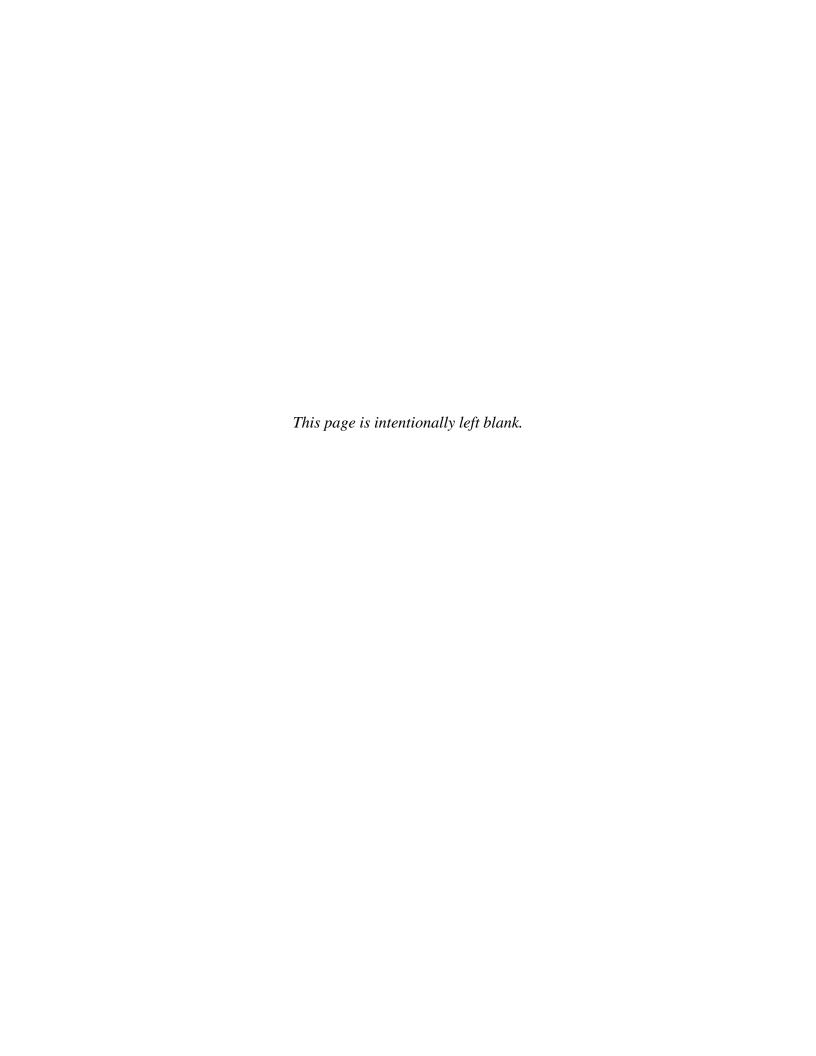
TECHNICAL BULLETIN

Tri-Service Food Code

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SUMMARY OF CHANGES

TB MED 530/NAVMED P-5010-1/AFMAN 48-147_IP Tri-Service Food Code

This revision, dated 30 July 2018—

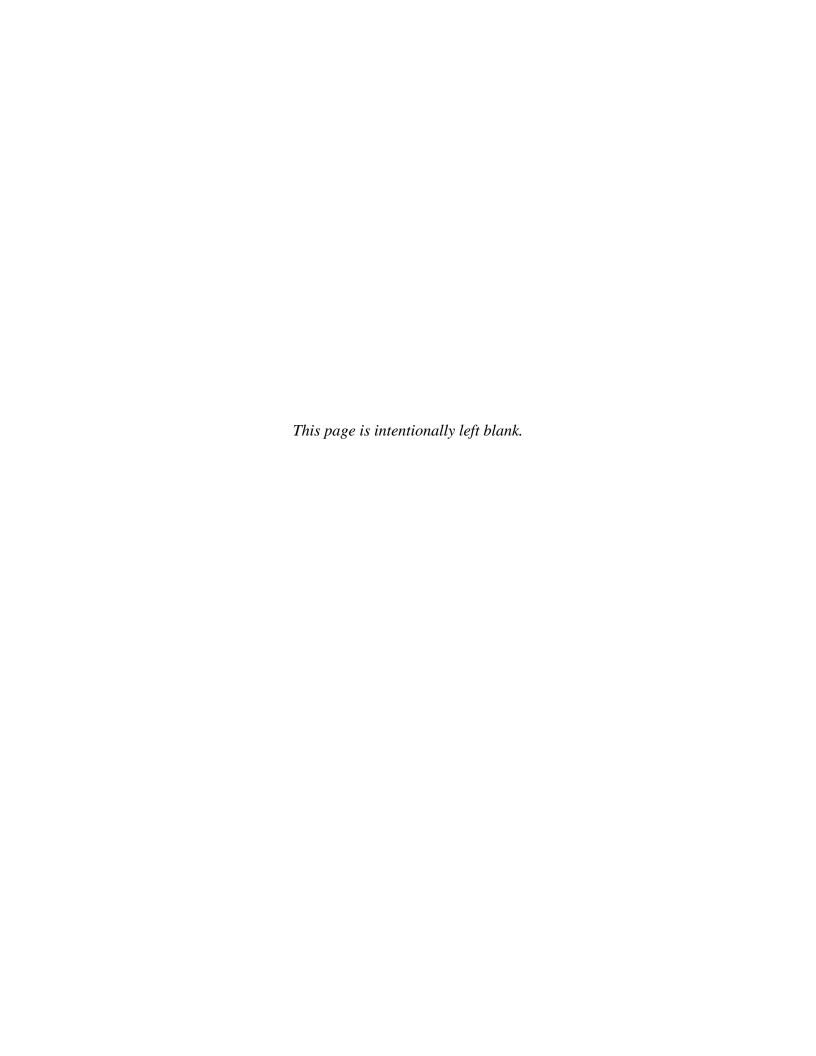
- Updates the table of contents to include the list of provisions contained under each subpart and hyperlinks each provision to the chapter.
- Amends Part 1-4 to clarify applicability of this document; amends the guidance in paragraph 1-6.c. to increase understanding on how to properly use this publication.
- Amends <u>2-102.11(A)</u> to include patterns of reoccurring violations as an assessment measure for demonstration of knowledge.
- Adds <u>2-102.12</u> to clarify a designated person in charge (PIC) must have supervisory or management authority [2013 FDA Food Code change].
- Amends <u>2-102.20</u> to clarify approved resources for attaining Food Protection Manager Certification.
- Adds paragraph <u>2-103.11(H)</u> requiring routine monitoring of food temperatures during hot and cold holding [2013 FDA Food Code change].
- Adds nontyphoidal *Salmonella* in sections <u>2-201.11</u>, <u>2-201.12</u>, and <u>2-201.13</u> as a reportable illness requiring exclusion or restriction [2013 FDA Food Code change].
- Adds new paragraph <u>2-301.14(I)</u> for washing hands after handling currency [2013 FDA Food Code change].
- Amends 2-301.16(A)(2) to address hand antiseptics as a food additive [2013 FDA Food Code change].
- Amends <u>2-501.11(B)</u> to clarify refresher training requirements for individuals certified as a Food Protection Manager.
- Amends <u>2-502.11</u> and <u>2-503.11</u> to address food employee training requirements when an establishment only serves food that does not require time or temperature control for safety.
- Amends <u>2-503.13(A)</u> to eliminate the minimum training time required for temporary food employees.
- Adds <u>2-601.11</u> to address clean-up of vomiting and diarrheal events [2013 FDA Food Code change].
- Adds new paragraph 3-301.11(D) to clarify allowances for bare hand contact with ready-to-eat (RTE) food
 [2013 FDA Food Code change].
- Adds new paragraph 3-304.11(C) to allow food contact with linens and napkins [2013 FDA Food Code change].
- Adds new paragraph <u>3-304.12(G)</u> to prohibit soaking in-use utensils in a sanitizing solution between uses.
- Amends <u>3-304.13</u> to clarify the term "napkin" refers to "cloth" napkins [2013 FDA Food Code change].
- Amends <u>3-304.15(A)</u> to clarify glove disposal requirements once removed from the hands [2013 FDA Food Code change]; amends guidance for powdered glove use, paragraph (F).
- Amends 3-304.17 to incorporate the criteria previously cited in 4-603.17 for cleaning and refilling returnables [2013 FDA Food Code change].
- Adds new paragraph 3-305.11(D) to address food storage at military food storage warehouses.
- Amends <u>3-306.11</u> to clarify conditions regarding protection of food on display.
- Amends <u>3-401.11(A)(2)</u> to clarify that pre-cracked eggs that are "pooled" and held prior to a customer order must be cooked to 155°F.
- Amends 3-401.14(C) and (D) to clarify requirements for noncontinuously cooked raw animal foods [2013 FDA Food Code change].
- Amends <u>3-402.11(B)</u> to identify scallop products excluded from parasite destruction through freezing [2013 FDA Food Code change].
- Amends <u>3-403.11(C)</u> to clarify the provision applies to all commercially processed time/temperature control for safety foods that are RTE [2013 FDA Food Code change].
- Adds new paragraph 3-501.13(E) to address thawing criteria for frozen fish that is packaged using a reduced oxygen packaging (ROP) method [2013 FDA Food Code change].

- Amends <u>3-501.16(A)</u> to clarify the temperature requirements for hot and cold food are intended to mean the internal food product temperature and not the ambient temperature maintained by the equipment.
- Amends <u>3-501.17(A)-(C)</u> to clarify date marking and retention criteria for "advanced prepared" food, commercially packaged food received frozen, commercially packaged food received fresh, and commercially processed RTE food that is opened and then stored cold.
- Adds new paragraph <u>3-501.17(G)</u> to exempt raw, live in-shell molluscan shellfish from date marking; amends subparagraph <u>3-501.17(H)(6)</u> for date marking shelf-stable dry fermented sausages [2013 FDA Food Code change].
- Amends <u>3-501.110</u> to increase the maximum leftover retention time to 7 days and provide conditions for retaining non-TCS leftover foods.
- Amends 3-502.11(D) to clarify the variance requirement only applies to TCS foods prepared under an ROP method [2013 FDA Food Code change].
- Amends 3-502.12 regarding ROP without a variance: subparagraphs (B)(3)(b) and (B)(4) changes the discard time 30 days; adds a new subparagraph (B)(7) regarding submission of a Hazard Analysis Critical Control Point (HACCP) Plan to the regulatory authority; amends subparagraph (D)(2) to apply cooking parameters in paragraphs 3-401.11(A), (B) and (C); amends subparagraph (D)(2)(e)(ii) to allow for cold holding at 41°F (5°C) for 7 days after cooling; deletes subparagraph (D)(2)(e)(iii); renumbered (D)(2)(e)(iv); and inserts a new paragraph (F) to identify conditions under which a HACCP Plan is not required for reduced oxygen packaged foods.
- Adds new provision <u>3-502.13</u> to address freezing food by the food establishment.
- Amends 3-503.11 to clarify restrictions and provide guidance for extending product shelf life.
- Amends 3-602.11 to clarify the information that should be included on a food label [2013 FDA Food Code change]; adds new paragraph (E) to address labeling requirements for advanced prepared and leftover food.
- Amends <u>3-701.11(A)</u> to include required actions when processing contaminated food stocks.
- Amends <u>3-801.11(C)</u> to clarify children ages 12 and under are treated as a highly susceptible population (HSP) only when subsisting in a school or other child care facility.
- Amends <u>4-204.16</u> to clarify criteria for cold-plate beverage cooling devices and beverage tubing separation with stored ice [2013 FDA Food Code change].
- Amends <u>4-204.112(B)</u> to clarify requirements for placing food thermometers inside refrigeration units.
- Adds new paragraph <u>4-205.12(E)</u> for notification of the regulatory authority prior to initiating food equipment modifications.
- Amends <u>4-301.14</u> by incorporating the ventilation and exhaust rate requirements previously addressed under subparagraphs 6-304.11(A)(3)-(6) and (B) and section 6-304.12.
- Amends 4-302.13 title to include mechanical warewashing; adds new paragraph 4-302.13(B) requiring use of an irreversible registering temperature indicator to monitor sanitizing temperatures in dish machines [2013 FDA Food Code change].
- Adds new Subpart 4-303 and <u>4-303.11</u> to address availability of cleaning agents and sanitizers [2013 FDA Food Code change].
- Corrects the provision designation for <u>4-501.111</u> as a critical requirement regarding the hot water sanitizing temperature during manual warewashing.
- Amends <u>4-501.112</u> to include cross-references to the provisions that address hot water sanitizing temperature for mechanical warewashing and associated temperature monitoring requirements.
- Corrects the provision designation for $\underline{4-501.115}$ as a critical requirement regarding use of detergent-sanitizers.
- Amends <u>4-501.200</u> to include mixing formulas for preparing a chlorine sanitizing solution using an 8.25 percent base product.
- Amends <u>4-602.11(B)</u> to remove the descriptive language involving "raw animal foods" and "fish" and replacing it with "raw meat and poultry" when addressing frequency for cleaning and sanitizing food contact surfaces that are in contact with a succession of different raw animal foods [2013 FDA Food Code changes].
- Amends <u>4-602.13(B)</u> to clarify requirements apply to local exhaust ventilation hoods and does not apply to fans and ducts associated with heating and ventilation systems.
- Deletes 4-603.17 and relocates the criteria for cleaning and refilling returnables to <u>3-304.17</u> [2013 FDA Food Code change].

- Adds paragraph 4-703.11(D) to clarify the minimum chlorine residual required when manually spraying the sanitizer onto a food-contact surface.
- Amends <u>4-802.11(C)</u> to clarify the term "napkins" applies only to cloth napkins [2013 FDA Food Code change].
- Corrects the provision designation for <u>5-101.14</u> as a critical requirement when using steam to disinfect foodcontact surfaces.
- Deletes paragraph 5-501.15(C) and relocates the criteria regarding location of compactor-type units to 5-501.19(F).
- Amends <u>6-304.11</u> to exclusively address room ventilation and relocates the criteria for exhaust ventilation hoods to 4-301.14(B).
- Deletes 6-304.12 and Table 6-1 and relocates the criteria for ventilation hood exhaust rates to 4-301.14(E)(2) and mechanical ventilation requirements to 6-304.11.
- Amends <u>6-501.14</u> to clarify the ventilation cleaning criteria presented in the provision applies to heating, ventilation and air conditioning systems, ventilation ducts and fans, and does not apply to local exhaust hoods.
- Amends <u>7-201.11</u> to align with the 2013 FDA Food Code by removing the requirement for storing poisonous or toxic materials in a locked room or cabinet.
- Amends 7-204.12(A) to clarify requirements regarding chemicals used to wash fresh fruits and vegetables.
 Adds new subparagraphs to address ingredients generally recognized as safe, effective food contact
 notifications, and 40 CFR 156 Labeling Requirements for Pesticides and Devices to allow use of other
 antimicrobial agents [2013 FDA Food Code change].
- Amends <u>8-201.11</u> to clarify the provision is intended to address construction and renovation plans. Criteria for submitting plans to operate a temporary food establishment was relocated to paragraphs <u>8-301.11(A)</u> and <u>8-302.11(C)</u>.
- Removes <u>8-201.12</u> from "reserve" status and specifies the minimum required plan contents when constructing or renovating a food establishment.
- Amends <u>8-201.13(B)</u> to require the food establishment to notify the Regulatory Authority and provide a HACCP Plan for ROP operations [2013 FDA Food Code change].
- Amends 8-201.14 to clarify requirements when submitting a HACCP Plan [2013 FDA Food Code change].
- Amends <u>8-301.11</u> to clarify preoperational requirements for new food operations and unit and organizational food events and adds <u>Table 8-1</u>, summarizing preoperational and inspection requirements.
- Renumbers Table 8-1 (inspection frequencies) as <u>Table 8-2</u>.
- Adds <u>8-301.12</u> to provide guidance for public health oversight of cottage food operations occurring in government housing.
- Removes <u>8-302.11</u>, <u>8-302.12</u>, and <u>8-302.14</u> from "reserve" status and specifies procedures and required content when submitting an application to operate a new food establishment.
- Amends <u>8-303.20</u> to clarify requirements for reviewing operational plans when an existing food establishment changes management or contract.
- Adds new paragraph <u>8-304.11(J)</u> requiring the food establishment to provide a means for informing customers of the establishment's food sanitation inspection results [2013 FDA Food Code change].
- Adds 8-400.11 requiring execution of food facility risk assessment surveys.
- Amends 8-401.10 to clarify criteria for determining food establishment inspection frequencies.
- Amends <u>8-401.30</u> to clarify the types of intervention strategies suitable for inspection substitution and improvement of active managerial controls in a food establishment. Renumbers Table 8-2 (inspection substitutions) as <u>Table 8-3</u>.
- Adds 8-402.10(B) requiring continuing education and access to training to maintain inspection personnel
 competencies.
- Amends <u>8-402.12</u> requirements for conducting self-evaluations and clarifies the provision applies to food service operations, not retail stores.
- Adds new provision <u>8-402.40</u> to provide guidance regarding installation farmers markets.
- Amends <u>8-403.20</u> to include guidance for implementing a letter-grading or color-coded inspection rating system; changes the scoring criteria for a "fully compliant" rating by allowing up to 4 noncritical findings that

- are corrected onsite; and provides scoring guidance when conducting Follow-up inspections. Renumbers Table 8-3 (inspection ratings) as <u>Table 8-4</u>.
- Adds new paragraph <u>8-403.40(B)</u> to clarify the timeframe in which a food sanitation inspection report prepared by Army Veterinary Services must be provided to the PIC.
- Amends <u>8-405.11</u> to clarify the conditions that qualify as "corrected onsite" for a critical item or imminent health hazard.
- Adds <u>8-406.10</u> prohibiting inspection personnel from elevating noncritical violations to a critical status.
- Amends paragraph 8-6.c. to clarify the characteristics and conduct of Routine inspections.
- Amends paragraph <u>8-6.d.</u> to clarify the characteristics and conduct of Walk-through inspections.
- Amends paragraph <u>8-6.e.(1)</u> to clarify requirements for Follow-up inspections.
- Adds new subparagraph <u>8-8.c.(3)</u> requiring Army Preventive Medicine and Veterinary Services to enter food
 operation inspection data in the Defense Occupational and Environmental Health Readiness System in
 accordance with Army Medical Command Policy.
- Amends <u>9-202.11</u> to clarify the requirements for physical facilities supporting field food operations and field food service establishments.
- Amends <u>9-203.11</u> to clarify structural sanitary controls for floors, walls, and ceilings where field feeding operations are conducted.
- Amends <u>9-303.11</u> to identify the specific components of a field food operation where potable water must be used
- Amends 9-502.14 to allow retention of non-TCS leftovers in a field/deployment setting.
- Amends chapter 10 title and applicable provisions to include mobile food establishments.
- Adds <u>10-102.20</u> to identify the provision in chapter 2 that addresses training criteria for employees operating a temporary food establishment.
- Adds new paragraph 10-201.14(B) to direct mobile water tank compliance according to Part 5-3.
- Adds new paragraphs <u>10-203.11(B)</u> and <u>(C)</u> for mobile food establishments to direct sewage and liquid waste holding tank compliance according to specified provision under Part 5-4.
- Adds 10-301.16 to specify requirements for outdoor surfaces where temporary food establishments are located.
- Amends <u>10-401.12</u> to direct requirements for submitting plans to operate a temporary, mobile, seasonal, or vending food operation and associated timeframes for submission are according to specified provisions in chapter 8.
- Amends <u>Appendix B</u> to reflect organizational name changes and contact information for Veterinary Services at the Defense Health Agency and the U.S. Army Public Health Center.
- Amends <u>Appendix C</u> to include instructions when using the tables of debitable provisions; amends the tables to identify the noncritical and swing paragraphs associated with a provision; identifies the item number on the inspection form where each violated provision is appropriately marked.
- Amends Appendix D, paragraph <u>D-6</u>, to clarify the frequency and conditions for updating a food facility risk assessment.
- Amends Appendix E, paragraph <u>E-3.a.</u>, to clarify the naming convention format when identifying facilities for data entry in the Defense Occupational and Environmental Health Readiness System (DOEHRS).
- Amends the following Items at Appendix E, Section II, Food Operation Inspection Report, to clarify assessment guidance and update the list for "applicable publication sections": Item 1, Item 4, Item 4, Item 16, Item 19, Item 25, Item 32, Item 37, Item 39, Item 40, Item 45, Item 44, Item 47, Item 49, and Item 51.
- Amends the following Items at Appendix E, Section III, Tactical Kitchen Inspection, to clarify assessment guidance and update the list for "applicable publication sections": <u>Item 2</u>, <u>Item 3</u>, <u>Item 6</u>, <u>Item 7</u>, <u>Item 8</u>, <u>Item 11</u>, <u>Item 13</u>, <u>Item 14</u>, <u>Item 15</u>, <u>Item 17</u>, <u>Item 20</u>, <u>Item 21</u>, <u>Item 22</u>, <u>Item 27</u>, <u>Item 28</u>, <u>Item 29</u>, <u>Item 30</u>, <u>Item 31</u>, <u>Item 35</u>, <u>Item 41</u>, <u>Item 42</u>, <u>Item 43</u>, <u>Item 44</u>, and <u>Item 46</u>.
- Amends Appendix F: adds paragraph F-1.c. to recognize risk assessment and inspection reports generated using DOEHRS as an official document in lieu of the prescribed Department of Defense (DD) forms; adds guidance in F-2 for using DD Form 2970, Application for Temporary Food Establishments; amends Table F-1 to clarify the minimum cooking temperatures for pork products.

- Adds <u>Appendix G</u> for public health reasons, which provide the science-based data and discussions that support the Tri-Service Food Code provisions [extracted from the 2013 FDA Food Code] and includes additional guidance and rationale agreed upon by the Food Code Working Group subject matter experts.
- Adds the following defined terms in the Glossary:
 - Cottage food
 - o Debit, debiting, debitable
 - o Farmers market
 - o Force provider
 - o Frozen
 - o General public
 - High-risk food
 - o <u>Installation commander</u>
 - o Low-risk food
 - o Military unit
 - Nonpublic water system
 - o Organizational food event
 - Qualified proctor
 - Safe temperature
 - o <u>Time/Temperature Control for Safety Food</u> (2013 FDA Food Code change)
- Amends the following defined terms in the Glossary:
 - o Advanced prepared
 - Enterohemorrhagic Escherichia coli (deleted due to 2013 FDA Food Code nomenclature change)
 - Field food operations
 - o Field food service establishment
 - o Food
 - o Food-contact surface (adds examples of nonfood-contact surfaces)
 - o <u>Food employee</u>
 - o Food establishment (adds paragraphs (3)(i)-(k) for other operations that are not a "food establishment")
 - o Highly susceptible population
 - o Leftovers
 - o Mobile food establishment
 - o Packaged (2013 FDA Food Code change)
 - o Person
 - o Person-in-charge
 - o Potentially Hazardous Food (deleted due to 2013 FDA Food Code nomenclature change)
 - o Reduced oxygen packaging (2013 FDA Food Code change)
 - o Shiga toxin-producing Escherichia coli, <u>STEC</u> (2013 FDA Food Code change)
 - o Temporary food establishment



Army Technical Bulletin Medical¹ Navy Bureau of Medicine and Surgery² Air Force Manual³ TB MED 530 NAVMED P-5010-1 AFMAN 48-147_IP

DEPARTMENTS OF THE ARMY, NAVY AND AIR FORCE WASHINGTON, DC, 1 March 2019

TRI-SERVICE FOOD CODE

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¹ This bulletin supersedes TB MED 530, 30 April 2014.

² This publication supersedes NAVMED P-5010, Chapter 1, 30 April 2014.

³ This manual supersedes AFMAN 48-147 IP, 30 April 2014.

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CHAPTER 1

INTRODUCTION

1-1. Purpose

The purpose of this publication is to establish standardized military food safety standards, criteria, procedures, and roles for the sanitary control and surveillance of food to mitigate risk factors known to cause foodborne illness. These provisions constitute the Tri-Service Food Code (TSFC), hereinafter referred to as "this publication." When sanitation principles and procedures vary, this publication takes precedence.

1-2. References

A list of applicable references and prescribed and referenced forms is provided in appendix A.

1-3. Abbreviations and terms

- a. The glossary defines abbreviations and terms as they are used in this publication.
- b. All words and terms that are capitalized within the text of this publication are defined in the glossary and alert the reader to the fact that—
 - (1) There is a specific meaning assigned to those words and terms, and
 - (2) The meaning of a provision is to be interpreted in the defined context.

1-4. Applicability

This publication-

- a. Applies to all operations that meet the defined meaning of the term "food establishment" as specified in the Glossary;
- b. Applies to all food activities purchased using appropriated or nonappropriated funds for the Active Army, Navy, Air Force, and Marine Corps; the U.S. Army, Navy, Marine Corps, and Air Force Reserves; Army and Air National Guard; and Department of Defense (DOD). Includes activities associated with contract food service, food concessions, food vendors, hospital food service, and retail stores operating on DOD installations, sites, and jurisdictions.
- c. Specifies requirements of military, Civilian, contract, and volunteer personnel providing military food service (for example, food operations occurring on a military installation and food establishments operated in an official capacity, except as indicated in paragraph 1-4.f., to support military members, DOD employees, and other beneficiaries.)
- d. Applies to all phases of training, exercises, and deployments to ensure that food prepared for and consumed by military personnel on DOD installations is unadulterated, honestly presented to the consumer, and poses minimal risk of foodborne illness.
- *e.* Is used as a guide by military public health regulators when developing local policies to address food-related activities or operations that do not meet the definition of a "food establishment," for example, farmers markets, a home business, unit food events, and local vegetable gardens supporting morale, wellness, and educational initiatives.
- f. Does not apply during exercises outside the continental United States (OCONUS) where Food and Water Risk Assessments are required. Guidance for conducting Food and Water Risk Assessments is provided in Military Standard 3041, Department of Defense Standard Practice: Requirements For Food and Water Risk Assessments (FWRA).

1-5. Technical assistance

Technical assistance related to the topics in this publication may be requested from the military and civilian organizations and laboratories listed in appendix B, in accordance with (IAW) local command and organization policies, by memorandum, and directly via telephone calls, e-mail messages, or online Web site requests.

1-6. Guidance for using the publication

- *a. Modifications.* The information provided in this publication includes excerpts and modifications from the U.S. Food and Drug Administration (FDA) Food Code, which is available at http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm.
- b. Cross-referencing with the FDA Food Code. The numerical designations used in the FDA Food Code 2013 are included at the beginning of each of the standards and criteria published in this publication.
 - c. Information to assist the user.
- (1) Provisions in this publication are either appropriate for citing as a violation ("debitable") on a food establishment inspection report, or they are not.
- (a) Paragraphs that are not designated as a *provision* are not debitable. Examples may be found in Chapter 8, Parts 8-6, 8-7, and 8-8. The information contained in these parts is intended to provide guidance to regulatory and management personnel in the administration of their programs or operations.
- (b) The numbers following the decimal point in the provision's numerical format are used to identify a debitable provision. Nondebitable provisions fall into two categories: those that end with two digits after the decimal point and the last digit is a zero (for example, § 2-102.20); and those that end with three digits after the decimal point and the last 2 digits are zeros (for example, § 4-204.200).
- (c) Appendix C provides a list of debitable publication provisions. Not all debitable provisions are accountable during a routine food operation inspection. Some provisions are program-level requirements essential for proper administration and oversight of the food safety program and are accountable during Command audits commonly associated with the Organizational Inspection Program or other inspection activities. For example, provision 5-102.13 requires sampling when water is obtained from a nonpublic water system. This requirement is not debitable on a food operation inspection report because the food establishment manager does not bear the responsibility for the action; responsibility belongs to another designated installation management entity (for example, Public Works, Facility Engineers, etc.). The provision is identified as a "debitable" provision because water sampling is a requirement if the installation allowed use of a nonpublic water system to supply a food operation.
- (2) Wherever possible, requirements in this publication are specified in the same location, paragraph and subparagraph, as they are in the FDA Food Code. New provisions from the FDA Food Code possessing a numerical value that is already assigned to an existing section within the TSFC are renumbered according to its appropriate placement in this publication. For example, Part 2-5 was added to the 2013 FDA Food Code to address clean-up of vomiting and diarrheal events. The Part and associated provision were renumbered in this publication as Part 2-6 and section 2-601.11, respectively, because Part 2-5 already existed in the TSFC to address training.
- (3) The publication's provisions added by the uniformed Services and not originally presented in the FDA Food Code are identified by a superscripted dagger † located at the end of the provision tagline or the paragraph that was added to an existing provision. Subordinate paragraphs associated with a marked paragraph are not marked with a dagger, but are understood to have been added by the military components.
- (4) Table 1–1 presents the structural nomenclature of the FDA Food Code and associated reference symbols as used in this document.

Table 1-1. The structural nomenclature of the FDA Food Code		
Nomenclature	Symbol	Example of Numerical Format
Chapter	None	9
Part	None	9-1
Subpart	None	9-101
Section (Provision)	§	9-101.11
Paragraph	¶	9-101.11(A)
Subparagraph	None	9-101.11(A)(1)

- (5) Two types of internal cross-referencing are widely used throughout this publication to eliminate the need for restating provisions.
- (a) The first type of cross-reference uses the phrase "as specified **under**..." followed by the relevant portion of the publication (for example, the provision number and paragraph). The purpose of this type of crossreference 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 publication under which a certain violation is properly cited/debited.
- (b) The second type of cross-reference uses the phrase "as specified in..." followed by the relevant portion of the publication. 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 publication (see ¶ 3-201.11(D) for an example); or
- (2) Refer the reader to a nondebitable provision of the publication which provides further information for consideration, such as provision for an exception or for an allowance to comply via an alternative method. For example, \P 3-303.12(B) begins with "Except as specified in $\P\P$ (C) and (D)..." and paragraphs (C) and (D) state the relevant exceptions to paragraph (B). Paragraph 3-201.11(F) states in part, "... as specified in \P 3-401.11(C)" and paragraph 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 (RTE) form. If the user reviews the exception in ¶ 3-303.12(B) and the allowance in ¶ 3-401.11(C), he or she will see that exceptions and allowances often contain conditions of compliance (that is, conditions that must be met in order for the exception or allowance to convey).
- (6) 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 publication 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 crossreference-
 - (a) Sends (via the word "under") the citing/debiting to another publication provision; or
 - (b) Incorporates (via the word "in") the referenced requirements into the publication provision.
- (7) This publication presents requirements by principle rather than by subject. For example, equipment requirements in Chapter 4 are grouped under functional headings such as Materials, Design and Construction, Numbers and Capacities, Location and Installation, and Maintenance and Operation rather than the equipment type (for example, refrigerators, thermometers, dishwashers). In this way, provisions need be stated only once when it applies to multiple equipment types rather than being repeated for each piece or category of equipment. Where there is a special requirement for certain equipment, the requirement is delineated under the appropriate principle (for example, Design and Construction) and listed as a separate provision.
- (8) Identifying the correct provision within this publication that appropriately addresses a violation requires proper determination of the primary principle that was violated. In some cases identifying the "primary principle" is similar to determining the" root cause" of the violation or the "key issue" creating the condition for the violation. Once determined, the reader uses the Part and Subpart titles within the applicable chapter to locate the

primary principle and the corresponding provision that was violated. For example, if an ice machine is located next to a food preparation sink and was found with food debris splattered along the side of the machine (nonfood-contact surface), two principles may be in violation: equipment cleaning and equipment location. Upon first glance it may appear appropriate to cite the violation using § 4-503.11 under Subpart 4-503—Ice Machines, which falls under the primary principle of "maintenance and operation" (Part 4-5). This, however, is incorrect. A review of § 4-503.11 and the associated cross-reference, subparagraph 4-602.11(E)(4), reveals the provision is intended to addresses cleaning the food-contact surface inside the ice bin and does not address cleanliness of the nonfood-contact surfaces of the machine. The provisions that correctly apply to this violation are § 4-401.12 under Part 4-4 and Subpart 4-401, which addresses the primary principle of equipment location and installation, and ¶¶ 4-601.11(C) and 4-602.13(A) under Part 4-6, which address cleaning nonfood-contact surfaces of equipment. Provision 4-401.12 specifies an ice machine must be located in a clean area that does not present a risk for ice contamination. The observation made in this example provides evidence that the ice machine is subject to contamination from food being splashed or sprayed from the food preparation sink. Paragraph 4-601.11(C) specifies the nonfood-contact surfaces of equipment must be kept free of accumulated food residues and ¶ 4-602.13(A) addresses cleaning frequency. In this case, the inspector must assess the situation to determine if the food residues are from recent activities. The Food Operation Inspection Report and Tactical Kitchen Sanitation Inspection forms are organized to help you determine the primary principle associated with a violation. The inspection forms are used with the information provided at Appendix E to help determine the correct provision for debiting.

- (9) Portions of some provisions 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 "should," "except for," "may," "need not" or "does not apply." Refer to ¶ 3-202.18(D) for an example.
- (10) Sections designated as *Reserved* are held for future consideration. Examples include $\S\S$ 2-301.13 and 2-504.10.
- (11) The scientific data and rationale that supports each provision is presented in the Public Health Reasons at Appendix G. Understanding the public health reasons is essential for public health regulators and food managers to effectively administer their food safety programs.
- (12) Provision number and other referenced items that are underlined indicate a hyperlink is provided. When using this document in electronic format, users can easily navigate to the chapter provisions, cross-referenced items, and the public health reasons used to develop the standard.
- (a) Selecting the provision number from the table of contents or from the item descriptions at Appendix E for proper marking of the inspection report takes you to the chapter where the provision or provision paragraph is located.
- (b) Selecting the provision number from the provision title in the chapter takes you to the corresponding public health reason at Appendix G.
- (c) Selecting a referenced provision under a public health reason takes you to the public health reason for the specified reference.
- d. Categories of importance. Requirements contained in this publication are presented as being in one of three categories of importance: critical; "swing" (that is, a critical requirement that may be downgraded to noncritical, depending on the circumstances); and noncritical. An asterisk * located at the end of a section title or tagline (which is the language immediately following a section number that introduces the subject of the section) indicates that all of the requirements within that section are critical unless otherwise indicated, as follows:
 - (1) Any provisions that are "swing" items are followed by the bold, superscripted letter S.
 - (2) Any provisions that are noncritical are followed by the bold, superscripted letter N.
 - (3) Any unmarked provisions within a section that has an asterisked tagline are critical.
 - (4) All provisions following a tagline that is not marked with an asterisk are noncritical.
 - e. Conventions. The following conventions are used in this publication:
 - (1) "Shall" means the act is imperative (that is, "shall" constitutes a command).
 - (2) "May not" means absolute prohibition.
 - (3) "May" is permissive and means the act is allowed.

- (4) "Should" means the action is recommended. The term is used in nondebitable portions of this publication.
 - (5) The term "means" is followed by a declared fact.

1-7. Background

- a. Foodborne illness estimates, risk factors and interventions.
- (1) Foodborne illness in the United States is a major cause of personal distress, preventable death, and avoidable economic burden. A 2011 analysis released by the Centers for Disease Control and Prevention (CDC) estimates 48 million foodborne illnesses occur each year in the United States, resulting in approximately 128,000 hospitalizations and 3,000 deaths. For many victims, foodborne illness results only in discomfort or lost time from the job. For others, especially preschool-age children, older adults in health care facilities, and those with impaired immune systems and decreased resistance to disease, foodborne illness is more serious and may be life-threatening. For the uniformed services, prevention of foodborne illness serves as a critical force multiplier. Individuals become sick, but their illness affects entire units, the workforce, and families.
- (2) The annual cost of foodborne illness in terms of pain and suffering, reduced productivity, and medical costs is estimated to be \$10–\$83 billion. As stated by Mead et al. (1999), 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, however, remains a challenge and 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:
 - (a) Improper holding temperatures,
 - (b) Inadequate cooking,
 - (c) Contaminated equipment,
 - (d) Food from unsafe sources, and
 - (e) Poor personal hygiene
- (3) This publication addresses controls for risk factors and further establishes five key public health interventions to protect service members, their families and other consumers' 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.
- (4) The 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.
 - b. Tri-Service Food Code history, purpose, and authority.
 - (1) History and purpose:
- (a) Prior to publishing the first edition of the TSFC in 2014, Army, Navy and Air Force maintained independent food safety regulations and guidance documents to meet their needs. The U.S. Army Veterinary Service along with the U.S. Air Force used earlier versions of the FDA Food Code.
- (b) The need for a uniform food safety standard became apparent with Joint basing, public health teams from multiple Services evaluating deployment food operations under the control of other Services, and the consolidation of Service schools.
- (c) The FDA develops and maintains an updated model food code 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

Chapter 1 5

distribution chain where the consumer takes possession of the food. This publication is based on the FDA Food Code, which was adapted to meet DOD needs; the TSFC was then created.

- (d) The FDA Food Code is neither Federal law nor Federal regulation and is not preemptive. Rather, it represents the FDA's best advice for a uniform system of regulation to ensure that food at the retail level is safe and properly protected and presented. This publication is designed to be consistent with the FDA Food Code.
- (e) Providing model up-to-date food safety information and food code interpretations and opinions is the mechanism through which the DOD, with the authors of this publication, is able to promote uniform implementation of food safety procedures among the Services. In addition, because this publication is based on the FDA Food Code, its requirements and policies are consistent with the several thousand Federal, state, and local agencies and tribes that have primary responsibility for the regulation or oversight of retail level food operations and have adopted the FDA Food Code.
- (2) Authority. The authority for providing food safety regulations within the DOD begins with the overarching Department of Defense Directive 6400.04E, Veterinary Public and Animal Health Services. From that document food protection programs are administered through service-specific Public Health, Preventive Medicine, and Veterinary regulations including, for the Army, Army Regulation (AR) 40-5 and AR 40-657/NAVSUP 4355.4H/MCO P10110.31H; for the Air Force, Air Force Instruction (AFI) 48-116; and for the Navy, Navy Medical Department (NAVMED) P-117.
 - c. Public health and consumer expectations.
- (1) 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.
- (2) Under the FDA's 2012 Mission Statement, the agency is responsible for "Protecting the public health by assuring the safety and security of our nation's food supply... and for advancing the public health by helping the public get the accurate, science-based information they need about foods to maintain and improve their health." Accordingly, the provisions of this publication 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.
- (3) This publication provides DOD public health, which includes veterinary personnel, with the means to support the Services' mission in a variety of environments.
 - d. Advantage of Uniform Standards.
- (1) The advantages of well-written, scientifically sound, and up-to-date model codes have long been recognized by industry and government officials.
- (2) Industry conformance with acceptable procedures and practices is far more likely when 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.
- (3) 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.
- (4) This publication is the cumulative result of the efforts and recommendations of many contributing individuals, agencies, and organizations with years of experience in food safety and working in DOD food protection. It embraces the concept that how we collectively provide and protect our food not only directly affects our ability to accomplish our assigned missions but also affects the quality of life, state of health, and welfare of DOD Civilians, Service members, their Families, and other authorized consumers.

1-8. Publication revision process and official interpretation

- a. Revision and publication cycles.
- (1) The FDA generally publishes a new edition of the Food Code every 4 years and may issue supplements to update an existing edition before the next publishing. The Tri-Service Food Code Working Group (FCWG) reviews each new edition of the FDA Food Code and associated supplements to determine the need for updating the

TSFC. It is the intent of the FCWG to publish an updated TSFC as often as practicable to keep this publication consistent with current and acceptable industry practices.

- (2) Recommended changes and suggestions for improving this publication may be submitted by users through a Service representative from one of the public health agencies specified in subparagraph b.(1), below, to the FCWG. When submitting a recommended change or addition, reference the page and paragraph number, provide recommended verbiage, and briefly explain why the addition or change is needed.
 - b. Official interpretation of publication provisions.
- (1) The FCWG is comprised of subject matter experts (SME) from the Air Force School of Aerospace Medicine Public Health and Preventive Medicine Department; Air Force Medical Support Agency; U.S. Army Public Health Center; Defense Health Agency (DHA) Veterinary Service; and Navy/Marine Corps Public Health Center, Preventive Medicine Department. The FCWG is the official consulting body for clarification, interpretation, and changes to this publication. The FCWG was established by the Food Risk Evaluation Committee—a Joint DOD advisory group providing guidance to the Chief, Defense Health Agency Veterinary Services and The Surgeons General of the military medical departments on matters relating to food safety and defense.
- (2) Service-unique interpretations are addressed by the respective Service's SME. Issues that have broad application across the DOD are forwarded through the Service SME to the FCWG for collaboration and publication of a unified interpretation.
- (3) Interpretations should be resolved at the lowest level and elevated through the appropriate technical chain of command.

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CHAPTER 2

MANAGEMENT AND PERSONNEL

2-1. Supervision

2-101 Responsibility

2-101.11 Assignment*

- (A) Except as specified in \P (B) of this section, the FOOD ESTABLISHMENT manager shall be the PERSON IN CHARGE (PIC) or shall designate a PIC who meets the required criteria, as specified under \P 2-102.12(A), and shall ensure that a PIC is present at the FOOD ESTABLISHMENT during all hours of operation.
- (B) In a FOOD ESTABLISHMENT with two or more separately operated departments that are the legal responsibility of the same FOOD ESTABLISHMENT manager and that are located on the same PREMISES, the FOOD ESTABLISHMENT manager may designate a single PIC who is present on the PREMISES during all hours of operation, and who (effectively observes and controls all of the FOOD ESTABLISHMENTS, and who is responsible for each separately operated FOOD ESTABLISHMENT on the PREMISES.) For example, food courts where one kitchen is shared by two or more FOOD OPERATIONS.†

2-102 Knowledge

2-102.11 Demonstration*

Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PIC shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the Hazardous Analysis Critical Control Point (HACCP) principles, and the requirements of this publication. Demonstration of knowledge is achieved by—

- (A) Complying with this publication by having—^S
 - (1) no multiple violations of CRITICAL ITEMS during the current inspection; and
- (2) no demonstrated pattern of multiple reoccurring or frequently occurring CRITICAL ITEMS on this inspection when compared to the previous two inspections.
- (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 and maintaining current FOOD protection certification; and
- (C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation. The areas of knowledge include– $^{\rm S}$
- (1) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a FOOD EMPLOYEE;
- (2) Explaining the responsibility of the PIC for preventing the transmission of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne disease;
 - (3) Describing the symptoms associated with the diseases that are transmissible through FOOD;
- (4) Explaining the significance of the relationship between maintaining the time and temperature of TIME/TEMPERATURE CONTROL FOR SAFETY FOODS (TCS FOODS) and the prevention of foodborne illness;
- (5) Explaining the HAZARDS involved in the consumption of raw or undercooked MEAT, POULTRY, EGGS, and FISH;
- (6) Stating the required FOOD temperatures and times for safe cooking of TCS FOODS including MEAT, POULTRY, EGGS, and FISH;

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- (7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of TCS FOODS;
- (8) Describing the relationship between the prevention of foodborne illness and the management and control of the following:
 - (a) Cross contamination,
 - (b) Hand contact with RTE FOODS,
 - (c) Handwashing, and
 - (d) Maintaining the FOOD ESTABLISHMENT in a clean condition and in good repair;
- (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.
 - (10) Explaining the relationship between FOOD safety and providing EQUIPMENT that is:
 - (a) Sufficient in number and capacity, and
 - (b) Properly designed, constructed, located, installed, operated, maintained, and cleaned;
- (11) Explaining correct procedures for cleaning and SANITIZING UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT;
- (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;
- (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;
- (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 IAW the requirements of this publication;
- (15) Explaining the details of how the PIC and FOOD EMPLOYEES comply with the HACCP PLAN if a plan is required by the LAW, this publication, or an agreement between the REGULATORY AUTHORITY and the FOOD ESTABLISHMENT;
 - (16) Explaining the responsibilities, rights, and authorities assigned by this publication to the:
 - (a) FOOD EMPLOYEE,
 - (b) CONDITIONAL EMPLOYEE,
 - (c) the PIC.
 - (d) REGULATORY AUTHORITY; and
- (17) Explaining how the PIC, FOOD EMPLOYEES, and CONDITIONAL EMPLOYEES comply with reporting responsibilities and EXCLUSION or RESTRICTION of FOOD EMPLOYEES.

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 with required information through passing a test that is part of an ACCREDITED PROGRAM as specified under \P 2-102.11(B) and as specified in § 2-102.20.
- (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 and as specified in \P 2-502.11(C).
- (C) Retail establishment (for example, commissary) departments including meat, produce, delicatessen, bakery, and seafood shall meet the requirements as specified in \P (A) of this section and IAW their contract if the FOOD products require further on-premises processing (cutting, chopping, grinding, slicing, trimming, forming, etc.).

2-102.20 Food protection manager certification

(A) Food Protection Manager certification is achieved through a Food Protection Manager certification examination process that is evaluated and listed by a Conference for Food Protection (CFP)-recognized accrediting agency as conforming to the CFP Standards for Accreditation of Food Protection Manager Certification Program.

A PIC who demonstrates knowledge by being a certified Food Protection Manager is deemed to comply with ¶2-102.11(B) as long as the certification remains current through a recertification exam IAW the certifying organization.

- (B) The following resources are recognized as authorized for providing food protection manager certification:
- (1) American National Standards Institute (ANSI)-CFP accredited programs. A list of accredited programs is available through the ANSI Web site at https://www.foodprotect.org/. certification/food-protection-manager/Directory and is also available from the CFP at https://www.foodprotect.org/.
- (2) Army distance learning and residential courses designed for food managers, preventive medicine services, and/or veterinary services personnel and sponsored by the Army Medical Department Center and School or approved by the Army Medical Command Deputy Chief of Staff for Public Health. Certification is achieved through an unassisted comprehensive examination process consisting of a minimum of 50 multiple choice questions that test an individual's knowledge regarding food safety standards and controls, food pathogens, employee health and hygiene requirements, facility and equipment standards and sanitation controls, HACCP principles, and the application of active managerial controls.
- (a) Food safety certification mechanisms developed by the Army Quartermaster Center and School, Joint Culinary Center of Excellence, and available through structured residential curriculum or distributed learning (for example, courses in the Army Learning Management System or U.S. Army Logistics University) are recognized as approved certification mechanisms when the course content, exam, and examination controls have been evaluated and approved by the Surgeon General's designated medical proponent for this action, the Army Medical Department Center and School or Army Medical Command Deputy Chief of Staff for Public Health, U.S. Army Public Health Center.
- (b) Army certification is valid for 5 years from the date of certification. Certification attained through an Army resource using an accredited commercial examination product (for example, ServSafe®) is valid for the period of time specified by the source.
- (c) Certification programs that are developed by Army organizations for the purpose of awarding "food safety" or "food protection manager" certification to military public health regulators, food service PICs, food managers, or food safety instructors, require periodic evaluation from the designated medical proponent to ensure subject materials remain current and the certification exam is adequately controlled by the administering organization. An Army certification exam is rendered invalid when it contains outdated criteria, the testing environment is uncontrolled, or the exam has been compromised. Required test controls include proctored exams from a QUALIFIED PROCTOR and time-controlled online testing with randomly generated questions that cannot be copied or reproduced. Exams administered online require additional controls to prevent unlimited test attempts following premature exam termination or failure.
- (3) The Navy and Marine Corps Public Health Center Catalog of Navy Training, Course B-322-2101, Food Safety Manager's/Supervisor's Course. For Naval personnel, contractors, and DOD personnel, all training requirements set forth in OPNAVINST 4061.4 and MCO 4061.1, *Food Safety Training Program*, must be adhered to.
- (4) Other comprehensive courses in food safety approved by a military Component's designated medical proponent for food safety or Medical Support Agency such as the organizations specified in Subparagraph $\underline{1-8b(1)}$ of this publication.

2-103 Duties

2-103.11 Person in charge

The PIC 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

PIC 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 publication;
- (D) EMPLOYEES are effectively cleaning their hands, by routinely monitoring the EMPLOYEES' handwashing;
- (E) EMPLOYEES are checking FOODS as they are received to determine that deliveries are authorized, delivered at the required temperatures, protected from contamination, unADULTERATED and accurately presented, have no evidence of tampering, and all discrepancies are reported to the appropriate REGULATORY AUTHORITY.
- (F) EMPLOYEES are properly cooking TCS FOODS, 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 $\S 4-203.11$ and $\P 4-502.11(B)$;
- (G) EMPLOYEES are using proper methods to rapidly cool TCS 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) EMPLOYEES are properly maintaining the temperature of TCS FOODS during hot and cold holding through daily oversight of the EMPLOYEES' routine monitoring of FOOD temperatures;
- (I) CONSUMERS who order raw; or partially cooked RTE FOODS of animal origin are informed as specified under § 3-603.11 that the FOOD is not cooked sufficiently to ensure its safety;
- (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;
- (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 $\S 3-304.16$;
- (L) Except when APPROVAL is obtained from the REGULATORY AUTHORITY as specified in ¶3-301.11(D), EMPLOYEES are preventing cross-contamination of RTE FOOD with bare hands by properly using suitable UTENSILS such as deli tissue, spatulas, tongs, single-use gloves, or dispensing EQUIPMENT;
- (M) EMPLOYEES are properly trained in FOOD safety, including food allergy awareness, as it relates to their assigned duties; and
- (N) FOOD EMPLOYEES and CONDITIONAL EMPLOYEES are informed of their responsibility to report IAW LAW, to the PIC, information about their health and activities as they relate to diseases that are transmissible through FOOD, as specified under ¶ 2-201.11(A). DD Form 2971, *Conditional Employee or Food Employee Reporting Agreement*, is discussed in Appendix F.

2-2. Employee health

2-201 Responsibilities of person in charge, food employees, and conditional employees

2-201.10 Deployment health criteria[†]

Health criteria for FOOD EMPLOYEES operating in a deployment setting (that is, supporting military or humanitarian support operations) are provided in $\S 9-103.11$.

2-201.11 Responsibility of person in charge, food employees, and conditional employees*

(A) The PIC shall require FOOD EMPLOYEES and CONDITIONAL EMPLOYEES to report to the PIC information about their health and activities as they relate to diseases that are transmissible through FOOD. A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report health information promptly and directly to allow the PIC to reduce the RISK of foodborne disease transmission. This health information includes 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 has:

- (1) Reportable symptoms. Has any of the following:
 - (a) Vomiting,
 - (b) Diarrhea,
 - (c) Jaundice,
 - (d) Sore throat with fever, 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,
 - (ii) On exposed portions of the arms, unless the lesion is protected by an impermeable cover, or
 - (iii) On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting

bandage.

- (2) A reportable diagnosis. Has an illness diagnosed by a HEALTH PRACTITIONER due to-
 - (a) Norovirus,
 - (b) Hepatitis A virus,
 - (c) Shigella spp.,
 - (d) SHIGA TOXIN-PRODUCING ESCHERICHIA COLI (STEC), or
 - (e) Typhoid fever (caused by Salmonella Typhi);
 - (f) Salmonella nontyphoidal;
- (3) *A reportable past illness*. Had Typhoid fever, diagnosed by a HEALTH PRACTITIONER, within the past 3 months, without having received antibiotic therapy, as determined by a HEALTH PRACTITIONER;
- (4) A <u>reportable history of exposure</u>. 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,
 - (b) STEC, or Shigella spp. within the past 3 days of the last exposure,
 - (c) Typhoid fever within the past 14 days of the last exposure, or
 - (d) Hepatitis A virus (HAV) within the past 30 days of the last exposure; or
- (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,
 - (b) STEC, or Shigella spp. within the past 3 days of the last exposure,
 - (c) Typhoid fever (caused by Salmonella Typhi) within the past 14 days of the last exposure, or
 - (d) HAV within the past 30 days of the last exposure.
- (B) *Responsibility of PIC to notify the regulatory authority*. The PIC shall immediately notify the REGULATORY AUTHORITY when a FOOD EMPLOYEE is:
 - (1) Jaundiced, or
- (2) Diagnosed with an illness due to a pathogen as specified under Subparagraphs (A)(2)(a)-(f) of this section.
- (C) Responsibility of the PIC to prohibit a conditional employee from becoming a food employee. The PIC 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; 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) of

this section, is prohibited from becoming a FOOD EMPLOYEE until the CONDITIONAL EMPLOYEE meets the criteria as specified under \P 2-201.13(J).

- (D) Responsibility of the PIC to exclude or restrict. The PIC 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 \P 2-201.12 (A) (C) or (G), and Subparagraphs 2-201.12(D)(1), (E)(1), (F)(1), or (H)(1) and in compliance with the provisions specified under \P 2-201.13(A) (H); or
- (2) RESTRICTED as specified under Subparagraphs 2-201.12(D)(2), (E)(2), (F)(2), (H)(2), or \P 2-201.12(I) or (J) and in compliance with the provisions specified under \P 2-201.13(D)-(I).
- (E) *Responsibility of food employees and conditional employees to report.* A FOOD EMPLOYEE or CONDITIONAL EMPLOYEE shall report to the PIC the information as specified under ¶ (A) of this section.
 - (F) Responsibility of food employees to comply. A FOOD EMPLOYEE shall-
- (1) Comply with an EXCLUSION as specified under $\P = \frac{2-201.12(A) (C)}{2-201.12(D)(1)}$, $P(C) = \frac{(G)}{2-201.12(A)}$, and Subparagraphs 2-201.12(D)(1), $P(C) = \frac{(C)}{2-201.12(A)}$, or $P(C) = \frac{(C)}{2-201.12(A)}$, or P(C) =
- (2) Comply with a RESTRICTION as specified under Subparagraphs 2-201.12(D)(2), (E)(2), (F)(2), (H)(2), or \P 2-201.12(G), (H) or (I) and comply with the provisions specified under \P 2-201.13(D) (J).

2-201.12 Exclusions and restrictions*

The PIC shall EXCLUDE or RESTRICT a FOOD EMPLOYEE from a FOOD ESTABLISHMENT IAW the following:

- (A) *Symptomatic with vomiting or diarrhea.* Except when the symptom is from a noninfectious condition, EXCLUDE a FOOD EMPLOYEE if the FOOD EMPLOYEE is:
 - (1) Symptomatic with vomiting or diarrhea; or
- (2) Symptomatic with vomiting or diarrhea and diagnosed with an infection from Norovirus, *Shigella* spp., *Salmonella* (nontyphoidal), or STEC.
 - (B) Jaundiced or diagnosed with hepatitis A infection. 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 PIC written medical documentation from a HEALTH PRACTITIONER specifying that the jaundice is not caused by HAV or other fecal-orally transmitted infection;*
- (2) Diagnosed with an infection from HAV within 14 calendar days from the onset of any illness symptoms, or within 7 calendar days of the onset of jaundice; or
 - (3) Diagnosed with an infection from HAV without developing symptoms.
- (C) *Diagnosed or reported previous illness with Typhoid fever*. EXCLUDE a FOOD EMPLOYEE who is diagnosed with Typhoid fever, or reports having Typhoid fever within the past 3 months as specified under Subparagraph 2-201.11(A)(3).
- (D) *Diagnosed with an asymptomatic infection from Norovirus*. 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; or
- (2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.
- (E) *Diagnosed with Shigella spp. infection and asymptomatic.* 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; or
- (2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.
- (F) *Diagnosed with STEC and asymptomatic*. If a FOOD EMPLOYEE is diagnosed with an infection from STEC, and is ASYMPTOMATIC:
- (1) EXCLUDE the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION; or

- (2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.
- (G) *Diagnosed with nontyphoidal Salmonella and asymptomatic.* If a FOOD EMPLOYEE is diagnosed with an infection from *Salmonella* (nontyphoidal) 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.
- (H) *Symptomatic with sore throat with fever*. 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; or
- (2) RESTRICT the FOOD EMPLOYEE who works in a FOOD ESTABLISHMENT not serving a HIGHLY SUSCEPTIBLE POPULATION.
- (I) *Symptomatic with uncovered infected wound or pustular boil.* 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.
- (J) Exposed to foodborne pathogen and works in food establishment serving highly susceptible population (HSP). 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.

2-201.13 Removal, adjustment, or retention of exclusions and restrictions*

The PIC 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 Typhoid fever or an infection from HAV:
- (1) *Removing exclusion for food employee who was symptomatic and not diagnosed.* Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraph 2-201.12(A)(1) if the FOOD EMPLOYEE—
- (a) Provides to the PIC written medical documentation from a HEALTH PRACTITIONER that states the symptom is from a non-infectious condition; or
- (b) Provides to the PIC written medical documentation from a HEALTH PRACTITIONER that states that the employee no longer has symptoms and is medically cleared to handle food. (*Note: Medical documentation must be in English and the employee's native language, if applicable.*)[†]
- (c) Exclusion removal for host country and third country nationals supporting military operations in deployment shall be based on standards set by LAW and approved by the senior MEDICAL AUTHORITY, such as the Task Force Medical Surgeon.[†]
- (2) Norovirus diagnosis—adjusting exclusion for food employee who was symptomatic and is now asymptomatic. If a FOOD EMPLOYEE was diagnosed with an infection from Norovirus and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):
- (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 (D)(2) of this section are met; or
- (b) Retaining exclusion for food employee who was asymptomatic and is now asymptomatic and works in food establishment serving highly susceptible populations. 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 (D)(2) of this section are met.
- (3) Shigella spp. diagnosis—adjusting exclusion for food employee who was symptomatic and is now asymptomatic. If a FOOD EMPLOYEE was diagnosed with an infection from Shigella spp. and EXCLUDED as specified under Subparagraph 2-201.12(A)(2)—
- (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 (E)(2) of this section are met; or

- (b) Retaining exclusion for food employee who was asymptomatic and is now asymptomatic. 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 (E)(2), or (E)(1) and (E)(3)(a) of this section are met.
- (4) *STEC diagnosis*. If a FOOD EMPLOYEE was diagnosed with an infection from STEC and EXCLUDED as specified under Subparagraph 2-201.12(A)(2)—
- (a) Adjusting exclusion for food employee who was symptomatic and is now asymptomatic. 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 (F)(2) of this section are met; or
- (b) Retaining exclusion for food employee who was symptomatic and is now asymptomatic and works in food establishment serving HSP. 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 (F)(2) are met.
- (5) *Nontyphoidal Salmonella diagnosis*. If a FOOD EMPLOYEE was diagnosed with an infection from *Salmonella* (nontyphoidal) and EXCLUDED as specified under Subparagraph 2-201.12(A)(2):
- (a) Adjusting exclusion for food employee who was symptomatic and is now asymptomatic. RESTRICT the FOOD EMPLOYEE, who is ASYMPTOMATIC for at least 30 days until conditions for reinstatement as specified under Subparagraphs (G)(1) or (G)(2) of this section are met; or
- (b) Retaining exclusion for food employee that remains symptomatic. Retain the EXCLUSION for the FOOD EMPLOYEE who is SYMPTOMATIC, until conditions for reinstatement as specified under Subparagraphs (G)(1) or (G)(2) of this section are met.
- (B) *Hepatitis A virus or jaundice diagnosis—removing exclusions*. Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under ¶ <u>2-201.12(B)</u> if the PIC 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;
- (2) The anicteric FOOD EMPLOYEE has been symptomatic with symptoms other than jaundice for more than 14 calendar days; or
- (3) The FOOD EMPLOYEE provides to the PIC written medical documentation (in English and the employee's native language, if applicable) from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of an HAV infection.
- (C) *Typhoid fever diagnosis—removing exclusions*. Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under ¶ 2-201.12(C) if—
 - (1) The PIC obtains APPROVAL from the REGULATORY AUTHORITY; and
- (2) The FOOD EMPLOYEE provides to the PIC written medical documentation (in English and the employee's native language, if applicable) from a HEALTH PRACTITIONER that states the FOOD EMPLOYEE is free from Typhoid fever.
- (D) *Norovirus diagnosis—removing exclusion or restriction*. 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 PIC obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:
- (1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PIC written medical documentation (in English and the employee's native language, if applicable) from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a Norovirus infection;
- (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; 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.
- (E) *Shigella spp. diagnosis—removing exclusion or restriction.* 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 PIC obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

- (1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PIC written medical documentation (in English and the employee's native language, if applicable) from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a Shigella spp. infection based on test results showing two consecutive negative stool specimen cultures that are taken:
 - (a) Not earlier than 48 hours after discontinuance of antibiotics, and
 - (b) At least 24 hours apart;
- (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; 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.
- (F) *STEC diagnosis—removing exclusion or restriction*. 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 PIC obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:
- (1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PIC written medical documentation (in English and the employee's native language, if applicable) from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of an infection from STEC based on test results that show two consecutive negative stool specimen cultures that are taken:
 - (a) Not earlier than 48 hours after discontinuance of antibiotics; and
 - (b) At least 24 hours apart;
- (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; 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.
- (G) Nontyphoidal Salmonella—removing exclusion or restriction. Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraph 2-201.12(A)(2) or who was RESTRICTED as specified under ¶ 2-201.12(G) if the PIC obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:
- (1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PIC written medical documentation (in English and the employee's native language, if applicable) from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of Salmonella (nontyphoidal) 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, and
 - (b) At least 24 hours apart.
- (2) The FOOD EMPLOYEE was RESTRICTED after symptoms of vomit or diarrhea resolved, and more than 30 days have passed since the FOOD EMPLOYEE became ASYMPTOMATIC; 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.
- (H) *Sore throat with fever—removing exclusion or restriction*. Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraphs 2-201.12(H)(1) or (H)(2) if the FOOD EMPLOYEE provides to the PIC written medical documentation (in English and the employee's native language, if applicable) 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;
 - (2) Has at least one negative throat specimen culture for Streptococcus pyogenes infection; or
- (3) Is otherwise determined by a HEALTH PRACTITIONER to be free of a *Streptococcus pyogenes* infection.

