriptions	n/a	0	
• Advertising		800.00	
• Printing/Copying	including copy machine lease	800.00	
• Equipment Maintenance	n/a	0	
• Professional Development/Staff Training	Brazelton	900.00	
• Conference Workshops/ Training Fees for Staff	n/a	0	
• Insurance	n/a	0	
• Program Materials		0	
• Program Supplies		2000.00	
• Scholarships		0	
• Program Incentives	literacy	2300.00	
NON-CAPITAL EQUIPMENT		**Non-Capital Sub Total**	**$**
Equipment $4,999 or less in value			
Subtotal Direct Program Costs:			**$**
ADMINISTRATIVE/INDIRECT COSTS		**Total Admin/Indirect**	**$12961.05**
Indirect/Admin Costs		$12042.50	$
Total		**$**	**$155,000.00**

Authorized signature _____ Date 9/18/12

Attachment F

Gila County Healthy Steps Program
9 Month Budget Narrative

Personnel
Lauren Savaglio is the Program Manager. She oversees all the Maternal and Child Health Programs and will be spending 25% of her time on the proposed program for the 9-month grant cycle to include attending program related meetings and training. She will provide assistance with purchasing, coordination and outreach of the program. The program manager will also be responsible for the quality assurance, staff supervision of the program. The manager's salary will total $7,583.34.
The position of Program Coordinator will be hired at a full-time basis. There will be two Program Coordinators. They will be responsible for daily oversight of program implementation for the 9 month grant cycle. They will provide home visitation services, working with each of the families and providing developmental screenings and follow-up for participants. They will be responsible for outreach, media campaign and coordination with other agencies. The Program Coordinators salaries will total $52,500.00.
Sarah Chavez is the accounting clerk. She will provide all the billing and fiscal management for the program. Each program who utilizes the clerk is responsible to pay $3,500.00 to cover her salary, and benefits for the 9-month grant cycle the total will be 2,041.66. Grand total of personnel expenses will be $62,125.00.
ERE/Fringe Benefits
The approved fringe benefits for all Gila County employees include: Arizona Retirement, Medicare, Social Security, Arizona Unemployment, Worker's Compensation, and health insurance. The program manager's portion will total $2,957.50. The program coordinator's portion will total $20,475.00. Grand total of fringe benefits will be $23,432.50.
Professional and Outside Services
Gila County will be required to attend the Healthy Steps Training institute for our site the cost will be $20,000.00. The ASQ online enterprise system is a one-time cost of $499.95, a technical support cost of $139.95, a Family Access fee of 349.95, an ASQ and an ASQ-SE liscense fee of $400.00 and $0.50 per screen over 100 ($200 for 400 screens) to implement in Gila County. Total amount is $1589.85
Travel Expenses
The program manager and two program coordinators will be required to attend one out of state training for Brazelton and the flight will be $700.00, hotel $168.00 a night for 4 nights, taxi fare of $100.00 and perdiem at $59.00 per day for four days. The total out-of –state travel costs will be $5,632.00. Staff will attend Gila Regional Partnership Council meetings every three months (200 miles 2 times) mileage .445 cents per mile for a total of $178.00. Staff will be required to attend monthly staff meetings (180 miles each trip for 6 months) mileage .445 cents per mile for a total of $480.60. Program travel for the manager and community health assistant is necessary in the successful implementation of the program including outreach, recruiting participants, coordination with local agencies and program implementation. We have estimated mileage to be 5000 miles at .445 per mile total $4,450.00. Total mileage $5,108.60. Perdiem is estimated to provide $25.00 per day for two staff for four days total $200.00. Two night hotel stay for the program manager and community health assistant total $400.00. Total travel expenses $11,340.60.
Other Operating Expenses
The routine office operating expenses will consist of paper, envelopes, business cards, mailings, appointments and referral cards the total price will be $1,091.00. Communication supplies will

consist of two cell phones prices at $70.00 per month and internet services for the Payson office at $70.00 per month. In Payson we will rent office space in the amount of $700.00 per month. The first nine month contract we will need to purchase office furniture for two of the staff members including desk, chairs, locking filing cabinets, client chairs, kid zone furnishings, staplers, tape dispensers, label printers and other misc. in the amount of $6,000.00. The program coordinators will need to purchase a laptop in the amount of $4000.00. This is a new program and they will need advertising in local newspapers, flyers and referral cards for $800.00. Each staff member will need to pay for coping expenses and a portion of the copy machine lease for each office for a total of $800.00. The Brazelton Institute Training will cost $300.00 for all three staff members to attend for a total of $900.00. Program materials and incentives will include books, educational materials, and participation incentives in the amount of $2,300.00. This results in a grand total of $23,551.00.

Indirect costs

As a Gila County employee there are indirect costs for personnel paperwork, finance, mail routing, and support staff which will be budgeted in the amount of $12,961.05 per year. This reflects approximately 8% of direct expenses.

Applicants must list either Option A or Option B and provide proper justification for expenses included:

X **Option A - Administrative Costs**: *with proper justification, sub grantees may include an allocation for administrative costs for up to 10% of the total direct funds requested of the grant request. Administrative costs may include allocable direct charges for: costs of financial, accounting, auditing, contracting or general legal services; costs of internal evaluation, including overall organization's management improvement costs; and costs of general liability insurance that protects the organization(s) responsible for operating a project, other than insurance costs solely attributable to the project. Administrative costs may also include that portion of salaries and benefits of the project's director and other administrative staff not attributable to the time spent in support of a specific project.*

OR

☐ ***Option B - Federally Approved Indirect Costs***: *If your organization has a federally approved indirect cost rate agreement in place, grantees may include an allocation for indirect costs for up to 10% of the grant request.* ***Applicants must provide a copy of their federally approved indirect cost rate agreement***.

Indirect costs are costs of an organization that are not readily assignable to a particular project, but are necessary to the operation of the organization and the performance of the project. The cost of operating and maintaining facilities, depreciation, and administrative salaries are examples of the types of costs that are usually treated as indirect.

Authorized signature_____ Date 9/18/12

Attachment G

DISCLOSURE OF OTHER FUNDING SOURCES*

Please list all other funding that your organization currently receives from State or Public Agencies, Federal Agencies, Non-Profit Organizations, or any other source providing funding for the proposed Program*. Statute ARS 8-1183 provides for a prohibition on supplanting of state funds by First Things First expenditures, meaning that no FTF monies expended are to be used to take the place of any existing state or federal funding for early childhood development and health programs.

Use a continuation sheet if necessary. The following form may be reproduced with word processing software or another form may be created that contains all the information requested.

Type of Funding (Federal, State, local, other)	Received From	Amount	✔ If used for match on this grant
N/A		0	
TOTAL:		0	

***This table should include only those funds that will support the program detailed in this Application.**

Authorized Signature: Tommie C. Martin Date: 9/18/12

Job Title: Tommie C. Martin, Chairman Board of Supervisors

Attachment H:

FIRST THINGS FIRST FINANCIAL SYSTEMS SURVEY

Name of Applicant: Gila County Division of Health and Emergency Services

Please answer every question by filling in the circle next to the correct answer. Attach materials and document comments as required.

As stewards of federal and state funds, First Things First awards funds to organizations (regardless of how small or large) that are both capable of achieving project goals/objectives and upholding their responsibility for properly managing *funds* as they achieve those objectives.

This survey will be used primarily for initial monitoring of the organization. This survey may also be used in evaluating the financial capability of the organization in the award process. Deficiencies should be addressed for corrective action and the organization should consider procuring technical assistance in correcting identified problems.

A. GENERAL INFORMATION

1. Has your organization received a Federal or State Grant within the last two years?	X YES o NO
2. Has your organization completed an A-133 Single Audit within the past two years? If yes, please **attach** a complete copy of your A-133 Audit, including, but not limited to, your Management Let Findings and Questioned Costs.	X YES o NO
3. If your organization has not completed an A-133 Single Audit, have your financial statements be audited, reviewed or compiled by an independent Certified Public Accountant within the past tv years? If yes, please **attach** a complete copy of the most recent audited, reviewed or compiled financial statements. NOTE THAT ONLY ONE COPY OF YOUR AUDIT NEEDS TO BE INCLUDED WIT THE APPLICATION MARKED "ORIGINAL". It is not necessary to include additional copies with ea copy of the completed Application.	o YES o NO
4. Please **attach** a schedule showing the TOTAL federal funds (by granting agency) expended by yo agency for the most recent fiscal year. Note: If your organization had an A-133 Single Audit, a copy of the "Schedule of Expenditures for Federal Awards" can be submitted. ONLY ONE COPY I NEEDED, TO BE INCLUDED WITH THE APPLICATION MARKED "ORIGINAL"	
5. Has your organization been granted tax-exempt status by the Internal Revenue Service?	o YES X NO o N/A
6. If you answered YES to question #5, under what section of the IRS code? O 501 C (3) O 501 C (4) O 501 C (5) O 501 C (6) O Other Specify:_____	
7. Does your organization have established policies related to salary scales, fringe benefits, travel reimbursement and personnel policies?	X YES o NO

B. FUNDS MANAGEMENT

1. Which of the following describes your organization's accounting system?	o Manual X Automated o Combination

2. How frequently do you post to the General Ledger?	o Daily X Weekly o Monthly o Other
3. Does the accounting system completely and accurately track the receipt and disbursements of funds by each grant or funding source?	X YES o NO
4. Does the accounting system provide for the recording of actual costs compared to budgeted co: for each budget line item?	X YES o NO
5. Are time and effort distribution reports maintained for employees working fully or partially on state or federal grant programs that account for 100% of each employee's time?	X YES o NO
6. Is your organization familiar with Federal Cost Principles (i.e. 2 CFR 220, 2 CFR 225, and 2 CFR 230)?	X YES o NO
7. How does your organization plan to charge common/indirect costs to this grant? **NOTE:** Those organizations using allocable direct charges **must attach** a copy of the methodology and calculations in determining those charges. Those organizations using a federally approved indirect cost rate **must attach** a copy of the approval documentation issued by the federal government.	X Direct Charges o Utilizing an Indirect Cost Allocation Plan or Rate

C. INTERNAL CONTROLS

1. Are duties of the bookkeeper/accountant segregated from the duties of cash receipt or cash disbursement?	X YES o NO
2. Are checks signed by individuals whose duties exclude recording cash received, approving vouchers for payment and the preparation of payroll?	X YES o NO
3. Are all accounting entries and payments supported by source documentation?	X YES o NO
4. Are cash or in-kind matching funds supported by source documentation?	X YES o NO
5. Are employee time sheets supported by appropriately approved/signed documents?	X YES o NO
6. Does the organization maintain policies that include procedures for assuring compliance with applicable cost principles and terms of each grant award?	X YES o NO

D. PROCUREMENT

1. Does the organization maintain written codes of conduct for employees involved in awarding or administering procurement contracts?	X YES o NO
2. Does the organization conduct purchases in a manner that encourages open and free competition among vendors?	X YES o NO
3. Does the organization complete some level of cost or price analysis for every major purchase?	X YES o NO
4. Does the organization maintain a system of contract administration to ensure Grantee conformance with the terms and conditions of each contract?	X YES o NO
5. Does the organization maintain written procurement policies and procedures?	X YES o NO

E. CONTACT INFORMATION

Please indicate the following information. In the event that First Things First has questions about this survey, this individual will be contacted.

Prepared By: Paula Horn

Job Title: Deputy Director of Prevention Services

Date: 08/14/12

Phone/Fax/Email: 928-402-8813/928-425-0794/phorn@co.gila.az.us

F. CERTIFICATION

I certify that this report is complete and accurate, and that the Grantee has accepted the responsibility of maintaining the financial systems.

Authorized Signature

G. COMMENT AND ATTACHMENTS

Please use the space below to comment on any answers in Sections A – D. Please indicate the Section and Question # next to each comment. Number of Attachments (please number each attachment): _____

COMMENTS:

Attachment I

Data Collection Form

Performance Measure	Plan for Data Collection	Plan for Using the Data	Quality Assurance
Care Coordination/ Medical Home Number of children served/ proposed service number	Case files and electronic data base	Report to FTF	Program Manager will review number of children every quarter.
Number of written care plans completed	Case files and electronic data base	Report to FTF and the assist families	Review all care plans and make appropriate referrals
Number of families receiving referrals for health insurance enrollment	Demographic paperwork developed to obtain information on enrollment	Report to FTF and to assist families with enrollment	Review cases to ensure enrollment assistance is given to all families requesting assistance
Number of referrals for health and human service providers	ASQ online system will provide the follow-up indicators to assist the staff to refer based on the score of the developmental screen.	Report to FTF. Assist children with needed referrals	Review cases to ensure enrollment assistance is given to all families requesting assistance
Developmental & Sensory Screening Number of children screened for developmental delays/ proposed service number	Case files and ASQ online system will track children	Report to FTF. Long term tracking of children from various agencies at vital developmental stages.	Review ASQ online reports on a quarterly basis

Exhibit A:

Scope of Work Reference/Information

Overview of First Things First

On November 7, 2006, Arizonans made an historic decision on behalf of our state's youngest citizens. By majority vote, they made a commitment to all Arizona children five and younger, that children would have the tools they need to arrive at school healthy and ready to succeed. The voters backed that promise with an 80-cent per pack increase on tobacco products to provide dedicated and sustainable funding for early childhood services for our youngest children. The initiative created the statewide First Things First board and the 31 regional partnership councils that share the responsibility of ensuring that these early childhood funds are spent on strategies that will result in improved education and health outcomes for kids 5 and younger.

First Things First is designed to meet the diverse needs of Arizona communities. The regional councils are comprised of community volunteers, with each member representing a specific segment of the community that has a role in ensuring that Arizona's children grow up to be ready for school, set for life: parents, leaders of faith communities, tribal representatives, educators, health professionals, business leaders, and philanthropists.

First Things First Strategic Direction

FTF's commitment to young children means more than simply funding programs and services. It means having a shared vision about what being prepared for kindergarten actually means. First Things First specifies that programs and services funded by the FTF Board and Regional Partnership Councils are to address one or more of the following Goal Areas as defined by the statute:

- Improve the quality of early childhood development and health programs.
- Increase the access to quality early childhood development and health programs.
- Increase access to preventive health care and health screenings for children through age five.
- Offer parent and family support and education concerning early childhood development and literacy.
- Provide professional development and training for early childhood development and health providers.
- Increase coordination of early childhood development and health programs and provide public information about the importance of early childhood development and health.

The FTF Board established a strategic framework with a set of school readiness indicators that provide a comprehensive composite measure to show whether young children are ready for success as they prepare to enter kindergarten. The strategies funded by FTF work collectively to develop a comprehensive system across the state and regionally to address the school readiness indicators. The FTF Board and Regional Partnership Councils determine the priorities and strategies to be funded across the state and throughout the regions assessing the challenges and building on the resources and assets in place.

School Readiness Indicators

1. #/% children demonstrating school readiness at kindergarten entry in the development domains of social-emotional, language and literacy, cognitive, and motor and physical
2. #/% of children enrolled in an early care and education program with a Quality First rating of 3-5 stars
3. #/% of children with special needs enrolled in an inclusive early care and education program with a Quality First rating of 3-5 stars
4. #/% of families that spend no more than 10% of the regional median family income on quality care and education with a Quality First rating of 3-5 stars
5. % of children with newly identified developmental delays during the kindergarten year
6. # of children entering kindergarten exiting preschool special education to regular education
7. #/% of children ages 2-5 at a healthy weight (Body Mass Index-BMI)
8. #/% of children receiving timely well child visits
9. #/% of children age 5 with untreated tooth decay
10. % of families who report they are competent and confident about their ability to support their child's safety, health and well being

What is the Funding Source?

First Things First provides for distribution of funding through both statewide and regional grants. Statewide programs are considered those implemented across regional boundaries and are designed to benefit Arizona's children as a whole. Regional funding is based on the approval of the Regional Partnership Council funding plans submitted to the FTF Board each year.

What is the Total Funding Amount Available in this Request for Grant Application?

This is a nine (9) month contract for the fiscal year ending June 30, 2013 with an option for renewal for two (2) additional twelve (12) month periods. Total funds available are approximately $150,000 to fund the Healthy Steps- Care Coordination program for the first funding period. An additional $5,000 is available to plan and implement an online Developmental Screening implementation pilot process during the first year as part of the Care Coordination Program. The total award for year one is $155,000. First Things First reserves the right not to award the entire amount of available funds or to award an amount that is greater than the posted available funds. Renewal will be contingent upon satisfactory contract performance, evaluation and availability of funds.

Scope of Work: What Strategy Will This Grant Fund and How Will It Make a Difference for Children?

Statement of need

Effective care coordination begins with recognizing the needs of families and the coordination between health providers and health systems. It is based upon the relationship between the

family, the health care providers and the care coordinator. It enhances access to needed services and resources, promotes optimal health and functioning of children, and supports improved quality of life. Data shows that primary care physicians struggle to fulfill the care-coordination needs of children, youth, and families. Care is coordinated and/or integrated across all elements of the complex health care and social services systems (e.g., subspecialty care, hospitals, home health agencies, home visitation services) and the patient's community (e.g., family, schools, childcare, public and private community-based services). Care coordinators enable medical practices to assure that their patients get the necessary services when and where they need it in a culturally and linguistically appropriate manner. An important component of a Care Coordination strategy is to insure children receive regular developmental screenings at six-month intervals. Developmental screening has been a practice used in multiple settings; however, integrating the information using an online web-based system from those settings into a common database is a relatively new option.

Regional Intent:

In 2010, Gila County ranked lowest in health outcomes in Arizona according to the County Health Rankings published by the Robert Woods Johnson Foundation report "Mobilizing Action Toward Community Health." While official reports show that approximately 12% of children in Gila County were uninsured, it is believed that this is significantly unreported and that many families are not accessing appropriate health care services for their young children. In the same year, 49% of all children ages 19-35 months had the recommended set of immunizations, while 96% of incoming kindergartners were fully immunized. Both facts illustrate a need for more coordinated care for this population.

Information from Gila County regional school districts reflects that many children are entering kindergarten with undiagnosed developmental delays, specifically in speech/language and social emotional domains. This phenomena creates a widely variety of readiness levels among many students in the region. In one school district, 67% of incoming pre-kindergarten children qualified for a special education pre-kindergarten program.

The Gila Regional Partnership Council feels strongly that children and families need access to coordination of services that will ensure universal preventive services are provided and have identified Care Coordination/Medical home as the mechanism to address this need.

The Gila Regional Partnership Council has also identified the need for parents to have more access to relevant and useful information about their children, as well as having someone available to answer their questions about child development, developmental concerns , discipline, well-baby visits (and getting the most out of them), nutrition, and other areas of development. The Gila Regional Partnership Council has identified the *Healthy Steps for Young Children National Model* as the mechanism to address these needs. Healthy Steps is a program model that is to be funded through the Regional Council's Care Coordination/Medical Home strategy, and through this Agreement. It will be implemented in either a community based or clinic-based model. Included in the Healthy Steps model is the possibility of doing short-term home visits with at risk families.

- The Clinic-Based Healthy Steps for Young Children program implemented through the County Health Department Clinics, faith based clinics and/or Federally Qualified Healthcare Clinic (FQHC) in the region by providing care coordination services to children and families who are served by the county public health or medical clinic practices.
- The Community-Based Healthy Steps for Young Children programs that brings together partners from the health community including the regions' birthing hospital, clinic-based programs, physician's offices or community-based programs, depending on which pediatrician the parents have selected and the desire of the parent to remain in the program.
- The Ages and Stages Questionnaire (ASQ) online developmental screening system ***must be included*** in the Healthy Steps model implementation during the first year.

The Gila Regional Council has identified the following needs within the region:

1. Improve parent awareness and knowledge of the community based health and social services that are available;
2. Increase the numbers of children who are accessing a medical home;
3. Improve the rates of toddlers who are fully immunized; and
4. Decrease the numbers of children who arrive at kindergarten with newly diagnosed developmental delays.

In addition, programs implemented under this care coordination strategy will support the connection between the family and their pediatrician or medical provider, will work to establish a pediatric medical home provide additional parental support and information. The Gila Regional Council intends to build an infrastructure of services that will be offered to all newborns and their families across the region, potentially reaching all children and their families.
The Gila Regional Council intends to fund a ***single administrative home*** that can provide Healthy Steps and the ASQ developmental screening administration in the Globe/Miami and Payson areas of the region. The Regional Council intends this strategy to be universally available for newborns, infants, toddlers, and preschoolers and their families with an emphasis on enrolling families of newborns.

Evidence based or best practice models of care coordination: There are a number of successful care coordination national models, which have demonstrated impressive health outcomes for children ages birth through five by offering high-risk families additional support to access health care and social services. Applicants are required by the Gila Regional Council to use the Healthy Steps National Model to provide care coordination services and the Ages and Stages Questionnaire (ASQ) online developmental screening tools and systems to be used for the trial implementation period.

Healthy Steps: The Healthy Steps Model has been implemented nationwide and has been proven to have positive outcomes for children and families. Specifically, the Healthy Steps program encourages using a medical home model within the pediatric medical field. The program has shown to have higher rates of child immunizations, higher rates of timely and appropriate

developmental screenings, as well as providing a medical environment that is supportive of parents as the experts on their child.

Programs implementing care coordination will:

- Assure that all program staff has the appropriate experience and education.
- Provide ongoing training and technical assistance to program staff to assure quality and fidelity to the Healthy Steps model. Successful applicants will be asked to identify the Healthy Steps Trainer that they plan to use with their program staff, to assure program fidelity to the model and to assure that staff has the necessary level of support that they need to be effective.
- Assure that all child and family information is handled in a confidential manner.
- Develop procedures for assuring confidentiality regarding the ASQ-3 Online system.
- Assure that appropriate consent is obtained for service delivery.
- Assure that the intake process assesses the strengths and needs of the child and family by utilizing standardized methods and procedures.
- Collaborate with local agencies/community partners.

Care Coordinators will be asked to accomplish the following:

1. Assist the practice to identify children with special healthcare needs, establish methods for tracking, and follow up of these children.
2. Conduct timely developmental and social emotion screening at six month intervals for all children enrolled using the online screening program.
3. Assist the practice to identify other children potentially in need of care coordination services.
4. Complete an intake assessment with full participation of the family. This assessment (including strengths and weaknesses) should consider medical status, developmental stage of the child and a variety of family protective factors such as parental resilience, social connections, knowledge of parenting and child development, concrete support in times of need and children's healthy social emotional development.
5. Work with families to develop a written plan of care. The intensity of care coordination should vary based upon identified needs/desires of the family.
6. Be able to, as appropriate, but not limited to:
   a. Work with the office referral staff to identify service referral needs, ensure completion of referral visits and outcomes of those visits
   b. Assist the family in following up with referrals
   c. Educate families on the importance of making follow up visits
   d. Assist in accessing health insurance as needed
   e. Provide information regarding community resources and linkage to those services
   f. Promote family independence by working to develop self-care skills
   g. Support care transitions
   h. Advocate for the family
7. Monitor the status of the care plan, making any necessary adjustments and communicating changes to the family.

8. Seek out feedback from families on the coordination processes and decisions of the providers serving the child.
9. Participate in quality/performance measurement processes related to the care coordination/medical home model.
10. Care Coordinators will NOT be responsible for performing medical procedures or treatments, giving medical advice, writing reports generally prepared by physicians or nurses and performing routine bookkeeping, clerical or billing functions.

Developmental Screening: The Gila Regional Partnership Council has also decided to use the Ages and Stages (ASQ) -3 online Enterprise Systems and the ASQ-Social and emotional (SE) online Enterprise system to be implemented as part of this grant. The ASQ developmental screening tools were selected by the Regional Council after reviewing the prevalence of current screening tools being used in the region and by other First Things First programs. The ASQ developmental screening tools are considered valid and reliable assessment and screening tools; and it is parent friendly.

ASQ Developmental Screening On-line System Pilot includes:

1. Purchase and implement the ASQ-3 and ASQ-SE online Enterprise Multi-site screening tool into the Healthy Steps – Care Coordination program.
2. Purchase, implement and integrate the Parent Access program to allow parents to complete the ASQ-3 and ASQ-SE online and conduct appropriate follow-up with families that use either the Parent Access Program or the paper version of the assessment tool.
3. Serve as program administrator for the enterprise system setting up appropriate policies and procedures to follow.
4. In Collaboration with First Things First Staff and the Gila Regional Partnership Council, convene community stakeholders groups to discuss expansion of the Enterprise to include other First Things First programs, schools, Head Start Programs, public and private medical clinics, Physician's offices, Child Find, AzEIP and other locations where families access services in the Gila Region.
5. Within six months of the start of the Grant award, a report on the pilot implementation of the online screening process, including a plan for expanding the Enterprise system to multi sites including the community partners, is expected. Included in the report should be information required for further expansion including cost estimates.
6. Serve as ongoing Enterprise administrator of the Gila Enterprise system and coordinate with community partners and the FTF HUB to ensure the success of the program.
7. Review parent initiated developmental screenings from the on-line parent access screening tool, communicate results to parents and make appropriate referrals for follow-up. The Healthy Steps program should serve as the triage with the families by either offering enrollment into the program to families or referral to other First Things First or community programs as appropriate to the needs of the families.
8. All individuals conducting developmental screening will obtain and maintain certification and/ or required training on the ASQ-3, ASQ-SE and the on-line system implementation. Trainings must be approved by the instrument developer to provide training for the on-line version of the instruments.

The intent of the Regional Council is to fund the establishment of a region wide ASQ enterprise system that allows various programs that come in contact with children birth through five to use a common system that also connects to clinical practices electronically in the region. This aspect of program development is considered a pilot that includes a 4-6 month period of planning, training and ongoing evaluation of the process.

It is expected that the ASQ online screening and reporting system will be implemented within the ***Healthy Steps*** program connected with the care coordination strategy implementation. The location of the ***Healthy Steps*** program will purchase the ASQ online enterprise license with the funds allocated to this strategy. The remainder of the funds will be used to support ongoing community collaboration and to encourage other programs to participate in using the online ASQ tools. It is expected that after the initial implementation phase, the Enterprise system will be expanded to include other community programs that currently have ASQ licenses or that are expecting to purchase their own license. This is a capacity building and trial implementation to identify successes and challenges in implementing this system in the region.

The Gila Regional Council intends that the trial implementation period of planning and implementation will occur during the first year of the grant period. It is a trial period with the intent to link the Gila Developmental Screening Enterprise system into a centralized ASQ HUB program to allow de-identified data reporting on developmental screening and delays as a result of the trial program.

Description of strategy including Standards of Practice

Effective care coordination begins with recognizing the needs of families and the coordination between health providers and health systems. It is based upon the relationship between the family, the health care providers and the care coordinator. It enhances access to needed services and resources, promotes optimal health and functioning of children, and supports improved quality of life. Data shows that primary care physicians struggle to fulfill the care-coordination needs of children, youth, and families. Care is coordinated and/or integrated across all elements of the complex health care and social services systems (e.g., subspecialty care, hospitals, home health agencies, home visitation services) and the patient's community (e.g., family, schools, childcare, public and private community-based services,). Care coordinators enable medical practices to assure that their patients get the necessary services when and where they need it in a culturally and linguistically appropriate manner.

An important component of care coordination is a child having a medical home. The medical home represents a standard in primary care where children and their families receive the care they need from a family physician, pediatrician or other healthcare professional that they trust. Healthcare professionals in partnership with the family work with appropriate community resources and systems to achieve the child's maximum potential and optimal health. A medical home addresses well-child care, acute care, and chronic care for all children from birth through their transition to adulthood.

Operating Structure

The intent of the care coordination strategy is to:

1) Provide care coordination services as funded by First Things First Regional Councils
2) Adhere to Healthy Steps - care coordination evidence based models that lead to improved coordination of health services for children 0-5 years of age
3) Adhere to the care coordination models that lead to more children 0-5 having a medical home
4) Adhere to the Care Coordination and Developmental Screening Standards of Practice that is attached (Attachment A).
5) Offer services free of charge to families. Programs implemented under this strategy are offered free of charge to all families who are interested.

Families with young children often face challenges accessing or coordinating needed care. Families in crisis, such as those experiencing homelessness, domestic violence or with chronic health care needs, often need multiple family support and health services. Referrals to such services are often quite haphazard, and families and service providers often struggle to figure out how to "piece together" a disconnected array of health resources. Families and service providers often need advice and assistance in obtaining available services, navigating complex systems and bureaucracies, and coordinating care. It is also necessary to identify and remove barriers that jeopardize care coordination for young children and prevent some families from accessing health care services that are vital to their child's overall well-being.

In order to address these issues and in collaboration with First Things First's goal to build on current efforts to collaborate to improve children's access to quality health care, and build on current efforts to increase the number of health care providers utilizing a medical home model.

First Things First School Readiness Indicators related to this strategy:

FTF is seeking successful applicants to implement this strategy and work collectively with FTF to impact the school readiness indicators below:

- #/% children demonstrating school readiness at kindergarten entry in the development domains of social-emotional, language and literacy, cognitive, and motor and physical
- % of families who report they are competent and confident about their ability to support their child's safety, health and well-being.

First Things First Goal Area to be Addressed:

- Health

Target Population to serve

The Regional Council targets newborns, infants, toddlers, and preschoolers and their families for these strategies. Initial focus will be on reaching 200 families accessing the Healthy Steps well-child care in community clinics and county health department services while concentrating

services to low or lower income families. Priority should be given to reaching children at birth or shortly after birth.
This program will also serve families that participate in the ASQ-3 screening process and follow up will be provided regarding this screening process. Target for Developmental Screening using the online system will be at least 250 children.

Geographic Area

The Gila Regional Partnership Council provides services to the communities of Gila County and the Tribal lands of the Tonto Apache Tribe. The Gila Region does ***not*** include the portion of the Fort Apache Indian Reservation (lands of the White Mountain Apache Tribe) within Gila County, or the portion of the San Carlos Apache Indian Reservation within Gila County. The implementation plan must include provision of services in the communities of Payson and Globe/Miami. Service provision to other locations in the region is optional.

Coordination and Collaboration

First Things First prioritizes coordination and collaboration among early childhood service providers as critical to developing a seamless service delivery system for children and families. As a result of coordination and collaboration, services are often easier to access and are implemented in a manner that is more responsive to the needs of the children and families. Coordination and collaboration may also result in greater capacity to deliver services because organizations are working together to identify and address gaps in service. Grantee must demonstrate capacity to work with and participate in coordination and collaboration activities occurring within the First Things First region being served. This may include but is not limited to participating in regular regional collaboration meetings. Depending upon the strategy, there may be additional statewide meetings, which the Applicant may be asked to attend, as noted in the Scope of Work. In order to accomplish this, Applicants should plan the appropriate staffing and budget to support travel to and attendance at monthly meetings within the regional area or statewide meetings, as appropriate.

Program Specific Data Collection and First Things First Evaluation

Successful Applicants agree to participate in the FTF evaluation and any program specific evaluation or research efforts. Data collection and FTF evaluation activities are directly connected with the Goals, Performance Measures and Units of Service aligned to the strategies described in this RFGA. In addition, ongoing evaluation of the ASQ implementation process should be reported in the narrative reports.

Unit of Service and related Target Service Number Definition:
A Unit of Service is a FTF designated indicator of performance specific to each FTF strategy. It is composed of a unit of measure and a number (Target Service Number). A Unit of Measure/Service can be a target population and/or a service/product that a grantee is expected to serve as part of an agreement. The Target Service Number represents the number of units (e.g. target population)

proposed to be served or number of products/services proposed to be delivered during the contract year.

For example, for the FTF strategy Home Visitation the FTF Unit of Service is "number of families served" and a Target Service Number of 50 represents the number of families the Applicant proposes to serve during the contract period. All FTF applicants must clearly state in the proposal a target service number for each strategy specific Unit of Service.
Performance Measures Definition:
Performance Measures measure (1) key indicators of performance (i.e. Unit of Service); (2) basic implementation of strategy; (3) alignment of program activities to strategy specific standards of practice, (4) performance or progress toward pre-established strategic goals. Performance measures may include the level or type of program activities conducted (e.g. serving families/children through home visits) and/or the direct services and products delivered by a program (e.g., providing scholarships).

Successful Applicants must have capacity to collect and submit FTF data requirements, securely and confidentially store client data, and utilize data to assess progress in achieving desired outcomes of the proposed strategy. Units of Service, Target Service Numbers, and Performance Measures outline how quarterly data submissions will be evaluated according to the contracted deliverables and standards of practice for that contract. Additionally, they are used by FTF to determine the key impacts of the strategies, programs and approaches being implemented.

Grantee will be provided with data reporting requirements by FTF and will meet the requirements of the FTF evaluation including, but not limited to, timely and regular reporting and cooperation with all FTF evaluation activities. Timely and regular reporting of all performance and evaluation data includes the electronic submission of data (as identified in data reporting templates designed for each strategy) through the FTF secure web portal known as PGMS.
(The FTF data reporting requirements for this strategy can be found at
http://www.azftf.gov/pages/WebMain.aspx?PageId=9E8669C97C0C408B9F3567C855744398&StrategyId=62

Grantee is required to collaborate with any FTF external evaluation activities, which means the Grantee must collaborate with external evaluation-led child assessment activities. Collaborative activities may include tracking and reporting data pertaining to participant attendance, enrollment, and demographic information. In addition, Grantee agrees to allow FTF and evaluation consultants of FTF to observe program activities on site and successful applicants must collaborate with FTF led and initiated evaluation activities to encourage parent consent for data collection. (Standards for data security for this strategy are found in Exhibit C.)

Units of Service and Performance Measures that are aligned to the Goal for the purposes of this RFGA are as follows:

Unit of Service:

- The targeted service units is 200 children birth to age five for care coordination and 250 children for the online developmental screening during the year.

For **Care Coordination/Medical Home,** the Unit of Service is:

- **Number of children served**

For **Developmental and Sensory Screening,** the Units of Service are:

- **Number of children screened for developmental delays**
- **Number of children receiving vision screening**
- **Number of children receiving hearing screening**

Performance Measures:

For **Care Coordination/Medical Home,** the performance measures are:

- Number of children served/ proposed service number
- Number of written care plans completed
- Number of families receiving referrals for health insurance enrollment
- Number of referrals for health and human service providers

For **Developmental & Sensory Screening,** the performance measures are:

Number of children screened for developmental delays/ proposed service number
(Note: Hearing and Vision screening are not a requirement of the developmental and sensory screening requirements of this grant. Hearing and vision may be a part of the care coordination program but are not required elements of the Developmental Screening component of this agreement)

For the quarterly narrative reports, the following information should be addressed: Description of the ASQ implementation into the Healthy Steps program should be reported. Challenges and successes in implementation should be addressed as well as solutions found. A separate report on the progress in implementation of the ASQ Enterprise On-line system must be submitted to the Gila Regional Director and the Gila Regional Council six months after the implementation of this agreement.

For more information on FTF Goal Areas, Goals and Performance Measures, please reference the FTF Strategy Toolkit at:
http://azftf.gov/pages/webmain.aspx?PageID=2D427ADB35B34BB09F353B77B74AB9BA
For more information on the ASQ-3 and ASQ-SE online system please refer to the Brooks Publisher Website at:
http://www.brookespublishing.com/store/books/squires-asq/proenterprise.htm

For more information on FTF Goal Areas, Goals and Performance Measures, please reference the FTF Strategy Toolkit at:
http://www.azftf.gov/pages/webmain.aspx?PageID=2D427ADB35B34BB09F353B77B74AB9BA

Exhibit B:

FIRST THINGS FIRST

Ready for School. Set for Life.

Standards of Practice

Care Coordination/Medical Home

I. Description of Health Issue

Data shows that primary care physicians struggle to fulfill the care-coordination needs of children, youth, and families. The medical home model represents a standard of primary care where children and their families receive the care they need from a family physician, pediatrician or healthcare professional that they trust. Healthcare professionals in partnership with the family work with appropriate community resources and systems to achieve the child's maximum potential and optimal health. A medical home addresses well-child care, acute care, and chronic care for all children from birth through their transition to adulthood.

A medical home is a building block needed to ensure accessible, patient-centered, and coordinated primary care for children. The medical home model is an approach to providing primary care that is focused on the relationship between the patient and the personal clinician. Championed by the American Academy of Pediatrics, the medical home is broadly defined as primary care that is "accessible, continuous, comprehensive, family-centered, coordinated, compassionate, and culturally effective." A medical home does not refer to an actual physical place but to an approach to providing health care that assures that patients have access to care, that their care is well coordinated, and that they are engaged in their care, patient centered care.