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- (I) *Uncovered infected wound or pustular boil—removing restriction*. Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under \P 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;
 - (2) An impermeable cover on the arm if the infected wound or pustular boil is on the arm; or
- (3) A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body.
- (J) Exposure to foodborne pathogen and works in food establishment serving HSP—removing restriction. Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under \P 2-201.12(J) and was exposed to one of the following pathogens as specified under Subparagraphs 2-201.11(A)(4)(a-d) or 2-201.11(A)(5)(a-d):
 - (1) *Norovirus*. 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; or
- (b) More than 48 hours have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.
 - (2) Shigella spp., or STEC. Shigella spp. or STEC 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; or
- (b) More than 3 calendar days have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.
- (3) *Typhoid fever* (S. Typhi.) Typhoid fever (caused by Salmonella 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; or
- (b) More than 14 calendar days have passed since the FOOD EMPLOYEE'S household contact became ASYMPTOMATIC.
 - (4) *Hepatitis A.* HAV and one of the following conditions is met:
 - (a) The FOOD EMPLOYEE is immune to HAV infection because of a prior illness from hepatitis A;
 - (b) The FOOD EMPLOYEE is immune to HAV infection because of vaccination against hepatitis A;
- (c) The FOOD EMPLOYEE is immune to HAV infection because of Immunoglobulin G (IgG) administration;
- (d) More than 30 calendar days have passed since the last day the FOOD EMPLOYEE was potentially exposed;
- (e) More than 30 calendar days have passed since the FOOD EMPLOYEE'S household contact became jaundiced; or
- (f) The FOOD EMPLOYEE does not use an alternative procedure that allows bare hand contact with RTE 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,
 - (ii) Proper handwashing procedures, and
 - (iii) Protecting RTE FOOD from contamination introduced by bare hand contact.

2-201.20 Medical screening criteria†

A determination of medical screening criteria for FOOD EMPLOYEES should be established in a local policy by the Command Surgeon or MEDICAL AUTHORITY. This publication establishes minimum reporting and exclusion criteria. Other considerations include screening for upper respiratory infections, such as Tuberculosis.

2-3. Personal cleanliness

2-301 Hands and arms

2-301.11 Clean condition*

- (A) FOOD EMPLOYEES shall keep their hands and exposed portions of their arms clean.
- (B) Hand sanitizers may supplement hand washing procedures for food employees as specified under § 2-301.16, but may not be substituted for the cleaning procedure specified under § 2-301.12.†

2-301.12 Cleaning procedure*

- (A) 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.
- (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 POTABLE, 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-
- (a) Paying particular attention to removing soil from underneath the fingernails during the cleaning procedure, and
- (b) Creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, the fingertips, under the fingernails, the cuticles, the areas between the fingers, and any exposed areas on the forearms:
 - (4) Thoroughly rinse under POTABLE, running warm water; and
- (5) Immediately follow the cleaning procedure with thorough drying using a method as specified under § 6-301.12.
- (C) To avoid recontaminating their hands or surrogate prosthetic devices, FOOD EMPLOYEES should 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 rest room 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 hand wash 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 when drinking from a closed container as specified in \P 2-401.11(B), and 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 RTE FOOD;

- (H) Before donning gloves to initiate a task that involves working with FOOD;
- (I) After handling currency or other methods of payment; and
- (J) After engaging in other activities that contaminate the hands.

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.

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; or
- (b) Have active antimicrobial ingredients that are listed in the FDA monograph for over-the-counter Health-Care Antiseptic Drug Products as an antiseptic hand wash, 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 Title 21, Code of Federal Regulations (CFR), Part 170.39 Threshold of regulation for substances used in food-contact articles; 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, 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, or
 - (d) A prior sanction listed under 21 CFR 181 Prior Sanctioned food Ingredients, or
 - (e) A FOOD Contact Notification that is effective, and
 - (3) Be applied only to hands that are cleaned as specified under § 2-301.12.
- (4) Alcohol-based hand sanitizers (hand antiseptics) shall contain a minimum of 60 percent ethyl alcohol and be used IAW label instructions. †
- (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, its use shall be—
- (1) Followed by thorough hand rinsing in clean DRINKING 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 hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 milligrams per liter (mg/L) chlorine.

2-302 Fingernails

2-302.11 Maintenance

- (A) FOOD EMPLOYEES shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable, are not rough, and do not extend more than ¼ inch above the fingertip.
- (B) A FOOD EMPLOYEE shall not wear fingernail polish, artificial fingernails, or fingernail jewelry when working with exposed FOOD.

2-303 *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.

2-304 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

2-401 Food contamination prevention

2-401.11 Eating, drinking, or using tobacco

- (A) Except as specified in ¶¶ (B) and (C) 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 cannot 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.
- (C) A FOOD EMPLOYEE may taste portions of the FOOD during preparation (e.g., recipe testing) provided the following steps are followed: †
- (1) The EMPLOYEE shall use a clean sanitized utensil or single service disposable utensil to withdraw the FOOD sample.
- (2) The FOOD shall be tasted away from the FOOD and in a manner which does not risk contamination of the FOOD.
 - (3) The utensil shall be used only once.

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.

2-402 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 and sweat 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 FOOD ESTABLISHMENT managers; 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.

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2-403 Animals

2-403.11 Handling prohibition

- (A) Except as specified in \P (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 the FOOD EMPLOYEES wash their hands as specified under \S 2-301.12 and \P 2-301.14(C) and change their outer garments if they become wet or soiled as a result of the handling activities.

2-5. Training

2-501 General principles

2-501.11 Training requirements[†]

- (A) FOOD EMPLOYEES shall be-
- (1) Trained to perform their duties in a safe manner and with the ability to protect themselves and others from intentional and unintentional food contamination.
- (2) Trained in the basic principles of food safety, which includes but is not limited to the CDC's five foodborne illness risk factors:
 - (a) FOOD from unsafe sources;
 - (b) Inadequate cooking;
 - (c) Improper holding/time-temperature;
- (d) Contaminated equipment/cross contamination protection. Discussion shall include general sanitation and food allergens; and
- (e) Poor personal hygiene. Discussion shall include the impact to public health, communicable diseases transmitted by FOOD EMPLOYEES, and EMPLOYEE health and hygiene.
- (B) Except for FOOD EMPLOYEES who serve in a supervisory role and maintain Food Protection Manager Certification as specified under § 2-502.11 and employees who do not prepare FOOD as specified in § 2-503.12, each FOOD EMPLOYEE shall receive a minimum of 4 hours of FOOD safety refresher training annually to reinforce training subjects identified in Subparagraph (A)(2) of this section.
 - (C) Refresher training-
- (1) Shall be conducted within a 12-month period beginning no earlier than one month following an EMPLOYEE'S initial training.
 - (2) May be executed incrementally throughout the year to achieve the 4-hour requirement.
- (D) FOOD ESTABLISHMENTS hold primary responsibility for funding and coordinating required training and certification of FOOD EMPLOYEES.

2-502 Supervisor training

2-502.11 Requirements and renewal[†]

- (A) Except as specified in \P (C) of this section, food service managers, supervisors, and designated PICs shall complete an APPROVED Food Protection Manager Certification process as specified in \S 2-102.20 and recertify IAW the interval prescribed by the certifying organization.
- (B) Except as specified in \P (D) of this section and \P 2-503.11(B), the designated PIC at a FOOD ESTABLISHMENT that only prepares and serves non-TCS FOODS shall complete the initial and annual food safety refresher training as specified in \S 2-501.11.

- (C) Food Protection Manager Certification is not required for food service managers, supervisors, and designated PICs if the FOOD ESTABLISHMENT only serves non-TCS FOODS.
- (D) Completion of annual refresher training is not required for food service managers, supervisors, and designated PICs who maintain a valid Food Protection Manager Certification.

2-503 Food employee training

2-503.11 General requirement[†]

- (A) Except as specified in \P (B) of this section and as specified under §§ 2-503.12 and 2-503.13, new FOOD EMPLOYEES shall receive a minimum of 4 hours of initial FOOD safety training, as specified under \P 2-501.11(A), within 30 days of beginning food service duties.
- (B) Basic food handler's training is not required for establishments that only serve non-TCS FOODS that are PACKAGED by a FOOD PROCESSING PLANT and remain in the original PACKAGING when sold to the consumer.

2-503.12 Bartenders, hostesses, wait staff, and counter staff[†]

- (A) Except as specified in \P (B) of this section, bartenders, hostesses, waiters, waitresses, and counter staff who do not prepare FOOD shall receive—
- (1) Four hours of initial FOOD sanitation and safety training within 30 days of beginning work in an establishment that serves FOOD; and
 - (2) Two hours of food sanitation refreshers training annually.
- (B) Bartenders, hostesses, waiters, waitresses, and counter staff who periodically prepare FOOD, such as plating salads or managing items on salad or buffet bars, shall receive the same training as other FOOD EMPLOYEES as specified under Subparagraph (A)(1) of this section and \P 2-501.11(B).

2-503.13 Temporary employees[†]

- (A) Except as specified in ¶ (B) of this section, temporary FOOD EMPLOYEES shall—
- (1) At a minimum, complete basic food handler's training, as specified under \P 2-501.11(A), within the past 12 months; or
- (2) Receive training as specified under § <u>2-503.11</u> before working as an intermittent, seasonal, or on-call FOOD EMPLOYEE in a permanent, MOBILE, or SEASONAL FOOD ESTABLISHMENT; or
- (3) Receive training that directly relates to the TEMPORARY FOOD ESTABLISHMENT, as specified under ¶ 2-501.11(A), prior to working within the TEMPORARY FOOD ESTABLISHMENT. Consult the REGULATORY AUTHORITY for questions regarding training for TEMPORARY FOOD ESTABLISHMENT employees.
- (B) Military personnel assigned additional duty as a dining facility attendant, Food Service Assistant (FSA), or Kitchen Patrol (KP), and the assigned duties do not involve food handling, shall receive specific food service sanitation training that is relevant to the assigned tasks prior to beginning their assigned duties.

2-503.20 Training resources[†]

Initial and annual refresher FOOD EMPLOYEE food safety training may be obtained from:

- (A) A QUALIFIED FOOD SAFETY INSTRUCTOR; or
- (B) A web-based presentation; audio/visual presentation, televised program, or other media that-
 - (1) Meets the basic requirements for FOOD safety annual training as specified under § 2-501-11; and
 - (2) Is initiated and supervised by a person specified in \P (C) of this section.
- (C) FOOD sanitation and safety training may be conducted by the following individuals:
 - (1) Any person who meets the requirements as specified in \P (A) of this section;
 - (2) Public health officers and technicians as specified in \P 8-6.a.;
- (3) A FOOD ESTABLISHMENT manager, PIC, or supervisor who has completed a Food Protection Manager Certification process as specified in § <u>2-102.20</u>.

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2-504 Other personnel requiring training

2-504.10 Public health inspection personnel[†]

Reserved. Refer to ¶ 8-6.a. and Subparagraphs 8-8.e.(8) & (9)

2-504.20 Contracting officer's representatives[†]

CONTRACTING OFFICER's REPRESENTATIVES (COR), quality assurance evaluators, and other representatives responsible for evaluating food service contract performance or providing management or operation oversight of a FOOD ESTABLISHMENT should complete a Food Manager Certification and recertification process as specified in § 2-102.20.

2-504.30 Nonfood employee, supervisors[†]

- (A) Except as specified in ¶ (B) of this section, individuals who are not FOOD EMPLOYEES (that is, drill sergeants, cadre, platoon sergeants) but are designated to supervise FSAs, dining facility attendants or military personnel detailed to food service operations such as KPs should receive a minimum of 4 hours of training in food safety, proper FOOD handling, EQUIPMENT and general sanitation, and basic vegetable preparation, as appropriate, based on the expected duties of personnel detailed to support a food service operation.
- (B) This requirement may be waived by the REGULATORY AUTHORITY in a deployment setting or other nongarrison or nonpermanent installation, base, or post setting.

2-504.40 Food service and food safety instructors[†]

Instructors at military training institutions who teach food service, food safety, and related food sanitation compliance criteria introduce and enforce regulatory requirements for food protection. Position descriptions for these instructors should include requirements for attaining and maintaining Food Manager Certification as specified in § 2-102.20.

2-505 Training records

2-505.11 Documentation, retention and presentation[†]

- (A) Training shall be documented, including the topics presented, the presenter's name, the names of personnel in attendance, the duration of the training, and the training date.
- (B) Except as specified in Subparagraph (B)(2) and \P (C) of this section, an original or copy of a FOOD EMPLOYEE'S certification document and training records shall be—
 - (1) Maintained at the FOOD ESTABLISHMENT, or where the EMPLOYEE works; and
 - (2) Available upon request by the REGULATORY AUTHORITY.
- (C) If an EMPLOYEE works at more than one FOOD ESTABLISHMENT, copies of his/her record should be available at each establishment.

2-6. Responding to Contamination Events

2-601 Procedures for responding

2-601.11 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 and fecal matter. A sample standing operating procedure (SOP) is available from the National Food Service Management

Institute, United States Department of Agriculture at http://nfsmi.org/documentlibraryfiles/PDF/20130701014447.pdf.

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CHAPTER 3

FOOD

3-1. Characteristics

3-101 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

3-201 Sources

3-201.11 Compliance with food law*

- (A) FOOD shall be obtained from sources that comply with LAW.
- (B) FOOD shall be obtained from APPROVED SOURCES.†
- (C) FOOD prepared in a private home, including COTTAGE FOODS, may not be used or offered for human consumption in a FOOD ESTABLISHMENT. Home-prepared FOODS, except home-canned FOODS, wild game and other meats, and dairy products from unAPPROVED SOURCES, may be authorized in support of special events such as organizational cookouts, bake sales, unit or chapel suppers, farmers markets, and similar events. Consultation with the REGULATORY AUTHORITY is required.
- (D) 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.
- (E) FISH, other than those specified in \P 3-402.11(B), that are intended for consumption in raw or undercooked form and allowed as specified in \P 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 \S 3-402.11; or if they are frozen on the PREMISES as specified under \S 3-402.11 and records are retained as specified under \S 3-402.12.
- (F) 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, upon request by the purchaser, packages the steaks and labels them, to indicate that the steaks meet the definition of WHOLE-MUSCLE, INTACT BEEF, 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, 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 (F)(1) of this section or identified as specified in Subparagraph (F)(2) of this section,
 - (b) Prepared so they remain intact, and
- (c) If PACKAGED for undercooking in a FOOD ESTABLISHMENT, labeled as specified in Subparagraph (F)(1) of this section or identified as specified in (F)(2) of this section.
- (G) MEAT and POULTRY that is not an RTE 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, including cooking temperatures, as specified in LAW, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

(H) 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.

3-201.13 Fluid milk*

Fluid milk shall be pasteurized and obtained from sources that comply with GRADE A STANDARDS as specified in LAW.

3-201.14 Fish*

- (A) Except as specified under \P (C) of this section and \P 3-201.17(C), 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) Privately caught FISH may be used for social functions as specified under \P 3-201.11(C).
 - (C) 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, FDA, 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*

Use of wild mushrooms is prohibited.[†]

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 U.S. Department of Agriculture (USDA) for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and APPROVED" IAW 9 CFR 352 Exotic animals; voluntary inspection of rabbits that are "inspected and certified" IAW 9 CFR 354 Voluntary inspection of rabbits and edible products thereof;
 - (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) Installations and organizations may serve field-dressed wild GAME ANIMALS and privately caught FISH provided the action is APPROVED by the installation veterinarian. (*Special Operations Force and similar training schools are exempt from this requirement.*) A routine inspection program is required to ensure wild GAME ANIMALS:
- (a) Except FISH, 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.
 - (C) Aboard Navy vessels, the consumption of privately caught fin FISH is at the commander's discretion. †

3-201.18 Fresh fruits and vegetables*†

Fresh fruits and vegetables (FF&V) grown in areas where Night Soil (human feces) is used as fertilizer may not be served in DOD FOOD ESTABLISHMENTS.

3-202 Specifications for receiving

3-202.11 Temperature*

- (A) Except as specified in \P (B) of this section, refrigerated, TCS FOOD shall be at a temperature of 41°F (5°C) or below when received.
- (B) If a temperature other than 41°F (5°C) for a TCS 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) Except in overseas locations when authorized by Command Policy (through advisement by the MEDICAL AUTHORITY or designated representative), raw EGGS shall be received in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or less.
- (D) TCS FOOD that is cooked to a temperature and for a time specified under §§ $\underline{3-401.11}$, $\underline{3-401.12}$, and $\underline{3-401.13}$ and received hot shall be at a temperature of $135^{\circ}F$ ($57^{\circ}C$) or above.
- (E) A FOOD that is labeled frozen and shipped frozen by a FOOD PROCESSING PLANT shall be received frozen. S
 - (F) Upon receipt, TCS 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 the 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.

3-202.13 Shell Eggs*

Except in overseas locations when authorized by Command Policy (through advisement by the MEDICAL AUTHORITY or designated representative), 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.

3-202.14 Eggs and milk products, pasteurized*

- (A) EGG PRODUCTS shall be obtained pasteurized.
- (B) Fluid and dry milk and milk products shall-
 - (1) Be obtained pasteurized; and
 - (2) Comply with GRADE A STANDARDS as specified in LAW.
- (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-

- (A) Made from DRINKING WATER;
- (B) From an APPROVED SOURCE IAW AR 40-657/NAVSUP 4355.4H/MCO P10110.31H when procured from a commercial source. Ice produced in a FOOD ESTABLISHMENT and not sold to food operations outside the organization is exempt but will be inspected and tested as specified in $\P(C)$ of this section. Ice produced from military field water operations is governed using TB MED 577/NAVMED P5010-10/AFMAN 48-138_IP †
- (C) Ice should receive bacteriological analysis as determined by the REGULATORY AUTHORITY or MEDICAL AUTHORITY's designated representative. †

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" or "best if used by" date for packages with a capacity of less than one-half gallon (1.89 liter (L)) or the date shucked for packages with a capacity of one-half gallon (1.89 L) 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 \P (A) of this section shall be subject to a hold order, as allowed by LAW, or seizure and destruction IAW 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—
- (1) Except as specified under \P (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 \P (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 \P (A) of this section shall be subject to a hold order, as allowed by LAW, or seizure and destruction IAW 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 HACCP Systems; N 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.

3-203 Original containers and records

3-203.11 Molluscan shellfish, original container

- (A) Except as specified in \P (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 \S 3-202.18 and recorded as specified under \S 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.
- (D) SHUCKED 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 $\S 3-202.17$, $\P 3-602.11(A)$, and Subparagraphs 3-602.11(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 is received until the container is empty.
- (B) The date when the last SHELLSTOCK from the container is sold or served shall be recorded on the tag or label.
- (C) The identity of the source of SHELLSTOCK that is 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—
- (1) Using an APPROVED recordkeeping system that stores the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under \P (B) of this section; and
 - (2) If SHELLSTOCK is removed from its tagged or labeled container:
- (a) Preserving source identification by using a recordkeeping system as specified under Subparagraph (C)(1) of this section, and
- (b) Ensuring that SHELLSTOCK from one tagged or labeled container is 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.

3-3. Protection from contamination after receiving

3-301 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, RTE 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 an RTE form. $^{\rm S}$
- (D) Paragraph (B) of this section does not apply to a FOOD EMPLOYEE that contacts exposed, RTE FOOD with bare hands at the time the RTE 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 $\P\P$ 3-401.11(A) and (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 145°F (63°C).
- (E) FOOD EMPLOYEES not serving a HIGHLY SUSCEPTIBLE POPULATION may contact exposed, RTE FOOD with their bare hands if—
 - (1) The PIC 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 RTE 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 \P 2-201.11(A),
- (b) Documentation that FOOD EMPLOYEES and CONDITIONAL EMPLOYEES acknowledge their responsibilities as specified under $\P\P$ 2-201.11(E) and (F), and
- (c) Documentation that the PIC acknowledges the responsibilities as specified under $\P\P$ 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 RTE 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 §§ <u>2-301.11</u>, <u>2-301.12</u>, <u>2-301.14</u>, and <u>2-301.15</u> during all hours of operation when the specific RTE FOODS are prepared;
- (6) Documentation that FOOD EMPLOYEES contacting RTE 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) Individual nailbrushes,
 - (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 (D)(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 and shall use procedures specified under \P 2-401.11(C).

3-302 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 Subparagraph (1)(c) below, separating raw animal FOODS during storage, preparation, holding, and display from:

- (a) Raw RTE FOOD, including other raw animal FOOD such as FISH for sushi or MOLLUSCAN SHELLFISH, or other raw RTE FOOD such as fruits and vegetables, and
 - (b) Cooked RTE FOOD;
- (c) Frozen, commercially processed and PACKAGED raw animal FOOD may be stored or displayed with or above frozen, commercially processed and PACKAGED, RTE FOODs.
- (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 \P 4-602.11(A) and SANITIZING as specified under \S 4-703.11;
- (4) Except as specified under Subparagraph 3-501.15(B)(2) and in \P (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 RTE 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—

- (A) Cooked as specified under Subparagraphs 3-401.11(A)(1) or (A)(2); or
- (B) Included in ¶ <u>3-401.11(D)</u>.

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 FF&V intended for raw consumption or to a FOOD considered to be a good source of vitamin B1; 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.

3-302.15 Washing fruits and vegetables

- (A) Except as specified in $\P(B)$ 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 DRINKING water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in RTE form.
- (B) Fruits and vegetables may be CHEMICALLY WASHED as specified under § 7-204.12 or washed and disinfected as specified in ¶¶ (C) and (D) of this section. FOOD ESTABLISHMENTS and retail stores may CHEMICALLY WASH FF &V to reduce suspected surface microbial contamination. †
 - (C) Procedures for initial washing: †
 - (1) The FF&V are thoroughly washed in DRINKING water to remove soil and other contaminants.
- (2) Any FF&V with physical characteristics conducive to scrubbing should be washed using a clean vegetable brush.
- (3) Head items, such as lettuce, cabbage, and celery, shall have the core/hearts removed prior to immersion in CHEMICAL WASH or disinfecting solution to facilitate thorough product exposure.
 - (D) Procedures for CHEMICAL WASH/disinfection: †
- (1) After the initial washing step, FF&V are CHEMICALLY WASHED using any FDA-APPROVED commercial chemical wash product as specified in § 7-204.12 and used IAW the manufacturers' instruction; or
 - (2) Apply chlorine bleach IAW the following procedures:
- (a) Use unscented bleach products or sodium hypochlorite with a base concentration rated no greater than 8.25 percent strength.
- (b) Prepare a 50–200 parts per million (ppm) Free Available Chlorine (FAC) solution (pH 6.0–7.5) as specified under \S 4-501.200. Verify the concentration of the prepared solution.
 - (c) Completely immerse FF&V for at least 1 minute in the disinfecting solution.
 - (d) Thoroughly rinse FF&V with DRINKING water before being served raw.

3-303 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 $\P\P$ (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 drinking 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.

3-304 Preventing contamination from equipment, utensils, and linens

3-304.11 Food contact with equipment, utensils, and linens*

FOOD shall only contact surfaces of-

- (A) EQUIPMENT and UTENSILS that are cleaned as specified under Part <u>4-6</u> of this publication and SANITIZED as specified under Part <u>4-7</u> of this publication;
 - (B) SINGLE-SERVICE and SINGLE-USE ARTICLES; or
- (C) LINENS, such as cloth napkins, as specified under \S 3-304.13, that are laundered as specified under Part 4-8 of this publication.

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 TCS 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 TCS; or
- (F) Except as specified in \P (D) of this section, in a container of water if the water is maintained at a temperature of at least 135°F (57°C) and the container is cleaned at a frequency specified under Subparagraph 4-602.11(D)(7).
 - (G) In-use utensils may not be stored in a chemical SANITIZING solution.

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 off of TABLEWARE and carry-out containers while 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 where wet wiping cloths are held between uses shall be free of FOOD debris and visible soil.
- (E) Containers of the chemical sanitizing solutions specified in Subparagraph (B)(1) of this section and 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 IAW U.S. Environmental Protection Agency (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 RTE FOOD or with raw animal FOOD, used for no other purpose, and discarded when damaged or soiled, or removed for any reason such as an interruption in the operation.
- (B) Except as specified in \P (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 RTE 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.*
 - (E) Use of latex gloves is prohibited.[†]
- (F) If used, powdered gloves shall be identified by the manufacturers as approved for use with FOOD or FOOD handling. †

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 \P (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 EOUIPMENT.
- (C) Drinking cups and containers may be reused by self-service CONSUMERS if refilling is a contamination-free process as specified under $\P\P$ 4-204.13(A), (B), and (D).

3-304.17 Refilling returnables

- (A) Except as specified in \P (B) (E) of this section, empty containers (for example, recycled bottles, jars, or plastic containers) returned to a FOOD ESTABLISHMENT for cleaning and refilling with FOOD shall be cleaned and refilled in a regulated FOOD PROCESSING PLANT.
- (B) A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with RTE FOOD if the FOOD container is:
 - (1) Designed and constructed for reuse and IAW the requirements specified under Parts 4-1 and 4-2;
- (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 <u>4-6</u> of this publication,
 - (b) Sanitized as specified under Part 4-7 of this publication; and
- (c) Visually inspected by a FOOD EMPLOYEE to verify that the container, as returned, meets the requirements specified under Parts 4-1 and 4-2.
- (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 TCS 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 $\P\P$ 4-204.13(A), (B), and (D) that cannot be bypassed by the container owner.
- (D) CONSUMER-owned 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 $\P\P$ 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.

3-305 Preventing contamination from the premises

3-305.11 Food storage

- (A) Except as specified in \P (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 6 inches (15 centimeters (cm)) above the floor.
- (4) For FOOD processing and food service areas, PACKAGED FOOD may be stored on National Sanitation Foundation (NSF®) International listed plastic pallets provided the pallets are kept clean, in sound condition, and are moved regularly so that the areas under the pallets are kept clean.† (NSF® is a registered trademark of NSF International.)
- (B) FOOD in packages and working containers may be stored less than 6 inches (15 cm) 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.
- (D) Additional DOD or branch-of-service-specific sanitation requirements pertaining to military food storage warehouses are DEBITED against this section. †

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

A TCS 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.

3-306 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; placement on a rack (covered or uncovered) behind a counter that is not accessible by customers and is not within a splash zone; use of service line or salad bar FOOD guards; display cases; or other protective barrier.

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:*
- (1) CONSUMER SELF-SERVICE of RTE 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) Open FOOD, including soups, shall be protected through use of lids or APPROVED sneeze guards.†
- (C) CONSUMER SELF-SERVICE operations for RTE FOODS shall be provided with suitable UTENSILS or effective dispensing methods that protect the FOOD from contamination.
- (D) CONSUMER SELF-SERVICE operations such as buffets and salad bars shall be monitored by FOOD EMPLOYEES trained in safe operating procedures. ^N
- (E) A TCS FOOD offered for CONSUMER SELF-SERVICE may not be retained as specified under Subparagraph $\frac{3-501.110(G)(3)}{1}$.

3-306.14 Returned food and re-service of food*

- (A) Except as specified in \P (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 \P 3-801.11(G), a container of FOOD that is not TCS 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.

3-306.15 Dispensing of milk, cream, and nondairy products[†]

(A) Except for retail food sales (that is, commissary, shoppette), milk and milk products for drinking purposes shall be provided to the CONSUMER—

- (1) In an unopened, commercially filled package not exceeding 16 fluid ounces (0.473 L) or 1 pint in capacity; or
- (2) Drawn for immediate consumption from a commercially filled container stored in a mechanically refrigerated bulk milk dispenser.
- (B) If a bulk dispenser for milk or milk product is not available and portions of less than $\frac{1}{2}$ pint are required for mixed drinks, cereal, dessert service, or in a glass for drinking, milk and milk products may be poured from a bulk, commercially filled plastic container of 1-gallon (3.785 L) capacity, and the bulk container is returned immediately to the refrigerated storage.
 - (C) Cream or half-and-half shall be—
 - (1) Provided in an individual service container;
- (2) Provided in a protected dispenser that pours, and such dispenser shall be washed and SANITIZED when emptied before reuse (refilling); or
 - (3) Drawn from a refrigerated dispenser designed for such service.
- (D) Ultra-high temperature (UHT) and aseptically PACKAGED dairy products, liquid nondairy creamer or whitening agents shall be provided in an individual service container that is maintained IAW the manufacturer's label
- (E) An exception is granted for CHILD CARE FACILITIES. Milk or milk products may be transferred from bulk milk dispensers or commercial 1-gallon (3.785 L) containers or smaller into a small, cleaned and SANITIZED serving pitcher. Pitchers shall be covered and transported immediately to the child activity room. Unconsumed milk remaining in the pitchers after the meal or snack period shall be discarded. Serving pitchers may not be used as storage containers.

3-307 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 to 3-306 of this publication.

3-4. Destruction of organisms of public health concern

3-401 *Cooking*

3-401.11 Raw animal foods*

- (A) Except as specified under \P (B) and in \P (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; refer to Appendix F, Table F-1 for the summary of required cooking temperatures:
 - (1) 145°F (63°C) or above for 15 seconds for:
- (a) Raw 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 (A)(3) and \P (B), and as specified in \P (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);
- (2) 155°F (68°C) for 15 seconds or the temperature specified in Table 3-1 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, which includes shell EGGS that are pre-cracked and pooled prior to an individual customer's order; or (3) 165°F (74°C) or above for 15 seconds for POULTRY, BALUTS, wild GAME ANIMALS as specified under Subparagraphs 3-201.17(A)(3) and (A)(4), stuffed FISH, stuffed MEAT, stuffed pasta, stuffed POULTRY, stuffed RATITES, or stuffing containing FISH, MEAT, POULTRY, or RATITES.

Table 3-1. Alternative minimum cooking temperatures and times for ratites, tenderized/injected meats, and comminuted fish, meat and commercial game animals

Minimum		
Temperature °F (°C)	Time	
145 (63)	3 minutes	
150 (66)	1 minute	
158 (70)	< 1 second (instantaneous)	

- (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 Table 3-2 and that is held at that temperature:

Table 3-2. Prescribed oven temperatures for corresponding whole meat roasting weights

Oven Type	Oven Temperature F	Oven Temperature Based on Roast Weight		
	Less than 10 lb (4.5 kg)	10 lb (4.5 kg) or More		
Still Dry	350°F (177°C) or more	250°F (121°C) or more		
Convection	325°F (163°C) or more	250°F (121°C) or more		
High Humidity ¹	250°F (121°C) or less	250°F (121°C) or more		

¹Relative 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 Table 3-3, to heat all parts of the FOOD to a temperature and for the holding time that corresponds to that temperature:

Temperature	Time ¹ in	Temperature	Time ¹ in
° F (° C)	Minutes	° F (° C)	Seconds
130 (54.4)	112	147 (63.9)	134
131 (55.0)	89	149 (65.0)	85
133 (56.1)	56	151 (66.1)	54
135 (57.2)	36	153 (67.2)	34
136 (57.8)	28	155 (68.3)	22
138 (58.9)	18	157 (69.4)	14
140 (60.0)	12	150 (70.0)	< 1 second
142 (61.1)	8	158 (70.0)	(instantaneous)
144 (62.2)	5		
145 (62.8)	4		

- (C) A raw or undercooked WHOLE-MUSCLE, INTACT BEEF steak may be served or offered for sale in an RTE 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 \P 3-201.11(E), and
- (3) The steak is cooked on both the top and bottom to a surface temperature of $145^{\circ}F$ ($63^{\circ}C$) 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 tartar; 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 $\P(C)$ of this section, may be served or offered for sale upon CONSUMER request or selection in an RTE form if:
- (1) As specified under $\P\P$ 3-801.11(C)(2) and (C)(3), 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; 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 $\P(A)$ or (B) of this section; or
- (4) The REGULATORY AUTHORITY grants a VARIANCE from $\P(A)$ or (B) of this section as specified in § 8-103.10 based on a HACCP PLAN that:
 - (a) Is submitted by the PERSON-IN-CHARGE 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 165°F (74°C) 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 135°F (57°C).

3-401.14 Noncontinuous cooking of raw animal foods*

Raw animal FOODS that are cooked using a NONCONTINUOUS COOKING process shall be-

- (A) Subject to an initial heating process that is no longer than 60 minutes in duration;
- (B) Immediately after initial heating, cooled according to the time and temperature parameters as specified under ¶ 3-501.14(A), for cooked TCS FOOD;
- (C) After cooling, held FROZEN or cold, as specified under Subparagraphs 3-501.16(A)(2) and 3-502.13(B)(4) and (B)(5), for TCS FOOD;
- (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 $\P 3-401.11(A)-(C)$;
- (E) Cooled according to the time and temperature parameters as specified under \P 3-501.14(A), for cooked TCS FOOD if not either hot held as specified under \P 3-501.16(A), served immediately, or held using time as a public health control as specified under \S 3-501.19, after complete cooking; and
 - (F) Prepared and stored according to written procedures that-
 - (1) Have obtained prior APPROVAL from the REGULATORY AUTHORITY;
- (2) Are maintained in the FOOD ESTABLISHMENT and are available to the REGULATORY AUTHORITY upon request;
- (3) Describe how the requirements specified under \P (A)-(E) of this Section are to be monitored and documented by the PIC and the corrective actions to be taken if the requirements are not met;
- (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 \P (D) of this section prior to being offered for sale or service; and
- (5) Describe how the FOODS, after initial heating but prior to cooking as specified under \P (D) of this section, are to be separated from RTE FOODS as specified under Subparagraph 3-302.11(A)(1).

3-402 Freezing

3-402.11 Parasite destruction*

- (A) Except as specified in \P (B) of this section, before service or sale in RTE form, raw, raw-marinated, partially cooked, or marinated-partially cooked FISH shall be—
- (1) Frozen and stored at a temperature of -4°F (-20°C) or below for a minimum of 168 hours (7 days) in a freezer;
- (2) Frozen at $-31^{\circ}F$ ($-35^{\circ}C$) or below until solid and stored at $-31^{\circ}F$ ($-35^{\circ}C$) or below for a minimum of 15 hours; or
- (3) Frozen at -31°F (-35°C) or below until solid and stored at -4°F (-20°C) or below for a minimum of 24 hours.
 - (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 skin and rinsed.

3-402.12 Records, creation and retention

- (A) Except as specified in \P 3-402.11(B) and \P (B) of this section, if raw, raw-marinated, partially cooked, or marinated-partially cooked FISH are served or sold in RTE form, the PIC 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.
- (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 RTE 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 PIC and retained in the records of the FOOD ESTABLISHMENT for 90 calendar days beyond the time of service or sale of the FISH.

3-403 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 $\P\P$ (B) and (C) and in \P (E) of this section, TCS FOOD that is cooked, cooled, and reheated for hot holding, to include reheated LEFTOVERS, shall be reheated so that all parts of the FOOD reach a temperature of at least $165^{\circ}F$ ($74^{\circ}C$) for 15 seconds.
- (B) Except as specified under \P (C) of this section, TCS 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 $165^{\circ}F$ ($74^{\circ}C$) and the FOOD is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating.
- (C) RTE TCS 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 135°F (57°C) when being reheated for hot holding.
- (D) Reheating for hot holding as specified under $\P\P$ (A)–(C) of this section shall be done rapidly, and the length of time in which the temperature of the FOOD is between 41°F (5°C) and the temperatures specified under $\P\P$ (A)–(C) of this section may not exceed 2 hours.
- (E) Remaining unsliced portions of MEAT roasts that are cooked as specified under \P 3-401.11(B) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under \P 3-401.11(B).

3-404 Other methods

3-404.11 Treating juice

- (A) Except as stated in (B), JUICE PACKAGED in a FOOD ESTABLISHMENT shall be-
- (1) Treated under a HACCP PLAN as specified in § <u>8-201.14</u> to attain a 5-log reduction, which is equal to a 99.999 percent reduction, of the most resistant microorganism of public health significance; or
- (2) Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance—
 - (a) As specified under § 3-602.11, and
- (b) 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."

(B) Fruit and vegetable juices prepared fresh based on an individual customer's order are exempt.†

3-5. Limitation of growth of organisms of public health concern

3-501 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 TCS FOOD that is SLACKED to moderate the temperature shall be held-

- (A) Under refrigeration that maintains the FOOD temperature at 41°F (5°C) or less; or
- (B) At any temperature if the FOOD remains FROZEN.

3-501.13 Thawing

Except as specified in ¶ (D) of this section, TCS FOOD shall be thawed-

- (A) Under refrigeration that maintains the FOOD temperature at 41°F (5°C) or less; or
- (B) As part of a cooking process if the FOOD that is frozen is-
 - (1) Cooked as specified under \P 3-401.11(A) or (B) or \S 3-401.12, or
- (2) Thawed in a microwave oven and immediately transferred to conventional cooking EQUIPMENT, with no interruption in the process; or
 - (C) Completely submerged under running DRINKING water-
 - (1) At a water temperature of 70°F (21°C) 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 RTE FOOD to rise above 41°F (5°C), or
- (4) For a period of time that does not allow thawed portions of a raw animal FOOD requiring cooking as specified under \P 3-401.11(A) or (B) to be above 41°F (5°C), for more than 4 hours including—
- (a) The time during which the FOOD is exposed to the running water and the time needed for preparation for cooking, or
- (b) The time during which the FOOD is under refrigeration to lower the FOOD'S temperature to $41^{\circ}F$ (5°C);
- (D) Using any procedure if a portion of frozen RTE 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 \P (A) of this section; or
- (2) Prior to, or immediately upon completion of, its thawing using procedures specified in \P (B) of this section.

3-501.14 Cooling*

- (A) Cooked TCS FOOD shall be cooled within a total of 6 hours from $135^{\circ}F$ ($57^{\circ}C$) to $41^{\circ}F$ ($5^{\circ}C$) or less, IAW the following criteria:
 - (1) Within 2 hours from $135^{\circ}F$ (57°C) to $70^{\circ}F$ (21°C); and
 - (2) Within 4 hours from 70° F (21° C) to 41° F (5° C).
- (B) The TCS FOOD shall be cooled within 4 hours to 41°F (5°C) or less if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna.

- (C) Except as specified under \P (D) of this section, a TCS FOOD received in compliance with LAWS allowing a temperature above 41°F (5°C) during shipment from the supplier as specified in \P 3-202.11(B), shall be cooled within 4 hours to 41°F (5°C) or less.
- (D) Raw EGGS shall be received as specified under \P 3-202.11(C) and immediately placed in refrigerated EQUIPMENT that maintains an ambient air temperature of 41°F (5°C) or less.

3-501.15 Cooling methods

- (A) Cooling shall be accomplished IAW 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 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 \P (B) and in \P (C) of this section, the internal product temperature of TCS FOOD shall be maintained—
- (1) At 135°F (57°C) or above, except that roasts cooked to a temperature and for a time specified in $\sqrt[9]{3-401.11(B)}$ or reheated as specified in $\sqrt[9]{3-403.11(E)}$ may be held at a temperature of 130°F (54°C) or above; or (2) At 41°F (5°C) or less.
- (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 41°F (5°C) or less.
- (C) The TCS FOOD in a homogenous liquid form, provided the FOOD is pasteurized and aseptically packaged, may be maintained outside of the temperature control requirements, as specified under \P (A) of this section, while contained within specially designed EQUIPMENT that complies with the design and construction requirements as specified under \P 4-204.13(D).
- (D) Raw plant FOODS that are cut, sliced, or diced as well as cooked plant FOODS shall be maintained as specified in Subparagraphs (A)(1)–(2) of this section. †

3-501.17 Time/temperature control for safety food, date marking and retention*

- (A) *On-premises preparation—prepare and hold cold.* ADVANCED PREPARED TCS FOODS. Except when PACKAGING FOOD using a REDUCED OXYGEN PACKAGING (ROP) method as specified under § 3-502.12, and except as specified in ¶¶ (E) and (F) of this section and § 3-502.13, refrigerated ADVANCED PREPARED TCS FOOD held in a FOOD ESTABLISHMENT shall be labeled as specified under ¶ 3-602.11(E) and 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 41°F (5°C) or less. The maximum refrigerated holding period for ADVANCED PREPARED FOODS may not exceed 7 days and the day of preparation shall be counted as Day-1.
 - (B) Commercially packaged food. †
- (1) *Received frozen.* TCS FOOD that is PACKAGED and FROZEN by a FOOD PROCESSING PLANT and then thawed by the FOOD ESTABLISHMENT—
 - (a) May not be REFROZEN, as specified under ¶ 3-502.13(F);

- (b) May not be retained for use or sale beyond the manufacturer's recommended shelf life or APPROVED extended shelf life as specified under $\P = \frac{3-503.11(C)}{(D)}$, $P = \frac{(G)}{(E)}$, and $P = \frac{(G)}{(E)$
- (c) Shall be clearly marked with the date the FOOD was removed from the freezer and shall be used, sold, or discarded within 7 days of removal from the freezer.
- (2) Received fresh. Except for FOOD that is FROZEN by the FOOD ESTABLISHMENT as specified under \P 3-502.13(A) and FOOD with an APPROVED shelf-life extension as specified in \P \P 3-503.11(C), (D), (E), and (F), raw and RTE TCS FOODS received fresh shall be used or sold by the manufacturer's use-by or expiration date, as specified under \P 3-503.11(A).
- (C) Commercially processed RTE food—open and hold cold. Except as specified in ¶¶ (F)–(H) of this section, refrigerated RTE TCS 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 in which the package was opened and 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:
- (1) The day the original container is opened in the FOOD ESTABLISHMENT shall be counted as Day 1; 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.
- (D) A refrigerated RTE TCS FOOD ingredient or a portion of a refrigerated RTE TCS 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.
 - (E) A date marking system that meets the criteria specified in $\P\P(A)$, (B) and (C) of this section may include—
- (1) Using a method APPROVED by the REGULATORY AUTHORITY for refrigerated, RTE TCS 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 \P (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 $\P(C)$ 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.
- (F) Paragraphs (A) and (C) of this section do not apply to individual meal portions served or rePACKAGED for sale from a bulk container upon a CONSUMER'S request.
 - (G) Paragraphs (A) and (C) of this section do not apply to SHELLSTOCK.
- (H) Paragraph (C) 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 IAW 21 CFR 117 Current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food;
- (2) <u>Hard cheeses</u> containing not more than 39 percent moisture as defined in 21 CFR 133 Cheeses and related cheese products, such as cheddar, gruyere, parmesan and reggiano, and romano;
- (3) <u>Semi-soft cheeses</u> containing more than 39 percent moisture, but not more than 50 percent 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 salami; and

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(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 $\P = \frac{3-501.17(A)-(C)}{2}$ shall be discarded if it:
- (1) Exceeds the temperature and time combination specified in \P 3-501.17(A), except time that the product is FROZEN:
 - (2) Is in a container or PACKAGE that does not bear a date or day; or
- (3) Is appropriately marked with a date or day that exceeds a temperature and time combination as specified in \P 3-501.17(A).
- (B) Refrigerated, RTE TCS 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 \P 3-501.17(A).

3-501.19 Time as a public health control*

- (A) Except as specified under \P (D) of this section, if time without temperature control is used as the public health control for a working supply of TCS FOOD before cooking, or for RTE TCS FOOD that is displayed or held for sale or service:
- (1) Written procedures shall be prepared and APPROVED by the REGULATORY AUTHORITY in advance. The procedures shall specify:
 - (a) Methods of compliance with Subparagraphs (B)(1)-(4) or (C)(1)-(5) of this section; and
- (b) Methods of compliance with § <u>3-501.14</u> for FOOD that is prepared, cooked, and refrigerated before time is used as a public health control.
- (2) These procedures shall be maintained in the FOOD ESTABLISHMENT and made available to the FOOD EMPLOYEE at all times and the REGULATORY AUTHORITY upon request. †
- (B) *Time—maximum up to 4 hours (hot or cold food)*. If time without temperature control is used as the public health control for up to a maximum of 4 hours:
- (1) The FOOD shall have an initial temperature of 41°F (5°C) or less when removed from cold holding temperature control, or 135°F (57°C) or greater when removed from hot holding temperature control;
- (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;
- (3) The FOOD shall be cooked and served, served at any temperature if RTE, or discarded, within 4 hours from the point in time when the FOOD is removed from temperature control; and
- (4) The FOOD in unmarked containers or PACKAGES or marked to exceed a 4-hour limit shall be discarded.
- (C) *Time—maximum up to 6 hours (cold food only)*. 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 41°F (5°C) or less when removed from temperature control, and the FOOD temperature may not exceed 70°F (21°C) within a maximum time period of 6 hours;
- (2) The FOOD shall be monitored to ensure the warmest portion of the FOOD does not exceed 70°F (21°C) during the 6-hour period.
 - (3) The FOOD shall be marked or otherwise identified to indicate:
 - (a) The time when the FOOD is removed from $41^{\circ}F$ (5°C) or less cold holding temperature control,
- (b) The time that is 6 hours past the point in time when the FOOD is removed from cold holding temperature control;
 - (4) The FOOD shall be-

and

- (a) Discarded if the temperature of the FOOD exceeds 70°F (21°C), or
- (b) Cooked and served, served at any temperature if RTE, or discarded within a maximum of 6 hours from the point in time when the FOOD is removed from $41^{\circ}F$ ($5^{\circ}C$) or less cold holding temperature control.
- (5) The FOOD in unmarked containers or PACKAGES or marked with a time that exceeds the 6-hour limit shall be discarded.

(D) Except for use of insulated containers in field feeding operations to transport FOOD, 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.

3-501.110 Leftovers, conditions for retention*†

- (A) Non-TCS FOODS removed from a customer self-service line, employee-controlled serving line, CUSTOMER tray, or the dining room may be retained as a LEFTOVER and offered for RE-SERVICE to CUSTOMERS under the following conditions:
- (1) Bulk products from a serving line are uncontaminated, as specified under $\P(B)$ of this section and Subparagraph 3-306.14(B)(1).
- (2) Products were protected during display by use of sneeze guards, closed display cabinets or other barrier, each equipped with a dedicated serving utensil, or pre-plated as individual portions. Plated items protected by a display case or sneeze guard do not require additional plastic wrapping in order to be retained.
- (3) The packaging for individual portions of commercially PACKAGED FOODS remains intact and uncontaminated, as specified under Subparagraph <u>3-306.14(B)(2)</u>.
- (4) Commercially bottled condiments are not refilled or topped off, are protected by a cap or lid, and the container is undamaged and wiped clean after each meal or at the end of the business day.
- (5) Refillable condiment dispensers are protected by a lid or cap, wiped clean after each meal or the end of the day, and cleaned and SANITIZED before refilling.
- (6) Unsliced, hard skinned fruits are washed as specified under § <u>3-302.15</u> prior to serving to a new CONSUMER.
- (7) Except for unwholesome or ADULTERATED FOODS as specified under § 3-101.11 and as specified in ¶ (B) of this section, LEFTOVER non-TCS FOODS may be retained until the product is consumed or discarded.
- (8) A label identifying the name of the non-TCS LEFTOVER FOOD, as specified under \P 3-602.11(E), is placed on the container when removed from service.
- (9) The bulk or individually PACKAGED FOOD was not from a patient or client as specified under \P 3-801.11(H).
- (B) Non-TCS FOODS that are visibly contaminated with debris from a TCS FOOD or other foreign contaminant may not be retained as a LEFTOVER as specified under § 3-101.11.
- (C) Non-TCS FOODS that were removed from its original PACKAGING may not be returned to the original PACKAGING for comingling with unused portions of the original product. ^N
- (D) Except as specified in Subparagraph (G)(3) of this section, TCS FOOD may be retained as a LEFTOVER under the following conditions:
- (1) Hot FOODS shall be held at $135^{\circ}F$ ($57^{\circ}C$) or above, and cold FOODS at $41^{\circ}F$ ($5^{\circ}C$) or below throughout the meal period as specified under \P 3-501.16(A).
 - (2) Hot items chilled for LEFTOVER retention shall be cooled as specified under § 3-501.14.
- (3) TCS LEFTOVERS shall have a label indicating, "Leftover," the food name, the date prepared, and the use-by date as specified under ¶ 3-602.11(E).
- (E) LEFTOVER TCS FOODS shall be retained for a period not to exceed 7 days from the initial date of preparation.
- (F) LEFTOVER TCS FOODS shall not be FROZEN for use beyond the 7-day retention period as specified in ¶ (E) of this section.
 - (G) Prohibited LEFTOVERS.
- (1) Except for commercially PACKAGED RTE FOODS as specified under ¶ 3-501.17(C), prohibited LEFTOVERS include, but are not necessarily limited to potato salad, chicken salad, turkey salad, macaroni salad, shrimp salad, EGG salad, and similar items prepared on the premises by the FOOD ESTABLISHMENT. Also included are FOODS that have been creamed or handled a great amount (for example, hashes, most gravies and dressings, creamed meats) and items that are highly perishable (for example, most seafood).
- (2) Except for unopened, heated or unheated, operational ration tray packs, LEFTOVER TCS FOOD from a FIELD FOOD OPERATION or FIELD FOOD SERVICE ESTABLISHMENT.
 - (3) LEFTOVER TCS FOOD removed from a CONSUMER SELF-SERVICE line.

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- (4) LEFTOVER TCS FOOD from a FOOD ESTABLISHMENT serving a HIGHLY SUSCEPTIBLE POPULATION.
- (5) LEFTOVER TCS FOODS that have been previously retained as a LEFTOVER or contain previously LEFTOVER FOODS as an ingredient.

3-502 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—

- (A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement;
- (B) Curing FOOD;
- (C) Using FOOD ADDITIVES or adding components such as vinegar:
 - (1) As a method of FOOD preservation rather than as a method of flavor enhancement, or
 - (2) To render a FOOD so that it is not a TCS FOOD;
- (D) Packaging TCS FOOD using an ROP method except where the growth of and toxin formation by Clostridium botulinum (C. botulinum) and the growth of Listeria monocytogenes (Lm) are controlled as specified under § 3-502.12;
- (E) Operating a MOLLUSCAN SHELLFISH life-support system display tank used to store or display shellfish that are offered for human consumption;
- (F) Custom-processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT:
- (G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE; or
 - (H) Sprouting seeds or beans.

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 TCS FOOD using an ROP method shall control the growth and toxin formation of *C. botulinum* and the growth of *Lm*.
- (B) Except as specified under \P (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TCS FOOD using an ROP method shall have a HACCP PLAN that contains the information specified under \P 8-201.14(D) and that—
 - (1) Identifies the FOOD to be PACKAGED;
- (2) Except as specified under $\P\P$ (C)—(E) of this section, requires that the PACKAGED FOOD shall be maintained at $41^{\circ}F$ ($5^{\circ}C$) or less and meet at least one of the following criteria:
 - (a) Has an aw 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 USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact PACKAGE, or
- (d) Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables;
- (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:
 - (a) Maintain the FOOD at 41°F (5°C) or below, and
- (b) Discard the FOOD if within 30 calendar days of its PACKAGING it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption;

- (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;
 - (5) Includes operational procedures that-
 - (a) Prohibit contacting RTE FOOD with bare hands as specified under ¶ 3-301.11(B),
 - (b) Identify a designated work area and the method by which-
- (i) Physical barriers or methods of separation of raw FOODS and RTE FOODS minimize cross-contamination, and
- (ii) Access to the processing EQUIPMENT is limited to responsible, trained personnel familiar with the potential HAZARDS of the operation, and
 - (c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; and
- (6) Describes the training program that ensures that the individual responsible for the ROP operation understands the—
 - (a) Concepts required for a safe operation,
 - (b) EQUIPMENT and facilities, and
 - (c) Procedures specified under Subparagraph (B)(5) of this section and \P 8-201.14(C) and (D).
- (7) Is provided to the REGULATORY AUTHORITY prior to implementation as specified under ¶ 8-201.13(B).
- (C) Fish. Except for FISH that is frozen before, during, and after PACKAGING, a FOOD ESTABLISHMENT may not PACKAGE FISH using an ROP method.
- (D) <u>Cook-Chill</u> or Sous Vide. Except as specified under $\P\P$ (C) and (F) of this section, a FOOD ESTABLISHMENT that PACKAGES TCS FOOD using a COOK-CHILL or SOUS VIDE process shall—
 - (1) Implement a HACCP PLAN that contains the information as specified under ¶ 8-201.14(D);
 - (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,
- (b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under $\P = 3-401.11(A)$, (B), and (C),
 - (c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4,
- (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 135°F (57°C),
 - (e) Cooled to 41°F (5°C) in the sealed PACKAGE or bag as specified under § 3-501.14 and-
- (i) Cooled to $34^{\circ}F$ ($1^{\circ}C$) within 48 hours of reaching $41^{\circ}F$ ($5^{\circ}C$) and held at that temperature until consumed or discarded within 30 days after the date of PACKAGING;
- (ii) Held at $41^{\circ}F$ ($5^{\circ}C$) or less for no more than 7 days, at which time the FOOD must be consumed or discarded;
 - (iii) Held FROZEN with no shelf-life restriction while frozen until consumed or used.
- (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,
- (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, and
 - (h) Labeled with the product name and the date PACKAGED; 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, and
 - (b) Hold such records for at least 6 months; 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.
- (E) $\it Cheese.$ Except as specified under \P (F) of this section, a FOOD ESTABLISHMENT that PACKAGES cheese using an ROP method shall—

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- (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;
- (2) Have a HACCP PLAN that contains the information specified under $\P = \frac{8-201.14(C)}{2}$ and $\frac{D}{2}$ and as specified under Subparagraphs (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section;
- (3) Label the PACKAGE on the principal display panel with a "use by" date that does not exceed 30 calendar days from its packaging date or the original manufacturer's "sell by" or "use by" date, whichever occurs first; and
- (4) Discard the REDUCED OXYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING.
- (F) A HACCP Plan is not required when a FOOD ESTABLISHMENT uses an ROP method to PACKAGE TCS FOOD that is always:
 - (1) Labeled with the production time and date,
 - (2) Held at $41^{\circ}F$ ($5^{\circ}C$) or less during refrigerated storage, and
 - (3) Removed from its PACKAGE in the FOOD ESTABLISHMENT within 48 hours after PACKAGING.

3-502.13 Freezing time/temperature control for safety foods[†]

- (A) Except as specified in \P (E) of this section, raw TCS FOOD received fresh and RTE TCS FOOD PACKAGED by a FOOD PROCESSING PLANT may be FROZEN by the FOOD ESTABLISHMENT under the following conditions:
- (1) Prior to freezing and before the FOOD has exceeded its shelf code date, the FOOD ESTABLISHMENT shall notify the REGULATORY AUTHORITY as specified in Subparagraph 3-503.11(C)(4) and 9-503.11(D) to determine the new use-by date.
 - (2) The product shall be wholesome as specified under § 3-101.11 prior to freezing.
 - (3) The product shall be clearly labeled with the use-by date prior to placement in the freezer.
- (4) The product shall be date-labeled upon removal from the freezer and retained no longer than 7 days, as specified under Subparagraph 3-501.17(B)(1)(c).
- (B) TCS FOOD that is ADVANCED PREPARED by the FOOD ESTABLISHMENT shall meet the following conditions if FROZEN—
- (1) The FOOD ESTABLISHMENT shall develop a written plan that outlines controls and monitoring procedures to ensure FOOD was properly cooked, cooled, and held at safe temperatures before freezing.
- (2) The product shall be cooled to 41°F (5°C) as specified under §§ 3-501.14 and 3-501.15 prior to placement in the freezer and a written record of the cooling log shall be retained on file.
- (3) The FOOD shall be labeled, as specified under Subparagraph <u>3-602.11(E)(1)-(3)</u>, to include the date the FOOD was placed in the freezer, and the use-by date, *which should not exceed 30 days*.
- (4) The product shall be placed in the freezer within 24 hours from the time the FOOD was originally prepared.
 - (5) The product shall be FROZEN to a temperature of $0^{\circ}F$ (-18°C) or below.
- (6) The product shall be labeled with the date in which it was removed from the freezer and shall be used, sold, or discarded within 7 days as specified under Subparagraph 3-501.17(B)(1)(c).
- (7) FOODS prepared using COOK-CHILL or SOUS VIDE processes shall be cooled and held FROZEN as specified under subparagraph 3-502.12(D)(2)(e).
 - (8) FOOD that was previously FROZEN and partially or fully thawed may not be reFROZEN.
- (C) LEFTOVER TCS FOODS removed from a serving line and FOODS containing LEFTOVERS as an ingredient may not be FROZEN as specified under \P 3-501.110(F) and Subparagraph 3-501.110(G)(5).
- (D) ADVANCED PREPARED non-TCS FOODS prepared by the FOOD ESTABLISHMENT and FROZEN may be retained without a time restriction.
- (E) Except for products which are produced at a commercial manufacturing plant (that is, Guaranteed Products), retail store operations may freeze fresh raw beef and pork products (steaks, roasts, chops, and ground beef or pork) under the following conditions—

- (1) The freezer temperature shall be $0^{\circ}F$ (-18°C) or below.
- (2) Retail operations shall adhere to their internal directives governing freezing fresh FOODS.
- (3) The maximum shelf life for these FROZEN products should not exceed 30 days from the date placed in the freezer.
- (4) Products may not show signs of deterioration and shall be in a salable condition throughout the new intended shelf life.
 - (5) Fresh meat products may not be reworked prior to freezing to make them salable.
- (6) Products shall be FROZEN before the original "sell-by" date and layered singly to ensure proper freezing.
- (7) Original product labels may not be covered or removed such that the original processing and sell-by dates cannot be validated.
- (F) TCS FOOD PACKAGED and FROZEN by a FOOD PROCESSING PLANT and received FROZEN at the FOOD ESTABLISHMENT and subsequently thawed may not be REFROZEN.

3-503 Outdated food

3-503.11 Restrictions for sale or service[†]

Except as specified in \P (F) of this section, evaluation of OUTDATED/EXPIRED FOODS is conducted by Army Veterinary Services or Air Force Public Health personnel serving in a position as the REGULATORY AUTHORITY.

- (A) Except as specified in $\P\P$ (C), (D), and (E) of this section, OUTDATED/EXPIRED TCS FOOD may not be served, displayed for sale, or otherwise used with expired shelf life or code dates (that is "best used by," "best sold by," or similar date markings).
 - (B) Over-the-counter medications and baby FOOD may not be displayed for sale past the expiration date.
- (C) The "expiration," "best used by," or "best sold by" date may be extended according to the following conditions and as specified in $\P\P$ (F) and (G) of this section—
- (1) Continental United States (CONUS) locations. Extension requests are evaluated on a case-by-case basis in support of Naval operations afloat and Air Force installations. Shelf-life extensions for FOOD other than operational rations are generally not granted at CONUS locations inspected under the jurisdiction of Army Veterinary Services IAW Army Veterinary ServicePolicy. The FOOD ESTABLISHMENT shall demonstrate strict adherence to First-in, First-out (FIFO) stock rotation before an extension may be granted.
- (2) **OCONUS locations.** Shelf life may be extended at OCONUS locations and as specified in \P (F) of this section as long as product wholesomeness and fitness for intended use are maintained.
- (3) Products shall be inspected and APPROVED by the REGULATORY AUTHORITY prior to the product's expiration date.
- (4) Freezing FOOD by the FOOD ESTABLISHMENT may be used to extend product shelf life when circumstances justify the practice. The FOOD ESTABLISHMENT shall request a product evaluation as specified under Subparagraph (C)(3) of this section and prior to freezing, as specified under Subparagraphs 3-502.13(A)(1).
- (5) The FOOD ESTABLISHMENT shall retain documentation of the shelf-life extension and shall present it to the inspector upon request during a FOOD ESTABLISHMENT inspection.
- (6) Operations under Air Force jurisdiction requiring any other evaluation of OUTDATED/EXPIRED PACKAGED FOODS should include a consultation between the Public Health Officer and food protection subject matter experts located at the United States Air Force School of Aerospace Medicine (USAFSAM), Public Health and Preventive Medicine Department.
- (D) When the manufacturer's shelf code date is based upon refrigerated storage and distribution conditions, and, due to supply line requirements, the product is FROZEN in a FOOD distribution facility prior to delivery to the FOOD ESTABLISHMENT or retail store, the manufacturer's assigned date no longer indicates the product's expected shelf life. Consultation with the REGULATORY AUTHORITY is required to determine the new shelf code date. The FOOD ESTABLISHMENT shall mark the new expiration ("sell-by" or "use-by") date on each individual FOOD PACKAGE.

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- (E) Under circumstances involving a naval vessel afloat or at port where a Veterinary Services representative is not present and it is not feasible to delay a product evaluation or discontinue use of the product, the MEDICAL AUTHORITY may extend the shelf life and authorize use of OUTDATED/EXPIRED FOOD that is found to be in wholesome condition and fit for its intended purpose as specified under § 3-101.11.
- (F) Except for FOOD FROZEN as specified in ¶ 3-502.13(A), the shelf life of TCS FOOD PACKAGED by a FOOD PROCESSING PLANT may not be extended in CONUS retail store operations. PACKAGED TCS FOODS that are held under refrigeration in food service operations may not be extended more than once and extension dates may not exceed 30 days from the original manufacturer's shelf code.
- (G) Shelf code extensions for non-TCS FOODS are determined locally by the REGULATORY AUTHORITY and present more of a-food quality rather than food safety issue.

3-6. Food identity, presentation, and on-premises labeling

3-601 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.

3-602 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 for PACKAGED FOOD 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 color or flavor 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;
- (6) Except as exempted in the Federal Food, Drug, and Cosmetic Act $\S 403(q)(3)$ -(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.
 - (E) Labels for ADVANCED PREPARED and LEFTOVER TCS FOODS shall contain—†
- (1) Markings (either written, color code, or other distinguishing label specified in an SOP) that identify the FOOD as "advanced prepared" or "leftover." ADVANCED PREPARED FOODS shall be further labeled to indicate whether the product is "raw," "partially cooked," or "RTE;"
 - (2) The name of the FOOD;
- (3) The date and time the FOOD was ADVANCED PREPARED or removed from service for retention as a LEFTOVER; and
 - (4) The use-by or discard date.

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.

3-603 Consumer advisory

<u>3-603.11</u> 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 RTE form or as an ingredient in another RTE FOOD, the PIC 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.
 - (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)"; 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.
- (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";
- (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."

3-7. Contaminated food

3-701 Disposition

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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 segregated, labeled, and discarded, according to an APPROVED procedure.
- (1) The PIC or person designated as the accountable officer for this type of action shall immediately identify stocks of hazardous foods upon notification of a DOD hazardous food and nonprescription drug recall (for example, ALFOODACT message). Actions to begin identifying and segregating implicated products may not be delayed pending assistance from the REGULATORY AUTHORITY.
- (2) Segregated products shall be retained in a Medical Hold status until removed from the food establishment. The PIC shall conduct a daily inventory to preclude further issue, sale, or use until the product is returned to the vendor or destroyed in an approved manner that is in accordance with the recall disposition instruction or other guidance from the REGULATORY AUTHORITY.
- (B) FOOD that is not from an APPROVED SOURCE as specified under §§ <u>3-201.11</u> through 3-201.18 shall be evaluated by the REGULATORY AUTHORITY for disposition.
- (C) READY-TO-EAT FOOD that may have been contaminated by an EMPLOYEE who has been RESTRICTED or EXCLUDED as specified under § <u>2-201.12</u> 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

3-801 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 years 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(A)(2) may not be served or offered for sale; and
- (3) UnPACKAGED JUICE that is prepared on the premises for service or sale in an RTE form shall be processed under a HACCP PLAN that contains the information specified under ¶¶ 8-201.14(C)—(E) and as specified in 21 CFR Part 120–HACCP Systems, Subpart B Pathogen Reduction, 120.24 Process controls.
 - (B) Pasteurized EGGS or EGG PRODUCTS shall be substituted for raw EGGS in the preparation of-
- (1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, Eggnog, ice cream, and EGG-fortified BEVERAGES, and
- (2) Except as specified in \P (F) of this section, recipes in which more than one EGG is broken and the EGGS are combined;
 - (C) The following FOODS may not be served in an RTE form:
- (1) For the purposes of this paragraph only, school-age children 12 years old or less are included as HIGHLY SUSCEPTIBLE POPULATIONS when receiving FOOD in a school, child care setting, or similar facility;
- (2) Raw animal FOODS such as raw FISH, raw marinated FISH, raw MOLLUSCAN SHELLFISH, and steak tartar.
- (3) A partially cooked animal FOOD such as lightly cooked FISH, rare MEAT, soft-cooked EGGS that are made from raw EGGS, and meringue; and
 - (4) Raw seed sprouts.
 - (D) FOOD EMPLOYEES may not contact RTE FOOD as specified under ¶¶ 3-301.11(B) and (D).

- (E) Time only, as the public health control as specified under ¶ 3-501.19(D), may not be used for raw EGGS.
- (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 an RTE 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 RTE 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 \P 8-201.14(D) including procedures that—
 - (i) Control cross-contamination of RTE 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.
- (G) <u>Re-service of food</u>. Except as specified in paragraph (H) of this section, FOOD may be re-served as specified under Subparagraphs 3-306.14(B)(1) and (B)(2).
 - (H) Prohibited re-service of food. 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, or receive their meals in their room via patient tray service, may not be re-served to others outside these environments.
- (2) Packages of FOOD from patients, clients, or other CONSUMERS may not be re-served to patients in protective environment isolation or who receive their meals via patient tray service.

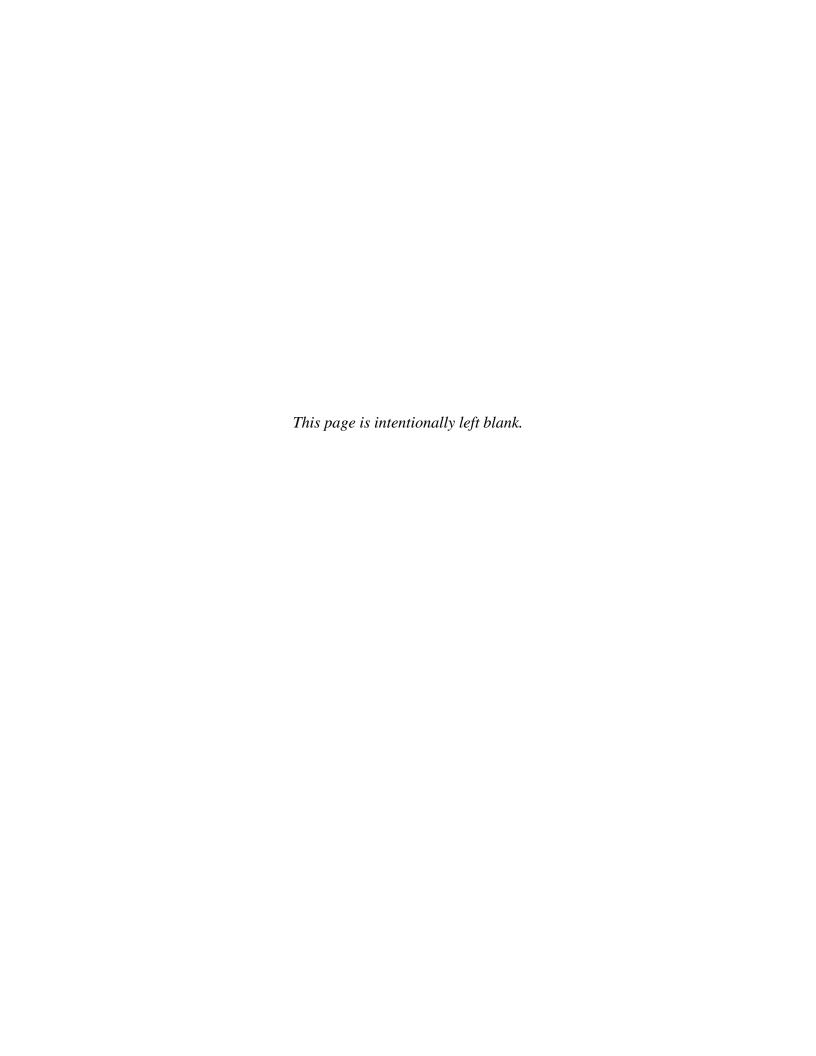
3-9. Food donations

3-901 Excess food

3-901.10 Donation of excess food to local relief organizations[†]

- (A) Only FOODS that have been protected from contamination and have been stored at SAFE FOOD TEMPERATURES may be donated.
- (B) Guidance for donation of excess food to local relief organizations and similar programs may be obtained from the REGULATORY AUTHORITY.

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CHAPTER 4

EQUIPMENT, UTENSILS, AND LINENS

4-1. Materials for construction and repair

4-101 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 \P (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 provided in Table 4-1.
- (B) Pewter alloys containing lead in excess of 0.05 percent may not be used as a FOOD-CONTACT SURFACE.
- (C) Solder and flux containing lead in excess of 0.2 percent may not be used as a FOOD-CONTACT SURFACE.

Table 4-1. Maximum lead content for food contact surfaces

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	

Note: milligrams per liter (mg/L)

4-101.14 Copper, use limitation*

- (A) Except as specified in \P (B) and (C) 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 pre-fermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.
- (C) Copper and copper alloys may be used with potable, noncarbonated water, pH 6.0 or above, under constant service pressure. †

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 Wood, use limitation

- (A) Except as specified in \P (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, sushi bamboo rolls, chopsticks; and
- (2) Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of $230^{\circ}F$ ($110^{\circ}C$) 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 fluoropolymer or other nonstick coating shall be used with nonscoring or nonscratching UTENSILS and cleaning aids. Some KITCHENWARE with nonstick coatings may have to be hand washed and sanitized. Care must be taken to avoid scratching or chipping the coatings or bonding agents.

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.

4-101.110 Paint or other coatings, application[†]

Paint or other coatings not APPROVED for application on FOOD-CONTACT SURFACES may not be applied to a FOOD-CONTACT SURFACE or SPLASH ZONE.

4-101.111 Sealing compounds[†]

Sealing compounds shall provide a water- and vermin-tight seal and shall be-

- (A) Sufficiently pliable for ease of application;
- (B) Somewhat elastic after application and adequately firm so as not to be gummy or sticky;
- (C) Nonshrinking;
- (D) Listed in the NSF White BookTM Nonfood Compounds Listings Directory, available at

<u>http://www.nsf.org/usda/Listings.asp</u>, if used on FOOD-CONTACT SURFACES and may not void the certification listing of the EQUIPMENT; and

(E) Shall meet the requirements specified under § 4-101.11.

4-101.112 Plastic, use prohibition[†]

Soft plastic containers not intended as multiuse EQUIPMENT, such as SINGLE-USE deli PACKAGES, pails, and milk jugs, may not be reused for FOOD storage.

4-101.113 Pallet use[†]

- (A) PACKAGED FOOD may be stored on NSF International-listed plastic pallets or wood pallets provided the pallets are in sound condition, kept clean, and moved regularly so that the area under the pallets is kept clean.
- (B) Except as specified in \P (C) of this section, wood pallets may not be used in FOOD preparation areas or any area where unPACKAGED FOOD is processed, prepared or handled.
- (C) Wooden pallets may be used for storage of bulk produce in retail stores where limited processing occurs (for example, commissary).

4-102 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

4-201 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.

4-201.13 Sealing compounds[†]

(A) Sealing compounds used in the installation of refrigeration, cooking, and warming EQUIPMENT shall be capable of withstanding the full range of operating temperatures (hot or cold) without cracking or unsealing.

(B) Materials or EQUIPMENT requiring use of sealing compounds shall be physically secured before the compounds are applied. Sealants may not be used to fill open spaces or voids resulting from improper installation, design, or fabrication. Do not exceed the manufacturer's maximum width for filling voids.

4-202 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 \P (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 Clean-in-place equipment

- (A) Clean-in-place (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) Any 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.
- (C) Fixed EQUIPMENT intended to be cleaned and sanitized using pressure spray methods shall be designed and APPROVED for pressure spray cleaning. †

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

The 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 shall be 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-

- (A) Tight fitting and adequately secured to prevent falling.†
- (B) Designed to be easily accessible and removable for cleaning and replacement if not designed to be cleaned in place.
 - (C) Installed at an angle not less than 45 degrees from the horizontal.[†]
 - (D) Equipped with a drip tray beneath the lower edge of the filters.
- (E) Protected by a fire suppression system. Kitchen exhaust systems shall meet the requirements of the National Fire Protection Association (NFPA Standard 96), Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations.[†]

4-203 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 $\pm 1^{\circ}$ C in the intended range of use.
- (B) FOOD TEMPERATURE MEASURING DEVICES that are scaled only in Fahrenheit shall be accurate to $\pm 2^{\circ}$ 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 $\pm 3^{\circ}$ 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 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.

4-204 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 two-tenths of an inch (5 millimeters).

- (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 \P (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) Bulk milk dispensers, multiservice shipping and dispenser containers, and dispensing tubes shall meet the requirements of NSF International Standard 20, Commercial Bulk Milk Dispensing Equipment. ^N
- (B) 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, and
- (1) The bulk milk container dispensing tube shall be cut IAW the manufacturer's instructions or on the diagonal, leaving no more than 1 inch protruding from the chilled dispensing head. †
- (2) For other FOODS, 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 un-PACKAGED 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-N
- (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. ^N
- (E) Dispensing EQUIPMENT in which TCS FOOD in a homogenous liquid form is maintained outside of the temperature control requirements as specified under \P 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; and
- (2) Conform to the requirements for this EQUIPMENT as specified in NSF/ANSI 18-2006 Manual Food and Beverage Dispensing Equipment.

4-204.14 Vending machine, vending stage closure

The dispensing compartment of a VENDING MACHINE, including a machine that is designed to vend pre-PACKAGED snack FOOD that is not TCS 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

- (A) Except as specified in ¶ (B) of this section, 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.
- (B) Safe food-grade lubricants shall be used when EQUIPMENT design does not prevent contact of lubricants with FOOD or FOOD-CONTACT SURFACES. †

4-204.16 Beverage tubing, separation

- (A) Except for cold plates that are constructed integrally with an ice storage bin and as specified in $\P(B)$ of this section, tubing and cold-plate BEVERAGE cooling devices may not be installed in contact with stored ice.
- (B) Ice that is in contact with tubing used to convey BEVERAGES or BEVERAGE ingredients to dispensing heads shall be rendered NONPOTABLE and may not be used for human consumption as specified under § 3-303.11.[†]

4-204.17 Ice units, separation of drains

Liquid waste drain lines of any type 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.

<u>4-204.19</u> Can openers on vending machines
The 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.
- (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 IAW a VARIANCE granted by the REGULATORY AUTHORITY as specified in § 8-103.10 and a HACCP PLAN that-
 - (1) Is submitted by the PERSON-IN-CHARGE 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 TCS 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 ¶ 3-501.16(A); 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 ¶ 3-501.16(A).
 - (B) When the automatic shutoff within a machine vending TCS FOOD is activated:

- (1) In a refrigerated vending machine, the ambient air temperature may not exceed 41°F (5°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 air temperature may not be less than $135\,^{\circ}F$ (57°C) 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 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 TCS 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 without the EQUIPMENT being opened. Placement of an additional thermometer inside the unit is not required if the built-in thermometer is functioning properly. The PIC verifies thermometer function during self-evaluations or monitoring activities by placing a properly calibrated FOOD TEMPERATURE MEASURING DEVICE inside the unit and comparing the temperature reading with the unit's device.
- (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, bainmarie, steam tables, insulated FOOD transport containers, and salad bars. If there is a failure or absence of an integrated or permanently affixed TEMPERATURE MEASURING DEVICE, application of a calibrated TEMPERATURE MEASURING DEVICE (which is not integral or permanently affixed) is appropriate for safe temperature management.
 - (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 2°F or 1°C 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 and 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

- (A) 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.
 - (B) Baffles and curtains shall be kept in good repair and replaced as needed.

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 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 171°F (77°C); 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, automatic dispensing of detergents and sanitizers

A WAREWASHING machine that is installed after adoption of this publication by the REGULATORY AUTHORITY, shall be equipped to—

- (A) Automatically dispense detergents and SANITIZERS; 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.

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 the water enters 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 ¼-inch or 6.4-millimeter size iron pipe 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 there is a 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 1/16 inch (1.5 millimeters) by—
- (1) Being covered with louvers, screens, or materials that provide an equivalent opening of not greater than 1/16 inch or 1.5 millimeters. Screening of 12-mesh to 1 inch (12- or more mesh to 2.5 cm) meets this requirement;
 - (2) Being effectively gasketed;
 - (3) Having interface surfaces that are at least ½-inch (13 millimeters) wide; or
 - (4) Having jambs or surfaces that 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 1/16 inch (1.5 millimeters.)

4-204.124 Mechanical warewashing equipment, heating device[†]

- (A) Hot water SANITIZING WAREWASHING machines shall be equipped with an adequately sized booster heater as specified in ¶ 4-204.116(A) and § 4-301.16.
- (B) Booster heaters may be required for wash, rinse and final rinse of WAREWASHING machines to ensure temperature compliance as specified under §§ 4-501.110, 4-501.112, and 4-501.114.

4-204.200 Manual warewashing equipment, swing-arm faucet[†]

Swing-arm faucets supplied with both hot and cold water that can serve more than one sink compartment should not be installed at the final rinse sink when hot water is the intended sanitizing mechanism. This is to prevent cold water from being added to the final rinse.

4-205 Acceptability

4-205.10 Food equipment, certification and classification

- (A) FOOD EQUIPMENT that is certified or classified for sanitation by an ANSI-accredited certification program is deemed to comply with Parts 4-1 and 4-2 of this chapter.
- (B) Except EQUIPMENT used in production and preparation areas of retail FOOD stores, such as commissary meat market, fresh seafood, deli, and produce departments, written approval to purchase EQUIPMENT that is industry or USDA-APPROVED, but not NSF International-APPROVED shall be obtained from the REGULATORY AUTHORITY prior to purchase for use in FOOD ESTABLISHMENTS and food service areas of retail FOOD stores. Consultative support for EQUIPMENT APPROVAL is available through the respective Services' Public Health/Preventive Medicine chain of command, to include the respective military Public Health Center/Command.[†]
- (C) OCONUS FOOD ESTABLISHMENTS may procure foreign-manufactured food service EQUIPMENT provided the EQUIPMENT meets sanitation standards outlined in \P (A) and (B) of this section. All questions should be referred to the REGULATORY AUTHORITY. Guidance is provided in \P 4-205.13(B) for foreign-manufactured equipment approval.[†]
- (D) Use of home-style FOOD EQUIPMENT, including refrigeration, dishwashing, storage cabinets and counters and similar appliances is authorized for demonstration kitchens in Middle Schools and Teen Facilities and for Wounded Warrior Family Guest Houses.[†]
- (E) Shipboard food service equipment must comply with NAVSUP PUB 533, Shipboard Food Service Equipment Catalog.[†]

4-205.11 Equipment and utensils, approval[†]

- (A) Except as specified in § <u>4-205.10</u>, all food service EQUIPMENT and UTENSILS used in a FOOD ESTABLISHMENT shall meet the applicable standards or criteria of:
 - (1) NSF International;

- (2) Underwriters Laboratories (UL®), Inc. (UL® is a registered trademark of UL, LLC.);
- (3) USDA;
- (4) Baking Industry Sanitation Standards Committee (BISSC) for bakery equipment; or
- (5) Other laboratory or national consensus standards acceptable to the REGULATORY AUTHORITY with consultative support through the respective Services' Public Health/Preventive Medicine chain of command and Public Health Center/Command food sanitation and safety representative.
- (B) VENDING MACHINES, including customer-operated water VENDING MACHINES, shall meet NSF International Standard 25 or National Automatic Merchandising Association (NAMA) standards.
- (C) Criteria specified in this section and § <u>4-205.10</u> shall be incorporated into appropriate specifications, contracts, and procurement documents for type classified, centrally or locally procured, leased and built-in-place food service EQUIPMENT and UTENSILS.

4-205.12 Equipment and utensils, compliance measures[†]

Compliance for all FOOD EQUIPMENT shall be demonstrated as specified in $\P(A)$ - (D) of this section.

- (A) Meeting NSF International standards or criteria by-
- (1) Displaying the NSF International mark on the EQUIPMENT and ensuring the EQUIPMENT is listed in the NSF International's Listing of Food Equipment and Related Products, Components, and Materials for the year the EQUIPMENT was manufactured (http://info.nsf.org/Certified/Food/);
 - (2) Successfully passing the NSF International's one-time evaluation program for government contracts;
- (3) Displaying the UL's marking, "Classified for Sanitation, meets NSF International Standard (Specify)," on the EQUIPMENT and ensuring the EQUIPMENT is listed in the UL's Directory, Food Service Equipment, Classified for Sanitation for the year the EQUIPMENT was manufactured; or
- (4) Obtaining certification from a recognized independent testing laboratory that is APPROVED by the REGULATORY AUTHORITY. This certificate shall state that the EQUIPMENT or UTENSILS meet applicable standards. The independent testing laboratory shall be evaluated and approved by ANSI to perform satisfactory testing of food service EQUIPMENT. Written approval of the independent testing laboratory by ANSI and results of EQUIPMENT evaluation should be forwarded to the respective Services' Public Health organization.
- (B) Meeting UL safety standards by testing or approval by UL or obtaining independent laboratory certification as specified in Subparagraph (A)(4) of this section.
- (C) Meeting BISSC standards by listing the manufacturer in the Directory of BISSC Registered Companies for the year of manufacturing and submitting the BISSC certificate issued by the manufacturer.
- (D) Meeting NAMA standards by ensuring the EQUIPMENT is listed in the NAMA directory for certified equipment (available at https://www.namanow.org/home, select "Vending" from the menu bar).
- (E) Prior to initiating a modification to FOOD EQUIPMENT, the FOOD ESTABLISHMENT manager or appropriate facilities and equipment representative shall notify the REGULATORY AUTHORITY and prepare a variance request as specified in Subpart <u>8-103</u>.

4-205.13 Overseas food operations[†]

Offshore procurement of foreign manufactured food service EQUIPMENT for use OCONUS where NSF, UL, or other EQUIPMENT that is approval-listed in § 4-205.11 is either not available or cannot be used because of utility incompatibility, host nation agreements, or other circumstances, shall be authorized by the Command MEDICAL AUTHORITY or designated representative using the following guidance:

- (A) The Command MEDICAL AUTHORITY or designated representative consults with the food sanitation and safety representative within the public health chain of command and, when required, consults with the respective Service's Public Health Center/Command, as specified under ¶ 4-205.10(B).
- (B) The Command MEDICAL AUTHORITY's authorization is based on the FOOD EQUIPMENT meeting the design, construction and materials intent of this publication and applicable NSF or UL standards as specified under Subparagraphs 4-205.12(A)(2) and (A)(4).
- (C) APPROVAL shall be obtained in writing from the MEDICAL AUTHORITY or designated representative before the EQUIPMENT is procured.

4-205.14 Mechanical warewashing equipment, modification[†]

- (A) Local modification to WAREWASHING machines is prohibited if it violates the manufacturer's warranty and NSF International listing. Local modification (for example, addition of an emergency backup chemical SANITIZER) that does not void the NSF listing and that meets SANITIZATION requirements shall be APPROVED in writing by the REGULATORY AUTHORITY after the installation provides written documentation from NSF International that the system was evaluated and meets NSF standards.
 - (B) Local permanent conversion from hot water to a chemical SANITIZING machine is prohibited.

4-205.15 Warewashing machine, prohibition[†]

- (A) Except as specified in \P (B) of this section, or specifically authorized by the MEDICAL AUTHORITY in deployment locations, home-style WAREWASHING machines may not be used in a FOOD ESTABLISHMENT.
- (B) Home-style dishwashers which meet NSF/ANSI Standard 184, "Residential Dishwashers" may be used in family-style guest houses such as the Wounded Warrior family quarters and demonstration kitchens in Middle Schools and Teen Facilities.

4-3. Numbers and capacities

4-301 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 three 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 routinely used in the FOOD ESTABLISHMENT. If EQUIPMENT or UTENSILS are too large for the WAREWASHING sink, a WAREWASHING machine or alternative EQUIPMENT as specified in \P (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) Two-compartment sinks as specified under $\P\P$ (D) and (E) of this section; or
 - (6) Receptacles that substitute for the compartments of a multi-compartment sink.
 - (D) Two-compartment sink. Before a two-compartment sink is used-
 - (1) The PIC shall have its use APPROVED by the REGULATORY AUTHORITY; and
- (2) The PIC shall limit the number of KITCHENWARE items cleaned and SANITIZED in the two-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 IAW 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 two-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.
- (F) Sink compartments shall be labeled with instructions, such as wash, rinse, sanitize, and air dry, along with the steps to properly prepare cleaning and chemical SANITIZING solutions. *Location of drainboards, booster heaters, etc. determines the direction of flow for WAREWASHING operations.*[†]

4-301.13 Drainboards

- (A) 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.
 - (B) Except as stated in $\P(C)$ this section, separate drainboards shall be provided for clean and soiled items.
- (C) When separate drainboards are not available, the REGULATORY AUTHORITY may approve use of a single drainboard, rack, or cart provided a written procedure is in place to ensure the drainboard, rack, or cart is washed and sanitized before use with cleaned and sanitized EQUIPMENT and UTENSILS.[†]

4-301.14 Ventilation hood systems, adequacy

- (A) Ventilation hood systems and devices shall be sufficient in numbers and capacity to prevent grease or condensation from collecting on walls and ceilings.
 - (B) Local exhaust ventilation shall—†
- (1) Except as specified in \P (D) of this section, be provided over all cooking EQUIPMENT that produces excessive smoke, grease-laden vapors, or odors.
- (2) Be equipped with attendant fire protection as specified in NFPA Standard 96 for all cooking EQUIPMENT that produces smoke or grease-laden vapor.
- (3) Be provided for all cooking EQUIPMENT producing steam condensate but not producing smoke or grease-laden vapors when general dilution ventilation does not provide adequate control and shall be exhaust to the outdoors.
- (C) FOOD ESTABLISHMENTS located in buildings served by a common building ventilation system shall exhaust all air from FOOD preparation, WAREWASHING, and serving lines to the outdoors and may not be recirculated.[†]
- (D) EQUIPMENT not requiring hoods or local exhaust systems (unless deemed necessary by the REGULATORY AUTHORITY or fire safety representative) include:
 - (1) Hot-holding units.
 - (2) Chemical dishwashing and glassware machines.
 - (3) Coney Island grills.
 - (4) Under-the-counter dishwashing machines.
 - (5) Pretzel machines.
 - (6) Popcorn machines.
 - (7) Enclosed electric (300°F/148°C maximum) ovens.
 - (8) Roller type hot dog machines.
 - (E) Exhaust ventilation hoods shall meet the following requirements:
 - (1) Existing hoods shall meet or be modified to meet NFPA Standard 96.
- (2) The capture velocity air flow at the cooking surface adequately entrains particles in the air stream and draws contaminated air into the hood at following prescribed velocity:
- (a) 50 feet per minute (fpm)—Nongrease-producing equipment (for example, kettles, ranges, small griddles).
 - (b) 75 fpm—Grease-producing equipment (for example, fryers, pressure fryers, griddles).
 - (c) 150 fpm—High heat-producing equipment (for example, char-broilers, upright broilers).
- (3) The exhaust rate for dishwashing machines shall meet the capture velocity recommended by the WAREWASHING manufacturer.

4-301.15 Clothes washers and dryers

- (A) Except as specified in \P (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 the wiping cloths intended to be used moist, or the wiping cloths are air-dried as specified under § 4-901.12, a mechanical clothes washer and dryer need not be provided.

4-301.16 Warewashing heating device, capacity[†]

- (A) The capacity and design of booster heaters and under-the-sink heaters shall be determined based on input water temperature, aggregate water-using EQUIPMENT requirements, and the WAREWASHING manufacturer's operating specifications.
- (B) The under-the-sink booster heater for a three-compartment sink shall provide an adequate volume of hot water to maintain the wash, rinse, and sanitizing rinse temperatures as specified under §§ 4-501.19, 4-501.111 and 4-501.114. Separate booster heaters are allowed for wash, rinse, and final rinse compartments.

4-302 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

- (A) FOOD TEMPERATURE MEASURING DEVICES shall be provided and readily accessible for use in ensuring attainment and maintenance of FOOD temperatures as specified under Part 3-4 and ¶ 3-501.16(A).
- (B) A TEMPERATURE MEASURING DEVICE with a suitable small diameter probe that is designed to measure the temperature of thin masses, *such as a thermocouple*, shall be provided and readily accessible to accurately measure the temperature in thin FOODS such as MEAT patties and FISH filets.

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.
- (B) In hot water mechanical WAREWASHING operations, an irreversible registering temperature indicator shall be provided and readily accessible for measuring the UTENSIL surface temperature. An irreversible registering temperature indicator may include single-use paper test strips that produce a color change or other marking when the specified temperature threshold has been reached or exceeded. Reusable devices such as digital thermometers are also appropriate if the device contains a maximum hold feature that locks the temperature measurement in the display, or the device is specifically designed to capture dishwashing cycle temperatures.

4-302.14 Sanitizing solutions, testing devices

A test kit or other device that accurately measures the concentration in mg/L or in ppm of SANITIZING solutions shall be provided and used any time a chemical sanitizer is used.

4-303 Cleaning agents and sanitizers

4-303.11 Cleaning agents and sanitizers, availability

- (A) Cleaning agents that are used to clean EQUIPMENT and UTENTSILS as specified under Part <u>4-6</u>, shall be provided and available for use during all hours of operation.
- (B) Except for those that are generated onsite at the time of use, chemical SANITIZERS that are used to SANITIZE EQUIPMENT and UTENSILS as specified under Part <u>4-7</u>, shall be provided and available for use during all hours of operation.

4-4. Location and installation

4-401 Location

4-401.10 General installation[†]

Food EQUIPMENT is installed using guidance provided in NSF International's *Installation Manual for Food Service Equipment*, or the FDA *Food Establishment Plan Review Guide* 2000, and the requirements specified in Part 4-4 of this publication.

4-401.11 Equipment, clothes washers and dryers, and storage cabinets, contamination prevention

- (A) Except as specified in \P (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; no clean EQUIPMENT, UTENSILS, and LINENS; and no unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES.

4-401.12 Ice machines[†]

Ice machines shall be installed in a clean area that allows adequate space for safe handling of ice and does not present a RISK for ice contamination.

4-402 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; or
- (2) Spaced from adjoining EQUIPMENT, walls, and ceilings a distance of not more than one thirty-second (1/32) inch (1 millimeter); 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 $\P\P$ (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 6-inch (15 cm) clearance between the floor and the EQUIPMENT.
- (B) If no part of the floor under the floor-mounted EQUIPMENT is more than 6 inches (15 cm) from the point of cleaning access, the clearance space may be only 4 inches (10 cm).
- (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 \P (E) of this section, COUNTER-MOUNTED EQUIPMENT that is not EASILY MOVABLE shall be elevated on legs that provide at least a 4-inch (10 cm) clearance between the table and the EQUIPMENT.
 - (E) The clearance space between the table and COUNTER-MOUNTED EQUIPMENT may be:
- (1) Three inches (7.5 cm) if the horizontal distance of the table top under the EQUIPMENT is no more than 20 inches (50 cm) from the point of access for cleaning; or
- (2) Two inches (5 cm) if the horizontal distance of the table top under the EQUIPMENT is no more than 3 inches (7.5 cm) from the point of access for cleaning.

4-5. Maintenance and operation

4-501 Equipment

4-501.10 Maintenance program[†]

- (A) Government and contract FOOD ESTABLISHMENT managers should coordinate with food service EQUIPMENT maintenance personnel, as appropriate, to meet the provisions of Subparts 4-501 and 4-502.
- (B) A semiannual cleaning program should be established for electric motors, refrigeration compressors, controls, and other areas of food service EQUIPMENT not normally accessed by FOOD EMPLOYEES. *Cleaning program intent is to improve the operation of the equipment and reduce insect and rodent harborage.*

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. The REGULATORY AUTHORITY shall limit or restrict use of EQUIPMENT with FOOD-CONTACT SURFACES that present HAZARDS due to cracks, chips, and similar imperfections.
- (B) EQUIPMENT components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted IAW 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.
- (D) The REGULATORY AUTHORITY may authorize continued use of food EQUIPMENT or UTENSILS that do not meet NSF International standards but are APPROVED as specified under §§ 4-205.10, 4-205.11, and 4-205.12, are serviceable, and do not present a HAZARD. †

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.
 - (D) WAREWASHING machines shall be drained and cleaned after each scheduled serving period.†

4-501.15 Warewashing machines, manufacturers' operating instructions

- (A) A WAREWASHING machine and its auxiliary components shall be operated IAW the machine's data plate and other manufacturer's instructions.
- (B) A WAREWASHING machine's conveyor speed and/or automatic cycle times shall be maintained as accurately timed IAW 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, wash produce, or thaw FOOD. Sinks used to wash produce 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 and rinse solution temperature

- (A) The temperature of the wash solution in manual WAREWASHING EQUIPMENT shall be maintained at not less than either 110°F (43°C) or the temperature specified on the cleaning agent manufacturer's label instructions.
- (B) The temperature of the rinse solution in manual WAREWASHING EQUIPMENT shall be maintained at not less than $120^{\circ}F$ ($49^{\circ}C$).

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, 165°F (74°C);
 - (2) For a stationary rack, dual temperature machine, 150°F (66°C);
 - (3) For a single tank, conveyor, dual temperature machine, 160°F (71°C); or
 - (4) For a multi-tank, conveyor, multi-temperature machine, 150°F (66°C).
- (B) The temperature of the wash solution in spray-type warewashers that use chemicals to SANITIZE may not be less than 120°F (49°C).

4-501.111 Manual warewashing equipment, hot water sanitization temperature*

If immersion in hot water is used for SANITIZING in a manual operation, the temperature of the water shall be maintained at 171°F (77°C) 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 194°F (90°C), or less than—
 - (1) For a stationary rack, single temperature machine, 165°F (74°C); or
 - (2) For all other machines, 180°F (82°C).
- (B) The maximum temperature specified under \P (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.
- (C) A minimum temperature as specified under \P <u>4-703.11(B)</u> shall be attained for proper SANITIZATION. The ability of the dish machine to produce the minimum required hot water SANITIZING temperature is dependent upon compliance with the wash temperatures specified in § <u>4-501.110</u> and the flow pressure specified in § <u>4-501.113</u>.
- (D) SANITIZING temperatures are verified using an irreversible registering temperature indicator as specified under ¶ 4-302.13(B). Checking temperatures in WAREWASHING machines may be accomplished using the guidelines contained in NSF International's pamphlet "Recommended Field Evaluation Procedures for Spray-Type Dishwashing Machines." †

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 5 pounds per square inch (35 kilopascals) or more than 30 pounds per square inch (200 kilopascals).

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 \P $\frac{4-703.11(C)}{2}$ shall meet the criteria specified under \P $\frac{7-204.11}{2}$, shall be used IAW the EPA-registered 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 Table 4-2 and shall be maintained at the prescribed temperature throughout the SANITIZATION process;

Table 4-2. Minimum prescribed temperatures for chlorine solutions prepared at specified concentrations

Concentration Range	Minimum Temperature		
mg/L	pH 10 or less °F (°C)	pH 8 or less °F (°C)	
25 – 49	120 (49)	120 (49)	
50 – 99	100 (38)	75 (24)	
100	55 (13)	55 (13)	

- (B) An iodine solution shall have a-
 - (1) Minimum temperature of 68°F (20°C),

- (2) A 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 75°F (24°C),
- (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 EPA-registered label use instructions:
- (D) If another solution of a chemical specified under $\P(A)$ –(C) of this section is used, the PIC 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 IAW the EPA-registered label use instructions.

4-501.115 Manual warewashing equipment, chemical sanitization using detergentsanitizers*

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

- (A) Concentration of the SANITIZING solution in manual and mechanical WAREWASHING shall be accurately determined by using a test kit or other device.
- (B) The pH of the SANITIZING solution should be accurately determined when chlorine or iodine SANITIZERS are used, and the total hardness of the water should be determined prior to using quaternary ammonium SANITIZERS. FOOD ESTABLISHMENTS may request assistance from the REGULATORY AUTHORITY at the beginning of operation and at least annually for determining pH and water hardness.†
- (C) Concentration of the SANITIZING solution shall be determined when the sanitizer solutions are initially prepared for manual WAREWASHING and throughout the period of use. For mechanical WAREWASHING, the residual concentration shall be measured at least daily on the dish or utensil surface at the end of the sanitizing cycle. The interval for testing the concentration can be lengthened with approval of the REGULATORY AUTHORITY based on a history of consistent stable results. For WAREWASHING machines with a POTABLE rinse after the chemical sanitizing rinse, the POTABLE rinse must be turned off during chemical testing.†

4-501.200 Chlorine sanitizing solution, preparation[†] Standard, nonscented household-type bleach or calcium hypochlorite (rated between 5 and 10 percent base strength) should be used when preparing chlorine SANITIZING solutions. The following formulas produce a 100-ppm FAC SANITIZING solution:

- (A) Using bleach with 5.25 percent base strength—
- (1) For spray bottle or small preparations: Mix 1/2 Tablespoon [0.5 ounces, or 7 milliliters (mL)] of bleach with 1 gallon [3.8 Liters (L)] of water; or
- (2) For a 3-compartment sink: Mix 2 Tablespoons (1 ounce, or 30 mL) of bleach for every 4 gallons (15.2
 - (B) Using bleach with 8.25 percent base strength—
- (1) For spray bottle or small preparations: Mix 1 teaspoon (5 mL) of bleach with 1 gallon (3.8 L) of water.
 - (2) For a 3-compartment sink: Mix 4 teaspoons (20 mL) of bleach for every 4 gallons (15.2 L) of water.

4-502 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 <u>4-1</u> and <u>4-2</u> or shall be discarded.
- (B) FOOD TEMPERATURE MEASURING DEVICES shall be calibrated IAW the manufacturer's specifications as necessary to ensure the DEVICES' accuracy.
- (C) Ambient air temperature, water pressure, and water TEMPERATURE MEASURING DEVICES shall be maintained in good repair and 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 <u>4-6</u> and <u>4-7</u> 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 only SINGLE-SERVICE ARTICLES for use by CONSUMERS.

4-502.13 Single-service and single-use articles, use limitation

SINGLE-SERVICE and SINGLE-USE ARTICLES may not be reused.

4-502.14 Shells, use limitation

Mollusk, crustacean, and similar shells with the shellfish intact (as received in the natural state) may not be used more than once as serving containers.

4-503 Ice machines

4-503.11 Maintenance of ice machines[†]

- (A) Ice machines shall be cleaned and sanitized as specified under Subparagraph 4-602.11(E)(4).
- (B) The procedures and frequency for cleaning and SANITIZING ice machines shall be provided in a SOP by the FOOD ESTABLISHMENT for FOOD EMPLOYEES.
- (C) Ice machine water and air filters shall be changed at a frequency recommended by the manufacturer or at least once every 6 months; and
- (D) Filter changes shall be documented in a maintenance log or annotated on the filter using permanent marker, indicating the date and name of the person who replaced the filter. Maintenance logs shall be available onsite for inspection by the REGULATORY AUTHORITY.

4-503.12 Operation, restrictions[†]

- (A) Except as specified in \P (B) of this section, the responsibility for packaging ice and cleaning and SANITIZING ice machines is restricted to EMPLOYEES who have received proper FOOD sanitation training as specified under \S 2-501.11, Subpart 2-503, and \S 2-504.30.
- (B) Cleaning and SANITIZING of ice machines may be performed by the equipment manufacturer or qualified cleaning personnel, as specified in the facility's service contract.

4-6. Cleaning of equipment and utensils

4-601 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. $^{\rm N}$

(C) NonFOOD-CONTACT SURFACES of EQUIPMENT shall be kept free of an accumulation of dust, dirt, FOOD residue, and other debris. ^N

4-602 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 \P (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 RTE FOODS;
 - (3) Between uses with raw FF&V and TSC FOODS;
 - (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 MEAT and POULTRY each requiring a higher cooking temperature as specified under \S 3-401.11 than the previous type.
- (C) Except as specified in \P (D) of this section, if used with TSC 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 TSC FOOD may be cleaned less frequently than every 4 hours if—
- (1) In storage, containers of TSC 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 Table 4-3 and:
- (a) The UTENSILS and EQUIPMENT are cleaned at the frequency and corresponding temperature noted in Table 4-3; and

Table 4-3.	Cleaning free	quencies for r	efrigerated f	food pre	paration rooms

Temperature	Cleaning Frequency	
41°F (5.0°C) or less	24 hours	
>41°F - 45°F (>5.0°C - 7.2°C)	20 hours	
>45°F - 50°F (>7.2°C - 10.0°C)	16 hours	
>50°F - 55°F (>10.0°C - 12.8°C)	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 RTE TSC 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 135°F (57°C) 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 $\S \frac{4-603.11}{N}$, surfaces of UTENSILS and EOUIPMENT contacting FOOD that is not TSC FOOD shall be cleaned: $\frac{N}{N}$
 - (1) At any time when contamination may have occurred;
- (2) At least every 24 hours for iced tea dispensers and every 8 hours for 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 and to prevent insect attraction.
 - (c) Surfaces that accumulate grease, sugars, and syrup shall be cleaned and SANITIZED daily.
- (d) Ice machines and dispensers are emptied, drained, cleaned, and SANITIZED at least every 30 days or as often as necessary to prevent accumulation of mold, mildew, or other debris. *Frequency may be increased by the REGULATORY AUTHORITY based on local conditions.*[†]

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

- (A) NonFOOD-CONTACT SURFACES of EQUIPMENT shall be cleaned at a frequency necessary to preclude accumulation of soil residues.
- (B) Local exhaust hoods, grease removal devices, and other appurtenances shall be cleaned at frequent intervals to prevent accumulation of grease, dirt, or other contaminants. Cleaning ventilation system fans and ducts are addressed in \S 6-501.14.
- (C) Collection containers attached to drip trays on grease removal devices shall be cleaned at least weekly. Collected grease shall be stored in a container with a tight-fitting lid as specified under § 5-501.113.†

4-603 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 a TSC FOOD.
- (B) Cleaning EQUIPMENT used in dry cleaning FOOD-CONTACT SURFACES may not be used for any other purpose.

4-603.12 Pre-cleaning

- (A) FOOD debris on EQUIPMENT and UTENSILS shall be scrapped 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 pre-flushed, pre-soaked, or scrubbed with abrasives. Personal protective equipment, such as WAREWASHING gloves and aprons, should be provided for EMPLOYEE safety IAW safety regulations to protect from scalding hazards if the water temperature exceeds 110°F (43°C).

4-603.13 Loading of soiled items, warewashing machinesSoiled 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.
- (C) Grease removal devices and grease filters shall be cleaned using APPROVED cleaning chemicals. Refer to 21 CFR 178.1010 or the NSF White Book for a listing of approved chemicals.
 - (D) Wet cleaning using a three-compartment sink:
- (1) Sinks shall be thoroughly cleaned, rinsed, and SANITIZED before each use or at a frequency to prevent recontamination of EQUIPMENT and UTENSILS.
- (2) Wash EQUIPMENT and UTENSILS in the first compartment of the three-compartment sink with a hot detergent solution as specified in \P 4-501.19(A).
- (3) Drain and prepare a fresh detergent solution when the water becomes visibly soiled with food debris or grease residue.
 - (4) APPROVED wash solutions shall be used per the manufacturer's instructions.
 - (E) Use of flammable solvents or other flammable cleaning products is strictly prohibited.[†]
 - (F) Wet cleaning using a two-compartment sink: †
 - (1) A two-compartment sink shall be used only as specified in $\P 4-301.12(D)$.
- (2) Washing, rinsing, and SANITIZING shall be accomplished as specified in ¶¶ (A) and (D) of this section and as specified under §§ 4-501.115, 4-603.16 and 4-703.11.
- (G) Basic guidance on mechanical cleaning and SANITIZING is contained in MIL HDBK-740 and NSF International's pamphlet "Recommended Field Evaluation Procedures for Spray-Type Dishwashing Machines." †

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 \P 4-301.12(C) IAW 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 three-compartment sink, rinse in the second compartment with POTABLE water that is kept clean and maintained as specified in $\P 4-501.19(B)$;
- (2) Alternative manual WAREWASHING EQUIPMENT equivalent to a three-compartment sink as specified in ¶ 4-301.12(C), or
- (3) A three-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 \P <u>4-301.12(C)</u> 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 two-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 nondistinct water rinse that is integrated in the application of the SANITIZING solution.

4-603.17 Returnables, cleaning for refilling*

This provision has been deleted; refer to $\S 3-304.17$.

4-603.18 Steel wool prohibition †

Steel wool or steel wool pads may not be used for cleaning FOOD-CONTACT SURFACES in any food service operation. *Use of woven brass or plastic pads is authorized for scrubbing pots and pans, barbeque grills, and stove cooking surfaces provided the pads are cleaned and SANITIZED after each cleanup period.*

4-7. Sanitization of equipment and utensils

4-701 Objective

4-701.10 Food-contact surfaces and utensils

EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED as specified under §§ 4-702.11 and 4-703.11.

4-702 Sanitizing frequency

4-702.11 Before use after cleaning*

UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT shall be SANITIZED before use after cleaning.

4-703 Sanitizing methods

S2 Chapter 4

4-703.11 Hot water, chemical, and steam*

After being cleaned, EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be SANITIZED in:

- (A) Hot water manual operations by complete immersion in the third compartment of a three-compartment sink for at least 30 seconds and at a SANITIZING temperature 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 SANITIZING temperature of 160°F (71°C) as measured by an irreversible registering temperature indicator; or
- (C) Except as specified under \P (E) of this section, 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 \S 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 15 seconds for a chlorine solution specified under \P 4-501.114(A),
- (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 100°F (38°C) or a pH of 8 or less and a temperature of at least 75°F (24°C),
 - (3) A contact time of at least 30 seconds for other chemical SANITIZING solutions, 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 the Glossary.
- (5) A second clear POTABLE water rinse shall be applied to SANITIZED EQUIPMENT and UTENSILS if the sanitizing solution concentration exceeds the following values: †
 - (a) Chlorine solution is 200 mg/L or more;
 - (b) Iodine solution is 25 mg/L or more; or
 - (c) Quaternary ammonium solution is 200 mg/L or more.
- (D) A minimum chlorine concentration of 100 ppm shall be used when SANITIZING surfaces using a spray application or manual swabbing with a wiping cloth. †
- (E) The application of a chemical SANITIZER using a <u>swabbing or wiping method</u> may not be used unless the cloth impregnated with the SANITIZER is tested to ensure availability of the active ingredient at the proper concentration. Remove the wiping cloth from the SANITIZING solution and wring out the excess liquid. Place the test paper onto the cloth; it should indicate the same concentration as the SANITIZING solution in the bucket.[†]
- (F) Except as specified under \S 5-101.14, direct, live-steam injection to heat SANITIZING water in manual WAREWASHING operations is prohibited.[†]

4-8. Laundering

4-801 Objective

4-801.11 Clean linens

Clean LINENS shall be free from FOOD residues and other soiling matter.

4-802 Frequency

4-802.11 Specifications

- (A) LINENS that do not come in direct contact with FOOD shall be laundered between operations if the LINENS become wet, sticky, or visibly soiled.
- (B) Cloth gloves used as specified in \P 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 \S 3-304.13 and cloth napkins shall be laundered between each use.
 - (D) Wet wiping cloths shall be laundered daily.

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(E) Dry wiping cloths shall be laundered as necessary to prevent the contamination of FOOD and clean serving UTENSILS.

4-803 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 \P (B) of this section, LINENS shall be mechanically washed.
- (B) In FOOD ESTABLISHMENTS in which only wiping cloths are laundered as specified in \P <u>4-301.15(B)</u>, the wiping cloths may be laundered in a mechanical washer, a sink designated only for laundering wiping cloths, or a WAREWASHING or FOOD preparation sink that is cleaned as specified under § <u>4-501.14</u>.

4-803.13 Use of laundry facilities

- (A) Except as specified in \P (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 (to include Family Child Care (FCC) homes) may also be used for laundering FOOD ESTABLISHMENT items.

4-9. Protection of clean items

4-901 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.
- (C) Use of chemical sanitization increases drying time as compared with hot water sanitization. It also increases the space requirements for drying and storing utensils as well as the amount of utensils and cooking equipment needed to support the operation. If used, drying chemicals must be APPROVED for use on FOOD-CONTACT SURFACES without POTABLE water rinse.†

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 recontamination of 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.

4-902 Lubricating and reassembling

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4-902.11 Food-contact surfaces

Lubricants as specified under § <u>7-205.11</u> 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.

4-903 *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 6 inches (15 cm) above the floor.
- (B) Clean EQUIPMENT and UTENSILS shall be stored as specified under \P (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 \P (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 6 inches (15 cm) 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.

4-904 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 pre-wrapped shall be presented so that only the handles are touched by EMPLOYEES and by CONSUMERS if CONSUMER SELF-SERVICE is provided.
- (C) When inserting bulk-PACKAGED, SINGLE-SERVICE TABLEWARE into holders or wrapping them, FOOD EMPLOYEES shall wash their hands immediately prior to sorting or wrapping the UTENSILS.

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(D) Except as specified under \P (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) TABLEWARE that is preset shall be protected from contamination by being wrapped, covered, or inverted.
- (B) Preset TABLEWARE is considered exposed if unused settings are not immediately removed when a CONSUMER is seated.
 - (C) Settings not removed when a CONSUMER is seated shall be cleaned and SANITIZED before further use.

4-904.14 Rinsing equipment and utensils after cleaning and sanitizing

Except as specified under Subparagraph 4-703.11(C)(5), 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 DRINKING water supply by a WAREWASHING machine that is maintained and operated as specified under Subparts <u>4-204</u> and <u>4-501</u>; 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.

CHAPTER 5

WATER, PLUMBING, AND WASTE

5-1. Water

5-101 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) A DRINKING WATER system shall be flushed, disinfected, and tested for chlorine residual 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.
- (B) The FACILITY ENGINEER or other facility manager shall notify the REGULATORY AUTHORITY when a system has been flushed and disinfected to determine if microbiological testing is required before operation. † N

5-101.13 Bottled and packaged drinking water*

BOTTLED WATER and PACKAGED DRINKING WATER used or sold in a FOOD ESTABLISHMENT shall be obtained from APPROVED sources IAW 21 CFR 129 - Processing and Bottling of Bottled Drinking Water, ¶ 3-201.11(B), and AR 40–657/NAVSUPINST 4355.4H/MCO P10110.31H. *TB MED 577/NAVMED P-5010-10/AFMAN 48-138_IP provides additional information concerning the use of bottled and packaged water during deployments.*[†]

5-101.14 Steam*[†]

- (A) Steam used for cleaning or SANITIZING FOOD-CONTACT SURFACES shall be free from any materials or ADDITIVES other than those ADDITIVES with concentrations listed in 21 CFR 173.310 as specified under § 7-204.13.
- (B) Except as specified in \P (C) this section, use of heat exchange-type steam generator units that produce steam from DRINKING WATER without the use of boiler water ADDITIVES is authorized.
 - (C) Direct use of steam generated from a central building boiler-
- (1) Is prohibited unless there is an ongoing system in place to evaluate concentration of boiler water ADDITIVES in the steam.
 - (2) Is prohibited for injecting steam to heat sanitizing water in manual WAREWASHING operations.
- (3) May be used as the heat source for a heat exchange unit as long as there is a system in place to ensure there is no CROSS-CONNECTION with the potable water supply and the steam generated by the heat exchanger is ADDITIVE-free.

5-102 *Quality*

5-102.11 Standards*

Except as specified under § 5-102.12 and ¶ (C) and (D), of this section—

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- (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 DRINKING WATER standards as specified in \P (A) of this section and according to military drinking water publications or applicable Service policy.
- (C) At facilities outside of the United States, DRINKING WATER quality shall meet the Overseas Environmental Baseline Guidance Document (OEBGD) or country-specific Final Governing Standards.[†]
- (D) DRINKING WATER quality for military installations in the United States and its territories shall meet the (Army) TB MED 576, (Air Force) AFI 48-144, or (Navy/Marine Corps) OPNAVINST 5090.1 Series/MCO P-5090, as applicable, for garrison operations; for field operations, TBMED577/NAVMED P-5010-10/AFMAN 48-139_IP; or for Naval vessels, NAVMED P-5010-6.†

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, and fire protection.

5-102.13 Sampling

- (A) Except when used as specified under § <u>5-102.12</u>, water from a NONPUBLIC WATER SYSTEM shall be sampled and tested at least annually and more often if required by state water quality regulations, or by the MEDICAL AUTHORITY or designated representative.
- (B) The MEDICAL AUTHORITY or designated representative shall ensure that the installation tests the DRINKING WATER at fixed FOOD ESTABLISHMENTS IAW respective Services' publications (TB MED 576, AFI 48-144, OPNAVINST 5090.1/MCO P-5090).†
- (C) Water used during field or deployment FOOD operations shall be tested per TB MED 577/NAVMED P-5010-10/AFMAN 48-138_IP. Food service managers are responsible for ensuring chlorine residual of bulk-supplied POTABLE water is tested daily.[†]

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 regulations (if applicable) or Service policy.

5-103 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.
- (C) Except during FIELD FOOD OPERATIONS, limited services, TEMPORARY FOOD ESTABLISHMENTS, and VENDING MACHINE FOOD operations, adequate quantities of both hot and cold running water under pressure shall be provided in all areas where FOOD is prepared or where EQUIPMENT, UTENSILS, or FOOD containers are washed or SANITIZED.†

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 $\P\P$ 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.

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5-104 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, or
 - (3) Water containers.

5-104.12 Alternative water supply

Water meeting the requirements specified under Subparts <u>5-101</u>, <u>5-102</u>, and <u>5-103</u> shall be made available for a MOBILE or TEMPORARY FOOD ESTABLISHMENT without a permanent water supply, and for a FOOD ESTABLISHMENT or SEASONAL 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) If APPROVED by the MEDICAL AUTHORITY or designated representative, piping, tubing, or hoses connected to an adjacent APPROVED source.

5-2. Plumbing system

5-201 Materials

5-201.11 Approved*

- (A) A PLUMBING SYSTEM and hoses conveying water shall be designed, constructed, and repaired with APPROVED materials according to LAW (Unified Facilities Criteria (UFC) 4-722-01F and FC-722-01N, the International Plumbing Code, and local plumbing codes).
 - (B) A water filter shall be made of SAFE MATERIALS.
 - (C) A water filter shall be provided IAW the food service EQUIPMENT specification and operator manual. N
 - (D) High pressure cleaning systems shall be filtered IAW equipment specifications. N

5-202 Design, construction, and installation

5-202.11 Approved system and cleanable fixtures*

Except as stated in chapter 9 for food operations occurring in the field and afloat-

- (A) A PLUMBING SYSTEM shall be designed, constructed, and installed according to LAW.
- (B) A PLUMBING FIXTURE such as a HANDWASHING SINK, toilet, urinal, or grease trap shall be EASILY CLEANABLE. $^{\rm N}$
- (C) FACILITY ENGINEERS shall size, install, maintain, and operate plumbing per the applicable plumbing code. †
 - (D) All piping shall be concealed to the greatest extent possible. N
- (E) Where metallic supply line piping cannot be concealed in new construction, it shall be stainless steel or chrome-plated. *In existing facilities, such piping should be stainless steel or chrome-plated.* † N

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<u>5-202.12</u> Handwashing sink, installation

- (A) A HANDWASHING SINK shall be equipped to provide water at a temperature of at least 100°F (38°C) through a mixing valve or combination faucet.
 - (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 IAW the manufacturer's instructions.
- (E) The temperature of the water shall not exceed 120°F (49°C). Desired range is 100° to 120° F (38° to 49° C).

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 1 inch (25 mm).

5-202.14 Backflow prevention device, design standard*

A backflow or back-siphonage prevention device installed on a water supply system shall meet the applicable plumbing code and UFC-4-722-01 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.

5-202.16 Food waste grinders and pulpers[†]

- (A) FOOD waste grinders shall be-
- (1) Provided with an adequate supply of water at a sufficient flow rate to ensure proper functioning of the unit;
- (2) Trapped separately from any other fixture or sink compartment (for example, no other fixture or equipment uses that trap);
 - (3) Installed to allow access for easy cleaning; and
 - (4) May not be connected to discharge through a grease trap or interceptor.
- (B) Pulping water extraction systems are authorized for FOOD waste provided the system is installed and operated in a sanitary manner and meets applicable plumbing codes.

5-203 Numbers and capacities

5-203.11 Handwashing sinks

- (A) Except as specified in ¶¶ (B) and (C) of this section, at least one 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.
- (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 one HANDWASHING SINK.
- (C) If APPROVED, when food exposure is limited, as specified in $\P(D)$ this section, and HANDWASHING SINKS are not conveniently available, such as in some MOBILE, SEASONAL, or TEMPORARY FOOD ESTABLISHMENTS or at some VENDING MACHINE OPERATION locations, EMPLOYEES may use chemically treated towelettes for handwashing. The active ingredients in the towelettes shall meet the criteria for hand antiseptics as specified under \S 2-301.16.

(D) Operations not equipped with HANDWASHING SINKS shall be limited to serving commercially PACKAGED RTE TCS FOOD and nonTCS FOOD, including hot coffee and tea and individually PACKAGED beverages.

5-203.12 Toilets and urinals

- (A) Except as specified in \P (B) of this section, at least one 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.
- (B) To the maximum extent possible, include separate toilets for customers and staff in all plans for new construction and renovated existing FOOD ESTABLISHMENTS, except for Army/Air Force Exchange Service (AAFES)/Navy Exchange (NEX)/Marine Corps Exchange (MCX) fast food facilities.†

5-203.13 Service sink

- (A) At least one service sink or one 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 bib if a hose is attached or on a hose bib 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

- (A) If not provided with an air gap as specified under § <u>5-202.13</u>, a dual check valve with an intermediate vent preceded by a screen of not less than 100-mesh to 1 inch (100-mesh to 25.4 millimeter) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.
- (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 $\P(A)$ of this section.