An important component of a medical home is service coordination and case management to provide linkages for children and their families with appropriate services and resources in a coordinated effort to achieve good health. According to the Medical Home Practice-Based Care Coordination Workbook (McAllistar, Presler, Cooley); "It has been suggested that you cannot be a strong medical home without the capacity to link families with a designated care coordinator."

Effective care coordination begins with recognizing the relationship between the family, the health care provider and the care coordinator. It enhances access to needed services and resources, promotes optimal health and functioning of children, and supports improved quality of life.

Care is coordinated and/or integrated across all elements of the complex health care and social services systems (e.g., subspecialty care, hospitals, home health agencies, home visitation services) and the patient's community (e.g., family, schools, childcare, public and private community-based services). Care coordinators will enhance the abilities of the physician and practice to assure that patients get the indicated care when and where they need and want it in a culturally and linguistically appropriate manner.

The non-profit health membership organization, National Quality Forum (NQF), has defined care coordination as a "function that helps ensure that the patient's needs and preferences for health services and information sharing across people, functions, and sites are met over time." In September 2010, NQF endorsed 10 performance measures and 24 preferred practices for care coordination. They can be found at:
http://www.qualityforum.org/projects/care_coordination.aspx

II. Implementation Standards

A. Programs implementing care coordination will:

1. Assure that all program staff has the appropriate experience and education.
2. Provide ongoing training to program staff to assure quality.
3. Assure that all patient and family information is handled in a confidential manner.
4. Assure that appropriate consent is obtained for service delivery.
5. Assure that the intake process assesses the strengths and needs of the child and family by utilizing standardized methods and procedures.
6. Collaborate with local agencies/community partners.

B. Individuals delivering care coordination services will:

1. Assist the practice to identify children with special healthcare needs and establish methods for tracking and follow up of these children.
2. Assist the practice to identify other children potentially in need of care coordination services.
3. Complete an intake assessment, with participation of the family. This assessment (including strengths and weaknesses) should consider medical status, developmental stage of the child and a variety of family protective factors such as parental resilience, social connections, knowledge of parenting and child development, concrete support in times of need and children's healthy social emotional development.
4. Review that intake assessment with the family and identify needs that might be addressed via care coordination.
5. Work with families and health plan, if appropriate, to develop a written plan of care. The intensity of care coordination should vary based upon identified needs/desires of the family.
6. Be able to, as appropriate but not limited to:

a. Work with the office referral staff to identify service referral needs, ensure completion of referral visits and outcomes of those visits
b. Assist the family in following up with referrals
c. Educate families on the importance of follow up
d. Facilitate access to care (insurance or social services)
e. Provide information regarding community resources and linkage to those services
f. Promote family independence by working to develop self-care skills
g. Lead or facilitate team conferences
h. Support care transitions
i. Advocate for the family

7. Monitor the status of the care plan, making any necessary adjustments and communicating changes to the family.
8. Seek out feedback from families on the coordination processes and decisions of the providers serving the child.
9. Participate in quality/performance measurement processes related to the care coordination/medical home model.

It is recommended that well child visits for children age 0-5 years follow the standards for well child visits based upon Early Periodic Screening Diagnostic and Treatment (EPSDT) guidelines. EPSDT funds well-child visits that provide comprehensive health care through primary prevention, early intervention, diagnosis and medically necessary treatment of physical and behavioral health problems for enrolled AHCCCS members less than 21 years of age. Standardized forms and guidelines for all EPSDT providers can be found at: http://www.azahcccs.gov/shared/Downloads/MedicalPolicyManual/AppendixB.pdf

Care Coordinators will NOT be responsible for performing medical procedures or treatments, giving medical advice, writing reports generally prepared by physicians or nurses and performing routine bookkeeping, clerical or billing functions.

III. Training and Qualifications Standards

Qualifications for a Care Coordinator include:

- Minimum of a Bachelor's Degree in health care, social work, nursing or related field and have experience working with children birth through five and their families.
- Have excellent communication and organizational skills that promote efficiency in care coordination.
- Have a comprehensive understanding of community, social and governmental resources available to support families.

IV. Cultural Competencies

Programs will also implement the following best practices and standards related to Cultural Competencies:

- To address cultural competency objectives, early childhood practitioners /early childhood service providers shall ensure that children and families receive from all staff members and program participants' effective, understandable, and respectful care that is provided in a culturally competent manner. Early childhood practitioners /early childhood service providers should ensure that staff and participants at all levels and across all disciplines receive ongoing education and training in culturally and linguistically appropriate service delivery. Early childhood practitioners/early childhood service providers should develop participatory, collaborative partnerships with communities and utilize a variety of formal and informal mechanisms to facilitate community and family-centered involvement to ensure that services are delivered in a manner that is consistent with the National Standards on Culturally and Linguistically Appropriate Services and/or the National Recommendations on Cultural and Linguistic Competence for the National Association for the Education of Young Children."
  http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15
  http://www.naeyc.org/positionstatements/linguistic
- Service providers should understand individual Tribes/Nations are distinct and separate communities from other Tribes/Nations and their governmental systems and structures are not reflective of each other. Services to Tribal communities and on reservations must be provided in a manner compatible with the Tribe's/Nation's cultural beliefs and practices, to include the preferred language of the community. Services must also be provided in accordance with the Tribe's/Nation's laws, policies and procedures. The effectiveness of services is directly related to the provider's consideration of the beliefs, customs and laws of the Tribe/Nation.
- Service providers can obtain information about providing services on tribal lands from a variety of sources. These include the FTF Regional Coordinator, Regional Council members, tribal websites and publications, as well as official representatives of the Tribe/Nation such as the governing body, standing committees and authorized departments.
- It is highly recommended that service providers seek guidance from one or more of these sources before initiating services on reservations. Failure to do so could result in contraventions of cultural beliefs, Tribal laws or sovereignty.
- The ideal applicant will demonstrate their ability to operate within these parameters through prior experience working with Tribes/Nations, demonstrating that staff is culturally competent, partnerships with agencies serving Native American families, knowledge of cultural beliefs, customs and laws of the Tribe/Nation or a combination of these elements.
- Related to data collection, evaluation or research activities:
  - In the United States, Native American Tribes are considered autonomous nations with all of the rights and responsibilities of a nation. Understanding this, Native American Tribes are charged with protecting the health and safety of their people. To this end, Tribes have full ownership over any data collected within their reservation boundaries. This means that Tribes can allow or not allow any program to collect data from or

related to any early childhood development and health program or activities on the reservation.

- Any grantee implementing programs in tribal communities must have official tribal permission to collect and utilize sensitive data from or related to any early childhood development and health program or activities. Such data can include but not be limited to:

    - Morbidity and mortality among children members of their communities
    - Information regarding child safety and welfare
    - Information regarding children in foster care
    - Infectious and chronic disease information among members of their communities
    - BMI and healthy weight information beginning at age 2 years and each year after that

V. References and Resources

Antonelli, R., Stille, C., and Freeman, L. Enhancing Collaboration Between Primary and Subspecialty Care Providers for Children and Youth With Special Health Care Needs, Georgetown University Center for Child and Human Development, Washington, DC, 2005.

Antonelli, R., McAllister, J.W., and Popp, J. (2009, May). Making Care Coordination a Critical Component of the Pediatric Health System: A Multidisciplinary Framework, The Commonwealth Fund.

Kurt, C., Stange, K.C., Nutting, P.A. , Miller, W.L. , Jaén, C.R. , Crabtree, B.F. , Flocke, S.A. and Gill, J.M. (2010). Defining and Measuring the Patient-Centered Medical Home. *J Gen Intern Med.* 2010 June; 25(6): 601–612. Published online 2010 May 14. doi: 10.1007/s11606-010-1291-3.

McAllister, J.W., Cooley, W.C, Presler, E., Medical Home Practice-Based Care Coordination: A workbook. Center for Medical Home Improvement (CMHI), Crotched Mountain Foundation and Rehabilitation Center; Greenfield, New Hampshire.

McCarthy, D. , Nuzum, R., Mika, S. et al. (2008). The North Dakota Experience: Achieving High-Performance Health Care Through Rural Innovation and Cooperation. May 15, 2008 | Volume 93. The Commonwealth Fund. **Contact:** dm@cmwf.org
http://www.commonwealthfund.org/Publications/Fund-Reports/2008/May/The-North-Dakota-Experience--Achieving-High-Performance-Health-Care-Through-Rural-Innovation-and-Coo.aspx

National Committee for Quality Assurance (NCQA) in 2011. Patient Centered Medical Home. Found at: http://www.ncqa.org/tabid/631/default.aspx

National Quality Forum standards for Care Coordination; can be found at: http://www.qualityforum.org/projects/care_coordination.aspx

Exhibit C:

FIRST THINGS FIRST

Ready for School. Set for Life.

Standards of Practice
Developmental and Sensory Screening
Administration Services

I. Description of Strategy Health Issue

As part of a comprehensive system of services to families, there is a need for additional services to screen and identify children who may have developmental delays or sensory (hearing, vision) problems. Many children who have spent time in a neonatal intensive care unit (NICU), and who may have had health problems when they were born, have a greater risk for developmental delays and require additional screening.

Many children with behavioral or developmental disabilities and sensory deficits miss important opportunities for early detection and intervention due to gaps in screening and availability of services. Delays in language development, other developmental areas or sensory deficits impact a child's ability to be ready for school. Less than 50% of these children are identified as having a problem before they start school and the opportunities for early intervention have been missed. The U.S. Department of Education regulates the early intervention program under Part C of the Individuals with Disabilities Education Act (IDEA). This program provides screening, evaluation and intervention services for infants and toddlers with developmental delays and disabilities and their families. Part C is administered by states that serves infants and toddlers through age 2 with developmental delays or who have diagnosed physical or mental conditions with high probabilities of resulting in developmental delays. However, many children are not Part C eligible initially and have delays that may not be identified.

Developmental screening administrative services funded by FTF are multi-tiered. They include community awareness programs to screen children for developmental delays, identification of children in child care centers with possible delays, and home visitation program staff who have identified children with possible delays. ***Screening for developmental delays or sensory deficits is not diagnostic and should not be represented as definitive***. Screening leads to a referral for a diagnostic assessment by a child's health care providers to determine if there is an actual delay and to plan for treatment through state agencies (AzEIP, school districts, Children's Rehabilitative Services) or private organizations that provide these specific services.

Screening is comprehensive in that it includes a review of children's development in the cognitive, communication, physical development, sensory deficits, social-emotional and adaptive domains. The results of the screening process can lead to further screening and diagnostic testing and early interventions.

There are a number of avenues that can facilitate basic screening and identification of children with potential developmental delays or sensory deficits:

- Quality First Child Care Health Consultants (CCHC)
- Home visitation programs staffed by nurses or trained staff – referrals to appropriate resources if screening cannot occur during home visit.
- Community based screening including mobile screening vans

Although developmental and sensory screening is merged together, awardees can be selected separately. The intent is to have screening be a more comprehensive effort.

I. Implementation Standards

All developmental or sensory screening administration includes the following standards:

Screening services should include the following:

- Discussion of concerns with parent and obtain parental consent for screening.
- Standard training for anyone who is conducting a screening on how to use screening instruments or equipment.
- Administration of age appropriate developmental screening instrument or age appropriate sensory testing equipment.
- Discussion of results of screening with parents.
- Plan for sequential screening if the child's response indicates follow up rather than a referral (could have been an off day, sick child with marginal results).
- Make appropriate referrals to AzEIP, local schools, health care providers, behavioral health professionals, or other community resources for a diagnostic evaluation if results warrant.
- Follow up with families about the result of the referral process and findings. Determine if they obtained an additional screening and what the next steps are for the child.

Screening Locations:

- While screening can occur in wide variety of settings, screenings that are conducted in environments where families maintain ongoing connections (as part of a medical home or child care centers) are preferred. The administration of screening at such locations will facilitate the follow up process, and ensure that routine screenings occur at recommended intervals.
- Screenings should occur in a quiet, well-lighted, non-distracting environment.

- Screenings optimally should occur in settings that are closely aligned to a child's natural environment (for example: where children typically are such as a home or child care center or other location with which the child has familiarity and is comfortable).

Developmental Screening Administration Standards:

Screening Tools

- Age appropriate and standardized screening tools and equipment should be used. Also, the most reliable and appropriate options for screening should be used to:
    - Ensure that the cognitive and motor skills being assessed appropriately match the age of the child.
    - Ensure that screening tools are comprehensive and assess children in all developmental domains: cognition, communication, physical, social-emotional, and adaptive.
- Developmental assessment instruments must have validity and a .80 reliability level.

Suggested developmental assessment tools for screening children birth-age three

a. PEDS (Parents Evaluation of Developmental Status): resources found in Appendix
b. Ages and Stages Questionnaires: link is in reference section, online screening can be considered
c. Ages and Stages Questionnaire: Social Emotional Scale (this tool needs to be supplemented by another tool to ensure all areas of development are covered)

Conducting Screening

- Parent or guardian consent to screening is required before screening can occur.
- The parent is actively involved in the screening process.
- Screening must occur in the child and family's primary language.
- Screenings should include additional confirmatory information (parent input, observations, etc.).
- A parent or other designated caretaker is present for all screening procedures conducted through home visitation or mobile screening activities.
- Parents receive written feedback from the screening as well as a written referral for additional screening and diagnostic services if necessary.

Sensory Screening Administration Standards

Screening Tools

- Screening instruments should be sensitive enough to identify problems, and specific enough to prevent unacceptable over-referrals.
- Screening tools should be designed to capture and hold a child's interest at an age appropriate level while minimizing distraction from other stimuli.
- Screening tools used must be age appropriate, meeting the cognitive and motor skills required for participation.
- Screening tools should be designed to actively engage a young child, giving the tester the

opportunity to observe and interact with the child during the screening process.

- Screening tools must be free from bias and appropriate to the population on which they are used.

Conducting Screening

Hearing

- Hearing screening should be performed using age appropriate, standardized screening tools, equipment and/or assessments.
- Hearing screenings require a quiet environment with ambient noise levels on average of less than 50 dBSPL. Although the space requirement is minimal, it is important that the hearing screenings be conducted in a room separate from the rest of the screening.
- Audiometers, if used, should be equipped with a full headset (two earphones), while audiometers equipped with only one earphone utilizing a handled method should be avoided.
- Hearing screeners should have additional, child friendly manipulatives available to help elicit results beyond the use of hardware and charts.
- All devices to test hearing shall have periodic testing for accuracy and proper functioning and include any required certificates stating that these standards have been met.

Vision

- Vision screening would be performed using age appropriate, standardized screening tools and/or assessments.
- Vision screenings should be conducted in areas that have minimal distraction, are well lighted, and have space appropriate for the test being used.
- Vision screeners should have additional, child friendly manipulatives available to help elicit results beyond the use of hardware and charts.

II. Training and Qualifications Standards

Conducting developmental screening requires specific education and skills.

- Educational level: minimum of a bachelor's degree or certification in child development, nursing, early childhood education, child and family studies, or closely related field is required.
- All individuals conducting developmental screening will obtain and maintain certification and/ or required training on all of the chosen methods and tools used in screening activities and attend re-certification or additional training courses as required by the tool, the instrument developers, and as it is determined necessary through supervision.
- Personnel, who do not meet the required education level or are newly trained in developmental screening activities, may administer developmental screening under the direct supervision of an individual who does meet the training and qualifications standards until it can be documented that the person conducting screening can do so in a reliable manner. This level of supervision is above and beyond the regular supervision activities required in the First Things First Home Visitation or other Standards of Practice. The supervisor will participate with the home visitor or program specialist in conducting

screenings and review all completed screening instruments until the home visitor or program specialist is able to consistently conduct screening in a reliable manner. This can be documented in staff's personnel file and family files.

- Areas of knowledge and competencies must be demonstrated in:
    a. Typical and atypical child development
    b. Routines based interviewing practices (see http://www.fpg.unc.edu/~inclusion/RBI.pdf)
    c. Objective child observation
    d. Use of appropriate screening tools for young children
- Individuals conducting screening will participate in continuing education to remain current and update skills and knowledge regarding developmental screening procedures and child development to meet the requirements of this scope of work.

Conducting sensory screening requires specific education, equipment and skills.

- Educational level: minimum of a bachelor's degree or certification in hearing or vision screening as well as certification in the use of the equipment used for screening.
- All individuals conducting sensory screening will obtain and maintain certification and/ or required training on all of the chosen equipment and tools used in screening activities and attend re-certification or additional training courses as required and as it is determined necessary through supervision.
- Personnel, who do not meet the required education level or are newly trained in sensory screening activities, may administer screening under the direct supervision of an individual who does meet the training and qualifications standards until it can be documented that the person conducting screening can do so in a reliable manner.
    a. This level of supervision is above and beyond the regular supervision activities required in the First Things First Home Visitation or other Standards of Practice. The supervisor will participate with the home visitor or program specialist in conducting screenings and review all completed abnormal or marginal screening results given to families.

III. Cultural Competencies

Programs will also implement the following best practices and standards related to Cultural Competencies:

- To address cultural competency objectives, early childhood practitioners /early childhood service providers shall ensure that children and families receive from all staff members and program participants' effective, understandable, and respectful care that is provided in a culturally competent manner. Early childhood practitioners /early childhood service providers should ensure that staff and participants at all levels and across all disciplines receive ongoing education and training in culturally and linguistically appropriate service delivery. Early childhood practitioners/early childhood service providers should develop participatory, collaborative partnerships with communities and utilize a variety of formal and informal mechanisms to facilitate community and family-centered involvement to ensure that services are delivered in a manner that is consistent with the National

Standards on Culturally and Linguistically Appropriate Services and/or the National Recommendations on Cultural and Linguistic Competence for the National Association for the Education of Young Children."
http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15
http://www.naeyc.org/positionstatements/linguistic

- Service providers should understand individual Tribes/Nations are distinct and separate communities from other Tribes/Nations and their governmental systems and structures are not reflective of each other. Services to Tribal communities and on reservations must be provided in a manner compatible with the Tribe's/Nation's cultural beliefs and practices, to include the preferred language of the community. Services must also be provided in accordance with the Tribe's/Nation's laws, policies and procedures. The effectiveness of services is directly related to the provider's consideration of the beliefs, customs and laws of the Tribe/Nation.
- Service providers can obtain information about providing services on tribal lands from a variety of sources. These include the FTF Regional Coordinator, Regional Council members, tribal websites and publications, as well as official representatives of the Tribe/Nation such as the governing body, standing committees and authorized departments.
- It is highly recommended that service providers seek guidance from one or more of these sources before initiating services on reservations. Failure to do so could result in contraventions of cultural beliefs, Tribal laws or sovereignty.
- The ideal applicant will demonstrate their ability to operate within these parameters through prior experience working with Tribes/Nations, demonstrating that staff is culturally competent, partnerships with agencies serving Native American families, knowledge of cultural beliefs, customs and laws of the Tribe/Nation or a combination of these elements.
- Related to data collection, evaluation or research activities:
  - In the United States, Native American Tribes are considered autonomous nations with all of the rights and responsibilities of a nation. Understanding this, Native American Tribes are charged with protecting the health and safety of their people. To this end, Tribes have full ownership over any data collected within their reservation boundaries. This means that Tribes can allow or not allow any program to collect data from or related to any early childhood development and health program or activities on the reservation.
  - Any grantee implementing programs in tribal communities must have official tribal permission to collect and utilize sensitive data from or related to any early childhood development and health program or activities. Such data can include but not be limited to:
    - Morbidity and mortality among children members of their communities
    - Information regarding child safety and welfare
    - Information regarding children in foster care
    - Infectious and chronic disease information among members of their communities

- BMI and healthy weight information beginning at age 2 years and each year after that

IV. References and Resources:

Ages and Stages Resources found at: http://agesandstages.com/
CDC Developmental Screening guidelines and tools found at:
http://www.cdc.gov/ncbddd/child/devtool.htm and
http://www.cdc.gov/ncbddd/child/improve.htm
Early developmental screening in early childhood systems: American Academy of Pediatrics and Healthy Child Care America and Child Care and Health Partnership (www.healthychildcare.org) found at: http://www.healthychildcare.org/pdf/DSECSreport.pdf

First signs: Autism spectrum disorder resource found at: http://www.firstsigns.org/

Meisels, S.J., & Atkins-Burnett. S. (2005) 5th edition. Developmental Screening in Early Childhood: A Guide. download at: http://www.naeyc.org/store/files/store/TOC/121.pdf

Exhibit D:

First Things First Target Units of Service Information
Care Coordination/Medical Home

Unit of Service and related Target Service Number

A Unit of Service is a FTF designated indicator of performance specific to each FTF strategy. It is composed of a unit of measure and a number (Target Service Number).

A Unit of Measure/Service can be a target population and/or a service/product that a grantee is expected to serve as part of an agreement. Target Service Number represents the number of units (e.g. target population) proposed to be served or number of products/services proposed to be delivered during the contract year.

For example, for the FTF strategy Home Visitation the FTF Unit of Service is "number of families served" and a Target Service Number of 50 represents the number of families the program proposes to serve during the contract period. All FTF applicants must clearly state in the proposal a target service number for each strategy specific Unit of Service.

For **Care Coordination/Medical Home,** the Unit of Service is:

Number of children served

Determining and Interpreting Target Service Numbers

Number of children served should reflect all children proposed to receive services for one grant contract period (in most cases, one year). This number should reflect a total headcount (aggregate) of children to receive services, including current caseload and potential enrollment within the contract period. Please note this may be a **duplicated** count since it is possible for a child to discontinue (disenroll) and re-enroll to receive services during the same grant contract period.

Performance Measures

Performance Measures measure (1) key indicators of performance (i.e. Unit of Service); (2) basic implementation of strategy; (3) alignment of program activities to strategy specific standards of practice, (4) performance or progress toward pre-established strategic goals. Performance measures may include the level or type of program activities conducted (e.g. serving families/children through home visits) and/or the direct services and products delivered by a program (e.g. providing scholarships).

For **Care Coordination/Medical Home,** the performance measures are:

Number of children served/ proposed service number
Number of written care plans completed
Number of families receiving referrals for health insurance enrollment
Number of referrals for health and human service providers

Exhibit E:

First Things First Target Service Unit Information

Developmental and Sensory Screening

Unit of Service and related Target Service Number

A Unit of Service is a FTF designated indicator of performance specific to each FTF strategy. It is composed of a unit of measure and a number (Target Service Number).
A Unit of Measure/Service can be a target population and/or a service/product that a grantee is expected to serve as part of an agreement. Target Service Number represents the number of units (e.g. target population) proposed to be served or number of products/services proposed to be delivered during the contract year.

For example, for the FTF strategy Home Visitation the FTF Unit of Service is "number of families served" and a Target Service Number of 50 represents the number of families the program proposes to serve during the contract period. All FTF applicants must clearly state in the proposal a target service number for each strategy specific Unit of Service.
For **Developmental and Sensory Screening,** the Units of Service are:

Number of children screened for developmental delays
Number of children receiving vision screening
Number of children receiving hearing screening

Determining and Interpreting Target Service Numbers

Number of children screened for developmental delays should reflect the total number of children receiving screening for developmental delays for one grant contract period (in most cases, one year) and may be a **duplicated** count since one child may receive multiple developmental delay screenings within a contract period.

Number of children receiving vision screening should reflect the total number of children receiving vision screening for one grant contract period (in most cases, one year) and may be a **duplicated** count since one child may receive multiple vision screenings within a contract period.
Number of children receiving hearing screening should reflect the total number of children receiving hearing screening for one grant contract period (in most cases, one year) and may be a **duplicated** count since one child may receive multiple hearing screenings within a contract period.

Performance Measures

Performance Measures measure (1) key indicators of performance (i.e. Unit of Service); (2) basic implementation of strategy; (3) alignment of program activities to strategy specific standards of practice, (4) performance or progress toward pre-established strategic goals. Performance

measures may include the level or type of program activities conducted (e.g. serving families/children through home visits) and/or the direct services and products delivered by a program (e.g. providing scholarships).

For **Developmental & Sensory Screening,** the performance measures are:

Number of children screened for developmental delays/ proposed service number
Number of children receiving vision screening / proposed service number
Number of children receiving hearing screening / proposed service number

Exhibit F:

First Things First - Arizona Early Childhood Development and Health Board Data Security Guidelines and Requirements for Collaborators

BACKGROUND:
The purpose of First Things First is to aid in the creation of a system that offers opportunities and supports for families and communities in the development of all children so they can grow up healthy and ready to succeed. Our work is accountable and transparent to decision-makers and the citizens of Arizona. Collaboration and direct funding of grantees to undertake work on behalf of the children and families of Arizona is fundamental to the purpose and mission of FTF. Regular submission of data related to funded work is an important part of ensuring accountability and maximum positive impact for young children.

Data Security Guidelines for Data Submission to FTF
The Arizona Early Childhood Development and Health Board (First Thing First - FTF) will ensure that resources allocated have maximum impact for the benefit of children and families. To ensure this accountability, FTF will establish data reporting requirements for all state and regional grantees. All funded providers will regularly submit programmatic and financial reports as identified in the FTF reporting requirements.
FTF data submissions are classified in one of three levels:

- **Public data**
- **Limited distribution data**
- **Confidential data**

The majority of FTF reporting submissions are completed through the FTF Partner and Grants Management System (PGMS). Subsequent to the award of a FTF contract, the grantee will receive general training on login and navigation within the PGMS system. With this login the grantee will be able to manage their contract information. An additional training on strategy-specific data submission requirements will also be conducted. During that training the grantee will be informed on submission of data reporting requirements through PGMS. All data submitted through PGMS is **public data** or **limited distribution data**. Because PGMS is located in a secure extranet environment, grantees using PGMS for data submission are not required to undertake additional security measures related to their data submission above those identified in the general and data submission orientations (password and login security, guidelines for upload of narrative and other reports).

A small group of grantees submit data requirements, through agreement between the grantee and FTF, directly through the FTF extranet, rather than a PGMS web-based entry form. These data are likely to contain limited distribution data and must follow the following protocols. Data

structure agreement, Login, ftp, revision request. Grantees that submit data through the FTF extranet must ensure that limited distribution data may not be intercepted or viewed at any time by parties other than the grantee and FTF and that throughout the reporting and submission process the data are secured.

Any grantee submitting data identified as confidential must file a formal data security policy with FTF. Confidential data will not be a part of standard data submission requirements. Grantee general orientation and data reporting orientation will identify data requirements as public data, limited distribution data, and/or confidential data.

Data Security Guidelines for Grantee Maintenance of Data

In order to submit data to FTF in fulfillment of reporting requirements, grantees must keep all data collected for their program(s) within their system (database) or hardcopies. While FTF data submissions are generally aggregated and contain no individually identifying information, grantee data is likely to contain highly sensitive information on individuals, their education and their health. These guidelines and requirements are for the maintenance of those data.

All grantees must have a data security policy in force which identifies how the organization ensures that data is protected in all its forms, during all phases of its life cycle, from inappropriate access, use, modification, disclosure, or destruction.

All grantees subject to HIPAA, FERPA, GITA, or other data regulation, are required to submit and maintain those approvals for all data. If HIPAA, FERPA or other data regulation requires that participating individuals give consent to data collection on their person and if in the course of regular data submissions to FTF such data will be provided to FTF, submission of personal data to FTF must be reflected in all data regulation documents.

GILA COUNTY ATTORNEY

Bradley D. Beauchamp

Re: County Attorney's Office approval of IGA pursuant to A.R.S. § 11-952(D).

To whom it may concern:

The County Attorney's Office has reviewed the Intergovernmental Agreement attached to this agenda item and has determined that it is in its "proper form" and "is within the powers and authority granted under the laws of this state to such public agency or public procurement unit" pursuant to A.R.S. § 11-952(D).

Explanation of the Gila County Attorney's Office Intergovernmental Agreement (IGA) Review

A.R.S. § 11-952(D) requires that

> every agreement or contract involving any public agency or public procurement unit of this state . . . before its execution, shall be submitted to the attorney for each such public agency or public procurement unit, who shall determine whether the agreement is in proper form and is within the powers and authority granted under the laws of this state to such public agency or public procurement unit.

In performing this review, the County Attorney's Office reviews IGAs to see that they are in "proper form" prior to their execution. "Proper form" means that the contract conforms to fundamental contract law, conforms to specific legislative requirements, and is within the powers and authority granted to the public agency. It does not mean that the County Attorney's Office approves of or supports the policy objectives contained in the IGA. That approval is solely the province of the public agency through its elected body.

Likewise, this approval is not a certification that the IGA has been properly executed. Proper execution can only be determined after all the entities entering into the IGA have taken legal action to approve the IGA. There is no statutory requirement for the County Attorney's Office to certify that IGAs are properly executed.

Nonetheless, it is imperative for each public agency to ensure that each IGA is properly executed because A.R.S. § 11-952(F) requires that "[a]ppropriate action … applicable to the governing bodies of the participating agencies approving or extending the duration of the … contract shall be necessary before any such agreement, contract or extension may be filed or become effective." This can be done by ensuring that the governing body gives the public proper notice of the meeting wherein action will be taken to approve the IGA, that the item is adequately described in the agenda accompanying the notice, and that the governing body takes such action. Any questions regarding whether the IGA has been properly executed may be directed to the County Attorney's Office.

Proper execution of IGAs is important because A.R.S. § 11-952(H) provides that "[p]ayment for services under this section shall not be made unless pursuant to a fully approved written contract." Additionally, A.R.S. § 11-952(I) provides that "[a] person who authorizes payment of any monies in violation of this section is liable for the monies paid plus twenty per cent of such amount and legal interest from the date of payment."

The public agency or department submitting the IGA for review has the responsibility to read and understand the IGA in order to completely understand its obligations under the IGA if it is ultimately approved by the public entity's board. This is because while the County Attorney's Office can approve the IGA as to form, the office may not have any idea whether the public agency has the capacity to actually comply with its contractual obligations. Also, the County Attorney's Office does not monitor IGA compliance. Hence the public entity or submitting department will need to be prepared to monitor their own compliance. A thorough knowledge of the provisions of the IGA will be necessary to monitor compliance.

Before determining whether an IGA contract "is in proper form," the County Attorney's Office will answer any questions or concerns the public agency has about the contract. It is the responsibility of the public agency or department submitting the IGA for review to ask any specific questions or address any concerns it has about the IGA to the County Attorney's Office at the same time they submit the IGA for review. Making such an inquiry also helps improve the County Attorney's Office review of the IGA because it will help focus the review on specific issues that are of greatest concern to the public agency. Failing to make such an inquiry when the agency does have issues or concerns will decrease the ability of the County Attorney's Office to meaningfully review the IGA.

ARF-2818 **Consent Agenda Item 4. H.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For:	Steve Stratton, Director	Submitted By:	Shannon Coons, Fiscal Services Manager, Public Works Division
Department:	Public Works Division	Division:	Fairground Facilities
Fiscal Year:	2015	Budgeted?:	Yes
Contract Dates Begin & End:	n/a	Grant?:	No
Matching Requirement?:	No	Fund?:	Renewal

Information

Request/Subject

Request for Waiver of Fees by Cobre Valley Regional Medical Center Foundation (CVRMC) for the use of the Gila County Fairgrounds Exhibit Hall from November 10, 2014, through November 15, 2014.

Background Information

The CVRMC Foundation is a group of community-minded citizens who raise funds to supplement the programs and equipment offered throught the hospital.

This year the CVRMC Foundation has requested to use the Fairgrounds Exhibit Hall from November 10, 2014, through November 15, 2014, in order to decorate before the Art and Wine Auction event on Friday, November 14, 2015. Clean-up will occur on November 15 ,2014.

Evaluation

The Gila County Fairgrounds Exhibit Hall is the most viable location for the art and wine fundraiser.

There is no conflict with the date, the certificate of insurance has been provided, and arrangements for security are being finalized. The Special Event Liquor License is attached.

Conclusion

The Cobre Valley Regional Medical Center Foundation is a vital and integral part of the community and deserves Gila County support.

Recommendation

It is the staff's recommendation that the County support the CVRMC Foundation in its efforts to raise funds to supplement programs and equipment offered through the Cobre Valley Community Hospital and waive the fees for the use of the County Fairgrounds' building.

Suggested Motion

Approval of a fee-waiver request submitted by the Cobre Valley Regional Medical Center Foundation for use of the Fairgrounds Exhibit Hall from November 10, 2014, through November 15, 2014, for the November 15th Art and Wine Auction.

Attachments

Letter & Application
Special Event Liquor License
Cert of Insurance

CV Foundation

cc: M. Sheppard
D. McDaniel
T. Martin
J. Marcanti
S. Stratton

July 21, 2014

Chairman Michael Pastor
Gila County Board of Supervisors
1400 E. Ash Street
Globe, AZ 85501

Dear Mr. Pastor:

The Cobre Valley Regional Medical Center Foundation will be hosting the Annual Art and Wine Auction on November 14, 2014 – *"Friday Night at the Movies."* Monies raised, through the dedication of many community-minded volunteers, will fund additional equipment, training, and education for the hospital. Equipment purchased this past year has included laptop computers, imaging equipment, infusion pumps, monitors, ultrasound electrical stimulation device, and iPads, to name a few.

Through the generosity of our community partners and hospital associates, the Foundation has seen much success in terms of attendance and funds raised for the hospital through this event and none of this would be possible without all of our supporters. Together we are stronger.

We have reserved the Gila County Fairgrounds Exhibit Building for Friday, November 14, 2014 and are hoping the county can partner with us by possibly reducing or even waiving the rental fee for this special event. If there is any help the county is able to offer in this regard, we would be most grateful.

Thank you for your consideration.

Sincerely,

Evelyn Vargas

Evelyn Vargas
Art and Wine Auction Chair
Cobre Valley Regional Medical Center Foundation, Ex-Officio

Welcome to the Gila County Fairgrounds Use Application and Policy

For your convenience, this document is in PDF format (free Adobe Reader or equivalent is needed to fill out application on line). Please print application, sign, and mail or hand-deliver original to:

Nicole Weaver
Administrative Clerk Specialist
Facilities Management
928-402-4368
fairgrounds@gilacountyaz.gov

If you have questions regarding the application you may e-mail or call Nicole Weaver at (928) 402-4368 for assistance.

APPLICATION TO RENT GILA COUNTY FAIRGROUNDS' FACILITIES

Name of Individual or Organization:	Cobre Valley Regional Medical Center Foundation		
Address of Individual or Organization:	5880 S. Hospital Drive		
Function to be Held:	Art and Wine Auction		
Contact Person for Event:	Evelyn Vargas		
Telephone No.:	(928) 402-1141		
Email Address:	evargas@cvrmc.org		
Date(s) Requested:	November 10, 2014	thru	November 15, 2014 (Clean up)
Time of Event:	6:00 PM	to	Approximately 9:30 PM
Estimate How Many People Will Attend Event:	300		
Liquor License No. and Sold by (Name):	CVRMC Foundation, license pending	Served only?	
Will this event be public or private?	Public x	Private	
If public, would you like this event listed on the Gila County Fairgrounds webpage?	Yes x	No	
Information to be posted on webpage:	Is there an entrance fee? Yes x	No	
Adults: $ 15.00	Children: $	Seniors: $	

Which facility will be rented? Please check appropriate box, fill in # of days or hours and enter Total Fee(s).

BUILDINGS

X	Exhibit Hall: The building is 60' x 120' (7200 sq ft) including kitchen and restrooms. Capacity is 480 people.		
	First Day of Event - $350.00		$350.00
	Each Additional Day of Event - $250.00	Days	
	($50.00 of cleaning deposit is non-refundable) Cleaning Deposit $150.00		$150.00
	Key Deposit - $25.00		$ 25.00
x	Commercial Building: Capacity is 320 people.		
	First Day of Event - $200.00		
	Each additional Day - $100.00	Days	

OUTDOOR FACILITIES

E.M.T. required for Go-Kart and all High Risk events. Horse Racing Events required to have ambulance and E.M.T.

	ATV Grounds		
	$75.00 per day; $300.00 per week (5 days)	Days	
	Rodeo Arena		
	First Day of Event - $1,200.00 + set up charges		
	$ 150.00 for each additional day	Days	
	$25.00 per hour for lights	Hours	
	Grandstand Area		
	First Day of Event - $500.00		
	$150.00 each additional day	Days	
	Livestock Shed A (60 x 120) $150.00 per day	Days	
	Livestock Shed B (80 x 120) $150.00 per day	Days	
	Livestock Shed C (30 x 120) $150.00 per day	Days	
	Horse Stall(s) $10.00 Each per day	EA Days	
	Car Track/Motor Cross $150.00 per day	Days	
	Other Areas at Fairgrounds $150.00 per day	Days	
		TOTAL FEE(S) DUE:	

POLICIES/PROCEDURES: Please read carefully.

1. Gila County requires the event sponsor/individual to provide security/traffic control personnel for events where:
   a. Alcohol/liquor is served or sold;
   b. Events are offered for public attendance;
   c. More than 480 persons are expected to attend a private event;
   d. Under all other circumstances the event sponsor/individual will provide adequate security. It is further understood that the number of security/traffic control personnel needed for the event will be determined by Detective Johnny Holmes. **At a minimum no less than two (2) law enforcement officers are required for every 480 persons in attendance. At least one (1) officer must be an Arizona Post Certified Officer and the other may be a Gila County Sheriff Posse Reserve.**
2. If alcohol/liquor is sold or served, it is the Gila County Board of Supervisors' policy **not to allow alcohol/liquor outside the building**. Law Enforcement Officers have been instructed to enforce this policy.
3. All functions are to end by 12 midnight. This includes removing all personal property. Gila County will not be responsible or liable for any personal property left after the function ends.
4. The refundable portion of the cleaning deposit will be forfeit if there are any damages to the building or related equipment.
5. Prior to picking up the key from the Public Works Facilities Department, all fees must be paid, arrangements for security secured, and certificate of insurance verified. Public Works Facilities Department' hours from 8am to 5pm, phone number 928-402-4368.
6. Insurance is required for all individual events. Some County sponsored events or functions may be required to provide additional insurance. A copy of the insurance certificate is required 10 days prior to the date of the event.
7. No tape of any kind, nails, thumb tacks, or pins will be allowed on the walls for decorating.
8. All requests to waive rent fees for the use of the Fairgrounds' facilities must be submitted 30 days in advance in written form and approved by the Gila County Board of Supervisors. The event contact will be notified via phone, cell phone, or e-mail of waiver status.
9. **The event contact person should communicate with Nicole Weaver (928) 402-4368 at least ten (10) working days before the event to review facility setup.**
10. The event application may be downloaded from the internet (www.gilacountyaz.gov) and completed on line, print, and mail original to: **Nicole Weaver, Admin. Clerk Specialist**
    745 N. Rose Mofford Way, Globe, AZ 85501
11. Events may be scheduled up to two (2) years in advance. The Fairgrounds' Master Calendar is maintained and coordinated by **Nicole Weaver**. Call 928-402-4368 to request the availability of specific dates and times.
12. Gila County reserves the right to unilaterally cancel a reservation for the Fairgrounds' facility due to unforeseen circumstances, such as damages from natural or man-made causes. A full refund will be issued to the reserving party if another suitable Fairgrounds' facility cannot be substituted.
13. The Fairgrounds Foreman will have the right to review simultaneously scheduled events for appropriateness, compatibility and safety. Alternate event dates will be offered to all requesters if criteria cannot be satisfied.
14. Rental rates for Fairgrounds' facilities shall be based on the Fairgrounds' Rate Schedule in effect on the date the approval is given by the Gila County Board of Supervisors.

I have read and understand this application:

Applicant Signature:	Evelyn Vargas	Date:	7/14/2014

(Do not write below this line)

E.M./F.G. Checklist:							
Conflict with dates:	No	Rental Fees:	to be waived	Security:		Insurance:	yes
		Approved:				**Disapproved:**	
Signature:	Steve Stratton					10/3/14	
					County Personnel Signature	**Date**	
Signature:							
					Chairman Gila County Board of Supervisors	**Date**	

APPLICATION FOR SECURITY AT THE GILA COUNTY FAIRGROUNDS FACILITY

Name of Individual or Organization:	Cobre Valley Regional Medical Center Foundation	
Address of Individual or Organization:	5880 S. Hospital Drive	
Function to be Held:	Art and Wine Auction	
Contact Person for Event:	Evelyn Vargas	
Telephone Number:	(928) 402-1141	
Date(s) Requested:	Friday, November 14, 2014	
Time of Event:	Start: 6:00 PM	End: Approximately 9:30 PM
Estimate How Many People Will Attend Event:	300	
Will Liquor Be on the Premises:	Yes x	No
Where Will Event Be Held:	Exhibit Hall x	Commercial Bldg. x
	Rodeo Arena	Grandstands
	Other Area:	
How Many AZ Post Certified Officers Needed:		
How Many Sheriff's Office Reserves Needed:		

I verify that the information I have provided is accurate and complete. I understand that it is my responsibility to notify **Nicole Weaver** (928-402-4368) and **Detective Johnny Holmes** from the Sheriff's Office (928 812-0828) of any cancellations or changes in this application.

Applicant Signature: Evelyn Vargas Date: 7 / 14 / 2014

(DO NOT WRITE BELOW THIS LINE)

Security Will Be Provide for the Above Event and Date:	YES ☐	NO ☐
Name of Officers Who Will Provide Security:		
Name of Reserves Who Will Provide Security:		

I verify that the above Officers and Reserves have been scheduled to be present as security for the event and event date listed above.

_____ Sheriff's Office Representative

____/____/____ Date

Sent to Detective Johnny Holmes 10/2/2014

STATE OF ARIZONA

DEPARTMENT OF LIQUOR LICENSES AND CONTROL

ALCOHOLIC BEVERAGE LICENSE

EVENT

License 15043722

Issue Date: 9/25/2014 Special Event

Issued To: SCHAEFER, TED
Event Name: CHARITABLE
Sponsor: COBRE VALLEY REGIONAL MEDICAL CENTER FOUNDATION
TaxID: 86 0732836

Event Dates: 11/14/2014

Location:
GILA COUNTY FAIRGROUNDS
HWY 60
GLOBE, AZ 85501

Mailing Address:
SCHAEFER, TED
8610 S SIX SHOOTER CAYON
GLOBE, AZ 85501

EXP 11/14/2014

LIQUOR LICENSES AND CONTROL ARIZONA

POST THIS LICENSE IN A CONSPICUOUS PLACE

312438

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 10/2/2014

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Commercial Lines - 602-528-3000
Wells Fargo Insurance Services USA, Inc.
100 West Washington Street, 4th Floor
Phoenix, AZ 85003-1808

CONTACT NAME: Jean Ann Morris
PHONE (A/C, No, Ext): 602-528-3036 **FAX (A/C, No):** 866-625-4510
E-MAIL ADDRESS: jean.ann.morris@wellsfargo.com

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A :	Columbia Casualty Company	31127
INSURER B :	Continental Insurance Company	35289
INSURER C :		
INSURER D :		
INSURER E :		
INSURER F :		

INSURED
Cobre Valley Regional Medical Center
5880 S. Hospital Drive
Globe, AZ 85501

COVERAGES **CERTIFICATE NUMBER:** 8251645 **REVISION NUMBER:** See below

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY	X		HMH 4032169073	04/01/2014	04/01/2015	EACH OCCURRENCE	$ 1,000,000
	X CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 50,000
	X Professional Liability Included						MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
B	AUTOMOBILE LIABILITY			6012640223	04/01/2014	04/01/2015	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB OCCUR			HMU 4032169087	04/01/2014	04/01/2015	EACH OCCURRENCE	$ $8,000,000
	EXCESS LIAB X CLAIMS-MADE						AGGREGATE	$ $8,000,000
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory In NH)	N / A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: Novemeber 14, 2014 Art & Wine Auction
Gila County Fairgrounds

Additional insured: Gila County Fairgrounds

CERTIFICATE HOLDER

Gila County
1400 East Ash Street
Globe, AZ 85501

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Jean Ann Morris

(This certificate replaces certificate# 8251640 issued on 10/2/2014)

ARF-2806 **Consent Agenda Item 4. I.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For: Eric Mariscal, Director

Submitted By: Cate Gore, Administrative Clerk, Elections Department

Department: Elections Department

Information

Request/Subject

Christopher Kohl's Fire District Governing Board Resignation and Appointment.

Background Information

ARS § 48-803 (B) provides that if a vacancy occurs on the district board other than from expiration of a term, the remaining board members shall fill the vacancy by the appointment of an interim member.

Evaluation

James Hagen resigned from the Christopher Kohl's Fire District Board of Directors. At the Christopher Kohl's Fire District governing board meeting of August 11, 2014, the governing board appointed Sharon L. Marksbury to complete James Hagen's term of office, which expires on December 31, 2016.

Conclusion

Sharon L. Marksbury has agreed to serve out the term of James Hagen.

Recommendation

The Elections Department recommends the Board of Supervisors acknowledge James Hagen's resignation from the Christopher Kohl's Fire District's Board of Directors and the appointment of Sharon L. Marksbury to said Board to fulfill Mr. Hagen's unexpired term of office.

Suggested Motion

Acknowledgment of the resignation of James Hagen from the Christopher Kohl's Fire District Board of Directors and the appointment of Sharon L. Marksbury to complete Mr. Hagen's unexpired term of office which expires on December 31, 2016.

Attachments

Appointment

Statute

OATH OF OFFICE

Christopher Kohl's Fire **District**

I, the undersigned, hereby execute this document in compliance with A.R.S. § 38-231 and § 11-542:
OFFICERS AND EMPLOYEES REQUIRED TO TAKE LOYALTY OATH; CLASSIFICATION; DEFINITION

A. In order to ensure the statewide application of this section on a uniform basis, each board, commission, agency and independent office of this state, and of any of its political subdivisions, and of any county, city, town, municipal corporation, school district and public educational institution, shall completely reproduce this section so that the form of written oath or affirmation required in this section contains all of the provisions of this section for use by all officers and employees of all boards, commissions, agencies and independent offices.

B. Any officer or employee who fails to take and subscribe to the oath or affirmation provided by this section within the time limits prescribed by this section is not entitled to any compensation until the officer or employee does so take and subscribe to the form of oath or affirmation prescribed by this section.

C. Any officer or employee having taken the form of an oath or affirmation prescribed by this section and knowingly at the time of subscribing to the oath or affirmation, or at any time thereafter during the officer's or employee's term of office or employment, does commit or aid in the commission of any act to overthrow by force, violence or terrorism defined in section 13-2301 the government of this state or any of its political subdivisions, or advocates the overthrow by force, violence or terrorism as defined in section 13-2301 of the government of this state or of any of its political subdivisions, is guilty of a class 4 felony and, on conviction under this section, the officer or employee is deemed discharged from the office or employment and is not entitled to any additional compensation or any other emoluments or benefits which may have been incident or appurtenant to the office or employment.

D. Any of the persons referred to in article XVIII, section 10, Constitution of Arizona, as amended, relating to the employment of aliens, are exempted from any compliance with this section.

E. In addition to any other form of oath or affirmation specifically provided by law for an officer or employee, before any officer or employee enters upon the duties of the office or employment, the officer or employee shall take and subscribe the following oath or affirmation: (Below)

F. For the purposes of this section, "officer or employee" means any person elected, appointed or employed, either on a part-time or full time basis, by this state or any of its political subdivisions or any county, city, town, municipal corporation, school district or public educational institution or any board, commission or agency of any county, city, town, municipal corporation, school district or public educational institution.

A.R.S. § 38-231 (E) Oath:

State of Arizona, County of Maricopa

I, Sharon MARKSBURY do solemnly swear (or affirm) that I will support the Constitution of the United States and the Constitution and laws of the State of Arizona; that I will bear true faith and allegiance to the same, and defend them against all enemies, foreign and domestic, and that I will faithfully and impartially discharge the duties of office of BOARD MEMBER according to the best of my ability, so help me God (or so do I affirm).

Sharon L Marksbury
Signature

Subscribed and sworn (or affirmed) to before me on this 8TH day of September, 2014.
(SEAL)

Linda D
Notary Public

OFFICIAL SEAL
LINDA M. DIGMAN
Notary Public - State of Arizona
GILA COUNTY
My Comm Expires February 1, 2015

To: CKFD Fire Board

From: James M. Hagen, Member

Subject: Resignation

Date submitted: 14 July 2014

I request your approval of my need and desire to resign from the CKFD Fire Board. I will serve as long as it takes for the board to appoint a replacement.

Thanks for your understanding approval. James M. Hagen
7-14-14

Approved	Date
Deborah Dawson	
Jeff Daniels	
Karen Thornton	
Steve Sundra	

Arizona Open Meeting Law
Christopher Kohl's Fire District

Arizona Revised Statute 38-431.01(A)

All meetings of any public body shall be public meetings and all persons so desiring shall be permitted to attend and listen to the deliberations and proceedings.

Arizona Revised Statue 38-431.09

It is the public policy of this state that meetings of public bodies be conducted openly and that notices and agendas be provided for such meetings which contain such information as is reasonable necessary to inform the public of the matters to be discussed or decided.

This is to certify that Sharon L. MARKSBURY has reviewed the Arizona Open Meeting Laws.

Dated: 8/11/2014

Signed: Sharon L Marksbury

At the July 14, 2014 the Board accepted the resignation of Jim Hagen.

At the 8-11-14 meeting the Board has appointed Sharon Marksbury.

We need to send a copy of the following to the County Board of Supervisors:

1. Mr. Hagen's resignation letter

2. Copy of the Board Meeting Minutes from July meeting

3. Full name, address, telephone number, e-mail address and term of office for the new member. December 2016

4. The original Oath of Officer form signed by new Board Member.

Sharon L. Marksbury
240 S. Short Road
Payson, AZ 85541

928 478-4835
SLMARKSAFB@yahoo.com

48-803. District administered by a district board; report

A. In a district that the board of supervisors estimates has a population of fewer than four thousand inhabitants, the district board may consist of three or five members. In a district that the board of supervisors estimates has a population of four thousand or more inhabitants, the district board shall consist of five members, and for a noncontiguous county island fire district formed pursuant to section 48-851, the board shall consist of five members. The estimate of population by the board of supervisors is conclusive and shall be based on available census information, school attendance statistics, election or voter registration statistics, estimates provided by state agencies or the county assessor, or other information as deemed appropriate by the board of supervisors. If the board of supervisors determines, at any time prior to one hundred twenty days before the next regular scheduled election for members of a district board, that the population of a fire district administered by a district board consisting of three members exceeds four thousand inhabitants, estimated as provided in this section, the board of supervisors shall order an increase in the number of members of the district board. If the board of supervisors determines at any time prior to one hundred eighty days before the next regularly scheduled election for members of a district board that the population of a fire district administered by a district board that consists of five members exceeds fifty thousand inhabitants as prescribed in this section, the board of supervisors shall inform the district board that it may expand to seven members. Any expansion to seven members shall occur by majority vote of the district board. The increase is effective for the election of the additional members at the next regular election of members of the district board.

B. If a vacancy occurs on the district board other than from expiration of a term, the remaining board members shall fill the vacancy by appointment of an interim member and except for a district formed pursuant to article 3 of this chapter, the remaining board members shall fill the vacancy within ninety days after the date the vacancy occurs. Except for a district formed pursuant to article 3 of this chapter, if the remaining district board members do not appoint an interim member within that ninety-day period, the board of supervisors shall appoint an interim member to the district board within sixty days after expiration of the ninety-day period, and if the district is located in more than one county, the board of supervisors of the county in which the majority of the assessed valuation of the district is located shall make the appointment after the expiration of the ninety-day period. If the entire board resigns or for any reason cannot fulfill its duties, the board of supervisors shall appoint an administrator to administer the district with the same duties and obligations of the elected board. If the board of supervisors fails to appoint an administrator within thirty days after the resignation of the entire board or its inability to fulfill its duties, a special election shall be held to fill the vacancies on the fire district board.

C. Members of the district board shall serve without compensation, but may be reimbursed for actual expenses incurred in performing duties required by law.

D. The board of a fire district shall appoint or hire a fire chief.

E. The district board shall elect from its members a chairman and a clerk. Except for a district formed pursuant to article 3 of this chapter, the election of the chairman and the clerk must occur at the district board meeting that first occurs in the month immediately following each general election.

F. For districts formed under article 3 of this chapter, of the members first elected to district boards consisting of three members, the two people receiving the first and second highest number of votes shall be elected to four-year terms, and the person receiving the third highest number of votes shall be elected to a two-year term. Of the members first elected to district boards consisting of five members, the three people receiving the first, second and third highest number of votes shall be elected to four-year terms, and the two people receiving the fourth and fifth highest number of votes shall be elected to two-year terms. Thereafter, the term of office of each district board member shall be four years from the first day of the month next following such member's election. Of the members elected as additional members to a five-member district board, the person with the highest number of votes is elected to a four-year term and the person with the second highest number of votes is elected to a two-year term. If a district resolves to increase the governing board to seven members pursuant to subsection A of this section, the governing board may appoint two additional members to serve until the next general election. After the general election at which the two additional members are elected, the newly elected member with the highest number of votes serves a four-year term and the other member serves a two-year term. Thereafter, the term of office for these two new members is four years.

G. For any fire district administered by a three-member board and that levies taxes in a fiscal year in the amount of five hundred thousand dollars or more, the district must be administered by a five-member board, beginning with the first general election held after the end of the fiscal year in which the district levied the prescribed amount, the change to a five-member board must occur as

prescribed in this subsection. On levying the prescribed amount, the district may not reorganize as a three-member board regardless of any subsequent change in the district's levy. For three-person boards with a single vacancy for an existing board membership position and that are adding two additional members, the three persons with the highest number of votes are elected to a four-year term of office. For three-person boards with two vacancies for existing board membership positions and that are adding two additional members, the three persons with the first, second and third highest numbers of votes are elected to four-year terms of office and the person with the fourth highest number of votes is elected to a two-year term of office. Thereafter, all terms of office for members of these five-person boards of directors must be four years. This subsection applies to any three-member board that is expanding to a five-member board, regardless of whether the expansion is the result of the amount of the district's levy. This subsection does not apply to districts formed under article 3 of this chapter.

H. Beginning with the 2014 general election and except for a district formed pursuant to article 3 of this chapter, all persons who are elected or appointed to a fire district board and the fire chief who is appointed or hired by the district board shall attend professional development training that is provided by an association of Arizona fire districts. District board members and the fire chief shall complete at least six hours of professional development training, with board members completing their training within one year after the date of the certification of their election and for the fire chief, within one year after the date of hiring. The fire district shall reimburse board members and the fire chief for the reasonable costs of the training. The professional development training must include training on open meetings laws, finance and budget matters and laws relating to fire district governance and other matters that are reasonably necessary for the effective administration of a fire district.

I. On or before December 31 of each year, the fire district association that has provided training required pursuant to subsection H of this section shall submit a report that describes the compliance with the training requirements to the county board of supervisors for every county in which the fire district operates. The annual report must include at least the following:

1. A compilation of the professional development training delivered by the association pursuant to this section and the names of the fire district board members and fire chiefs who are compliant and noncompliant with the requirements of this section.

2. Recommendations regarding improvements to the laws of this state or to administrative actions that are required under the laws of this state pertaining to fire districts.

J. For fire district governing board members and fire chiefs who are required to attend professional development training pursuant to subsection H of this section, a fire district governing board member or fire chief who fails to complete the professional development training within the time prescribed in this section is guilty of nonfeasance in office. Any person may make a formal complaint to the county board of supervisors regarding this failure to comply, and the county board of supervisors may submit the complaint to the county attorney for possible action. The county attorney may take appropriate action to achieve compliance, including filing an action in superior court against a fire district governing board member or a fire chief for failure to comply with the professional development training requirements prescribed in this section. If the court determines that a fire district governing board member or fire chief failed to comply with the professional development training requirements prescribed in this section, the court shall issue an order removing the fire district governing board member from office or the fire chief from employment or appointment with the district. Any vacancy in the office of a fire district governing board as a result of a court order that is issued pursuant to this subsection must be filled in the manner provided by law.

ARF-2744 **Consent Agenda Item 4. J.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For: Eric Mariscal, Director

Submitted By: Cate Gore, Administrative Clerk, Elections Department

Department: Elections Department

Information

Request/Subject

Round Valley/Oxbow Estates Fire District Governing Board Resignation and Appointment.

Background Information

A.R.S. § 48-803 (B) provides that if a vacancy occurs on the district board other than from expiration of a term, the remaining board members shall fill the vacancy by the appointment of an interim member.

Evaluation

At the Round Valley/Oxbow Estates Fire District governing board meeting of March 20, 2014, the governing board appointed Charlene Hall to complete Teri L. Peterson's term of office, which expires on December 31, 2016. Ms. Peterson resigned from said Board as she moved out of town.

Conclusion

Charlene Hall has agreed to serve out the term of Teri L. Peterson.

Recommendation

The Elections Department recommends that the Board of Supervisors acknowledge the appointment of Charlene Hall as the new governing board member for the Round Valley/Oxbow Estates Fire District.

Suggested Motion

Acknowledgment of the resignation of Teri L. Peterson from the Round Valley/Oxbow Estates Fire District Board of Directors and the appointment of Charlene Hall to complete Ms. Peterson's unexpired term of office through December 31, 2016.

Attachments

Round Valley/Oxbow Estates Fire District Oath and Minutes

Round Valley / Oxbow Estates Fire District Meeting

03/20/14

Attendees: Larry White, Jane Burlison, Charlene Hall, Teri Peterson.

Meeting Called to Order: 6:00pm by Larry White

Old Business:

12/20/13 - phone meeting.
Treasurer paid Fire District annual dues for $350.00.

10/16/13 - phone meeting.
Treasurer paid liability insurance to Crabdree Insurance for $1,180.00.

07/15/13 - phone meeting.
Treasurer posted the annual budget in the Payson Round Up newspaper. Cost for the ad was $28.53.

06/06/13 - Treasurer paid the fire bill to Payson Fire Department for $111,106.77.

New Business:

Special District Governing Board update – Teri Peterson resigned because she has moved out of the District.

Teri Peterson is replaced by Charlene Hall who is a resident of this district.

Charlene Hall was appointed by current members.

Resignation/New Member form has been completed and sent to the Gila Court Department of Elections.

Disclosure statement as of March 20, 2014 has been mailed.

Jane Burlison will mail the 2013 Annual Budget report to Globe.

We have received the 2014 Gila County Assessor's levee budget worksheet.

Treasurer's Report: As of February 28, 2014: $94,653.60.

Next Meeting: June, 2014.

Meeting Adjourned: 7:00pm

OATH OF OFFICE

PAYSON FIRE **District**

I, the undersigned, hereby execute this document in compliance with A.R.S. § 38-231 and § 11-542:

OFFICERS AND EMPLOYEES REQUIRED TO TAKE LOYALTY OATH; CLASSIFICATION; DEFINITION

A. In order to ensure the statewide application of this section on a uniform basis, each board, commission, agency and independent office of this state, and of any of its political subdivisions, and of any county, city, town, municipal corporation, school district and public educational institution, shall completely reproduce this section so that the form of written oath or affirmation required in this section contains all of the provisions of this section for use by all officers and employees of all boards, commissions, agencies and independent offices.

B. Any officer or employee who fails to take and subscribe to the oath or affirmation provided by this section within the time limits prescribed by this section is not entitled to any compensation until the officer or employee does so take and subscribe to the form of oath or affirmation prescribed by this section.

C. Any officer or employee having taken the form of an oath or affirmation prescribed by this section and knowingly at the time of subscribing to the oath or affirmation, or at any time thereafter during the officer's or employee's term of office or employment, does commit or aid in the commission of any act to overthrow by force, violence or terrorism defined in section 13-2301 the government of this state or any of its political subdivisions, or advocates the overthrow by force, violence or terrorism as defined in section 13-2301 of the government of this state or of any of its political subdivisions, is guilty of a class 4 felony and, on conviction under this section, the officer or employee is deemed discharged from the office or employment and is not entitled to any additional compensation or any other emoluments or benefits which may have been incident or appurtenant to the office or employment.

D. Any of the persons referred to in article XVIII, section 10, Constitution of Arizona, as amended, relating to the employment of aliens, are exempted from any compliance with this section.

E. In addition to any other form of oath or affirmation specifically provided by law for an officer or employee, before any officer or employee enters upon the duties of the office or employment, the officer or employee shall take and subscribe the following oath or affirmation: (Below)

F. For the purposes of this section, "officer or employee" means any person elected, appointed or employed, either on a part-time or full time basis, by this state or any of its political subdivisions or any county, city, town, municipal corporation, school district or public educational institution or any board, commission or agency of any county, city, town, municipal corporation, school district or public educational institution.

A.R.S. § 38-231 (E) Oath:

State of Arizona, County of Gila

I, Charlene Hall *do solemnly swear (or affirm) that I will support the Constitution of the United States and the Constitution and laws of the State of Arizona; that I will bear true faith and allegiance to the same, and defend them against all enemies, foreign and domestic, and that I will faithfully and impartially discharge the duties of office of* PAYSON FIRE BOARD *according to the best of my ability, so help me God (or so do I affirm).*

Charlene Hall

Signature

Subscribed and sworn (or affirmed) to before me on this 5 day of August, 2014.

(SEAL)

Sonja Bramble

Notary Public

SONJA BRAMBLE
NOTARY PUBLIC - ARIZONA
GILA COUNTY
My Commission Expires
May 26, 2015

ARF-2804 **Consent Agenda Item 4. K.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Submitted For: Eric Mariscal, Director

Submitted By: Cate Gore, Administrative Clerk, Elections Department

Department: Elections Department

Information

Request/Subject

Order to Cancel Elections and Appoint Governing Board Members for County Improvement Districts.

Background Information

Water districts, waste water districts, and sanitary districts are collectively known as county Improvement Districts. County improvement districts are covered in Title 48 of the Arizona Revised Statutes. School Districts are covered in Title 15. Elections are covered in Title 16.

ARS §16-410 provides for the cancellation of elections and the appointment of governing board members for the fire districts, water and waste water improvement districts, sanitary districts, and vocational technology districts. Further, this statute provides that canceled elections shall not appear on any ballot.

ARS §15-424 (D) and §15-1442, in conjunction with ARS §16-140, provide for the cancellation of elections and the appointment of governing board members for school districts and college districts.

Evaluation

The ability to cancel elections and appoint board members under these circumstances results in significant cost saving for each of the special districts, the school districts, and the County. The districts do not have to pay the County for the election and the County does not have to include these candidates on a ballot where they would have been automatically elected anyway. Additionally, the County is not required to create numerous different ballot styles for each of these individual districts.

Conclusion

Arizona Revised Statutes provide for the cancellation of elections and the appointment of board members for the County Improvement Districts, fire districts, water and waste water improvement districts, sanitary districts, technology school districts, provisional college districts, and school districts; and appointing governing board members to those districts as listed on Attachments A through E of this order. The implementation of the Order to cancel and appoint results is cost savings to the taxpayers of Gila County.

Recommendation

The Elections Department recommends that the Board of Supervisors adopt the Order to cancel the regularly scheduled November 4, 2014, governing board elections for fire districts, water and waste water improvement districts, sanitary districts, technology school districts, provisional college districts as listed on Attachments A through E.

Suggested Motion

Adoption of an Order to cancel the November 4, 2014, governing board elections for the fire districts, water and waste water improvement districts, sanitary districts, technology school districts, provisional college districts, and school districts; and to appoint governing board members to those districts as listed on Attachments A through E of this Order.

Attachments

Order Cancelling 11-4-14 Elections of Governing Board Members

Statutes

ORDER

ORDER OF THE GILA COUNTY BOARD OF SUPERVISORS CANCELLING ELECTIONS AND APPOINTING GOVERNING BOARD MEMBERS TO FIRE DISTRICTS, WASTEWATER DISTRICTS, SANITARY DISTRICTS, TECHNOLOGY SCHOOLS DISTRICTS, AND PROVISIONAL COMMUNITY COLLEGE DISTRICTS, AND SCHOOL DISTRICTS; AND APPOINTING GOVERNING BOARD MEMBERS TO THOSE DISTRICTS AS LISTED ON ATTACHMENTS A THROUGH E OF THIS ORDER.

WHEREAS, pursuant to A.R.S. §16-410 the Gila County Board of Supervisors may cancel the scheduled November 4, 2014, governing board elections for fire districts, water districts and wastewater improvement districts, and sanitary districts when the total number of persons who filed a nomination petition for a candidate and the number of persons who filed a nomination paper for a write-in candidate is less than or equal to the number of positions to be filled at the election for which the nomination petition or nomination paper is filed for the fire districts listed on Attachment A, the water and wastewater improvement districts listed on Attachment B, the sanitary districts listed on Attachment C; and

WHEREAS, pursuant to A.R.S. §15-424(D), 15-1442, and §16-410 the Gila County Board of Supervisors may cancel the scheduled November 4, 2014, governing board elections when the total number of persons who filed a nomination petition for a candidate and the number of persons who filed a nomination paper for a write-in candidate is less than or equal to the number of positions to be filled at the election for which the nomination petition or nomination paper is filed for the technology college and provisional community college districts listed on Attachment D and the school districts listed on Attachment E; and

WHEREAS, pursuant to the aforementioned Arizona Revised Statutes the Gila County Board of Supervisors may appoint those persons who filed nomination petitions or nomination papers for the district governing boards and;

WHEREAS, each person appointed pursuant to the aforementioned Arizona Revised Statutes is fully vested with the powers and duties of the office as if elected to that office;

NOW, THEREFORE BE IT ORDERED, that the Gila County Board of Supervisors does hereby cancel the November 4, 2014, governing board elections and appoint the persons listed on Attachment A to the respective fire district governing boards; the persons listed on Attachment B to the respective water and wastewater improvement district governing boards; the persons listed on Attachment C to the respective sanitary district governing boards; the persons listed on Attachment D to the respective technological district governing boards; and the persons listed on Attachment E to the respective school district governing boards.

PASSED AND ADOPTED this 21st day of October 2014 in Globe, Gila County, Arizona.

Attest: **GILA COUNTY BOARD OF SUPERVISORS**

_____ _____

Marian Sheppard, Clerk of the Board Michael A. Pastor, Chairman

Approved as to form:

_____

Bryan Chambers, Deputy County Attorney/Civil Bureau Chief

FIRE DISTRICTS

Governing Board Member Appointments 2014 - 2018

District	Governing Board Member
Beaver Valley Fire District	Friend, Keith
Canyon Fire District	McCreary, Gerald
	Toler, Casey B.
Christopher Kohl's Fire District	Daniels, Jeff
	Dawson, Deborah
East Verde Park Fire District	Gardner, Matalyn
	Kinnaman, Tamara
Gisela Valley Fire District	no candidates
Hellsgate Fire District	Monnich, Garah
	Runzo, Mark
Houston Mesa Fire District	Sizemore, Dick
	Webster, John
Pleasant Valley Fire District	Hunt, Kathy
	Sexton, Tom
	Tucci, Thad
Round Valley/Oxbow Estates Fire District	Burlison, Jane
	White, Larry
Tonto Basin Fire District	France, John
	Marriage, Jim
	Williams, Travis E.
Tri-City Fire District	Chism, John
	Guthrey, Danny
	Malkovich, Mitch
Whispering Pines Fire District	Hull, Robert
	Kendall, Henry
	Oberg, Chris

WATER AND WASTEWATER DISTRICTS

Governing Board Member Appointments 2014 - 2018

District	Governing Board Member
Alhambra Domestic Wastewater Improvement District	LaPine, Leah
	Sturges, Nancy
Beaver Valley DWID	No candidates
Canyon DWID	Lennox, Myrna
Canyon River Ranch DWID	No candidates
Little Creek Land Company DWID	No candidate
Pine Creek Canyon DWID	Johnson, Allan
	Roberts, Michael J.
	Semrad, Jim
Pine-Strawberry WID	Brock, Russell
	Hazine, Maher
	Schwalm, Sam
	Weeks, Thomas
Pine Water Association DWID	Cantu, Manuel
	Clement, Melvin
	Ward, Michael
Rim Trail DWID	Rice, J. P. "Buddy"
	Richardson, Gary
	Tanner, Ray
	Tenison, Jay
Solitude Trails DWID	Miotto, Roger
	Peschman, Mark
Strawberry Hollow DWID	Nystrom, David
	Peterson, Diane
Strawberry Hollow Wastewater Imp District	Nystrom, David
	Peterson, Loren
Sunflower Mesa DWID	Frandsen, Michael
	Perkins, Kenneth
	Philippe, Donald
Tonto Village DWID	Fitch, Nick
	Shaw, Jeff
Whispering Pines DWID	Bruner, Terry
	Tan, Lisa

SANITARY DISTRICTS

Governing Board Member Appointments 2014 - 2018

District	Governing Board Member
Northern Gila County Sanitary District	Easton, Bill
	Sanders, Robert
Tri-City Regional Sanitary District	Kenney, Kevin
	Zache, Bob

TECHNOLOGY SCHOOL DISTRICTS & PROVISIONAL COMMUNITY COLLEGE DISTRICT

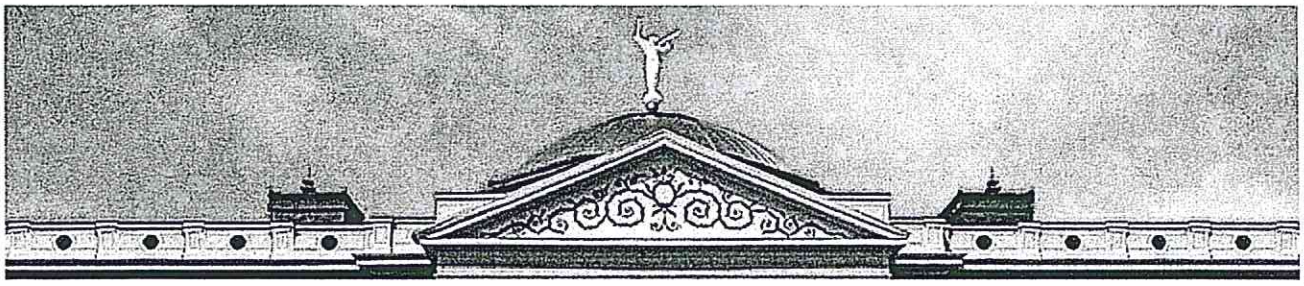
Governing Board Member Appointments 2014- 2020

District			Governing Board Member
Cobre Valley Institute of Technology			
of Technology			
Globe	(4Year Term)	2018	Fane, Mike
Miami	(4 Year Term)	2018	Gregovich-Benton, Franceen
San Carlos	(2 Year Term)	2016	Lees, Yvonne
Whiteriver	(4 Year Term)	2018	no candidate
Gila County Community College			
GCC # 1 (2 Year Term)		2016	Zilisch, John
GCC # 2 (6 Year Term)		2020	Brocker, Janet
GCC # 3 (6 Year Term)		2020	Spehar, Jay
GCC # 4 (2 Year Term)		2016	McCreary, Gerald

SCHOOL DISTRICTS

Governing Board Member Appointments 2014 - 2018

District	Governing Board Member
Hayden School District	**Term Ends 2018**
	Pinkard, Bernadine
	Cruz, Hortencia
Hayden School District (2 Year Term)	**Term Ends 2016**
	Guzman, Anna
Pine School District	**Term Ends 2018**
	Horne, Robert
	Prechtel, Dave
Pine School District (2 Year Term)	no candidate
San Carlos School District (2 Year Term)	**Term Ends 2016**
	Harris, Sherrie
Tonto Basin School District	**Term Ends 2018**
	Cline, Jarrett
	Cline, Teri



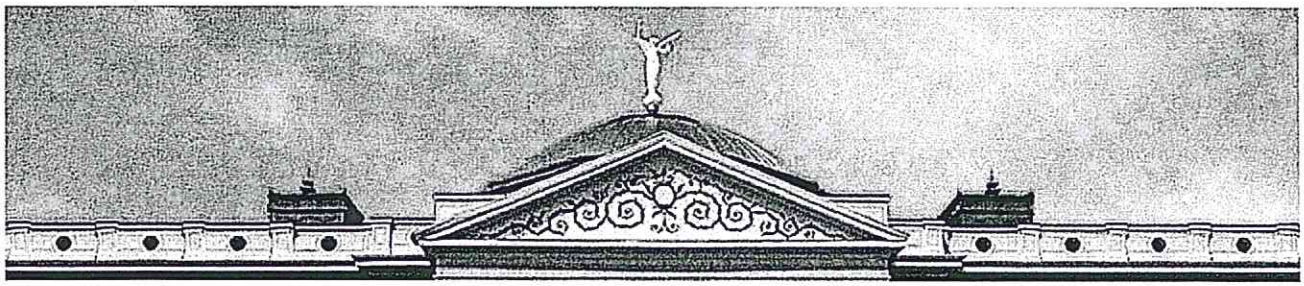
16-410. Cancellation of certain elections; appointment to office; filling vacancies

A. Notwithstanding any other law, in any election that is to be held pursuant to title 15, title 48 or section 16-822, if the total of the number of persons who file a nomination petition for a candidate and the number of persons who file a nomination paper for a write-in candidate as prescribed by chapter 3, articles 2 and 3 of this title is less than or equal to the number of positions to be filled at the election for which the nomination petition or nomination paper is filed, the county board of supervisors may cancel the election no earlier than seventy-five days before the election and appoint the person or persons who filed the nomination petition or nomination paper to fill the position for the term of office for which the candidate was nominated by the qualified electors.