5-204 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; and
 - (B) In, or immediately adjacent to, toilet rooms.

<u>5-204.12</u> 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.

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5-204.14 Floor drains, location[†]

- (A) Floor drains shall be properly installed and trapped as specified under \P 5-201.11(A) and 5-202.11(A) and located to facilitate drainage in the following areas:
 - (1) Floors water-flushed for cleaning.
 - (2) Floors receiving water discharges or other fluid waste from EQUIPMENT.
 - (3) Areas where pressure-spray methods for cleaning EQUIPMENT are used.
- (B) Where EQUIPMENT discharges onto the floor, a drain shall be provided with a sump and removable protective grate to receive the waste.

5-205 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.
- (B) A HANDWASHING SINK may not be used for purposes other than handwashing.
- (C) An automatic handwashing facility shall be used IAW manufacturer's instructions.

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.
- (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
- (C) A hose may not be attached to a faucet unless backflow prevention is provided. Where continuous pressure exists and hose bib vacuum breakers cannot be used, an APPROVED continuous pressure backflow device shall be installed.[†]

<u>5-205.13</u> 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 IAW the manufacturer's instructions and as necessary to prevent device failure based on local water conditions. Records demonstrating inspection and service shall be maintained at the FOOD ESTABLISHMENT by the PIC.

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 IAW manufacturer's specifications; and
- (2) Cleaned IAW manufacturer's specifications or according to the procedures specified under \P (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.
- (C) The reservoir shall be located away from general customer access and shall be protected from contamination. $^{\dagger\,N}$

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

<u>5-205.16</u> Water conditioning device, replacing cartridges and filters[†]

Replacement of cartridges and filters shall be based on either the manufacturer's recommendation or field water chemistry tests. Cartridges shall be marked with the date and initials of the person servicing the unit.

5-3. Mobile water tank and mobile food establishment water tank

5-301 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; N and
- (C) Finished to have a SMOOTH, EASILY CLEANABLE surface. N

5-302 Design and construction

<u>5-302.11</u> 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 ½ inch (13 millimeters); 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) A 16-mesh to 1 inch (16-mesh to 25.4 millimeters) 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;

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- (B) Durable, CORROSION-RESISTANT, and nonabsorbent; N
- (C) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition; N
- (D) Finished with a SMOOTH interior surface; N
- (E) Clearly and durably identified as to its use if not permanently attached; N and
- (F) The hose connection for the DRINKING WATER shall be a different diameter or thread size than the waste drain connection. $^{\dagger N}$

5-303 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) Three-fourths inch (19.1 millimeters) 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.

5-304 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.

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 \P (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

5-401 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 1 inch (25 millimeters) in inner diameter or greater, equipped with a shut-off valve.

5-402 Retention, drainage, and delivery

5-402.10 Establishment drainage system

FOOD ESTABLISHMENT drainage systems, including grease traps, that convey SEWAGE shall be designed and installed as specified under \P 5-202.11(A).

5-402.11 Backflow prevention*

- (A) Except as specified in \P (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.
- (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 5 feet (1.5 meters) 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, but it must be properly trapped.

5-402.12 Grease trap

- (A) If used, a grease trap shall be located to be easily accessible for cleaning as specified in \P 6-501.12(C).
- (B) Grease traps shall be located outside the building in new construction or renovation. *Coordination with the REGULATORY* AUTHORITY *and FACILITY ENGINEERS is required for any VARIANCE to allow installation of a grease trap indoors.*[†]
- (C) Except as specified in \P (D) of this section, grease traps are required to support all sinks used for cleaning and SANITIZING FOOD EQUIPMENT, utility sinks, and WAREWASHING machines.
 - (D) Grease traps are not required in CHILD CARE FACILITIES that do not fry FOODS.†

5-402.13 Conveying sewage*

- (A) 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.
- (B) Nonwater-carriage SEWAGE disposal systems (composting toilets, waste bladders, etc.) are prohibited for fixed FOOD ESTABLISHMENTS, but may be authorized by the REGULATORY AUTHORITY for use in conjunction with TEMPORARY FOOD ESTABLISHMENTS or FIELD FOOD SERVICE ESTABLISHMENTS.^{† N}

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. Liquid waste shall be discharged into an approved sanitary SEWAGE system.

5-403 Disposal facility—design and construction

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<u>5-403.11</u> Approved sewage disposal system*

SEWAGE and waste generated from FOOD processing and cleaning shall be disposed of 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 the point of discharge to disposal according to LAW.

5-5. Refuse, recyclables, and returnables

5-501 Facilities on the premises

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 through 6-201.18, 6-202.15, and 6-202.16.

<u>5-501.11</u> 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 \P (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.

<u>5-501.14</u> 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 onsite compactor shall be installed so that accumulations 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.

5-501.16 Storage areas, rooms, and receptacles, capacity and availability

- (A) An inside storage room and area, 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.

<u>5-501.18</u> Cleaning implements and supplies

- (A) Except as specified in \P (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.

<u>5-501.19</u> 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.
- (D) With the exception of compactors, bulk collection dumpsters shall be located more than 50 feet (15 meters) from the FOOD ESTABLISHMENT's entrance doors and adjacent to the receiving area.
- (E) Trash receptacles in toilet rooms should be located near the exit door to promote employee practice of using a clean paper towel to open the door after handwashing †
 - (F) Compactor-type wet trash units shall be-
 - (1) Located on a surface as specified under § <u>5-501.11</u>.
- (2) Outside the FOOD ESTABLISHMENT adjacent to waste access doors, but as far from the FOOD delivery area as possible.

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.

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5-501.112 Outside storage prohibitions

- (A) Except as specified in \P (B) of this section, REFUSE receptacles not meeting the requirements specified under \P 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

Except as specified in \P 5-501.112(B) and \P (C) of this section, 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.
- (C) Garbage and trash receptacles in active use inside the FOOD ESTABLISHMENT may remain uncovered temporarily while in use, but shall be covered immediately upon completion of the task.[†]

<u>5-501.114</u> Using drain plugs

Drains in receptacles and waste handling units for REFUSE, recyclables, and returnables shall have drain plugs in place.

<u>5-501.115</u> 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 wastewater 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.
- (C) Large garbage receptacles, dumpsters, and compactors that are cleaned at or near the FOOD ESTABLISHMENT shall be cleaned using hot, high-pressure water and detergent soap or a high-pressure spray with a self-contained vacuum residue collector. †
- (1) In-place cleaning of bulk waste receptacles and compactors at a FOOD ESTABLISHMENT is prohibited unless cleaning operations are located on a hardstand with wash down and drainage capabilities.
 - (2) An area shall be designated at the FOOD ESTABLISHMENT for cleaning and air-drying trash cans.
 - (D) Dumpsters and compactors moved to a central location for cleaning shall be:
 - (1) Transported to minimize spilling of liquid or solid waste; and
 - (2) Cleaned following the in-place cleaning procedure specified in \P (C) of this section.

5-502 Removal

<u>5-502.11</u> 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.

<u>5-502.12</u> 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.

5-503 Facilities for disposal and recycling

<u>5-503.11</u> 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, a commercial or APPROVED installation composting facility, or an individual REFUSE facility such as a landfill or incinerator which is sized, constructed, maintained, and operated according to LAW.

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CHAPTER 6

PHYSICAL FACILITIES

6-1. Materials for construction and repair

6-101 Indoor areas

6-101.11 Surface characteristics

- (A) Except as specified in $\P(B)$, (C) and (D) 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. For new construction or renovation, gypsum wallboard or similar pervious material may not be used in FOOD preparation, serving, SELF-SERVICING AREAS; WAREWASHING and pot and pan washing areas; toilet areas; or other areas subject to water damage or high humidity.
 - (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, windblown dust, and debris.
- (C) Acoustical material used in areas exposed to grease or high humidity should be constructed and installed to provide a reasonably nonabsorbent, EASILY CLEANABLE surface. These materials require periodic replacement to maintain sanitary standards.[†]
- (D) Water/mold-resistant gypsum wallboard protected by a cement backerboard or green board and ceramic tile may be used to sheath stud walls.[†]
- (E) Binding cement, mortar, or grout (epoxy) jointed materials used for walls and ceilings (including doors, windows, skylights, and similar closures) shall be waterproof, grease proof, and erosion resistant. †

6-102 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, prevent muddy conditions, and pooling of water.
- (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 $\S 5-501.11$ and 5-501.12.

6-2. Design, construction, and installation

6-200 General requirements

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6-200.11 Food operations, fixed facilities[†]

- (A) Except as specified in \P (B) of this section, FOOD ESTABLISHMENTS at fixed installations shall be used solely for FOOD operations.
- (B) Areas in which food service operations occur within retail stores, such as mini-marts, service stations, and Express stores, shall adhere to all of the design criteria, EQUIPMENT, and maintenance provisions of this publication.

6-201 Cleanability

6-201.11 Floors, walls, and ceilings

- (A) Except as specified under §§ 6-201.14 and 9-203.11 and except for anti-slip 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.
 - (B) Walls and ceilings shall be light-colored in all FOOD preparation areas for easy identification of soil.
- (C) The floor area shall be waterproofed within 2 feet (60 cm) from toilet base and urinal lip with a SMOOTH, EASILY CLEANABLE, NONABSORBENT material.†
- (D) Toilet and locker room walls shall be waterproofed at a minimum 4 feet (120 cm) above the floor and at least 1 foot (30 cm) to each side of the urinal with a SMOOTH, EASILY CLEANABLE, NONABSORBENT material. Use of water/mold resistant gypsum wall board painted with epoxy paint is acceptable. †

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 one thirty-second (1/32) inch (1 millimeter).
- (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 and serving 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. *Carpeting is authorized in administrative and customer dining areas of a FOOD operation.*
 - (B) If carpeting is installed in areas specified in ¶ (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.
 - (3) Maintained in good repair.

6-201.15 Floor covering, mats, and duckboards

(A) Mats and duckboards shall be designed to be removable and EASILY CLEANABLE, shall meet NSF International Standard 52 requirements, and shall be kept clean.

(B) Wooden duckboards or pallets which do not meet NSF International Standard 52 requirements may not be used as flooring material except when used in FIELD or TEMPORARY FOOD ESTABLISHMENTS.[†]

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.
 - (C) Lead-based paint and paint containing pesticides may not be used inside FOOD ESTABLISHMENTS.†
- (D) Exposed corners of glazed structural units, concrete masonry unit partitions, and columns subjected to damage from portable food service EQUIPMENT shall be protected through the use of corner protective guards. These guards should extend at least 72 inches (180 cm) above the finished floor. †
 - (E) The wall-floor intersections shall be coved and sealed to prevent moisture from entering the wall.

6-201.17 Walls and ceilings, attachments

- (A) Except as specified in \P (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, maintained in good repair, and mounted so as to minimize vermin harborage or entrance to the unit.
- (B) In CONSUMER dining areas and administrative offices, wall and ceiling surfaces, 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

- (A) Except for TEMPORARY FOOD ESTABLISHMENTS and as specified under $\P\P$ (B) and (C) of this section, studs, joists, and rafters may not be exposed in areas subject to moisture.
- (B) If exposed in areas outside the FOOD preparation areas (including walk-in refrigeration units, EMPLOYEES' dressing and locker areas, toilet rooms, vestibules, and other similar rooms or areas), studs, joists, and rafters shall be finished to provide a SMOOTH, EASILY CLEANABLE surface.[†]
- (C) Theme designs in customer service areas are permitted provided all wood is sealed and the areas are kept free from moisture accumulation and dust. †

6-202 Functionality

6-202.11 Light bulbs, protective shielding

- (A) Except as specified in \P (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, including any toxic chemical residue 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.

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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.
- (3) They are wall-mounted type only. The REGULATORY AUTHORITY may waive this requirement if the facility demonstrates a need. †
- (4) The center of the device is not more than 3 feet (90 cm) above the floor and no closer than 5 feet (150 cm) from exposed FOODs, FOOD-contact surfaces, or clean EQUIPMENT and UTENSILS.[†]
- (5) They are accepted, certified, listed, labeled, or otherwise determined to be safe by a nationally recognized testing laboratory acceptable to the REGULATORY AUTHORITY and the Armed Forces Pest Management Board.[†]

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 $\P(B)$, (C), and (E) and under $\P(D)$ 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, ceilings
 - (2) Closed, tight-fitting windows; and
 - (3) Solid, self-closing, outward-opening, 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 $\P\P$ (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 if a TEMPORARY FOOD ESTABLISHMENT is not provided with windows and doors as specified under \P (A) of this section, the openings shall be protected against the entry of insects and rodents by—
 - (1) Sixteen-mesh to 1 inch (16-mesh to 25.4 millimeters) screens;
 - (2) Properly designed and installed air curtains to control flying insects.
 - (a) Air curtains will be installed and directed to blow pests away from building entrances.
- (b) Air velocity, measured 3 feet (90 cm) above the floor, shall be at least 600 fpm for personnel-only entrances and 1,600 fpm for service entrances (See NSF International Standard 37 for guidance); 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, altitude, or other limiting condition. The REGULATORY AUTHORITY should be consulted for determination of barrier control.

(F) Exterior doors to FOOD ESTABLISHMENTS shall be kept closed while not in use.[†]

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 only canned BEVERAGES, if located outside, machines which 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 IAW LAW and shall be curbed and graded to drain to collect and dispose of liquid waste generated 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 floor-to-ceiling partitioning and solid self-closing doors.

6-3. Numbers and capacities

6-301 Handwashing sinks

6-301.10 Minimum number

HANDWASHING SINKS shall be provided as specified under § 5-203.11.

6-301.11 Handwashing cleanser, availability

- (A) Each HANDWASHING SINK or group of two adjacent HANDWASHING SINKS shall be provided with a supply of hand cleaning liquid, powder, or bar soap.
 - (B) HANDWASHING SINKS shall be equipped with a self-draining soap dish when bar soap is used.[†]

6-301.12 Hand-drying provision

Each HANDWASHING SINK or group of adjacent HANDWASHING SINKS shall be provided with:

- (A) Individual, disposable towels;
- (B) A heated-air hand drying device; or
- (C) A hand drying device that employs an air-knife system that delivers high-velocity, pressurized air at ambient temperatures.

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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 $\S 6-301.11$ and $\S 5-501.16$ and $\S 5-501.16$.

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. Multilingual signs shall be provided when appropriate.

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 \P <u>5-501.16(C)</u>. The waste receptacle should be placed near the entrance.

6-302 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.

6-303 Lighting

6-303.11 Intensity

The light intensity shall be-

- (A) At least 108 lux (10 foot candles) at a distance of 30 inches (75 cm) 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 30 inches (75 cm) above the floor in areas used for handwashing, WAREWASHING, and EOUIPMENT 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.
- (D) Lighting intensity should be verified during preopening inspections and whenever new lighting fixtures and walk-in refrigeration units are installed.

6-304 Ventilation

6-304.11 Mechanical

(A) Mechanical (area/room) ventilation of sufficient capacity shall be provided if necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes.

- (B) Mechanical ventilation shall be provided in WAREWASHING and pot and pan washing areas; FOOD preparation, processing, and serving areas; dressing or locker rooms; toilet rooms; and indoor garbage or REFUSE storage areas.[†]
 - (C) The minimum exhaust rate for a WAREWASHING area shall provide at least 20 air changes per hour.
- (D) Mechanical ventilation systems in new construction shall be designed to provide at least 10 air changes per hour in all toilet rooms.

6-304.12 Exhaust rates[†]

This provision has been deleted; refer to Subparagraph 4-301.14(E)(2).

6-305 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.

6-306 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

6-401 Handwashing sinks

6-401.10 Conveniently located

HANDWASHING SINKS shall be conveniently located as specified under § 5-204.11.

6-402 Toilet rooms

6-402.11 Convenience and accessibility

Toilet rooms shall be conveniently located and accessible to EMPLOYEES during all hours of operation.

6-403 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 cannot occur.

6-404 Distressed merchandise

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6-404.11 Segregation and location

Products that are held by the PIC for medical inspection, 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. FOOD products returned by the CONSUMER due to FOOD safety or quality concerns shall be put aside for public health inspection before disposal.

6-405 Refuse, recyclables, and returnables

<u>6-405.10</u> 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

6-501 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.
- (C) Grease traps, FOOD grinders, and other plumbing fixtures used to trap, grind, or pulverize FOOD wastes shall be cleaned as often as necessary to prevent obnoxious odors and pest harborage.

6-501.13 Cleaning floors, dustless methods

- (A) Except as specified in \P (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 for the heating, ventilation, and air conditioning system and ventilation ducts and fans for exhaust hoods 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.

<u>6-501.16</u> Drying and maintaining mops

- (A) After use, mops shall be placed in a position that allows them to air dry without soiling walls, EQUIPMENT, the mop handle, or supplies. The preferred method of storing mops is head down. An angled rack that allows the mop head to hang freely without draining onto the mop handle is also acceptable.
 - (B) Mop heads shall be kept trimmed and shall be replaced when heavily soiled or no longer serviceable.

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 visually 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. If they are directed to only change their clothes in the establishment, dressing rooms must be provided.
- (B) Lockers or other suitable facilities shall be used for the orderly storage of EMPLOYEE clothing, purses, backpacks, 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;
 - (D) Eliminating harborage and entry conditions using an integrated pest management approach; and
 - (E) Employing proper stock rotation, "FIFO" or the manufacturer's "use by" date.

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

- (A) The PREMISES shall be free of-
- (1) Items that are unnecessary to the operation or maintenance of the establishment such as EQUIPMENT that is nonfunctional or no longer used; and

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- (2) Litter.
- (B) The FOOD ESTABLISHMENT PIC is responsible for ensuring the PREMISES are kept clean. Specific collection requirements for waste disposal are contained in publications that govern facilities management, such as AR 420-1, and TM 5-634/NAVFAC MO-213/AFI 32-7042, Solid Waste Management.[†]

6-501.115 Prohibiting animals

- (A) Except as specified in $\P\P$ (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 cannot 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) Except as specified in Subparagraph (B)(6) of this section, 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 or otherwise protected from contamination 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.
- (6) At Army installations, only animals engaging in Animal Assisted Therapies or in Animal Assisted Activities are authorized in the common dining areas of institutional care facilities.[†]
- (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 cannot result.

6-501.116 Plants[†]

Live plants and decorative artificial plants are authorized in NONFOOD preparation areas of FOOD ESTABLISHMENTS provided that:

- (A) They do not contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES; and
 - (B) They are clean and do not provide a harborage area for pests.

6-502 Unauthorized personnel

6-502.11 Restricted access[†]

Except for planned tours, traffic of unauthorized PERSONS through FOOD preparation, FOOD storage, or WAREWASHING areas is prohibited.

CHAPTER 7

POISONOUS OR TOXIC MATERIALS

7-1. Labeling and identification

7-101 Original containers

7-101.11 Identifying information, prominence

- (A) Containers of POISONOUS OR TOXIC MATERIALS and PERSONAL CARE ITEMS shall bear a legible manufacturer's label.
- (B) Chemicals that bear the EPA's registration or HAZARD COMMUNICATION label shall be kept in their original containers when required by LAW. †

7-102 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. The common name shall be written in English and in the predominant language in the workplace if other than English.

7-2. Operational supplies and applications

7-201 *Storage*

7-201.11 Separation*

POISONOUS OR TOXIC MATERIALS shall be stored so they cannot contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES by—

- (A) Separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning; ⁸ 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.

7-202 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.
- (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 publication,
- (2) Manufacturer's use directions included in label; for pesticides, 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; N 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, UTENSILS, countertops, and other FOOD CONTACT SURFACES after the application.
- (C) A RESTRICTED USE PESTICIDE shall be applied only by a certified applicator as defined in Title 7 U.S. Code (USC) Section 136 (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. ^N
 - (D) Chemical pest control-
 - (1) May not be applied by the FOOD EMPLOYEE; N
 - (2) Shall only be applied by a certified applicator or as specified under ¶ (C) of this section; N and
 - (3) Shall be approved for use in a food service area or establishment.

7-203 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.

7-204 Chemicals

7-204.11 Sanitizers, criteria*

Chemical SANITIZERS and other chemical antimicrobials applied to FOOD-CONTACT SURFACES shall 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)*.

7-204.12 Chemicals for washing, treatment, storage and processing fruits and vegetables, criteria*

- (A) Chemicals, including those generated onsite, 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 173.315, or
 - (2) Be GRAS for this intended use, 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), and
 - (4) Meet the requirements in 40 CFR 156 Labeling Requirements for Pesticide and Devices.
- (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. N

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.

7-205 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.

7-206 Pesticides

7-206.11 Restricted use pesticides, criteria*

RESTRICTED USE PESTICIDES specified under \P 7-202.12(C) shall meet the requirements specified in 40 CFR 152 Subpart I - Classification of Pesticides.

7-206.12 Rodent bait stations*

- (A) Rodent bait shall be-
 - (1) Contained in a covered, tamper-resistant bait station; and
 - (2) Inspected as often as necessary to ensure effectiveness.^{† N}
- (B) The PIC shall have access to a map of bait station locations throughout the facility, which is maintained and updated by the pest control operator. $^{\dagger N}$

7-206.13 Tracking powders, pest control and monitoring*

- (A) Except as specified in \P (B) of this section, 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

7-207 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. N
- (B) Personal 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*

Personal 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, leak-proof container that is identified as a container for the storage of medicines; and
 - (B) Located so they are inaccessible to children.

7-208 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.

7-209 Other personal care items

7-209.11 Storage

Except as specified under §§ $\frac{7-207.12}{6-305.11}$ and $\frac{7-208.11}{6-305.11}$, EMPLOYEES shall store their PERSONAL CARE ITEMS in facilities as specified under ¶ $\frac{6-305.11(B)}{6-305.11}$.

7-3. Stock and retail sales

7-301 Storage and display

7-301.11 Separation*

POISONOUS or TOXIC MATERIALS shall be stored and displayed for retail sale by the following means so they cannot contaminate FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES by—

- (A) Separating the POISONOUS or TOXIC MATERIALS from FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES by spacing or partitioning; ⁸ 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

8-1. Applicability

8-101 Use for intended purpose

8-101.10 Public health protection

- (A) The REGULATORY AUTHORITY shall apply this publication to promote its underlying purpose, as specified in Part <u>1-1</u>, 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 publication, the REGULATORY AUTHORITY assesses existing facilities and EQUIPMENT that were in use before the effective date of this publication based on the following considerations:
- (1) Whether the facilities or EQUIPMENT are sufficient in size, quantity, and good operating condition to protect FOOD safety, and are capable of being maintained in a sanitary condition;
 - (2) Whether FOOD-CONTACT SURFACES comply with Subpart <u>4-101</u>;
- (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, such as a Work Order, with the FOOD ESTABLISHMENT that the facilities or EQUIPMENT will be replaced or repaired as specified under \P 8-304.11(F) if it does not meet the requirements in this publication. The FOOD ESTABLISHMENT should have written procedures for managing Work Orders and should follow up on active Work Orders through periodic contact with the FACILITY ENGINEER.

8-102 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 publication that are authorized by LAW. *Implementation of additional or more restrictive requirements by the REGULATORY AUTHORITY does not constitute a VARIANCE.*
- (B) The REGULATORY AUTHORITY must document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. Documentation is provided to the FOOD ESTABLISHMENT manager and the CONTRACTING OFFICER (KO) for contracted FOOD ESTABLISHMENTS, and a copy is maintained in the REGULATORY AUTHORITY's file for the FOOD ESTABLISHMENT until the condition warranting the additional requirement no longer exists.

8-103 Variances

8-103.10 Modifications and waivers

The REGULATORY AUTHORITY may grant a VARIANCE by modifying or waiving the requirements of this publication 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 retains the information specified under § 8-103.11 in its records for the FOOD ESTABLISHMENT.

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8-103.11 Documentation of proposed variance and justification

- (A) Before a VARIANCE from a requirement of this publication is APPROVED, the following information shall be provided by the PERSON requesting the VARIANCE:
- (1) A statement of the proposed VARIANCE of this publication requirement citing relevant publication section numbers;
- (2) An analysis of the rationale for how potential public health HAZARDS and nuisances addressed by the relevant publication sections will be alternatively addressed by the proposal; and
- (3) A HACCP PLAN if required as specified under \P 8-201.13(A) that includes the information specified under \S 8-201.14 as it is relevant to the VARIANCE requested.
 - (B) A copy of the APPROVED VARIANCE shall be retained on file by the REGULATORY AUTHORITY.
- (C) The REGULATORY AUTHORITY shall forward copies of a locally APPROVED VARIANCE to the supported Service's public health organization as specified in Subparagraph 8-7.g.(1).†
- (D) A VARIANCE with potential Service- or DOD-wide application should be forwarded through the respective Service's Public Health/Preventive Medicine/Veterinary chain of command, to include the applicable Service's Public Health Center/Command for approval. Service- and installation-unique interpretations are addressed by respective Service SMEs; however, Preventive Medicine, food safety, and Veterinary representatives from the Services' Public Health Centers/Commands collaborate on issues applicable to multiple Services to ensure continuity through a unified interpretation or response.†
- (E) A VARIANCE from this publication is shall not be implemented until the VARIANCE has been signed and APPROVED by the REGULATORY AUTHORITY.†

8-103.12 Conformance with approved procedures*

If the REGULATORY AUTHORITY grants a VARIANCE as specified in § <u>8-103.10</u>, or a HACCP PLAN is otherwise required as specified under § <u>8-201.13</u>, the FOOD ESTABLISHMENT manager or PIC shall—

- (A) Comply with the HACCP PLAN and procedures that are submitted as specified under § <u>8-201.14</u> and APPROVED as a basis for the modification or waiver; and
- (B) Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under \P 8-201.14(D) and Subparagraph 8-201.14(E)(3) that demonstrate that the following are routinely employed: N
 - (1) Procedures for monitoring the CRITICAL CONTROL POINTS,
 - (2) Monitoring of the CRITICAL CONTROL POINTS,
 - (3) Verification of the effectiveness of the operation or process, and
 - (4) Necessary corrective actions if there is failure at a CRITICAL CONTROL POINT.

8-2. Plan submission and approval

8-201 Facility and operating plans

8-201.11 When plans are required

- (A) The KO or designated installation representative shall submit through the INSTALLATION COMMANDER and the MEDICAL AUTHORITY to the REGULATORY AUTHORITY properly prepared design and construction plans and specifications, as specified under § 8-201.12, for review and approval IAW local procedures for construction and design review a minimum of 60 days prior to—
 - (1) The construction of a new FOOD ESTABLISHMENT;
 - (2) The conversion of an existing structure for use as a FOOD ESTABLISHMENT;
- (3) The remodeling of a FOOD ESTABLISHMENT or a physical change in the type or characteristic of the FOOD ESTABLISHMENT or FOOD operation as specified under \P 8-302.14(B) or (C) if the REGULATORY AUTHORITY determines that plans and specifications are necessary to ensure compliance with this publication.
- (B) Prior to starting a new FOOD operation or implementing the modifications made to an existing FOOD operation, the responsible PERSON (for example, FOOD ESTABLISHMENT manager or sponsoring organization such as AAFES, NEX, MCX, Morale, Welfare, and Recreation (MWR)) shall submit through the INSTALLATION

COMMANDER and the MEDICAL AUTHORITY to the REGULATORY AUTHORITY operational specifications, as specified under \P 8-302.11(B) and as specified in § 8-303.20.

(C) Plans for commissary facilities shall be submitted as specified in DODI 1330.17, Armed Services Commissary Operations; DODI 7700.18, Commissary Surcharge, Nonappropriated Fund (NAF), and Privately Financed Construction Reporting Procedures; and DeCA Commissary Design Guidance – General Design Requirements. When a commissary construction plan or renovation plan is initiated, the Defense Commissary Agency (DeCA) shall notify the installation MEDICAL AUTHORITY or designated REGULATORY AUTHORITY representative as specified in the DeCA P-Plan document.

8-201.12 Contents of the plans and specifications

- (A) Except as specified in ¶ (B) this section, the plans and specifications for new FOOD ESTABLISHMENT construction, 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 process, and the FOODS prepared, the following information to demonstrate its ability to conform with this publication's provisions—
 - (1) Intended menu:
- (2) Anticipated volume of FOOD to be stored, prepared, and sold or served, including FOOD delivery schedules;
 - (3) Proposed layout, mechanical schematics, construction materials, and finish schedules;
- (4) Proposed EQUIPMENT types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;
- (5) Evidence that standard procedures that ensure compliance with the requirements of this publication are developed or are being developed; and
- (6) Other information required by the REGULATORY AUTHORITY and as specified under §§ <u>8-302.12</u> and <u>8-302.14</u> for the proper review of the proposed construction, conversion or modification, and procedures for operating a FOOD ESTABLISHMENT.
- (B) Plans for Armed Services commissary operations shall contain design specifications as specified in DODI 7700.18, in the *DeCA Commissary Design Guidance* document, and, when applicable, in § <u>8-201.13</u> to demonstrate conformance with this publication's provisions. †
- (C) Plans are prepared and submitted by the FOOD ESTABLISHMENT sponsoring organization and routed through the INSTALLATION COMMANDER and the MEDICAL AUTHORITY to the REGULATORY AUTHORITY.†

8-201.13 When a HACCP plan is required

- (A) Before engaging in an activity that requires a HACCP PLAN, the FOOD ESTABLISHMENT manager or PIC 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 publication 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 as specified under § 8-201.12, an inspectional finding, or a VARIANCE request.
- (B) Before engaging in ROP without a VARIANCE as specified under § 3-502.12, the FOOD ESTABLISHMENT shall submit a properly prepared HACCP PLAN to the REGULATORY AUTHORITY.
 - (C) A HACCP PLAN is specifically required for:
 - (1) COOK-CHILL operations;
 - (2) FOOD ESTABLISHMENTS which request or require a VARIANCE from this publication; and
 - (3) Patient Tray Service at DOD medical facilities when required for accreditation.
- (D) FOOD safety plans for franchise FOOD operations can be considered a HACCP PLAN, provided the plan meets the requirements as specified under \S 8-201.14 and are APPROVED by the REGULATORY AUTHORITY as specified under \S 8-103.11.

8-201.14 Contents of a HACCP plan

For a FOOD ESTABLISHMENT that is required under § <u>8-201.13</u> to have a HACCP PLAN, the plan and specifications shall indicate:

- (A) General information such as the name of the establishment owner or manager, the FOOD ESTABLISHMENT address, and contact information;
 - (B) A categorization of the types of TCS FOOD that are to be controlled under the HACCP PLAN;
 - (C) A flow diagram or chart for each specific FOOD or category type that identifies:
 - (1) Each step in the process;
 - (2) The HAZARDS and controls for each step in the flow diagram or chart;
 - (3) The steps that are CRITICAL CONTROL POINTS;
 - (4) Ingredients, materials, and EQUIPMENT used in the preparation of that FOOD, and
- (5) Formulations or recipes that delineate methods and procedural control measures that address the FOOD safety concerns involved;
- (D) A CRITICAL CONTROL POINTS summary for each specific FOOD or category type that clearly identifies:
 - (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 designated FOOD EMPLOYEE or the PIC,
- (4) The method and frequency for the PIC to routinely verify that the FOOD EMPLOYEE is following SOPs and monitoring CRITICAL CONTROL POINTS,
- (5) Action to be taken by the designated FOOD EMPLOYEE or PIC if the CRITICAL LIMITS for each CRITICAL CONTROL POINT are not met, and
- (6) Records to be maintained by the PIC to demonstrate that the HACCP PLAN is properly operated and managed; and
 - (E) Supporting documents such as:
 - (1) FOOD EMPLOYEE and supervisory training plan that addresses the FOOD safety issues of concern;
 - (2) Copies of blank records forms that are necessary to implement the HACCP PLAN;
- (3) Additional scientific data or other information, as required by the REGULATORY AUTHORITY, supporting the determination that FOOD safety is not compromised by the proposal.

8-202 Confidentiality

8-202.10 Trade secrets

The REGULATORY AUTHORITY shall protect IAW LAW, information that meets the criteria specified in LAW for a trade secret and is contained on FOOD ESTABLISHMENT inspection reports and in the plans and specifications submitted as specified under §§ 8-201.12 and 8-201.14. This includes content of FOOD safety plans as identified in

¶ <u>8-201.13(D)</u>.

8-203 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 will achieve the following requirements:

- (A) The establishment is constructed and equipped IAW the APPROVED plans and APPROVED modifications of those plans;
- (B) The establishment has prepared SOPs as specified under Subparagraph 8-201.12(A)(5); and
 - (C) The establishment is in compliance with LAW and this publication as specified under § 8-301.11.

8-204 Construction standards

8-204.11 Construction requirements[†]

Applicable construction and design review publications shall be used to evaluate existing FOOD ESTABLISHMENTS prior to remodeling or major renovations and to perform reviews of drawings, specification, and solicitations for renovations and new construction. Publications include, but are not limited to the following:

- (A) DOD 4270.1M, DOD Construction Criteria Manual;
- (B) UFC 4-010-01, 4-020-02, and 4-023-03;
- (C) Service-specific technical guides for FOOD ESTABLISHMENT design review; and
- (D) NAVSEA S9-AAO-AA-SPN-010/GENSPEC, General Specifications for Ships of the United States Navy.

8-3. Authorization to operate

8-301 Requirements

8-301.11 Prerequisite for operation*

- (A) Except as specified in ¶¶ (E) and (F) of this section and as indicated in <u>Table 8-1</u>, a PERSON may not operate a FOOD ESTABLISHMENT or dispense FOOD to the GENERAL PUBLIC without an authorization to operate issued by the REGULATORY AUTHORITY. Preoperational coordination and preopening inspection shall be conducted for—
- (1) Newly constructed or renovated FOOD ESTABLISHMENTS as specified under $\P\P$ 8-201.11(A) and 8-302.11(A) and (B), and as specified in §§ 8-203.10 and 8-303.10.†
- (2) TEMPORARY FOOD ESTABLISHMENTS as specified in § 8-203.10 and as specified under ¶ 8-302.11(C). †
- (B) A new FOOD ESTABLISHMENT shall attain a preoperational inspection rating of Fully Compliant in order to be APPROVED by the REGULATORY AUTHORITY. An exception may be granted at the discretion of the REGULATORY AUTHORITY for NONCRITICAL deficiencies identified on an inspection report rated Substantially Compliant. A FOOD ESTABLISHMENT that received a Substantially Compliant rating from a preoperational inspection may be APPROVED to operate conditionally and may have the APPROVAL revoked at the REGULATORY AUTHORITY'S discretion if the NONCRITICAL violations are not corrected by the time specified for the Follow-up inspection.^{† N}
- (C) An ORGANIZATIONAL FOOD EVENT that is open to the GENERAL PUBLIC on the installation and involves the preparation or sale of TCS FOODS shall have the FOODS and associated controls reviewed by the REGULATORY AUTHORITY prior to the scheduled event.^{† N}
- (D) A PERSON may not sponsor a farmers market on the installation without prior coordination, review, and approval by the REGULATORY AUTHORITY and as specified in § <u>8-402.40</u>. A farmers market is a seasonal event, requiring a new review each year, and as needed during the season when new operators request entry into the market.[†]
- (E) Except as specified under ¶¶ 8-301.12(D), preoperational inspection and APPROVAL is not required for a home business in which FOOD is prepared and sold to consumers outside of the installation and is operating under State or local Health Department guidelines for COTTAGE FOODS. $^{\dagger N}$
- (F) Preoperational coordination and inspection is not required for a MILITARY UNIT or organizational function when— $^{\dagger\,N}$
- (1) TCS FOOD is prepared by the unit or organization members and is not open to the GENERAL PUBLIC. The unit commander or organizational leader assumes responsibility for food safety and should consult with the REGULATORY AUTHORITY for guidance.
- (2) Catered TCS FOOD is prepared off of the installation by a commercial FOOD vendor, is intended for exclusive use by the MILITARY UNIT or organization, and is not offered to the GENERAL PUBLIC.
 - (3) The ORGANIZATIONAL FOOD EVENT only dispenses non-TCS FOOD.

Table 8-1. Summary of preoperational coordination and inspection requirements

	Requirements			
Food Facility Type, Location, or Event Scenario ¹	Certified PIC	Plan Review & Approval (Preoperational)	Preoperational & Reoccurring Sanitation Inspections	
Fixed, seasonal, mobile, and vending food service business	YES ²	YES	YES	
Temporary food establishment (e.g., commercial food vendors)	YES^2	YES	YES	
Retail food stores and retail food concessions	YES	YES	YES	
Child care and youth services facility kitchens	YES	YES	YES	
Unit or organizational food events not open to the general public (e.g., unit barbeque, picnic, office pot luck)	NO	NO	NO	
Unit or organizational fundraising event that dispenses TCS food to the general public	NO	YES	NO	
Unit or organizational fundraising event that only dispenses non-TCS food (e.g., bake sale)	NO	NO	NO	
Church supper or similar private group event	NO	NO	NO	
Guest lodging facilities (e.g., breakfast area & restaurant)	YES	YES	YES	
United Service Organization & Military Entrance Processing Station operated on the installation (e.g., cafeteria, snack bars)	YES	YES	YES	
Cottage food operation in government housing	NO	YES	NO	
Farmers market on installation	NO	YES	YES ³	

¹The list of facility or event types is not all inclusive and is intended to represent likely scenarios.

8-301.12 Cottage food operations*†

Home businesses operating in government housing involving FOOD production and sale are not subject to public health inspection as a FOOD ESTABLISHMENT under the TSFC. However, there are specific requirements governing production and sale of COTTAGE FOODS.

- (A) COTTAGE FOODS may not be sold in a FOOD ESTABLISHMENT or retail store operating on a military installation.
- (B) COTTAGE FOODS produced in nongovernment housing are regulated by the State or local Health Department. COTTAGE FOOD operations occurring in privatized government housing are expected to meet the regulatory requirements specified by the State or local Health Department in addition to the contents of this provision.
- (C) Service-specific policies apply governing the approved sale or restriction of COTTAGE FOODS at Farmers Markets operated on a military installation.

² Food Protection Manager Certification is not required when only non-TCS foods are dispensed [2-502.11(C)].

³ At least one inspection conducted at start of season; local policy may direct reoccurring inspections conducted by the REGULATOR AUTHORITY.

- (1) For Army, Navy, and Marine Corps installations, Army Veterinary Service food protection requirements for Farmers Markets apply..
 - (2) For Air Force installations, consultation with the REGULATORY AUTHORITY is required.
- (D) A home business operating in government housing or privatized government housing shall register as a COTTAGE FOOD operator through the REGULATORY AUTHORITY for review and approval of proposed COTTAGE FOODS prior to initiating the sale of such FOODS. The registration shall be a written document containing:
 - (1) The street address of the location where the COTTAGE FOOD will be produced;
 - (2) A list of the COTTAGE FOODS that will be produced;
- (3) A copy of the recipe for each FOOD produced. Recipes shall identify all of the ingredients and a description of the production method and process controls (for example, cooking equipment, product holding/storage, packaging); and
- (4) The method of advertising or point of sale location in which the COTTAGE FOOD will be provided to the consumer.
 - (E) The COTTAGE FOOD operator shall—
- (1) Produce the COTTAGE FOOD in the kitchen or residence that was stated in the registration packet and is identified on the food label as specified in Subparagraph (E)(5)(a) of this section.
- (2) Maintain a copy of each COTTAGE FOOD recipe and provide a copy to the REGULATORY AUTHORITY upon request.
 - (3) Be the original processor of the FOOD. The FOOD may not be repackaged from another producer.
 - (4) Package or wrap the FOOD using clean food containers or food-grade foils or plastic wrap.
 - (5) Place a label on the PACKAGED FOOD to indicate—
 - (a) The name, address, and phone number of the COTTAGE FOOD producer;
- (b) Ingredients that are known food allergens: milk, eggs, fish, crustacean, shellfish, tree nuts, wheat, peanuts and soy beans or a FOOD ingredient that contains a protein derived from a FOOD specified in this sentence; and
- (c) A consumer notice that specifies, "This food was produced in a home kitchen not subject to public health inspection."
- (F) Except as specified in \P (G) of this section, a home business may not sell HIGH-RISK FOODS or the following LOW-RISK FOODS:
 - (1) Honey.
 - (2) Home-canned vegetables, meats, or stews.
- (G) The following FOODS may be APPROVED by the REGULATORY AUTHORITY on a case-by-case basis when suitable controls are identified and maintained:
- (1) *Cream- or custard-filled bakery products (for example, pies and pastries) and cheesecake.* These products are considered a TCS FOOD and shall be refrigerated.
- (2) *High-acid FOODS (for example, jams and jellies)*. The producer shall test the acidity of each batch of the final product using acceptable test mechanism, such as withdrawing a small sample of the product and testing using pH paper. A log of testing results shall be retained by the COTTAGE FOOD producer for 1 year.

8-302 Application procedures

8-302.11 Submission, timeframe before proposed start date

Except as specified in \P (D) and (E) of this section, an application to operate, as specified under §§ 8-302.12 and 8-302.14, shall be submitted to the REGULATORY AUTHORITY for— †

(A) New construction or renovation. The PERSON responsible for the safe operation of a newly constructed or renovated FOOD ESTABLISHMENT shall submit an application to operate or conduct preoperational coordination, as specified under Subparagraph 8-301.11(A)(1), at least 30 calendar days prior to the scheduled opening of the operation. A separate application is not required if a comprehensive plan was previously submitted as specified under \P 8-201.12(A); however, coordination for the preoperational inspection is required.

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- (B) *Modified operations*. The manager of a FOOD ESTABLISHMENT undergoing one of the following types of operational change shall submit an application for approval of proposed changes at least 30 calendar days prior to the intended start of the new services:
 - (1) Change in establishment type, (for example, coffee shop is converted to a sandwich shop).
- (2) Menu becomes more complex (for example, the operation previously limited to serving baked goods and ice cream is expanded to serve sandwiches and salads that are prepared onsite).
- (3) FOOD processing becomes more complex(for example, change from serving prePACKAGED RTE FOOD to preparing TCS FOODS onsite from raw ingredients).
- (C) *Temporary operations*. The FOOD ESTABLISHMENT'S sponsoring organization (for example, AAFES, NEX, MCX, MWR, or other) or designated installation representative shall notify the REGULATORY AUTHORITY and submit an application to operate a minimum of 14 days prior to the scheduled start date of a TEMPORARY FOOD ESTABLISHMENT.
- (D) *Organizational food event.* The PERSON responsible for the safe operation of an ORGANIZATIONAL FOOD EVENT involving TCS FOOD shall request a review as specified under ¶ <u>8-301.11(C)</u> at least 48 hours prior to the scheduled event date.
- (E) *Home business.* A COTTAGE FOOD operation shall register with the REGULATORY AUTHORITY as specified under ¶ 8-301.12(D).

8-302.12 Form of submission

A PERSON desiring to operate a FOOD ESTABLISHMENT shall submit to the REGULATORY AUTHORITY a written application to operate containing the information specified under § 8-302.14, using the format or form required by the REGULATORY AUTHORITY. Use of DD Form 2970 [OMB No. 0702-0132], Application for Temporary Food Establishment, and DD Form 2975, Temporary Food Event Coordinator's Application, may require additional documentation in order to meet all of the application criteria specified in § 8-302.14. Refer to Appendix F for use of these forms.

8-302.13 Qualifications and responsibilities of applicants

To qualify for approval to operate a FOOD ESTABLISHMENT on an installation or area governed by this publication, the FOOD ESTABLISHMENT manager, sponsoring organization, or KO shall—

- (A) Ensure compliance with the requirements of this publication; and
- (B) As specified under \S 8-402.11, agree to allow access to the FOOD ESTABLISHMENT and to provide required information.

8-302.14 Contents of the application

The application to operate a new or modified FOOD ESTABLISHMENT shall include information as specified under \P 8-201.12(A) and—

- (A) The name, business mailing address, business telephone number, and signature of the PERSON submitting the application; and the name, mailing address, and location of the FOOD ESTABLISHMENT;
- (B) Information specifying whether the FOOD ESTABLISHMENT is owned by the government, an association, corporation, individual, partnership, or other legal entity, to include FOOD operations occurring in privatized facilities;
 - (C) A statement specifying whether the FOOD ESTABLISHMENT—
 - (1) Is TEMPORARY or permanent and MOBILE or SEASONAL;
 - (2) Is a MOBILE platform that is intended to operate in a static location; and
 - (3) Is an operation that includes one or more of the following activities:
 - (a) Prepares, offers for sale, or serves TCS FOOD under the following conditions:
 - (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 TCS FOOD in advance using a FOOD preparation method that involves two or more steps which may include combining TCS FOOD ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing,
- (c) Prepares FOOD as specified under Subparagraph (C)(3)(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)(3)(b) of this section for service to a HIGHLY SUSCEPTIBLE POPULATION,
 - (e) Prepares only FOOD that is not TCS FOOD, or
 - (f) Does not prepare, but offers for sale only prePACKAGED FOOD that is not a TCS FOOD;
- (4) Prepares FOOD at a facility located off of the installation. In this case, the facility's address and the conveyance method for FOODS that are transported from off-post sites or between facilities on post shall be provided in the application.
- (D) The name, title, telephone number, and official email 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 \P (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 \P (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 publication, 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.

8-303 Issuance

8-303.10 New, converted, or remodeled establishments

For FOOD ESTABLISHMENTS that are required to submit plans as specified under § <u>8-201.11</u> the REGULATORY AUTHORITY shall approve the application to operate after—

- (A) A properly completed application is submitted;
- (B) The required plans, specifications, and information are reviewed and APPROVED;
- (C) A preoperational inspection as specified in § <u>8-203.10</u> shows that the establishment is built or remodeled IAW the APPROVED plans and specifications and that the establishment is in compliance with this publication.

8-303.20 Existing establishments, changing management or contract[†]

The REGULATORY AUTHORITY is required to review the operational plans for an existing FOOD ESTABLISHMENT under new ownership or management as specified in ¶ (A) of this section and when an operational change occurs as specified under ¶ 8-302.11(B). The agency (for example, AAFES, NEX, MWR, DeCA) responsible for sponsoring the FOOD ESTABLISHMENT must ensure all contracts require REGULATORY AUTHORITY review of operational plans. The REGULATORY AUTHORITY may approve the operation after a completed application is submitted, reviewed, and APPROVED, and an inspection shows that the establishment is in compliance with this publication.

- (A) Except as specified in \P (B) of this section, a change in management applies when:
- (1) A FOOD ESTABLISHMENT previously managed by military personnel is converted to a contracted operation (in part or in full) and the manager is nonmilitary;

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- (2) A FOOD ESTABLISHMENT previously managed by a civilian contract is converted to a military-managed operation; or
- (3) The FOOD ESTABLISHMENT management contract is terminated and a new contract is awarded to a different company or different food vendor.
- (B) Changes in management personnel within an existing contract or operation do not require submission of a new application to operate.

8-303.30 Denial of application to operate, notice

If an application to operate is denied, the REGULATORY AUTHORITY shall provide the applicant with a notice that includes:

- (A) The specific reasons and publication citations for the denial;
- (B) The actions, if any, that the applicant must take to qualify to operate; and
- (C) Advisement of the applicant's right to reapply.

8-304 Conditions of retention

8-304.10 Access to the Tri-Service Food Code[†]

- (A) Contracted Food Operations. KOs shall ensure that this publication is incorporated by reference in the FOOD ESTABLISHMENT contract.
- (B) Upon request, the REGULATORY AUTHORITY will provide the web address for access to this publication.

8-304.11 Responsibilities of the food manager

Upon approval of the application to operate issued by the REGULATORY AUTHORITY, the FOOD ESTABLISHMENT shall—

- (A) Comply with the provisions of this publication, including the conditions of a granted VARIANCE as specified under § 8-103.12, and APPROVED plans as specified under § 8-201.12;
- (B) If a FOOD ESTABLISHMENT is required under § <u>8-201.13</u> to operate under a HACCP PLAN, comply with the plan as specified under § <u>8-103.12</u>;
- (C) Immediately contact the REGULATORY AUTHORITY to report an illness of a FOOD EMPLOYEE or CONDITIONAL EMPLOYEE as specified under \P 2-201.11(B);
- (D) Immediately discontinue operations and notify the REGULATORY AUTHORITY if an IMMINENT HEALTH HAZARD (IHH) may exist as specified under § 8-404.11;
- (E) Allow representatives of the REGULATORY AUTHORITY access to the FOOD ESTABLISHMENT as specified under § 8-402.11;
- (F) Replace or repair (through work order submission and appropriate follow-up) existing facilities and EQUIPMENT specified in § 8-101.10 with facilities and EQUIPMENT that comply with this publication if—
- (1) The REGULATORY AUTHORITY directs the replacement or repair 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 or repair 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;
- (G) Comply with directives of the REGULATORY AUTHORITY, including time frames for corrective actions as specified under §§ 8-405.11 and 8-406.11, and inspection reports, notices, orders, warnings, and other directives issued by the REGULATORY AUTHORITY and in regards to the FOOD ESTABLISHMENT or in response to a declared state of emergency:
 - (H) Accept notices issued and served by the REGULATORY AUTHORITY according to LAW; and

- (I) Be subject to the administrative, civil, injunctive, and criminal remedies authorized in LAW for failure to comply with this publication or a directive of the REGULATORY AUTHORITY, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.
- (J) Inform 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 Approval to operate, not transferable

An APPROVED application to operate a FOOD ESTABLISHMENT 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 by the REGULATORY AUTHORITY.

8-304.30 Suspension of approval, vending operations[†]

The MEDICAL AUTHORITY or designated representative may, without prior warning or notice, suspend approval to operate a VENDING MACHINE OPERATION on the installation if the operation serves TCS FOODS and constitutes an IHH to the public.

- (A) When approval is suspended, the REGULATORY AUTHORITY shall notify the operator by telephone and in writing. The vending operation will cease on initial notification.
- (B) Suspension of approval may be withdrawn following re-inspection if correction of noted deficiencies has been accomplished.

8-4. Inspections and correction of violations

8-400 Philosophy of inspection

8-400.10 Inspection goals[†]

- (A) The goals of FOOD safety and sanitation inspection programs are—
 - (1) To ensure public health protection through FOOD safety,
 - (2) To reduce the occurrence of foodborne illness, and
 - (3) To ensure compliance with the requirements in this publication.
- (B) Ultimately, the responsibility for providing safe FOOD lies with the PIC of the FOOD ESTABLISHMENT.
- (C) Sanitation inspections and education programs are the REGULATORY AUTHORITY's primary tools for identifying procedures, practices, facilities, and EQUIPMENT that may be hazardous, and for initiating actions necessary to correct deficiencies. Sanitation inspections serve the commander and the FOOD ESTABLISHMENT by—
- (1) Identifying potential problems and providing reasonable solutions to correct sanitation and FOOD safety problems before outbreaks of foodborne illness occur;
- (2) Identifying procedural, training, and management needs, and providing guidance for FOOD EMPLOYEES; and
 - (3) Assisting the FOOD ESTABLISHMENT's PIC to identify deficiencies in EQUIPMENT and facilities.
- (D) The REGULATORY AUTHORITY shall place emphasis on those practices and procedures that have a direct bearing on the prevention of foodborne illness.
- (E) It is impossible to delineate every discrepancy and possible interpretation of requirements within this publication. Items that, in the opinion of the REGULATORY AUTHORITY, constitute a health hazard shall be reported along with suitable recommendations, even though the items are not specifically addressed in this publication or any other military publication.

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8-400.11 Food facility risk assessment survey[†]

- (A) Except as specified in Subparagraph (A)(2) of this section, a food facility risk characterization shall be conducted for fixed (permanent), MOBILE, and SEASONAL FOOD ESTABLISHMENTS.
- (1) An initial facility risk assessment is conducted for new FOOD ESTABLISHMENTS and existing establishments that have never been assessed in order to establish a baseline risk value for the operation.
- (2) Risk assessments are optional for retail food stores and may be conducted at the discretion of the REGULATORY AUTHORITY having inspection jurisdiction.
- (3) Facility risk assessments should be updated periodically as specified in Appendix D, paragraph <u>D-6.a.</u> of this publication in order to identify operational changes that may increase or decrease the FOOD ESTABLISHMENT'S risk rating, thereby, impacting the frequency in which inspection should be conducted.
- (B) The food facility risk assessment shall be conducted by the REGULATORY AUTHORITY having inspection jurisdiction over the FOOD ESTABLISHMENT and the person conducting the assessment shall be—
- (1) A Civilian, officer, warrant officer, or noncommissioned officer who is the Section Chief, or designated person responsible for food inspection program activities; or
- (2) A public health technician who is competent and experienced in food safety and inspection activities. The completed risk survey shall be reviewed by a senior food safety professional as specified in Subparagraph (B)(1) of this section or elevated through the technical support chain, as appropriate, to ensure the survey was completed correctly.
- (C) Facility risk characterizations shall be documented using the Food Facility Risk Assessment Survey Form (DD 2972) and the guidance provided at Appendix D.
- (D) Risk ratings derived using DD Form 2972 may be used to establish the frequency in which the FOOD ESTABLISHMENT is inspected; however, the maximum time between inspections may not exceed the period of time that corresponds to the risk category's minimum inspection frequency depicted in Table 8-1.

8-400.20 Inspection types[†]

The five types of food safety and sanitation inspections are Preoperational, Routine, Follow-up, Walk-through, and Complaint. These inspections are conducted by the REGULATORY AUTHORITY and are characterized as follows:

- (A) Preoperational inspections are coordinated in advance with the FOOD ESTABLISHMENT manager or PIC and conducted for new or modified FOOD ESTABLISHMENTS as specified in § <u>8-203.10</u> and under § <u>8-301.11</u>. The inspection provides assurance that a FOOD ESTABLISHMENT can safely store, prepare, serve, or sell FOOD.
- (B) Routine inspections are unannounced, formal sanitary inspections conducted as part of regular, ongoing public health surveillance activities and are administered as specified in \P 8-6.c.
- (C) Follow-up inspections are announced, formal sanitary inspections that are administered as specified in Subparagraph 8-6.e.(1).
- (D) Walk-through inspections are informal, sanitary inspections performed to assist management in preventing foodborne illness, protecting the public's health, and maintaining the establishment in a sanitary condition. The inspection, administered as specified in Subparagraph <u>8-6.d.</u>, is used to identify potential problems with facilities, EQUIPMENT, or FOOD handling procedures and to initiate corrective actions before a formal sanitary inspection is conducted.
- (E) Complaint inspections are initiated in response to a customer complaint involving a FOOD ESTABLISHMENT and/or FOOD-related public health issue and administered as specified under Subparagraph 8-6.e.(2).

8-400.30 Installation food vulnerability assessment[†]

Installation food vulnerability assessments (IFVA) are comprehensive security inspections for FOOD DEFENSE. Installation food vulnerability assessments are not regulated by this publication. The REGULATORY AUTHORITY participates in conducting IFVAs; however, the program is managed by the following antiterrorism and force protection regulations: DODI 2000.12, DODI 2000.16, and other Service-specific publications. For Air Force installations, the HHQ Food Defense program is managed by the Food Protection Section based at the

USAFSAM. The AFIs 10-245 and 10-246 govern the Air Force Installation Vulnerability Assessment and the Food Vulnerability Assessment programs, respectively.

8-401 Frequency

8-401.10 Establishing inspection interval

- (A) Except as specified in \P (B)-(E) of this section, the REGULATORY AUTHORITY shall inspect each FOOD ESTABLISHMENT and retail FOOD store at a frequency—
 - (1) That corresponds to the operation's derived risk rating, as specified in \P 8-400.11(D); \dagger or
- (2) In accordance with the minimum frequency identified in <u>Table 8-2</u> for the designated type of FOOD ESTABLISHMENT.[†]
- (B) Inspection frequency for retail stores under Army Veterinary Services jurisdiction are determined as specified in Army Veterinary Service documents.[†]
- (C) The REGULATORY AUTHORITY may increase the interval (for example, decrease the inspection frequency) between required routine inspections if—
- (1) The FOOD ESTABLISHMENT is fully operating under an APPROVED and validated HACCP PLAN as specified under §§ <u>8-103.12</u> and <u>8-201.14</u> and has demonstrated compliance with the plan during previous inspections;
- (2) A food facility risk assessment, as specified under ¶ 8-400.11(A) and outlined in Appendix D, is conducted and supports a reduction in frequency. When using this method, a written RISK-based inspection schedule should be uniformly applied throughout the REGULATORY AUTHORITY's jurisdiction. Furthermore, in addition to conducting the requisite number of inspections designated by the Risk Category, the REGULATORY AUTHORITY should contact the FOOD ESTABLISHMENT by telephone, Walk-through inspection, or other means at least once every 3 months (for semiannual inspection intervals) or 6 months (for annual inspection intervals) to ensure that the establishment manager and the nature of the FOOD operation are not changed; or
- (3) The FOOD ESTABLISHMENT involves only coffee service and other unPACKAGED or prePACKAGED non-TCS FOOD such as carbonated BEVERAGES, chips, nuts, popcorn, pretzels, and other baked goods.
- (D) The REGULATORY AUTHORITY shall periodically inspect throughout its approved period of "active" operation, all TEMPORARY and SEASONAL FOOD ESTABLISHMENTS that prepare, sell, or serve unPACKAGED TCS FOOD and that—
- (1) Have 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) Have inexperienced FOOD EMPLOYEES.
- (E) The REGULATORY AUTHORITY may increase the frequency of inspections, as specified in § 8-401.20, without prior notice and for a period of time that is deemed necessary if— †
 - (1) The results of the food facility risk assessment indicate a risk rating other than Low:
 - (2) There is an overriding regulatory requirement to conduct more frequent inspection;
- (3) In the absence of a food facility risk assessment, the FOOD ESTABLISHMENT has recently demonstrated poor performance and conformance to this publication's provisions; or
 - (4) Public health resources allow for a more robust inspection program.

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Table 8-2. Minimum inspection frequencies[†]

Risk Category	Inspection Frequency	Examples of Facilities	
Extremely High	Monthly	Shipboard; Hospital nutrition care (inpatient & outpatient services); Child Care Facilities ¹ ; field food operations	
High	Quarterly	Dining facility (DFAC); Fast-food (Burger King, Popeye's, Subway; Anthony's Pizza; Exchange Food Court, etc.); Community clubs	
High	Quarterly	Retail Store ² : Provides one or more Advanced ³ food services: rotisserie chicken; onsite macaroni, tuna, egg, or potato salad prep, sandwich prep/Panini; sushi bar; self-serve salad/soup/buffet bar; bakery (onsite mixing of raw ingredients); fresh seafood department	
Moderate	6 months	Small food concessions limited to sandwich/soup/salad prep; Coffee shop (pastries, sandwiches, & salads are commercially packaged and not prepared onsite); Ice cream shop; Mobile snack truck limited to serving hot hold/cold TCS foods and nonTCS foods (no raw food prep)	
Moderate	6 months	Retail Store ² : Provides <i>Basic</i> ³ services: Mini-mart, Express, or gas station retail store. Characteristics include typical grocer services (commercially packaged goods) and any of the following: limited bakery (frozen products or pre-mixed dough); deli with no cooking or food prep from raw ingredients; self-serve sandwiches (hot breakfast or commercially packaged); hot dogs, pizza, or other precooked foods held in hot holding for individual service.	
Low	Annual	Vending machine snack bars (TCS foods)	
UNRATED	Preopening & periodic when in operation	Temporary food establishments; Seasonal food establishments	

¹ Inspection intervals for child care facilities are prescribed in AFI 48-117, AR 608-10, and OPNAVISNT 1700.9 Series. Monthly inspections apply only to facilities caring for preschool-age children; inspection frequency may not be reduced unless authorized by the governing regulation.