B. A person who is appointed pursuant to subsection A of this section is fully vested with the powers and duties of the office as if elected to that office.

C. If no nomination petitions for a candidate and no nomination papers for a write-in candidate have been filed to fill the position for which the election was being held, the position is deemed vacant and shall be filled in accordance with laws governing the filling of those vacancies.

D. Canceled elections shall not appear on any ballot, but if a withdrawal or disqualification of one or more candidates results in the cancellation of an election after the ballots have been printed, the results of any vote for that office shall not be canvassed.



15-424. Election of governing board members; terms; statement of contributions and expenditures

A. A regular election shall be held for each school district at the time and place, and in the manner, of general elections as provided in title 16.

B. Except as provided in subsection C of this section and sections 15-429 and 15-430, the term of office for each member shall be four years from January 1 next following the member's election.

C. At the first general election held for a newly formed district, three members shall be elected. The candidate receiving the highest number of votes shall be elected to a four year term, and the candidates having the second and third highest number of votes shall be elected to two year terms. A district increasing its governing board to five members shall elect at the next general election members in the following manner:

1. If one of the previous three offices is to be filled, the three candidates receiving the highest, the second highest and the third highest number of votes shall be elected to four year terms.

2. If two of the previous three offices are to be filled, the candidates receiving the highest, the second highest and the third highest number of votes shall be elected to four year terms. The candidate receiving the fourth highest number of votes shall be elected to a two year term. Thereafter all such offices shall have four year terms.

D. If only one person files or no person files a nominating petition or nomination paper for a write-in candidate for an election to fill a district office, the board of supervisors no earlier than seventy-five days before the election may cancel the election for the position and appoint the person who filed the nominating petition or nomination paper to fill the position. If no person files a nominating petition or nomination paper for an election to fill a district office, the board of supervisors no earlier than seventy-five days before the election may cancel the election for that office and that office is deemed vacant and shall be filled as provided in section 15-302. A person who is appointed pursuant to this subsection is fully vested with the powers and duties of the office as if elected to that office.

E. If two or more candidates receive an equal number of votes for the same office, and a higher number than any other candidate for that office, whether upon the tally by the school election board or canvass of returns by the board of supervisors, or upon recount by a court, the officer or board whose duty it is to declare the result shall determine by lot and in the presence of the candidates which candidate shall be declared elected.

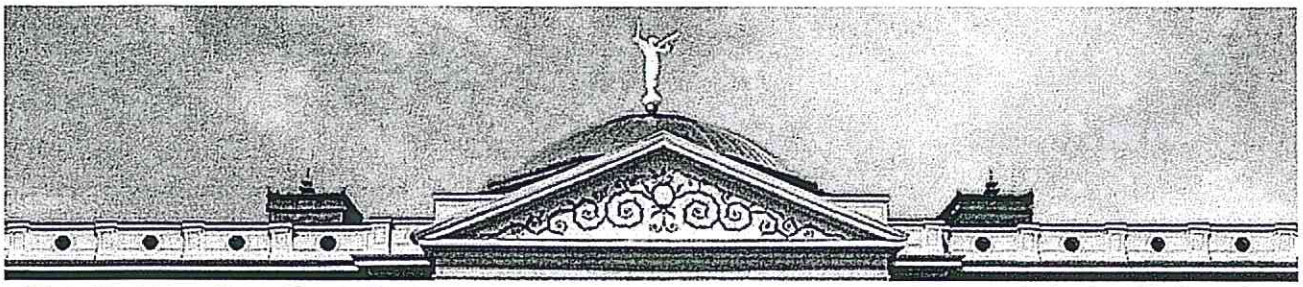
F. Position of the names of candidates for each office shall be rotated so that each candidate occupies each position on the ballot an equal number of times, insofar as is possible, for each ballot style. For candidates seeking election to fill a vacancy on the governing board, the ballot shall be designated as provided in section 16-502.

G. This section does not require that a school election at which no member is to be elected be held on a general election day.

H. All candidates for the office of school district governing board member shall file with the county school superintendent a statement of contributions and expenditures as provided in section 16-913.

Arizona State Legislature

Bill Number Search:



Fifty-first Legislature - Second Regular Session

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ARS TITLE PAGE NEXT DOCUMENT PREVIOUS DOCUMENT

15-1442. Nominating petitions; election; returns; results; certificate of election; statement of contributions and expenditures

A. Candidates for the district board must file nominating petitions, conforming to section 16-314, with the appropriate county officer.

B. Members of the district board shall be elected at the time and place, and in the manner, of general elections as provided in title 16.

C. If only one person files or no person files a nominating petition or nomination paper for a write-in candidate for an election to fill a community college board office, the county school superintendent no earlier than seventy-five days before the election may cancel the election for the position and appoint the person who filed the nominating petition or nomination paper to fill the position. If no person files a nominating petition or nomination paper for an election to fill a community college board office, the county board of supervisors no earlier than seventy-five days before the election may cancel the election for that office and that office is deemed vacant and shall be filled as provided in section 15-1441. A person who is appointed pursuant to this subsection is fully vested with the powers and duties of the office as if elected to that office.

D. The county school superintendent and the chairman of the board of supervisors shall meet on the seventh day following the election to canvass the returns in accordance with procedures for the canvass of returns in a general election. The county school superintendent shall declare the results of the election, declare elected the person receiving the highest number of votes for each office to be filled and issue to that person a certificate of election.

E. All candidates for the office of community college district governing board member shall file with the clerk of the board of supervisors a statement of contributions and expenditures as provided in section 16-913.

ARF-2815 **Consent Agenda Item 4. L.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Reporting Period: July 2014 and August 2014

Submitted For: Kaycee Stratton **Submitted By:** Kaycee Stratton, Chief Deputy Recorder, Recorder's Office

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Information

Subject

Recorder's Office Monthly Reports for July and August 2014

Suggested Motion

Acknowledgment of the July and August 2014 monthly activity reports submitted by the Recorder's Office.

Attachments

August 2014

July 2014

GILA COUNTY RECORDER

REPORT FOR THE MONTH OF AUG 2014

I, Sadie Jo Bingham, County Recorder in and for the County of Gila, State of Arizona hereby state and certify that the fees earned for this month are as set forth in the attached report.

Sadie Jo Bingham

Sadie Jo Bingham, Gila County Recorder

GILA COUNTY RECORDER

Report for August 2014

SECTION I		**CREDIT**	**DEBIT**	**TOTAL**	**EXPLANATION**
1005 (GENERAL FUND)	**PAID INTO SUSPENSE ACCT**	$6,685.00	$0.00	$6,685.00	
	PAID OUT OF SUSPENSE ACCT	$0.00	$8,581.20	$8,581.20	
	RECORDING FEES	$12,769.20	$0.00	$12,769.20	
	REFUNDS-EXCESS FEES	$0.00	$6.00	$6.00	
	INTEREST PD TO ACCT	$0.54	$0.00	$0.54	
Staled Checks		$0.00	$0.00	$0.00	
TOTAL 1005 FUNDS		$19,454.74	$8,587.20	$10,867.54	
SECTION II					
	7145 FUND (RECORDER)	$4,011.50	$0.00	$4,011.50	
	7146 FUND (MINING - 80% STATE TREAS)	$48.00	$48.00	$0.00	
	7146 FUND (MINING - 20% RECORDER)	$12.00	$0.00	$12.00	
	7147 FUND (COMPUTER SVCS)	$920.00	$0.00	$920.00	
TOTAL SEC II FUNDS		$4,991.50	$48.00	$4,943.50	
COMBINED TOTALS - TOTAL FEES COLLECTED		$24,446.24	$8,635.20	$15,811.04	

M,ADOT,APS,APSR,ARARS,AWC,AZDOR,AZDORI,AZRE/COPIES,AZRE/RECORDING,CARD,CRSI,CTS,DOCUT,DS,EPN,EQUIT,ERAY,EXCEL,FARES,FATM,FATR2,FB,FNDS,GCCD,HANSEN-ENGINEERING,IMAPP,INDECOMM,INDEPTH,Ingeo,IRS,IRS2,LA001,MHK,NBOA,NBOAC,NDTS-TSG,NewAcct1,NTC,PIONE,PTP2,Public Works Floodplain,RSSI,RUI,simplifile,SOUTHWES DIV,TD,Title 1 copy,tyler,VOTER

House Account ID	House Account Name	Starting Balance	Charges	Payments	Ending Balance
ACCU	ACCUSEARCH	($68.00)	$1.00	$0.00	($67.00)
ADOR-M	STATE OF ARIZONA - DEPT OF REVENUE	($117.97)	$46.80	$0.00	($71.17)
ADOT	AZ DEPT OF TRANS	($273.00)	$0.00	$0.00	($273.00)
APS	APS/COPIES	($185.00)	$0.00	$0.00	($185.00)
APSR	APS/RECORDINGS	($431.00)	$0.00	$0.00	($431.00)
ARARS	AZ RESEARCH &AMP RETRIEVAL SVCS	($25.00)	$21.00	($200.00)	($204.00)
AWC	ARIZONA WATER COMPANY	($189.00)	$0.00	$0.00	($189.00)
AZDORI	ADOR ACCOUNTS PAYABLE	($1,680.40)	$16.00	$0.00	($1,664.40)
AZRE/RECORDING	ARIZONA DEPT OF REALESTATE	($2,042.00)	$0.00	$0.00	($2,042.00)
CARD	Cardon Hiatt / The Vineyrd Group	($105.00)	$0.00	$0.00	($105.00)
CRSI	Colorado Records Sooner Inc	($80.00)	$0.00	$0.00	($80.00)
CTS	COMPLETE TITLE SOLUTIONS	($23.00)	$7.00	$0.00	($16.00)
DS	DATA SERVICES	($1,000.00)	$0.00	$0.00	($1,000.00)
EPN	eRecording Partners Network	($1,000.00)	$0.00	$0.00	($1,000.00)
EQUIT	EQUITY SERVICES	($127.00)	$0.00	$0.00	($127.00)
EXCEL	EXCEL DOCUMENT SERVICES	($25.00)	$0.00	$0.00	($25.00)
FARES	CORELOGIC	($236.40)	$190.00	$0.00	($46.40)
FATM	FIRST AMERICAN MICROFICHE	($27.60)	$335.40	($3,000.00)	($2,692.20)
FB	FLOYD BLEAK / NANCY SHEPPARD	($549.00)	$0.00	$0.00	($549.00)
FNDS	BLACK KNIGHT FINANCIAL SERVICES	($728.20)	$190.00	$0.00	($538.20)
GCCD	GILA COUNTY COMMUNITY DEVELOPMENT	$164.50	$0.00	$0.00	$164.50
HANSEN-ENGINEERING	HANSEN ENGINEERING & SURVEYING	($104.00)	$0.00	$0.00	($104.00)
IMAPP	IMAPP , INC	($53.40)	$0.00	$0.00	($53.40)
INDECOMM	INDECOMM	($1,000.00)	$106.00	($106.00)	($1,000.00)
INDEPTH	INDEPTH SOLUTIONS INC	($20.00)	$0.00	$0.00	($20.00)
Ingeo	Ingeo - eRecording	($1,028.00)	$754.00	($781.00)	($1,055.00)
IRS	INTERNAL REVENUE SERVICE	($82.00)	$72.00	($72.00)	($82.00)
LA001	First American Title Lenders Advantage	($428.50)	$0.00	$0.00	($428.50)
MHK	MORRIS HALL KINGHORN	($266.00)	$0.00	$0.00	($266.00)
NDTS-TSG	FIRST AMERICAN TITLE INSURANCE COMPANY	($877.00)	$0.00	$0.00	($877.00)
NewAcct1	Applied Technology Resources Inc	($200.00)	$0.00	$0.00	($200.00)
NTC	NATIONWIDE TITLE CLEARING	($1,000.00)	$171.00	($162.00)	($991.00)
PIONE	PIONEER TITLE AGENCY FICHE	($6,821.00)	$175.00	$0.00	($6,646.00)
PTP2	PIONEER TITLE AGENCY RECORDINGS 2	($6,935.00)	$4,124.00	$0.00	($2,811.00)
Public Works Floodplain	Gila County	($100.00)	$0.00	$0.00	($100.00)

Immediate and Deferred Accounts: ACCU,ADOR-M,ADOT,APS,APSR,ARARS,AWC,AZDOR,AZDORI,AZRE/COPIES,AZRE/RECORDING,CARD,CRSI,CTS,DOCUT,DS,EPN,EQUIT,ERAY,EXCEL,FARES,FATM,FATR2,FB,FNDS,GCCD,HANSEN-ENGINEERING,IMAPP,INDECOMM,INDEPTH,Ingeo,IRS,IRS2,LA001,MHK,NBOA,NBOAC,NDTS-TSG,NewAcct1,NTC,PIONE,PTP2,Public Works Floodplain,RSSI,RUI,simplifile,SOUTHWES DIV,TD,Title 1 copy,tyler,VOTER

House Account ID	House Account Name	Starting Balance	Charges	Payments	Ending Balance
RSSI	RECORD SEARCHING SERVICES INC	($90.00)	$4.00	$0.00	($86.00)
RUI	RESEARCH UNLIMITED INC	($88.00)	$0.00	$0.00	($88.00)
simplifile	Simplifile - eRecording	($1,089.00)	$2,364.00	($2,364.00)	($1,089.00)
SOUTHWES DIV	FIRST AMERICAN TITLE	($1,104.20)	$4.00	$0.00	($1,100.20)
TD	Timely Documents	($100.00)	$0.00	$0.00	($100.00)
Totals		**($30,134.17)**	**$8,581.20**	**($6,685.00)**	**($28,237.97)**

Sadie Bingham
Gila County Recorder

New Fiscal Year Form

FY **2014-2015**

Month	No of Doc.	Recorder Storage & Retrieval 7145	Recording Fees 1005	Computer Svcs 7147	Mining fees 7146	Recorder Check to Treasurer
July	988	3,620.50	12,426.93	770.00	6.00	16,823.43
Aug	1,079	4,011.50	10,867.54	920.00	12.00	15,811.04
Sept						0.00
Oct						0.00
Nov						0.00
Dec						0.00
Jan						0.00
Feb						0.00
Mar						0.00
Apr						0.00
May						0.00
June						0.00
Total	**2,067**	**7,632**	**23,294.47**	**1,690.00**	**18.00**	**32,634.47**

Fiscal Year All Monies **32,634.47**

ARIZONA STATE TREASURER'S OFFICE
1700 West Washington, Phoenix, Arizona 85007-2812
(602) 604-7800 FAX: (602) 542-7176

STATE REMITTANCE REPORT

Report Period: August 2014

Date: 09 / 30 / 2014

Depositor Code # 5393

Prepared By: Kaycee Stratton

Title: Chief Deputy Recorder

Phone #: 928-402-8734

Depositor Name: Gila County Recorder

Address: 1400 E. Ash St.
Globe, AZ 85501

negative amounts are not to be used on this form

(contact this Office for guidance regarding negative entries)

DESCRIPTION	STATUTE (ARS #)	AMOUNT
FINES & FEES		
Confidential Inter Fund	08-135; 12-284.03A8	
Juvenile Family Counseling	08-263C	
Victim's Rights – Juvenile	08-418; 41-191.08	
AHCCCS	11-292	
JCEF-Filing Fees	12-284.03A7; 22-281C1; 22-404C1	
JCEF - Time Payment	12-116B	
JCEF – Diversion Fee	12-114	
JCEF- Probation Assessment	12-114.01	
DNA Penalty Assessment	12-116.01C, J	
Domestic Violence	12-284.03A2	
Drug Prevention Res Center	12-284.03; 41-2402H	
Child Abuse	12-284.03A3	
Sex Offender Assessment	13-3824	
Anti-Racketeering Fund	13-811B; 13-2314.01	
Drug & Gang Enforce Acct	13-811C; 41-2402	
Community Punishment Program Drug Fines	13-821; 12-299	
Citizens Clean Election Fund	16-949D; 16-954C	
Game & Fish - Wildlife	17-313A	
AZ Lengthy Trial Fund	21-222	
Alternative Dispute Resolution Fund	22-281C2; 12-135; 12-284.03A5	
Mining Fees	27-208D	48.00
Child Passenger Restraint	28-907C	
DPS – Civil Penalty	28-2533C; 28-4139	
DUI Abatement Fund	28-1304; 28-1382, 3	
Civil Penalties (Gen. Fund)	28-737; 28-876; 28-2416; 32-1166	
AZ Highway Fines (HURF)	28-5438F; 28-2533C	
Victim Comp/Assistance	31-411F; 31-466B	
Registrar of Contractors	32-1107; 32-1124	
MSEF Penalty Assessment	36-2219.01; 12-116.02F	
CJEF Penalty Assessment	41-2401; 12-116.01	
Arson Detection Reward Fund	41-2167	
FTG Penalty Assessment 7%	41-2421J; 12-116.01B	
Prison Const & Ops Fund	41-1651; 5-395.01A4	
Dept of Law – Crim. Cases	41-2421E4	
GITEM	41-1724; 11-1051	

DESCRIPTION	STATUTE (ARS #)	AMOUNT
FINES & FEES (continued)		
DUI, OUI Assessment (public safety equip fund)	5-395.01; 5-396, 7; 28-1381-3; 28-8284, 6-8; 14-1723	
FARE General Services Fee		
FARE Delinquent Fee		
FARE Special Collections Fee		
FARE Installment Fee		
Constable Ethics Fund	11-445 (80%)	
Constable Ethics Fund	11-445 (20%)	
Photo Enforcement Fee	41-1722	
Photo Enforcement Process Serving Fee		
OTHER FINES & FEES (describe and indicate ARS #)		
TAXES		
Prior Year Real Property	42-208	
Personal Property	42-208	
County Education District	15-991.01A	
Property-Min School Tax	15-992B, C	
State Water Banking	48-3715.03; 45-2425	
C.A.W.C.D.	48-3715	
Groundwater Replenishment	48-3773.A3; 48-3772	
OTHER TAXES (describe and indicate ARS #)		
90/10 REVENUE		
Mobile Home Relocation	33-1476.03 (90%)	
Mobile Home/Ins. & Cost	33-1476.03 (10%)	

TOTAL AMOUNT REMITTED:

By Check

By Cr Advice (Wire)

TOTAL 48.00

NOTES:

FOR STATE TREASURER USE ONLY

Certain funds are required to be remitted to the State Treasurer directly, while others are to be remitted to other entities; i.e., county treasurer, city treasurer, etc. Only use this form to remit funds to the Arizona State Treasurer as required by Arizona Revised Statutes (A.R.S.). For all other remittances, please check with your city or county. Form TRE 102A is to be used by counties for required detailed information. Please keep a copy of this report for your records.

Bank Deposit

From08/01/2014To08/31/2014

Total	$24,445.70	$24,445.70
Non-Deposit Total	($12,066.20)	($12,066.20)
Deposit Total	**$12,379.50**	**$12,379.50**
Total Till Over/Short		$0.00

Journal Activity

Account		Debits	Credits	Net
Asset				
1005SuspensePrePayAccounts	1005 Suspense - Prepay	$5,114.20	($3,200.00)	$1,914.20
Cash	Cash/Check	$12,379.50	$0.00	$12,379.50
D-1005-120-01-4612-003	Postage(deferred)	$9.00	($9.00)	$0.00
D-1005-120-01-4612-023	Recording Fee (deferred)	$27.00	($27.00)	$0.00
D-7145-120-01-4775-004	Recorder Storage and Retrieval (deferred)	$36.00	($36.00)	$0.00
ETransfer	Electronic Transfers	$3,485.00	$0.00	$3,485.00
	Total	**$21,050.70**	**($3,272.00)**	**$17,778.70**
Liability				
1005SuspenseChargeAccounts	1005 Suspense - Charge	$72.00	($72.00)	$0.00
	Total	**$72.00**	**($72.00)**	**$0.00**
Expense				
	Total	**$0.00**	**$0.00**	**$0.00**
Revenue				
1005-120-01-4612-001	Copies	$0.00	($416.00)	($416.00)
1005-120-01-4612-002	Certified Seal	$0.00	($36.00)	($36.00)
1005-120-01-4612-003	Postage	$0.00	($747.20)	($747.20)
1005-120-01-4612-005	Affidavit of Property Value	$0.00	($374.00)	($374.00)
1005-120-01-4612-008	Additional Transaction Fee	$0.00	($57.00)	($57.00)
1005-120-01-4612-012	Overpayment	$0.00	($42.00)	($42.00)
1005-120-01-4612-018	Misc Fees (Notification)	$0.00	($53.00)	($53.00)
1005-120-01-4612-023	Recording Fee	$0.00	($11,038.00)	($11,038.00)
1005-120-01-4612-026	Refunds	$0.00	($6.00)	($6.00)
7145-120-01-4775-004	Recorder Storage and Retrieval	$0.00	($4,011.50)	($4,011.50)
7146-120-01-4612	Mining Fees	$0.00	($12.00)	($12.00)
7146-120-01-4776-009	State Mining Fees	$0.00	($48.00)	($48.00)
7147-120-01-4612-018	Voter	$0.00	($10.00)	($10.00)
7147-120-01-4774-031	Miscellaneous	$0.00	($910.00)	($910.00)
eRecording	eRecording	$3,395.00	($3,413.00)	($18.00)
	Total	**$3,395.00**	**($21,173.70)**	**($17,778.70)**
	Total	**$24,517.70**	**($24,517.70)**	**$0.00**

Range Summary

Range	Account	Debits	Credits	Net
Cash/Check				
	Cash Cash/Check	$12,379.50	$0.00	$12,379.50
	Range Total	**$12,379.50**	**$0.00**	**$12,379.50**

GILA COUNTY RECORDER

REPORT FOR THE MONTH OF JULY 2014

I, Sadie Jo Bingham, County Recorder in and for the County of Gila, State of Arizona hereby state and certify that the fees earned for this month are as set forth in the attached report.

Sadie Jo Bingham

Sadie Jo Bingham, Gila County Recorder

GILA COUNTY TREASURER'S RECEIPT
GILA COUNTY, ARIZONA

DATE 9-22-14

CONTRACT # _____

GRANT # _____

DEPOSIT TO FUND General FUND # 1005

REMITTING AGENCY Recorder (120)

BILLING PERIOD July 1, 2014 - July 31, 2014

Account Code	Direct Deposit / Check #	Revenue Description	Amount	
1005.120.3400.99		Recorder Fee's	12,426.	93
7145.120.3400.99		Recorder Storage	3,620.	50
7146.120.3400.99		Mining Fee's	6.	00
7147.120.3400.99		Computer Svs.	770.	00
			16,823.	43

Preparer Signature: Kayce Strath Title Chief Deputy

Approved Signature: Sadie Bingham Title Recorder

SUMMARY OF DEPOSIT

Currency	
Coins	
Checks	
Total	

TREASURER By _____ Date _____

TREASURER 127424

GILA COUNTY RECORDER

Report for July 2014

SECTION I		**CREDIT**	**DEBIT**	**TOTAL**	**EXPLANATION**
1005 (GENERAL FUND)	**PAID INTO SUSPENSE ACCT**	$9,918.00	$0.00	$9,918.00	
	PAID OUT OF SUSPENSE ACCT	$0.00	$7,420.60	$7,420.60	
	RECORDING FEES	$10,146.10		$10,146.10	
	REFUNDS-EXCESS FEES	$0.00	$217.00	$217.00	
	INTEREST PD TO ACCT	$0.43	$0.00	$0.43	
Staled Checks		$0.00	$0.00	$0.00	
TOTAL 1005 FUNDS		$20,064.53	$7,637.60	$12,426.93	
SECTION II					
	7145 FUND (RECORDER)	$3,620.50	$0.00	$3,620.50	
	7146 FUND (MINING - 80% STATE TREAS)	$24.00	$24.00	$0.00	
	7146 FUND (MINING - 20% RECORDER)	$6.00	$0.00	$6.00	
	7147 FUND (COMPUTER SVCS)	$770.00	$0.00	$770.00	
TOTAL SEC II FUNDS		$4,420.50	$24.00	$4,396.50	
COMBINED TOTALS - TOTAL FEES COLLECTED		$24,485.03	$7,661.60	$16,823.43	

Sadie Bingham
Gila County Recorder

New Fiscal Year Form

FY **2014-2015**

Month	No of Doc.	Recorder Storage & Retrieval 7145	Recording Fees 1005	Computer Svcs 7147	Mining fees 7146	Recorder Check to Treasurer
July	988	3,620.50	12,426.93	770.00	6.00	16,823.43
Aug						0.00
Sept						0.00
Oct						0.00
Nov						0.00
Dec						0.00
Jan						0.00
Feb						0.00
Mar						0.00
Apr						0.00
May						0.00
June						0.00
Total	**988**	**3,621**	**12,426.93**	**770.00**	**6.00**	**16,823.43**

Fiscal Year All Monies **16,823.43**

ARIZONA STATE TREASURER'S OFFICE
1700 West Washington, Phoenix, Arizona 85007-2812
(602) 604-7800 FAX: (602) 542-7176

STATE REMITTANCE REPORT

Report Period: July 2014
Date: 09 / 22 / 2014
Depositor Code # 5393

Prepared By: Kaycee Stratton
Title: Chief Deputy Recorder
Phone #: 928-402-8734

Depositor Name: Gila County Recorder
Address: 1400 E. Ash St.
Globe, AZ 85501

negative amounts are not to be used on this form
(contact this Office for guidance regarding negative entries)

DESCRIPTION	STATUTE (ARS #)	AMOUNT
FINES & FEES		
Confidential Inter Fund	08-135; 12-284.03A8	
Juvenile Family Counseling	08-263C	
Victim's Rights – Juvenile	08-418; 41-191.08	
AHCCCS	11-292	
JCEF-Filing Fees	12-284.03A7; 22-281C1; 22-404C1	
JCEF - Time Payment	12-116B	
JCEF – Diversion Fee	12-114	
JCEF- Probation Assessment	12-114.01	
DNA Penalty Assessment	12-116.01C, J	
Domestic Violence	12-284.03A2	
Drug Prevention Res Center	12-284.03, 41-2402H	
Child Abuse	12-284.03A3	
Sex Offender Assessment	13-3824	
Anti-Racketeering Fund	13-811B, 13-2314.01	
Drug & Gang Enforce Acct	13-811C; 41-2402	
Community Punishment Program Drug Fines	13-821, 12-299	
Citizens Clean Election Fund	16-949D; 16-954C	
Game & Fish - Wildlife	17-313A	
AZ Lengthy Trial Fund	21-222	
Alternative Dispute Resolution Fund	22-281C2, 12-135, 12-284.03A5	
Mining Fees	27-208D	24.00
Child Passenger Restraint	28-907C	
DPS – Civil Penalty	28-2533C, 28-4139	
DUI Abatement Fund	28-1304, 28-1382, 3	
Civil Penalties (Gen. Fund)	28-737; 28-876, 28-2416, 32-1166	
AZ Highway Fines (HURF)	28-5438F, 28-2533C	
Victim Comp/Assistance	31-411F, 31-466B	
Registrar of Contractors	32-1107, 32-1124	
MSEF Penalty Assessment	36-2219.01, 12-116.02F	
CJEF Penalty Assessment	41-2401; 12-116.01	
Arson Detection Reward Fund	41-2167	
FTG Penalty Assessment 7%	41-2421J; 12-116.01B	
Prison Const & Ops Fund	41-1651; 5-395.01A4	
Dept of Law – Crim. Cases	41-2421E4	
GITEM	41-1724; 11-1051	

DESCRIPTION	STATUTE (ARS #)	AMOUNT
FINES & FEES (continued)		
DUI, OUI Assessment (public safety equip fund)	5-395.01; 5-396, 7, 28-1381-3, 28-8284, 6-8; 14-1723	
FARE General Services Fee		
FARE Delinquent Fee		
FARE Special Collections Fee		
FARE Installment Fee		
Constable Ethics Fund	11-445 (80%)	
Constable Ethics Fund	11-445 (20%)	
Photo Enforcement Fee	41-1722	
Photo Enforcement Process Serving Fee		
OTHER FINES & FEES (describe and indicate ARS #)		
TAXES		
Prior Year Real Property	42-208	
Personal Property	42-208	
County Education District	15-991.01A	
Property-Min School Tax	15-992B, C	
State Water Banking	48-3715.03; 45-2425	
C.A.W.C.D.	48-3715	
Groundwater Replenishment	48-3773 A3, 48-3772	
OTHER TAXES (describe and indicate ARS #)		
90/10 REVENUE		
Mobile Home Relocation	33-1476.03 (90%)	
Mobile Home/Ins. & Cost	33-1476.03 (10%)	

TOTAL AMOUNT REMITTED:

By Check
By Cr Advice (Wire)
TOTAL 24.00

FOR STATE TREASURER USE ONLY

NOTES:

Certain funds are required to be remitted to the State Treasurer directly, while others are to be remitted to other entities; i.e., county treasurer, city treasurer, etc. Only use this form to remit funds to the Arizona State Treasurer as required by Arizona Revised Statutes (A.R.S.). For all other remittances, please check with your city or county. Form TRE 102A is to be used by counties for required detailed information. Please keep a copy of this report for your records.

Bank Deposit

From07/01/2014To07/31/2014

3716	Jul 23, 2014	3_ReceiptStation1_Wed / 3663	$412.00	$412.00	Bank Account
3721	Jul 31, 2014	previousday / 3759	$107.00	$107.00	Bank Account

Total	$24,582.60	$24,582.60
Non-Deposit Total	($10,436.60)	($10,436.60)
Deposit Total	$14,146.00	$14,146.00
Total Till Over/Short		$0.00

Journal Activity

Account		Debits	Credits	Net
Asset				
1005SuspensePrePayAccounts	1005 Suspense - Prepay	$4,377.60	($7,000.00)	($2,622.40)
Cash	Cash/Check	$14,146.00	$0.00	$14,146.00
D-1005-120-01-4612-003	Postage(deferred)	$14.00	($14.00)	$0.00
D-1005-120-01-4612-023	Recording Fee (deferred)	$42.00	($42.00)	$0.00
D-7145-120-01-4775-004	Recorder Storage and Retrieval (deferred)	$56.00	($56.00)	$0.00
ETransfer	Electronic Transfers	$3,016.00	$0.00	$3,016.00
	Total	$21,651.60	($7,112.00)	$14,539.60
Liability				
1005SuspenseChargeAccounts	1005 Suspense - Charge	$112.00	($112.00)	$0.00
	Total	$112.00	($112.00)	$0.00
Expense				
	Total	$0.00	$0.00	$0.00
Revenue				
1005-120-01-4612-001	Copies	$0.00	($418.00)	($418.00)
1005-120-01-4612-002	Certified Seal	$0.00	($48.00)	($48.00)
1005-120-01-4612-003	Postage	$0.00	($661.60)	($661.60)
1005-120-01-4612-005	Affidavit of Property Value	$0.00	($332.00)	($332.00)
1005-120-01-4612-008	Additional Transaction Fee	$0.00	($57.00)	($57.00)
1005-120-01-4612-012	Overpayment	$0.00	($33.00)	($33.00)
1005-120-01-4612-018	Misc Fees (Notification)	$0.00	($52.00)	($52.00)
1005-120-01-4612-023	Recording Fee	$0.00	($8,327.50)	($8,327.50)
1005-120-01-4612-026	Refunds	$0.00	($217.00)	($217.00)
7145-120-01-4775-004	Recorder Storage and Retrieval	$0.00	($3,620.50)	($3,620.50)
7146-120-01-4612	Mining Fees	$0.00	($6.00)	($6.00)
7146-120-01-4776-009	State Mining Fees	$0.00	($24.00)	($24.00)
7147-120-01-4774-031	Miscellaneous	$0.00	($770.00)	($770.00)
eRecording	eRecording	$2,931.00	($2,904.00)	$27 00
	Total	$2,931.00	($17,470.60)	($14,539.60)
	Total	$24,694.60	($24,694.60)	$0.00

Range Summary

Range	Account	Debits	Credits	Net
Cash/Check				
	Cash Cash/Check	$14,146.00	$0.00	$14,146.00
	Range Total	$14,146.00	$0.00	$14,146.00

Immediate and Deferred Accounts: ACCU,ADOR-M,ADOT,APS,APSR,ARARS,AWC,AZDOR,AZDORI,AZRE/COPIES,AZRE/RECORDING,CARD,CRSI,CTS,DOCUT,DS,EPN,EQUIT,ERAY,EXCEL,FARES,FATM,FATR2,FB,FNDS,GCCD,HANSEN-ENGINEERING,IMAPP,INDECOMM,INDEPTH,Ingeo,IRS,IRS2,LA001,MHK,NBOA,NBOAC,NDTS-TSG,NewAcct1,NTC,PIONE,PTP2,Public Works Floodplain,RSSI,RUI,simplifile,SOUTHWES DIV,TD,Title 1 copy,tyler,VOTER

House Account ID	House Account Name	Starting Balance	Charges	Payments	Ending Balance
ACCU	ACCUSEARCH	($70.00)	$2.00	$0.00	($68.00)
ADOR-M	STATE OF ARIZONA - DEPT OF REVENUE	($133.97)	$16.00	$0.00	($117.97)
ADOT	AZ DEPT OF TRANS	($273.00)	$0.00	$0.00	($273.00)
APS	APS/COPIES	($185.00)	$0.00	$0.00	($185.00)
APSR	APS/RECORDINGS	($431.00)	$0.00	$0.00	($431.00)
ARARS	AZ RESEARCH &AMP RETRIEVAL SVCS	($35.00)	$10.00	$0.00	($25.00)
AWC	ARIZONA WATER COMPANY	($189.00)	$0.00	$0.00	($189.00)
AZDORI	ADOR ACCOUNTS PAYABLE	($1,735.20)	$54.80	$0.00	($1,680.40)
AZRE/RECORDING	ARIZONA DEPT OF REALESTATE	($2,042.00)	$0.00	$0.00	($2,042.00)
CARD	Cardon Hiatt / The Vineyrd Group	($105.00)	$0.00	$0.00	($105.00)
CRSI	Colorado Records Sooner Inc	($80.00)	$0.00	$0.00	($80.00)
CTS	COMPLETE TITLE SOLUTIONS	($24.00)	$1.00	$0.00	($23.00)
DS	DATA SERVICES	($1,000.00)	$0.00	$0.00	($1,000.00)
EPN	eRecording Partners Network	($1,000.00)	$0.00	$0.00	($1,000.00)
EQUIT	EQUITY SERVICES	($131.00)	$4.00	$0.00	($127.00)
EXCEL	EXCEL DOCUMENT SERVICES	($25.00)	$0.00	$0.00	($25.00)
FARES	CORELOGIC	($426.40)	$190.00	$0.00	($236.40)
FATM	FIRST AMERICAN MICROFICHE	($209.40)	$181.80	$0.00	($27.60)
FB	FLOYD BLEAK / NANCY SHEPPARD	($549.00)	$0.00	$0.00	($549.00)
FNDS	BLACK KNIGHT FINANCIAL SERVICES	($918.20)	$190.00	$0.00	($728.20)
GCCD	GILA COUNTY COMMUNITY DEVELOPMENT	$164.50	$0.00	$0.00	$164.50
HANSEN-ENGINEERING	HANSEN ENGINEERING & SURVEYING	($104.00)	$0.00	$0.00	($104.00)
IMAPP	IMAPP , INC	($53.40)	$0.00	$0.00	($53.40)
INDECOMM	INDECOMM	($1,000.00)	$90.00	($99.00)	($1,009.00)
INDEPTH	INDEPTH SOLUTIONS INC	($20.00)	$0.00	$0.00	($20.00)
Ingeo	Ingeo - eRecording	($1,055.00)	$534.00	($507.00)	($1,028.00)
IRS	INTERNAL REVENUE SERVICE	($82.00)	$112.00	($112.00)	($82.00)
LA001	First American Title Lenders Advantage	($428.50)	$0.00	$0.00	($428.50)
MHK	MORRIS HALL KINGHORN	($266.00)	$0.00	$0.00	($266.00)
NDTS-TSG	FIRST AMERICAN TITLE INSURANCE COMPANY	($877.00)	$0.00	$0.00	($877.00)
NewAcct1	Applied Technology Resources Inc	($200.00)	$0.00	$0.00	($200.00)
NTC	NATIONWIDE TITLE CLEARING	($1,000.00)	$138.00	($138.00)	($1,000.00)
PIONE	PIONEER TITLE AGENCY FICHE	($6,996.00)	$175.00	$0.00	($6,821.00)
PTP2	PIONEER TITLE AGENCY RECORDINGS 2	($3,486.00)	$3,551.00	($7,000.00)	($6,935.00)
Public Works Floodplain	Gila County	($100.00)	$0.00	$0.00	($100.00)

Immediate and Deferred Accounts: ACCU,ADOR-M,ADOT,APS,APSR,ARARS,AWC,AZDOR,AZDORI,AZRE/COPIES,AZRE/RECORDING,CARD,CRSI,CTS,DOCUT,DS,EPN,EQUIT,ERAY,EXCEL,FARES,FATM,FATR2,FB,FNDS,GCCD,HANSEN-ENGINEERING,IMAPP,INDECOMM,INDEPTH,Ingeo,IRS,IRS2,LA001,MHK,NBOA,NBOAC,NDTS-TSG,NewAcct1,NTC,PIONE,PTP2,Public Works Floodplain,RSSI,RUI,simplifile,SOUTHWES DIV,TD,Title 1 copy,tyler,VOTER

House Account ID	House Account Name	Starting Balance	Charges	Payments	Ending Balance
RSSI	RECORD SEARCHING SERVICES INC	($92.00)	$2.00	$0.00	($90.00)
RUI	RESEARCH UNLIMITED INC	($88.00)	$0.00	$0.00	($88.00)
simplifile	Simplifile - eRecording	($1,089.00)	$2,169.00	($2,062.00)	($982.00)
SOUTHWES DIV	FIRST AMERICAN TITLE	($1,104.20)	$0.00	$0.00	($1,104.20)
TD	Timely Documents	($100.00)	$0.00	$0.00	($100.00)
Totals		**($27,538.77)**	**$7,420.60**	**($9,918.00)**	**($30,036.17)**

ARF-2830 **Consent Agenda Item 4. M.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Reporting Period: September 30, 2014

Submitted For: Marian Sheppard, Clerk

Submitted By: Laurie Kline, Deputy Clerk, Clerk of the Board of Supervisors

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Information

Subject

September 30, 2014, Board of Supervisors' Special meeting minutes and the September 30, 2014, Work Session meeting minutes.

Suggested Motion

Approval of the September 30, 2014, Board of Supervisors' Special meeting minutes and the September 30, 2014, Work Session meeting minutes.

Attachments

09-30-14 BOS Special Meeting Minutes

09-30-14 BOS Work Session Meeting Minutes

BOARD OF SUPERVISORS MINUTES
GILA COUNTY, ARIZONA

Date: September 30, 2014

MICHAEL A. PASTOR Chairman	**MARIAN E. SHEPPARD** Clerk of the Board
TOMMIE C. MARTIN Vice-Chairman	By: Marian Sheppard Clerk of the Board
JOHN D. MARCANTI Member	Gila County Courthouse Globe, Arizona

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PRESENT: Michael A. Pastor, Chairman; Tommie C. Martin, Vice-Chairman (via ITV); John D. Marcanti, Member; Don E. McDaniel, Jr., County Manager; Bryan B. Chambers, Deputy County Attorney/Civil Bureau Chief; Marian E. Sheppard, Clerk of the Board; and Laurie J. Kline, Deputy Clerk.

COMMUNITY DEVELOPMENT DIVISION STAFF PRESENT: Bob Gould, Director; Scott Buzan, Chief Building Official; Jake Garrett, Environmental Engineering Manager; and Margie Chapman, Code Enforcement Supervisor (via ITV).

DEFENDANTS: Barbara Mahaffey, David Wicks and Kelly Mahaffey.

GUESTS: Mike Harper, Attorney for David Wicks and Kelly Mahaffey, and Karri Hansen.

Item 1 – CALL TO ORDER

The Gila County Board of Supervisors met in a special session at 3:00 p.m. this date in the Board of Supervisors' hearing room. Chairman Pastor called the meeting to order and announced the names and titles of County staff and others present at the meeting, both in Globe and Payson.

Item 2 - REGULAR AGENDA ITEMS:

A. Information/Discussion/Action to affirm, modify, or reverse the decision of the Gila County Hearing Officer regarding Community Development Division Complaint No. HCP1402-003.

Bob Gould, Community Development Division Director, advised the Board of Supervisors that due to some recent circumstances that occurred after the hearing with the Gila County Hearing Officer and before today's meeting, it has

forced the Community Development Division staff to reconsider its recommendation to the Board of Supervisors regarding a suggested motion on this case. Mr. Gould reviewed the Hearing Officer's ruling on this case, as follows: Defendant David Wicks was ordered to immediately pay a fine of $500; vacate the subject property within 72 hours; and pay a daily fine of $500 until the property is brought into compliance with County Building Code requirements. The deadline for compliance was set for September 12, 2014. (Note: Mr. Gould stated that Mr. Wicks was assessed the fines, etc.; however, the ruling also applies to Defendant Kelly Mahaffey.) Mr. Gould added that during that hearing, Defendant Barbara Mahaffey, owner of the subject property, stated that she would not allow a septic system to be installed on her property. Mr. Gould advised that because Mrs. Mahaffey stated that she would not allow a new septic system to be installed on her property, it would be impossible for Ms. Mahaffey and Mr. Wicks to bring the property into compliance.

Mr. Gould advised that on September 19, 2014, he met with Mrs. Mahaffey at which time she agreed to allow a septic system to be installed on her property, and she also agreed to allow Ms. Mahaffey and Mr. Wicks to temporarily live in an RV (recreational vehicle) on the property for 60 days until the septic system is installed.

Mr. Gould advised that he would propose some options for the Board's consideration. He stated that the first option would be to request that Mrs. Mahaffey allow the septic system to temporarily be reconnected to the house for up to 60 days until a new septic system would be installed; however, he added that it is actually not Mrs. Mahaffey's choice because the property where the septic system is located is owned by Mrs. Mahaffey's son, Kevin Mahaffey. Mr. Gould then provided some background information regarding this case, as follows: A one-acre parcel of land was initially purchased by Gerald Mahaffey (deceased) and Barbara Mahaffey, husband and wife. The parcel was split and one-half acre of land was deeded to Kevin Mahaffey. The initial intent was for Mr. and Mrs. Mahaffey to deed ownership of the other half-acre of land to their daughter, Kelly Mahaffey; however, to date Mrs. Mahaffey is the property owner. Each parcel of land contains a house. Kevin Mahaffey resides in a house on his property with Karri Hansen; and Kelly Mahaffey and David Wicks reside in a house that is owned by Mrs. Mahaffey. Since the initial installation of the septic system, it has provided wastewater service to both houses until recently when Kevin Mahaffey had the septic system capped to the house that is occupied by Ms. Mahaffey and Mr. Wicks. Mr. Gould stated that if permission were given for the septic system to be temporarily reconnected for up to 60 days, he would like the Board to also order Ms. Mahaffey and Mr. Wicks to submit plans for the installation of a new septic system to the County by October 3, 2014. If the plans are not submitted to the County by that date, he would like the Board to order Ms. Mahaffey and Mr. Wicks to vacate the property no later than October 8, 2014, and levy a $200 per day fine on the

property owner (Mrs. Mahaffey) and the occupants (Kelly Mahaffey and David Wicks) for non-compliance after the date of October 5, 2014. Mr. Gould advised that to date, Mr. Wicks has been assessed fines in the total amount of $25,200. Mr. Gould stated that if Mr. Wicks requests the Board to waive the fines, he would have no objections. Mr. Gould added that if plans are submitted to the County, he would like the Board to order that the porta-john be removed from the property due to complaints from neighboring property owners regarding odors. Mr. Gould and Jake Garrett, Environmental Engineering Manager, inspected the property last week and Mr. Gould advised that odors were not evident nor was there any wastewater on the ground; however, they both believe that it would be best to remove the porta-john if the RV is temporarily allowed to be used upon the property. If an RV is allowed upon the property, Mr. Gould advised that a temporary use permit must also be obtained from the County. He added that the septic system installation would need to be completed by November 24, 2014, and a Discharge Authorization and Certificate of Occupancy would need to be issued by the County no later than November 26, 2014. If the installation has not been completed and the Discharge Authorization and Certificate of Occupancy have not been issued by the County by November 26th, Mr. Gould recommends that the Board order Ms. Mahaffey and Mr. Wicks to vacate the property by December 1, 2014, of which that process is outlined in the County Building Code.

Chairman Pastor called on Mrs. Mahaffey to speak. Mrs. Mahaffey did not have any statements at this time; however, she offered to answer any questions. Mr. Gould then asked Mrs. Mahaffey if she thought there was any possibility that the septic system could be temporarily reconnected for 60 days. Karri Hansen replied "absolutely not" and she proceeded to explain that she and Keven Mahaffey chose to cap the system because the situation had become "volatile" between the occupants of both properties. Ms. Hansen advised that the power was on a shared system, and it has been disconnected to the house occupied by Ms. Mahaffey and Mr. Wicks. She stated that "ample" notice was provided to Ms. Mahaffey and Mr. Wicks before the power and septic system were disconnected from the house. Mrs. Mahaffey provided an explanation regarding Mr. Mahaffey's ownership of one-half of the original parcel of land and the reason Ms. Mahaffey had not been given ownership of the other half of the property. Chairman Pastor clarified that prior to the septic system being capped to the house occupied by Ms. Mahaffey and Mr. Wicks, both houses were using the same septic system for the past 16 years.

Mr. Wicks presented his position on this situation, as follows: It is his belief that the septic system is still connected because gray water has been released from the property onto Columbine (Road). The system has been capped, so he and Ms. Mahaffey have been "gravely injured by this situation." The location of the septic system should not be an issue because Ms. Mahaffey and Mr. Wicks have used that system for 16 years, and it is Mr. Wicks' belief that the County

would not have previously permitted the house to be built without confirming information related to a septic system for the house. He believes that Ms. Hansen instigated the capping of the septic system in order to drive Ms. Mahaffey and Mr. Wicks off of the property. He stated that testimony has been provided in justice court that the property is owned by Ms. Mahaffey. All of the non-compliance issues are a result of actions taken by Ms. Hansen and Mr. Mahaffey. He requested that the Board waive any fines imposed upon Ms. Mahaffey and himself due to this situation, and to impose any fines on Ms. Hansen and Mr. Mahaffey as they caused the situation. Prior to September 19, 2014, Mr. Wicks submitted plans for the new septic system to Mr. Garrett on two separate occasions. At no time was Mr. Wicks told to obtain Mrs. Mahaffey's signature on the plans.

In reference to Mr. Wicks' statement that the septic system is still connected to the home that he and Ms. Mahaffey occupy, Mr. Garrett confirmed that he has seen pictures which show that the septic line was cut and capped to the house.

Mike Harper, Attorney for Ms. Mahaffey and Mr. Wicks, advised that he represents Ms. Mahaffey in a pending court case with regard to the ownership of her property, which has been ongoing for a couple of years. He stated that there have been efforts made to remove Ms. Mahaffey and Mr. Wicks from the property. There were two separate forcible detainers efforts made by Mrs. Mahaffey to remove Ms. Mahaffey and Mr. Wicks from the property and Mrs. Mahaffey lost both cases. He emphasized that Ms. Mahaffey and Mr. Wicks used the septic system for 15 years until the line was capped. Capping the line caused the property to be in non-compliance because others decided the system should be capped and, as a result, there are fines assessed to Ms. Mahaffey and Mr. Wicks of approximately $25,000. After the septic line had been capped, Ms. Mahaffey and Mr. Wicks paid an engineer to develop plans for a new septic system. He knows that to be a fact because the engineer that was hired is Mr. Harper's father. He added that fines are being assessed daily to Ms. Mahaffey and Mr. Wicks, even though they took no action to cap the septic line. Mrs. Mahaffey is the property owner; however, it is Mr. Harper's clients that are being fined. To date, the County has refused to accept the plans for the new septic system. Mr. Harper advised that the plans are ready to be submitted to the County.

A discussion ensued as to the status of the plans for a new septic system to be installed on the subject property. Mr. Garrett summarized the actions that have been occurred to date regarding the plans. He verified that Mr. Wicks had tried twice to submit the plans to the County; however, when those plans were submitted the County was unable to accept them because there was no written proof that the property owner, Mrs. Mahaffey, had agreed to the plans. He advised that Mrs. Mahaffey has since signed a Power of Attorney document giving Mr. Wicks authority to install a new septic system on her property. The County also has a signed copy of the Power of Attorney document. Mr. Garrett

listed the remaining steps that need to be taken for the installation of a new septic system to be hooked up to the house that is occupied by Ms. Mahaffey and Mr. Wicks, as follows: 1) The plans need to be submitted to the County and at that time a fee needs to be paid (There is a $775 fee if the plans are submitted as an owner/builder, or a $475 fee if the owner chooses to have the system installed by a licensed contractor.); 2) Upon receipt of the plans and the fee, the County will review and approve the plans; 3) Mr. Wicks may then proceed to have the new septic system installed upon Mrs. Mahaffey's property. 4) The County will inspect the system several times during installation and then if it has been installed correctly, the County will issue the final approval documents.

Vice-Chairman Martin asked for clarification regarding the fees and she inquired if there would be a problem with the porta-john remaining on the property. Mr. Garrett clarified the fees that could be charged. He advised that per Arizona State law, a porta-john is allowed on the property if it is approved by a County ordinance; however, Gila County's ordinance is "silent" on that issue. Mr. Gould felt that a porta-john could be allowed on the property during the time a septic system is being installed as it would fall under the guise of the County Building Code Ordinance as long as there were no odors or wastewater on the ground from the porta-john.

Chairman Pastor asked Mr. Wicks if he was ready to submit the plans to the County. Mr. Wicks stated that the plans are ready to be submitted to the County, but his concern is the fines that have been assessed. He asked the Board to waive those fines as it will be a financial burden to pay for the materials and installation of the new septic system in addition to the expenses he has already paid regarding the septic system. If the fines cannot be waived, Mr. Wicks requested an extension of time to install the septic system due to his limited income. Vice-Chairman Martin replied that she would agree to waive the fines, but not any of the required County fees. Supervisor Marcanti expressed a desire to also come up with a resolution so that the septic system could be expeditiously installed. Mr. Gould reiterated his earlier comment that due to unusual circumstances pertaining to this particular case, it was impossible for Ms. Mahaffey and Mr. Wicks to comply with County requirements; therefore, he was in favor of the Board of Supervisors waiving the fees that, to date, total $25,200. Mr. Gould was more concerned with establishing a time frame for the installation of the septic system and he advised that a time frame of 60 days is ample.

The discussion then focused on the porta-john and whether or not it should be allowed to remain on the property during construction of the septic system. Mr. Wicks advised that since the time the porta-john was placed upon the property, it has been serviced on a weekly basis; and there have been no odors and no wastewater on the ground; therefore, he believes it has all been done "legally." He stated that he could place an RV upon the property during

construction. It was agreed that the porta-john could remain on the property for 60 days and an RV could be temporarily placed upon the property for 60 days in order to utilize running water with the condition that the gray water from the RV must not be released upon the property.

The Board discussed the information that would be required in their motion. Bryan Chambers, Deputy County Attorney/Civil Bureau Chief, advised the Board that in forming the motion, the Board may want to consider the course of action that needs be taken in the event that the septic system is not installed within the required 60-day time frame. He recommended that the Board of Supervisors continue this proceeding for 60 days and to have a provision included in the motion that at the end of the 60 days, the fines ($25,200) will be waived ***if*** all of the Board of Supervisors' requirements have been met. In that way, the Board would have a "built-in enforcement mechanism." The Board agreed to Mr. Chambers' recommendation.

Vice-Chairman Martin made a motion to hold this hearing open for 60 days to allow the occupants (Ms. Mahaffey and Mr. Wicks) to live in an RV upon the property that will contain the gray water; allow the use of a porta-john with the condition that it is serviced on a weekly basis; reduce the County's permitting fee to $475 for the installation of a new septic system; and at the end of the 60-day period, if the new septic system is in place, the Board of Supervisors will waive the fines totaling $25,200 and close the hearing. If the Board's requirements have not been met at the end of the 60 days, the Board will start proceedings to evict Ms. Mahaffey and Mr. Wicks from the property for non-compliance of the septic system. Supervisor Marcanti seconded the motion; however, Vice-Chairman Martin continued revising the motion as more comments were being made to which the Board members were in agreement as each change in the motion was added. Vice-Chairman Martin amended her motion to add that the Board is requiring the plans to be submitted to the County and she reiterated that the permitting fee would be reduced to $475 and that everything related to this issue must be completed within 60 days. Mr. Garrett suggested that the Board's motion include a deadline of November 24th to submit the final paperwork to the County because upon receipt of the final paperwork from Mr. Wicks, the County would need to do their final tests of the installed septic system and final paperwork. Mr. Gould suggested the date of December 1, 2014, as the end of the 60-day period. Vice-Chairman Martin added to her motion that December 5, 2014, would be better because "we may be more in line with fines that these folks have coming in." Chairman Pastor announced that December 5, 2014, would be the 60-day deadline. Scott Buzan, Chief Building Official, stated that gray water from the RV could not be released on the property. Mr. Chambers stated that if the Board is agreeing to the date of December 5, 2014, as the 60-day deadline; he suggested adding a date certain for the continuance of this hearing. He mentioned that December 5th is a Friday, and he suggested that the Board may want to set the date for a regular Board meeting day, which would be December 2nd. Vice-Chairman

Martin revised her motion by stating that December 9th would be a better day to set the hearing to which the Board agreed. Chairman Pastor stated that the motion was made and seconded, and he asked for the vote. Each Board member said "aye" to the vote, but before he announced that the motion passed with a unanimous vote, Vice-Chairman Martin advised that Mrs. Mahaffey had a question. Mrs. Mahaffey asked if there is a time frame to allow the RV upon the property or "just anytime we get around to it?" Chairman Pastor responded that Ms. Mahaffey and Mr. Wicks have 60 days (until December 5, 2014) to complete the entire project, so he recommended that actions need to be taken immediately in order to meet that 60-day deadline. In response to Mrs. Mahaffey's question, Vice-Chairman Martin stated that it is her expectation that Ms. Mahaffey and Mr. Wicks immediately move into the RV. Chairman Pastor added that it is also his expectation.

To ascertain that all Board members were in agreement to all of the requirements added to the motion, Chairman Pastor asked the Board for another vote on the motion. Each Board member voted in favor of the motion, and Chairman Pastor announced that the motion carried by a unanimous vote.

Complete Motion as Approved:

Vice-Chairman Martin made a motion to continue this hearing until December 9, 2014, to allow the owners/occupants to install an approved septic system on the property. The time between September 30, 2014, and December 9, 2014, shall be used to complete the installation of an approved septic system including: plan submittal, permit issuance, installation and final inspection & approval by the Community Development Department. The County agrees to reduce the permit fee to $475.00.

Further, during the time between September 30, 2014, and December 9, 2014, the owners/occupants are allowed to: 1) live in an RV on the property; 2) use the RV to collect the gray water only and properly dispose of it off-site; and, 3) use of a porta-john with the condition that it will be serviced and emptied on a no less than weekly basis.

Further, if at the December 9, 2014, continued hearing, all conditions have been met and the septic system has been installed and approved by the County, the Board of Supervisors will waive the fines totaling $25,200 and close the hearing. However, if at the December 9, 2014, continued hearing all conditions have not been met and the septic system has not been properly installed and approved by the County, the Board of Supervisors will immediately start proceedings to evict the owners/occupants from the property for non-compliance of the septic system regulations.

Item 3 - CALL TO THE PUBLIC: Call to the Public is held for public benefit to allow individuals to address the Board of Supervisors on any issue

within the jurisdiction of the Board of Supervisors. Board members may not discuss items that are not specifically identified on the agenda. Therefore, pursuant to Arizona Revised Statute §38-431.01(H), at the conclusion of an open call to the public, individual members of the Board of Supervisors may respond to criticism made by those who have addressed the Board, may ask staff to review a matter or may ask that a matter be put on a future agenda for further discussion and decision at a future date.

There were no comments from the public.

Item 4 - At any time during this meeting pursuant to A.R.S. §38-431.02(K), members of the Board of Supervisors and the County Manager may present a brief summary of current events. No action may be taken on issues presented.

There were no comments from the Board members or the County Manager.

There being no further business to come before the Board of Supervisors, Chairman Pastor adjourned the meeting at 3:55 p.m.

APPROVED:

_____

Michael A. Pastor, Chairman

ATTEST:

_____

Marian Sheppard, Clerk of the Board

BOARD OF SUPERVISORS MINUTES
GILA COUNTY, ARIZONA

Date: September 30, 2014

MICHAEL A. PASTOR Chairman	**MARIAN E. SHEPPARD** Clerk of the Board
TOMMIE C. MARTIN Vice-Chairman	By: Laurie J. Kline Deputy Clerk
JOHN D. MARCANTI Member	Gila County Courthouse Globe, Arizona

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PRESENT: Michael A. Pastor, Chairman; Tommie C. Martin, Vice-Chairman (via ITV); John D. Marcanti, Member; Don E. McDaniel, Jr., County Manager; Jacque Griffin, Assistant County Manager/Librarian; Bryan B. Chambers, Deputy County Attorney/Civil Bureau Chief; and Marian E. Sheppard, Clerk of the Board.

Item 1 – CALL TO ORDER - PLEDGE OF ALLEGIANCE

The Gila County Board of Supervisors met in a work session at 10:00 a.m. this date in the Board of Supervisors' hearing room. Steve Sanders led the Pledge of Allegiance.

Chairman Pastor moved regular agenda item 2-E directly after regular agenda item 2B.

Item 2 – REGULAR AGENDA ITEMS:

A. Information/Discussion/Action to approve an Intergovernmental Agreement-Economic Development Grant between Gila County and the Town of Star Valley in an amended amount of $10,000 to assist the Park Water Well Improvement Project which will allow the development of the B. Diane McDaniel Park and provide a back-up water supply for the citizens of Star Valley; and further the Board determines this is for the benefit of the public and will improve or enhance the economic welfare of the inhabitants of Gila County.

Don McDaniel, County Manager, introduced Shelley McPherson, the County's new Human Resources/Risk Management Director.

Mr. McDaniel then stated that this item is a request for economic development funds in order to upgrade a well-site in the Town of Star Valley and create an uninterrupted water supply in the event of a mechanical failure with the

current water systems. It is the recommendation of management staff to fund this request in the amount of $10,000 rather than the entire fund request of $26,329.

Supervisor Marcanti stated that he was contacted by the Timothy Grier, Town of Star Valley Manager, to discuss that there is only one primary water well site for the Town of Star Valley with a 160,000 gallon water storage tank. If the water well fails, there is an approximate two-day water supply. He added that these funds are being requested in order to bring the water well up to good working condition which will benefit the community. Supervisor Marcanti broke down the funding request as shown below and stated that he was in favor of funding the amount requested at this time.

Well rehabilitation - $ 1,810; new pump, wire, & pipe - $ 2,500; ADEQ new source water test - $ 2,769; connection plumbing & seal - $ 4,250; establish electricity - $15,000; TOTAL - $ 26,329

Chairman Pastor clarified that the Town of Star Valley has an upper and a lower water system to supply water to the community. The lower system utilizes the Milky Way and Quail Valley well sites which have been improved in capacity and efficiency with funding from Community Development Block Grants. The upper water system will utilize the Knolls, Pine Ridge the Knolls (PRTK) and the PRTK back up well sites to provide an adequate water supply. Chairman Pastor stated that he didn't have an issue granting this funding request in the amount of $10,000 as recommended by management staff; however, he would have an issue if the County is later asked to fund any further portions of the Town of Star Valley Park Water Well Improvement Project. Upon motion by Supervisor Marcanti, seconded by Vice-Chairman Martin, the Board unanimously approved an Intergovernmental Agreement-Economic Development Grant between Gila County and the Town of Star Valley in the amount of $26,329 to assist the Park Water Well Improvement Project, which will allow the development of the B. Diane McDaniel Park and provide a back-up water supply for the citizens of Star Valley; and further the Board determines this is for the benefit of the public and will improve or enhance the economic welfare of the inhabitants of Gila County.

B. Information/Discussion/Action to amend Policy No. BOS-FIN-003, Procurement-Purchasing, for immediate implementation to allow Gila County to use U.S. General Services Administration (GSA) contracts from time to time.

Jeff Hessenius, Finance Division Director, stated that this amendment will allow the County to have the option to utilize U.S. General Services Administration (GSA) contracts when it is prudent and beneficial to the County. Supervisor Marcanti was concerned that this may affect the local contractors' ability to participate in the competitive bidding process currently in use by the County. Steve Stratton, Public Works Division Director, replied

that the use of GSA contracts would be for the convenience of the County and not used as a common practice.

Mr. Hessenius concurred and stated that the GSA contracts would only be utilized when it would be financially advantageous to the County.

Chairman Pastor verified that this additional paragraph would be added to the existing County policy with regard to purchasing. Mr. Hessenius affirmed that Chairman Pastor was correct. Chairman Pastor asked Mr. Hessenius to send an email to County management staff for further review of the policy. He also requested Mr. Hessenius to email the newly amended policy to County employees to which Mr. Hessenius agreed. Upon motion by Vice-Chairman Martin, seconded by Supervisor Marcanti, the Board unanimously amended Policy No. BOS-FIN-003, Procurement-Purchasing, for immediate implementation to allow Gila County to use U.S. General Services Administration (GSA) contracts from time to time.

E. Information/Discussion regarding Amendment No. 3 to the Gila County Long Range Facilities Management Plan.

Mr. McDaniel provided a recap of the direction the Board has provided with regard to the Gila County Long Range Facilities Management Plan and the progress that has been made thus far. The NAPA building in Payson is to be used for court rooms, hearing rooms, offices or all of the above. Also, that the assistance of Caryn Paige, the County's internal architect, is needed to develop a sally port and a jail booking room on the north side of the jail in Payson. Additionally, it was recommended to obtain a price quote to install a modular building at the old auto shop location in Globe to house the Probation Department; it was discussed to order a formal appraisal of the Four Amigos property in Globe; and finally to confirm the appraisal of the Michaelson building that had previously been completed. These items have been completed and Steve Stratton, Public Works Division Director, is present to provide the Board with an update.

Mr. Stratton provided a slide presentation with the layout of the existing NAPA building for the Payson Courts site, the old shop area, and Globe new administration building. The Board had a discussion regarding the changes with regard to the Courts in Payson. He stated that he is aware of a couple of issues that have arisen with regard to the Courts in Payson which are being addressed. Chairman Pastor indicated that he was aware of a concern regarding "sight and sound" if juveniles are present. Vice-Chairman Martin stated that currently there are no juveniles housed in Payson. Another request was to have all of the courts in the same building including the Clerk of the Court, to which Mr. Stratton stated that the concern is being addressed and will be accommodated.

Mr. Stratton then briefly discussed the Globe facility changes. Chairman Pastor advised Mr. Stratton to work out the logistical issues with the Courts in Globe as well.

Supervisor Marcanti wanted clarification regarding the storage space. Mr. Stratton indicated that the County is exploring areas for off-site storage as well as a place to store microfilm for the County.

C. Information/Discussion/Action to approve the purchase of a 20,160 square-foot used modular building from Modular Solutions, Ltd. in the amount of $482,094.87, thereby reducing the amount of private office space currently being rented by Gila County because the Probation, Finance, Human Resources and Library District departments and personnel will be relocated to the newly acquired modular building.

Mr. Hessenius stated that Mr. Stratton was thorough in explaining the logistics and positive results of this phase of the Long Range Facilities Management Plan in the previous agenda item, and then stated that he would answer any questions. The Board had a discussion and agreed that this is a necessary action which will save the County money. There was further discussion regarding the method and terms of payment and Mr. Hessenius stated that it was decided to finance the modular building rather than pay cash because the amount of money saved by the Probation Department being moved from rented office space would pay for the modular building in a short period of time.

Chairman Pastor inquired as to the time frame of completion of this phase of the project. Mr. Stratton replied that there is a great deal of demolition and preparation work that is currently being completed. Bids are being received with regard to relocating the fuel tank in the old shop area, and the Finance Department staff is working on getting three quotes for that portion of the preparation work. He stated that the goal is to have this phase of the project completed in 6 to 8 months to avoid paying rent and an installment payment on the modular building.

Chairman Pastor inquired as to the meaning of "METRO" seam to which Mr. Stratton replied that line item is to put the modular building together at the seam. Chairman Pasto also verified that the total amount of $482,094.87 was all inclusive. Mr. Stratton stated that the amount, as stated, is all inclusive and the attachment to the agenda item is a breakdown of those costs.

Upon motion by Supervisor Marcanti, seconded by Vice-Chairman Martin, the Board unanimously approved the purchase of a 20,160 square-foot used modular building from Modular Solutions, Ltd. in the amount of $482,094.87, thereby reducing the amount of private office space currently being rented by Gila County because the Probation, Finance, Human Resources and Library District departments and personnel will be relocated to the newly acquired modular building.

D. Information/Discussion/Action to approve Modification 1 to Road Project Agreement No. 14-RO-11031200-022 between the United States Department of Agriculture, Forest Service, Tonto National Forest, and Gila County to extend the expiration date from September 30, 2014, to December 31, 2015, which will allow the County to use $342,644 in the Spring of 2015 to complete the aggregate resurfacing of Forest Road 512 (Young Road).

Mr. Hessenius stated that this item is for the County to remain in compliance with the end of the fiscal year time frame of United States Department of Agriculture, Forest Service, Tonto National Forest, and to extend the contract currently in place.

Steve Sanders, Public Works Deputy Director, added that there was some confusion as to the deadline of the submission of the agreement as described above; therefore, the agreement has been signed by the Chairman in order to meet the deadline of submission of the agreement to the Forest Service. Upon motion by Vice-Chairman Martin, seconded by Supervisor Marcanti, the Board unanimously approved Modification 1 to Road Project Agreement No. 14-RO-11031200-022 between the United States Department of Agriculture, Forest Service, Tonto National Forest, and Gila County to extend the expiration date from September 30, 2014, to December 31, 2015, which will allow the County to use $342,644 in the Spring of 2015 to complete the aggregate resurfacing of Forest Road 512 (Young Road).

F. Information/Discussion regarding the following Countywide Operational policy to be included in the Countywide Policy Manual: Policy No. BOS-ADM-001, Development, Review & Approval of Policies & Procedures.

Mr. McDaniel stated that this is a necessary policy in order to outline the expectations in terms of the format and the content of each policy that is brought before the Board. The policy clearly defines the importance of having policies and procedures that are uniform and consistent before they are brought to the Board for final adoption. It also outlines the policy review process; specifically, any new or revised policy is presented to the Countywide Policies Committee, followed by the management team and the County Attorney. It is then reviewed with the Board during a work session and finally brought to the Board for final adoption.

Supervisor Marcanti stated that he thought it was the responsibility of the Clerk of the Board to set up the policy format and that it would take too much time to get a policy ready for adoption by the Board. Vice-Chairman Martin stated that she agreed that it may take quite some time to get a policy adopted by the Board using this method. Mr. McDaniel explained that the final end product is far superior when using this procedure because the time has been invested by management staff to formulate a more complete, comprehensive,

and well-thought out policy to present to the Board. He advised that process has been followed for the past four years, but the formal policy is now being presented to the Board for adoption.

Marian Sheppard, Clerk of the Board, agreed that this procedure has been in place for approximately four years and she believes that it works very well to maintain uniformity and consistency, but more importantly it allows for a review by County staff at many levels.

Item 3 – CALL TO THE PUBLIC: Call to the Public is held for public benefit to allow individuals to address the Board of Supervisors on any issue within the jurisdiction of the Board of Supervisors. Board members may not discuss items that are not specifically identified on the agenda. Therefore, pursuant to Arizona Revised Statute §38-431.01(H), at the conclusion of an open call to the public, individual members of the Board of Supervisors may respond to criticism made by those who have addressed the Board, may ask staff to review a matter or may ask that a matter be put on a future agenda for further discussion and decision at a future date.

There were no comments from the public.

Item 4 – At any time during this meeting pursuant to A.R.S. §38-431.02(K), members of the Board of Supervisors and the County Manager may present a brief summary of current events. No action may be taken on issues presented.

Each Board member presented information on current events.

There being no further business to come before the Board of Supervisors, Chairman Pastor adjourned the meeting at 11:32 a.m.

APPROVED:

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Michael A. Pastor, Chairman

ATTEST:

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Marian Sheppard, Clerk of the Board

ARF-2819 **Consent Agenda Item 4. N.**

Regular BOS Meeting

Meeting Date: 10/21/2014

Reporting Period: September 26, 2014; and October 3, 2014

Submitted For: Jeffrey Hessenius, Finance Director

Submitted By: Jeannie Sgroi, Contracts Administrator, Finance Division

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Information

Subject

Report for County Manager Approved Contracts Under $50,000 for Weeks Ending 9-26-14; and 10-3-14.

Suggested Motion

Acknowledgment of contracts under $50,000 which have been approved by the County Manager for the weeks of September 22, 2014, to September 26, 2014; and September 29, 2014, to October 3, 2014.

Attachments

Report for County Manager Approved Contracts Under $50,000 for Weeks Ending 9-26-14, and 10-3-14

Gold Service Agreement with ThyssenKrupp Elevator Corporation

Service Contract Agreement CNT003055-06 with Multicard

Professional Services Contract No. 091514-2 with Kimley-Horn and Associates

Amendment No. 1 to Service Agreement No. 071613-1 with TAPI

Service Agreement No. 071814 with Hye Tech Network and Security Solutions

Renewal with West-Thomson Reuters

Service Agreement No. 092914 with Mountain Retreat Builders

Amendment No. 1 to Service Agreement No. 082814 with Mountain Retreat Builders

Amendment No. 1 to Professional Services Contract No. 060914 with Brad Crider

Authorization to Utilize City of Avondale Contract for Electrified Touch-Sense Panic Bars

Amendment No. 1 to Service Agreement No. 043014 with Advanced Controls

COUNTY MANAGER APPROVED CONTRACTS UNDER $50,000

September 22, 2014 to September 26, 2014

Number / Vendor	Title	Amount	Term	Approved	Renewal Option	Summary
ThyssenKrupp Elevator Corporation	Gold Service Agreement	$7,506.24 plus sales tax	7-1-14 to 6-30-19	9-24-14	Automatically Renews	ThyssenKrupp Elevator has serviced the County elevators since 2000. They have always responded promptly when we have called them with a problem. Annual costs, not including parts or labor for non-covered repairs is less than $8000. If a need arises for repairs not covered, an amendment will need to be issued to increase the contract amount.
CNT003055-06 Multicard	Service Contract Agreement No. CNT003055-06	$1,520.00	8-15-14 to 8-14-15	9-24-14	Expires	Renewal for Maintenance Agreement on the two Sheriff's Office fingerprint scanners, card printers and related equipment. Includes one preventative maintenance service per year per card printer and all parts, labor, travel and mileage. Consumables not included.
091514-2 Kimley-Horn & Associates	Professional Services Contract No. 091514-2 Final Work Performed under Contract No. SS71803D New Bridge over Tonto Creek	$3,248.74	9-24-14 to 9-23-15	9-24-14	Expires	Tonto Creek Bridge geotechnical borings at the bridge site changed with the flooding in January 2010. The creek bottoms were rearranged, creating ditches and berms that would not allow access for the drill rigs. The borings were requested to discover approved depth of pylons for the bridge. Due to an amendment error in Amendment No. 2 which was executed on 09-06-11, additional monies for the extra cost to bring in a contractor to correct the creek bottom was not added to the Amendment. Per Public Works, this was during a transition period for Finance and Public Works and the rules were not clearly defined for changes under $50,000. After consulting with Bryan Chambers, this contract has been issued to pay the final amount due for those additional costs omitted from Amendment #2.