8-401.20 Performance- and risk-based inspections

Within the parameters specified in § <u>8-401.10</u>, the REGULATORY AUTHORITY shall prioritize and conduct more frequent inspections based upon its assessment of a FOOD facility or operation's history of compliance with this publication's and the establishment's potential as a vector of foodborne illness by evaluating—

- (A) Past performance for nonconformance with this publication's or the HACCP PLAN's requirements that are CRITICAL ITEMS;
- (B) Past performance for numerous or repeat violations of this publication's or HACCP PLAN's requirements that are SWING or NONCRITICAL ITEMS;
 - (C) Past performance for customer complaints investigated and found to be valid;

² Minimum frequency for sanitary inspections conducted by Army Veterinary Service personnel are prescribed in Army Veterinary Service documents.

³ The terms *advanced* and *basic* are used to distinguish between a traditional grocery store typically supplying only packaged foods and may operate a limited service deli and bakery. "Limited-service deli" is defined as serving meats, cheeses, and/or dispensing from bulk, commercially packaged products for individual customer orders.

- (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.

8-401.30 Routine inspection substitution[†]

- (A) Except for inspections conducted by Army Veterinary Services, routine sanitary inspections may be substituted with interventions at the frequencies prescribed in Table 8-3 and as defined in ¶ (B) of this section.
 - (B) Inspection interventions may include one or more of the following activities:
- (1) HACCP training. HACCP training must be tailored to address specific food processes and food safety procedures that apply to the operation. Training is intended to improve active managerial controls and employee understanding of associated controls and corrective actions. Personnel expected to attend include FOOD EMPLOYEES, PICs, and FOOD managers. *The REGULATORY AUTHORITY (or trainer) conducting HACCP training should have completed formal HACCP training in order to use this intervention.*
- (2) FOOD safety/sanitation training. Training must be tailored to address weaknesses (or reoccurring violations) associated with the FOOD operation and must discuss recommended practices designed to improve active managerial controls
- (3) One or more consultation visits with the FOOD ESTABLISHMENT or operation's PIC that results in development or improvement of a written plan or procedure designed to improve active managerial controls. Consultations must engage supervisory personnel as well as FOOD EMPLOYEES in order to fully understand the challenges and limitations that may impact the operation's ability to implement or sustain recommended practices. A consultative intervention may incorporate requirements for the PIC to conduct and document self-evaluations as specified under § 8-402.12. Other items generally considered for consultation include strategies for improving or implementing an integrated pest management plan, using Time as a Public Health Control, and developing food-process models and identifying CRITICAL CONTROL POINTS and monitoring procedures.
 - (C) The following actions may not be used as an intervention:
- (1) Follow-up inspections. Follow-up inspections are those inspections conducted to verify compliance with previously documented deficiencies.
- (2) Telephonic communications between the REGULATORY AUTHORITY and the FOOD ESTABLISHMENT.
 - (3) Walk-through inspections.
- (4) Except as specified in Subparagraph (B)(1) of this section, initial or refresher HACCP training associated with a HACCP PLAN that is required as specified under § 8-201.13.
- (5) Except as specified in Subparagraph (B)(2) of this section, initial or annual refresher food safety training and Food Protection Manager Certification as specified under §§ 2-501.11 and 2-502.11.
- (6) Except as specified in Subparagraph (B)(3) of this section, a consultation to address a corrective action recommended during a routine inspection.
- (D) Interventions shall be thoroughly documented to substitute for an inspection. Documentation must include the date or inclusive dates in which the intervention was conducted; the identified problem, situation, or reason for the specified intervention; a description of the intervention activities, product, or training outline; and a list of intervention participants and their assigned job title/function.
- (E) Training interventions must involve at least 50 percent of all assigned FOOD management staff and FOOD EMPLOYEES across all shifts; several training iterations may be required to capture the target population.
- (F) Training interventions are expected to be of sufficient duration and involve practical exercises or individual or group learning activities that directly engage participants.
- (G) Consultations, such as development or improvement of facility procedures or sanitation standing operating procedures, should involve representatives of both FOOD management staff and supervisory level personnel from each work shift within the operation (weekday, weekend, and evening).

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Table 8-3. Authorized inspection substitutions^{1†}

Required Inspection Frequency ²	Required Number of Routine Inspections ³	Number of Interventions ³ Authorized	
Annual	1	0 ⁴ (phone contact after 6 months)	
6 Months	2	0 ⁴ (phone contact after 3 months)	
Quarterly	4	0	
	3	1	
	2	2	
Monthly	12	0	
	11	1	
	10	2	
	9	3	
	8	4	
	7	5	
	6	6	

¹ AR 40-657 prescribes minimum frequency for Army Veterinary Services inspections; interventions may not be substituted for retail store inspections.

8-402 Inspection process

8-402.10 Competency of inspectors

(A) An authorized representative of the REGULATORY AUTHORITY who inspects a FOOD ESTABLISHMENT or conducts a plan review for compliance with this publication shall have the knowledge, skills, and ability to adequately perform the required duties. An exception may be granted by the MEDICAL AUTHORITY where designated inspection personnel are under direct supervision of the REGULATORY AUTHORITY. For example, a Navy Independent Duty Corpsman may supervise other individuals who received on-the-job training in food safety and are designated to conduct inspections.

(B) The REGULATORY AUTHORITY shall ensure that authorized representatives who inspect a FOOD ESTABLISHMENT or conduct a plan review for compliance with this publication have access to training and continuing education, as needed, to properly identify violations and apply the TSFC.

8-402.11 Access, allowed at reasonable times after due notice

After the REGULATORY AUTHORITY presents official credentials and informs the PIC upon entering the facility of the purpose and intent to conduct an inspection, the PIC shall allow the REGULATORY AUTHORITY access to

² Inspection frequency is IAW with Table 8-2, a facility risk assessment, or as directed by the Regulatory Authority.

³ Required number of inspections and corresponding interventions to be completed within a 12-month period. No more than half of the required quarterly or monthly inspections may be substituted by interventions. Interventions may not be substituted for annual or semiannual inspections.

⁴ Phone contact or Walk-through inspection is required at the mid-point for annual and semiannual inspections to identify operation or menu has changes.

the facility to determine if the FOOD ESTABLISHMENT is in compliance with this publication. Access shall be granted during the FOOD ESTABLISHMENT's hours of operation and other reasonable times, including pre- and post-operational periods when FOOD is received, placed into storage or prepared, or during cleanup activities. Access also includes allowing inspection and providing information and records specified in this publication to which the REGULATORY AUTHORITY is entitled according to LAW.

8-402.12 Food service facility, self-evaluations[†]

- (A) The food service operation manager or PIC shall conduct daily self-evaluations to ensure compliance with their duties and responsibilities, as specified under \P 2-103.11(B)—(N) and § 8-304.11. (See also \P 8-6.f.)
- (B) The REGULATORY AUTHORITY, military service component representative, or other program management entity may require documentation of self-evaluations and for the PIC to provide a copy upon request.

8-402.13 Conducting formal inspections[†]

The REGULATORY AUTHORITY conducting the sanitary inspection shall—

- (A) At the time of inspection, notify the PIC of the FOOD ESTABLISHMENT prior to commencing the inspection and ask that he or she, or an appropriate representative, accompany the inspector through the FOOD ESTABLISHMENT.
- (B) Emphasize control of practices and conditions that have been associated with outbreaks of foodborne illness. This emphasis does not minimize the need to evaluate other areas or practices, but it allows effective use of resources in promoting and enforcing FOOD safety and sanitation programs. If the FOOD ESTABLISHMENT has implemented an APPROVED HACCP PLAN or FOOD Safety Plan, inspections will include evaluating the effectiveness of, and compliance with, the HACCP program.
- (C) Make every effort to avoid interfering with the FOOD ESTABLISHMENT operation while conducting the sanitary inspection.
- (D) Explain to the management representative or PIC all findings that are in violation of the TSFC. Comments or discussions of problems should not be conducted in the presence of customers.
- (E) Provide recommended corrective actions for issues that could not be resolved at the time of inspection and, when applicable, actions that should be taken to reduce the potential for future related violations.
- (F) Obtain a signature on the inspection report from the PIC or management representative and provide a copy of the inspection document as specified in § <u>8-403.40</u>.

8-402.14 Inspection of multi-shift operations[†]

Inspections of multi-shift operations shall be scheduled throughout the year to ensure evaluation of all shifts and associated periods of meal preparation, service, and cleanup as specified in Subparagraph <u>8-6.c.(5)</u>. The REGULATORY AUTHORITY may schedule a portion of the FOOD ESTABLISHMENT inspection outside of the inspector's normal duty hours, including weekends, to fully assess FOOD operation practices and employees.

8-402.20 Inspection of off-installation food establishments[†]

Inspection of off-installation FOOD ESTABLISHMENTS (restaurants, not retail stores or FOOD production factories) that are frequented by military personnel may be conducted by local preventive medicine or veterinary service personnel in conjunction with appropriate civilian health authorities. Preventive medicine should first determine if the FOOD ESTABLISHMENT is Directory Listed as an APPROVED SOURCE and consult with supporting Veterinary Services, as appropriate. When a FOOD ESTABLISHMENT is suspected of presenting a foodborne illness risk to military personnel, performance of a joint inspection is recommended. When correction is not obtained through local (city/county/state) public health departments, the MEDICAL AUTHORITY or designated representative recommends to the installation or senior tactical commander that the FOOD ESTABLISHMENT be placed off limits.

8-402.30 Inspection of atypical food service establishments[†]

Service-specific sanitary requirements for evaluation of food service operations at CHILD CARE FACILITIES are contained in AFI 48-117, AR 608-10, and OPNAVINST 1700.9E. The principles of food safety presented in this publication are used when evaluating food operations that do not fit the definition of a FOOD ESTABLISHMENT.

8-402.40 Installation farmers market[†]

- (A) Guidance for administration of a farmers market on military installations is provided in DOD or Service policy.
- (B) TEMPORARY FOOD ESTABLISHMENTS operated at a farmers market require preapproval and inspection as specified under \P 8-301.11(A).

8-403 Report of findings

8-403.10 Documenting information and observations

The REGULATORY AUTHORITY shall document inspection findings using DD Form 2973, *Food Operation Inspection Report*, as specified in paragraph 8-6.b. and Appendix E.

- (A) Fill in all administrative information about the FOOD ESTABLISHMENT and record the inspection's *Start time* and the *Inspector's* identification information. Upon completion of the inspection, record the *End time*.
- (B) Specific factual observations of noncompliant inspection items or deviations from this publication will be identified by a check mark next to the corresponding item number and by providing specific details in the Remarks section regarding the observed conditions. Repeat findings from the last inspection report will also be identified by a check mark in the appropriate column for the corresponding item number. Observations that are corrected onsite (COS) are annotated in the Remarks section of the form. CRITICAL violations, to include IHHs, are identified by an asterisk (*) next to the item number or appropriate provision number within the item grouping.

8-403.20 Inspection ratings[†]

- (A) Except as specified in \P (C) of this section, the inspection rating for Preoperational and Routine food sanitation inspections that are documented by the REGULATORY AUTHORITY using DD Form 2973, Food Operation Inspection Report, or DD Form 2974, Tactical Kitchen Food Sanitation Inspection, are identified as "Fully Compliant," "Substantially Compliant," "Partially Compliant," or "Noncompliant."
 - (B) The scoring criteria presented in Table 8-4 is used to assign the inspection rating.
- (C) A letter-grading or color-grading system that is similar to the system applied by the local health department outside of the installation may be implemented by the REGULATORY AUTHORITY in lieu of the inspection rating specified in \P (A) of this section. The following implementation guidelines apply—
 - (1) A formal Policy should be published announcing the use of the letter- or color-grading system.
- (2) The scoring criteria used to establish the letter or color grade must be consistent with the scoring criteria delineated in Table 8-4.
- (3) The letter or color grade is applied for all Routine inspections conducted within the REGULATORY AUTHORITY'S inspection jurisdiction and as specified in ¶ (D) of this section.
 - (4) The scoring criteria presented in <u>Table 8-4</u> must be used and may not be modified or waived.
- (5) At a minimum, the inspection rating is displayed and may be used in combination with the corresponding color-code or letter grade.
 - (D) Follow-up inspection ratings are awarded IAW the following guidelines:
 - (1) A Preoperational inspection Follow-up is rated as specified in ¶¶ (A) and (B) of this section.
- (2) Routine inspection follow-ups are assessed as "pass" or "fail"—*currently not indicated on official inspection forms*—and the resulting facility inspection rating is awarded as follows—
- (a) A passing score for a Follow-up inspection requires correction of all CRITICAL violations identified during the Routine inspection and on the spot correction of any new CRITICAL violations observed during the Follow-up inspection. A passing score is also awarded when the only remaining uncorrected violations are NONCRITICAL.

- (b) Except for a Preoperational inspection follow-up, as specified in Subparagraph (D)(1) of this section, the rating from a Follow-up inspection meeting the "pass" criteria specified in Subparagraph (D)(2)(a) of this section essentially converts the "Noncompliant" rating of the original Routine inspection to a "Partially-Compliant" inspection rating.
- (c) A failing score for a Follow-up inspection is awarded when there are CRITICAL violations found that remain uncorrected at the conclusion of the Follow-up inspection. When the Follow-up inspection yields a failing score, the inspection remains posted as "Noncompliant."

Table 8-4. Inspection ratings †

Table 8-4. Inspection ratings						
Inspection Rating	Letter Grade Equivalent	Color Code Equivalent		Criteria		
Fully Compliant	A	Green	Green	 No violations observed; or Four or less Noncritical violations COS¹ 		
Substantially Compliant	В	Green	Amber	 No Imminent Health Hazard (IHH)²; Two or less Critical violations COS; and/or Five or less Noncritical violations 		
Partially Compliant	С	Amber	Red	 No IHH; Three or more Critical violations COS; and/or Six or more Noncritical violations 		
Noncompliant	F	Red	Black	 IHH is present; or Any Critical violations not COS		

¹ Presence of any Critical finding that cannot be corrected onsite results in a Noncompliant rating.

8-403.30 Specifying time frame for corrections and follow-up inspection

- (A) The REGULATORY AUTHORITY annotates on the inspection document the time frame for correction of violations as specified under §§ 8-404.11 (Imminent Health Hazards), 8-405.11 (Critical violations), and 8-406.11 (Noncritical violations), and the date in which a follow-up inspection will be conducted as specified in \P (B) of this section.
- (B) A follow-up inspection is required for FOOD ESTABLISHMENTS rated as Noncompliant. Follow-up inspections shall be conducted no later than 5 <u>calendar</u> days following the Noncompliant inspection.

8-403.40 Issuing report and obtaining acknowledgment of receipt

Signatures on the inspection report provide acknowledgment that a formal inspection was conducted by the REGULATORY AUTHORITY and a summary of findings as specified under \P 8-402.13(D) and (E) was provided to the PIC or food establishment manager at the conclusion of the inspection.

- (A) *Inspections conducted at food service establishments*. Inspection reports are signed and distributed to the PIC or manager according to the following:
- (1) The REGULATORY AUTORITY and PIC or management representative signs the original hard copy inspection form at the conclusion of the inspection. The REGULATORY AUTHORITY retains the original form and a copy is provided to the PIC or manager representative before the inspector departs the facility; or
- (2) The REGULATORY AUTHORITY signs the electronic document or, if completed in DOEHRS, marks the inspection survey "complete" at the conclusion of the inspection and—

² Presence of an uncontrolled condition that constitutes an IHH results in a Noncompliant rating.

- (a) Attains a capture signature from the PIC or management representative on the digital form at the time of inspection and then provides an electronic copy of the signed form within 24 hours or the next business day following the inspection; or
- (b) Provides a printed copy of the digital report and obtains a handwritten signature from the PIC or management representative within 24 hours or the next business day following the inspection. A copy of the signed report is scanned and uploaded to the corresponding survey file in DOEHRS, when applicable, and retained on file at the REGULATORY AUTHORITY'S office according to military recordkeeping procedures.
- (B) Sanitary inspections conducted by Army Veterinary Services. For sanitary inspections conducted at retail stores by Army Veterinary Service personnel and documented using the Food Operation Inspection Report, a copy of the final report is provided to the PIC no later than the end of the next business day following the inspection. Upon conclusion of the inspection, the REGULATORY AUTHORITY—
 - (1) Reviews the preliminary report findings with the PIC;
 - (2) Requests a signed acknowledgment of the review; and
 - (3) Provides a copy of the signed preliminary report to the PIC upon request.
- (C) *Refusal to sign.* When the FOOD ESTABLISHMENT PICor manager refuses to sign acknowledgment of receipt of the inspection document, the REGULATORY AUTHORITY—
 - (1) Informs the PERSON who declines to sign that—
 - (a) An acknowledgment of receipt is not an agreement with findings,
- (b) Refusal to sign an acknowledgment of receipt will not affect the FOOD ESTABLISHMENT PIC's obligation to correct the violations noted in the inspection document within the time frame specified, and
- (c) Refusal to sign an acknowledgment of receipt is noted in the inspection document and conveyed to the REGULATORY AUTHORITY's historical record for the FOOD ESTABLISHMENT; and
 - (2) Makes a final request that the PIC sign an acknowledgment receipt of inspectional findings.

8-403.50 Public information

Except as specified in § 8-202.10, the REGULATORY AUTHORITY and the PIC shall treat the inspection report as a public document and shall make it available as specified under ¶ 8-304.11(J) for disclosure to a PERSON who requests it as provided in LAW. This provision does not prohibit the INSTALLATION COMMANDER from establishing a program to publish inspection results; nor does it require posting of the inspection results in the facility.

8-404 Imminent health hazard

8-404.11 Ceasing operations and reporting

- (A) Except as specified in ¶ (B) of this section, a FOOD ESTABLISHMENT shall immediately discontinue operations and notify the REGULATORY AUTHORITY if an IHH may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service (greater than 2 hours), 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 FOOD ESTABLISHMENT need not discontinue operations in an area of an establishment that is unaffected by the IHH.

8-404.12 Resumption of operations

- (A) If operations are discontinued due to an IHH as specified under § <u>8-404.11</u> or otherwise according to LAW, the PIC shall obtain approval from the REGULATORY AUTHORITY before resuming operations.
- (B) Raw or RTE TCS FOOD that has been exposed to temperatures outside the SAFE TEMPERATURE ZONE as specified in § 3-501.16 for less than 4 hours, but has not been exposed to any known contaminants, may be served with approval of the REGULATORY AUTHORITY, provided it is—†
 - (1) Rapidly reheated as specified in § 3-403.11 for raw or RTE TCS FOOD; or

(2) Reconditioned based on the risks associated with the particular FOOD without compromising the health of the CONSUMER as specified in § 3-701.11.

8-405 Critical deficiencies, correction

8-405.11 Timely correction

- (A) Except as specified in ¶ (B) of this section, a FOOD ESTABLISHMENT shall at the time of inspection correct or mitigate all CRITICAL violations by taking appropriate actions to modify or eliminate conditions that contribute to the CRITICAL hazard. Corrective actions shall be implemented 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 5 calendar days after the inspection, for the FOOD ESTABLISHMENT to either mitigate the CRITICAL conditions or correct the CRITICAL violation and HACCP PLAN deviations.
- (C) A CRITICAL violation that is mitigated at the time of inspection by removing or altering the conditions in the operation that resulted in the CRITICAL hazard is considered to be COS for the inspection. The mitigation strategy should remain in place until a permanent remedy (for example, repair) is completed to prevent reoccurrence of the CRITICAL violation.

8-405.20 Verification and documentation of correction

- (A) After observing at the time of inspection corrective actions for a CRITICAL or NONCRITICAL deficiency or HACCP PLAN deviation, the REGULATORY AUTHORITY shall enter the violation and information about the corrective action on the inspection report form.
- (B) As specified under ¶ <u>8-405.11(B)</u>, after receiving notification that the PIC has corrected a CRITICAL deficiency 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 a Follow-up inspection report, and enter the report in the REGULATORY AUTHORITY's records.

8-406 Noncritical deficiencies, correction

8-406.10 Elevating noncritical to critical, prohibition[†]

The REGULATORY AUTHORITY may not elevate NONCRITICAL findings to CRITICAL ITEM status regardless of the number of NONCRITICAL violations found during the inspection or the number of times a specific NONCRITICAL violation has been recorded in the past.

8-406.11 Time frame for correction

- (A) Except as specified in \P (B) and (C) of this section, a FOOD ESTABLISHMENT shall initiate actions to correct NONCRITICAL violations at the time of inspection.
- (B) Except as specified in \P (C) of this section, all NONCRITICAL deficiencies shall be corrected by the date and time specified by the REGULATORY AUTHORITY, but no later than 30 calendar days after the inspection.
- (C) The REGULATORY AUTHORITY may approve a compliance schedule that extends beyond the time limits specified under \P (B) of this section if a written schedule of compliance is submitted by the FOOD ESTABLISHMENT and no health HAZARD exists or will result from allowing an extended schedule for compliance.

8-5. Prevention of foodborne disease transmission by employees

8-501 Investigation and control

8-501.11 Obtaining information: personal history of illness, medical examination, and specimen analysis

- (A) 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—
- (1) Securing a confidential medical history of the FOOD EMPLOYEE or CONDITIONAL EMPLOYEE suspected of transmitting disease or making other investigations as deemed appropriate; and
- (2) Requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected FOOD EMPLOYEE or CONDITIONAL EMPLOYEE.
- (B) For deployments where adequate civilian medical support, including a medical laboratory, is not available, the senior MEDICAL AUTHORITY (Theater Surgeon/Task Force Surgeon) shall be consulted regarding the use of U.S. medical resources for this purpose. †

8-501.20 Restriction or exclusion of food employee, or suspension of operation

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 PIC 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) Coordinating with the installation or senior tactical commander (holding command authority) to suspend operation of the implicated FOOD ESTABLISHMENT.†

8-501.30 Restriction or exclusion order

Based on the findings of the investigation as specified in § <u>8-501.11</u> and to control disease transmission, the REGULATORY AUTHORITY may issue an order (in a formal letter or memorandum) of RESTRICTION or EXCLUSION to a suspected FOOD EMPLOYEE or the PIC without prior warning if the order—

- (A) States the reasons for the RESTRICTION or EXCLUSION that is ordered;
- (B) States the criteria that the FOOD EMPLOYEE or PIC shall provide in order to demonstrate that the reasons for the RESTRICTION or EXCLUSION are eliminated; and
- (C) States that the suspected FOOD EMPLOYEE or the PIC may request an appeal by the MEDICAL AUTHORITY or designated representative by submitting a timely written request as provided in LAW; and
- (D) Provides the name and address of the REGULATORY AUTHORITY representative to whom a request for an appeal 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.

8-6. Inspection guidance[†]

Food sanitation inspections are conducted by military Preventive Medicine, Public Health, and Veterinary Services personnel as stated in paragraph *a*. of this section. Other military personnel tasked to perform food sanitation inspections will undergo comprehensive on-the-job training to ensure competency. Service-specific regulations, as referenced in paragraphs <u>8-8.a.-c.</u>, should be consulted regarding collaboration and communication of inspection activities between Preventive Medicine/Public Health and Veterinary Services personnel at the installation level.

a. Authorized inspectors

The following Service-specific officer and enlisted job series personnel are generally recognized as qualified to conduct inspections based on the education received during their occupational specialty training. This list is not all-inclusive; DOD Civilians and contracted employees with food safety education and associated certification are considered qualified. Additionally, Joint-basing, deployment, or absence of local public health assets may result in designation of qualified inspectors that are approved by the MEDICAL AUTHORITY to perform in an official capacity on vessels, installations, or at facilities not affiliated with their assigned Service. *This list is not intended to delineate jurisdiction of inspection authority by installation or facility type*.

- (1) *Air Force*. Air Force Public Health Officers, Public Health Technicians, Flight Surgeons, and Independent Duty Medical Technicians.
- (2) *Army*. Preventive Medicine Technicians and NCOs; Environmental Science and Engineering Officers; Veterinarians, Veterinary Warrant Officers, and Veterinary NCOs.
- (3) *Navy and Marine Corps*. Environmental Health Officers; Preventive Medicine Technicians; Independent Duty Corpsmen; or other Hospital Corpsmen authorized by the Medical Authority.
 - b. Inspection forms.
- (1) The *Food Operation Inspection Report* form prescribed in this publication is used by all Services when conducting sanitary inspections at FOOD ESTABLISHMENTS. Inspection of military units operating tactical feeding systems should be documented using DD Form 2974. Procedures for using these forms are provided in Appendix E.
- (2) FOOD ESTABLISHMENT inspections may also be documented through the Defense Occupational and Environmental Health Readiness System (DOEHRS) by means of the *Food Operation Inspection Report*, which replaced the *Food Establishment Survey Report*.
- (a) DOEHRS, available at https://doehrs-ih.csd.disa.mil/, is a DOD data repository and requires user registration for access to the Web site.
- (b) In order to facilitate data mining and queries in DOEHRS, direct keystroke entry on applicable inspection reports is required using a desktop computer or DOEHRS-Mobile platform.
- (c) When the DOEHRS Web site is unavailable, inaccessible, or not practical for direct data entry during an inspection, the manual forms specified in Subparagraph 8-6.b.(1) should be used.
 - c. Routine inspections.
- (1) Routine inspections are comprehensive in nature and shall examine or account for the following aspects of the FOOD operation:
- (a) Food receipt, storage, expiration dates, and approved sources. Actions include evaluation of food delivery conveyance, verification of approved sources, review of product shelf life, and assessment of storage and product wholesomeness conditions.
- (1) Army Veterinary inspectors conduct receipt inspections of food deliveries and conduct periodic surveillance inspections of subsistence while in storage at Army, Navy, and Marine Corps installations.
- (2) Close collaboration between Army Veterinary Services and Army and Navy Preventive Medicine is needed due to shared interests in this aspect of inspection. Army and Navy Preventive Medicine inspectors should collaborate with Veterinary Services personnel to review recent delivery receipt inspections and discuss any unapproved sources found before conducting a sanitary inspection. This collaboration establishes consistency in the inspection program and reduces the likeliness of conflicting information reported by Preventive Medicine and Veterinary Services to food establishment managers.
 - (b) Food preparation and cooking.
 - (c) Hot/cold holding (includes active serving lines).
 - (d) Warewashing.
 - (e) General facility sanitation.
 - (f) Condition of physical facilities.
 - (g) Employee hygiene & training.
- (h) Components of the food operation that cannot be adequately assessed due to inactivity within the operation at the time of inspection should be evaluated within 30 days of the Routine inspection using a Walkthrough inspection. Actions must be taken when scheduling future Routine inspections to target a date and time that allows optimum observance of operational activities.

- (2) Routine inspections are conducted with the PIC or the FOOD ESTABLISHMENT's designated representative and may include other personnel such as the FACILITY ENGINEER or COR. This is especially important when there are chronic problems associated with the physical facilities or frequent occurrence of violations at contracted operations.
- (3) The inspector may need to visit the operation at various timeframes throughout the day in order to assess the majority of the operational components specified in Subparagraph c.(1) of this section.
- (4) An appropriate amount of time must be planned for conducting Routine inspections. Large, complex operations, such as dining facilities and community clubs, may require three or more hours (consecutive or nonconsecutive) to complete the inspection an may require scheduling the inspection after the inspector's traditional duty hours (that is, evenings, weekends, and holidays) to properly assess the entire operation.
- (5) A Routine inspection is typically conducted within a single calendar day; exceptions apply to inspection during a "midnight meal" or "third shift" which crosses over into a new calendar day. The inspector does not need to evaluate each work shift during a single inspection. The inspection program must be diversified as specified under § 8-402.14 to allow evaluation of most work shifts associated with the operation (that is, daytime, evening, weekday, and weekend) at least once during the year.
 - d. Walk-through inspections.
- (1) Walk-through inspections may be initiated by the REGULATORY AUTHORITY or at the request of the FOOD ESTABLISHMENT PIC.
 - (2) Walk-through inspections are cursory in nature and may include:
- (a) Spot checking general sanitation conditions, time/temperature controls, and employee hygienic practices.
 - (b) Evaluating aspects of the operation requested by the PIC for consultative support.
- (c) Evaluating aspects of the operation that could not be assessed during the last Routine inspection due to operational inactivity.
- (3) Walk-through inspections are documented using DD Form 2973, a memorandum for record, or other document, and do not generate an inspection rating, except as specified in Subparagraph d.(5) of this section.
- (4) Findings from a Walk-through inspection are not formally reported through command or official reporting channels unless required by local reporting protocols or requested by the FOOD ESTABLISHMENT PIC, the COR, or the KO.
- (5) If an IHH is discovered or if a CRITICAL deficiency is found and not corrected onsite, the REGULATORY AUTHORITY may convert the inspection to a formal, Routine inspection, initiate action, as specified under § 8-404.11, and report findings, as specified in Part 8-7, as applicable.
- (6) Walk-through inspections that are converted to a Routine inspection may replace the next scheduled Routine inspection.
- e. Follow-up and complaint inspections. Follow-up and Complaint inspections are typically limited in focus, depending on the circumstances triggering the inspection; it is the REGULATORY AUTHORITY's discretion to conduct a comprehensive assessment of the FOOD ESTABLISHMENT.
- (1) Follow-up inspections. Follow-up inspections are required, as specified under $\P 8-403.30(B)$ and 8-404.12(A), following a Noncompliant inspection rating or verification of a reported IHH at the FOOD ESTABLISHMENT. A Follow-up inspection conducted after a Noncompliant inspection rating is intended to verify corrective actions were completed for CRITICAL ITEMS that were not corrected at the time the original inspection was conducted.
 - (a) The inspection is documented using DD Form 2973.
- (b) Follow-up inspections are conducted until all corrective actions for IHHs or CRITICAL ITEMS noted on the last Routine inspection have been completed.
 - (2) Complaint inspections.
- (a) Investigation of a customer complaint involving a public health concern at a FOOD ESTABLISHMENT shall be conducted within 24 hours of the reported issue or as soon as reasonably feasible based on the REGULATORY AUTHORITY's mission priority and operating tempo.
- (b) During the investigation, the REGULATORY AUTHORITY has the discretion to dismiss the complaint due to insufficient findings, or conduct a Complaint-driven inspection of the FOOD ESTABLISHMENT.

- (c) Complaint inspections may be documented using DD Form 2973, or in an informal memorandum (memorandum for record). Whenever possible, the customer presenting the original complaint will be contacted by the REGULATORY AUTHORITY and apprised of the inspection results.
 - (3) Report distribution. Report distribution is conducted as specified in Part 8-7.
 - f. Self-evaluations.
- (1) Self-evaluations conducted by the FOOD ESTABLISHMENT may be documented using DD Form 2973, or any applicable retail self-evaluation sanitary checklist.
- (2) Self-evaluations are comprehensive and assess employee hygienic practices; status of internal food temperatures during cooking, holding, and storage; status of ambient temperatures inside hot and cold holding/storage units; sanitizing temperature or chemical concentration; condition of physical facilities and equipment; and status of work orders.

8-7. Report distribution[†]

- a. General distribution.
 - (1) Army.
- (a) Copies of all Routine and Follow-up inspection forms and reports, and select Complaint inspection reports specified in Subparagraph 8-6.e.(2)(c), shall be directed to the PIC's unit commander or supervisor and distributed as specified under paragraphs b.-g. of this section. A courtesy copy of inspections conducted at retail store FOOD concessions (that is, contracted concessions located inside the commissary, or food service operations inside the Mini-mart or Express) should be provided to the Preventive Medicine or Veterinary Services office, as appropriate, to promote collaboration and ensure visibility of facility status or conditions.
- (b) Significant repeated discrepancies or Noncompliant ratings shall be reported to the next higher command level having jurisdiction over the FOOD ESTABLISHMENT, for example, the INSTALLATION COMMANDER.
- (c) Where corrections of CRITICAL or repeated deficiencies are not obtained or are beyond the capability of the local INSTALLATION COMMANDER or tactical commander, the conditions noted and recommended corrective actions will be summarized in a memorandum to the Command Surgeon. A copy of the completed and signed inspection form shall be attached to the memorandum.
- (d) Applicable portions or copies of the inspection form shall be provided to the local installation support activities (COR, Engineers/Directorate of Engineering and Housing, Director of Logistics) whenever coordination is needed for deficiency correction.
- (e) A copy of the original signed inspection form is provided to the PIC upon conclusion of a food service inspection conducted by Preventive Medicine.
- (2) Air Force. The Air Force report distribution should be conducted IAW the most current version of AFI 48-116.
 - (3) Navy. The completed DD Form 2973, shall be distributed as follows:
- (a) Original to the commanding officer having direct responsibility for the FOOD ESTABLISHMENT.
 - (b) Copy to the PIC.
 - (c) File copy retained for the Preventive Medicine Authority.
 - b. Troop dining food establishments.
- (1) Except as specified in Subparagraph b.(4), this section, when rating troop dining FOOD ESTABLISHMENTS, information copies of all Routine, Follow-up, and select Complaint inspection forms shall be forwarded to the appropriate installation Food Program Manager.
- (2) When a contractor-operated FOOD ESTABLISHMENT is rated, the information copies of all Routine, Follow-up, and select Complaint inspection forms shall be forwarded to the installation Food Program Manager and the appropriate COR.
- (3) To enhance awareness of contractor-operated FOOD ESTABLISHMENTS and maintain an open communication dialogue, the COR should forward copies of all evaluations (that is , self-evaluations and quality assurance evaluations) involving FOOD safety and sanitation deficiencies at contractor-operated FOOD ESTABLISHMENTS to the REGULATORY AUTHORITY.

- (4) Air Force report distribution should be conducted IAW the most current version of AFI 48-116.
- c. AAFES/NEX/MCX food establishments. When an inspection of any AAFES, NEX, or MCX FOOD ESTABLISHMENT or affiliated FOOD concessionaire results in a Noncompliant rating, the inspecting office, after coordination with command channels, shall send a copy of the report to the appropriate AAFES/NEX General Manager and the AAFES Staff Veterinarian as follows:
- (1) AAFES food establishments. Information copies of all Noncompliant inspections for AAFES FOOD ESTABLISHMENTS within CONUS, the Pacific, and Europe shall be forwarded to the AAFES Staff Veterinarian via organizational e-mail account at: food-drug.safety@aafes.com. Alaska, Panama, and Puerto Rico are included in CONUS, and the Pacific includes Hawaii, Japan, Korea, and other Pacific installations.
- (2) NEX food establishments. Information copies of all Noncompliant inspections for NEX FOOD ESTABLISHMENTS within CONUS, the Pacific, and Europe shall be forwarded to: NEX General Manager and Director Food Service Program, Navy Exchange Service Command, 3280 Virginia Beach Boulevard, Virginia Beach, VA 23452-5724. The Pacific includes Hawaii, Japan, Guam, and other Pacific installations.
- (3) MCX food establishments. Information copies of all Noncompliant inspections for MCX NEX FOOD ESTABLISHMENTS within CONUS, the Pacific, and Europe shall be forwarded to: Marine Corps Community Service/MCX General Manager and Branch Head Food & Hospitality & Entertainment Headquarters, United States Marine Corps, 3044 Catlin Avenue, Quantico, VA 22134-5099. The Pacific includes Hawaii, Japan, Guam, and other Pacific installations.
- d. NAF food establishments. Information copies of Noncompliant inspection reports of NAF dining FOOD ESTABLISHMENTS (officer, noncommissioned officer, community, and enlisted clubs, except AAFES) shall be forwarded to the installation Director of Personnel and Community Activities.
- *e. DeCA food establishments* When an inspection of a DeCA FOOD ESTABLISHMENT results in a Noncompliant rating, the inspecting office, after coordination with appropriate command channels, shall send a copy of the report to the DeCA, Consumer Safety Officer via email at foodsafety4@deca.mil (or phone 804-734-8000 extension 48364 for assistance), from which it will be routed to the appropriate DeCA Area Consumer Safety Officer.
- *f. Vending machine operations, contracted.* Information copies of Noncompliant reports of VENDING MACHINES shall be forwarded to the owner and the VENDING MACHINE KO.
 - g. Documents forwarded to military public health organization.
- (1) Information copies of all FOOD ESTABLISHMENT (nonretail store) Noncompliant inspection reports and APPROVED FOOD ESTABLISHMENT VARIANCES shall be sent to the appropriate military Public Health organization:
 - (a) Air Force. Noncompliant inspection reports are routed IAW AFI 48-116.
- (b) Army. U.S. Army Public Health Center. Electronic mail communication is preferred. Refer to Appendix B for contact information.
- (c) Navy and Marine Corps. Submission of noncompliant inspection reports is optional but highly encouraged. Reports should be submitted to the Navy and Marine Corps Public Health Center. Electronic mail communication is preferred; contact the Navy representative at the number provided in Appendix B to obtain appropriate email address.
- (2) Submittal of Noncompliant reports to the Service's public health organization is for informational purpose only; actions regarding noncompliance are managed by the REGULATORY AUTHORITY at the installation level. Forwarded reports are evaluated by the respective military public health organizations to determine necessary changes or clarification to this publication, trends in FOOD safety and sanitation RISK factors, and to assist in developing training programs.
- (3) Successful submission of a completed DOEHRS food sanitation inspection report to the DOEHRS Repository using DOEHRS-Mobile or direct keystroke entry in the DOEHRS Web site shall be considered as compliance with this requirement. Reports that are scanned and posted to DOEHRS as a PDF file must be submitted as specified in Subparagraph g.(1) of this section.

8-8. Responsibilities[†]

- a. Air Force. Responsibilities for oversight and management of food sanitation activities at Air Force installations are provided in AFI 48-116.
- *b. Navy and Marine Corps.* The Manual of the Medical Department, NAVMED P-117, assigns the responsibility for oversight and management of food sanitation activities. In accordance with BUMED 6240.12 Series, effective 1 January 2018, inspection data must be entered in DOEHRS-IH.
- c. Army. Responsibilities for oversight and management of food sanitation and safety program activities are as follows:
- (1) The staff veterinarian at major Army Commands, medical regions, and installation medical facilities serves as the MEDICAL AUTHORITY designated representative, and veterinary officers and qualified enlisted inspectors will serve as REGULATORY AUTHORITY for—
- (a) Conducting necessary sanitary inspections or audits of FOOD ESTABLISHMENTS; investigating reports of FOOD infested, ADULTERATED, or damaged by pests; and reporting damage as per the guidance in AR 40-657/NAVSUPINST 4355.4F/MCO P10110.31G;
- (b) Conducting other inspections related to veterinary aspects of FOOD procurement; processing, storing, shipping, receiving, and distributing per AR 40-657/NAVSUPINST 4355.4F/MCO P10110.31G;
 - (c) Conducting HACCP PLAN verification at retail stores;
 - (d) Serving as the lead medical coordinator for FOOD DEFENSE; and
- (e) Advising the INSTALLATION COMMANDER of the food sanitation and food safety implications of military facilities and operations.
- (2) Preventive medicine officers and qualified enlisted personnel serving as the MEDICAL AUTHORITY's designated representative are the REGULATORY AUTHORITY that conducts the actions specified in paragraph 8-8.e. to ensure compliance with this publication.
- (3) FOOD ESTABLISHMENT inspection report data and food facility risk assessment survey data are entered in DOEHRS. When inspection data is initially documented on paper or electronically using a fillable form rather than direct data entry in the DOEHRS, the original signed report shall be scanned and uploaded to the survey file when created in DOEHRS.
 - (a) Veterinary Services records are entered under the Food Safety Module.
 - (b) Preventive medicine records are entered under the Environmental Health Module.
 - d. Installation commander. The INSTALLATION COMMANDER—
 - (1) Maintains the sanitary control of all FOOD and BEVERAGES served or dispensed at the installation.
- (2) Ensures that FOOD and BEVERAGES are served only through APPROVED FOOD ESTABLISHMENTS or VENDING MACHINES and operations.
- (3) Ensures that the construction, alteration, or modifications of FOOD ESTABLISHMENTS are accomplished only after the plans and specifications have been reviewed and APPROVED by the MEDICAL AUTHORITY or designated representative. Upon completion of such projects, ensures that the FOOD ESTABLISHMENT does not begin operations without a satisfactory onsite evaluation by the MEDICAL AUTHORITY or designated representative.
- (4) Ensures the FOOD ESTABLISHMENT's supervisory personnel and FOOD EMPLOYEES are trained as specified in § 2-102.20 and Part 2-5.
- (5) Ensures that all individuals handling or serving FOOD have received medical clearances as required in Part 2-2.
 - e. Medical Authority. The MEDICAL AUTHORITY or designated representative—
- (1) Advises the INSTALLATION COMMANDER of the food sanitation and food safety implications of military operations.
- (2) Conducts inspections of FOOD ESTABLISHMENTS to ensure compliance with this publication and reference documents.
 - (3) Determines the requirements for providing medical examinations of FOOD EMPLOYEES.
- (4) Conducts medical examinations as required in <u>Part 2-2</u> and ensures the requirements of § <u>2-201.13</u> are followed if medical examinations of contract FOOD EMPLOYEES are provided at a contractor's cost by the MEDICAL AUTHORITY.

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- (5) Conducts, coordinates, and provides technical guidance, assistance, and education to reduce the potential of a foodborne illness occurrence.
- (6) Reviews plans; blueprints; specifications; intended menus; anticipated volume of FOOD to be stored, prepared, sold, or served; and HACCP PLANS, when applicable, for all new construction, renovation, or modification of existing FOOD ESTABLISHMENTS, EQUIPMENT, and UTENSILS.
 - (7) Conducts epidemiological investigations of suspected FOODBORNE DISEASE OUTBREAKS.
- (8) Ensures that preventive medicine and public health personnel conducting inspections of FOOD ESTABLISHMENTS and assisting FOOD ESTABLISHMENT personnel in matters of FOOD safety and sanitation are qualified as specified in §§ 2-102.20 and 8-402.10 and paragraph 8-6.a.
- (9) Ensures that preventive medicine, public health, and veterinary services personnel have completed training as specified in § 2-504.10 and ¶ 2-501.11(B), or performs assigned tasks under direct supervision of an individual certified in food safety and as specified in Subparagraph e.(9) of this section.
- (10) Participates in integrated pest management (IPM) programs through pest surveillance of insects, rodents, and other pests in food products and FOOD ESTABLISHMENTS, and provides results to pest management personnel.
- (11) Provides guidance to FOOD ESTABLISHMENT personnel on nonchemical control measures to prevent or control pests; notifies pest management personnel when nonchemical techniques have failed to control the presence or infestations of insects and when supplementary chemical control measures may be needed.
- (12) Coordinates joint evaluations, inspections, training programs, and epidemiological investigations with the local U.S. Army Veterinary Services personnel, and/or local, State, or Federal agencies, as applicable.
 - f. Food program manager.
- (1) The installation-level Food Program Manager may be a Navy Food Management Team Officer, a Brigade or Corps Food Advisor, or a Theater Food Advisor.
 - (2) The installation food program manager—
- (a) Ensures food service contracts include requirements that contractor PIC and FOOD EMPLOYEES, including contracted KP personnel, receive required sanitation training specified in Part 2-5 of this publication;
- (b) Assists the COR, in coordination with the MEDICAL AUTHORITY or designated representative, in developing contract food service sanitation and food safety standards and evaluating contractor performance of food service sanitation and safety requirements;
- (c) Provides the REGULATORY AUTHORITY with local distribution and dissemination instructions for inspection reports and evaluations of contract food operations;
- (d) Ensures that military personnel detailed as an additional duty to perform other than primary food preparation duties, such as KP, receive adequate training to perform their appointed duties. Appointed duties may include some or all of the following tasks: pot and pan washing and SANITIZING, vegetable preparation, cleaning and SANITIZING food service EQUIPMENT and FOOD CONTACT SURFACES, and basic housekeeping;
- (e) Ensures that additional duty military KP supervisors, in addition to completing the training for military KP as specified in Subparagraph f(2)(d) of this section, receive appropriate training in basic food safety and sanitation as specified in § 2-504.30 and that such training is documented as specified under § 2-505.11 prior to the detail assignment; and
- (f) Provides the REGULATORY AUTHORITY with a list of military KP supervisors who have completed training as specified in Subparagraph f(2)(e) of this section.
 - g. Food establishment manager. The FOOD ESTABLISHMENT manager—
- (1) Provides safe FOOD prepared under clean sanitary conditions and in compliance with all provisions of this publication;
- (2) Shall be properly trained as specified under § 2-102.12 on the principles of food service sanitation and food safety and demonstrates knowledge of foodborne disease prevention, application of the HACCP principles, and the requirements of this publication as specified under § 2-102.11;
- (3) Ensures that all assigned FOOD EMPLOYEES are trained as specified in <u>Part 2-5</u> of this publication. Training is a condition of employment for FOOD EMPLOYEES, and it is the FOOD ESTABLISHMENT's fundamental responsibility to plan, coordinate, and fund the requisite training to ensure compliance with this

publication. The installation MEDICAL AUTHORITY provides guidance and approves training to be executed by the REGULATORY AUTHORITY when requested and operationally feasible but is not financially responsible for a FOOD ESTABLISHMENT's training needs.

- (4) Ensures that all FOOD EMPLOYEES comply with the provisions of this publication; and
- (5) Maintains a copy of this publication at each FOOD ESTABLISHMENT. VENDING MACHINE locations and MOBILE FOOD ESTABLISHMENTS are exempt from this requirement.

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CHAPTER 9

FIELD AND DEPLOYMENT FOOD OPERATIONS

9-1. General provisions

9-101 Introduction and objective

9-101.10 High-risk environments and highly susceptible populations[†]

- (A) Personnel operating in a deployment setting in support of combat, stability, contingency, humanitarian, or similar operations and exercises, to include food service conducted on an air frame; a tactical training environment; or operations afloat are categorized as a HIGHLY SUSCEPTIBLE POPULATION.
- (B) Field feeding and operations specified in \P (A) of this section, especially in austere or high-risk environments, can allow FOOD to become vehicles in the transmission of communicable diseases, thus compromising the health and effectiveness of Service Members and decreasing unit (mission) readiness. Effective FOOD sanitation practices and requirements are considered a must in any type of food service environment, but alternative practices may be necessary in field feeding operations. This chapter provides guidance and basic requirements for FIELD FOOD OPERATIONS and FIELD FOOD SERVICE ESTABLISHMENTS in order to ensure FOOD safety and reduce the potential risk of foodborne illness.
- (C) Modifications to the guidance provided in this publication to meet unique circumstances associated with field operations should—
 - (1) Be coordinated between the PIC and the REGULATORY AUTHORITY;
- (2) Focus on real HAZARDS associated with FOOD and on the control procedures in place to minimize or eliminate associated HAZARDS;
- (3) Use a risk-based or HACCP PLAN to deviate from specific requirements if the HAZARDS associated with applicable FOOD are properly identified and if control mechanisms are in place to eliminate or minimize the HAZARDS; and
- (4) Ensure monitoring is conducted to identify when deviations are out of control and where HAZARDS may still exist.
 - (D) The MEDICAL AUTHORITY or designated representative may—
- (1) Impose additional requirements to protect against health HAZARDS related to the conduct of the FIELD FOOD SERVICE; or
- (2) Waive or modify requirements when HAZARDS are minimized or non-existent. Waivers or modifications are conducted by applying composite risk management and should be documented using appropriate risk management worksheets or forms with the signature of the risk decision authority designated for the level of residual risk.

9-102 Standards and conformance

9-102.10 Food, equipment, and facilities, management[†]

- (A) Except where specified in the sections of this chapter or in the Theater Policy applicable in the deployed setting or contingency area of operations, FIELD FOOD OPERATIONS, FIELD FOOD SERVICE ESTABLISHMENTS, and afloat food service operations incorporate the standards specified in Chapters 2-10 of this publication.
 - (B) Non-U.S. controlled FOOD ESTABLISHMENTS:

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- (1) Examples include North Atlantic Treaty Organization (NATO) contracted and host nation-operated facilities. U.S. military and Civilian personnel may be required to eat at these establishments when U.S. facilities are not available.
- (2) The MEDICAL AUTHORITY should establish a partnership with its host nation or coalition force counterpart to ensure force health protection.
- (3) The REGULATORY AUTHORITY should conduct joint inspections of FOOD ESTABLISHMENTS with its host nation or coalition force counterparts.
- (4) The REGULATORY AUTHORITY communicates inspection findings and concerns to the MEDICAL AUTHORITY for action.
- (5) A FOOD AND WATER RISK ASSESSMENT is conducted for local FOOD operations supporting deployed forces during short-term deployments, initial entry deployment, exercises, and other short-term operations conducted outside the U.S. or U.S. territories. The assessment, performed by preventive medicine and/or veterinary personnel, should be conducted prior to the intended use in order to identify, mitigate, and minimize RISK from intentional and unintentional contamination of FOOD.
 - (C) The following publications should be referenced as applicable—
 - (1) For FOOD operations governed by the U.S. military:
- (a) Army Tactics Techniques and Procedures (ATTP) 4-41 provides guidance for Army Field Feeding and Class I Operations;
 - (b) ATP 4-25.12 provides guidance for Unit Field Sanitation Teams.
 - (c) NAVMED P-5010-6, Water Supply Afloat.
 - (d) NAVMED P-5010-9, Preventive Medicine for Ground Forces.
- (e) Pamphlet, Food Service Equipment and Field Feeding Systems, DOD Combat Feeding Directorate, Natick Soldier Research Development & Engineering Center, http://nsrdec.natick.army.mil and http://nsrdec.natick.army.mil/media/print/FSE_3ED.pdf.
- (2) For FOOD operations governed by Coalition forces, consult NATO Standardization Agreement (STANAG) 2550, Food Safety and Defense for Deployed Operations, STANAG 2982, Essential Field Sanitary Requirements, and NATO Allied Medical Publication (AMedP)-25, Minimum Standards of Food Safety and Hygiene in Deployment.
- (3) For FOOD operations governed by other coalition partners, for example, a DFAC under contract through a country other than the United States, consult the CODEX Alimentarius (international standard for food) available at http://www.codexalimentarius.org/Standards. These facilities are normally inspected by public health assets from the country in which the food service contract was awarded and are regulated under STANAG 2550 or the applicable CODEX Alimentarius.

9-102.11 Minimum operational requirements*†

At a minimum, FIELD FOOD OPERATIONS and FIELD FOOD SERVICE ESTABLISHMENTS shall—

- (A) Ensure handwashing facilities are provided at FOOD preparation and serving areas and at latrines designated for FOOD EMPLOYEES.
- (B) Provide a sanitation center or dishwashing line that is capable of cleaning and SANITIZING field feeding components, EOUIPMENT, and UTENSILS.
- (C) Provide a safe and adequate supply of DRINKING WATER through an APPROVED system as specified under § 9-301.11.
- (D) Collect, store, and dispose of solid waste in a manner to minimize insect and rodent attraction. For example, bury, incinerate, return to the forward supply point, or dispose per local requirements. ^N
- (E) Collect, store, and dispose of liquid wastewater. Examples of field-expedient methods, such as soakage pits, trenches, and grease traps, are provided in ATP 4-25.12. $^{\rm N}$
 - (F) Protect FOOD during storage as specified under §§ 3-305.11 and 9-204.11.
- (G) Provide adequate mechanical refrigeration or ice chests to maintain proper FOOD temperature as specified under § 9-502.11 for perishable rations (A-type rations) and TCS FOODS.
- (H) Use designated ration breakpoint areas for thawing frozen FOOD at SAFE TEMPERATURES, or provide adequate refrigeration support at the field feeding site as specified under $\P(G)$ of this section.

(I) Protect FOOD from potential contamination by transporting in clean, covered vehicles as specified under § 9-502.18.

9-103 Medical screening

9-103.11 Health and medical screening*†

- (A) Deployed military FOOD EMPLOYEES and food service EMPLOYEES aboard military Sealift Command vessels shall be evaluated IAW the applicable Command Medical Policy for the deployment area of operations and reportable symptoms and diseases specified in Part 2-2 of this publication. Military FOOD EMPLOYEES conducting FIELD FOOD OPERATIONS in a nondeployment setting shall comply with the health reporting requirements and work restrictions as specified in Part 2-2.
- (B) DOD Civilians, American expatriates/U.S. contracted personnel, host nation, and third country nationals employed in food service or DRINKING WATER processing/production for U.S. military forces shall be medically screened and cleared regarding the reportable symptoms and diseases as specified under Part 2-2 of this publication and IAW applicable Command Medical Policy for the deployment area of operations. *Policy for a theater of operations is generally developed by the Surgeon at the senior command level*. In the absence of a Theater policy, requirements for medical screening of personnel working in food service or DRINKING WATER processing or production shall be developed at the appropriate command level responsible for medical oversight in the area of operations or at the camp, forward operating base, or equivalent level.
- (C) The REGULATORY AUTHORITY shall verify the medical clearance of DOD Civilians, American expatriates/U.S. contracted personnel, host nation, and third country nationals serving as FOOD EMPLOYEES.

9-2. Design, construction, and installation

9-201 Site selection

9-201.11 Location[†]

Establishing and selecting a site for a field kitchen requires careful consideration of traffic flow; location of sleeping areas, toilets, and handwashing facilities; drainage; and potential insect and rodent control issues.

- (A) Unless operational requirements prohibit, FIELD FOOD OPERATIONS and FIELD FOOD SERVICE ESTABLISHMENTS shall be—
- (1) At least 300 feet (100 yards) from latrines, waste storage, and disposal areas, taking into account the gradient and the predominant wind direction (for example, uphill and upwind); and
 - (2) At least 90 feet (30 yards) from sleeping areas and bodies of water.
 - (B) Special considerations for the sanitation center or mess kit laundry include the following:
 - (1) Drainage from this operation shall be downhill from the food operation.
 - (2) Establish procedures to reduce potential insect and rodent harborage.

9-202 Physical Facilities

9-202.11 Field food operation, facilities[†]

- (A) The design and color of field kitchen (tactical system) walls, floors, and ceilings shall be considered acceptable when maintained in a serviceable condition as required by supporting tactical kitchen equipment technical manuals and as specified under § 9-203.11.
- (B) FIELD FOOD OPERATIONS conducted in a structure or shelter other than its prescribed tactical feeding system configuration shall be—
 - (1) In the best available structure; and
 - (2) Improved as specified under Subparagraph (D)(1) of this section.

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- (C) Physical facilities supporting FIELD FOOD SERVICE ESTABLISHMENTS shall meet the requirements specified under \P (D) of this section and \P 9-203.11(C) and as specified in \P (F) of this section.
 - (D) Except as specified in ¶ (E) of this section, FIELD FOOD OPERATIONS shall—
- (1) Be continuously improved to comply with the provisions of Chapter 6, this publication, if the operation remains static and is modified to incorporate use of physical facilities or structures other than the prescribed tactical system configuration (for example, conducting food preparation and service, equipment sanitation, or dining in a building converted for such use or a temporary structure fabricated using plywood or other materials).
- (2) Comply with the SEASONAL FOOD ESTABLISHMENT facility requirements as specified in Chapter 10 of this publication when the facility is routinely used for food service and is operated for multiple (intermittent) periods (of varying duration) throughout the deployment/contingency operation time frame.
- (E) A military field kitchen operated in its original tactical configuration may be used for an unlimited amount of time, as prescribed by doctrine, without structural improvement other than those actions necessary to maintain system serviceability.
- (F) FIELD FOOD SERVICE ESTABLISHMENTS are typically supplied with permanent (or semi-permanent) utilities, such as plumbed water generated from a water treatment facility and sewage discharged to a gray water collection system, and are treated as a FIXED FOOD ESTABLISHMENT requiring compliance with the provisions specified in Chapter 6 of this publication.

9-202.12 Toilets[†]

Patron and FOOD EMPLOYEE toilets shall be located at least 300 feet (100 yards) downwind from the FIELD FOOD OPERATION, taking into account the gradient and the predominant wind direction.

9-202.13 Handwashing facilities[†]

At a minimum, field-expedient or plumbed handwashing facilities shall be provided at the following locations:

- (A) Field latrines and toilet facilities;
- (B) Warewashing areas;
- (C) FOOD preparation and FOOD serving areas; and
- (D) The customer entrance to the serving line for FIELD FOOD OPERATIONS.

9-203 Cleanability

9-203.11 Floors, walls, and ceilings[†]

- (A) Floor surfaces shall be kept as dry as possible.
- (B) Except for operations conducted on a tactical feeding platform (for example, trailer assembly), food service activities including warewashing and seated dining located on an unpaved surface shall install an improvised floor with an impermeable barrier to prevent development of mud or excessive dust from foot traffic and ensure cleanability as specified under § 6-201.15.
 - (C) Physical facilities for FIELD FOOD SERVICE ESTABLISHMENTS shall—
- (1) Meet the requirements of a TEMPORARY FOOD ESTABLISHMENT as specified in <u>Chapter 6</u> and <u>Part 10-3</u> of this publication when operated for 14 days or less; or
 - (2) Be constructed or improved as specified under ¶ 6-201.11(A).
- (B) Walls and ceilings shall be free of dirt, cobwebs, peeling paint, and other contaminants that can fall into FOOD or onto FOOD CONTACT SURFACES.

9-204 Functionality

9-204.11 Wood pallets[†]

Wood pallets are authorized for storage of FOOD and supplies in FIELD FOOD OPERATIONS and operations afloat and shall be—

- (A) Placed in areas where the ground is firm and the weight of the pallets and contents will not lead to the FOOD or supplies coming into direct contact with the ground or standing water; and
 - (B) Exchanged when new supplies are delivered.
- (C) Covered, when used as a subfloor, with an impermeable and easily cleanable material to prevent accumulation of FOOD debris and liquid and promote pest harborage. The use of pallets to create a subfloor should be of limited duration. Facilities (and flooring) should be improved over time as specified under Subparagraph 9-202.11(D)(1).

9-204.12 Handwashing facilities[†]

- (A) Except as specified in \P (C) of this section, field-expedient handwashing facilities shall include soapy water, rinse water, paper towels, and a covered receptacle for paper waste.
- (B) Handwashing facilities shall use POTABLE WATER as specified under \P <u>9-303.11(A)</u> and may not recirculate the water.
- (C) The REGULATORY AUTHORITY may authorize waterless handwashing using an APPROVED hand antiseptic (sanitizing gel) as specified under § 2-301.16. FOOD EMPLOYEES shall wear single-use disposable gloves, as specified under § 3-304.15, when waterless handwashing is the only available means for EMPLOYEE handwashing. The REGULATORY AUTHORITY may impose additional FOOD handling restrictions when use of an APPROVED hand sanitizer is the only available means for EMPLOYEE handwashing.

9-204.13 Ventilation[†]

- (A) Ventilation mechanisms, such as mechanical or manual methods (for example, ceiling vent ports), for military field kitchens shall be employed IAW the applicable equipment operator's technical manual.
- (B) Ventilation for FIELD FOOD OPERATIONS conducted in a permanent structure or improvised facility shall be improved as specified under Subparagraph 9-202.11(D)(1) to control grease and humidity.

9-204.14 Lighting[†]

Considering the tactical situation, adequate lighting shall be provided to allow proper FOOD storage, preparation, and serving, and cleaning, and SANITIZING of FOOD EQUIPMENT and UTENSILS. During tactical blackout conditions or periods when evening lighting is inadequate, the unit commander should consider serving FOODS which require minimal or no preparation (for example, Meals-Ready-to-Eat (MRE), heat-and-eat FOODS, or other RTE FOODS).

9-3. Water

9-301 Source

9-301.11 Approved system*†

- (A) Water used for food service operations shall be obtained from an APPROVED source that meets the requirements specified in TB MED 577/NAVMED P-5010-10/AFMAN 48-138_IP.
 - (B) Shipboard treated water shall conform to the provision specified in NAVMED P-5010-6.
- (C) BOTTLED WATER and PACKAGED DRINKING WATER shall be acquired from an approved source as specified under ¶ 3-201.11(B) and § 5-101.13.
- (D) Source water for field PACKAGED WATER operations shall meet the requirements specified in TB MED 577/NAVMED P-5010-10/AFMAN 48-138_IP.

9-302 Quantity

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9-302.11 Capacity[†]

The water source and system supplying FIELD FOOD SERVICE ESTABLISHMENTS and FIELD FOOD OPERATIONS shall be of sufficient capacity to meet all FOOD operation requirements: cooking, sanitation, handwashing, and warewashing.