September 22, 2014 to September 26, 2014

Number / Vendor	Title	Amount	Term	Approved	Renewal Option	Summary
071613-1 The Arizona Partnership for Immunization	Amendment No. 1 to Service Agreement No. 071613-1 Immunization-Cost Recovery Program-Billing	See summary	8-21-14 to 8-20-15	9-24-14	Option to renew for one (1) one (1) year period.	The contractor shall coordinate billing services in order for the County Health Department to be compensated for immunization services provided to health plan members. The first year the county will receive 70% of the claims received. Over time that percentage will go up as more counties and public health clinics share the cost of the program. This contract term expires August 20, 2014. Amendment No. 1 will serve to extend the contract term to August 20, 2015.
071814 Hye Tech Network & Security Solutions, LLC	Service Agreement No. 071814 UC Upgrade	Not to exceed $15,500.00	8-1-14 to 6-30-15	9-24-14	Expires	Contractor will upgrade our current VoIP phone system from version 7 to the newest version, and change platform from physical servers to virtual servers.
Thomson Reuters/West	West Order Form-Conversion to Assured Print Pricing Service	$3,107.61	36 Complete Calendar Months	9-24-14	Expires at the end of 36 complete calendar months	The County subscribes to the service provided by Thomson Reuters/West to received updates for Arizona Revised Statutes as they become available.

September 29, 2014 to October 3, 2014

Number / Vendor	Title	Amount	Term	Approved	Renewal Option	Summary
092914 Mountain Retreat Builders	Service Agreement No. 092914 Weatherization Project No. HH#8139	$4,555.00	10-1-14 to 6-30-15	10-1-14	Expires	The purpose of this weatherization project is to improve quality of life, reduce utility costs, and improve the health and safety for HH#9401's home. The need for this weatherization project fits into the Housing Departments mission, "Improving the quality of life for all residents, one life at a time". This project includes, but is not limited to, repair furnace, service furnace, service cooler, install ASHREA fan, repair belly pan and install new skirting.
082814 Mountain Retreat Builders	Amendment No. 1 to Service Agreement No. 082814 Major Rehabilitation No. HH#9834	$650.00	7-1-14 to 6-30-15	10-1-14	Expires	Scope of work to include, but not limited to: remove infiltration, install ASHREA Fan, Remove cooler in living room and seal up, DUCT leakage, install split system, repair belly pan and insulate as needed. Amendment No. 1 has been issued to cover the additional cost for replacing Electric Dryer with Gas Dryer to free up power necessary for AC Electric.
060914 Brad Crider	Amendment No. 1 to Professional Services Contract No. 060914 Legal Services	N/A	6-24-14 to 6-25-15	10-1-14	Expires	Contractor provides legal services to the Gila County Superior Court. Amendment No. 1 has been issued to clarify the billing and payment language contained in the executed contract. Per BOS–FIN-002, if neither the scope or amount of the originally Board approved contract has been changed, the County Manager has the authority to execute an amendment to the contract.
13412 Stanley Security Solutions	Authorization to Utilize City of Avondale contract with Stanley Security Solutions for Electrified Touch-Sense Panic Bars	$6,995.34	10-1-14 to 10-17-14	10-1-14	Expires	Current panic bars on all main double doors in the Globe Courthouse have a sensor allowing the contact to break when someone comes close in order to allow access out or in. Unless the doors are retrofitted with new panic bars, the potential for entries without access cards is a distinct possibility. Installation will take from 2 to 3 days, depending upon court traffic.

September 29, 2014 to October 3, 2014

Number / Vendor	Title	Amount	Term	Approved	Renewal Option	Summary
043014 Advanced Controls Corporation	Amendment No. 1 to Service Agreement No. 043014 Fire Alarm System Inspections and Repair	$5,000.00	1-1-14 to 12-31-15	10-1-14	Expires	Inspections of all Fire Alarm Panels in Gila County Buildings in accordance with International Fire Code annual inspection 901.6.1 (Fire protection systems shall be inspected, tested and maintained in accordance with the referenced standards). Amendment No. 1 will serve to increase the contract amount for various repairs to fire panels and smoke alarms in Gila County buildings, should the need arise.

Gold Service Agreement

Purchaser: GILA COUNTY FINANCE DEPT
1400 E ASH ST
GLOBE, AZ 85501-1483

Hereinafter referred to as "Purchaser", "you", and "your".

By: ThyssenKrupp Elevator Corporation
3902 E. University Dr. Suite 1
Phoenix, AZ 85034
Phone: 602-257-0216
Fax: 602-258-2641
www.thyssenkruppelevator.com

Hereinafter referred to as "ThyssenKrupp Elevator Corporation", "ThyssenKrupp Elevator", "we", "us" and "our".

GOLD SERVICE AGREEMENT

ThyssenKrupp Elevator agrees to maintain Purchaser's elevator equipment described below in accordance with this agreement. We will endeavor to provide a comprehensive maintenance program designed to protect your investment and maximize the performance, safety, and life span of the elevator equipment to be maintained.

Equipment To Be Maintained

Building Name	Building Location	Manufacturer	Type Of Unit	Unit ID	# Of Stops	
GILA COUNTY COURTHOUSE	1400 E ASH ST	Dover	Hydraulic	US60187 Ser# E46955	3 -stops	DC
GILA COUNTY COURTHOUSE	1400 E ASH ST	Dover	Hydraulic	US60188 Ser# E46956	3 -stops	DC

ThyssenKrupp

COPY

Gold Service Agreement

Purchaser: GILA COUNTY FINANCE DEPT
1400 E ASH ST
GLOBE, AZ 85501-1483

Hereinafter referred to as "Purchaser", "you", and "your".

By: ThyssenKrupp Elevator Corporation
3902 E. University Dr. Suite 1
Phoenix, AZ 85034
Phone: 602-257-0216
Fax: 602-258-2641
www.thyssenkruppelevator.com

Hereinafter referred to as "ThyssenKrupp Elevator Corporation", "ThyssenKrupp Elevator", "we", "us" and "our".

GOLD SERVICE AGREEMENT

ThyssenKrupp Elevator agrees to maintain Purchaser's elevator equipment described below in accordance with this agreement. We will endeavor to provide a comprehensive maintenance program designed to protect your investment and maximize the performance, safety, and life span of the elevator equipment to be maintained.

Equipment To Be Maintained

Building Name	Building Location	Manufacturer	Type Of Unit	Unit ID	# Of Stops
GILA COUNTY COURTHOUSE	1400 E ASH ST	Dover	Hydraulic	US60187	3
GILA COUNTY COURTHOUSE	1400 E ASH ST	Dover	Hydraulic	US60188	3

Gold Service Agreement

Preventative Maintenance Program
We will service your equipment described in this agreement on a regularly scheduled basis. These service visits will be performed during normal business working days and hours, which are defined as Monday through Friday, 7:30 AM to 4:30 PM (except scheduled holidays). All work performed before or after normal business working days and hours shall be considered "Overtime".

ThyssenKrupp Elevator will perform the following services:

- Examine your elevator equipment for optimum operation. Our examination, lubrication and adjustment will cover the following components of your elevator system:
  - Control and landing positioning systems
  - Signal fixtures
  - Machines, drives, motors, governors, sheaves, and wire ropes
  - Power units, pumps, valves, and jacks
  - Car and hoistway door operating devices and door protection equipment
  - Loadweighers, car frames and platforms, and counterweights
  - Safety mechanisms
- Lubricate equipment for smooth and efficient performance
- Adjust elevator parts and components to maximize performance and safe operation

Full Coverage Parts Repair and Replacement
ThyssenKrupp Elevator will provide full coverage parts repair and/or replacement for all components worn due to normal wear, unless specifically excluded in the "Items Not Covered" or "Other Conditions" provisions herein. We maintain a comprehensive parts inventory to support our field operations. All replacement parts used in your equipment will be new or refurbished to meet the quality standards of ThyssenKrupp Elevator. Most specialized parts are available within 24 hours, seven days a week. We will relamp all signals as required (during regularly scheduled visits).

Maintenance Control Program
ThyssenKrupp Elevator performs service in accordance with A17.1 – 2010 / CSA B44-10. Section 8.6 of the code requires the unit owner to have a Maintenance Control Program (MCP), ThyssenKrupp's MCP meets or exceeds all requirements outlined in Section 8.6. The Maintenance Control Program includes ThyssenKrupp Elevator's Maintenance Tasks & Records documentation which shall be used to record all maintenance, repairs, replacements and tests performed on the equipment and is provided with each unit as required by code. ThyssenKrupp Elevator also provides per Section 8.6 of the code, a maintenance tasks procedures manual with each unit; TKE calls this manual the BEEP Manual, or Basic Elevator, Escalator Procedures Manual. We do not perform any tests unless such tests are specifically listed as included elsewhere in this agreement.

Quality Assurance
To help increase elevator performance and decrease downtime, our technicians utilize the latest industry methods and technology available to us for your specific brand of elevator. They will be equipped with our tools, documentation and knowledge to troubleshoot your unique system, as well as access to a comprehensive parts replacement inventory system.

Behind our technicians is a team devoted to elevator excellence. Technicians are supported around the clock by a team of engineers and field support experts. Our North American technical support facilities continuously research advancements in the industry and in your equipment. Also, our internal quality control program ensures optimum and reliable operation of your elevator equipment.

To assure that quality standards are being maintained, we may conduct periodic field quality audit surveys. Your

dedicated ThyssenKrupp Elevator representative will be available to discuss your elevator needs with you in all aspects of service and modernization. In addition, you may receive recommendations for upgrades that will also provide you with budget options designed to enhance the appearance, performance and safety of or meet Code requirements for your equipment over time.

Service Requests During Normal Working Days and Hours

Service requests are defined as any request for dispatch of our technician to the location of the equipment covered in this agreement from one or more of the following: you or your representative, the building or building's representative, emergency personnel, and/or passengers through the elevator's communication device and/or from Vista Remote Monitoring through the elevator's communication line. Service requests include minor adjustments and response to emergency entrapments that can be accomplished in two hours or less (excluding travel time) and do not include regularly scheduled maintenance visits.

We will respond to service requests during normal business working days and hours, as defined above, at no additional charge.

Overtime Service Requests

On all overtime service requests, you will be responsible for all labor costs including travel time, travel expenses, and time spent on the job. Such costs will be invoiced at our standard overtime billing rates. Overtime service requests are performed before or after normal business working days and hours.

☒ **VIEW®**

VIEW is Thyssen Krupp Elevator's customer oriented, online service activity reporting system. VIEW allows building owners and managers to monitor maintenance and service call activity. VIEW can be accessed via the Internet any time, day or night. You can "VIEW" service tickets associated with a single elevator serviced under this agreement, for all the elevators at the locations serviced under this agreement, or across an entire portfolio of elevator equipment that is serviced by ThyssenKrupp Elevator. Special considerations regarding VIEW are included herein.

☐ **VISTA®(Check box if included)**

VISTA Remote Monitoring is ThyssenKrupp Elevator's exclusive service for monitoring the status and performance of you elevator(s). VISTA monitors compatible equipment 24 hours per day, 7 days per week,and 365 days per year. Constantly monitor performance data on your equipment provides ThyssenKrupp Elevator the ability to respond to operational irregularities quickly and more efficiently. With VISTA, we can often dispatch a service technician to your location before any interruption in elevator service occurs. Service visits based on VISTA data will be made during normal business hours on normal business days.

☒ **ThyssenKrupp Communications® (Check box if included)**

ThyssenKrupp Communications is ThyssenKrupp Elevator's 24-hour telephone monitoring and emergency call service. Our representatives are trained to handle elevator calls and they can assess the situation and quickly dispatch a technician when necessary. If needed, they can stay on the line to reassure a stranded passenger that help is on the way. ThyssenKrupp Communications maintains digital recordings and computerized records of the time, date, and location of calls received and action taken for the benefit of passengers and building owners. Special considerations regarding ThyssenKrupp Communications are set forth below.

Through its centralized ThyssenKrupp Communications call center, ThyssenKrupp Elevator will provide 7 days per week, 24 hours per day, 365 days per year dispatching service for calls placed by Purchaser after normal business working days and hours to the local ThyssenKrupp Elevator branch office and telephone monitoring on all elevator(s) maintained under this Agreement that have operational telephone equipment capable of placing a call to that call center. Depending on the nature of the call and circumstances, ThyssenKrupp Elevator's operators can call one or more of the following: Purchaser's

Gold Service Agreement

Designated Contacts set forth in Section 2 below; Local Emergency Services at phone numbers provided by Purchaser in Section 3 below; and/or a local ThyssenKrupp Elevator service technician to be dispatched to the location of the equipment.

Purchaser hereby acknowledges that as a condition precedent to ThyssenKrupp Elevator's placement of calls to Purchaser's Designated Contacts and any Local Emergency Services under this Agreement, Purchaser must first complete Sections 1 and 2 below. Purchaser further acknowledges that it is Purchaser's sole responsibility to advise ThyssenKrupp Elevator immediately in writing of any changes to the information contained in those two (2) sections during the term of this Agreement. Purchaser acknowledges that no revision to that information will be made without ThyssenKrupp Elevator first receiving such request in writing from Purchaser's authorized representative.

Under those circumstances where ThyssenKrupp Elevator is unable to reach Purchaser's Designated Contacts set forth in Section 2 below, Purchaser hereby gives ThyssenKrupp Elevator express permission to dispatch a ThyssenKrupp Elevator service technician to the location of the equipment at Purchaser's expense in accordance with ThyssenKrupp Elevator's applicable billing rates. Purchaser further agrees that ThyssenKrupp Elevator does not assume any duty or responsibility to advise any caller, regardless of his or her location within or outside the elevator, to take or not take any specific action resulting from a medical or other emergency or any other situation including, but not limited to, entrapment of persons, evacuation, repair or return to service of any equipment.

In the event that a ThyssenKrupp Elevator call center operator perceives that a call from within the elevator constitutes a medical or other emergency, Purchaser hereby gives ThyssenKrupp Elevator the express permission to call Local Emergency Services at the telephone numbers provided by the Purchaser in Section 3 below at ThyssenKrupp Elevator's sole discretion. Under those circumstances, Purchaser agrees to pay all related charges for services provided by any Local Emergency Services in response to that call. Purchaser agrees that ThyssenKrupp Elevator shall not be responsible for ensuring an appropriate (or any) response by Local Emergency Services to that call.

None of the services described anywhere in this Agreement includes maintenance of any type or kind of the Purchaser's telephone or other communication equipment. The Purchaser retains possession and control of its telephone and other communication equipment and is responsible for ensuring uninterrupted operation of that equipment so that it is capable of placing a call to ThyssenKrupp Communication's call center.

Gold Service Agreement

ThyssenKrupp Communications Contact Information - To Be Completed by Purchaser

Section 1, Elevator Detail:

Total number of elevators in Building : 2

Elevator #	Elevator Telephone Number including Area Code		Elevator #	Elevator Telephone Number including Area Code
#1				
#2				

Section 2, Purchaser Designated Contacts:

In the event of an emergency, or perceived emergency affecting the equipment covered by this Agreement, the Purchaser designates the following as its decision-making contacts:

		Contact Name	Title	Primary Telephone #	Secondary Telephone #
X	1	ROBERT HICKMAN	FACILITIES MANAGER	928-200-1643	928-402-8591
X	2	DAVID HOM	FACILITIES LEAD TECH	928-200-1641	928-402-4259
X	3	STEVE STRATTON	PUBLIC WORKS DIRECTOR	928-812-0173	928-402-8501

Section 3, Local Emergency Services Contact Information:

Phone # for Local Police Department: (928) 402-1872 SHERIFF DISPATCH

Phone # for Local Fire Department: (928) 425-4431

Section 4, Purchaser's Special Instructions:

The following are special instructions provided by Purchasers with respect to the information supplied above:

☒ **Periodic Safety Testing (Check box if included)**

ThyssenKrupp Elevator will test your equipment in accordance with those periodic testing requirements as outlined in the American National Safety Code for Elevators and Escalators, ANSI A 17.1, which are in effect at the time this agreement is executed. In the event that the state, city or local governing authority in which the equipment is located has adopted different requirements, ThyssenKrupp Elevator will test your equipment in accordance with those periodic testing requirements in effect at the time this agreement is executed. You agree to pay for any costs of the inspector and/or inspection fees. Special Considerations regarding periodic safety testing are set forth below.

Product Information

You agree to provide ThyssenKrupp Elevator with current wiring diagrams that reflect all changes, parts catalogs, and maintenance instructions for the equipment covered by this agreement (exception: we will supply all of the above for new ThyssenKrupp elevators at no additional cost). You agree to authorize us to produce single copies of any programmable device(s) used in the equipment for the purpose of archival back-up of the software embodied therein. These items will remain your property.

Safety

You agree to instruct or warn passengers in the proper use of the equipment and to keep the equipment under continued surveillance by competent personnel to detect irregularities between elevator examinations. You agree to immediately report any condition that may indicate the need for correction before the next regular examination. You agree to immediately shut down the equipment upon manifestation of any irregularities in either the operation or the appearance of the equipment, to immediately notify us, and to keep the equipment shut down until the completion of any repairs. You agree to give us immediate verbal notice and written notice within ten (10) days after any occurrence or accident in or about the elevator. You agree to provide our personnel with a safe place to work. You agree to provide a suitable machine room, including secured doors, waterproofing, lighting, ventilation, and appropriate air temperature control to maintain that room at a temperature between 50°F and 90°F. You also agree to maintain the elevator pit in a dry condition at all times. Should water or other liquids become present, you will contract with others for removal and the proper handling of such liquids. We reserve the right to discontinue work in the building whenever, in our sole opinion, our personnel do not have a safe place to work. You also agree that if ThyssenKrupp Elevator's inspection of a piece of equipment serviced under this agreement reveals an operational problem which, in ThyssenKrupp Elevator's sole judgment, jeopardizes the safety of the riding public, ThyssenKrupp Elevator may shut down the equipment until such time as the operational problem is resolved. In that event, ThyssenKrupp Elevator will immediately advise you in writing of such action, the reason for such action, and whether any proposed solution is covered by the terms of this agreement.

Other

You agree not to permit others to make alterations, additions, adjustments, or repairs or replace any component or part of the equipment during the term of this agreement. You agree to accept our judgment as to the means and methods employed by us for any corrective work under this agreement. Since ThyssenKrupp Elevator's top priority is the satisfaction of its customers, if you should have any concern(s) with the means and methods used to maintain or repair the equipment covered under this agreement, you agree to provide us with written notice of that concern and give us thirty (30) days to respond either in writing or commence action to appropriately resolve it.

In the event of the sale, lease or other transfer of the ownership or management of the premises in which the elevator(s) or equipment described herein are located, you agree to see that such transferee is made aware of this agreement and agrees to assume and/or be bound by the conditions hereof for the balance of the unexpired term of this agreement. Should the transferee fail to assume this agreement, you shall remain liable for all unpaid amounts, including those owed for the balance of the current unexpired term of this agreement.

In consideration of ThyssenKrupp Elevator performing the services herein specified, you expressly agree, to the fullest extent permitted by law, to indemnify, defend, save harmless, discharge, release and forever acquit ThyssenKrupp Elevator Corporation, our employees, officers, agents, affiliates, and subsidiaries from and against any and all claims, demands, suits, and proceedings brought against ThyssenKrupp Elevator, our employees, officers, agents, affiliates and subsidiaries for loss, property damage (including damage to the equipment which is the subject matter of this agreement), personal injury or death that are alleged to have been caused by the Purchaser or any others in connection with the presence, use, misuse, maintenance, installation, removal, manufacture, design, operation or condition of the equipment covered by this agreement, or the associated areas surrounding such equipment. Your duty to indemnify does not apply to the extent that the loss, property damage (including damage to the equipment which is the subject matter of this agreement), personal injury or death is determined to be caused by or resulting from the negligence of ThyssenKrupp Elevator and/or our employees. You recognize that your obligation to ThyssenKrupp Elevator under this clause includes payment of all attorney's fees, court costs, judgments, settlements, interest and any other expenses of litigation arising

out of such claims or lawsuits.

Insurance

You expressly agree to name ThyssenKrupp Elevator Corporation along with its officers, agents, affiliates and subsidiaries as additional insureds in your liability and any excess (umbrella) liability insurance policy(ies). Such insurance must insure ThyssenKrupp Elevator Corporation, along with its officers, agents, affiliates and subsidiaries for those claims and/or losses referenced in the above paragraph, and for claims and/or or losses arising from the sole negligence or responsibility of ThyssenKrupp Elevator Corporation and/or its officers, agents, affiliates and subsidiaries. Such insurance must specify that its coverage is primary and non-contributory. You hereby waive the right of subrogation.

Items Not Covered

We do not cover cosmetic, construction, or ancillary components of the elevator system, including the finishing, repairing, or replacement of the cab enclosure, ceiling frames, panels, and/or fixtures, hoistway door panels, door frames, swing door hinges and closing devices, sills, car flooring, floor covering, lighting fixtures, ceiling light bulbs and tubes, main line power switches, breaker(s), feeders to controller, below ground or unexposed hydraulic elevator system, including but not limited to, jack cylinder, piston, PVC or other protective material; below ground or unexposed piping, alignment of elevator guide rails, smoke and fire sensors, fire service reports, all communication and entertainment devices, security systems not installed by us, batteries for emergency lighting and emergency lowering, air conditioners, heaters, ventilation fans, pit pumps and all other items as set forth and excluded in this agreement.

Other Conditions

With the passage of time, equipment technology and designs will change. If any part or component of your equipment covered under this agreement cannot, in our sole opinion, be safely repaired and is no longer stocked and readily available from either the original equipment manufacturer or an aftermarket source, that part or component shall be considered obsolete. You will be responsible for all charges associated with replacing that obsolete part or component as well as all charges required to ensure that the remainder of the equipment is functionally compatible with that replacement part or component. In addition, we will not be required to make any changes or recommendations in the existing design or function of the unit(s) nor will we be obligated to install new attachments or parts upon the equipment as recommended or directed by insurance companies, governmental agencies or authorities, or any other third party. Moreover, we shall not be obligated to service, renew, replace and/or repair the equipment due to any one or more of the following: anyone's abuse, misuse and/or vandalism of the equipment; anyone's negligence in connection with the use or operation of the equipment; any loss of power, power fluctuations, power failure, or power surges that in any way affect the operation of the equipment; fire, smoke, explosions, water, storms, wind, lightening, acts of civil or military authorities, strikes, lockouts, other labor disputes, theft, riot, civil commotion, war, malicious mischief, acts of God, or any other reason or cause beyond our control that affects the use or operation of the equipment. You expressly agree to release and discharge us and our employees for any and all claims and/or losses (including personal injury, death and property damage, specifically including damage to the property which is the subject matter of this agreement) associated therewith or caused thereby. ThyssenKrupp Elevator shall also automatically receive an extension of time commensurate with any delay in performance caused by or related to the aforementioned and you expressly agree to release and discharge ThyssenKrupp Elevator from any and all claims for consequential, special or indirect damages arising out of the performance of this agreement. In no event shall ThyssenKrupp Elevator's liability for damages arising out of this agreement exceed the remaining unpaid installments of the current, unexpired term of this agreement

Should your system require any of the safety tests on the commencement date of this agreement, ThyssenKrupp Elevator assumes no responsibility for the day-to-day operation of the governor or safeties on traction elevators, or the hydraulic system on hydraulic elevators under the terms of this agreement until the test has been completed and the equipment passed. Should the respective system fail any of those tests, it shall be your sole responsibility to make necessary repairs and place the equipment in a condition that we deem acceptable for further coverage under the terms of this agreement. We shall not be liable for any damage to the building structure or the elevator resulting from the

performance of any safety tests we perform at any time under this agreement. If during the initial firefighter's service test, that feature is found to be inoperable, you shall be responsible for all costs associated with necessary repair(s) to bring the elevator(s) into compliance with the applicable elevator codes in your local jurisdiction.

In the event an Attorney is retained to enforce, construe or defend any of the terms and conditions of this agreement or to collect any monies due hereunder, either with or without litigation, the prevailing party shall be entitled to recover all costs and reasonable attorney's fees.

You hereby waive trial by jury. You agree that this agreement shall be construed and enforced in accordance with the laws of the state where the equipment is located. You consent to jurisdiction of the courts, both state and Federal, of the state in which the equipment is located as to all matters and disputes arising out of this agreement.

In the event any portion of this agreement is deemed invalid or unenforceable by a court of law, public policy or statute, such finding shall not affect the validity or enforceability of any other portion of this agreement.

Our rights under this agreement shall be cumulative and our failure to exercise any rights given hereunder shall not operate to forfeit or waive any of said rights and any extension, indulgence or change by us in the method, mode or manner of payment or any of its other rights shall not be construed as a waiver of any of its rights under this agreement.

Price.
The price for the services as stated in this agreement shall be Six Hundred Twenty Five Dollars and Fifty Two Cents ($625.52) per month, excluding taxes, payable Quarterly in advance.

Term
This agreement is effective for Sixty (60) month(s) starting 07/01/2014 and is non-cancelable. To ensure continuous service, this agreement will be automatically renewed for successive Sixty (60) month periods, unless either party timely serves written notice upon the other party of its intention to cancel renewal at least ninety (90) days but not more than 120 days before the end of the initial Sixty (60) month period, or at least ninety (90) days but not more than 120 days before the end of any subsequent Sixty (60) month renewal period. Notice shall be sent by certified mail, return receipt requested to the address set forth on page 1 of this agreement. Time is of the essence.

Annual Price Adjustments
Since our costs to provide you with the service set forth in this agreement may increase, we reserve the right to adjust the price of our service under this agreement accordingly. In the event this occurs, we will adjust your monthly price based on the percentage change in the average rate paid to elevator examiners. This rate paid to elevator examiners consists of the hourly rate paid to examiners plus fringe benefits and union welfare granted in place of or in addition to the hourly rate. Fringe benefits include pensions, vacations, paid holidays, group insurance, sickness and accident insurance, and hospital insurance. We also reserve the right to make additional adjustment to the price of our service under this agreement and/or enact surcharges as needed to account for increased fuel prices when such increases exceed the Consumer Price Index (CPI) current rate. We also reserve the exclusive right to make additional adjustment to the price of our service under this agreement in the event that the equipment covered by this agreement is modified from its present state.

Early Payment Discount
You may elect to pay in advance for twelve (12) months of service described in this agreement. Such a pre-payment entitles you to a 3% discount from the annual price in effect at the time of payment.

Overdue Invoices

Gold Service Agreement

A service charge of 1½% per month, or the highest legal rate, whichever is more, shall apply to all overdue accounts you have with ThyssenKrupp Elevator that are in any way related to your equipment described in this agreement. If you do not pay any sum due to ThyssenKrupp Elevator related to your equipment described in this agreement, regardless of whether it is billed pursuant to this agreement or any other with us, within sixty (60) days from the billing date, we may also choose to do one or more of the following: 1) suspend all service until all amounts due have been paid in full, and/or 2) declare all sums for the unexpired term of this agreement due immediately as liquidated damages and terminate our obligations under this agreement. If ThyssenKrupp Elevator elects to suspend service, we shall not be responsible for personal injury, death, damage to property (including damage to the equipment that is the subject matter of this agreement) or losses of any other type or kind that is in any way related the ThyssenKrupp Elevator's suspension of service. Upon resumption of service, you will be responsible for payment to ThyssenKrupp Elevator for all costs we incur that result from our suspension of service and to remedy any damage caused to your equipment during that time. Time is of the essence.

Special Considerations

TRAVEL TIME AND EXPENSE:

Contract coverage includes regulartime travel time and expense for preventive maintenance services and covered service callbacks.

ATTACHMENT "A:

Attachment "A" by mention made a binding part of this contract as set forth herein.

Gold Service Agreement

Acceptance

Your acceptance of this agreement and its approval by an authorized manager of ThyssenKrupp Elevator will constitute exclusively and entirely the agreement for the services herein described. All other prior representations or agreements, whether written or verbal, will be deemed to be merged herein and no other changes in or additions to this agreement will be recognized unless made in writing and properly executed by both parties.Should your acceptance be in the form of a purchase order or other similar document, the provisions of this agreement will govern, even in the event of a conflict. This proposal is hereby accepted in its entirety and shall constitute the entire agreement as contemplated by you and us. This proposal is submitted for acceptance within one-hundred twenty (120) days from the Date Submitted by the ThyssenKrupp Elevator representative indicated below.

No agent or employee shall have the authority to waive or modify any of the terms of this agreement without the prior written approval of an authorized ThyssenKrupp Elevator manager.

ThyssenKrupp Elevator Corporation:	GILA COUNTY FINANCE DEPT:	ThyssenKrupp Elevator Corporation Approval:
By: _____ (Signature of ThyssenKrupp Elevator Representative)	By: _____ (Signature of Authorized Individual)	By: _____ (Signature of Authorized Individual)
Angela Clark Senior Account Manager angela.clark@thyssenkrupp.com	DON E. McDANIEL, JR. (Print or Type Name) COUNTY MANAGER (Print or Type Title)	Fred Stallone Sales Manager
09-17-14 (Date Submitted)	9/24/14 (Date of Approval)	9/18/14 (Date of Approval)

ATTACHMENT "A"

Gila County Contractor Standard Terms and Conditions Addendum

A. Addendum Applicability

Contractor and Gila County agree that the terms and conditions of this Addendum shall apply to and govern the contractual relationship between Contractor and Gila County and shall supplement any other contract or agreement entered into between the parties. In the event that the terms and conditions in this Addendum conflict with any provision of any other agreement entered into between the Contractor and Gila County (including a superiority provision similar to this provision), the terms and conditions of this Addendum shall control the contractual relationship between the parties and shall supersede any conflicting provisions found in any other contract or agreement. Contractor understands that acceptance of the terms and conditions contained in this Addendum is a condition precedent to entering into a contractual relationship with Gila County.

B. Contract Defined

As used in this Addendum, the term "Contract" shall refer to any written agreement between Gila County and a person, organization, corporation, company or other entity that provides supplies or services to Gila County regardless of the title or other name applied to that written agreement. The term includes by this reference all the terms and conditions of this Addendum.

C. Contractor Defined

As used in this Addendum, the term "Contractor" shall refer to a person, provider, organization, corporation, company or other entity providing supplies or services to Gila County pursuant to a written agreement regardless of the title or other name applied to "Contractor" in that written agreement.

D. Relationship to Parties

Contractor is an independent contractor of the County. Contractor represents that he has or will secure, at his own expense, all personnel required in performing the services under this contract. Such personnel shall not be employees of or have any contractual relationship with the County. All personnel engaged in work under this contract shall be fully qualified and shall be authorized or permitted under State and local law to perform such services. It is further agreed by Contractor that he shall obey all state and federal statutes, rules, and regulations which are applicable to provisions of the services called for herein. Neither Contractor nor any employee of the Contractor shall be deemed an officer, employee, or agent of the County.

E. Non-Appropriations Clause

Contractor acknowledges that the County is a governmental entity, and the contract validity is based upon the availability of public funding under its authority. In the event that public funds are unavailable and not appropriated for the performance of County's obligations under this contract, then this contract shall automatically expire without penalty to County after written notice to Contractor of the unavailability and non-appropriation of public funds. It is expressly agreed that the County shall only activate this non-appropriation provision as an emergency fiscal measure. The County shall not activate this non-appropriation provision for its convenience, to circumvent the requirements of this contract, or to enable the County to contract with another Contractor for the same supplies or services covered under this Addendum.

F. Hold Harmless/Indemnification Clause

The Contractor agrees to defend, indemnify, and hold harmless the County of Gila and its officers, officials, agents, and employees (hereinafter referred to as "Indemnitee") from all losses, liability, claims or expenses (including reasonable attorney's fees) arising from bodily injury, including death or property damage, to any person or persons caused in whole or in part by the negligence or misconduct of the Contractor, except to the extent same are caused by the negligence or willful misconduct of the County. It is the intent of this section to require the Contractor to indemnify the County to the extent permitted under Arizona Law.

G. Entire Contract Clause

The Contractor and the County have read this Contract and agree to be bound by all of its terms, and further agree that it constitutes the entire contract between the two parties and may only be modified by a written mutual contract signed by the parties. No oral provision in conflict with this Contract shall have any force or effect.

H. Non-Waiver of Enforceability

Failure of the County to enforce, at any time, any of the provisions of this Contract, or to request at any time performance by Contractor of any of the provisions hereof, shall in no way be construed to be a waiver of such provisions, nor in any way affect the validity of this contract or any part thereof, or the right of the County to enforce each and every provision.

I. Governing Law

Both parties agree that this Contract shall be governed by the laws of the state of Arizona. The parties further agree that the jurisdiction for any legal disputes arising out of this Contract shall be the Superior Court of the State of Arizona. The parties agree that even if this Contract does not specifically reference any provision required by state or federal law, those state and federally required provisions are incorporated into this Contract by this reference as though they were specifically listed herein.

J. Cancellation

Cancellation pursuant to A.R.S. §38-511. This contract is subject to the cancellation provisions of A.R.S. §38-511.

K. Legal Arizona Workers Act Compliance

Contractor hereby warrants that it will at all times during the term of this Contract comply with all federal immigration laws applicable to Contractor's employment of its employees, and with the requirements of A.R.S. § 23-214 (A) (together the "State and Federal Immigration Laws"). Contractor shall further ensure that each subcontractor who performs any work for Contractor under this contract likewise complies with the State and Federal Immigration Laws.

County shall have the right at any time to inspect the books and records of Contractor and any subcontractor in order to verify such party's compliance with the State and Federal Immigration Laws.

Any breach of Contractor's or any subcontractor's warranty of compliance with the State and Federal Immigration Laws, or of any other provision of this section, shall be deemed to be a material breach of this Contract subjecting Contractor to penalties up to and including suspension or termination of this Contract. If the breach is by a subcontractor, and the subcontract is suspended or terminated as a result, Contractor shall be required to take such steps as may be necessary to either self-perform the services that would have been provided under the subcontract or retain a replacement subcontractor as soon as possible so as not to delay project completion.

Contractor shall advise each subcontractor of County's rights, and the subcontractor's obligations, under this Article by including a provision in each subcontract substantially in the following form: "Subcontractor hereby warrants that it will at all times during the term of this contract comply with all federal immigration laws applicable to Subcontractor's employees, and with the requirements of A.R.S. § 23-214 (A). Subcontractor further agrees that County may inspect the Subcontractor's books and records to insure that Subcontractor is in compliance with these requirements. Any breach of this paragraph by Subcontractor will be deemed to be a material breach of this contract subjecting Subcontractor to penalties up to and including suspension or termination of this contract."

Any additional costs attributable directly or indirectly to remedial action under this Article shall be the responsibility of Contractor.

ThyssenKrupp Elevator

Contractor

9/17/14
Date

SERVICE CONTRACT AGREEMENT

Contract # CNT003055-06

3370 San Fernando Rd, #202
Los Angeles, CA 90065
Phone: 888-916-0160 FAX: 888-916-0164

To: Gila County Finance Dept.
1400 E. Ash Street
Globe, AZ 85501

Contract #	CNT003055-06	Contract Description	QUOTED: Awaiting acceptance	Start Date	08/15/2014	End Date	08/14/2015
Period Billing Int	1 Year	Terms	Net 30 Days	**Total Contract Charge**		$1,520.00	

Categories of Parts Excluded from Contract

Supplies

Notes

This renewal is for the renewal of your maintenance agreement for the equipment listed and the dates stated. This agreement includes the following services:

- 1 Preventive Maintenances (PMs) per year per card printer.
- All parts, labor, travel time, mileage
- Card usage of 30,000 cards per card printer per year is the maximum covered under this agreement

Consumables are not included. If you have any questions or require information about your equipment service contract, please contact us at (888) 383-6083 x 108.
Please refer to the reverse side for complete Terms and Conditions.

Equipment Included under Contract

Equipment Location Address Gila County Sheriff's Office
Gloria Stuhmer
1100 South Street
Globe, AZ 85501

Serial No	Q94046		
Description	CP60 Plus Printer, Color, Duplex, 100 card hopper	**Equip Charge**	$839.00
Serial No	GS65010335		
Description	ID Centre Gold v6.5 Upgrade for customers using ID Centre Gold, or ID Works Enterprise	**Equip Charge**	$449.00
Serial No	8L3952		
Description	Signature Pointe Solution	**Equip Charge**	$171.00
Serial No	U04050		
Description	Fingerprint Scanner	**Equip Charge**	$61.00

'ease return this signed agreement with your check, signed credit card authorization form and/or purchase order before the start date of the contract.
hank You!

UBJECT TO ALL THE TERMS, CONDITIONS AND LIMITATIONS INCORPORATED BY REFERENCE AS SHOWN ON THE BACK HEREOF.

	Print Name	Signature	Date
Customer Signature	DON E. McDANIEL, JR.		9/29/14
Multicard Representative	Mariela Martinez		08/14/2014

ATTACHMENT "A"

Gila County Contractor Standard Terms and Conditions Addendum

A. Addendum Applicability

Contractor and Gila County agree that the terms and conditions of this Addendum shall apply to and govern the contractual relationship between Contractor and Gila County and shall supplement any other contract or agreement entered into between the parties. In the event that the terms and conditions in this Addendum conflict with any provision of any other agreement entered into between the Contractor and Gila County (including a superiority provision similar to this provision), the terms and conditions of this Addendum shall control the contractual relationship between the parties and shall supersede any conflicting provisions found in any other contract or agreement. Contractor understands that acceptance of the terms and conditions contained in this Addendum is a condition precedent to entering into a contractual relationship with Gila County.

B. Contract Defined

As used in this Addendum, the term "Contract" shall refer to any written agreement between Gila County and a person, organization, corporation, company or other entity that provides supplies or services to Gila County regardless of the title or other name applied to that written agreement. The term includes by this reference all the terms and conditions of this Addendum.

C. Contractor Defined

As used in this Addendum, the term "Contractor" shall refer to a person, provider, organization, corporation, company or other entity providing supplies or services to Gila County pursuant to a written agreement regardless of the title or other name applied to "Contractor" in that written agreement.

D. Relationship to Parties

Contractor is an independent contractor of the County. Contractor represents that he has or will secure, at his own expense, all personnel required in performing the services under this contract. Such personnel shall not be employees of or have any contractual relationship with the County. All personnel engaged in work under this contract shall be fully qualified and shall be authorized or permitted under State and local law to perform such services. It is further agreed by Contractor that he shall obey all state and federal statutes, rules, and regulations which are applicable to provisions of the services called for herein. Neither Contractor nor any employee of the Contractor shall be deemed an officer, employee, or agent of the County.

E. Non-Appropriations Clause

Contractor acknowledges that the County is a governmental entity, and the contract validity is based upon the availability of public funding under its authority. In the event that public funds are unavailable and not appropriated for the performance of County's obligations under this contract, then this contract shall automatically expire without penalty to County after written notice to Contractor of the unavailability and non-appropriation of public funds. It is expressly agreed that the County shall only activate this non-appropriation provision as an emergency fiscal measure. The County shall not activate this non-appropriation provision for its convenience, to circumvent the requirements of this contract, or to enable the County to contract with another Contractor for the same supplies or services covered under this Addendum.

F. Hold Harmless/Indemnification Clause

Contractor shall indemnify, defend, save and hold harmless the County of Gila and its officers, officials, agents, and employees (hereinafter referred to as "Indemnitee") from and against any and all claims, actions, liabilities, damages, losses, or expenses (including court costs, attorneys' fees, and costs of claim processing, investigation and litigation) (hereinafter referred to as "Claims") for bodily injury or personal injury (including death), or loss or damage to tangible or intangible property caused, or alleged to be caused, in whole or in part, by the negligent or willful acts or omissions of Contractor or any of its owners, officers, directors, agents, employees or subcontractors. This indemnity includes any claim or amount arising out of or recovered under the Workers' Compensation Law or arising out of the failure of such Contractor to conform to any federal, state or local law, statute, ordinance, rule, regulation or court decree. It is the specific intention of the parties that the Indemnitee shall, in all instances, except for Claims arising solely from the negligent or willful acts or omissions of the Indemnitee, be indemnified by Contractor from and against any and all claims. It is agreed that the Contractor will be responsible for primary loss investigation, defense and judgment costs where this indemnification is applicable. In

consideration of the award of this contract, the Contractor agrees to waive all rights of subrogation against the County, its officers, officials, agents and employees for losses arising from the work performed by the Contractor for the County.

G. Entire Contract Clause

The Contractor and the County have read this Contract and agree to be bound by all of its terms, and further agree that it constitutes the entire contract between the two parties and may only be modified by a written mutual contract signed by the parties. No oral provision in conflict with this Contract shall have any force or effect.

H. Non-Waiver of Enforceability

Failure of the County to enforce, at any time, any of the provisions of this Contract, or to request at any time performance by Contractor of any of the provisions hereof, shall in no way be construed to be a waiver of such provisions, nor in any way affect the validity of this contract or any part thereof, or the right of the County to enforce each and every provision.

I. Governing Law

Both parties agree that this Contract shall be governed by the laws of the state of Arizona. The parties further agree that the jurisdiction for any legal disputes arising out of this Contract shall be the Superior Court of the State of Arizona. The parties agree that even if this Contract does not specifically reference any provision required by state or federal law, those state and federally required provisions are incorporated into this Contract by this reference as though they were specifically listed herein.

J. Cancellation

Cancellation pursuant to A.R.S. §38-511. This contract is subject to the cancellation provisions of A.R.S. §38-511.

K. Legal Arizona Workers Act Compliance

Contractor hereby warrants that it will at all times during the term of this Contract comply with all federal immigration laws applicable to Contractor's employment of its employees, and with the requirements of A.R.S. § 23-214 (A) (together the "State and Federal Immigration Laws"). Contractor shall further ensure that each subcontractor who performs any work for Contractor under this contract likewise complies with the State and Federal Immigration Laws.

County shall have the right at any time to inspect the books and records of Contractor and any subcontractor in order to verify such party's compliance with the State and Federal Immigration Laws.

Any breach of Contractor's or any subcontractor's warranty of compliance with the State and Federal Immigration Laws, or of any other provision of this section, shall be deemed to be a material breach of this Contract subjecting Contractor to penalties up to and including suspension or termination of this Contract. If the breach is by a subcontractor, and the subcontract is suspended or terminated as a result, Contractor shall be required to take such steps as may be necessary to either self-perform the services that would have been provided under the subcontract or retain a replacement subcontractor as soon as possible so as not to delay project completion.

Contractor shall advise each subcontractor of County's rights, and the subcontractor's obligations, under this Article by including a provision in each subcontract substantially in the following form: "Subcontractor hereby warrants that it will at all times during the term of this contract comply with all federal immigration laws applicable to Subcontractor's employees, and with the requirements of A.R.S. § 23-214 (A). Subcontractor further agrees that County may inspect the Subcontractor's books and records to insure that Subcontractor is in compliance with these requirements. Any breach of this paragraph by Subcontractor will be deemed to be a material breach of this contract subjecting Subcontractor to penalties up to and including suspension or termination of this contract."

Any additional costs attributable directly or indirectly to remedial action under this Article shall be the responsibility of Contractor.

L. Warranty

Contractor expressly warrants that all goods or services furnished under this agreement shall conform to all specifications and appropriate standards, will be new, and will be free from defects in material or workmanship. Contractor warrants that all such goods or services will conform to any statements made on the containers or labels or advertisements for such goods, or services, and that any goods will be adequately contained, packaged, marked and labeled. Contractor warrants that all goods or services furnished hereunder will be merchantable, and will be safe and appropriate for the purpose for which goods or services of that kind are normally used. If Contractor knows or has reason to know the particular purpose for which County intends to use the goods or services, Contractor warrants that such goods or services will be fit for such particular purpose. Contractor warrants that goods or services furnished will conform in all respects to samples. Inspection, test, acceptance of use of the goods or services furnished hereunder shall not affect the Contractor's obligation under this warranty, and such warranties shall survive inspection, test, acceptance and use. Contractor's warranty shall run to County, its successors, and assigns. Contractor agrees to replace or correct, at Contractor's sole cost and expense, defects of any goods or services not conforming to the foregoing warranty, or improperly installed, as well as guarantee to the County and to the Owner, against liability, losses or damage to any or all parts of the work arising from said installation during a period of two (2) years from date of completion. All guarantees will inure to the benefit of the County and the Owner, their successors or assigns, including equipment warranties, ordinary wear and tear and unusual abuse or neglect excepted.

In the event of failure of Contractor to correct defects in or replace nonconforming goods or services promptly, County, after reasonable notice to Contractor, may make such corrections or replace such goods and services and charge Contractor for the cost incurred by the County in doing so. Contractor recognizes that County's requirements may require immediate repairs in reworking of defective goods, without notice to the Contractor. In such event, Contractor shall reimburse County for those costs, delays, or other damages which County has incurred.

D. Callaghan

Multicard Inc.

Date 14TH AUG 2014

VP. PROFESSIONAL SERVICES.

Title

Tommie C. Martin, District I
610 E. Highway 260, Payson, AZ. 85547
(928) 474-2029

Michael A. Pastor, District II
1400 E. Ash St. Globe, AZ. 85501
(928) 425-3231 Ext. 8753

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GILA COUNTY

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Don E. McDaniel, Jr., County Manager
Phone (928) 425-3231

Jeff Hessenius, Finance Director
Phone (928) 425-3231 Ext. 8743

FAX (928) 425-0319
TTY: 7-1-1

PROFESSIONAL SERVICES CONTRACT NO. 091514-2

NEW BRIDGE OVER TONTO CREEK

FINAL WORK PERFORMED UNDER CONTRACT NO. SS71803D

THIS AGREEMENT, made and entered into this 24TH day of SEPTEMBER, **2014**, by and between Gila County, a political subdivision of the State of Arizona, hereinafter designated the **COUNTY,** and Kimley-Horn and Associates, Inc. of the City of Phoenix, County of Maricopa, State of Arizona, hereinafter designated the **ENGINEER**.

WITNESSETH: That the **Engineer**, for and in consideration of the sum to be paid him by the **County**, in the manner and at the time hereinafter provided, and of the other covenants and agreements herein contained, hereby agrees, for himself, his heirs, administrators, successors, and assigns as follows:

ARTICLE I – SCOPE OF SERVICES: Kimley-Horn has been the engineering firm on the Tonto Creek Bridge and Oak Creek Bridge design from the inception. Contract No. SS71803D was entered into between Gila County and Kimley-Horn on November 3, 2009. The contract provided for the Tonto Creek Bridge and Oak Creek Bridge design to be completed in two phases. Phase 1, Design Concept Report and Environmental Studies, was to be performed on a lump sum basis, with a not-to-exceed without written authorization budget of $1,744,997. Phase 2, Final Design (Plans, Specifications and Estimates), was to be performed on a lump sum basis, with a not-to-exceed without written authorization budget of $747,309, for a total cost of $2,492,306.

Amendment No. 1 was executed on January 4, 2011 to increase the authorized amount for Phase 2 by an additional $202,683, for a new completed authorized budget, for Phase 2 of $949,992. Per the terms of the original contract, prior to Phase 2 beginning, the Engineer and County would review and refine the scope of services for Phase 2, as may be required as a result of design, scope and management decisions made during Phase 1. After completion of Phase 1, it was necessary to modify the design and scope of work, resulting in a cost increase to complete Phase 2 of the project.

Amendment No. 2 was executed on September 6, 2011 to extend the term of the contract to June 30, 2012. Due to massive flooding in January 2010 rearranged the creek bottoms, creating ditches and berms that would not allow access for the drill rigs to the bore hole locations, without assistance from a large front end loader. A Phase 2 increase of $12,641 was supposed to have been added to Amendment No. 2 for the additional cost for a loader and operator to smooth out the creek bottom and pull the rig through the sand if needed. The increase failed to get added to Amendment No. 2.

Amendment No. 3 was executed on March 6, 2012 to increase the authorized budget amount of Phase 2, from $949,992 to $1,007,166. The increase of $57,174 was for value engineering of the geotechnical results and the second year of the Willow Flycatcher surveys.

Due to an oversight, the contract term was not extended after the June 30, 2012 date. The final work for Phase 2 was completed on August 31, 2014, resulting in a final cost increase for Phase 2 of $3,248.74 on Contract No. SS71803D.

ARTICLE II – INDEMNIFICATION CLAUSE: Engineer shall indemnify, defend, save and hold harmless the County of Gila and its officers, officials, agents, and employees (hereinafter referred to as "Indemnitee") from and against any and all claims, actions, liabilities, damages, losses, or expenses (including court costs, attorneys' fees, and costs of claim processing, investigation and litigation) (hereinafter referred to as "Claims") for bodily injury or personal injury (including death), or loss or damage to tangible or intangible property to the extent caused, or alleged to be caused, in whole or in part, by the negligent or willful wrongful acts or omissions of Engineer or any of its owners, officers, directors, agents, employees or subcontractors. This indemnity includes any claim or amount arising out of or recovered under the Workers' Compensation Law or arising out of the failure of such Engineer to conform to any federal, state or local law, statute, ordinance, rule, regulation or court decree. It is the specific intention of the parties that the Indemnitee shall, in all instances, except for Claims arising solely from the negligent or willful acts or omissions of the Indemnitee, be indemnified by Engineer from and against any and all claims arising from its services under this Contract. It is agreed that the Engineer will be responsible for primary loss investigation, defense and judgment costs where this indemnification is applicable and that Engineer shall defend the claims that appear to fall within the scope of the indemnification, even though Engineer is subsequently found not liable under this Indemnification. In consideration of the award of this contract, the Engineer agrees to waive all rights of subrogation against the County, its officers, officials, agents and employees for losses arising from the work performed by the Engineer for the County.

ARTICLE III - INSURANCE REQUIREMENTS: Engineer and subcontractors shall procure and maintain until all of their obligations have been discharged, including any warranty periods under this Contract are satisfied, insurance against claims for injury to persons or damage to property which may arise from or in connection with the performance of the work hereunder by the Engineer, his agents, representatives, employees or subcontractors.

The insurance requirements herein are minimum requirements for this Contract and in no way limit the indemnity covenants contained in this Contract. The County in no way warrants that the minimum limits contained herein are sufficient to protect the Engineer from liabilities that might arise out of the performance of the work under this contract by the Engineer, his agents, representatives, employees or subcontractors and Engineer is free to purchase additional insurance as may be determined necessary.

A. **MINIMUM SCOPE AND LIMITS OF INSURANCE**: Engineer shall provide coverage with limits of liability not less than those stated below.

1. **Commercial General Liability – Occurrence Form**

   Policy shall include bodily injury, property damage and broad form contractual liability coverage.

   - General Aggregate $2,000,000
   - Products – Completed Operations Aggregate $1,000,000
   - Personal and Advertising Injury $1,000,000
   - Each Occurrence $1,000,000

   a. The policy shall be endorsed to include the following additional insured language: **"The County of Gila shall be named as an additional insured with respect to liability arising out of the activities performed by, or on behalf of the Engineer".**

2. **Worker's Compensation and Employers' Liability**

Workers' Compensation	Statutory
Employers' Liability	
Each Accident	$100,000
Disease – Each Employee	$100,000
Disease – Policy Limit	$500,000

   a. Policy shall contain a **waiver of subrogation** against the County of Gila.

3. **Professional Liability (Errors and Omissions Liability)**

Each Claim	$1,000,000
Annual Aggregate	$2,000,000

   a. In the event that the professional liability insurance required by this Contract is written on a claims-made basis, Engineer warrants that any retroactive date under the policy shall precede the effective date of this Contract; and that either continuous coverage will be maintained or an extended discovery period will be exercised for a period of two (2) years beginning at the time work under this Contract is completed.

B. **ADDITIONAL INSURANCE REQUIREMENTS:** The policies shall include, or be endorsed to include, the following provisions:

1. On insurance policies where the County of Gila is named as an additional insured, the County of Gila shall be an additional insured to the full limits of liability purchased by the Engineer even if those limits of liability are in excess of those required by this Contract.
2 The Engineer's insurance coverage shall be primary insurance and non-contributory with respect to all other available sources.
3. Coverage provided by the Engineer shall not be limited to the liability assumed under the indemnification provisions of this Contract.

C. **NOTICE OF CANCELLATION:** Each insurance policy required by the insurance provisions of this Contract shall provide the required coverage and shall not be suspended, voided, canceled, reduced in coverage or endorsed to lower limits except after thirty (30) days prior written notice has been given to the County. Such notice shall be sent directly to Jeannie Sgroi, 1400 E. Ash St., Globe, AZ 85501 and shall be sent by certified mail, return receipt requested.

D. **ACCEPTABILITY OF INSURERS:** Insurance is to be placed with insurers duly licensed or approved unlicensed companies in the state of Arizona and with an "A.M. Best" rating of not less than B+ VI. The County in no way warrants that the above-required minimum insurer rating is sufficient to protect the Engineer from potential insurer insolvency.

E. **VERIFICATION OF COVERAGE:** Engineer shall furnish the County with certificates of insurance (ACORD form or equivalent approved by the County) as required by this Contract. The certificates for each insurance policy are to be signed by a person authorized by that insurer to bind coverage on its behalf.

All certificates and endorsements are to be received and approved by the County before work commences. Each insurance policy required by this Contract must be in effect at or prior to commencement of work under this Contract and remain in effect for the duration of the project. Failure to maintain the insurance policies as required by this Contract or to provide evidence of renewal is a material breach of contract.

All certificates required by this Contract shall be sent directly to Jeannie Sgroi, 1400 E. Ash St., Globe, AZ 85501. The County project/contract number and project description shall be noted on the certificate of insurance. The County reserves the right to require complete, certified copies of all insurance policies required by this Contract at any time.

F. **SUBCONTRACTORS:** Engineers' certificate(s) shall include all subcontractors as additional insured's under its policies **or** Engineer shall furnish to the County separate certificates and endorsements for each subcontractor. All coverage's for subcontractors shall be subject to the minimum requirements identified above.

G. **APPROVAL:** Any modification or variation from the insurance requirements in this Contract shall be made by the County Attorney, whose decision shall be final. Such action will not require a formal Contract amendment, but may be made by administrative action.

ARTICLE IV – LEGAL ARIZONA WORKERS ACT COMPLIANCE: Engineer hereby warrants that it will at all times during the term of this Contract comply with all federal immigration laws applicable to Engineer's employment of its employees, and with the requirements of A.R.S. § 23-214 (A) (together the "State and Federal Immigration Laws"). Engineer shall further ensure that each subcontractor who performs any work for Engineer under this contract likewise complies with the State and Federal Immigration Laws.

County shall have the right at any time to inspect the books and records of Engineer and any subcontractor in order to verify such party's compliance with the State and Federal Immigration Laws.

Any breach of Engineer's or any subcontractor's warranty of compliance with the State and Federal Immigration Laws, or of any other provision of this section, shall be deemed to be a material breach of this Contract subjecting Engineer to penalties up to and including suspension or termination of this Contract. If the breach is by a subcontractor, and the subcontract is suspended or terminated as a result, Engineer shall be required to take such steps as may be necessary to either self-perform the services that would have been provided under the subcontract or retain a replacement subcontractor, as soon as possible so as not to delay project completion.

Engineer shall advise each subcontractor of County's rights, and the subcontractor's obligations, under this Article by including a provision in each subcontract substantially in the following form:

"Subcontractor hereby warrants that it will at all times during the term of this contract comply with all federal immigration laws applicable to Subcontractor's employees, and with the requirements of A.R.S. § 23-214 (A). Subcontractor further agrees that County may inspect the Subcontractor's books and records to insure that Subcontractor is in compliance with these requirements. Any breach of this paragraph by Subcontractor will be deemed to be a material breach of this contract subjecting Subcontractor to penalties up to and including suspension or termination of this contract."

Any additional costs attributable directly or indirectly to remedial action under this Article shall be the responsibility of Engineer. In the event that remedial action under this Article results in delay to one or more tasks on the critical path of Engineer's approved construction or critical milestones schedule, such period of delay shall be deemed excusable delay for which Engineer shall be entitled to an extension of time, but not costs.

ARTICLE V – SCHEDULE & FEES: Post Design Services will be invoiced on a Time and Material basis in an amount not to exceed **$3,248.74**.

ARTICLE VI – LAWS AND ORDINANCES: This agreement shall be enforced under the laws of the State of Arizona. Engineer shall maintain in current status all Federal, State and Local licenses and permits required for the operation of the business conducted by the Engineer. The Engineer shall comply with the applicable provisions of the Americans with Disabilities Act (Public Law 101-336, 42 U.S.C. 12101-12213) and applicable federal regulations under the Act.

ARTICLE VII – TERM: This contract commences on the date it is signed by the County Manager and remains in effect for a period of one year from that date, unless terminated earlier pursuant to this contract.

ARTICLE VIII – CANCELLATION: This agreement is subject to cancellation pursuant to **A.R.S. § 38-511.** If the Agreement is terminated, the county shall be liable only for payment for services rendered and accepted material received by the County before the effective date of termination. The Engineer shall be considered in default of this contract and such default will be considered as cause to terminate the contract for any of the following reasons if the Engineer:

a. Fails to perform the work under the contract within the time specified in the "Notice to Proceed"; or
b. Fails to perform the work or fails to provide sufficient workers, equipment or data to assure completion of work in accordance with the terms of the contract; or
c. Performs the work unsuitably or neglects or refuses to follow the Scope of Work; or
d. Discontinues the prosecution of the work; or
e. Fails to resume work which as been discontinued within a reasonable time after notice to do so; or
f. Becomes insolvent or is declared bankrupt, or commits any act of bankruptcy or insolvency; or
g. Makes assignment for the benefit or creditors.
h. If it is found that gratuities were offered or given by the Engineer or any agent or representative of the Engineer, to any officer or employee of the County.

ARTICLE IX – PAYMENT: The Scope of Services as outlined above will be performed on a Time and Material basis, with a not-to-exceed without written authorization budget of **$3,248.74**.

Compensation shall follow guidelines for **A.R.S. §34-221.** Each invoice must include itemized task and dollar figure for each task completed. Each invoice must show a signature by the county representative confirming services rendered and authorizing payment.

IN WITNESS WHEREOF, two (2) identical counterparts of this contract, each which shall include original signatures and for all purposes be deemed an original thereof, have been duly executed by the parties hereinabove named, on the date and year first above written.

In return for the performance of the Contract by the **Engineer** the **County** agrees to pay the amount of not more than $ 3,248.74 including all applicable taxes through a payment schedule as described in the Contract documents and as may be modified and executed by change orders.

PROFESSIONAL CONSULTING SERVICES CONTRACT NO. 091514-2
FINAL WORK PERFORMED UNDER CONTRACT NO. SS71803D

GILA COUNTY

Don E. McDaniel Jr., County Manager

Date: 9/29/14

KIMLEY-HORN AND ASSOCIATES, INC.

Signature

DAVID J. LEISTIKO
Print Name

AMENDMENT NO. 1 to SERVICE AGREEMENT NO. 071613-1

The following amendments are hereby incorporated into the agreement for the below project

---

IMMUNIZATION-COST RECOVERY PROGRAM-BILLING

THE ARIZONA PARTNERSHIP FOR IMMUNIZATION

Effective August 21, 2013, Gila County and The Arizona Partnership for Immunization entered into a contract whereby the Gila County Health Department shall operate vaccination clinics on behalf of Gila County and the Contractor shall coordinate billing services in order for the County Health Department to be compensated for immunization services provided to health plan members.

Service Agreement No. 071613-1 will expire on August 20, 2014. **Per Article 13-Term,** Gila County shall have the right, at its sole option, to renew the contract for two (2) additional (1) year periods.

AMENDMENT NO. 1 to **Service Agreement No. 071613-1**, will allow for Gila County to exercise the option to renew the term of the Agreement for one (1) one (1) year term, from August 21, 2014 to August 20, 2015.

All other terms, conditions and provisions of the original Contract, shall remain the same and apply during the August 21, 2014 to August 20, 2015 renewal period.

IN WITNESS WHEREOF, two (2) identical counterparts of this amendment, each which shall include original signatures and for all purposes be deemed an original thereof, have been duly executed by the parties hereinabove named, on this 24TH day of SEPTEMBER, 2014.

GILA COUNTY:

Don E. McDaniel Jr., County Manager

Date: 9/24/14

THE ARIZONA PARTNERSHIP FOR IMMUNIZATION

Signature

PATTY GAST

Print Name

Tommie C. Martin, District I
610 E. Highway 260, Payson, AZ. 85547
(928) 474-2029

Michael A. Pastor, District II
1400 E. Ash St. Globe, AZ. 85501
(928) 425-3231 Ext. 8753

John D. Marcanti, District III
1400 E. Ash St. Globe, AZ. 85501
(928) 425-3231 Ext. 8511

GILA COUNTY
www.gilacountyaz.gov

Don E. McDaniel Jr., County Manager
Phone (928) 425-3231 Ext.8761

Jeff Hessenius, Finance Director
Phone (928) 425-3231 Ext. 8743
Fax: (928)425-7056

1400 E. Ash Street
Globe, AZ 85501

SERVICE AGREEMENT NO. 071814

UC UPGRADE

THIS AGREEMENT, made and entered into this 10th day of SEPTEMBER, **2014**, by and between Gila County, a political subdivision of the State of Arizona hereinafter designated the County, and **Hye Tech Network & Security Solutions, LLC**, of the City of Phoenix, State of Arizona, hereinafter designated the Contractor.

WITNESSETH: The Contractor, for and in consideration of the sum to be paid him by the County, in the manner and at the time hereinafter provided, and of the other covenants and agreement's herein contained, hereby agrees, for himself, his heirs, administrators, successors, and assigns as follows:

ARTICLE 1 – SCOPE OF SERVICES: The Contractor shall provide the services and products listed in the Scope of Work below for UC Upgrade, and shall do so in a good, workmanlike and substantial manner and to the satisfaction of the County under the direction of the IT Director or designee.

Scope of Work: Refer to attached Attachment "A" to Service Agreement No. 071814, by mention made a binding part of this agreement as set forth herein.

Contractor Fee's: Refer to Attachment "A" to Service Agreement No. 071814, by mention made a binding part of this agreement as set forth herein.

ARTICLE 2 – TERMINATION: The County reserves the right to terminate the Contract, in whole or in part at any time, when in the best interest of the County, without penalty or recourse. Upon receipt of the written notice, the Contractor shall stop all work as directed in the notice. If the contract is terminated, the County shall be liable only for the services rendered under this contract and accepted material received by the County before the effective date of termination.

ARTICLE 3 - INDEMNIFICATION: Contractor shall indemnify, defend, save and hold harmless the County of Gila and its officers, officials, agents, and employees (hereinafter referred to as "Indemnitee") from and against any and all claims, actions, liabilities, damages, losses, or expenses (including court costs, attorneys' fees, and costs of claim processing, investigation and litigation) (hereinafter referred to as "Claims") for bodily injury or personal injury (including death), or loss or damage to tangible or intangible property caused, or alleged to be caused, in whole or in part, by the negligent or willful acts or omissions of Contractor or any of its owners, officers, directors, agents, employees or subcontractors. This indemnity includes any claim or amount arising out of or recovered under the Workers' Compensation Law or arising out of the failure of such contractor to conform to any federal, state or local law, statute, ordinance, rule, regulation or court decree. It is the specific intention of the parties that the Indemnitee shall, in all instances, except for Claims arising solely from the negligent or willful acts or omissions of the Indemnitee, be indemnified by Contractor from and

against any and all claims. It is agreed that Contractor will be responsible for primary loss investigation, defense and judgment costs where this indemnification is applicable. In consideration of the award of this contract, the Contractor agrees to waive all rights of subrogation against the County, its officers, officials, agents and employees for losses arising from the work performed by the Contractor for the County.

ARTICLE 4 – INSURANCE REQUIREMENTS: Contractor and subcontractors shall procure and maintain until all of their obligations have been discharged, including any warranty periods under this Contract are satisfied, insurance against claims for injury to persons or damage to property which may arise from or in connection with the performance of the work hereunder by the Contractor, his agents, representatives, employees or subcontractors.

The insurance requirements herein are minimum requirements for this Contract and in no way limit the indemnity covenants contained in this Contract. The County in no way warrants that the minimum limits contained herein are sufficient to protect the Contractor from liabilities that might arise out of the performance of the work under this contract by the Contractor, his agents, representatives, employees or subcontractors and Contractor is free to purchase additional insurance as may be determined necessary.

A. **MINIMUM SCOPE AND LIMITS OF INSURANCE:** Contractor shall provide coverage with limits of liability not less than those stated below.

1. **Commercial General Liability – Occurrence Form**
   Policy shall include bodily injury, property damage and broad form contractual liability coverage.
   - General Aggregate $2,000,000
   - Products – Completed Operations Aggregate $1,000,000
   - Personal and Advertising Injury $1,000,000
   - Each Occurrence $1,000,000

   a. The policy shall be endorsed to include the following additional insured language: **"The County of Gila shall be named as an additional insured with respect to liability arising out of the activities performed by, or on behalf of the Contractor".**

2. **Worker's Compensation and Employers' Liability**

Workers' Compensation	Statutory
Employers' Liability	
Each Accident	$100,000
Disease – Each Employee	$100,000
Disease – Policy Limit	$500,000

   a. Policy shall contain a **waiver of subrogation** against the County of Gila.

3. **Professional Liability (Errors and Omissions Liability)**

Each Claim	$1,000,000
Annual Aggregate	$2,000,000

   a. In the event that the professional liability insurance required by this Contract is written on a claims-made basis, Contractor warrants that any retroactive date under the policy shall precede the effective date of this Contract; and that either continuous coverage will be maintained or an extended discovery period will be exercised for a period of two (2) years beginning at the time work under this Contract is completed.

B. **ADDITIONAL INSURANCE REQUIREMENTS:** The policies shall include, or be endorsed to include, the following provisions:

1. On insurance policies where the County of Gila is named as an additional insured, the County of Gila shall be an additional insured to the full limits of liability purchased by the Contractor even if those limits of liability are in excess of those required by this Contract.
2. The Contractor's insurance coverage shall be primary insurance and non-contributory with respect to all other available sources.

3. Coverage provided by the Contractor shall not be limited to the liability assumed under the indemnification provisions of this Contract.

C. **NOTICE OF CANCELLATION:** Each insurance policy required by the insurance provisions of this Contract shall provide the required coverage and shall not be suspended, voided, canceled, reduced in coverage or endorsed to lower limits except after thirty (30) days prior written notice has been given to the County. Such notice shall be sent directly to **Gila County Purchasing Department, 1400 E. Ash St., Globe, AZ, 85501** and shall be sent by certified mail, return receipt requested.

D. **ACCEPTABILITY OF INSURERS:** Insurance is to be placed with insurers duly licensed or approved unlicensed companies in the state of Arizona and with an "A.M. Best" rating of not less than B+ VI. The County in no way warrants that the above-required minimum insurer rating is sufficient to protect the Contractor from potential insurer insolvency.

E. **VERIFICATION OF COVERAGE:** Contractor shall furnish the County with certificates of insurance (ACORD form or equivalent approved by the County) as required by this Contract. The certificates for each insurance policy are to be signed by a person authorized by that insurer to bind coverage on its behalf.

All certificates and endorsements are to be received and approved by the County before work commences. Each insurance policy required by this Contract must be in effect at or prior to commencement of work under this Contract and remain in effect for the duration of the project. Failure to maintain the insurance policies as required by this Contract or to provide evidence of renewal is a material breach of contract.

All certificates required by this Contract shall be sent directly to **Gila County Purchasing Department, 1400 E. Ash St., Globe, AZ, 85501,** or emailed to Jeannie Sgroi at jsgroi@gilacountyaz.gov . The County project/contract number and project description shall be noted on the certificate of insurance. The County reserves the right to require complete, certified copies of all insurance policies required by this Contract at any time.

F. **SUBCONTRACTORS:** Contractors' certificate(s) shall include all subcontractors as additional insured's under its policies **or** Contractor shall furnish to the County separate certificates and endorsements for each subcontractor. All coverage's for subcontractors shall be subject to the minimum requirements identified above.

G. **APPROVAL:** Any modification or variation from the insurance requirements in this Contract shall be made by the County Attorney, whose decision shall be final. Such action will not require a formal Contract amendment, but may be made by administrative action.

ARTICLE 5 – LEGAL ARIZONA WORKERS ACT COMPLIANCE: Contractor hereby warrants that it will at all times during the term of this Contract comply with all federal immigration laws applicable to Contractor's employment of its employees, and with the requirements of A.R.S. § 23-214 (A) (together the "State and Federal Immigration Laws"). Contractor shall further ensure that each subcontractor who performs any work for Contractor under this contract likewise complies with the State and Federal Immigration Laws. County shall have the right at any time to inspect the books and records of Contractor and any subcontractor in order to verify such party's compliance with the State and Federal Immigration Laws.

Any breach of Contractor's or any subcontractor's warranty of compliance with the State and Federal Immigration Laws, or of any other provision of this section, shall be deemed to be a material breach of this Contract subjecting Contractor to penalties up to and including suspension or termination of this Contract. If the breach is by a subcontractor, and the subcontract is suspended or terminated as a result, Contractor shall be required to take such steps as may be necessary to either self-perform the services that would have been provided under the subcontract or retain a replacement subcontractor as soon as possible so as not to delay project completion.

Contractor shall advise each subcontractor of County's rights, and the subcontractor's obligations, under this Article by including a provision in each subcontract substantially in the following form: "Subcontractor hereby warrants that it will at all times during the term of this contract comply with all federal immigration laws applicable to Subcontractor's employees, and with the requirements of A.R.S. § 23-214 (A). Subcontractor further agrees that County may inspect the Subcontractor's books and records to insure that Subcontractor is in compliance with these requirements. Any breach of this paragraph by Subcontractor will be deemed to be a material breach of this contract subjecting Subcontractor to penalties up to and including suspension or termination of this contract."

Any additional costs attributable directly or indirectly to remedial action under this Article shall be the responsibility of Contractor. In the event that remedial action under this Article results in delay to one or more tasks on the critical path of Contractor's approved construction or critical milestones schedule, such period of delay shall be deemed excusable delay for which Contractor shall be entitled to an extension of time, but not costs.

ARTICLE 6 – LAWS AND ORDINANCES: This agreement shall be enforced under the laws of the State of Arizona. Contractor shall maintain in current status all Federal, State and Local licenses and permits required for the operation of the business conducted by the Contractor. The Contractor shall comply with the applicable provisions of the Americans with Disabilities Act (Public Law 101-336, 42 U.S.C. 12101-12213) and applicable federal regulations under the Act.

ARTICLE 7 – CANCELLATION: This agreement is subject to cancellation pursuant to A.R.S. §38-511. If the Agreement is terminated, the county shall be liable only for payment for services rendered and accepted material received by the County before the effective date of termination.

ARTICLE 8 – RELATIONSHIP OF THE PARTIES: Contractor is an independent contractor of the County. Contractor represents that he has or will secure, at his own expense, all personnel required in performing the services under this contract. Such personnel shall not be employees of or have any contractual relationship with the County. All personnel engaged in work under this contract shall be fully qualified and shall be authorized or permitted under State and local law to perform such services. Contractor warrants that he has obtained or will obtain Worker's Compensation Insurance for his employees working on this contract and that any subcontractors will likewise obtain Worker's Compensation Insurance for of their employees working on this contract. It is further agreed by Contractor that he shall obey all state and federal statutes, rules, and regulations which are applicable to provisions of the services called for herein. Neither Contractor nor any employee of the Contractor shall be deemed an officer, employee, or agent of the County.

ARTICLE 9 – NON-APPROPRIATIONS CLAUSE: Contractor acknowledges that the County is a governmental entity, and the contract validity is based upon the availability of public funding under its authority. In the event that public funds are unavailable and not appropriated for the performance of County's obligations under this contract, then this contract shall automatically expire without penalty to County after written notice to Contractor of the unavailability and non-appropriation of public funds. It is expressly agreed that the County shall only activate this non-appropriation provision as an emergency fiscal measure. The County shall not activate this non-appropriation provision for its convenience, to circumvent the requirements of this contract, or to enable the County to contract with another Contractor for the same supplies or services covered under this Addendum.

ARTICLE 10 – ENTIRE CONTRACT CLAUSE: The Contractor and the County have read this Contract and agree to be bound by all of its terms, and further agree that it constitutes the entire contract between the two parties and may only be modified by a written mutual contract signed by the parties. No oral agreement or oral provision outside this Contract shall have any force or effect.

ARTICLE 11 – NON-WAIVER OF ENFORCEABILITY: Failure of the County to enforce, at any time, any of the provisions of this Contract, or to request at any time performance by Contractor of any of the provisions hereof, shall in no way be construed to be a waiver of such provisions, nor in any way affect the validity of this contract or any part thereof, or the right of the County to enforce each and every provision

ARTICLE 12 – GOVERNING LAW: Both parties agree that this Contract shall be governed by the laws of the state of Arizona. The parties further agree that the jurisdiction for any legal disputes arising out of this Contract shall be the Superior Court of the State of Arizona. The parties agree that even if this Contract does not specifically reference any provision required by state or federal law, those state and federally required provisions are incorporated into this Contract by this reference as though they were specifically listed herein.