9-303 Quality

9-303.11 Drinking water quality, standards*†

- (A) Water used for FOOD preparation, FOOD EQUIPMENT cleaning and SANITIZING operations, and handwashing shall be POTABLE and shall meet the military field DRINKING WATER quality standards prescribed in TB MED 577/NAVMED P-5010-10/AFMAN 48-138 IP.
- (B) DRINKING WATER for Naval operations afloat shall conform with BUREAU OF MEDICINE INSTRUCTION (BUMEDINST) 6240.10 SERIES, Standards for Potable Water, and NAVMED P-5010-6.

9-303.12 Chlorine residual, requirement*†

- (A) Except as specified in ¶ (B) of this section, POTABLE water used in field or deployment food operations shall be chlorinated and shall retain a free available chlorine residual IAW TB MED 577/NAVMED P-5010-10/AFMAN 48-138 IP or NAVMED P-5010-6, as appropriate.
- (B) The chlorine residual requirement shall be specified by the MEDICAL AUTHORITY when conditions require a change to TB MED $577/NAVMED\ P5010-10/AFMAN\ 48-138_IP$. N

9-303.13 Chlorine residual, monitoring*†

- (A) Preventive medicine or personnel designated by the MEDICAL AUTHORITY shall test the chlorine residual during each sanitary inspection (or at least monthly). *The chlorine residual should be checked at the following locations: a supplied FOOD EQUIPMENT located farthest from the hose connection to the bulk water supply; the bulk water container; and the ice machine if provided.* N
 - (B) The FOOD operations manager shall—
- (1) Ensure the chlorine residual of bulk DRINKING WATER directly servicing the FOOD operation is tested each time a bulk delivery occurs or the water trailer is refilled. ^N
- (2) Test the chlorine residual at the outlet of the FOOD EQUIPMENT that is located at the point farthest from the hose connection to a bulk water source each time a hose is connected or reconnected between the FOOD EQUIPMENT and the water source.
- (3) Take corrective actions to re-chlorinate any bulk water that falls below the minimum prescribed residual. $^{\rm N}$
- (C) The chlorine residual of bulk water supplying FOOD operations shall be monitored daily. *Multiple testing may be required each day in hot climates where chlorine is likely to dissipate more rapidly. Weekly or monthly testing conducted by preventive medicine personnel or the MEDICAL AUTHORITY's designated representative does not preclude testing by FOOD EMPLOYEES or unit field sanitation teams.* N
 - (D) Inspection and chlorine residual records shall be maintained at the FOOD ESTABLISHMENT. N
- (E) UGR-As or A-type (perishable) rations and TCS FOODS prepared from raw ingredients may not be prepared when a chlorine residual cannot be achieved or sustained. Alternate rations and enhancements which do not require water as an ingredient, such as MREs, UGR-H&S, and RTE FOODS PACKAGED by a FOOD PROCESSING PLANT, shall be served until a chlorine residual of bulk supplied POTABLE water is achieved. BOTTLED or PACKAGED WATER shall be used for hot and cold beverage service when there is no chlorine residual in the supplied bulk POTABLE water. ^N

9-304 Plumbing System

9-304.10 Pressure[†]

Bulk water that supplies FOOD operations does not have to be under pressure.

9-304.11 Bulk water, storage container[†]

- (A) Water that supplies FOOD operations shall be obtained from water bladders and water trailers that meet the requirements outlined in TB MED 577/NAVMED P-5010-10/AFMAN 48-138_IP.
- (B) Water trailers and bulk POTABLE water storage containers shall be inspected before, during, and after use IAW the equipment operator's technical manual, the criteria specified in TB MED 577/NAVMED P-5010-10/AFMAN 48-138 IP, and applicable theater or command policy.

9-304.12 Pipes and hoses, connections*†

- (A) Hoses used to connect an APPROVED water source to a FIELD FOOD SERVICE ESTABLISHMENT or FIELD FOOD OPERATION shall—
 - (1) Meet NSF/ANSI listed standards for POTABLE water:
 - (2) Be kept in a clean and dry location when not in use; and
- (3) Be SANITIZED and tested as specified in Subparagraph <u>9-303.13(B)(2)</u> when connected to the water source.
- (B) To prevent accidental CROSS-CONNECTION, a DRINKING WATER hose connection shall be of a different thread design and diameter than any waste line hose connection as specified under \P 5-302.16(F) and configured with appropriate backflow prevention as specified under \P 5-203.14 and \P 5-205.12(C).

9-4. Maintenance

9-401 Premises

9-401.11 Cleaning, frequency and methods[†]

Except as specified in \P (A) and (B) of this section, cleaning shall be conducted as specified under §§ $\underline{6-501.12}$ and $\underline{6-501.13}$.

- (A) FIELD FOOD OPERATIONS shall be kept as clean as possible; consideration should be made for available facilities and EQUIPMENT and the anticipated length of stay for the operation.
- (B) Floors, walls, ceilings, customer eating areas, and FOOD preparation and storage areas shall be free of accumulated FOOD waste, trash, and standing water.

9-402 Equipment and utensils

9-402.10 Good repair and operation[†]

- (A) FOOD EQUIPMENT and UTENSILS are maintained in a state of repair and condition as specified in Parts 4-1, 4-2, and 4-5 of this publication.
- (B) Field FOOD EQUIPMENT procured using a commercial item description should meet NSF International standards or other appropriate standards as specified under $\S 4-205.13$.
- (C) Replacement components for field kitchens should conform with applicable military specifications for field kitchens or undergo evaluation of its design and construction by the following entities to ensure conformance to the provisions specified in Chapter 4:
- (1) DOD Food Service Equipment and Field Feeding Systems, U.S. Army Soldier Systems Command, Natick Research, Development and Engineering Center, Natick, MA; or
 - (2) A food safety representative from one of the military Public Health organizations.

9-403 Pest control measures

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9-403.10 Pest management[†]

- (A) The FOOD operations manager should implement IPM principles within the FOOD operation and adjacent areas.
- (B) The FOOD ESTABLISHMENT PIC or designated food service workers should conduct daily indoor and outdoor inspections of the FOOD operation area for evidence of pests or harborage conditions.
- (C) The IPM actions beyond the unit or FOOD ESTABLISHMENT's capability should be requested from the supporting medical command or preventive medicine unit.

9-403.11 Animals and pest control[†]

- (A) For FIELD FOOD OPERATIONS, insect and rodent controls shall meet the requirements as specified under § 6-202.13.
- (B) For FIELD FOOD SERVICE ESTABLISHMENTS, insect and rodent controls and exclusions shall meet the requirements as specified under §§ 6-202.13, 6-202.15, and 6-202.16.
 - (C) Animal prohibitions shall conform as specified under §§ 2-403.11 and 6-501.115.

9-5. Food

9-501 Sources

9-501.11 Approved sources*†

FOOD shall be obtained from APPROVED SOURCES as specified under ¶ 3-201.11(B).

9-502 Preparation, storage, transport, and service

9-502.11 Frozen and refrigerated foods, management*†

- (A) FROZEN FOODS may not be thawed or SLACKED at ambient temperature or in standing water.
- (B) FROZEN FOODS shall be-
 - (1) Stored at 0°F (-17.7°C) or below; N and
 - (2) Thawed at a ration breakpoint and maintained at 41°F (5°C) or below; or
 - (3) Transported FROZEN to the FIELD FOOD OPERATION or FIELD FOOD SERVICE

ESTABLISHMENT and either prepared and cooked immediately from the FROZEN state or thawed in a refrigeration unit.

- (C) Except as specified in Subparagraph (D) of this section—
 - (1) Refrigerated TCS FOOD shall be stored at 41°F (5°C) or below; and
- (2) Perishable FOODS shall not be used when adequate refrigeration or ice chests are not available to maintain product temperature as specified in Subparagraph (C)(1) of this section.
- (D) Unopened containers of UHT milk do not require refrigeration during storage and may be chilled immediately prior to offering for CONSUMER consumption. Chilled UHT milk that is unopened may be removed from refrigerated storage and subsequently re-chilled at a later time.

9-502.12 Cooking and hot holding, temperatures*†

- (A) TCS FOODS that require cooking or are intended to be eaten hot shall be cooked or heated to an internal product temperature of $165^{\circ}F$ ($74^{\circ}C$) for 15 seconds.
- (B) Except as specified under \P 9-502.13(E), hot TCS FOODS shall be held at 135°F (57°C) or above throughout the meal period.

9-502.13 Insulated food containers*†

- (A) Insulated food containers (IFCs) used for holding or transporting TCS FOODS shall be—
 - (1) Cleaned and SANITIZED prior to use;

- (2) Pre-chilled or pre-heated before filling with TCS FOODS; and
- (3) Labeled with the common name of the FOOD, the time and product temperature when the IFC was filled, and the time as specified in \P (D) of this section in which the FOOD should be consumed or discarded by. ^N
- (B) Hot and cold FOODS shall be placed in the IFC inserts. Except for whole/uncut fruit, placement of unPACKAGED FOOD, in the IFC without use of inserts is prohibited. $^{\rm N}$
- (C) Filling the IFCs for meal service at a remote feeding site shall be coordinated with the supported unit to minimize the holding time before the food can be transported. ^N
- (D) When TCS FOODS are initially placed in IFCs, the internal product temperature of hot TCS FOODS shall be 135°F (57°C) or above, and cold TCS FOODS shall be 41°F (5°C) or below.
- (E) When using IFCs, "time" as a Public Health Control (TPHC) is automatically applied; TCS FOODS in IFCs should be consumed within 4 hours from the time the IFC was filled. If the receiving unit is equipped with a calibrated TEMPERATURE MEASURING DEVICE and the FOOD is within the SAFE TEMPERATURE zone at the time the IFC is opened, then the FOOD shall be consumed within 4 hours from time the SAFE TEMPERATURE measurement was taken. Any TCS FOODS not consumed within this time period shall be discarded. TCS FOODS exceeding the 4-hour time limit for consumption may not be reheated for continued use.

9-502.14 Leftover foods*†

- (A) Except as specified in Subparagraph (B) of this section, unconsumed TCS FOOD prepared for a specific meal period may not be retained as LEFTOVERS.
- (B) On-premises prepared sandwiches may be retained for up to 4 hours beyond the end of the current meal period and then served at the next scheduled meal, provided that:
 - (1) Chilled sandwiches are maintained as specified under Subparagraph 9-502.11(C)(1); or
 - (2) Hot sandwiches are maintained as specified under ¶ 9-502.12(B).
- (C) LEFTOVER non-TCS FOODS may be retained as specified in \P 3-501.110(A), but shall comply with the criteria as specified under \P 3-501.110(B) and (C).

9-502.15 Condiments[†]

Condiments PACKAGED as individual serving portions shall be protected from contamination. *Condiments may be dispensed from bulk sanitary dispensers as specified under* ¶ 3-306.12(A).

9-502.16 Milk and milk products[†]

Milk and milk products for drinking purposes shall be—

- (A) Provided to the CONSUMER in an unopened, commercially filled individual PACKAGE not exceeding 16 fluid ounces, 1 pint, or 0.5 liter equivalent in volume; or
- (B) Drawn for immediate consumption from a commercially filled container only when mechanically refrigerated bulk milk dispensers are functional and used; and
- (C) Except as specified in Subparagraph <u>9-502.11(C)(3)</u>, maintained at 41°F (5°C) or below during storage, display, and service.

9-502.17 Raw fruits and vegetables*†

- (A) Except as specified in $\P\P$ (C) and (D) of this section, before being cut, combined with other ingredients, cooked, served, or offered for human consumption in RTE form, raw fruits and vegetables shall be thoroughly washed and subjected to a CHEMICAL WASH (disinfection) process as specified in § 3-302.15.
- (B) The alternate APPROVED nonchemical method for reducing microbial contamination requires submersing raw fruits and vegetables in 140°F (60°C) DRINKING WATER for 1 minute.
- (C) Vegetables that are PACKAGED in an RTE form (that is, bagged salad) are handled IAW manufacturers' specifications and may not require washing before being served.
- (D) Foods grown with human fecal material as fertilizer may not be purchased or offered for consumption as specified under § 3-201.18.

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9-502.18 Transporting food, vehicle and prohibition[†]

- (A) Except as specified in \P (B) of this section, vehicles used to transport FOOD shall be clean, covered, and used exclusively for transporting FOOD.
 - (B) Multipurpose vehicles used to transport personnel, equipment, supplies, and other items:
- (1) Prior to the transport of FOOD for each meal period, the cargo area of the vehicle shall be completely washed with soapy water and rinsed to remove dirt, debris, and fuel, oil, or chemical residues. The vehicle shall be allowed to air dry prior to transporting FOOD.
- (2) FOOD containers, packages of SINGLE-USE items, and UTENSILS shall be placed on clean, dry pallets or other dunnage to prevent direct contact with the vehicle floor.
 - (3) FOOD may not be transported with bulk fuel or chemicals.
- (4) Transport of FOOD with equipment and nonchemical supplies may be approved by the REGULATORY AUTHORITY if required by the tactical situation and there is little or no risk of FOOD CONTAMINATION or ADULTERATION.

9-6. Personnel.

9-601 Personal hygiene

9-601.10 Customers[†]

Personnel subsisting at FIELD FOOD OPERATIONS should be encouraged to wash their hands. Hand wash devices or hand sanitizers should be placed near the serving line entrance as specified under ¶ 9-202.13(D).

9-601.11 Camouflage paint and food employee uniforms[†]

- (A) Camouflage paint or other toxic skin coatings are:
 - (1) POISONOUS or TOXIC MATERIALS when consumed.
- (2) Except as specified in \P (B) this section, prohibited on the hands, arms, or face of FOOD EMPLOYEES or detailed personnel (for example, KPs) if the individual is:
 - (a) Preparing FOOD;
 - (b) Serving FOOD; or
 - (c) Washing and SANITIZING FOOD EQUIPMENT.
- (B) Commanders may dictate that personnel maintain combat operational readiness in extreme tactical situations, which may include the wearing of camouflage paint or other coatings. At remote feeding sites, individuals serving FOOD or performing basic site cleanup, such as collecting trash, may wear camouflage paint or other skin coatings on the face, hands, and arms, but the hands shall be covered with disposable, SINGLE-USE gloves.
- (C) Military uniforms worn by cooks and KP personnel shall be free from heavy soil and residues from handling fuel and other petroleum products. Cooks should wear a clean uniform every day and should minimize wearing tactical gear that may present a safety issue or may potentially contaminate FOOD during preparation or service. If conditions (determined by tactical commanders) require cooks and KP personnel to wear tactical gear and camouflage paint or other chemical coatings on the hands, forearms, and face, the food operation supervisor or senior leader should consider curtailing the use of A-type rations and replace them with individual or unitized group rations (heat-and-serve type rations) until conditions are more conducive for the management of hygienic controls.

CHAPTER 10

MOBILE, TEMPORARY, SEASONAL, AND VENDING FOOD OPERATIONS

10-1. Chapter scope

10-101 Purpose

10-101.10 Provisions for mobile, temporary, seasonal, and vending food operations[†]

The purpose of this chapter is to identify the special requirements and standards applicable to MOBILE, TEMPORARY, SEASONAL, and VENDING MACHINE FOOD ESTABLISHMENTS, and to provide a quick reference to the section(s) of this publication under which an exception to such a standard is authorized.

10-102 Referencing other areas of this publication

10-102.10 Applying exceptions to the publication's provisions[†]

- (A) Except as stated in the sections of this chapter, MOBILE, TEMPORARY, SEASONAL, and VENDING MACHINE FOOD ESTABLISHMENTS apply and conform to the provisions outlined in Chapters 2 through 8 of this publication.
- (B) The FOOD ESTABLISHMENT PIC must review the chapters of this publication, as stated in \P (A) of this section, to ensure full compliance of MOBILE, TEMPORARY, SEASONAL, and VENDING MACHINE FOOD operations.

10-102.20 Temporary food employee, training[†]

Training as specified under § <u>2-503.13</u>, is required for individuals designated to serve or handle FOOD in support of a TEMPORARY FOOD ESTABLISHMENT or hired as a temporary worker in a FOOD ESTABLISHMENT.

10-2. Water, plumbing, and waste

10-201 Water

10-201.11 Approved system*†

- (A) DRINKING WATER shall be acquired from an APPROVED source as specified under ¶ 5-101.11.
- (B) For TEMPORARY and SEASONAL FOOD operations—
- (1) In addition to the pre-opening testing and evaluation requirements specified in Subparagraph (B)(4) of this section, safety of the supporting water supply shall be established during the initial approval process for the operation.
- (2) The REGULATORY AUTHORITY may authorize the use of a NONPUBLIC potable water supply. Approval for use of a NONPUBLIC water supply shall be requested, as specified under Subparagraph (B)(4) of this section, and obtained in writing before the FOOD operation's opening date. N
- (3) POTABLE water shall be delivered, as specified under §§ <u>5-104.12</u> and <u>5-301.11</u>, to the operation if the requested NONPUBLIC WATER SYSTEM is not available or is not APPROVED. N
- (4) Except as specified in Subparagraph (4)(a) of this section, the FOOD operation manager shall contact the supporting REGULATORY AUTHORITY at least 2 weeks prior to the start of the operation to test and evaluate the supporting PUBLIC or NONPUBLIC WATER SYSTEM. The following requirements apply:

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- (a) A PUBLIC WATER SYSTEM that is routinely tested as part of the installation's DRINKING WATER surveillance program does not require additional testing if the water is drawn directly from the system. Water drawn from the PUBLIC WATER SYSTEM and retained in bulk storage at the FOOD ESTABLISHMENT shall be tested. N
 - (b) Water testing shall include the chlorine residual and microbiological quality of the water. N
- (c) The FOOD ESTABLISHMENT shall not begin FOOD preparation or service until the results from water testing have been received and APPROVED by the REGULATORY AUTHORITY.
- (C) Water distribution system components, including hoses and valves, shall be approved, as specified under $\S\S 5-104.11$ and 5-201.11, and meet NSF International standards for POTABLE water, or equivalent standards for components purchased OCONUS. ^N

10-201.12 Capacity, exception[†]

TEMPORARY and VENDING MACHINE FOOD ESTABLISHMENTS shall provide a water system of sufficient capacity as specified under $\S \frac{5-103.11}{5-103.11}$, but are exempted from the requirement of supplying both hot and cold running water as specified under $\P \frac{5-103.11}{5-103.11}$.

10-201.13 Pressure, exception[†]

Water need not be under pressure when supplied using alternative means as specified under $\P = \frac{5-104.12(A)}{5-104.12(A)}$ or $P = \frac{B}{5-104.12(A)}$ or $P = \frac{B}{5-104.12(A)}$

10-201.14 Alternative water supply[†]

- (A) An alternative water supply shall be made available as specified under § <u>5-104.12</u> for a MOBILE or TEMPORARY FOOD ESTABLISHMENT without a permanent water supply.
- (B) Use of a mobile water tank and MOBILE FOOD ESTABLISHMENT water tanks shall conform to the provisions specified in Part 5-3.

10-201.15 Potable water, not available[†]

MOBILE, TEMPORARY, SEASONAL, and VENDING MACHINE FOOD ESTABLISHMENTS that do not have adequate POTABLE water shall be restricted to the sale of canned or PACKAGED RTE FOOD in individual-serving portions, and hot beverages, such as coffee, tea, and hot chocolate, provided the water used to prepare the drinks (such as BOTTLED WATER) is from an APPROVED SOURCE as specified under ¶ 3-201.11(B) and § 5-101.13.

10-202 Plumbing systems

10-202.11 Handwashing sink, exception[†]

An exception to \P 5-203.11(A), HANDWASHING SINK requirement, is authorized when FOOD exposure is limited and HANDWASHING SINKS are not conveniently available. If APPROVED, EMPLOYEES may use chemically treated towelettes for Handwashing as specified under \P 5-203.11(C), and FOOD operations shall be limited as specified under \P 5-203.11(D).

10-203 Sewage and waste

10-203.11 Conveying sewage, exception[†]

(A) SEWAGE shall be conveyed through an APPROVED sanitary SEWAGE system as specified under § 5-402.13. An exception for use of a nonwater-carriage SEWAGE disposal system (composting toilets, waste bladders, etc.) is provided for TEMPORARY FOOD ESTABLISHMENTS and FIELD FOOD SERVICE ESTABLISHMENTS and may be authorized for SEASONAL FOOD ESTABLISHMENTS limited to serving PACKAGED RTE FOODS when APPROVED by the REGULATORY AUTHORITY.

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- (B) A SEWAGE holding tank in a MOBILE FOOD ESTABLISHMENT shall meet the requirements specified under § 5-401.11.
- (C) SEWAGE and other liquid wastes shall be removed from a MOBILE FOOD ESTABLISHMENT as specified under § 5-402.14.

10-3. Physical facilities

10-301 Design and construction

10-301.11 Indoor surface characteristics, exception[†]

- (A) Except as specified in \P (B) this section, materials for indoor floor, wall, and ceiling surfaces shall comply with the surface characteristics as specified under \S 6-101.11.
- (B) An exception is authorized for floors, as specified in ¶ 6-101.11(B), for TEMPORARY FOOD ESTABLISHMENTS when APPROVED by the REGULATORY AUTHORITY as specified under § 10-301.12.

10-301.12 Structural requirements[†]

MOBILE, SEASONAL and TEMPORARY FOOD ESTABLISHMENTS shall meet the same structural requirements specified in <u>Part 6-2</u> of this publication for a fixed FOOD ESTABLISHMENT, unless a waiver, as specified in § <u>8-103.10</u>, is requested from and APPROVED by the REGULATORY AUTHORITY during the preoperational review process as specified in § <u>8-301.11</u>.

10-301.13 Wooden duckboards or pallets, exception[†]

An exception to § 6-201.15 is authorized in TEMPORARY FOOD ESTABLISHMENTS for use of wooden duckboards or pallets which do not meet NSF International Standard 52 requirements.

10-301.14 Exposed studs, joists, and rafters, exception[†]

An exception to § 6-201.18 for exposed studs, joists, and rafters in areas subject to moisture is authorized for TEMPORARY FOOD ESTABLISHMENTS.

10-301.15 Outer openings, protected, exception[†]

- (A) Except as specified in \P (B) of this section, outer openings to TEMPORARY, SEASONAL and VENDING MACHINE FOOD ESTABLISHMENTS shall comply as specified under \S 6-202.15.
- (B) If a TEMPORARY FOOD ESTABLISHMENT is not provided with protected windows and doors, the openings shall be protected against the entry of insects and rodents as specified under \P 6-202.15(D).

10-301.16 Outdoor areas, surface characteristics[†]

- (A) Exterior surfaces and outdoor walking and driving areas where a MOBILE or TEMPORARY FOOD ESTABLISHMENT is located shall meet the requirements specified under § 6-102.11.
- (B) A TEMPORARY FOOD ESTABLISHMENT may not be installed over or immediately adjacent to standing water or mud. A ground barrier such as a tarp or elevated flooring using pallets, plywood or other materials should be placed over unimproved surfaces (that is, grass and dirt) where development of muddy conditions is likely.

10-4. Facility and operating plans

10-401 Plan submission

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10-401.11 Requirements and procedures[†]

Except as specified under § 10-401.12, the plan requirements, submission, and approval procedures for MOBILE, TEMPORARY, SEASONAL, and VENDING MACHINE FOOD ESTABLISHMENTS shall comply as specified under § 8-301.11.

10-401.12 Time frames for submission[†]

- (A) Plans to operate a TEMPORARY FOOD ESTABLISHMENTS shall be submitted as specified under \$-302.11(C) and \$-302.12.
- (B) Plans to operate a MOBILE, SEASONAL, or VENDING MACHINE FOOD ESTABLISHMENT shall be submitted as specified under ¶ 8-302.11(A) and § 8-302.12.
- (C) Plans for construction or building renovation for a new SEASONAL or VENDING MACHINE FOOD ESTABLISHMENT shall be submitted as specified under ¶ 8-201.11(A).

10-5. Vending machine operations

10-501 Administrative requirements

10-501.11 Approval[†]

- (A) Authority to operate VENDING MACHINES dispensing TCS FOODS or hot or cold cup BEVERAGES may be granted by the INSTALLATION COMMANDER based on approval by the MEDICAL AUTHORITY or designated representative. The operator shall provide the REGULATORY AUTHORITY with a HACCP PLAN or SOP for all phases of the vending operation. The HACCP PLAN or SOP shall detail the types of FOOD dispensed, including source, and any special processing, such as acidification.
- (B) APPROVAL from the REGULATORY AUTHORITY shall be obtained following satisfactory pre- and post-FOOD ESTABLISHMENT and EQUIPMENT installation inspections and HACCP PLAN or SOP review as specified under §§ 8-301.11 and 8-302.14. The approval covers the VENDING MACHINE EQUIPMENT and its location; the transport system; supply, storage, servicing, and SANITIZING facilities; and the commissary or other supporting FOOD ESTABLISHMENTS governed under the provisions of this publication.
 - (C) Approvals are not transferable as specified in § <u>8-304.20</u>.

10-501.12 Identity[†]

The operator shall conspicuously display the company name, complete mailing address, and service telephone number on a permanent label affixed to each VENDING MACHINE or in a conspicuous location adjacent to a bank of VENDING MACHINES.

10-501.13 Operator procedures[†]

In addition to complying with the provisions of this publication, the VENDING MACHINE operator shall—

- (A) Maintain a list of all VENDING MACHINES and the route servicing schedule for all VENDING MACHINES operated within the jurisdiction of the MEDICAL AUTHORITY.
- (B) Maintain a complete address of each VENDING MACHINE LOCATION and of all commissaries or other FOOD ESTABLISHMENTS that service these VENDING MACHINES.
- (C) Provide the information in \P (A) and (B) of this section to the REGULATORY AUTHORITY and keep this information current.
- (D) Obtain MEDICAL AUTHORITY or designated representative approval for each VENDING MACHINE LOCATION where TCS FOODS and hot and cold cup BEVERAGE VENDING MACHINES will be placed in operation.
- (E) Obtain REGULATORY AUTHORITY approval prior to any changes in operations, including changes to the HACCP PLAN or SOP, involving new types of VENDING MACHINES or the conversion of existing machines to dispense products other than those for which the machines were APPROVED.

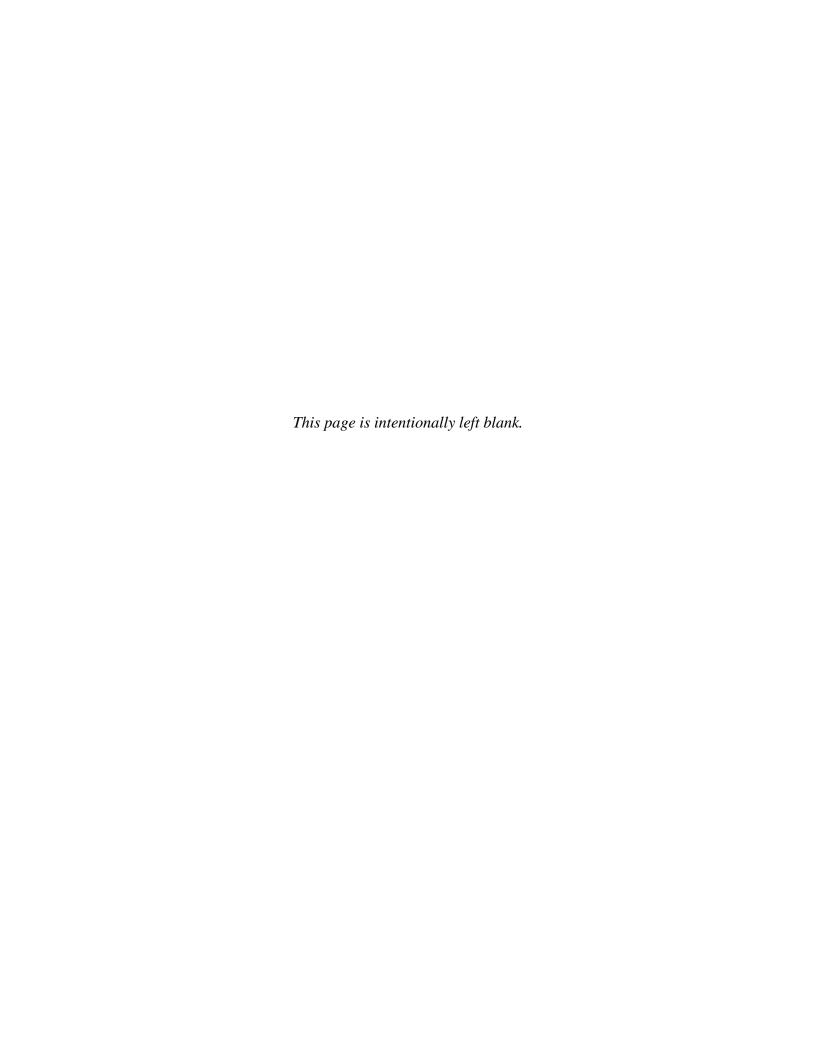
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10-502 Vending equipment

10-502.10 Equipment conformance standards referenced in this publication[†]

- (A) The dispensing compartment of a VENDING MACHINE shall be equipped with a self-closing door or cover as specified under § 4-204.14.
- (B) VENDING MACHINES, including water VENDING MACHINES, shall be NAMA- or NSF International-listed as specified in ¶ 4-205.11(B) or shall be certified by an equivalent agency if procured OCONUS.

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APPENDIX A

REFERENCES

Section I Required Publications

There are no entries for this section.

Section II Related Publications

A related publication is a source of additional information. The user does not have to read it to understand this publication. Air Force publications are available at http://www.e-publishing.af.mil and http://www.e-publishing.af.mil and https://www.e-publishing.af.mil and https://www.e-publishing.af.mil and https://www.publications are available online from the U.S. Army Publishing Directorate Web site: https://armypubs.army.mil/. Technical manuals are available at https://armypubs.army.mil/. Technical manuals are available at https://www.acq.osd.mil/eie/afpmb/techguides.html. Codes of Federal Regulations are available online from the National Archives and Records Administration Web site: http://www.gpoaccess.gov/cfr/index.html. Standardization Agreements (NATO) (STANAG) and the Quadripartite Standardization Agreement are available online at http://assist.daps.dla.mil/. The NFPA Standards listed are available from the NFPA, Batterymarch Park, Quincy, MA 02269. Unified Facilities Criteria are available online from https://www.wbdg.org/ffc/dod/.

A-1. DOD and Joint/Multiservice Publications

DOD Instruction O-2000.16, Volume 1 & 2 DOD Antiterrorism (AT) Program Implementation

DOD Instruction 4150.07 DOD Pest Management Program

DODVSA Policy #B-017

Inspection Support to Military Troop Feeding Activities [Available at https://www.milsuite.mil/book/groups/army-veterinary-services; select the Food Protection tab.]

DODVSA Policy #B-020

Food Protection Requirements for Food Products Supplied to Installation Farmers Markets Located on Military Installations [Available at https://www.milsuite.mil/book/groups/army-veterinary-services; select the Food Protection tab.]

AR 40-656/NAVSUPINST 4355.10A/MCO 10110.48 Veterinary Surveillance Inspection of Subsistence

AR 40-657/NAVSUP 4355.4H/MCO P10110.31H

Veterinary/Medical Food Safety, Quality Assurance, and Laboratory Service

AFPMB TG 18

Installation Pest Management Program Guide

AFPMB TG 20

Pest Management Operations in Medical Treatment Facilities

AFPMB TG 27

Stored Product Pest Monitoring Method

AFPMB TG 29

Integrated Pest Management (IPM) in and Around Buildings

TB MED 577/NAVMED P-5010-10/AFMAN 48-138_IP

Sanitary Control and Surveillance of Field Water Supplies

TM 5-634/NAVFAC MO-213/AFI 32-7042

Solid Waste Management

UFC 4-010-01

DoD Minimum Antiterrorism standards for Building

UFC 4-023-03

Design of Building to Resist Progressive Collapse

UFC 4-722-01N

Navy and Marine Corps Dining Facilities

A-2. Air Force Publications

AFI 48-116

Food Safety Program

AFI 48-117

Public Facility Sanitation

AFI 10-245

Antiterrorism (AT)

AFMAN 10-246

Food and Water Protection Program

UFC 4-722-01F

Air Force Dining Facilities

A-3. Army Publications

AR 30-22

The Army Food Program

AR 40-5

Preventive Medicine

AR 420-1

Army Facilities Management

AR 608-10

Child Development Services

DA PAM 30-22

Operating Procedures for the Army Food Program

DA PAM 40-11

Preventive Medicine

TB MED 576

Sanitary Control and Surveillance of Water Supplies at Fixed Installations

ATP 4-25.12

Unit Field Sanitation Teams

ATP 4-45 (formerly FM 4-20.07)

Force Provider Operations

ATP 5-19

Risk Management

ATTP 4-41

Army Field Feeding and Class 1 Operations

TC 4-02.3

Field Hygiene and Sanitation

TM 4-41.11 (formerly FM 10-23-2)

Dining Facility Operations

TM 4-41.12 (formerly FM 10-23-2)

Food Program Operations

MIL HDBK 740

Dishwashing Operations

MIL HDBK 3006C

Guidelines for Auditing Food Establishments

U.S. Army Corps of Engineers, Technical Instructions 800-01 Design Criteria

A-4. Navy and Marine Corps Instructions/Publications

BUMEDINST 6220.12C

Medical Surveillance and Notifiable Event Reporting Event Reporting

BUMEDINST 6240.10B

Water Quality Standards

MCO P1700.27B

Marine Corps Community Services Policy Manual

MCO P5090.2A

Environmental Compliance and Protection Manual

MCO P10110.14M

Marine Corps Food Service and Subsistence Program

MCO P10110.48

Veterinary Surveillance Inspection of Subsistence

NAVMED P-117

Manual of the Medical Department

NAVMED P-5010

Chapter 5, Water Supply Ashore

NAVMED P-5010

Chapter 6, Water Supply Afloat

NAVMED P-5010

Chapter 8, Navy Entomology and Pest Control

NAVSUP P-486

Food Service Management, General Messes

NAVSUP 4355.H

Veterinary/Medical Food Safety, Quality Assurance, and Laboratory Service

NAVSUPINST 4355.10

Veterinary Surveillance Inspection of Subsistence

OPNAVINST 1700.9E

Child and Youth Program

OPNAVINST 4060.4C

Establishment of Auxiliary Resale Outlets (AROS)

OPNAVINST 4061.4 / MCO 4061.1

Food Safety Training Program

OPNAVINST 5090.1C

Environmental Readiness Program Manual

SECNAVINST 3300.2B

Department of the Navy (DON) Antiterrorism (AT) Program

A-5. Other Publications

9 CFR 301.2

Definitions

9 CFR 317

Labeling, Marking Devices, and Container

9 CFR 317 Subpart B

Nutrition Labeling

9 CFR 319

Definitions and standards of identity or composition

9 CFR 319 Subpart A

General

9 CFR 352

Exotic animals

9 CFR 362.1

Voluntary Poultry Inspection Regulations, Definitions

9 CFR 381

Subpart N Labeling and Containers

9 CFR 381.1

Poultry Products Inspection Regulations Definitions, Poultry

9 CFR 381.125(b)

Special handling label requirements

9 CFR 424.21

Use of Food Ingredients and Sources of Radiation

9 CFR 590

Inspection of Eggs and Egg Products (Egg Products Inspection Act)

9 CFR Subpart C Section 424.21(b)

Food Ingredients and Sources of Radiation

21 CFR 101

Food labeling

21 CFR 101.17(g)

Food Labeling, Warning, Notice, and Safe Handling Statements

21 CFR 113

Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers

21 CFR 114

Acidified foods

21 CFR 117

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

21 CFR Part 120

HACCP Systems

21 CFR Part 120, Subpart B

HACCP Systems, Pathogen Reduction

21 CFR Part 120.24

Process Controls

21 CFR 129

Processing and Bottling of Bottled Drinking Water

21 CFR 130

Food Standards: General

21 CFR 131

Milk and Cream

21 CFR 133

Cheeses and Related Cheese Products

21 CFR 133.150

Hard cheeses

21 CFR 133.169

Pasteurized Process Cheese

21 CFR 133.187

Semisoft Cheeses

21 CFR 135

Frozen Desserts

21 CFR 136

Bakery Products

21 CFR 137

Cereal Flours and Related Products

21 CFR 139

Macaroni and Noodle Products

21 CFR 145 Canned Fruits

21 CFR 146

Canned Fruit Juices

21 CFR 150

Fruit Butters, Jellies, Preserves, and Related Products

21 CFR 152

Fruit Pies

21 CFR 155

Canned Vegetables

21 CFR 158

Frozen Vegetables

21 CFR 160

Eggs and Egg Products

21 CFR 161

Fish and Shellfish

21 CFR 163

Cacao Products

21 CFR 164

Tree Nut and Peanut Products

21 CFR 165

Beverages

21 CFR 166

Margarine

21 CFR 168

Sweeteners and Table Sirups

21 CFR 169

Food Dressings and Flavorings

21 CFR 170

Food Additives

21 CFR 170.39

Threshold of Regulation for Substances Used in Food-Contact Articles

21 CFR 171

Food Additive Petitions

21 CFR 172

Food Additives Permitted for Direct Addition to Food for Human Consumption

21 CFR 173

Secondary Direct Food Additives Permitted in Food for Human Consumption

21 CFR 173.310

Boiler Water Additives

21 CFR 173.315

Chemicals Used in Washing or To Assist In The Peeling Of Fruits And Vegetables

21 CFR 173.368

Ozone

21 CFR 174

Indirect Food Additives: General

21 CFR 175

Indirect Food Additives: Adhesives and Components of Coatings

21 CFR 176

Indirect Food Additives: Paper and Paperboard Components

21 CFR 177

Indirect Food Additives: Polymers

21 CFR 178

Indirect Food Additives: Adjuvant, Production Aids and Sanitizers

21 CFR 178.1010 Sanitizing Solutions

21 CFR 178.3570

Lubricants with Incidental Food Contact

21 CFR 178.3800

Preservatives for Wood

21 CFR 179

Irradiation in the Production, Processing and Handing of Food

21 CFR 180

Food Additives Permitted in Food or in Contact with Food on an Interim Basis Pending Additional Study

21 CFR 181

Prior-Sanctioned Food Ingredients

21 CFR 182

Substances Generally Recognized as Safe

21 CFR 184

Direct Food Substances Affirmed as Generally Recognized as Safe

21 CFR 186

Indirect Food Substances Affirmed as Generally Recognized as Safe

21 CFR 1030.10

Microwave ovens

21 CFR Subpart D

Specific Administrative Decisions Regarding Interstate Shipments

21 CFR Subpart D Section 1240.60(d)

Molluscan shellfish

40 CFR 141

National Primary Drinking Water Regulations

40 CFR 152 Subpart I

Classification of Pesticides

40 CFR 152.175

Pesticides classified for restricted use

40 CFR 180

Tolerances for pesticides chemicals in food, and exceptions

40 CFR 180.940

Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (Food Contact Surface Sanitizing Solutions)

50 CFR 17

Endangered and threatened wildlife and plants

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NFPA Standard 13

Installation of Sprinkler Systems.

NFPA Standard 96

Ventilation Control and Fire Protection of Commercial Cooking Operations.

NSF International Standard 2

Food Equipment. (This and the NSF International standards listed below are available from NSF International, ATTN: Publications, PO Box 130140, Ann Arbor, MI 48113-0140.)

NSF International Standard 3

Commercial Warewashing Equipment.

NSF International Standard 4

Commercial Cooking, Rethermalization and Powered Hot Food Holding and Transport Equipment.

NSF International Standard 7

Commercial Refrigerators and Storage Freezers.

NSF International Standard 8

Commercial Powered Food Preparation Equipment.

NSF International Standard 12

Automatic Ice Making Equipment.

NSF International Standard 18

Manual Food and Beverage Dispensing Equipment.

NSF International Standard 25

Vending Machines for Food and Beverages.

NSF International Standard 29

Detergent and Chemical Feeders for Commercial Spray-Type Dishwashing Machines.

NSF International Standard 37

Air Curtains for Entranceways in Food and Food Service Establishments.

NSF International Standard 52 Supplemental Flooring.

NSF International Standard 59 Mobile Food Carts.

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Section III Prescribed Forms

Unless otherwise indicated, DD Forms are available on the Office of the Secretary of Defense (OSD) web site https://www.esd.whs.mil/Directives/forms.

DD FORM 2970

Application for Temporary Food Establishment

DD FORM 2971

Conditional Employee or Food Employee Reporting Agreement

DD FORM 2972

Food Facility Risk Assessment Survey

DD FORM 2973

Food Operation Inspection Report

DD FORM 2974 Tactical Kitchen Food Sanitation Inspection

DD FORM 2975

Temporary Food Event Coordinator's Application

Section IV Referenced Forms

Unless otherwise indicated, DA forms are available on the Army Publishing Directorate (APD) web site https://armypubs.army.mil; DD Forms are available on the Office of the Secretary of Defense (OSD) web site https://www.esd.whs.mil/Directives/forms.

AF FORM 847 Recommendation for Change of Publication

DA FORM 2028

Recommended Changes to Publications and Blank Forms

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APPENDIX B

TECHNICAL SUPPORT

DEFENSE HEALTH AGENCY VETERINARY SERVICES

The Defense Health Headquarters (DHHQ) Chief, Defense Health Agency Veterinary Services 7700 Arlington Boulevard Falls Church, VA 22042

DSN: (312) 761-3061/7757; COM (703) 681-3061/7757;

FAX: (703) 681-3059

AIR FORCE

U.S. Air Force School of Aerospace Epidemiology Consult Service USAFSAM/PHR

2510 5th Street

WPAFB, OH 45433-7913

DSN: (312) 798-3207; COM: (937) 938-3207

E-mail: foodprotection@wpafb.af.mil

ARMY

U.S. ARMY PUBLIC HEALTH CENTER

8252 Blackhawk Road E5158 MCHB-PH-VHS

Aberdeen Proving Ground, MD 21010-5403

After hours (24-hour toll free): 1-800-222-9698, or DSN: (314) 584-4375

Public Health Sanitation Branch

DSN: (312) 584-2475/5458; COM: (410) 436-2475/5458

E-mail: usarmy.apg.medcom-aphc.mbx.environmentalhealthsanitation@mail.mil

Veterinary Food Protection

DSN: (312)867-3147; COM: (410) 417-3147

E-mail: usarmy.apg.medcom-aphc.mbx.iph-vet@mail.mil

DOD FOOD ANALYSIS AND DIAGNOSTIC LABORATORY

Public Health Command-Central ATTN: Food Analysis Laboratory 2899 Schofield Road, Suite 2630 Fort Sam Houston, TX 78234-7583 COM: (210) 295-4708/4761

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U.S. ARMY QUARTERMASTER CENTER AND SCHOOL

Direct all questions regarding dining facility food equipment and tactical feeding to:

Joint Culinary Center of Excellence ATTN: Facilities and Equipment Branch

DSN: (312) 687-3354/3450; COM: (804) 734-3354/3450 http://www.quartermaster.army.mil/jccoe/jccoe_main.html

E-mail: leeejccoeweb@conus.army.mil

NAVY/MARINE CORPS

Navy and Marine Corps Public Health Center 620 John Paul Jones Circle, Suite 1100 Portsmouth, VA 23708-2103 DSN: (312) 377-0700; COM: (757) 953-0700

http://www.nmcphc.med.navy.mil/

Navy Environmental and Preventive Medicine Unit Two (NEPMU2)

1285 West D Street, Bldg. U238 Norfolk, VA 23511-3394

DSN: (312) 377-6600; COM: (757) 953-6600

http://www.med.navy.mil/sites/nepmu2

E-mail: NEPMU2-FleetandFMFSupport@med.navy.mil

Navy Environmental and Preventive Medicine Unit Five (NEPMU5)

3235 Albacore Alley San Diego, CA 92136

DSN: (312) 526-7070; COM: (619) 556-7070;

http://www.med.navy.mil/sites/nmcsd/nepmu5/Pages/index.htm

Navy Environmental and Preventive Medicine Unit Six (NEPMU6)

385 South Ave, Bldg. 618 JBPHH, HI 96860

DSN: (315) 471-0237; COM: (808) 471-0237

http://www.med.navy.mil/sites/nmcsd/nepmu6/Pages/index.html

Navy Environmental and Preventive Medicine Unit Seven (NEPMU7)

PSC 819 Box 67 FPO AE 09645-0067

DSN: (314) 727-2230; COM: 011-34-956-82-2230

E-mail: NEPMU7@eu.navy.mil

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APPENDIX C

DEBITABLE PROVISIONS DURING FOOD ESTABLISHMENT INSPECTIONS

The tables presented in this appendix are provided to assist inspection personnel by identifying the provisions in this publication that are debitable on inspection reports. The tables also identify—

- a. The provisions that are marked as a Critical tagline. These are indicated with an asterisk *.
- b. The paragraph(s) under a *Critical* tagline that are marked with a superscripted "N" and scored as "noncritical" on the inspection report when violated.
- c. The paragraph(s) under a *Critical* tagline that are designated as "swing" items. *Swing* items are *Critical* requirements that may be scored as "noncritical" under certain conditions and is based solely on the professional judgment of the regulatory authority. *Swing* paragraphs are depicted in the table with the word "Swing" followed by the swing paragraph number.
- d. The *Item Number*, which represents the item grouping on the inspection checklist for the specified inspection document (for example, DD 2973 or DD 2974). A provision can only be debited under a single Item Number unless different criteria listed under separate paragraphs within the provision are violated. When multiple Item Numbers are listed in the table for the provision, the inspector uses the guidance at Appendix E to help match the provision's violated paragraph with the corresponding Item Number on the inspection report. Additionally, the applicable paragraph from the provision is also depicted in subscripted parenthesis next to the Item Number in which the violation is marked on the inspection report. For example—
 - Table C-1 indicates a violation of provision 2-201.11 is marked using checklist Item Number "2" or "5" and is depicted under the *Item Number* column as " $2_{(A)}$; $5_{(A)-(F)}$." In order to mark checklist Item "2," the violation must involve the criteria specified in paragraph (A) of the provision. If one or more criterion cited in paragraphs (B), (C), (D), (E), or (F) are violated, then checklist Item Number 5 is marked.
 - A violation involving Subparagraph 3-501.16(A)(1) is marked using checklist Item Number 31; whereas, a violation involving Subparagraph (A)(2) of the same provision is marked using checklist Item Number 32 (refer to Table C-2.)
 - When multiple Item Numbers are listed for a provision and only some of the provision paragraphs are accounted for in the table, then the unaccounted provisions are either nondebitable (for example, italicized text) or it contained a cross-reference to another provision where the violation is appropriately cited under.

Table C-1. Chapter 2 debitable provisions

Provision Number	Noncritical Paragraphs	Item Number ¹	Provision Number	Noncritical Paragraphs	Item Number ¹
2-101.11*		1	2-303.11		7
2-102.11*	Swing: (A), (C)	1	2-304.11		7
2-102.12		1	2-401.11		8
2-103.11		2	2-401.12		5
2-201.11*		2 _(A) ; 5 _{(A)-(F)}	2-402.11		7
2-201.12*		5	2-403.11		24
2-201.13*		5	2-501.11 [†]		2
2-301.11*		4	2-502.11 [†]		2
2-301.12*		4	2-503.11 [†]		2
2-301.13	RESERVED		2-503.12 [†]		2
2-301.14*		4	2-503.13 [†]		2
2-301.15		4	2-505.11 [†]		2
2-301.16		4	2-601.11		51
2-302.11		7			

¹ Item Numbers presented in this table apply to DD Form 2973.

Table C-2. Chapter 3 debitable provisions

Provision Number	Noncritical Paragraphs	Item Number ¹	Provision Number	Noncritical Paragraphs	Item Number ¹
3-101.11*		10	3-202.18*		11
3-201.11*		9	3-202.19		10
3-201.12*		9	3-202.110*	(A)	9
3-201.13*		9	3-203.11		12
3-201.14*		9	3-203.12*		11
3-201.15*		9	3-301.11*	Swing: (C)	6
3-201.16*		9	3-301.12*		8
3-201.17*		9	3-302.11*		15
3-201.18*†		9	3-302.12		12
3-202.11*	Swing: (E)	10	3-302.13*		19
3-202.12*		20	3-302.14*		20
3-202.13*		9	3-302.15		16
3-202.14*		9	3-303.11*		21
3-202.15*		10	3-303.12		21
3-202.16*		9	3-304.11*		19
3-202.17		12	3-304.12		36

continued

Table C-2 (continued)

Provision Number	Noncritical Paragraphs	Item Number ¹	Provision Number	Noncritical Paragraphs	Item Number ¹
3-304.13		19	3-404.11		34
3-304.14		23	3-501.11		51
3-304.15		22	3-501.12		26
3-304.16		19	3-501.13		26
3-304.17		19	3-501.14*		29
3-305.11		15	3-501.15		30
3-305.12		15	3-501.16*		31 _{(A)(1)} ; 32 _{(A)(2),(B)}
3-305.13		12	3-501.17*		14
3-305.14		19	3-501.18*		14
3-306.11		19	3-501.19*		34
3-306.12		19	3-501.110*†	(C)	13
3-306.13*	(D)	19	3-502.11*		34
3-306.14*		18	3-502.12*		34
3-306.15 [†]		19	3-502.13 [†]		51
3-307.11		19	3-503.11 [†]		51
3-401.11*		27	3-601.11		12
3-401.12*		27	3-601.12		10
3-401.13		28	3-602.11		12
3-401.14*		27	3-602.12		12
3-402.11*		11	3-603.11*		33
3-402.12		11	3-701.11*		18
3-403.11*		27	3-801.11*		6 _(D) ; 18 _{(A)-(C),(E),(H)}

¹ Item Numbers presented in this table apply to DD Form 2973.

Table C-3. Chapter 4 debitable provisions

Provision Number	Noncritical Paragraphs	Item Number ¹	Provision Number	Noncritical Paragraphs	Item Number ¹
4-101.11*	(B), (C), (D), (E)	37	4-101.18		37
4-101.12		37	4-101.19		37
4-101.13		37	4-101.110 [†]		37
4-101.14*		37	4-101.111 [†]		37
4-101.15*		37	4-101.112 [†]		37
4-101.16		23	4-101.113 [†]		37
4-101.17		37	4-102.11*	(A)(2), (B)(2)	39

continued

Table C-3 (continued)

Provision Number	Noncritical Paragraphs	Item Number ¹	Provision Number	Noncritical Paragraphs	Item Number ¹
4-201.11		37	4-204.123		37
4-201.12*		37	4-204.124 [†]		37
4-201.13 [†]		37	4-205.11 [†]		37
4-202.11*		37	4-205.12 [†]		37
4-202.12		37	4-205.13 [†]		37
4-202.13		37	4-205.14 [†]		40
4-202.14		37	4-205.15 [†]		40
4-202.15		37	4-301.11		30
4-202.16		37	4-301.12		40
4-202.17		37	4-301.13		40
4-202.18		49	4-301.14		49
4-203.11		35	4-301.15		37
4-203.12		35	4-301.16 [†]		37
4-203.13		40	4-302.11		37
4-204.11		49	4-302.12		35
4-204.12		37	4-302.13		35 _(A) ; 40 _(B)
4-204.13*	(A), (C), (D)	37	4-302.14		40
4-204.14		37	4-303.11 [†]		40
4-204.15		37	4-401.11		37
4-204.16		37	4-401.12 [†]		50
4-204.17		37	4-402.11		37
4-204.18		37	4-402.12		37
4-204.19		37	4-501.11		37
4-204.110		34 _(B) ; 37 _(A)	4-501.12		37
4-204.111*		37	4-501.13		37
4-204.112		35	4-501.14		40
4-204.113		40	4-501.15		40
4-204.114		40	4-501.16		40
4-204.115		40	4-501.17		40
4-204.116		40	4-501.18		40
4-204.117		40	4-501.19		40
4-204.118		40	4-501.110		40
4-204.119		40	4-501.111*		17
4-204.120		40	4-501.112		17 _(C) ; 40 _{(A),(D)}
4-204.121		37	4-501.113		40
4-204.122		37	4-501.114*		17

continued

Table C-3 (continued)

Provision Number	Noncritical Paragraphs	Item Number ¹	Provision Number	Noncritical Paragraphs	Item Number ¹
4-501.115*		17	4-603.18 [†]		40
4-501.116		40	4-702.11*		17
4-502.11		35 _(B) ; 37 _{(A),(C)}	4-703.11*		17
4-502.12*		39	4-801.11		38
4-502.13		39	4-802.11		38
4-502.14		39	4-803.11		38
4-503.11 [†]		50	4-803.12		38
4-503.12 [†]		50	4-803.13		47
4-601.11*	(B), (C)	17 _(A) ; 41 _{(B),(C)}	4-901.11		38
4-602.11*	(E)	17	4-901.12		23
4-602.12		41	4-902.11		37
4-602.13		41 _{(A),(C)} ; 49 _(B)	4-902.12		37
4-603.11		37	4-903.11		38 _{(A),(B)} ; 39 _{(A),(C)}
4-603.12		40	4-903.12		38; 39
4-603.13		40	4-904.11		38 _{(A),(B)} ; 39 _{(A)-(D)}
4-603.14		40	4-904.12		38
4-603.15		40	4-904.13		38
4-603.16		40	4-904.14		40
4-603.17	DELETED; see 3-3	04.17			

¹ Item Numbers presented in this table apply to DD Form 2973.

Table C-4. Chapter 5 debitable provisions

Provision Number	Noncritical Paragraphs	Item Number ¹	Provision Number	Noncritical Paragraphs	Item Number ¹
5-101.11*		43	5-104.12		43
5-101.12*	(B)	43	5-201.11*	(C), (D)	43
5-101.13*		9	5-202.11*	(B), (D), (E)	43
5-101.14*†		17	5-202.12		3
5-102.11*		N/A^2	5-202.13*		43
5-102.12*		43	5-202.14*		43
5-102.13		N/A^2	5-202.15		43
5-102.14		51	5-202.16 [†]		44
5-103.11		42	5-203.11		3
5-103.12		42	5-203.12		46
5-104.11		43	5-203.13		44

continued

Table C-4 (continued)

Provision Number	Noncritical Paragraphs	Item Number ¹	Provision Number	Noncritical Paragraphs	Item Number ¹
5-203.14*		43	5-401.11		44
5-203.15		43	5-402.11*		44
5-204.11		3	5-402.12		44
5-204.12		43	5-402.13*	(B)	44
5-204.13		43	5-402.14		44
5-204.14 [†]		44	5-402.15		44
5-205.11		3	5-403.11*		44
5-205.12*	(B)	43	5-403.12		44
5-205.13		43	5-501.11		45
5-205.14*	(C)	43	5-501.12		45
5-205.15*	Swing: (B)	43	5-501.13		45
5-205.16 [†]		43	5-501.14		45
5-301.11*	(B), (C)	43	5-501.15		45
5-302.11		43	5-501.16		45
5-302.12		43	5-501.17		46
5-302.13		43	5-501.18		45
5-302.14		43	5-501.19		45
5-302.15		43	5-501.110		45
5-302.16*	(B), (C), (D), (E),	43	5-501.111		45
3-302.10	(F)	43	5-501.112		45
5-303.11*		43	5-501.113		45
5-303.12		43	5-501.114		45
5-303.13		43	5-501.115		45
5-304.11*		43	5-501.116		45
5-304.12		43	5-502.11		45
5-304.13		43	5-502.12		45
5-304.14*		43	5-503.11		45

¹ Item Numbers presented in this table apply to DD Form 2973. ² N/A = not applicable; The provision is assessed independent of the food operation inspection and is a component of drinking water surveillance activities.

Table C-5. Chapter 6 debitable provisions

Provision Number	Noncritical Paragraphs	Item Number ¹	Provision Number	Noncritical Paragraphs	Item Number ¹
6-101.11		47	6-301.14		3
6-102.11		47	6-302.11		46
6-200.11 [†]		47	6-303.11		48
6-201.11		47	6-304.11		49
6-201.12		47	6-304.12 [†]	REMOVED; see 4-301	.14 & 6-304.11
6-201.13		47	6-305.11		47
6-201.14		47	6-402.11		46
6-201.15		47	6-403.11		47
6-201.16		47	6-404.11		19
6-201.17		47	6-501.11		47
6-201.18		47	6-501.12		47
6-202.11		48	6-501.13		47
6-202.12		49	6-501.14		49
6-202.13		24	6-501.15		47
6-202.14		46	6-501.16		47
6-202.15		24	6-501.17		47
6-202.16		24	6-501.18		46
6-202.17		47	6-501.19		46
6-202.18		47	6-501.110		47
6-202.19		47	6-501.111		24
6-202.110		45	6-501.112		24
6-202.111*		47	6-501.113		47
6-202.112		47	6-501.114		47
6-301.11		3	6-501.115		24
6-301.12		3	6-501.116 [†]		51
6-301.13		3	6-502.11 [†]		51

¹ Item Numbers presented in this table apply to DD Form 2973.

Table C-6. Chapter 7 debitable provisions

Provision Number	Noncritical Paragraphs	Item Number ¹	Provision Number	Noncritical Paragraphs	Item Number ¹
7-101.11		25	7-205.11*		25
7-102.11		25	7-206.11*		25
7-201.11*	Swing: (A)	25	7-206.12*	(A)(2), (B)	25
7-202.11		25	7-206.13*	(B)	25
7-202.12*	(A)(4), (C), (D)(1), (D)(2)	25	7-207.11*	(A)	25
7-203.11*		25	7-207.12*		25
7-204.11*		25	7-208.11*	Swing: (A)	25
7-204.12*	(B)	25	7-209.11		25
7-204.13*		25	7-301.11*	Swing: (A)	25
7-204.14*		25			

¹ Item Numbers presented in this table apply to DD Form 2973.

Table C-7. Chapter 8 debitable provisions

Provision Number	Noncritical Paragraphs	Item Number ¹	Provision Number	Noncritical Paragraphs	Item Number ¹
8-103.11		34	8-302.14		N/A ²
8-103.12*	(B)	34	8-304.11		2
8-201.11		N/A ²	8-400.11†		<i>N/A</i> ³
8-201.12		N/A ²	8-402.11		2
8-201.13		34	8-402.12 [†]		2
8-201.14		34	8-402.13		<i>N/A</i> ³
8-204.11		N/A ²	8-402.14 [†]		<i>N/A</i> ³
8-301.11*	(B), (C), (E), (F)	1 _{(A), (D)} , <i>N/A</i> ³ _{(B), (C)}	8-404.11		2
8-301.12*†		N/A	8-404.12		2
8-302.11		N/A ²	8-405.11		2
8-302.12		N/A ²	8-406.11		2
8-302.13		N/A ²	8-501.11		<i>N/A</i> ³

NOTE: Chapter 8 contains programmatic level information for food managers and public health regulators. The criteria in Chapter 8 provide a foundation for installation leaders and food managers to plan and coordinate activities associated with new or existing food establishments. For regulatory personnel the Chapter outlines procedures for food sanitation surveillance and enforcement. Many of the provisions that are numbered using a "nondebitable" coding value, such as 8-403.10 and 8-403.20, are accountable by the regulatory authority during organizational-level evaluations conducted by a higher headquarters.

N/A = not applicable

¹ Item Numbers presented in this table apply to DD Form 2973.

² The provision is part of preplanning criteria that is applied before the preoperational inspection phase for new food establishments.

³ The provision is a regulatory authority function.