ARTICLE 13– TERM: Contract shall be effective August 1, 2014 and expires June 30, 2015.

ARTICLE 14 – PAYMENT/BILLING: Contractor will bill for services pursuant to Attachment "A" to Service Agreement No. 071814, but in no event shall charges for the August 1, 2014 to June 30, 2015 term exceed **$15,500.00** without prior written agreement of the County.

All invoices shall be submitted to Gila County Accounts Payable, 1400 E. Ash St, Globe, Arizona and include the following information:

- Purchase Order Number
- Contract Number
- Invoice Number
- Service Location
- Vendor Name and Address
- Description of Service

Any alterations to the scope of work resulting in a change in cost must have prior written approval by the County. Any unauthorized work may result in non-payment to the vendor.

Gila County employs a "Net 15" payment term for services meaning the payment will be issued fifteen (15) days from the date the County receives the invoice from the Contractor. Purchase orders sent to the Contractor reflect these terms and conditions.

The Contractor shall have a current I.R.S. W-9 form on file with the County unless not required by law. The County shall not remit payment if the Contractor does not have a current W-9.

IN WITNESS WHEREOF, two (2) identical counterparts of Service Agreement No. 071814, each which shall include original signatures and for all purposes be deemed an original thereof, have been duly executed by the parties hereinabove named, on this 24 day of SEPTEMBER, 2014.

GILA COUNTY

Don E. McDaniel, Jr., County Manager

HYE TECH NETWORK SECURITY SOLUTIONS, LLC

Authorized Signature

SAEO HAYAN

Print Name/Title

UC Upgrade

Proposal 1025-013

for

Gila County

Developed by

HYE TECH NETWORK & SECURITY SOLUTIONS, LLC

ADSPO12-024661

May 7, 2013

4802 E Ray Road
Suite 23-414
Phoenix, Arizona 85044
www.htnetsec.com
saro@htnetsec.com

Objectives

Hye Tech will meet the following Service objectives:

- Upgrade Cisco Voice over IP infrastructure to 9.1 release
- Migrate to virtualized UC solution from stand-alone servers
  - Cisco Unified Call Manager (CUCM)
- Install virtualized UC solution for:
  - Unity Connections (CXN)

Scope of Work

Install and Migrate CUCM

- Export BAT configuration from existing CUCM
- Build virtual servers and deploy CUCM software
- Configure CUCM server with customer credentials and specifics
- Upgrade CUCM to latest service patch
- Install Licenses
- Activate services
- Configure critical service parameters that require phone resets if configured later
- Import BAT file into CUCM
- Verify that BAT completed with no errors
- Look over critical configuration on CUCM to make sure all parameters are correct
  - Route Patterns
  - Route Groups
  - Route Lists
  - Gateways
  - Partitions
  - CSS
  - Etc.
- Verify database replication among all servers
- Integrate CUCM and Unity Connection using Cisco best practices
  - Dual SIP Trunks with correct SIP profiles and SIP Security profiles
- Integrate CUCM and CER using Cisco best practices
- Integrate New CUCM cluster with Old CUCM cluster using a SIP trunk

Install and Migrate CXN

- Gather requirements
  - Authentication
  - Single Inbox (Unified Messaging)
  - Auto-attendant(s)
  - Directory/Call handlers
- Build virtual servers and deploy CXN software
- Configure CXN server with customer credentials and specifics
- Upgrade CXN to latest service patch

- Install Licenses
- Activate services
- Build port group
  - Add ports to port group
  - Verify operation
  - Verify MWI
- Configure end user authentication parameters
- Configure end user templates
  - Standard User
  - Single Inbox User
- Configure Single Inbox with parameters given from the Exchange admin
- Rebuild Call handlers if necessary
- Verify voicemail operation with and without single inbox

User Migration

- Bring up test phones and verify registration
- Place test calls between two test phones
  - Verify codec is g.722
- Identify pilot group for fist migration
- Modified route plan
  - International
  - National
  - Local
  - On Cluster
  - Verify 911 calls via proper gateway
  - Voicemail
    - Verify MWI
    - Verify Single Inbox functionality
    - Verify synchronization between email and MWI light
    - Verify call handlers if necessary (DTMF)
- Identify downtime to plan for full migration
- During outage window
  - Change DHCP pools for phones
  - Reset all phones
  - Verify they register on new CUCM cluster
  - Migrate Voice Gateways to new Cluster during downtime
- Verify failover

Knowledge Transfer and Documentation

- Work with Gila County staff and provide knowledge transfer to enable the day-to-day operations of the new UC environment.
- Provide information for basic Adds/Moves/Changes
- Provide as-built network diagrams and any related documentation to the project**

** THIS DOES NOT INCLUDE ANY DIRECT USER TRAINING OR CUSTOMIZED "HOW TO" DOCUMENTATION.

Fees

- See Appendix A

Requirements

The following assumptions and requirements apply for this Services engagement.

- Gila will provide HyeTech an overview of relevant policies associated with the project.
- Gila will provide access to all of Gila's information, documentation and technology necessary for consultant to perform the Services.
- All required hardware, software and licenses shall be provided by Gila prior to the commencement of the project
- All travel and expenses are not included in the cost of the project and may be billed separately
  - Travel costs are calculated at $100/night, this includes all expenses
- HyeTech/Gila will build VMware environment per Cisco specifications
- Gila will provide the following for all UC users
  - Extension
  - First Name, Last Name
  - User ID

Deliverables

- **Upgrade Cisco Voice over IP infrastructure**
  - **Cisco Unified Call Manager (CUCM)**
  - **Unity Connections (CXN)**
- **Knowledge transfer**
  - **As-Built Diagrams**
  - **Documentation**

Proposal No. 1025-013 - UC Upgrade.docx

Appendix A

Hye Tech performs all necessary steps and work to finish above tasks

Cisco Voice Upgrade:

Description	Rate
UC upgrade/migration	$15,500

Hye Tech Network & Security Solutions, LLC

Signature: _____

Name: SAED HAYAN

Title: CTO/ FOUNDER

Gila County

Signature: _____

Name: Don E. McDaniel, Jr.

Title: County Manager

WEST ORDER FORM – Conversion to Assured Print Pricing Service
610 Opperman Drive, P.O. Box 64833
St. Paul, MN 55164-1803
Tel: 651/687-8000

THOMSON REUTERS

Check West account status below as applicable: Rep Name & Number Brandon Benson 0068402

New ____ (NACI Form attached) **Existing with Increase Credit Limit** ____ (NACI Form attached)

Existing with no changes ____ **Existing with changes** ____ (Permanent name change must attach a Customer Name Change Form)

Acct # 1000314910 Quote # ____ PO # ____ Date 9/22/2014

Name/Subscriber GILA COUNTY SUPERVISORS BOARD Bill To Acct # ____

Order Confirmation Contact Name Janice Cook

E-Mail jcook@gilacountyaz.gov

Permanent Address Change ____ **One-Time Ship To** ____ **Additional Ship To** ____ **Additional Bill To** ____

Name ____ Attn: ____

Address ____ Suite/Floor ____

City ____ State ____ County ____ Zip ____

Print Product(s) Converting to Assured Print Pricing

Full Svc #	Assured Print Pricing Service Products	Quantity	List Charges	Other	Monthly Charges
39030002	AZ LEGIS SERV DISCOUNTED SUB	1	$0.00		$0.00
21040304	AZ REV STAT SUB	1	$214.15		$214.15
21043761	AZ REV STAT V3A SUB	2	$4.63		$9.26
40036023	AZ SESSION LAWS BV SUB	1	$15.05		$15.05

Notes: promo 601817C10153

*** Total Monthly Charges $** 238.46

* Total Charges includes charges from attached page 2, if applicable.

Monthly charges ("Monthly Charges") are billed on the date West processes Subscriber's order and continue for the term of complete calendar months elected by Subscriber below ("Minimum Term").

initial desired term

____ **Subscriber's Initials for 24 Month Service Minimum Term.** Subscriber agrees to commit to a Minimum Term of 24 complete calendar months and the Monthly Charges for the second 12 months not to increase by more than 6% over Monthly Charges for the initial 12 months.

____ **Subscriber's Initial for 36 Month Service Minimum Term.** Subscriber agrees to commit to a Minimum Term of 36 complete calendar months and the Monthly Charges for the second 12 months not to increase by more than 5% over Monthly Charges for the initial 12 months and Monthly Charges for the third 12 months not to increase by more than 5% over Monthly Charges for the second 12 months.

____ **Subscriber's Initials for Automatic Renewal Terms.** Upon conclusion of the Minimum Term, Subscriber hereby request that West provide subscription services for the above products, billed as set forth above. The Assured Print Pricing Service will automatically renew for consecutive 12-month periods ("Renewal Term"), and the Monthly Charges for the Renewal Term(s) will increase 7% per year unless either party gives written notice of cancellation to the other party at least 30 days in advance of the expiration of the then-current term. Subscriber's notice of cancellation should be sent to the address set forth above, Attention: Customer Service. Additionally, West may at its discretion provide Subscriber with notice at least 60 days in advance of any Renewal Term of a Monthly Charges increase different from 7% after which Subscriber shall have 30 days to provide West with written notice of cancellation if Subscriber does not wish to renew.

initial here

Subscription services consist of updates and/or supplements to the service, including but not limited to: pocket parts, pamphlets, replacement volumes, or loose-leaf pages. West's sales representatives will provide information regarding frequency and updates.

For transportation charges and returns see "Additional Terms" below.

Additional Terms

Returns. Assured Print Pricing Service products are not returnable.

Transportation Charges. Print products are shipped FOB origin. Transportation charges will only be added to expedited shipments at Subscriber's request at then-current carrier rates.

General Provisions for Non-Government Subscribers Only. This Order Form is subject to approval by West, a Thomson Reuters business ("West") in St. Paul, Minnesota and is governed by Minnesota law and may not be terminated during the Minimum Term. The state and federal courts sitting in Minnesota will have exclusive jurisdiction over any claim arising from or related to this agreement. All payments are due 30 days from date of invoice. Applicable sales, use, personal property, value added tax (VAT) or equivalent, ad valorem and other taxes are payable by Subscriber. Subscriber may be charged interest for overdue charges. If any charges remain unpaid 30 days after becoming due, all amounts that are or would become due and payable for the remaining Term shall become immediately due and payable at the sole option of West. Interest charges may be adjusted to the then-highest current rate allowable on Minnesota contracts. This Order Form may not be assigned, sublicensed or otherwise transferred by Subscriber without West's prior written consent. All collection fees, including but not limited to attorneys fees, are payable by Subscriber. West may request a current financial statement and/or obtain consumer credit report on the undersigned individual to determine creditworthiness. West will only request consumer credit information on the undersigned if the

undersigned is applying for credit as an individual or if the undersigned's consumer credit information is necessary for West to consider granting credit to the aforementioned company. If Subscriber inquires whether a credit report was requested, West will provide information of such, if a report was received and the name, address and telephone number of the agency that supplied the report.

General Provisions for Government Subscribers Only. This Order Form is subject to approval by West in St. Paul, Minnesota, and is governed by the laws of Subscriber's state. The courts sitting in Subscriber's state will have exclusive jurisdiction over any claim arising from or related to this agreement. If Subscriber is a U.S. Federal Government subscriber, this Order Form is governed by the laws of the United States of America. Applicable sales, use, personal property, value added tax (VAT) or equivalent, ad valorem and other taxes are payable by Subscriber. This Order Form may not be assigned, sublicensed or otherwise transferred by Subscriber without West's prior written consent.

AUTHORIZED REPRESENTATIVE FOR ORDER FORM

Printed Name Don E. McDaniel, Jr.

Title County Manager

Date 9/29/14

Signature X

sign and date here

Tommie C. Martin, District I
610 E. Highway 260, Payson, AZ. 85547
(928) 474-2029

Michael A. Pastor, District II
1400 E. Ash St. Globe, AZ. 85501
(928) 425-3231 Ext. 8753

John Marcanti, District III
1400 E. Ash St. Globe, AZ. 85501
(928) 425-3231 Ext. 8511

GILA COUNTY
www.gilacountyaz.gov

Don E. McDaniel Jr., County Manager
Phone (928) 425-3231 Ext.8761

Jeff Hessenius, Finance Director

1400 E. Ash Street
Globe, AZ 85501

SERVICE AGREEMENT NO. 092914

WEATHERIZATION PROJECT NO. HH#8139

THIS AGREEMENT, made and entered into this 01ST day of OCTOBER, **2014,** by and between Gila County, a political subdivision of the State of Arizona hereinafter designated the County, and **Mountain Retreat Builders**, of the City of Globe, State of Arizona, hereinafter designated the Contractor.

WITNESSETH: The Contractor, for and in consideration of the sum to be paid him by the County, in the manner and at the time hereinafter provided, and of the other covenants and agreement's herein contained, hereby agrees, for himself, his heirs, administrators, successors, and assigns as follows:

ARTICLE 1 – SCOPE OF SERVICES: The Contractor shall provide the services and products listed in the Scope of Work below for Weatherization Project HH#8139, and shall do so in a good, workmanlike, and substantial manner and to the satisfaction of the County under the direction of the Housing Services Manager or designee.

All work performed by the Contractor shall be completed to local codes and regulation per Gila County and the State of Arizona and consistent with all Weatherization guidelines.

Scope of Work: Refer to Attachment "A" to **Service Agreement 092914** by mention made a binding part of this agreement as set forth herein.

Contractor Fee's: Refer to Attachment "A" to Service **Agreement No. 092914**, by mention made a binding part of this agreement as set forth herein. Contractor will be paid fifty (50) percent upon presentation of an invoice at the beginning of the project, and the remaining fifty (50) percent upon presentation of an invoice upon completion of the project. To the extent that the terms and conditions of this Service Agreement conflict with the Terms and Conditions of Attachment "A", the terms and conditions of this service agreement will prevail and govern the contractual relationship between the parties.

ARTICLE 2 – TERMINATION: The County reserves the right to terminate the Contract, in whole or in part at any time, when in the best interest of the County, without penalty or recourse. Upon receipt of the written notice, the Contractor shall stop all work as directed in the notice. If the contract is terminated, the County shall be liable only for the services rendered under this contract and accepted material received by the County before the effective date of termination.

ARTICLE 3 - INDEMNIFICATION: Contractor shall indemnify, defend, save and hold harmless the County of Gila and its officers, officials, agents, and employees (hereinafter referred to as "Indemnitee") from and against any and all claims, actions, liabilities, damages, losses, or expenses (including court costs, attorneys' fees, and costs of claim processing, investigation and litigation) (hereinafter referred to as "Claims") for bodily injury or personal injury (including death), or loss or damage to tangible or intangible property caused, or alleged to be caused, in whole or in part, by the negligent or willful acts or omissions of Contractor or any of its owners, officers, directors, agents, employees or subcontractors. This indemnity includes any claim or amount arising out of or recovered under the Workers' Compensation Law or arising out of the failure of such contractor to conform to any federal, state or local law, statute, ordinance, rule, regulation or court decree. It is the specific intention of the parties that the Indemnitee shall, in all instances, except for Claims arising solely from the negligent or willful acts or omissions of the Indemnitee, be indemnified by Contractor from and against any and all claims. It is agreed that Contractor will be responsible for primary loss investigation, defense and judgment costs where this indemnification is applicable. In consideration of the award of this contract, the Contractor agrees to waive all rights of subrogation against the County, its officers, officials, agents and employees for losses arising from the work performed by the Contractor for the County.

ARTICLE 4 – INSURANCE REQUIREMENTS: Contractor and subcontractors shall procure and maintain until all of their obligations have been discharged, including any warranty periods under this Contract are satisfied, insurance against claims for injury to persons or damage to property which may arise from or in connection with the performance of the work hereunder by the Contractor, his agents, representatives, employees or subcontractors.

The insurance requirements herein are minimum requirements for this Contract and in no way limit the indemnity covenants contained in this Contract. The County in no way warrants that the minimum limits contained herein are sufficient to protect the Contractor from liabilities that might arise out of the performance of the work under this contract by the Contractor, his agents, representatives, employees or subcontractors and Contractor is free to purchase additional insurance as may be determined necessary.

A. **MINIMUM SCOPE AND LIMITS OF INSURANCE:** Contractor shall provide coverage with limits of liability not less than those stated below.

1. **Commercial General Liability – Occurrence Form**
   Policy shall include bodily injury, property damage and broad form contractual liability coverage.
   - General Aggregate $2,000,000
   - Products – Completed Operations Aggregate $1,000,000
   - Personal and Advertising Injury $1,000,000
   - Each Occurrence $1,000,000

   a. The policy shall be endorsed to include the following additional insured language: **"The County of Gila shall be named as an additional insured with respect to liability arising out of the activities performed by, or on behalf of the Contractor".**

2. **Worker's Compensation and Employers' Liability**

Workers' Compensation	Statutory
Employers' Liability	
Each Accident	$100,000
Disease – Each Employee	$100,000
Disease – Policy Limit	$500,000

   a. Policy shall contain a **waiver of subrogation** against the County of Gila.

3. **Professional Liability (Errors and Omissions Liability)**

Each Claim	$1,000,000
Annual Aggregate	$2,000,000

a. In the event that the professional liability insurance required by this Contract is written on a claims-made basis, Contractor warrants that any retroactive date under the policy shall precede the effective date of this Contract; and that either continuous coverage will be maintained or an extended discovery period will be exercised for a period of two (2) years beginning at the time work under this Contract is completed.

B. **ADDITIONAL INSURANCE REQUIREMENTS:** The policies shall include, or be endorsed to include, the following provisions:

1. On insurance policies where the County of Gila is named as an additional insured, the County of Gila shall be an additional insured to the full limits of liability purchased by the Contractor even if those limits of liability are in excess of those required by this Contract.
2 The Contractor's insurance coverage shall be primary insurance and non-contributory with respect to all other available sources.
3. Coverage provided by the Contractor shall not be limited to the liability assumed under the indemnification provisions of this Contract.

C. **NOTICE OF CANCELLATION:** Each insurance policy required by the insurance provisions of this Contract shall provide the required coverage and shall not be suspended, voided, canceled, reduced in coverage or endorsed to lower limits except after thirty (30) days prior written notice has been given to the County. Such notice shall be sent directly to **Gila County Purchasing Department, 1400 E. Ash St., Globe, AZ, 85501** or and shall be sent by certified mail, return receipt requested.

D. **ACCEPTABILITY OF INSURERS:** Insurance is to be placed with insurers duly licensed or approved unlicensed companies in the state of Arizona and with an "A.M. Best" rating of not less than B+ VI. The County in no way warrants that the above-required minimum insurer rating is sufficient to protect the Contractor from potential insurer insolvency.

E. **VERIFICATION OF COVERAGE:** Contractor shall furnish the County with certificates of insurance (ACORD form or equivalent approved by the County) as required by this Contract. The certificates for each insurance policy are to be signed by a person authorized by that insurer to bind coverage on its behalf.

All certificates and endorsements are to be received and approved by the County before work commences. Each insurance policy required by this Contract must be in effect at or prior to commencement of work under this Contract and remain in effect for the duration of the project. Failure to maintain the insurance policies as required by this Contract or to provide evidence of renewal is a material breach of contract.

All certificates required by this Contract shall be sent directly to **Gila County Purchasing Department, 1400 E. Ash St., Globe, AZ, 85501** or email to jsgroi@gilacountyaz.gov,. The County project/contract number and project description shall be noted on the certificate of insurance. The County reserves the right to require complete, certified copies of all insurance policies required by this Contract at any time.

F. **SUBCONTRACTORS:** Contractors' certificate(s) shall include all subcontractors as additional insured's under its policies **or** Contractor shall furnish to the County separate certificates and endorsements for each subcontractor. All coverage's for subcontractors shall be subject to the minimum requirements identified above.

G. **APPROVAL:** Any modification or variation from the insurance requirements in this Contract shall be made by the County Attorney, whose decision shall be final. Such action will not require a formal Contract amendment, but may be made by administrative action.

ARTICLE 5 – LEGAL ARIZONA WORKERS ACT COMPLIANCE: Contractor hereby warrants that it will at all times during the term of this Contract comply with all federal immigration laws applicable to Contractor's employment of its employees, and with the requirements of A.R.S. § 23-214 (A) (together the "State and Federal Immigration Laws"). Contractor shall further ensure that each subcontractor who performs any work for Contractor under this contract likewise complies with the State and Federal Immigration Laws. County shall have the right at any time to inspect the books and records of Contractor and any subcontractor in order to verify such party's compliance with the State and Federal Immigration Laws.

Any breach of Contractor's or any subcontractor's warranty of compliance with the State and Federal Immigration Laws, or of any other provision of this section, shall be deemed to be a material breach of this Contract subjecting Contractor to penalties up to and including suspension or termination of this Contract. If the breach is by a subcontractor, and the subcontract is suspended or terminated as a result, Contractor shall be required to take such steps as may be necessary to either self-perform the services that would have been provided under the subcontract or retain a replacement subcontractor as soon as possible so as not to delay project completion.

Contractor shall advise each subcontractor of County's rights, and the subcontractor's obligations, under this Article by including a provision in each subcontract substantially in the following form: "Subcontractor hereby warrants that it will at all times during the term of this contract comply with all federal immigration laws applicable to Subcontractor's employees, and with the requirements of A.R.S. § 23-214 (A). Subcontractor further agrees that County may inspect the Subcontractor's books and records to insure that Subcontractor is in compliance with these requirements. Any breach of this paragraph by Subcontractor will be deemed to be a material breach of this contract subjecting Subcontractor to penalties up to and including suspension or termination of this contract."

Any additional costs attributable directly or indirectly to remedial action under this Article shall be the responsibility of Contractor. In the event that remedial action under this Article results in delay to one or more tasks on the critical path of Contractor's approved construction or critical milestones schedule, such period of delay shall be deemed excusable delay for which Contractor shall be entitled to an extension of time, but not costs.

ARTICLE 6 – LAWS AND ORDINANCES: This agreement shall be enforced under the laws of the State of Arizona. Contractor shall maintain in current status all Federal, State and Local licenses and permits required for the operation of the business conducted by the Contractor. The Contractor shall comply with the applicable provisions of the Americans with Disabilities Act (Public Law 101-336, 42 U.S.C. 12101-12213) and applicable federal regulations under the Act.

ARTICLE 7–WARRANTY: Contractor expressly warrants that all goods or services furnished under this agreement shall conform to all specifications and appropriate standards, will be new, and will be free from defects in material or workmanship. Contractor warrants that all such goods or services will conform to any statements made on the containers or labels or advertisements for such goods, or services, and that any goods will be adequately contained, packaged, marked and labeled. Contractor warrants that all goods or services furnished hereunder will be merchantable, and will be safe and appropriate for the purpose for which goods or services of that kind are normally used. If Contractor knows or has reason to know the particular purpose for which County intends to use the goods or services, Contractor warrants that such goods or services will be fit for such particular purpose. Contractor warrants that goods or services furnished will conform in all respects to samples. Inspection, test, acceptance of use of the goods or services furnished hereunder shall not affect the Contractor's obligation under this warranty, and such warranties

shall survive inspection, test, acceptance and use. Contractor's warranty shall run to County, its successors, and assigns. Contractor agrees to replace or correct, at Contractor's sole cost and expense, defects of any goods or services not conforming to the foregoing warranty, or improperly installed, as well as guarantee to the County and to the Owner, against liability, losses or damage to any or all parts of the work arising from said installation during a period of two (2) years from date of completion. All guarantees will inure to the benefit of the County and the Owner, their successors or assigns, including equipment warranties, ordinary wear and tear and unusual abuse or neglect excepted.

In the event of failure of Contractor to correct defects in or replace nonconforming goods or services promptly, County, after reasonable notice to Contractor, may make such corrections or replace such goods and services and charge Contractor for the cost incurred by the County in doing so. Contractor recognizes that County's requirements may require immediate repairs in reworking of defective goods, without notice to the Contractor. In such event, Contractor shall reimburse County for those costs, delays, or other damages which County has incurred.

ARTICLE 8 – CANCELLATION: This agreement is subject to cancellation pursuant to A.R.S. §38-511. If the Agreement is terminated, the county shall be liable only for payment for services rendered and accepted material received by the County before the effective date of termination.

ARTICLE 9 – RELATIONSHIP OF THE PARTIES: Contractor is an independent contractor of the County. Contractor represents that he has or will secure, at his own expense, all personnel required in performing the services under this contract. Such personnel shall not be employees of or have any contractual relationship with the County. All personnel engaged in work under this contract shall be fully qualified and shall be authorized or permitted under State and local law to perform such services. Contractor warrants that he has obtained or will obtain Worker's Compensation Insurance for his employees working on this contract and that any subcontractors will likewise obtain Worker's Compensation Insurance for of their employees working on this contract. It is further agreed by Contractor that he shall obey all state and federal statutes, rules, and regulations which are applicable to provisions of the services called for herein. Neither Contractor nor any employee of the Contractor shall be deemed an officer, employee, or agent of the County.

ARTICLE 10 – NON-APPROPRIATIONS CLAUSE: Contractor acknowledges that the County is a governmental entity, and the contract validity is based upon the availability of public funding under its authority. In the event that public funds are unavailable and not appropriated for the performance of County's obligations under this contract, then this contract shall automatically expire without penalty to County after written notice to Contractor of the unavailability and non-appropriation of public funds. It is expressly agreed that the County shall only activate this non-appropriation provision as an emergency fiscal measure. The County shall not activate this non-appropriation provision for its convenience, to circumvent the requirements of this contract, or to enable the County to contract with another Contractor for the same supplies or services covered under this Addendum.

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ARTICLE 13 – GOVERNING LAW: Both parties agree that this Contract shall be governed by the laws of the state of Arizona. The parties further agree that the jurisdiction for any legal disputes arising out of this Contract shall be the Superior Court of the State of Arizona. The parties agree that even if this Contract does not specifically reference any provision required by state or federal law, those state and federally required provisions are incorporated into this Contract by this reference as though they were specifically listed herein.

ARTICLE 14– TERM: Contract shall be effective date signed by the County Manager and expire on June 30, 2015.

ARTICLE 15 – PAYMENT/BILLING: Contractor shall be paid a flat fee of **$4,555.00** for completion of the projects as outlined in the Article 1-Scope of Services.

All invoices shall be submitted to Gila County Accounts Payable, 1400 E. Ash St, Globe, Arizona and include the following information:

- Purchase Order Number
- Contract Number
- Invoice Number
- Service Location
- Vendor Name and Address
- Description of Service

Any alterations to the scope of work resulting in a change in cost must have prior written approval by the County. Any unauthorized work may result in non-payment to the vendor.

Gila County employs a "Net 15" payment term for services meaning the payment will be issued fifteen (15) days from the date the County receives the invoice from the Contractor. Purchase orders sent to the Contractor reflect these terms and conditions.

The Contractor shall have a current I.R.S. W-9 form on file with the County unless not required by law. The County shall not remit payment if the Contractor does not have a current W-9.

IN WITNESS WHEREOF, Service Agreement No. 092914 has been duly executed by the parties hereinabove named, on the date and year first above written.

GILA COUNTY

Don E. McDaniel Jr., County Manager

Date: 10/1/14

MOUNTAIN RETREAT BUILDERS

Signature

John DiDonato

Print Name

Estimate for Chaparlie Costillo

Mountain Retreat Builders, LLC.
ROC #170186

745 E. Senita Dr.
Globe AZ 85502
Phone 928-606-4674

TO:
Gila County Community Services Division
Weatherization Program
5515 S. Apache Ave. Suite #200
Globe, AZ 85501
928-425-7631

FOR:
Chaparlie Costillo
7999 Pinal View # 2 Four Star MHP
Globe,AZ 85501

Item	DESCRIPTION	
	Included below for Weatherization Walk Thru on Monday 15th,	
	Repair furnace Only per Line 4----------	
	Service Furnace Line 5 per walk thru----------	
	Service Cooler – Repair per Line 6 ----------	
	Install ASHREA Fan-Line 7 ----------	
	Repair --Belly Pan as Needed Line 8----------	
	"""""""Install New Skirting """"""– Added at walk thru to Line 8----------	
	Repair Front Door per Line 9----------	
	Patch all holes in Exterior wall for Infiltration per Line 10----------	
	Taxes----------	
	Notes : Not working on roof so no warranty if roof leaks in future.	
	TOTAL----------	$4,555.00

AMENDMENT NO. 1 to SERVICE AGREEMENT NO. 1

The following amendments are hereby incorporated into the agreement for the below project

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SERVICE AGREEMENT NO. 082814
MAJOR REHABILITATION NO. HH#9834
MOUNTAIN RETREAT BUILDERS

Effective September 2, 2014, Gila County and Mountain Retreat Builders entered into a contract whereby Mountain Retreat Builders agreed to provide labor and materials required for performing all work for construction in Weatherization Project #9834, in Globe, AZ.

Service Agreement No. 082814 was issued for a total flat fee of $8,900.55 **Amendment No. 1 to Service Agreement 082814** is being issued to request an addition to the contract scope in the amount of Six Hundred Fifty dollars and no/100's ($650.00) to install a gas dryer to free up power needed for AC Electric. Refer to attached Attachment "A" **to Amendment No. 1 to Service Agreement No. 082814** by mention made a binding part of this Amendment.

Consequently, the contract is amended to increase the contract amount by $650.00 for a new total contract amount of Nine Thousand Five Hundred, Fifty dollars and 55/100's ($9550.55).

All other terms, conditions and provisions of the original Contract, shall remain the same and apply during the July 1, 2014 to June 30, 2015 renewal period.

IN WITNESS WHEREOF, two (2) identical counterparts of this amendment, each which shall include original signatures and for all purposes be deemed an original thereof, have been duly executed by the parties hereinabove named, on this 1 day of OCTOBER, 2014.

GILA COUNTY:

Don E. McDaniel Jr., County Manager

Date: 10/1/14

MOUNTAIN RETREAT BUILDERS

Signature

John Oddonetto

Print Name

Invoice for Vicki Morgan

Mountain Retreat Builders, LLC.
ROC #170186

745 E. Senita Dr.
Globe AZ 85502
Phone 928-606-4674

TO:
Gila County Community Services Division
Weatherization Program
5515 S. Apache Ave. Suite #200
Globe, AZ 85501
928-425-7631

FOR:
Vicki Morgan
2165 N. Westfield's Rd
Globe,AZ 85501
HH# 9834

Date- 8-21-2014

Item	DESCRIPTION	
	Gas Dryer to free up Power needed for AC Electric Change Order	
	Tax Included,,	
	TOTAL----------	$650

AMENDMENT NO. 1 TO PROFESSIONAL SERVICES CONTRACT NO. 060914

The following amendments are hereby incorporated into the contract documents for the below stated project:

PROFESSIONAL SERVICES CONTRACT 060914
LEGAL SERVICES

BRAD J. CRIDER

Effective July 15, 2014, Gila County and Brad J. Crider entered into a contract whereby Brad J. Crider agreed to provide Legal Services to the Superior Court in Gila County.

Amendment No. 1 to Professional Services Contract No. 060914 will serve to **add** the following language to Section III-Compensation, Costs and Billing Procedures; Item A-Indigent Dependency Representation, "Invoices may be submitted bi-weekly for payment in Net 15". Payment for said invoice amount will be issued fifteen (15) days from the date Gila County receives the invoice, with agreement of the Attorney and with approval by the Court Administrator and the Presiding Judge", in.

Additionally, **Amendment No. 1 to Professional Services Contract No. 060914** will serve to replace the language in C-1 Submission and Payment, from "The Attorney should submit a monthly invoice for each month's services" **with** "The Attorney may submit an invoice bi-weekly for each month's services", and will delete Item C2-Due Date for Invoices, in its entirety, from Section III-Compensation, Costs and Billing Procedures.

All other terms and conditions of the original agreement shall remain in full force and affect during the term of the contract.

IN WITNESS WHEREOF, two (2) identical counterparts of this amendment, each which shall include original signatures and for all purposes be deemed an original thereof, have been duly executed by the parties hereinabove named, on this 1 day of OCTOBER, 2014.

GILA COUNTY:

Don E. McDaniel Jr., County Manager

Date: 10/1/14

BRAD J. CRIDER

Signature

Brad Crider

Print Name

EXECUTIVE SUMMARY FORM

Contract Name: Electrified Touch-Sense Panic Bars

Contract No.: 13412 City of Avondale/S.A.V.E. Co-op

Statement of Purpose and Need (3-5 Sentences)
Current panic bars on all main double doors in the Globe Courthouse have a sensor allowing the contact to break when someone comes close in order to allow access out or in. Unless the doors are retrofitted with new panic bars, the potential for entries without access cards is a distinct possibility. Installation will take from 2 to 3 days, depending upon court traffic.

Contract End Date: 10-01-14 to 10-17-14

Renewal Option: ☐ Yes ☒ No

Maximum Dollar Limit: $6,995.34 including tax

Contract Information

Firm Name: Stanley Security Solutions

Contact Person: Matt Alvey

Address: 4666 S. Ash Avenue

Phone No: 480-216-9273

City: Tempe **State:** AZ **Fax:** **Email:** malvey@stanleyworks.com

Fund: Superior & JP Courts Security/Finance/Gen Admin/Capital Outlay-Construction in Progress

Fund Code: 1124.201.140.4500.19 FM-0101SEC-ALL

Type of Funds:
☐ Restricted
☐ Grant
☐ General Fund
☐ Other

Date Sent for Legal Review: n/a

Date Returned:

Special Notes:
Gila County is part of the Strategic Alliance for Volume Expenditures (S.A.V.E.), which includes the City of Avondale, for cooperative purchasing. By using the City of Avondale contract with Stanley Security Solutions., it will save the county in both time and money for a rate that already been established in the City of Avondale bidding process.

Authorization to use a Cooperative Purchasing Agreement with the City of Avondale, Contract No. 13412, for Security Electronic Systems: Parts, Maintenance & Repair approved this 1 day of OCTOBER, 2014.

GILA COUNTY MANAGER

Don E. McDaniel, Jr.

STANLEY
Security Solutions

GILA COUNTY
1400 E ASH ST
GLOBE, AZ 85501

Proposal Generated: 9/25/2014

Qty	Description	Part Number	Unit Price	Total Price
8	Touch Sense Bar, Black 36in	SN-TSBBK	$467.91	$3,743.28
8	XTRA DOOR CORD W/GRY/BK CAP	SN-TSBC	$32.12	$256.96
	Equipment Total			**$4,000.24**

	Total Price
Labor Total	$2,624.76
Subcontractor	$0.00
Account Administration	$0.00
Labor & Additional Total	**$2,624.76**
Tax	**$370.34**
Actual Install Sale Price	**$6,995.34**

All terms and conditions of City of Avondale Contract No.13412 apply

AMENDMENT NO. 1 to SERVICE AGREEMENT NO. 043014

The following amendments are hereby incorporated into the agreement for the below project

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REPAIRS TO FIRE PANELS AND SMOKE ALARMS IN GILA COUNTY BUILDINGS

ADVANCED CONTROLS CORPORATION

Effective July 2, 2014, Gila County and Advanced Control Corp. entered into a contract whereby Advanced Control Corp. agreed to provide inspections for all Fire Alarm Panels, for various Gila County Buildings in Gila County for a term of two (2) years, ending December 31, 2015.

The Public Works Department would like to increase the contract amount by and an additional Five Thousand dollars and no/100's ($5,000.00) to include the cost of repairs, **should they be needed to be performed**, during the contract term ending on December 31, 2015.

AMENDMENT NO. 1 **to Service Agreement No. 043014**, will serve to increase the contract amount by Five Thousand dollars and no/100's ($5,000.00) for a new contract amount of Eleven Thousand, Four Hundred Seventy-Six dollars and 40/100's (11,476.40).

All other terms, conditions and provisions of the original Contract, shall remain the same and apply during the January 1, 2014 to December 31, 2015 renewal period.

IN WITNESS WHEREOF, two (2) identical counterparts of this amendment, each which shall include original signatures and for all purposes be deemed an original thereof, have been duly executed by the parties hereinabove named, on this 01ST day of OCTOBER, 2014.

GILA COUNTY:

Don E. McDaniel Jr., County Manager

Date: 10/1/14

ADVANCED CONTROLS CORPORATION

Signature

Bryan Kauffman

Print Name