Table C-8. Chapter 9 debitable provisions

Provision Number	COMMENTS	Noncritical Paragraphs	Item Number ¹
9-102.11* [†]		(D), (E)	$4_{(A)}; 6_{(B)}; 9_{(E)}; 10_{(D)}; 17_{(G)}; 18_{(H)}; 22_{(F),(I)}; 34_{(C)}$
9-103.11*†	Cite using §§ 2-201.11 & 2-201.12, as applicable		38
9-201.11†			1
9-202.11†			2 _{(B)-(F)} ; 3 _(A)
9-202.12†			5
9-202.13†			4
9-203.11†			3
9-204.11†			3 _(C) ; 11 _{(A),(B)} ; 22 _(A)
9-204.12†			4 _(A) ; 34 _(B) ; 44 _(C)
9-204.13†			7
9-204.14 [†]			8
9-301.11*†			34
9-302.11†			36
9-303.11*†			34
9-303.12*†		(B)	37
9-303.13*†		(A), (B)(1), (B)(3), (C), (D), (E)	37
9-304.11†			35
9-304.12*†			35
9-401.11†			31
9-403.11 [†]			12 _{(A),(B)} ; 13 _(C)
9-501.11*†	Cite using § 3-201.11		15
9-502.11*†		(B)(1), (B)(3)	17 _{(B),(C)} ; 18 _{(A),(B)} ; 25 _(C)
9-502.12*†			19 _(A) ; 20 _(B)
9-502.13*†		(A)(3), (B), (C)	20 _(E) ; 24 _{(A),(B),(C),(D)}
9-502.14*†			25
9-502.15 [†]			22
9-502.16 [†]			17
9-502.17*†			21
9-502.18 [†]			22
9-601.11 [†]			40 _(C) ; 42 _(A) ; 44 _(B)

¹ Item Numbers presented in this table for Chapter 9 apply only toDD Form 2974.

Table C-9. Chapter 10 debitable provisions

Provision Number	COMMENTS	Noncritical Paragraphs	Item Number ¹
10-201.11* [†]	Para (A) cited using § 5-101.11; all others use § 10-201.11	(B)(2), (B)(3), (B)(4)(a & b), (C)	43
$10\text{-}201.12^\dagger$	Cite using § 5-103.11		42
10-201.13 [†]	Cite using § 5-104.12		42
10-201.14 [†]	Cite using § 5-104.12		42
10-201.15 [†]			51
10-202.11 [†]	Cite using § 5-203.11		3
10-203.11 [†]			44
10-301.11 [†]	Cite using § 6-101.11		47
10-301.12 [†]	Cite as applicable using criteria under Part 6-2		24; 45; 47; 48; 49 [refer to Table C-5 to match the provision to the correct inspection Item Number]
10-301.13 [†]	Cite using § 6-201.15		47
10-301.14 [†]	Cite using § 6-201.18		47
10-301.15 [†]	Cite using § 6-202.15		24
10-301.16 [†]	Cite using § 6-102.11		47; 51 _(B)
10-401.11 [†]			<i>N/A</i> ²
10-401.12 [†]			<i>N/A</i> ²
10-501.11 [†]			51
10-501.12 [†]			51
10-501.13 [†]			51

¹ Item Numbers presented in this table apply to DD Form 2973.

² N/A = not applicable; The provision is part of preplanning criteria that is applied before the preoperational inspection phase for new food establishments.

APPENDIX D

FOOD FACILITY RISK ASSESSMENT

D-1. Purpose

Provide a model risk assessment process for determining minimum food sanitation inspection frequency of retail stores and food establishments.

D-2. Abstract

Risk assessment models provide a systematic approach to determine the frequency of inspections and other interventions for retail food establishments and food stores containing food concessions or food processing operations. The model risk assessment plan outlined in this appendix is based on inherent risks associated with food service operations and the knowledge and understanding of factors that cause foodborne illnesses. Implementation of this plan will improve the allocation of personnel and other resources and, when coupled with a risk-based inspection process, will optimize inspection effectiveness.

D-3. Applicability

Preventive medicine and veterinary services should conduct food sanitation inspections at the recommended frequencies outlined in Chapter 8, <u>Table 8-2</u>. Constraints due to manpower shortages, other mission priorities, or widely dispersed facilities within the area of responsibility may necessitate adjustment to prescribed frequencies. The *Food Facility Risk Assessment Survey* serves as a tool to help justify either a reduction or increase to prescribed inspection frequencies.

D-4. Method

The frequency of sanitation inspections may be determined based on the risk categorization of food establishments and retail stores, referred to in this appendix as food facilities. Risk categorization is determined by identifying activities and conditions associated with five risk factors and tabulating the corresponding weighted points using DD Form 2972.

- a. Complete items 1 through 6 on DD Form 2972. In item 1, mark the *Food Service* block if the facility meets the definition of a food establishment; mark the block for *Retail Store* if the primary function of the facility involves the sale of packaged products, for example, the commissary and Express. Retail stores may operate food concessions within the store, such as a salad bar, breakfast sandwiches or other RTE foods heated onsite and held in hot holding, or other operations involving food preparation and service.
- *b. Scoring the facility.* Food facilities are assigned one of four risk ratings extremely high, high, moderate, and low based on total points assessed for each of the risk factor groups. The five risk factors and scoring methods are—
- (1) Factor I, Food Properties. Food and its components may allow food to become a vehicle for, or a source of, foodborne illness. Item 8 on the form provides a list of foods and/or groups of foods with common characteristics.
- (a) Factor I takes into consideration the properties associated with the food, for example, time-temperature relationships affected by acidity or alkalinity (pH); water activity (a_w), product ingredients, such as salts and preservatives; and common micro flora associated with the product or its environment.
- (b) Identify all of the relevant activities/conditions present in the facility at the time of the survey and those activities/conditions that, although not present at the time of the survey, are routine practices within the food facility. Mark the YES block if the condition applies; mark the NO block if the condition does not apply.
 - (c) Item 8.n., Retail Sales, applies only to retail food stores.
- (1) Mark YES in the box for line item 8.n.(1) and award 1 point for retail food stores that only conduct the sale of commercially packaged foods; this may include non-TCS foods, such as hot beverages and bakery items

(donuts, cake muffins, cookies) that are delivered pre-prepared to the facility. Other characteristics of the retail store applicable to this section are: bulk foods, such as potato or macaroni salads, are not opened and dispensed in smaller portions at the request of the customer; and equipment is not available for customers to reheat or cook food on the premises.

- (2) For retail stores that conduct food service-related activities, mark NO in the box for line item 8.n.(1) and mark YES for all of the applicable food service categories described in items 8.n.(2) (4) as follows:
- *i. Sandwiches.* This category applies to retail stores that offer commercially packaged (sealed) chilled sandwiches and/or sandwiches wrapped in loose paper packaging or plastic wrap that are delivered to the facility and offered for service either hot or chilled.
- ii. Limited food preparation. This category involves sales of food items requiring limited preparation onsite. This includes baking pre-made or frozen cookies, cakes, or muffins, and heating fully cooked FOODS, such as hot dogs, burritos, pizza, chicken wings, and sandwiches. Also included in this category are bakery services operated within the retail store that do not prepare products by mixing raw ingredients. Deli operations are limited to dispensing commercially bulk-prepared foods, such as meats, cheeses, and salads, and do not cook or otherwise mix ingredients onsite.
- *iii.* Food concessions or expanded food preparation. This category typically includes retail stores operating a salad/soup bar; sushi bar; a full service deli department that roasts meats, prepares fresh salads (for example, tuna, macaroni, potato) and sandwiches onsite; rotisserie chicken operations, seafood department involving steaming/cooking, and/or bakery operations in which raw ingredients are mixed onsite.
- (3) When scoring item 8.n., only 1 point may be assessed if item 8.n.(1) is selected; items 8.n.(2)-(4) may not be selected if 8.n.(1) is marked *YES*. Marking *YES* for applicable items in 8.n.(2)-(4) may result in a minimum of 6 points or maximum of 33 points assessed for retail sales.
 - (d) When evaluating food establishments, mark NO for all of the conditions outlined under item 8.n.
- (e) When evaluating retail stores, assess all conditions listed in Factor I except item 8.m. (operational rations preparation).
- (f) Award the corresponding points associated with each YES response, and insert the total awarded points for Factor I in the space provided at the end of item 8. A maximum value of 44 points for food establishments and 75 points for retail stores is possible for Factor I.
- (2) Factor II, Population Served. Specific populations, such as the young, the aged, and the infirmed, are predisposed to illness caused by foodborne pathogens or toxins. Service members and Civilians are also more susceptible when exposed to high operational tempo, increased physical and emotional stress, and sleep deprivation generally associated with initial entry training, field training exercises greater than 2 weeks, and deployment. Additionally, the larger the population served and the greater number of meals and volume prepared, the higher the risk of an outbreak of foodborne illness. Item 9 on the form characterizes the population served by identifying the number of meals or customers served and the typical facility patronage. It further distinguishes shipboard subsistence as higher risk due to increased population susceptibility (associated with a high operational tempo), the absence of subsistence options, and the potential impact to mission readiness.
- (a) For food establishments, identify the average number of meals or customers served per day. When there is a significant difference between the average weekday and weekend patronage, use the higher value. Only one item in section 9.a.(1) through (4) should be marked as YES. For retail stores, mark YES for item 9.a.(4), and award zero points.
- (b) Item 9.b. applies to all food facilities; only one of the three subcategories should be marked as YES.
- (1) Shipboard. Mark YES in item 9.b.(2) for all subsistence operations conducted aboard a nautical vessel when in port and deployed (at sea); the associated weighted point value includes the characterization of a highly susceptible population; therefore, item 9.b.(1) must not be marked YES.
- (2) Retail stores. Mark YES in item 9.b.(3) for all retail food stores. Exceptions include retail stores operated in a medical treatment facility with inpatient service, stores operating in a combat or contingency deployment setting, and stores operating aboard a nautical vessel.
- (c) Tabulate the awarded points for item 9, and insert the total value in the space provided at the end of item 9 on the form. A maximum value of 28 points is possible for Factor II.

- (3) Factor III, Food Operations. Operational risks are those risks that exist due to processes or procedures that influence survivability of microorganisms. Examples include cooking, cooling, storage, and multiple handling steps; and environmental settings, such as remote feeding and temporary food establishments, where diminished controls are likely to exist.
- (a) Item 10 on the form identifies characteristics of food operations and food preparation activities. This section is assessed for both food establishments and retail food stores.
- (b) When item 10.h. (cook-chill; sous-vide) is marked YES, other associated processes outlined in item 10.a.-c. must also be marked YES. For example, a food establishment prepares large batches of beef stew using a cook-chill-reheat process. This process requires marking YES for item 10.h. (cook-chill) and awarding 2 points. The facility also prepares pasta, rice, potatoes, and other vegetables fresh for each meal and often retains leftovers for the next meal service. These activities require checking items 10.a. (cooking), 10.b. (cooling), and 10.c. (reheating), with corresponding point values of 6, 4, and 4, respectively. The total point value for Factor III in this example is 16.
- (c) Award the corresponding points associated with each YES response, and insert the total point value in the space provided at the end of item 10 on the form. A maximum point value of 27 is possible for Factor III.
- (4) Factor IV, Facilities and Equipment. To minimize foodborne illness risks, FOOD operations will possess adequate amounts of functional equipment to support its operation.
- (a) Factor IV assesses adequacy in the quantity of required equipment on hand and operability of the equipment on hand. Mark the YES block as appropriate for each item, such as when equipment is missing, equipment does not provide suitable capacity to support the operation, or equipment is inoperable or poorly functioning.
- (b) If multiple deficiencies exist under the same category, points are assessed one time, and a comment is entered in item 14, *Remarks*. For example, a facility with only one walk-in refrigerator is consistently found over packed with boxes of meat and produce being stored on the floor. Additionally, one of three reach-in refrigerators consistently operates at an ambient temperature of 45°F. Two deficiencies exist under line item 11.b.: inadequate number of refrigeration units on hand, and existing refrigeration units are not operating at the proper cold storage temperature. Although two deficiencies exist under the same item number, only 2 points are awarded for item 11.b.
 - (c) Item 11 is evaluated for both food establishments and retail food stores.
- (d) Award the corresponding points associated with each YES response, and insert the total point value in the space provided at the end of item 11 on the form. A maximum point value of 13 is possible for Factor IV.
- (5) Factor V, Inspection and Employee History. The inspection history is based on critical violations noted on the previous inspections and may include the current inspection if conducted in conjunction with the annual facility risk assessment. Conduct a review of 10-12 of the most recent official inspections (routine and follow-up) that were conducted by the regulatory authority.
- (a) Two points are awarded if the food facility received two or more "unsatisfactory" or "noncompliant" inspection ratings within the previous 10-12 inspections. *Note: The assessment period may extend beyond 12 months in order to review a sufficient number of inspections.*
- (b) Four points are awarded if inspection reports indicate the PIC was not present or was unable to demonstrate knowledge of the public health requirements outlined in the TSFC. (Inspection reports need not implicate the same PIC in order to apply this deficiency.)
- (c) Award the corresponding points associated with each YES response, and insert the total point value in the space provided at the end of the item 12 on the form. A maximum point value of 6 is possible for Factor V.
- c. Total score. Calculate the Total Score by adding the total points awarded for Factors I through V (items 8 through 12), and insert the score in item 13 on the form. The maximum points possible for food operations/food establishments is 118; the maximum point possible for retail stores is 121.
- d. Risk category. The total score is used to determine the risk category of the food facility. Compare the *Total Score* to the *Risk Category* points located in item 7 of the form; mark the box for the corresponding risk category. Circle the recommended minimum inspection frequency designated for the risk category.

e. Signing the form.

- (1) The person conducting the facility risk assessment completes item 15 on the form by printing his/her full name, rank, and duty position (15a.), phone (15b), assessment date (15c), official email address (15d), and assigned duty organization (15e). The duty organization is the name of the medical treatment facility, preventive medicine, or veterinary unit.
- (2) The Food Facility Risk Assessment Survey form is not complete until it has been reviewed and signed (item 16) by a public health supervisor or leader with regulatory oversight of the food facility. This is typically the officer in charge of the Preventive Medicine Department, Environmental Health Section, or Veterinary Service Activity for food inspection. Review authority may be delegated to a senior noncommissioned officer or warrant officer responsible for managing the food sanitation inspection program at the installation or region level, as appropriate.

D-5. Factors Influencing the Rating

- a. The types of foods and associated operations within a food facility and populations served typically remain constant. Prescribed inspection intervals outlined in Chapter 8, <u>Table 8-2</u>, are based on risks associated with the expected activities for the various types of food facilities. Expectations include specific foods dispensed, number and type of population(s) served, and related operational support or food processing activities. The following are examples that identify basic assumptions applied to each risk category, which were used to determine the inspection frequencies noted in Table 8-2. The assumptions were based on operations without Code violations/deficiencies:
- (1) Extremely high risk—shipboard. Stuffed foods and leftovers are allowed; total meals/customers served daily are greater than or equal to 900.
- (2) *High risk—dining facility*. Comprehensive food operation; may serve raw/undercooked foods and game animals (commercial); not a field food prep operation; occasionally supports remote/field feeding; serves a medium-sized population with 300-899 meals daily; not serving a highly susceptible population.
- (3) *High risk—retail food store with advanced food service activities*. Facility contains a food concession (sushi bar) or expanded deli operations as specified in subparagraph <u>D-4.b.(2)iii</u>; facility does not serve pre-cooked foods or supply self-serve hot/chilled sandwiches.
- (4) *Moderate risk—basic retail food store*. Facility operates as a "traditional" grocery or convenience store (commissary or Exchange) with limited food service operations as defined in subparagraph <u>D-4.b.(2)ii</u>.
- (5) *Moderate risk—fast food operations*. Primarily frozen, pre-cooked, or bulk commercially prepared foods are prepared/served; no raw/undercooked or stuffed foods are served; no game animals; soups/stews/sauces not prepared onsite from raw ingredients; no whole RTE fruits and vegetables; time as a public health control is practiced; variance is not present; serves 300-899 customers daily; HSP not serviced.
- (6) Low risk—vending machine operation; small food concession. Operation contains vending only with no onsite food preparation; small food concessions are limited to serving nonTCS foods or dispensing commercially prepared RTE foods that are individually packaged.
- (7) *Unrated—temporary and seasonal operations*. The inspection frequency for temporary and seasonal operations varies due to the limited timeframe in which they operate. Typically, a preopening or preoperational inspection is conducted, and periodic inspections occur thereafter.
- b. Food facilities operating under the assumptions noted in paragraph a. of this section and under optimum conditions will likely fall into their prescribed risk category if assessed using the Food Facility Risk Assessment Survey form.
- (1) Using DD Form 2972 may justify reduction in a prescribed inspection frequency. Influencing factors include facilities operating with fewer Food Properties (item 8), servicing a smaller population (item 9), and/or supporting less diverse Food Operations (item 10).
- (2) Factors that may justify increasing a facility's inspection frequency include foods obtained from non-approved sources (item 8.a.), an increase in the size or a change in the type of population served (item 9), and deficiencies noted in item 11, Facilities and Equipment, and item 12, Inspection and Employee History.

D-6. Implementation

- a. Food facility risk assessment surveys are conducted by environmental health, preventive medicine, veterinary services, and other designated public health personnel with direct regulatory oversight of food operations in the area of responsibility. Surveys are intended to be conducted once during a 12 to 24 month period. The following are the recommended frequencies for updating facility risk assessments:
 - (1) Conduct an annual update for facilities rated Extremely High or High risk.
 - (2) Facilities rated Moderate or Low risk should receive an update every 18 to 24 months.
- (3) A new survey should be conducted whenever there is a major change within the evaluated food facility, such as when the menu is diversified or reduced, a change in patronage size or type occurs, or major facility/equipment renovations occur.
- (4) A new survey is not required for facilities whose performance has significantly declined during the current assessment period. The REGULATORY AUTHORITY should increase the inspection frequency until performance is stabilized and then resume the original inspection schedule until the next scheduled risk assessment update.
- b. Collaboration between veterinary and preventive medicine services supporting a common area of operations is recommended for overall food sanitation program continuity and efficiency.
- c. Survey information is recorded on DD Form 2972. The supervisor or program manager, as specified in subparagraph <u>D-4.e.(2)</u>, of the person completing the form will review the assessment for accuracy and completeness of the form. When all data is accurate and complete, the supervisor approves and completes the form by signing in item 16.f.
- d. The regulatory authority will reassess the facility risk score and risk category annually to evaluate changes that affect the facility's risk rating. This review should include verification of the menu and operations and recalculation of the risk score. The risk assessment procedure and resulting risk category should be discussed with the food facility's PIC. An electronic database may be used at the local level to allow ease of retrieval and referral of applicable data. The regulatory authority should also consider outside factors that may influence inspection schedules (for example, PIC and personnel turnover).
 - e. The original risk assessment form shall be maintained on file by the appropriate inspection office for 3 years.
- f. A copy of the completed facility risk assessment shall be provided to the food facility's PIC and shall be maintained on file at the evaluated food facility.

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APPENDIX E

INSTRUCTIONS FOR MARKING FOOD SANITATION INSPECTION FORMS

Section I. GENERAL ADMINISTRATION

E-1. Purpose

Appendix E is intended for use during inspections to ensure that observations of the TSFC provisions are not overlooked during the inspection and are accurately recorded when either the *Food Operation Inspection Report* or the *Tactical Kitchen Food Sanitation Inspection* form is used.

E-2. Organization of the form

- a. Administrative information is contained at the top portion on each page of the inspection form.
- b. Page one of the form provides a summarized list of this publication's provisions that are grouped into related subject areas. These are listed as items 1 to 51 and 1 to 49 under block 12, *Compliance Status*, on DD Forms 2973 and 2974, respectively.
- (1) Asterisks immediately following item numbers indicate that all of the provisions included in the group are critical violations.
- (2) Item numbers that are not distinguished by an asterisk are generally noncritical violations. Within these groupings, however, there may be one or more provisions that are critical deficiencies. Critical deficiencies noted within this group are identified by bold font followed by an asterisk.
- c. Page two of the form provides blank spaces for the inspector to document temperature measurements taken from multiple equipment locations or food items and to further describe the observations and corrective actions related to the violations that were marked on page one.
- d. A quick reference guide is provided at the bottom of page two to assist the inspector when assigning the inspection rating.
- e. The bottom of page two provides spaces for the inspector and food operation PIC to sign and date the form upon conclusion of the inspection and brief-back to the PIC.
 - f. A continuation page is provided to document additional remarks and temperature measurements.
- g. An instruction page is provided as a quick reference for inspectors when marking the form and to identify the provisions to assess for each item number.

E-3. Administrative information

- a. Facility name. Provide the "usual/common" name of the food establishment at the top of pages one and two of the form and on all associated continuation pages.
- (1) Include the building number with the facility name. This will help to distinguish facilities that share a common name and provides a system of reference when entering or searching data in DOEHRS. For food operations located in retail store settings (for example, Exchange food court, Express store, or commissary) or hospitals, provide the food concession name or description if different from the "usual/common" name. Examples: 3310 DFAC #2; 42115 Burger King; 608 Burger King Exchange; 1536 Subway Hospital.
- (2) Ensure the naming convention used to identify each food operation has been standardized and consistently applied each time a new inspection is conducted for the operation.
 - b. Facility address.
- (1) For inspections conducted in a retail store setting or hospital, include the name of the facility or building descriptor (for example, commissary, Exchange, hospital) where the food operation is located.
 - (2) Provide the street address of the actual business location and include the city, state, and zip code.
 - (3) Installation. Provide the name of the installation or naval vessel in which the food operation is located.
 - c. Date. Provide the date of the inspection, using an alpha-numeric format with a 4-digit year as follows:

yyyy/mm/dd (2012/10/30) or dd-mmm-yyyy (30 OCT 2012). Include the date on page two and all associated continuation pages.

- d. Inspection type. Identify the reason for the inspection—routine, complaint, follow-up (reinspection), preoperational, other—by marking an "X" in the box corresponding to the inspection type. If "other" is marked, specify the type/reason for the inspection in the space provided. Also mark the inspection type at the top of page two and all associated continuation pages.
- *e. Inspector.* Provide the first and last name of the person conducting the inspection. For military personnel, include the individual's rank.
- f. Inspector phone. Provide the official commercial contact telephone number, with area code, of the inspector or regulatory authority office. For OCONUS locations, use the guidance specified in paragraph e. of this section.
 - g. Inspector e-mail. Provide the official (unit/organization) electronic mailing address of the inspector.
- *h. Inspector unit/organization.* Identify the military unit or organization to which the inspector is assigned or attached at the time of the inspection.
 - i. Start time. Annotate the actual time the inspection begins.
 - j. End time. Annotate the actual time the inspection officially ends.
- k. Various timeframes. Mark an "X" in the box when the inspection process occurs intermittently at various time periods throughout the day to capture different aspects of the operation. For example, the inspection is initiated (time in) in the early morning during receiving operations. After 45 minutes of assessment, the inspector departs the facility and returns mid-morning to observe food preparation and service activities for the lunch meal. The inspector then chooses to return to the facility during clean-up operations following the last meal served for the day. Following this period of observation, the inspection is completed (time out).
 - l. PIC. Provide the first and last name of the food establishment manager or PIC.
- *m. PIC phone.* Provide the PIC's official (business) commercial contact telephone number, with area code, at the establishment's location. For OCONUS operations, specify the type of number used (for example, DSN, SVOIP (mobile)), or include the country code if a commercial (landline) phone number is provided.
- n. PIC official e-mail. Provide the official business electronic mailing address of the manager or PIC identified in the previous block.
- o. Number and type of violations. At the conclusion of the inspection, report the total number of inspection items containing critical and noncritical violations as follows:
- (1) *Critical*. Count the number of inspection items containing a critical violation by counting the number of boxes checked in items 1-50 that contain an asterisk; include non-asterisked items containing critical provisions (bold font) that were marked within the item grouping.
- (a) Critical item groupings that contain one or more provisions with a SWING or noncritical paragraph contain the statement "Only a Non-Critical violation cited." Mark this box when the only violation occurring within the item grouping is designated or assessed as a noncritical, and count the item grouping as noncritical when scoring the inspection report.
- (b) If multiple critical violations were noted in a single item grouping, score the critical violation only once for that group. For example, if two violations occurred in item 14, one for provision 2-301.11* and one for provision 2-301.14*, each would be marked, but only 1 point would be added to the total number of critical items when scoring the inspection report. Place the total count in the space provided under *Number and Type of Violations*.
- (2) *Noncritical*. Count the number of inspection items containing noncritical violations by counting the number of boxes checked in items 1 to 51 that do not contain an asterisk, did not contain a critical violation marked within the item grouping, and critical item groupings where *Only a Non-Critical violation cited* was marked. If multiple violations were noted in a single item grouping, score the noncritical violation only once for that group. Place the total count in the space provided under *Number and Type of Violations*.
- (3) Item numbers with "N/A" (not applicable) or "N/O" (not observed) marked are not included in the totals.
- p. Inspection rating. At the conclusion of the inspection, score the food operation's level of compliance to Code provisions using the criteria outlined in chapter 8, Table 8-3 (also located at the bottom of page 2 of the form.)
 - (1) Deviation from the prescribed scoring criteria is not authorized.

- (2) Inspections are rated as fully compliant, substantially compliant, partially compliant, or noncompliant.
- (3) For inspections rated as noncompliant, provide the calendar date on which a follow-up inspection will be conducted. Follow-up inspections should be conducted as soon as reasonable to correct the critical violation and no later than 5 calendar days from the initial inspection. Corrective actions to remove or resolve the critical condition must not be delayed by the PIC. In many cases it is reasonable to conduct the Follow-up 24 to 48 hours following the initial inspection.
- q. Continuation pages. The continuation page provides additional space for documenting food temperatures and remarks used to characterize the violations found during the inspection. The first continuation page is numbered as page 3 of the report. If additional pages are used, insert the page number and the total number of pages associated with the inspection. Do not count the instruction pages as part of the report.
 - r. Signing and dating the form.
- (1) Signature by the PIC represents acknowledgement that the he or she has been briefed on all of the violations noted on the form, the corrective actions and associated timeframe for their completion, the final inspection rating, and, for inspections rated as noncompliant, the date on which a follow-up inspection will be conducted.
- (a) The PIC must sign the form upon receiving the brief-back by the inspector. The PIC's signature on the form does not constitute agreement or disagreement with the inspector's findings.
 - (b) The PIC provides the date on which he/she was briefed and signed the form.
- (2) The inspector signs and dates the form upon completion of the inspection. This signature provides a formal indication that an inspection was completed on the specified date.
- (3) The inspector and PIC must sign or initial the continuation page if it contains additional findings from the inspection.

E-4. Marking DD Form 2973

- a. Abbreviations used for compliance status.
- (1) "N/A" means that the item (all contents of the provision grouping) is not applicable to the food establishment because the associated activities would never occur due to the types of food or food processes associated with the operation.
- (2) "N/O" means that the activities associated with the item grouping do apply to the operation and will occur at some point in time within the food establishment. However, at the time of the inspection there were no related activities occurring; therefore, the inspector could not observe and evaluate compliance for contents of the item grouping.
- (3) "COS" means that violations within the item/provision grouping were corrected onsite. The term "corrected" means appropriate actions were taken to remove or eliminate the hazardous condition. When completing the DD form in hard copy or electronically as a fillable form, marking the COS box means all of the violations within the item grouping were corrected. When completing the survey report in DOEHRS, a COS box is applied to individual provisions within the item grouping.
 - (4) "R" means a repeat violation occurred from the previous inspection within the provision grouping.
- (5) Additional abbreviations found on the DOEHRS survey report. "C" means the item grouping is compliant. "NC" means the item grouping was noncompliant or a violation occurred for the corresponding provision. "N/I" means the item grouping was not inspected, which is different from N/O. The N/I box is only marked when there was insufficient time or a missed opportunity to properly evaluate select activities within the operation or the physical condition of the facility. NOTE: All inspections should be comprehensive and conducted at appropriate times (and duration) to allow maximum observation and evaluation.
 - b. Compliance.
- (1) All routine and preoperational inspections are comprehensive. Inspectors must assess or account for each item grouping listed on the inspection form.
- (2) For provision groupings that are either not applicable or were not observed at the time of the inspection, mark the appropriate designator: "N/A" or "N/O." If at least one provision within the group applies to the operation, "N/A" may not be marked. Select "N/O" if none of the applicable provisions within the group were evaluated.

(3) When all of the provisions within an item grouping are fully compliant, the item number check box remains unmarked. An unmarked checklist item indicates an evaluation was completed for the provisions associated with the item grouping and no violations were found.

c. Deficiencies.

- (1) Mark an "X" in the box immediately following the item number to indicate that a deficiency/violation occurred within the specified provision grouping.
- (a) Paragraph E-5 specifies which reference guide to use within this appendix when marking the inspection form. The reference guide identifies the provisions or portion of applicable provisions intended to be assessed under each item number.
- (b) Inspection personnel must review listed provisions in the chapters to ensure it addresses the cited violation and to ensure proper marking of the inspection form.
- (c) Compliance status should be determined based on the observed conditions and circumstances contributing to the noncompliant condition. For example, a refrigerator that is registering an ambient temperature of 44°F may appear to be noncompliant. If the circumstances confirm that the refrigerator door was frequently opened within the past 20-30 minutes due to placement of food that was recently received, then action must be taken by the inspector to spot-check the internal product temperature of foods in storage prior to delivery and to reassess the ambient temperature of the unit after the door has remained closed for at least 30 minutes or more. If the ambient temperature begins to decrease and the internal temperature of the foods are at 41°F or below, then a violation had not occurred.
- (d) When a critical violation occurs within an item number not marked by an asterisk, the applicable critical provision number must be marked within the item grouping description. Do not mark the critical provision in the item grouping if the provision is identified as a SWING item and the associated violation is rated noncritical, or the violated paragraph is marked with a superscripted letter "N" in the chapter, designating it as noncritical.
 - (e) Item groupings
- (2) Further indicate the status of the violation by marking an "X" in the corresponding box for each noncompliant item number to indicate "COS" and/or "R."
- (a) 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 *Remarks* section of the inspection report. For example, *Item 3*, *Hand wash facilities*, is marked "out of compliance" because the establishment does not have soap and paper towels at the handwashing sink. The PIC 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 *Remarks*, but "COS" is **not** marked for *Item 3* because all violations under that item were not corrected.
- (b) Marking "R" indicates that the same violation under a particular item number was cited on the last inspection report. Using the same scenario from above, if the provision of soap and paper towels is not in violation on the subsequent inspection but employees are not washing their hands in the correct sink (which is also cited under *Item 3*), "R" would **not** be marked because the latter is a new violation which was not cited on the previous inspection report.
- (3) Marking the check box for *Item 51* indicates a violation occurred for a provision that is not otherwise specified in the provision groupings for items 1–50. If marked, identify the specific provision number from the publication, and provide a brief description of the violation in the *Remarks* section of the form. Include the violation, as appropriate, when tallying the total number of critical and noncritical violations.
- (a) There are no critical provisions marked using *Item 51*. All of the critical provisions are accounted for under one of the other checklist item groupings.
- (b) Item 51 is only counted as 1 point when scored, regardless if there are multiple unrelated violations cited.
- (4) An unmarked checklist item groupings indicates all assessed elements within the provision grouping are compliant.
 - d. Observations and violations.
- (1) *Temperature observations*. Inspection personnel are expected to take representative measurements of food internal temperatures and the ambient temperature of hot and cold food holding/storage equipment using their

own calibrated thermometer. Temperature measurements taken from food items and equipment are recorded in the spaces provided under *Temperature Observations* on page 2 of the form. Fifteen spaces are provided for recording equipment ambient operating temperatures and the internal product temperature of foods at various points throughout the food operation: cold storage, cooking, hot holding, and serving.

- (a) For food items, record the common name of the food as well as the condition, process, or location of the food at the time of monitoring, for example, "meatloaf; main serving line;" "leftover chili, refer #1."
- (b) When measuring equipment holding temperatures, specify the equipment type, and provide the location if not otherwise distinguished, for example, "hot hold cabinet #2;" "main serving line;" "reach-in short order refer."
 - (c) Temperatures in compliance and out of compliance should be documented on the inspection form.
- (d) Record the temperature measurement indicated on the inspector's thermometer. Specify the measurement scale used—Fahrenheit (°F) or Celsius (°C)—by circling the appropriate unit of measure on the form.
- (e) If there is insufficient space for the number of temperatures taken, record the additional temperatures in the *Remarks* section of the inspection report.
- (2) Violations and corrective actions. Use the Remarks section to document each violation. The Remarks should paint a clear picture of the conditions observed that led to the violation. Document the Remarks by including the following for each violation: Item Number where the violation was marked in the checklist; violated provision number (and paragraph, where applicable); violation weight (critical or noncritical); "COS" if corrected onsite; a summary of specific observations that indicate a violation; and if uncorrected at the time of inspection, recommendations to immediately correct the problem or mitigate the food safety risk. For frequently occurring violations, provide recommended actions/controls that will reduce the likeliness for reoccurrence of the violation in the future. Do not restate the provision requirements; identifying the violated provision and paragraph provides a reference for the PIC to research the requirement.
- e. IHH. An IHH exists when the critical condition that presents the IHH has not been mitigated or corrected at the time of inspection. If an IHH is identified during the inspection, mark an "X" in the box located in the Remarks section. Identify the provision (and checklist item grouping) associated with the IHH and briefly explain the imminent nature of the health threat if immediate action is not taken. If conditions presenting the IHH cannot be fully resolved at the time of inspection, recommend immediate actions that should be taken to mitigate the hazard and protect public health. The IHH is considered COS if actions to mitigate the hazard are applied at the time of inspection. However, this does not remove responsibility for the PIC or facility manager to initiate a more permanent corrective action (such as a facility or equipment repair) to prevent reoccurrence of the conditions that resulted in the IHH.

E-5. Documenting conformance and violations

Specific guidance for marking violations on the *Food Operation Inspection Report* form and the *Tactical Kitchen Food Sanitation Inspection* form are provided in Sections II (paragraph E-7) and III (paragraph E-11), respectively.

Section II. FOOD OPERATION INSPECTION REPORT

E-6. Applicability

The DD Form 2973 is used to record formal inspections of appropriated fund and nonappropriated fund food operations and food concessions in garrison, to include hospital nutrition care operations, and central kitchens operated by lodging facilities. The form is also used for temporary, seasonal, mobile, and vending machine operations in garrison, and for nontactical feeding systems in deployment settings [refer to Section III, Tactical Kitchen Inspection]. The DD Form 2973 may be used when inspecting kitchens at child care and youth services facilities and schools when food safety evaluation is not otherwise captured in other designated inspection documents for these facilities.

E-7. Guidance for debiting specific item numbers on DD Form 2973

a. Supervision and training.

Item 1*. *PIC:* present, demonstrates knowledge, approved to operate. The primary provisions assessed in this grouping are *critical*, with the exception of 2-102.11(C), which is a *swing* item. A *critical* violation occurs when a qualified PIC is not on premises when the inspection begins or the PIC does not have proof of a valid (and unexpired) food safety certification on file. The designated PIC must meet the requirements in 2-102.12 by having the authority to supervise and direct the actions of the food employees. Do not mark this item "N/A" or "N/O." Mark this item "noncompliant" if any **one** of the following items is found:

A. A designated PIC is not present as required in 2-101.11(A) and (B). A food employee who does not have "supervisory" or "management" authority is the only person on premises in possession of a valid food safety certification. Although the employee may be designated as the PIC based on his/her certification, if the employee does not have the authority to influence or change the behaviors, practices, or activities within the food operation, the employee does not meet the criteria required for designation as a PIC.

B. The designated PIC does not have a food safety certificate from an accredited program as specified in 2-102.20 or the certificate has expired. Expiration dates vary between 3 and 5 years, depending on the certifying source.

C. A critical violation regarding failure to demonstrate knowledge may also be awarded based on observations combined with questioning. Two conditions in Section 2-102.11 (paragraphs (A) and (C)) are used in combination to assess the PIC's ability to demonstrate knowledge even when a valid food safety certificate is on file. Paragraphs (A) and (C) are swing violations. A pattern of finding multiple critical violations during inspections may be due to the PIC's inability to recognize conditions that present food safety hazards, which is indicative of lack of knowledge, experience, or both. When multiple critical violations are observed during an inspection, the inspector should ask the PIC to discuss or demonstrate proper procedures relevant to the critical violations. Questions should be open-ended to evaluate the PIC's understanding of the associated health effects that may result from the violations. 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 allow the inspector to make an informed decision concerning the PIC's knowledge of this publication's requirements and of general public health principles as they apply to the operation. The dialogue should be extensive enough to reveal whether or not the PIC's knowledge will enable him/her to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented. The PIC's inability to correctly respond to the inspector's questions coupled with one or more critical violations is indicative of failure to demonstrate knowledge. "Demonstration of knowledge" cannot be corrected onsite. The PIC may become more informed as a result of the inspection process and dialog with the inspector, but knowledge can only be demonstrated by independently identifying and resolving critical food safety conditions and not having critical violations found during subsequent inspections.

D. A violation of provision 8-301.11 is cited if the food establishment is operating on the installation without prior approval from the regulatory authority. A preoperational inspection was not coordinated and conducted before the operation officially opened for business and the facility has been serving customers.

Applicable publication section:

<u>2-101.11</u>* Assignment

2-102.11* Demonstration

[2-102.12] Certified food protection manager – a violation of this provision results in a violation of 2-101.11] 8-301.11* (A) or (D) Approval to operate

Item 2. *PIC duties; employee training.* Do not mark this item "N/A" or "N/O." This item is fully compliant when the following criteria are met:

A. Duties of the PIC. Compliance is based on the inspector's interaction with and observation of 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, associated managerial

responsibilities identified in § 8-304.11, conducting self-evaluations, correcting deficiencies, and reporting conditions that present an imminent health hazard, and ceasing operations impacted by the imminent health hazard. This is accomplished by having a discussion with the PIC and verifying through observation that the systems or controls are actually being implemented. This concept is commonly referred to as Active Managerial Control. Item 2 must be marked "out of compliance" when there is a pattern of noncompliance and obvious failure by the PIC to ensure employees are complying with the duties listed in § 2-103.11; multiple *critical* violations found during the inspection is an indication of the PIC's failure to perform his duties. 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.

- B. Training. Compliance is demonstrated by—
- 1. Presenting evidence (a record per 2-505.11) such as a curriculum/outline and attendance rosters documenting that each employee has completed a training program which includes all the information required in \P 2-501.11(A) to include employee illness reporting responsibilities as specified in \P 2-201.11(A); or
- 2. A certificate of training or food manager certification by an accredited program as specified in 2-102-20; and
- 3. A record indicating refresher training and/or certification renewal is current as specified in \P 2-501.11(C), 2-502.11, and 2-503.12.
- C. A *critical* violation may exist if employees disclose they were never trained or counseled regarding their requirement to report or disclose health information such as reportable illnesses and infections as specified in paragraph 2-201.11(A) **and** there is no record of training or counseling for employee health disclosure requirements. Satisfactory compliance may be documented by (1) a signed acknowledgement by the employee, such as DD Form 2971, *Conditional Employee or Food Employee Reporting Agreement*, or other similar state or local form containing the same information; **or** (2) presenting evidence such as a curriculum and attendance rosters documenting that each employee has completed a training program which includes reporting responsibilities. A violation involving an ill employee who should have been restricted or excluded, has an infected wound/skin condition, or has discharges from the eye, nose, or mouth, is debited using *Item 5*.

Applicable publication sections:

- 2-103.11 Person in charge—duties
- 2-201.11* (A) Responsibility of person in charge—failure of the PIC to inform food employees of their reporting requirements
- 2-501.11 Training requirements
- 2-502.11 (Supervisor) requirements and renewal
- 2-503.11 General requirements—food employee timeframe to complete initial training
- 2-503.12 Bartenders, hostesses, wait staff, and counter staff
- 2-503.13 Temporary employees
- <u>2-505.11</u> Documentation, retention and presentation
- <u>8-304.11</u> Responsibilities of the food manager
- 8-402.11 Access, allowed at reasonable times after due notice
- 8-402.12 Self-evaluations
- <u>8-404.11</u> Ceasing operations and reporting—imminent health hazards
- 8-404.12 Resumption of operations—prior to approval from the regulatory authority
- 8-405.11 Timely correction—critical deficiencies
- <u>8-406.11</u> Time frame for correction—noncritical deficiencies
 - b. Health and hygiene.

Item 3. Hand wash sink: available; supplied; accessible. Do not mark this item "N/A" or "N/O." Compliance is based on observations to determine that handwashing sinks are properly equipped and conveniently located for food employee use. This item must be marked "noncompliant" when any of the following conditions exists: the facility is not stocked with soap, hand drying provisions, or equipped with the required signage; the handwashing sink is not located to be available to food employees who are working in food preparation, food dispensing and

warewashing areas; the sink is blocked by portable equipment or stacked full of soiled utensils or other items; a handwashing sink is unavailable for regular employee use.

Applicable publication sections:

- 5-202.12 Handwashing sinks, installation
- 5-203.11 Handwashing sinks—numbers and capacities
- 5-204.11 Handwashing sinks—location and placement
- 5-205.11 Using a handwashing sink—operation and maintenance
- 6-301.11 Handwashing cleanser, availability
- 6-301.12 Hand drying provision
- <u>6-301.13</u> Handwashing aids and devices, use restrictions
- 6-301.14 Handwashing signage

Item 4. *Handwashing.* Some of the provisions contained within this grouping are *critical*. Do not mark this item "N/A." This item may be marked "N/O" for operations only in the rare case when there are no food workers present at the time of inspection. This item is fully compliant only when employees are observed using proper handwashing techniques at appropriate times and places. 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 noncompliant. Noncompliance also occurs when employees are observed using a food preparation sinks or other non-approved sinks for handwashing. To further demonstrate and emphasize compliance to this publication, inspectors should wash their hands before beginning the walk-through portion of the inspection.

Applicable publication sections:

- 2-301.11* Clean condition—hands and arms
- 2-301.12* Cleaning procedure
- 2-301.14* When to wash
- 2-301.15 Where to wash
- 2-301.16 Hand antiseptics
- **Item 5*.** *Ill employee: report, restrict, exclude.* Four of the five provisions assessed within this item grouping are reported as *critical*. Do not mark this item "N/A" or "N/O." If noncompliance is based <u>solely</u> on violation of Section 2-401.12 (Discharges from the Eyes, Nose, and Mouth), score the item as *noncritical*. A *critical* violation involving discharges from the eyes, nose or mouth occurs when the inspector observes the employee not washing his or her hands after coughing, sneezing, or wiping their nose. When this occurs, mark the critical violation under <u>Item</u> 4, citing paragraph 2-301.14(C), When to wash. The following criteria are assessed when determining overall compliance for <u>Item 5</u>:
- A. Direct observations of food employees. There must be no ill employees, employees experiencing symptoms requiring reporting, or any reason for the PIC to exclude or restrict an employee observed at the time of the inspection. 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 the PIC's knowledge of this publication. When an ill employee or food employee with an infected wound is found working, the violation is marked using this item grouping and the applicable provision and paragraph that was violated is cited. This item should be marked "noncompliant" when—
- 1. The inspector observes a working employee with specific reportable symptoms (subparagraph 2-201.11 (A)(1)); or
- 2. 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 or exclude an employee as required by this publication (§ 2-201.12) & (§2-201.13); or
- 3. The inspector becomes aware that the PIC has not notified the Regulatory Authority that an employee is jaundiced or has been diagnosed with an illness due to a pathogen as specified under subparagraphs 2-201.11 (A)(2)(a)-(e) of the publication.
- 4. There are food employees working in the food establishment that have been diagnosed with Norovirus, HAV, shigellosis, STEC, or typhoid fever; has active symptoms of vomiting and/or diarrhea; or is

working with food, food contact equipment, utensils, or single-service articles with an open, uncovered infected wound or pustule, or with a sore throat with a fever, or has discharges from the eyes, nose, or mouth. 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.

B. Employees have a responsibility to report illness and the PIC must exclude workers as appropriate. Failure to report by employees and failure to exclude or restrict ill or infected employees is debited under this item grouping, but requires further investigation for possible violations involving training and duties of the PIC (see paragraph C in *Item 2*). Employee reporting responsibilities should be included in the initial employee training or briefing conducted by the PIC regarding employee duties and responsibilities. When an ill employee or employee with an infected wound is found working at the facility and the employee states he or she was never informed of their reporting responsibilities, the inspector must assess whether training/counseling was provided and must record any violations regarding the absence of training under *Item 2*, specifically citing paragraphs 2-103.11(M) for duties of the PIC and 2-505.11(A) for lack of training documentation.

Applicable publication sections:

2-201.11* (A), (E) & (F) Responsibility of person in charge, food employees, and conditional employees—failure of an employee to report listed illnesses or symptoms and comply with a restriction or exclusion 2-201.11* (B) Responsibility of person in charge, food employees, and conditional employees—responsibility of the PIC to report

[2-201.11(C) & (D) are debited using 2-201.12 and 2-201.13, as specified in the provision.]

<u>2-201.12</u>* Exclusions & restrictions—failure of the PIC to exclude or restrict an employee with reportable illness or symptoms

2-201.13* Removal, adjustment, or retention of exclusions & restrictions

2-401.12 Discharges from the eyes, nose, and mouth

Item 6*. Bare hand/arm contact with food. The provision assessed within this item grouping is generally reported as critical; the exception applies to paragraph 3-301.11(C), which is designated as a swing item. This item may be marked "N/A" for establishments that provide only packaged or bulk food items that are not RTE. This item may be marked "N/O" for establishments that prepare RTE foods only, but no food preparation was performed at the time of inspection. This Item Number is also used to assess minimizing bare hand and arm contact with food that is not in an RTE form, such as meat being processed for retail sales. Compliance for this item occurs when employees are observed using suitable utensils or gloves to prevent bare hand contact with RTE foods or are observed properly following a pre-approved alternative procedure to "no bare hand contact." This item should be marked "noncompliant" if one person is observed touching RTE food with his/her bare hands in the absence of a prior approval and written procedures for bare hand contact. A listing of conditions that must be met in order to receive prior approval by the regulatory authority are provided in subparagraph 3-301.11(D)(1)-(7). Bare hand contact by food employees serving a highly susceptible population is prohibited, and no alternative procedure to "no bare hand contact" is allowed with such a population. The swing violation for food that is not in RTE form under paragraph 3-301.11(C) is rated critical when the employee processing the food has unprotected cuts/wounds on exposed hands or arms. The swing violation may be assessed as noncritical if an employee processing or preparing food had exposed arms due to improper wear of the work coat (that is, sleeves were pushed up to the elbows), but there were no cuts or other open wounds on the hands or forearms. When the swing provision is assessed as noncritical and no other critical violation occur within the item grouping, the item grouping is counted as noncritical when the inspection is scored.

Applicable publication sections:

3-301.11* Preventing contamination from hands

3-801.11* (D) Pasteurized foods, prohibited re-service, and prohibited foods [cited using 3-301.11(B) or (D)]

Item 7. *Personal hygiene: clothing, hair, jewelry.* This item may not be marked "N/A" or "N/O." Observation of facility personnel for clean outer clothing, effective hair restraints, prohibited jewelry, and the condition or protection of fingernails must be made.

Applicable publication sections:

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2-302.11 Maintenance—fingernails
2-303.11 Prohibition—jewelry
2-304.11 Clean condition—outer clothing
2-402.11 Effectiveness—hair restraints
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Item 8. Eating, drinking, tobacco use in food prep /service areas; tasting procedures. One of the provisions contained within this grouping is critical. Do not mark this item "N/A." This item may be marked "N/O" only in the rare case when there are no food workers present at the time of inspection. Compliance is based on direct observations or discussions of the appropriate hygienic practices of food employees. Provision compliance occurs when food employees are observed drinking from a closed beverage container subsequently stored on a nonfood-contact surface and separated from exposed food, clean equipment, and unwrapped single-service and single-use articles. This item should be marked "noncompliant" when food employees are observed improperly tasting food, eating, drinking, or smoking, or there is supporting evidence of these activities taking place in nondesignated areas of the establishment. An open container of liquid in the kitchen preparation area does not necessarily constitute marking this item "noncompliant." 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.

Applicable publication sections:

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2-401.11 Eating, drinking, or using tobacco 3-301.12* Preventing contamination when tasting
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c. Food source, identification, condition.

Item 9*. Approved sources; food specifications. All violations contained within this item grouping are reported as *critical*. Do not mark this item "N/A" or "N/O." This item includes ice. Compliance determination is based on direct observations of food products, food labels and packaging, bottled water analyses, and discussion with the PIC or other food employees. 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. This item should be marked "noncompliant" when an approved food source cannot be determined.

Applicable publication sections:

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3-201.11* Compliance with food law
3-201.12* Food in a hermetically sealed container
3-201.13* Fluid milk and milk products
3-201.14* Fish
3-201.15* Molluscan shellfish
3-201.16* Wild mushrooms
3-201.17* Game animals
3-201.18* Fresh fruits and vegetables
3-202.13* Eggs
3-202.14* Eggs and milk products, pasteurized
3-202.16* Ice
3-202.110* Juice treated—commercially processed [Paragraph (A) is noncritical.]
5-101.13* Bottled and packaged drinking water
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Item 10. Food condition; receipt temperatures. Three out of five provisions contained within this item grouping are reported as *critical*. Paragraph 3-202.11(E) is a *swing* item and may be scored as *noncritical*. Count this item group as noncritical when the only violation occurring within this item grouping is noncritical. Do not mark this item "N/A" or "N/O." Compliance is based on—

- A. Condition and packaging. Observe the integrity of product packaging, wholesomeness, and signs of adulteration. This item is considered "compliant" 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 "noncompliant" when the integrity of food packaging has been compromised or the true appearance, color, or quality of a food has been intentionally altered.
- B. Receiving temperature. Obtain actual food temperature measurements of TCS foods being received. Compliance is achieved when food is received and found to be at proper temperatures during the inspection (that is, a catered meal for a child care center arrives during the inspection, and the regulatory authority verifies the receiving temperature). This item should be marked "noncompliant" 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 this publication.

Applicable publication sections:

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3-101.11* Safe, unadulterated
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3-202.11* Temperature

3-202.15* Package integrity

3-202.19 Shellstock, condition

3-601.12 Honestly presented

Item 11*. Required records: shellstock tags, parasite destruction. Three out of four provisions contained within this grouping are critical. 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 in this publication as exempted from freezing. 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. Compliance determination is based on direct observations of fish in storage, shellstock tags, and/or records of freezing of fish for parasite destruction. This item is "compliant" if the PIC provides a statement from supplier(s) identifying that fish sold as raw, raw-marinated, or undercooked is frozen by the supplier for parasite destruction; or there are freeze records maintained by the food establishment when fish are frozen for parasite destruction on the premises. This item should be marked "noncompliant" 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 listed in paragraph 3-402.11(B).

Applicable publication sections:

3-202.18* Shellstock identification

3-203.12* Shellstock, maintaining identification

3-402.11* Parasite Destruction

3-402.12 Records, creation, & retention

Item 12. Food labels; original container; major food allergens. Do not mark this item "N/A." This item may be marked "N/O" if there were no bulk foods removed from their original packaging present in the facility at the time of the inspection and food packaging is not conducted at the establishment. Packaged foods are required to conform to specific labeling laws. Foods packaged within the food establishment, such as cook-chill products and bulk foods (meals-to-go) available for consumer self-dispensing (3-602.11(C)), must also conform to the appropriate labeling laws, with considerations given to accuracy of the labels as well as to their not being misleading. Minimum labeling requirements for individually wrapped items and boxed meals include the common name or description of each item prepared by the food establishment and should specify when major food allergens are included as an ingredient. Working containers and bulk foods removed from their original packaging require some level of assessment as to how recognizable the food is without labeling it by its common name. Labels for working containers should provide a date indicating when the product was opened; date marking and retention for these products as specified in 3-501.17 are assessed using <u>Item 14</u>. Molluscan shellfish and vended TCS foods must be assessed based on their specific packaging and labeling requirements. The visual quality of a food must not be misrepresented by using

color-enhancing additives, special lighting, or color overwraps to increase consumer perception of the product's freshness.

Applicable publication sections:

- 3-202.17 Shucked shellfish, packaging and identification
- 3-203.11 Molluscan shellfish, original container
- 3-302.12 Food storage containers identified with common name of food
- 3-305.13 Vended time/temperature control for safety food, original container
- 3-601.11 Standards of identity
- 3-602.11 Food labels
- 3-602.12 Other forms of information

Item 13*. *Leftovers.* Deficiencies noted within this item represent a *critical* violation. This item may be marked "N/A" if the food facility has an established policy that prohibits the retention of leftover foods. This item may be marked "N/O" if the establishment does practice the retention of leftovers, but there were no leftover foods present in the facility at the time of the inspection. Noncompliance occurs when labels are missing or do not contain the item name and the date and time the item was removed from service; leftovers are retained beyond the maximum retention period; prohibited items are retained; improper reheating temperature; freezing leftovers; subsequent retention of a leftover or foods containing a previously leftover item; or serving leftovers to a highly susceptible population. A non-TCS leftover that was removed from a customer self-service line or display case and is showing signs of contamination due to comingling with a TCS food or other debris as characterized in 3-501.110(A) is marked as a violation using *Item 18*.

Applicable publication sections:

3-501.110*(B)—(G) Leftovers [Paragraph (C) is noncritical.]

Item 14*. *TCS food: date marking, retention, & disposition.* All violations contained within this item grouping are reported as *critical*. This item may be marked "N/A" when the food processes occurring within the operation do not include, at any time, the preparation of RTE, TCS foods on-premises and holding the RTE TCS food beyond the current business day; and at no time are commercial containers of bulk RTE, TCS food opened and held beyond the current business day at the establishment. 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. Compliance for date marking is generally found when there is a system in place for date marking all foods that are required to be date marked and such a system 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, as specified in the provision. Compliance for food disposition occurs when foods are properly date labeled and are within the prescribed date marked time limits. Violations involving outdated food, as indicated by exceeding the "use-by," "sell-by," or other manufacturer's specified "expiration" date, are marked using *Item 51* and provision 3-503.11.

Applicable publication sections:

- 3-501.17* Time/temperature control for safety food, date marking and retention
- 3-501.18* Ready-to-eat time/temperature control for safety food, disposition
 - d. Contamination protection and prevention.

Item 15. Food separated & protected in storage. Some of the provisions contained within this grouping are *critical*. This item may not be marked "N/A" or "N/O." Compliance is based on direct observations of conditions that can lead to contamination during food storage. This item should be marked "noncompliant" when RTE foods are subject to potential contamination by raw animal foods; raw animal foods are not properly separated or segregated by shelving based on minimum required cooking temperatures; or food is not packaged or covered during storage. An exception is applied to loosely covered pans of hot foods that are placed in the refrigerator for

cooling, as long as the pans are located on the top shelf and are not subject to contamination from the fan, condensation, or other sources that may drip or splash into the food. When this condition exists, a violation does not occur unless there is a potential for contamination or the food that was being cooled remains uncovered/partially covered beyond the reasonable time needed to cool the food. Violations are also cited when stored food is subjected to contamination due to improper storage conditions or storage in prohibited areas. A violation involving improper cooling of food as specified under § 3-501.14 is marked using *Item 29*. Violations involving contamination during food preparation, display, or service are marked using *Item 19*.

Applicable publication sections:

- 3-302.11* Packaged and unpackaged food-separation, packaging, and segregation
- <u>3-305.11</u> Food storage—preventing contamination from the premises
- 3-305.12 Food storage—prohibited areas

Item 16. FF&V properly washed. This item may be marked "N/A" if FF&V are not prepared by the food establishment and the service of FF&V, when practiced, is limited to commercially packaged items portioned for individual sale (for example, salads and fruit bowls). This item may not be marked "N/O." Chemicals are allowed for washing fruits and vegetables, as is washing them in water. Raw fruits and vegetables are to be washed prior to their preparation or being offered as RTE. Discussion with the PIC and food employees will help determine the establishment's practice. This item is marked "noncompliant" when FF&V are not washed to remove visible soil. Violations involving use of unauthorized chemicals are to wash or disinfect FF&V are assessed using <u>Item 25</u>. **Applicable publication sections:**

3-302.15 Washing fruits and vegetables

Item 17*. Clean/sanitizing food-contact surfaces. All of the provisions assessed within this item grouping are critical. 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. This item may not be marked "N/O." Compliance is based on direct observations regarding cleanliness of food contact surfaces of equipment and utensils; observing cleaning and sanitizing procedures; discussion of cleaning and sanitizing procedures with the PIC or other food employees; and actual measurements/readings of chemical sanitizer concentration and/or hot water sanitizing temperature using test strips, heat-sensitive tapes, and calibrated thermometers, as appropriate. There should be an overall assessment of the food-contact surfaces of equipment and utensils located in clean storage (shelves and racks) and in use (dispensers) 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 "noncompliant" 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. The inspector must assess whether such food residue is the result of current or prior use. Cleanliness of cooking and baking equipment (for example, griddle tops, waffle irons, and oven interior) presents a low risk; violations associated with unclean cooking or baking equipment are noncritical and are marked using <u>Item 41</u>. Compliance regarding proper use of warewashing equipment and manual and mechanical warewashing procedures is assessed using Item 40.

Applicable publication sections:

- 4-501.111* Manual warewashing equipment, hot water sanitization temperatures
- 4-501.112 (C) Mechanical warewashing equipment, hot water sanitization temperatures [cited using 4-703.11(B)]
- 4-501.114* Manual and mechanical warewashing equipment, chemical sanitization—temperature, pH, concentration, and hardness
- 4-501.115* Manual warewashing equipment, chemical sanitization using detergent-sanitizers
- 4-601.11* (A) Equipment, food-contact surfaces and utensils
- 4-602.11* Equipment, food-contact surfaces, and utensils—frequency [Paragraph (E) is noncritical.]
- 4-702.11* Before use after cleaning
- 4-703.11* Hot water and chemical methods
- <u>5-101.14</u>* Steam

Item 18*. Food: returned; previously served; reconditioned; HSP prohibitions. All violations contained within this item grouping are reported as *critical*. Do not mark this item "N/A" or "N/O." This item is marked "noncompliant" if previously-served unwrapped, unprotected food is observed being re-served, and in situations where RTE food is contaminated by employees and is not discarded or reconditioned according to an approved procedure. This item grouping is also used to mark violations when prohibited foods are served to a highly susceptible population.

Applicable publication sections:

3-306.14* Returned food and re-service of food

3-701.11* Discarding or reconditioning unsafe, adulterated, or contaminated food

3-801.11* (A)-(C), (E), & (H) Pasteurized foods, prohibited re-service, and prohibited food—highly susceptible populations

Item 19. Contamination prevented during food prep, service & display. Some of the provisions contained within this grouping are critical. Do not mark this item "N/A" or "N/O." 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 (that is, salad bars). Contamination due to improper separation or protection while in storage is assessed using <u>Item 15</u>. Contamination from ice is assessed using <u>Item 21</u>. Contamination due to improper disposable glove use is assessed using <u>Item 22</u>.

Applicable publication sections:

3-302.13* Pasteurized eggs, substitute for raw eggs for certain recipes

3-304.11* Food contact with equipment, utensils, and linens

3-304.13 Linens and napkins, use limitations

3-304.16 Using clean tableware for second portions and refills

3-304.17 Refilling returnables

<u>3-305.14</u> Food preparation—environmental contamination

3-306.11 Food display—preventing contamination by consumers

3-306.12 Condiments, protection

3-306.13* Consumer self-service operations [Paragraph (D) is noncritical.]

3-306.15 Dispensing of milk, cream, and nondairy products

3-307.11 Miscellaneous sources of contamination

6-404.11 Segregation and location—distressed merchandise

Item 20*. Food additives: approved, proper use. All violations contained within this item grouping are reported as *critical*. This item may be marked "N/A" if the food establishment does **not** use any additives or sulfites on the premises. Do not mark this item "N/O." Compliance is based on direct observations of food ingredients in storage and listed as product ingredients, supplemented by discussion with the PIC. This item is compliant if approved food and color additives are onsite and used properly or if sulfites are on the premises but are not applied to fresh fruits/vegetables for raw consumption. Approved food additives are listed and have threshold limits IAW the CFRs; this item does not apply to food additives that are considered GRAS, such as salt, pepper, etc. This item group is marked "noncompliant" if unapproved additives are found on the premises or if approved additives are improperly used, such as sulfites being applied to fresh fruits or vegetables.

Applicable publication sections:

3-202.12* Ādditives

3-302.14* Protection from unapproved additives

Item 21. *Ice used as coolant; food contact with water/ice.* Some of the provisions contained within this grouping are *critical*. Do not mark this item "N/A" or "N/O." Noncompliance occurs when ice previously used as a coolant is subsequently added to food, such as a beverage, or a packaged food is placed in direct contact with the ice and the

type of food packaging is insufficient to prevent water intrusion through the packaging material. Noncompliance also occurs when unpackaged food that do not meet the criteria specified in paragraphs 3-303.12(C) and (D) is in direct contact with ice or water.

Applicable publication sections:

3-303.11* Ice used as exterior coolant, prohibited as ingredient 3-303.12 Storage or display of food in contact with water or ice

Item 22. Gloves used properly. This item may be marked "N/A" when only commercially-packaged, RTE foods are served at the food establishment. This item may be marked "N/O" in the rare case when there is no food preparation or service occurring at the time of the inspection. 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. If misused, gloves may serve as a source of cross-contamination. Look at the package label to ensure powdered gloves are suitable for use with food.

Applicable publication sections:

3-304.15 Gloves, use limitations

Item 23. Wiping cloths: use, storage. This item may be marked "N/A" when only commercially packaged RTE foods are served at the food establishment. Do not mark this item "N/O." 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 are assessed using <u>Item 25</u>. Sponges, if present, are not to be used in contact with clean/sanitized food contact surfaces.

Applicable publication sections:

3-304.14 Wiping cloths, use limitation

4-101.16 Sponges use limitation

4-901.12 Wiping cloths, air-drying location

Item 24. *Insects, rodents, animals.* Do not mark this item "N/A" or "N/O." 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 the removal of pests and their evidence. Insect trapping devices must not be located over food preparation or serving areas, stored clean utensils, or other food contact surfaces.

Applicable publication sections:

2-403.11 Handling prohibition—animals

6-202.13 Insect control devices, design and installation

6-202.15 Outer openings, protected

6-202.16 Exterior walls and roofs, protective barrier

<u>6-501.111</u> Controlling pests

6-501.112 Removing dead or trapped birds, insects, rodents, and other pests

6-501.115 Prohibiting animals

Item 25*. Toxic substances: authorized; properly identified, stored & used. The majority of provisions contained within this grouping are critical. Paragraphs 7-201.11(A), 7-208.11(A), and 7-301.11(A) are swing items and may be assessed as noncritical when reasonable controls are in place to further reduce the potential for contamination. Do not mark this item "N/A" or "N/O." Compliance is based on direct observations of container labeling, storage, reconstitution, and application of the following: bulk and working containers of cleaning agents and sanitizers; personal care items; first aid supplies; medicines; pesticides; and potential toxic and poisonous substances. Compliance is achieved when bulk and working containers of cleaning agents and sanitizers are labeled; sanitizing solutions do not exceed 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 a certified applicator or a supervised associate who is not a food employee. This item should be marked "noncompliant" if unauthorized cleaning and sanitizing agents are used on food-contact surfaces; prohibited pesticides are used or pesticides are applied by food employees; chemicals are not properly identified and stored; a sanitizing solution is being applied at a higher concentration than prescribed; and medicines or first aid kits are improperly labeled and stored.

Applicable publication sections:

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7-101.11 Identifying information, prominence—original containers
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- 7-102.11 Common name—working containers
- 7-201.11* Separation—storage
- 7-202.11 Restriction—presence and use
- 7-202.12* Conditions of use [Paragraphs (A), (C) and (D) contain noncritical items.]
- 7-203.11* Poisonous or toxic material containers—container prohibitions
- 7-204.11* Sanitizers, criteria—chemicals
- 7-204.12* Chemicals for washing, treatment, storage and processing fruits and vegetables [Paragraph (B) is noncritical.]
- 7-204.13* Boiler water additives, criteria
- 7-204.14* Drying agents, criteria
- 7-205.11* Incidental food contact, criteria—lubricants
- 7-206.11* Restricted use pesticides, criteria
- 7-206.12* Rodent bait stations [Paragraphs (A) and (B) contain noncritical items.]
- 7-206.13* Tracking powders, pest control and monitoring
- 7-207.11* Restriction and storage—medicines [Paragraph (A) is noncritical.]
- 7-207.12* Refrigerated medicines, storage
- 7-208.11* Storage—first aid supplies
- <u>7-209.11</u> Storage—other personal care items
- 7-301.11* Separation—storage and display, stock, and retail sale
 - e. Temperature Control.

Item 26. Thawing frozen TCS foods. This item may be marked "N/A" if TCS foods are not thawed or slacked; frozen foods used at the facility are cooked from a frozen state. This item may be marked "N/O" if food is sometimes thawed, but thawing was not observed during the inspection. Observing and then gaining an understanding of the establishment's thawing method(s) will help in determining whether a violation of the approved thawing methods found under 3-501.13 exists, 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 publication sections:**

3-501.12 Time/temperature control for safety food, slacking

3-501.13 Thawing

Item 27*. Cooking/reheating time & temperatures. All violations contained within this item grouping are reported as critical. This item may be marked "N/A" if the food establishment only serves prepackaged RTE foods. This item may be marked "N/O" when the inspector is unable to determine the cooking temperature of any food because cooking activities have already been completed. The inspection should be arranged at an optimum time for measuring at least one item as it nears its terminal cooking time. 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 compliance determination. 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. The time of inspections should be varied so that cooking can be observed. Use a calibrated food temperature measuring device to check food items prior to their placement in hot

holding. This item group should be marked "noncompliant" if the food items checked do not meet the temperature requirements for cooking and if the employee doing the cooking attempts to serve the product without returning it to the cooking process. Reheated food items are noncompliant if the food is not reheated to the required temperatures or reheated within 2 hours prior to hot holding. Improper reheating of leftovers is assessed in *Item 13*. If a food is undercooked (cooked below the required temperature) but the facility has an approved Consumer Advisory or an approved variance within the HACCP plan for that food item, the item is considered to be compliant; record the temperature and document the reason it is in compliance. A violation involving undercooked foods without a Consumer Advisory is marked using *Item 33*.

Applicable publication sections:

3-401.11* Raw animal foods-cooking

3-401.12* Microwave cooking

3-401.14* Noncontinuous cooking of raw animal foods

3-403.11* Reheating for hot holding

Item 28. Fruits/vegetables heated for hot holding. This item may be marked "N/A" if vegetables and fruits are not cooked for hot holding in the establishment. This item may be marked "N/O" when plant foods are cooked for hot holding but are not available for observation during the inspection. In determining compliance, observation must occur, and an actual cooking temperature must be obtained.

Applicable publication section:

3-401.13 Plant food cooking for hot holding

Item 29*. Cooling time & temperatures. The provision assessed within this item is critical. 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. 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. 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 hours, provided that the food is cooled from 135°F to 70°F within the first 2 hours. There are two critical limits that must be met with cooling. Discussions with the PIC along with observations should be used to determine compliance. For instance, during discussion, the PIC states that a food product was cooled overnight in the walk-in cooler. The product is checked, and its temperature is 50°F. Eight hours have elapsed from closing to opening. This item should be marked "noncompliant" because the product did not cool from 135°F to 70°F within 2 hours and from 135°F to 41°F or less within a total of 6 hours. Temperatures that are in compliance and out of compliance should be recorded in the "Temperature Observations" section of the inspection report. Because the entire cooling process is difficult to observe during an inspection, a determination of whether foods are currently being cooled should be made at the onset of the inspection. If cooling is taking place, temperature measurements should be made to determine whether proper cooling is possible with the procedures being used. Compliance for this provision should be based on actual temperatures of TCS foods in the cooling process. The basis for determining compliance can also be supported through discussion and/or record review which would provide the inspector with reliable data of the "start time" for cooling from 135°F.

Applicable publication sections:

3-501.14* Cooling

Item 30. Cooling: methods; adequate equipment. 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. Do not mark this item "N/O." 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 of the cooling methods in use. There should be enough equipment with sufficient capacity used for the cooling, heating, and

hot/cold holding/storage 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.

Applicable publication sections:

3-501.15 Cooling methods

4-301.11 Cooling, heating, and holding capacities—equipment

Item 31*. Hot holding. The provision assessed within this item is *critical*. This item may be marked "N/A" if the establishment does not hot-hold food or if it uses TPHC. 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 the inspection. Inspections should be conducted during a time when hot holding temperatures can be taken. **NOTE:** Temperatures in compliance and out of compliance should be recorded in the "Temperature Observations" section of the inspection report. Compliance for this item is based on actual food temperature measurements taken using a calibrated food temperature measuring device. Unless TPHC is used for the TCS food found out of compliance, this item is marked "noncompliant." Evaluation of TPHC is assessed under <u>Item 34</u>.

Applicable publication sections:

3-501.16* (A)(1) Time/temperature control for safety food, hot and cold holding

Item 32*. Cold holding/storage. This item may be marked "N/A" when the establishment does not cold-hold food. This item may not be marked "N/O." NOTE: Temperatures in or out of compliance should be recorded in the "Temperature Observations" section of the inspection report. Compliance is based on actual temperature measurements of food or on a combined assessment of the equipment's ambient temperature and the internal temperature of food held in the equipment, taken 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 "noncompliant" if one TCS food is found to be out of temperature, with supportive evidence, unless TPHC is used for that TCS food. Foods intended to be stored under freezer conditions that are found partially thawed due to inadequate freezer holding temperatures are evaluated against provisions 3-501.11 and 3-503.11(E) and violations are marked using Item 51.

Applicable publication sections:

3-501.16* (A)(2) & (B) Time/temperature control for safety food, hot and cold holding

Item 33*. Consumer advisory: raw/undercooked food. The provision assessed within this item is critical. This item may be marked "N/A" when a food establishment does not serve an RTE food that necessitates an advisory (that is, an animal food that is raw, undercooked, or not otherwise processed to eliminate pathogens). Do not mark this item "N/O." Assessment of this item is 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 is used as an ingredient or is 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 is compliant if the establishment provides an advisory that meets the intent of this publication for both the disclosure and reminder components. This item should be marked "noncompliant" 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

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 noncontinuous cooking process.

Applicable publication sections:

 $\underline{3-603.11}^*$ Consumption of animal foods that are raw, undercooked, or not otherwise processed to eliminate pathogens

Item 34. *Time as a public health control; HACCP; variance procedures.* Some of the provisions contained within this grouping are *critical*. This item may be marked "N/A" when the establishment does not use "time only" as the public health control; the establishment is not required by the regulatory authority to have a variance or

HACCP plan; juice is not packaged; or ROP is not done on the premises. Do not mark this item "N/O." This item is assessed by direct observations, record review, a discussion with the PIC to determine if there are specialized food processes (that is, smoking food, curing food, ROP, using food additives to render a food so that it is not TCS food, cook chill, sous vide, etc.), and the review of any standing operating procedures to determine if the intent of this publication for use of TPHC is met and proper HACCP documentation is achieved. NOTE: When a food establishment wants to deviate from a requirement in this publication, utilizing Specialized Processing Methods as specified in 3-502.11, such as Smoking Food for Preservation or curing food, 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.

A. Time as a Public Health Control. 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. This item is compliant for TPHC if there is a written procedure at the food establishment that identifies which food products will be held using time only as the control, 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 properly marked food items do not exceed the 4-hour limit at any temperature or the 6-hour limit at 70°F or less. This item should be marked "noncompliant" when the PIC implies the use of TPHC but does not have an approved written procedure; an effective mechanism for indicating the point in time when the food is removed from temperature control and the point in time that represents the food's mandatory use or discard time. TPHC is used for foods not identified in the approved plan or when the approved TPHC procedures are not being followed. When TPHC is employed without an approved plan, violations are debited under *Item 31* (hot holding) or *Item 32* (cold holding).

B. Variance or HACCP. This item is compliant for a variance when observations of food operations and review of available records indicate compliance is being met with regards to specialized food processes. This item should be marked "noncompliant" if the inspection reveals specialized food processes that are not approved by the regulatory authority are performed, or specialized food processes are not conducted IAW the approved variance.

Applicable publication sections:

3-404.11 Treating juice

3-501.19* Time as a public health control

3-502.11* Variance requirement

3-502.12* Reduced oxygen packaging, criteria

4-204.110 (B) Molluscan shellfish tanks

8-103.11 Documentation of proposed variance and justification

8-103.12* Conformance with approved procedures [Paragraph (B) is noncritical.]

8-201.13 When a HACCP Plan is required

8-201.14 Contents of a HACCP Plan

f. Utensils and equipment.

Item 35. Thermometers: provided & accurate. This item may be marked "N/A" if the establishment only dispenses non-TCS foods. Do not mark this item "N/O." Thermometers provide a means for assessing active managerial control of TCS food temperatures and sanitizing rinse for warewashing. 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 publication sections:

<u>4-203.11</u> Temperature measuring devices, food—accuracy

4-203.12 Temperature measuring devices, ambient air and water—accuracy

4-204.112 Temperature measuring devices—functionality

<u>4-302.12</u> Food temperature measuring devices

4-302.13 (A) Temperature measuring devices, manual warewashing –availability

4-502.11 (B) Good repair and calibration

Item 36. *In-use utensil storage*. This item may be marked "N/A" if the establishment only dispenses commercially prepackaged foods. Do not mark this item "N/O." 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 utensils are 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 with their handles up in an ice bin/tray.

Applicable publication sections:

3-304.12 In-use utensils, between-use storage

Item 37. Food equipment: installation, condition, use. Some of the provisions contained within this grouping are critical. Do not mark this item "N/A" or "N/O." 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 and for preventing accumulations 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 (for example, equipped with automatic shutoff, etc.) from potential contamination. Equipment such as calibrated food thermometers must be properly used and in proper adjustment..

Applicable publication sections:

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4-101.11* Characteristics—materials for construction and repair [Paragraphs (B)-(E) are noncritical.]
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- <u>4-101.12</u> Cast iron, use limitations
- 4-101.13 Lead, use limitation
- 4-101.14* Copper use limitation
- 4-101.15* Galvanized metal, use limitation
- 4-101.17 Wood, use limitation
- 4-101.18 Nonstick coatings, use limitation
- 4-101.19 Nonfood-contact surfaces
- 4-101.110 Paint or other coatings, application
- 4-101.111 Sealing compounds--characteristics
- 4-101.112 Plastic, use prohibition
- 4-101.113 Pallet use
- 4-201.11 Equipment and utensils—durability and strength
- 4-201.12* Food temperature measuring devices
- 4-201.13 Sealing compounds—durability, installation and application
- 4-202.11* Food-contact surfaces—cleanability
- 4-202.12 CIP equipment
- 4-202.13 "V" threads, use limitation
- 4-202.14 Hot oil filtering equipment
- 4-202.15 Can openers
- 4-202.16 Nonfood-contact surfaces
- 4-202.17 Kick plates, removable
- 4-204.12 Equipment openings, closures and deflectors
- 4-204.13* Dispensing equipment, protection of equipment and food [Paragraphs (A), (C) & (D) are noncritical.]
- 4-204.14 Vending machine vending stage closure
- 4-204.15 Bearings and gear boxes, leakproof
- 4-204.16 Beverage tubing, separation
- 4-204.17 Ice units, separation of drains
- 4-204.18 Condenser unit, separation
- 4-204.19 Can openers on vending machines
- 4-204.110 (A) Molluscan shellfish tanks
- 4-204.111* Vending machines, automatic shutoff
- 4-204.121 Vending machines, liquid waste products
- 4-204.122 Case lot handling apparatuses, moveability

- 4-204.123 Vending machine doors and openings 4-204.124 Mechanical warewashing equipment, heating device 4-205.11 Equipment and utensil, approval 4-205.12 Equipment and utensil, compliance measures 4-205.13 Overseas food operations 4-301.15 Clothes washers and dryers 4-301.16 Warewashing heating device, capacity 4-302.11 Utensils, consumer self-service 4-401.11 Equipment, clothes washers, dryers and storage cabinets, contamination prevention—location 4-402.11 Fixed equipment, spacing or sealing—installation 4-402.12 Fixed equipment, elevation or sealing 4-501.11 Good repair and proper adjustment—equipment 4-501.12 Cutting surfaces 4-501.13 Microwave ovens 4-502.11 (A) & (C) Good repair and calibration—utensils and temperature and pressure measuring devices 4-603.11 Dry cleaning—methods 4-902.11 Food-contact surfaces—lubricating and reassembling 4-902.12 Equipment—lubricating and reassembling
- **Item 38.** *Utensils, equipment, linens: drying, storage, handling.* This item may be marked "N/A" if the establishment only dispenses commercially packaged RTE TCS foods or non-TCS foods and only utilizes single-use/single-service articles. Do not mark this item "N/O." An assessment is made of the overall storage practices and handling of clean equipment, utensils, and tableware located in the various areas within an establishment, to include the basement, wait station and dining room. Equipment must be air-dried prior to storage, and linens must be properly cleaned and stored. Violations involving single-use/single-service items are marked using *Item 39*.

Applicable publication sections:

- 4-801.11 Clean linens
- 4-802.11 Specifications—laundering frequency
- 4-803.11 Storage of soiled linens
- 4-803.12 Mechanical washing--linens
- 4-901.11 Equipment and utensils, air-drying required
- 4-903.11 (A) & (B) Equipment, utensils, linens and single-service and single-use articles—storing
- 4-903.12 Prohibitions—storage location for cleaned & sanitized equipment, utensils, and linens
- 4-904.11 (A) & (B) Kitchenware and tableware—preventing contamination of cleaned & sanitized utensils
- 4-904.12 Soiled and clean tableware
- 4-904.13 Preset tableware
- **Item 39.** Single-use/service item: storage & use. Some of the provisions contained within this grouping are critical. Do not mark this item "N/A" or "N/O." Single-use/single-service items are not designed to be cleaned and re-used; therefore, they must be properly stored and protected to prevent possible contamination. Food establishments without facilities for cleaning and sanitizing kitchenware and tableware shall provide only single-use and single-service articles.

Applicable publication sections:

- 4-102.11* Characteristics—single-service and single-use [Paragraphs (A) and (B) contain noncritical items.]
- 4-502.12* Single-service and single-use articles, required use
- 4-502.13 Single-service and single-use articles—use limitations
- 4-502.14 Shells, use limitations
- 4-903.11 (A) & (C) Equipment, utensils, linens and single-service and single-use articles—storing
- 4-903.12 Prohibitions—storage location for single-service and single-use articles
- 4-904.11 Kitchenware and tableware—preventing contamination of single-service tableware

Item 40. Warewashing: equipment, procedures, cleaners/sanitizers, test kits. This item may be marked "N/A" if the establishment only dispenses commercially packaged RTE TCS foods or non-TCS foods and if only single-use/single-service articles are provided to customers eating on the premises. Do not mark this item "N/O." Adequate warewashing facilities and supplies must be available and used for the cleaning and sanitization of food contact surfaces, including the availability of means to monitor the concentration of chemical sanitizers. Observations of manual and mechanical warewashing methods are made to assess the procedure for cleaning and sanitizing equipment and utensils. Compliance with the criteria for proper sanitizing (temperature or chemical concentration) is assessed in <u>Item 17</u>. Compliance for air drying cleaned and sanitized equipment and utensils is assessed using <u>Item 38</u>.

Applicable publication sections:

- 4-203.13 Pressure measuring devices, mechanical warewashing equipment
- 4-204.113 Warewashing machine, data plate operation specifications
- 4-204.114 Warewashing machines, internal baffles
- 4-204.115 Warewashing machines, temperature measuring devices
- <u>4-204.116</u> Manual warewashing equipment, heaters and baskets
- 4-204.117 Warewashing machines, automatic dispensing of detergents and sanitizers
- 4-204.118 Warewashing machines, flow pressure device
- 4-204.119 Warewashing sinks and drainboards, self-draining
- 4-204.120 Equipment compartments, drainage
- 4-205.14 Mechanical warewashing equipment modification
- 4-205.15 Warewashing machine, prohibition
- 4-301.12 Manual warewashing, sink compartment requirements
- 4-301.13 Drainboards
- 4-302.13 (B) Temperature measuring devices, mechanical warewashing (irreversible thermometer for measuring surface temperatures)
- 4-302.14 Sanitizing solutions, testing devices
- 4-303.11 Cleaning agents and sanitizers, availability
- 4-501.14 Warewashing equipment, cleaning frequency
- 4-501.15 Warewashing machines, manufacturers' operating instructions
- 4-501.16 Warewashing sinks, use limitation
- 4-501.17 Warewashing equipment, cleaning agents
- 4-501.18 Warewashing equipment, clean solutions
- 4-501.19 Manual warewashing equipment, wash solution temperature
- 4-501.110 Mechanical warewashing equipment, wash solution temperature
- 4-501.112 (A) & (D) Mechanical warewashing equipment, hot water sanitization temperatures minimum and maximum temperature entering the manifold
- 4-501.113 Mechanical warewashing equipment, sanitization pressure
- 4-501.116 Warewashing equipment, determining chemical sanitizer concentration
- 4-603.12 Precleaning
- 4-603.13 Loading of soiled items, warewashing machines
- 4-603.14 Wet cleaning
- 4-603.15 Washing, procedures for alternative manual warewashing equipment
- 4-603.16 Rinsing procedures
- 4-603.18 Steel wool prohibition
- 4-904.14 Rinsing equipment and utensils after cleaning and sanitizing

Item 41. *Nonfood-contact surfaces; cooking/baking surfaces.* Do not mark this item "N/A" or "N/O." Observations are made to determine if the frequency of cleaning is adequate to prevent accumulation of food debris or encrusted food residues (for example, grease or burnt food) on the food-contact surface of cooking and baking equipment (for example, griddle tops, waffle irons, and oven interior) and on nonfood-contact surfaces of equipment (for example, floor or shelves inside walk-in refrigeration/freezer units).

Applicable publication sections:

4-601.11 (B) & (C) Equipment, food-contact surfaces, nonfood-contact surfaces, and utensils—cleanliness of cooking and baking equipment and nonfood contact surfaces

4-602.12 Cooking and baking equipment—cleaning frequency

4-602.13 (A) & (C) Nonfood-contact surfaces—cleaning frequency

g. Physical facilities.

Item 42. Hot & cold water: available; capacity, pressure. Do not mark this item "N/A" or "N/O." The availability of hot and cold water is essential for proper handwashing and warewashing. A violation occurs when there is a disruption in the potable water system and the facility continues to prepare and serve food that is not exclusively prepackaged. Adequate pressure is to be maintained at all fixtures during peak demand; system capacity provides hot water at times of peak hot water demand. Failure to supply hot water to a dishwashing machine or 3-compartment sink affects proper cleaning and sanitizing and is assessed using <u>Items 17</u> and <u>40</u>, as appropriate. An improvised handwashing station must allow a free-flow of water to prevent recontamination of hands and is assessed under <u>Item 3</u>.

Applicable publication sections:

<u>5-103.11</u> Capacity—quantity and availability

<u>5-103.12</u> Pressure

Item 43. Potable water; plumbing system; cross-connections. Some of the provisions contained within this grouping are critical. This item may be marked "N/A" for temporary and mobile food establishments when there is no connection to a plumbing system (for drinking water or nondrinking water) a mobile water tank, or well. Do not mark this item "N/O." A cross-connection survey of the complete plumbing system is generally conducted during preoperational inspections. 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. The inspector examines equipment, devices, and drainage lines connected to the potable water supply to determine whether a violation exists. When a nonregulated water supply (for example, well) is used and there is no evidence of water quality testing as required under 5-102.13 and 5-102.14, the water supply is considered to be nonapproved and results in a violation of provision 5-101.11. Unregulated wells must be inspected and sampled to ensure compliance with drinking water standards prior to being used to supply a food event or establishment. Sampling should be conducted within 30 days of the intended use if routine periodic sampling is not conducted multiple times throughout the year. The vendor must retain a copy of the sampling results as proof of potability. Wells that are routinely monitored for regulatory compliance are "regulated" and associated sampling results are generally retained by the installation.

Applicable publication sections:

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5-101.11* Approved water source
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- 5-101.12* System flushing and disinfection [Paragraph (B) is noncritical.]
- 5-102.12* Nondrinking water
- 5-104.11 System—distribution, delivery, and retention
- 5-104.12 Alternative water supply
- 5-201.11* Approved materials [Paragraphs (C) and (D) are noncritical.]
- 5-202.11* Approved system and cleanable fixtures [Paragraphs (B), (D) and (E) are noncritical.]
- 5-202.13* Backflow prevention, air gap
- 5-202.14* Backflow prevention device, design standard
- 5-202.15 Conditioning device, design
- 5-203.14* Backflow prevention device, when required
- 5-203.15 Backflow prevention device. carbonator
- 5-204.12 Backflow prevention device, location
- 5-204.13 Conditioning device, location
- 5-205.12* Prohibiting a cross connection [Paragraph (B) is noncritical.]

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5-205.13 Scheduling inspection and service for a water system device
5-205.14* Water reservoir of fogging devices, cleaning [Paragraph (C) is noncritical.]
5-205.15* System maintained in good repair
<u>5-205.16</u> Water conditioning device, replacing cartridges and filters
5-301.11* Approved-materials, mobile water tank [Paragraphs (B) and (C) are noncritical.]
5-302.11 Enclosed system, sloped to drain
5-302.12 Inspection and cleaning port, protected and secured
5-302.13 "V" type threads, use limitation
5-302.14 Tank vent, protected
5-302.15 Inlet and outlet, sloped to drain
5-302.16* Hose, construction and identification [Paragraphs (B)-(F) are noncritical.]
5-303.11* Filter, compressed air
5-303.12 Protective cover or device
5-303.13 Mobile food establishment tank inlet
5-304.11* System flushing and sanitization-operation and maintenance
5-304.12 Using a pump and hoses, backflow prevention
5-304.13 Protecting inlet, outlet and hose fitting
5-304.14* Tank, pump and hoses, dedication
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Item 44. Sewage/wastewater system; disposal; grease traps. Some of the provisions contained within this grouping are CRITICAL. Do not mark this item "N/A" or "N/O." There are two types of systems: the public sewage treatment plant and an individual sewage disposal system. Observations of the facility's overall sewage and wastewater system are necessary to determine if a violation exists. Indications that a system is not functioning properly may include the presence of sewage backing up into the establishment or outdoors on the ground. Condensate drippage and other nonsewage wastes must be drained to a system in accordance to law, and backflow prevention, if required, must be 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 publication sections:

5-202.16 Food waste grinders and pulpers
5-203.13 Service sink
5-204.14 Floor drains, location
5-401.11 Capacity and drainage
5-402.11* Backflow prevention
5-402.12 Grease trap
5-402.13* Conveying sewage [Paragraph (B) is noncritical.]
5-402.14 Removing mobile food establishment wastes
5-402.15 Flushing a waste retention tank
5-403.11* Approved sewage disposal system
5-403.12 Other liquid wastes and rainwater

Item 45. Garbage/refuse: disposal; facilities; covered receptacles. Do not mark this item "N/A" or "N/O." 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. Garbage, waste, and grease receptacles should be covered/closed when not in active use.

Applicable publication sections:

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
5-501.18 Cleaning implements and supplies
5-501.19 Storage areas, redeeming machines, receptacles and waste handling units, location
5-501.110 Storing 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
5-502.11 Frequency—removal
5-502.12 Receptacles or vehicles

Item 46. Restrooms: proper install; supplied; clean. Do not mark this item "N/A" or "N/O." 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 are provided; fixtures and facilities are being kept clean; and the door self-closes to prevent recontamination of hands.

Applicable publication sections:

- 5-203.12 Toilets and urinals
- 5-501.17 Toilet room receptacle, covered

5-503.11 Community or individual facility

6-202.110 Outdoor refuse areas, curbed and graded to drain

- 6-202.14 Toilet rooms, enclosed
- 6-302.11 Toilet tissue, availability
- 6-402.11 Conveniently located
- 6-501.18 Cleaning of plumbing fixtures
- 6-501.19 Closing toilet room doors

Item 47. Physical facilities: proper install, repair, clean. Do not mark this item "N/A" or "N/O." Observations are made of the overall conditions or practices related to the physical facility (for example, materials used in construction of floors/walls/ceilings, 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 impact to public health if compliance is not met. Examples of noncompliance include, but are not limited to, broken floor tiles, missing grout between floor tiles, torn/missing window screens, absorbent acoustic tiles located on ceiling in kitchen, unserviceable lighting fixtures and sinks, and excessive dust on decorative items and wall fixtures in dining room. Also included within this item grouping are the storage of maintenance tools, disposal of mop water, storage of personal belongings, and separation of food operations from living/sleeping quarters.

Applicable publication sections:

- 4-803.13 Use of laundry facilities
- 6-101.11 Surface characteristics—indoor areas
- 6-102.11 Surface characteristics—outdoor areas
- 6-200.11 Food operations, fixed facilities
- 6-201.11 Floors, walls and ceilings—cleanability
- 6-201.12 Floors, walls, and ceilings, utility lines
- 6-201.13 Floor and wall junctures, coved, and enclosed or sealed
- 6-201.14 Floor carpeting, restrictions and installation
- 6-201.15 Floor covering, mats and duckboards
- 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
- 6-202.17 Outdoor food vending areas, overhead protection

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6-202.18 Outdoor servicing areas, overhead protection
6-202.19 Outdoor walking and driving surfaces, graded to drain
6-202.111* Private homes and living or sleeping quarters, use prohibition
6-202.112 Living or sleeping quarters, separation
6-305.11 Designation—dressing areas and lockers
6-403.11 Designated areas—employee accommodations for eating/drinking/smoking
6-501.11 Repairing—premises, structures, attachments, and fixtures—methods
6-501.12 Cleaning, frequency and restrictions
6-501.13 Cleaning floors, dustless methods
6-501.15 Cleaning maintenance tools, preventing contamination
6-501.16 Drying mops
6-501.17 Absorbent materials on floors, use limitation
6-501.110 Using dressing rooms and lockers
6-501.113 Storing maintenance tools
6-501.114 Maintaining premises, unnecessary items and litter
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Item 48. Lighting: adequate; proper fixtures. Do not mark this item "N/A" or "N/O."

Observations should be made to ensure that facility and equipment illumination are at an adequate light intensity to safely conduct food operations and to easily observe soiled conditions. Initial assessment should be conducted using a light meter during preopening inspections and when new fixtures are installed. The observation of missing or blown light bulbs may be cited as a facility repair issue under Item 47. The inspector must use professional judgment when marking this item. Mark a violation in both Item 47 and this item grouping when the area in question is very dimly light, causing a potential safety hazards, and there is indication that the lighting fixture is unserviceable, for example, replaced bulbs do not work or are frequently blown. Proper shielding of light bulbs is also assessed in food preparation, service, and storage areas.

Applicable publication sections:

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6-202.11 Light bulbs, protective shielding
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6-303.11 Intensity—lighting

Item 49. *Ventilation & hoods: adequate, maintained.* This item may be marked "N/A" if the establishment only dispenses commercially packaged RTE foods. Do not mark this item "N/O." 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. Provision 6-304.11(E) may only be cited on an inspection when air velocity measurements are taken using an appropriate air velocity meter. Hood and fan velocities are typically assessed during preoperational inspections and are not normally measured during routine sanitation inspections. Indications of poor ventilation are cited using 6-304.11(A) when velocity measurements are not taken.

Applicable publication sections:

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4-202.18 Ventilation hood systems, filters
4-204.11 Ventilation hood systems, drip prevention
4-301.14 Ventilation hood systems, adequacy
4-602.13 (B) Nonfood contact surfaces—local exhaust hood cleaning frequency
6-202.12 Heating, ventilation, air conditioning system vents
6-304.11 Mechanical—ventilation
6-501.14 Cleaning ventilation systems, nuisance and discharge prohibition
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Item 50. *Ice machines properly maintained, operated.* This item may be marked "N/A" if the establishment does not have an ice machine on the premises. Do not mark this item "N/O." Location of ice machines should not present a risk for ice contamination. Patrons of the food establishment should not have access to ice machines supporting food operations. Proper maintenance of ice machines is assessed through observation of mold and other

residues inside of the ice bin and condensation coils. Filter changes should be conducted IAW manufacturers' specifications and properly documented as specified in paragraph 4-503.11(D). Potential cross-contamination associated with the location of condensation drainage lines or water supply lines should be addressed using *Item 43*. **Applicable publication sections:**

<u>4-401.12</u> Ice machines

4-503.11 Ice machines—maintenance

4-503.12 Operation, restrictions

Item 51. Other findings. This item is used to distinguish deficiencies not otherwise addressed in *Items 1-50* on the inspection report. Before checking this item, review the Applicable Publication Sections that are listed for *Items 1-50*. Violations noted under this item grouping should be identified by provision number and described with detailed observations in the *Remarks* section of the inspection form. Appendix C provides a list of debitable provisions. Multiple violations documented using *Item Number 51* should only be counted as one deficiency when tallying the *Number* and *Type of critical* and *noncritical violations* on page 1 of the report. Examples of other findings are listed below and may include requirements established through local Policy by the regulatory authority:

- <u>2-601.11</u>, Clean-up of vomiting and diarrheal events. Absence of an SOP within the food establishment to address clean-up procedures.
- 3-501.11, Frozen food. Food held in a freezer with the intent of being frozen, but is found partially or completely thawed with a product temperature of 41°F or below. When this occurs additional assessment should be made to determine potential violations regarding suitable equipment capacity and procedures to rapidly freeze advanced prepared foods (3-502.13) or equipment serviceability (*Item 37*; 4-501.10 & 4-501.11). Violations involving thawed products having an internal product temperature above 41°F are marked using *Item 32*.
- <u>3-502.13</u>, Freezing time/temperature control for safety food. When frozen advanced prepared TCS food is being thawed and is not properly labeled with the date removed from the freezer and the use-by/discard date, or is retained beyond 7 days under refrigeration, the *critical* violation is marked using *Item 14*.
- <u>3-503.11</u>, **Restrictions for sale.** The sale or use of outdated foods affects food quality and does not present a *critical* food safety hazard unless there are indications that the food has been adulterated. When outdated food is present and adulterated, a *critical* violation is also marked using <u>Item 10</u>.
- <u>5-102.14</u>, Sample report—potable water. A food establishment is only required to present a copy of a water quality analysis report when the food establishment began operating prior to receiving approval from the regulatory authority and a nonpublic water system is being used to support the operation. Since the regulatory authority did not have the opportunity to evaluate use of the nonpublic water system prior to operation, it is the responsibility of the food establishment to provide a copy of the water sampling report. Food establishments that underwent a preoperational inspection and are using a nonpublic water system that is monitored by preventive medicine are not required to retain a copy of the water sample report on file
- 6-501.116, Plants. Artificial plants have excessive dust accumulation, or there is evidence of pest harborage due to unclean conditions associated with live or artificial plants. Contamination of food, food equipment, or linens is cited when plants are in direct contact with these items and when there is displaced soil or dead foliage found on the surface of food packages, in food, on stored lines, or other food contact surfaces.
- <u>6-502.11</u>, **Restricted access.** Personnel other than food employees are observed entering food storage, food preparation, and warewashing areas without an escort or prior coordination with the food manager or PIC. Restricted access applies to maintenance personnel, food delivery personnel, employee family members, and military personnel.
- <u>10-201.15</u>, **Potable water**, **not available**—**food restrictions.** A food operation is preparing and serving TCS foods and the operation does not have a consistent potable water supply either from a plumbed system or storage tanks and is limited to use of bottled water.

- 10-301.16 (B) Outdoor areas, surface characteristics. A violation occurs when a temporary food establishment is located on terrain that allows creation of mud or standing water in the food prep and serving areas and high-traffic areas by patrons without providing improvised flooring to preclude surface erosion.
- **Vending machine operators.** Violations of the following provisions for vending machine operations are documented using this item grouping:
 - 10-501.11 Approval—not transferable
 - <u>10-501.12</u> Identity—vending machine operator
 - <u>10-501.13</u> Operator procedures
- Service- or Component-Level Policies. The food establishment is in violation of a service- or component-level requirement published in an official policy letter or other regulatory document signed by the medical or command authority for the installation or specified jurisdiction. Referenced provisions: When a policy is provided containing requirements that are not otherwise specified in the TSFC and a violation of such policy is found during inspection, debit the violation by citing the most appropriate TSFC provision number which addresses the underlying principle.

Section III. TACTICAL KITCHEN INSPECTION

E-8. Applicability

The DD Form 2974 is used for inspecting military tactical feeding operations executed by military personnel utilizing field feeding equipment and systems. Applicable use includes evaluation of field food operations such as Force Provider facilities. This form is not intended for inspection of nonappropriated fund establishments (for example, AAFES, NCX, MCX, or MWR) or contracted food service facilities operated in a combat or contingency operation base camp.

E-9. Administrative Information

The DD Form 2974 is organized and scored similarly to DD Form 2973, with the following exceptions:

- *a. Military unit.* Provide the unit name by identifying the numbered unit operating the tactical food operation. Include the company/troop and battalion/regiment designators (for example, C/225th INF BN). Include the unit name on page 2 and all associated continuation pages of the inspection report.
 - b. Geographic location of operation.
 - (1) Do NOT provide the military grid coordinate of the unit on this inspection report.
- (2) Provide the name of the training site, camp, forward operating base, patrol base, or installation in which the operation is located at the time of the inspection. Include the state (CONUS) or country (OCONUS).
- c. Setting. Mark the applicable box if the food operation is supporting a field training event or is deployed in support of contingency, combat, or humanitarian operations.

E-10. Marking DD Form 2974

- a. Compliance.
 - (1) All items listed on the form must be evaluated for compliance during the inspection.
- (2) Do not place a mark in the item number check box if all of the assessed provisions within the grouping were fully compliant.
- b. Deficiencies. Paragraph E-11 identifies the provisions or portion of an applicable provision that is intended to be assessed under each item number.
 - (1) Follow the instructions provided in paragraph <u>E-4.c.</u> for proper marking of violations..
- (2) Marking a check box for *Items* 47-49 indicates a violation occurred for a provision or sanitation criteria that is not otherwise specified in *Items* 1-46. If marked, identify the specific provision number from this publication

and provide a brief description of the violation in the *Remarks* section of the form. Include the violation, as appropriate, when tallying the total number of critical and noncritical violations.

- (4) An unmarked item indicates all assessed elements within the provision grouping were compliant.
- *c. Findings.* Temperature measurements, observations, and corrective actions are documented on page 2 of the form as specified in paragraph <u>E-4.d.</u> of this appendix.

E-11. Guidance for debiting specific item numbers on the form

a. Facilities.

Tac-Item 1. Location/site selection: proximity to latrines, waste disposal; drainage. Adherence to minimum prescribed distances may not be achieved under certain operational settings. Additionally, optimum application of prescribed distances may not fully preclude pest infestations (that is, flies and mosquitoes) associated with large bodies of water or waste storage or disposal areas. In either case, inspection personnel should mark the item noncompliant and provide strategies for reducing associated risks.

Applicable publication section:

9-201.11 Location

Tac-Item 2. Nonstandard military structures/facilities; Field food service establishment facilities. Tactical feeding platforms, which include associated tents, kitchen chassis, and sanitation centers, are assessed for serviceability according to their governing military publications (for example, technical or operations manual). Buildings and improvised structures that are used to support food operations are evaluated for hazards that may contribute to food contamination. Force Provider food operations are managed as tactical systems until nontactical physical facilities are incorporated to support or sustain the operation. Force Provider systems that exceed the maximum expected operational period of 2 years are expected to be replaced or improved to conform to fixed food facility standards. Similarly, nontactical field food service establishments in a deployment setting should show a programmed plan for improvement as the supported camp or operational base matures. Inspectors should look to see if work orders have been submitted and document the status (that is, pending approval; approval date) of these projects when evaluating this item.

Applicable publication section:

9-202.11 (B)—(F) Field food operation, facilities

Tac-Item 3. Floors, walls, ceiling: clean, serviceable, no standing water. Food operations in austere environments are subject to excessive dust and standing water. Administrative controls coupled by an active cleaning and maintenance program will facilitate compliance with this item. Inspectors should ask to see the manager's cleaning schedule and maintenance support logs to help further identify factors contributing to deficiencies. Deficiencies are noted when pallets used as a subfloor and other improvised wood flooring are not covered with an impermeable and easily cleanable material; fabric (tent) walls are torn; walls or ceilings have peeling paint; or there is standing water or heavy mud on unimproved walking surfaces within the food prep, storage, serving, or dining areas.

Applicable publication sections:

9-202.11 (A) Field food operation, facilities

9-203.11 Floors, wall, and ceilings

9-204.11 (C) Wood pallets—used as a subfloor

Further supported by:

6-201.11 (A) Floors, walls, ceilings—cleanability

6-201.15 Floor covering, mats, and duckboards

Tac-Item 4. Hand wash facilities: supplied, accessible, and used. Compliance is based on observations which determine whether handwashing sinks are properly equipped and conveniently located for food employee use. This

item must be marked "noncompliant" when any of the following conditions exists: potable water or disinfected nonpotable water is not supplied for handwashing; the facility is not stocked with soap, hand drying provisions, or equipped with the required signage; the handwashing sink/station is not conveniently located where it can be easily accessed by food employees who are working in food preparation, food dispensing, and warewashing areas; the handwashing sink is blocked by equipment or other items; a handwashing sink is unavailable for regular food employee use. Signage to remind food employees to wash their hands is only required when the toilet facility is constructed as part of the food establishment or is located specifically to support food operation employees. A violation involving the use of nonpotable water at hand wash stations is marked using *Item 34*. Violations involving failure to wear disposable gloves when waterless handwashing has been approved are marked using *Item 44*.

Applicable publication sections:

- 9-102.11* (A) Minimum operational requirements (handwashing facilities)
- 9-202.13 Handwashing facilities (physical facilities)
- 9-204.12 (A) Handwashing facilities (functionality)

Further supported by:

- 2-301.16 Hand antiseptics
- 5-205.11 Using a handwashing sink—operation and maintenance
- 6-301.11 Handwashing cleanser, availability
- 6-301.12 Hand drying provision
- 6-301.14 Handwashing signage

Tac-Item 5. *Toilets: location.* Portable and field-improvised toilet facilities are typically not under the operational control of supported food facility managers; however, an assessment of the toilets' location proximate to the food operation must be conducted and documented when determined to be a contributing factor for unsanitary conditions such as pest infestations (flies, rodents) or facility contamination from poorly controlled raw sewage.

Applicable publication section:

9-202.12 Toilets

Tac-Item 6. Warewashing facility: 3-compartment sink system; drainboard; proper use and maintained; test kits. Adequate warewashing facilities must be available and used for the cleaning and sanitization of food contact surfaces, including the availability of means to monitor the facilities' use and the effectiveness of sanitization. Observations of manual and mechanical warewashing methods are made to assess the procedure for cleaning and sanitizing equipment and utensils. Compliance with the criteria for proper sanitizing is assessed in Item 28.

Applicable publication section:

9-102.11* (B) Minimum operational requirements (sanitation center/dishwashing line)

Further supported by:

- 4-204.116 Manual Warewashing equipment, heaters and baskets
- 4-204.119 Warewashing sinks and drainboards, self-draining
- 4-301.12 Manual warewashing, sink compartment requirements
- 4-301.13 Drainboards
- 4-302.13 Temperature measuring devices, manual warewashing
- <u>4-302.14</u> Sanitizing solutions, testing devices
- 4-303.11 Cleaners and sanitizers, availability
- 4-501.14 Warewashing equipment, cleaning frequency
- 4-501.16 Warewashing sinks, use limitation
- 4-501.17 Warewashing equipment, cleaning agents
- 4-501.18 Warewashing equipment, clean solutions
- 4-501.19 Manual warewashing equipment, wash solution temperature
- 4-501.113 Mechanical warewashing equipment, sanitization pressure
- 4-501.116 Warewashing equipment, determining chemical sanitizer concentration
- 4-603.15 Washing, procedures for alternative manual warewashing equipment
- 4-603.16 Rinsing procedures

Tac-Item 7. Ventilation maintained according to governing military publications; grease and humidity control when operating in an alternate trailer, building, or structure. Ventilation for tactical kitchens (for example, Mobile Kitchen Trailer, Containerized Kitchen) is governed by supporting technical and field manuals and should be assessed accordingly. Inspectors who are unfamiliar with the tactical equipment requirements should request to see a copy of the applicable manual(s). Food operations conducted in semi-permanent or fixed structures must provide mechanical exhaust ventilation to control both humidity and grease-laden vapors, implementing the standards specified in Sections 4-301.14 and 6-304.11.

Applicable publication section:

9-204.13 Ventilation

Further supported by:

4-301.14 Ventilation hood systems, adequacy

6-304.11 Mechanical (ventilation)

Tac-Item 8. Lighting: adequate for tactical situation or alternate facilities used. In the absence of a light meter to assess the actual intensity of lighting as prescribed under 6-303.11 for food preparation areas, inspectors should utilize their best judgment regarding lighting adequacy. Lighting is considered inadequate when food operators experience difficulty viewing temperature measurements and settings on equipment and thermometers, or when soiled conditions are not easily observed. Proper shielding of light bulbs is also assessed in all food preparation, service, and storage areas.

Applicable Publication Section:

9-204.14 Lighting

Further supported by:

6-202.11 Light bulbs, protective shielding

6-303.11 Intensity—lighting

<u>6-501.11</u> Repairing

Tac-Item 9. *Sewage, grease, and wastewater properly disposed.* Assess onsite plumbing, bulk wastewater (for example, gray water) storage containers or soakage pits, and grease traps that directly support the food operation. Minimum standards of compliance must conform to acceptable military field sanitation criteria.

Applicable publication sections:

9-102.10 (C) Food, equipment, and facilities, management (supporting publications) [provides general guidance; not debitable]

9-102.11 (E) Minimum operational requirements (liquid waste)

Tac-Item 10. Garbage/refuse proper disposal; facilities maintained; covered receptacles. 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. Garbage, waste, and grease receptacles should be covered/closed when not in active use. Assess waste receptacles directly supporting the food operation and solid waste storage/holding areas located immediately adjacent to the food operation. Report deficiencies regarding location of waste disposal collection areas using <u>Item 1</u>.

Applicable publication sections:

9-102.10 (C) Food, equipment, and facilities, management (supporting publications) [provides general guidance; not debitable]

9-102.11 (D) Minimum operational requirements (solid waste)

Further supported by:

<u>5-501.113</u> Covering receptacles

<u>5-501.115</u> Maintaining refuse areas and enclosures

5-501.116 Cleaning receptacles

Tac-Item 11. Wood pallet use: clean; exchanged; serviceable. Deficiencies are noted when pallets used to store food off the ground are broken (cannot support the load) and are not exchanged when new supplies arrive. Pallets that are heavily soiled, wet, or show evidence of mold are also deficient.

Applicable publication section:

9-204.11 (A) & (B) Wood pallets

Tac-Item 12. Pest control measures and devices: proper use prevents food contact surface contamination. Insect trapping devices must not be located over food preparation or serving areas, stored clean utensils, or other food contact surfaces. Assess the condition of the physical facilities for conditions that may allow pest entry. Violations involving improper use or application of pesticides are marked using *Item 14*.

Applicable publication section:

<u>9-403.10</u> Pest management (provides general guidance; not debitable)

9-403.11 (A) & (B) Animal and pest control

Further supported by

6-202.13 Insect control devices, design and installation

6-202.15 Outer openings, protected

6-202.16 Exterior walls and roofs, protective barrier

6-501.111 Controlling pests

Tac-Item 13. *Insects, rodents, animals: not present.* An assessment is made through observation and discussion with the PIC for measures taken to control the presence of pests in food preparation, storage, service, and dining areas. Examine potential entry points around the perimeter of food operation structures (tents) and the initiatives to eliminate harborage areas. Assessment includes observing evidence of pests such as droppings, gnawed food packages, or directly observing their presence. Feral cats and dogs or evidence of feeding these animals should not be present; military working dogs should not be present in food preparation areas, to include food service or dining areas and food equipment sanitation centers. An exception is provided for military working dogs when conducting official duties (for example, area surveillance or searches). During these activities food and food-contact surfaces must be protected from potential contamination.

Applicable publication section:

9-403.10 Pest management (provides general guidance; not debitable)

9-403.11 (C) Animal and pest control—animal prohibitions

Further supported by:

2-403.11 Handling prohibition—animals

6-501.112 Removing dead or trapped birds, insects, rodents, and other pests

6-501.115 Prohibiting animals

Tac-Item 14. *Toxic substances properly identified, stored, and used.* Some of the provisions contained within this grouping are *critical*. Paragraphs 7-201.11(A) and 7-208.11(A) are *swing* items and may be assessed as *noncritical* when reasonable controls are in place to further reduce the potential for contamination. Compliance is based on direct observations of container labeling, storage, reconstitution, and application of bulk and working containers of cleaning agents and sanitizers; petroleum, oil, and lubricants; personal care items; first aid supplies; pesticides; and other potential toxic or poisonous substances. Compliance is achieved when bulk and working containers of cleaning agents, sanitizers and other chemicals are labeled; sanitizing solutions do not exceed the maximum concentrations; personal care items, first aid supplies, medicines, and chemicals are stored separate from and not above food, equipment, utensils, 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 "noncompliant" if unapproved chemicals are used for cleaning or sanitizing food equipment; toxic substances are not properly identified and stored; a sanitizing solution is being applied at a higher concentration than prescribed; or medicines and first aid kits are improperly labeled and stored.

Applicable publication sections:

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7-101.11 Identifying information, prominence—original containers
7-102.11 Common name—working containers
7-201.11* Separation—storage
7-202.11 Restriction—presence and use
7-202.12* Conditions of use
7-203.11* Poisonous or toxic material containers—container prohibitions
7-204.11* Sanitizers, criteria—chemicals
7-204.12* Chemicals for washing, treatment, storage and processing fruits and vegetables, criteria
7-204.14* Drying agents, criteria
7-205.11* Incidental food contact, criteria—lubricants
7-206.11* Restricted use pesticides, criteria
7-206.12* Rodent bait stations
7-206.13* Tracking powders, pest control and monitoring
7-207.11* Restriction and storage—medicines
7-207.12* Refrigerated medicines, storage
7-208.11* Storage—first aid supplies
7-209.11 Storage—other personal care items
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b. Food.

Tac-Item 15*. Food and bottled water from approved sources. All violations contained within this item grouping are reported as *critical*. This item includes ice. Compliance determination is based on direct observations of food products, food labels and packaging, bottled water analyses, and discussion with the PIC. For food items not from the military operational ration system, review the supplier names and shipment invoices to document approved food sources; consultation with supporting veterinary services may be required. This item should be marked "noncompliant" when an approved food source cannot be determined. Field packaged water is assessed using *Item 34*.

Applicable publication sections:

9-501.11* Approved sources (food)

Further supported by:

- 3-201.11* Compliance with food law
- 3-201.12* Food in a hermetically sealed container
- 3-201.13* Fluid milk and milk products
- 3-201.14* Fish
- 3-201.15* Molluscan shellfish
- 3-201.16* Wild mushrooms
- 3-201.17* Game animals
- 3-202.13* Eggs
- 3-202.14* Eggs and milk products, pasteurized
- 3-202.16* Ice
- 3-202.110* Juice treated—commercially processed
- 5-101.13* Bottled and packaged drinking water

Tac-Item 16*. Food in good condition, safe and unadulterated; receipt temperatures. All violations contained within this item grouping are reported as *critical*, except for \P 3-202.11(E), which is a *swing* item and may be scored as *noncritical*. Count this item group as noncritical when the only violation occurring within this item grouping is noncritical. Compliance is based on—

A. Condition and packaging. Observe the integrity of product packaging, wholesomeness, and signs of adulteration. This item is considered "compliant" 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 "noncompliant" when the integrity of food packaging has been compromised or the true appearance, color, or quality of a food has been intentionally altered.

B. Receiving temperature. Obtain actual food temperature measurements of TCS foods being received. Compliance is achieved when food is received and found to be at proper temperatures during the inspection (that is, rations are received during the inspection, and the regulatory authority verifies the receiving temperatures). This item should be marked "noncompliant" 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 this publication.

Applicable publication sections:

3-101.11* Safe, unadulterated and honestly presented

3-202.11* Temperature

3-202.15* Package integrity

Tac-Item 17. Proper cold holding temperature and refrigeration/cold storage facilities. The primary provision assessed within this group is *critical*. Temperatures in or out of compliance should be recorded in the "Temperature Observations" section of the inspection report. Compliance is based on actual temperature measurements of food or a combined assessment of the equipment's ambient temperature and the internal temperature of food held in the equipment; a calibrated food temperature measuring device is used. This item should be marked "noncompliant" if one TCS food is found out of temperature, with supportive evidence. Unopened containers of UHT milk do not require refrigeration. A violation does not occur when previously refrigerated UHT milk is subsequently held at ambient temperature as long as the package remains sealed. Foods intended to be stored under freezer conditions that are found partially thawed due to inadequate freezer holding temperatures are evaluated against provisions 3-501.11 and 3-503.11(E) and violations are marked using under "Other Findings," Items 47-49.

Applicable publication sections:

9-102.11* (G) Minimum operational requirements (refrigeration/cold holding)

9-502.11* (B) & (C) Frozen and refrigerated foods, temperature management

9-502.16 Milk and milk products (storage and display)

Further supported by:

3-501.16* (A)(2) & (B) Time/temperature control for safety food, hot and cold holding—cold holding temperatures

Tac-Item 18*. Proper thawing and slacking for frozen TCS foods. All violations contained within this item grouping are reported as *critical* due to the highly susceptible population being served. Observing and then gaining an understanding of thawing method(s) employed by the Class I point or the tactical food service operator will help to determine whether a violation of the approved thawing methods found under 3-501.13 exists, 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 publication sections:

9-102.11* (H) Minimum operational requirements (thawing frozen food)

9-502.11* (A) & (B) Frozen and refrigerated foods, management.

Further supported by:

3-501.12 Time/temperature control for safety food, slacking

<u>3-501.13</u> Thawing

Tac-Item 19*. Proper cooking temperature. All violations contained within this item grouping are reported as critical. The inspection should be arranged at an optimum time for measuring at least one cooked item. **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 compliance determination. Temperatures that are both in compliance and out of compliance should be recorded in the "Temperature Observations" section of the inspection report. The time of inspections should be varied so that cooking can be observed. Prior to being placed in hot holding, food items are checked with a calibrated food temperature measuring device. This item should be marked

"noncompliant" 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 it to the cooking process. Fully cooked foods which are intended to be served hot, such as operational tray rations and canned or frozen vegetables, must be reheated to 165°F before being placed in insulated food containers or on the serving line. Fully cooked operational rations that are either frozen or contained in a tray-pack for group feeding are considered noncompliant if the food is not reheated to 165°F.

Applicable publication section:

9-502.12* (A) Cooking and hot holding, temperatures

Tac-Item 20*. Proper hot holding temperature and/or use of TPHC. All of the provisions assessed within this item are critical. Inspections should be conducted during a time when hot holding temperatures can be taken. **NOTE:** Temperature measurements that are both in compliance and out of compliance should be recorded in the "Temperature Observations" section of the inspection report. Compliance for this item is based on actual food temperature measurements taken with a calibrated food temperature measuring device. Unless TPHC is being used (with prior approval from the regulatory authority), TCS foods held at unsafe temperatures are marked "noncompliant." TPHC is automatically applied to all TCS foods serviced from insulated food containers and does not require pre-approval from the regulatory authority; containers must be labeled with the date and time filled, and the food must be consumed or discarded within 4 hours to retain its compliance. When TCS food retained in IFCs exceed the 4-hour period from the time the container was filled, a violation of TPHC is cited under this item grouping. **Note:** Operational rations contained in a sealed tray-pack such as the UGR H&S are fully cooked items. Tray-packs that are heated for a specified meal and are unused may be retained without temperature control as long as the tray-pack remains sealed. Previously heated (unopened) tray-packs may be retained for future use and are not considered to be a leftover.

Applicable publication sections:

3-501.19* Time as a public health control

9-502.12* (B) Cooking and hot holding, temperatures

9-502.13* (E) Insulated food containers (time as a public health control)

Tac-Item 21. FF&V: washed; night soil/sewage fertilizer restrictions. Some of the provisions assessed within this item are *critical*. Approved disinfecting solutions per 3-302.15 and 7-204.12 must be used for washing fruits and vegetables. Raw fruits and vegetables are to be washed with potable water and disinfected prior to their preparation or their being offered as RTE. This item is noncompliant when unauthorized chemicals are used to wash or disinfect FF&V, or when RTE FF&V are not washed properly. This item is also rated "noncompliant" when concentrations of approved disinfection solutions exceed the maximum prescribed strength, and FF&V are not subsequently rinsed with clear, potable water following disinfection.

Applicable publication sections:

9-502.17* Raw fruits and vegetables

Further supported by:

3-201.18* Fresh fruits and vegetables—sources where human waste is used as fertilizer

3-302.15 Washing fruits and vegetables

7-204.12 Chemicals for washing, treatment, storage and processing fruits and vegetables, criteria

Tac-Item 22. Food separated and protected: storage, prep, transport, service. Some of the provisions contained within this grouping are critical. Compliance is based on direct observations of food storage and food handling practices. This item should be marked "noncompliant" when RTE foods are subject to potential contamination by raw animal foods; raw animal foods are not properly separated or segregated in storage to prevent potential cross-contamination; food is not packaged or covered during storage; unpackaged food is in direct contact with soiled equipment and utensils; or when the dunnage (that is, wood pallets) used to store food is damaged and does not prevent food/containers from coming into contact with the floor/ground. Noncompliance may also occur when serving second portions or refilling customer food containers. Customers must use a new (clean) plate when

returning to the service line for a second or subsequent portions. When tactical feeding involves preparation of insulated food containers for remote-site feeding, observations should be made to assess food transport to ensure vehicles are clean, covered, and do not present a risk of contamination from toxic chemicals transported with food. Assessment for proper insulated food container use is marked using *Item 24*.

Applicable publication sections:

9-102.11* (F) & (I) Minimum operational requirements (contamination prevention during storage and transport)

9-204.11 (A) Wood pallets (food storage)

<u>9-502.15</u> Condiments (protected from contamination)

9-502.18 Transporting food, vehicle and prohibition

Further supported by:

3-302.11* Packaged and unpackaged food—separation, packaging, and segregation

3-304.11* Food contact with equipment and utensils

3-304.16 Using clean tableware for second portions and refills

3-304.17 Refilling returnables

3-305.11 (A) Food storage

3-305.14 Food preparation

3-306.13* Consumer self-service operations

3-307.11 Miscellaneous sources of contamination

Tac-Item 23*. Prohibition for serving raw/undercooked TCS food to highly susceptible populations. The provision assessed within this item is *critical*. Raw or undercooked TCS foods may not be served from a tactical kitchen or to populations meeting the definition of a highly susceptible population.

Applicable publication section:

<u>9-101.10</u> High-risk environments and highly susceptible populations (general information; this item is not debitable)

<u>3-801.11</u>* Pasteurized foods, prohibited re-service, and prohibited food (food establishments serving a highly susceptible population)

Tac-Item 24. *Insulated food containers: proper use; labeled.* Insulated food containers must be serviceable, as indicated by adequate seals and latches, the presence and use of inserts, and the absence of holes or cracks. When IFCs are being prepared for use, observations should be made to evaluate pre-warming or pre-chilling of inserts and to measure the temperature of the foods when they are placed in the containers. Inspectors should also examine container labels to ensure the product name is provided along with the date and time the food was placed in the IFC. For IFCs being distributed to other locations, the receiving unit's name, the quantity of servings provided in the IFC, and the time in which the food must be served by should also be included on the label. Improper time and temperature management of foods placed in IFCs are marked using *Item 20*.

Applicable publication section:

9-502.13 (A)—(D) Insulated food containers

Tac-Item 25*. Leftover TCS food prohibition; retention of sandwiches limited to 1 meal period. All of the provisions contained within this grouping are critical. Condiments and unopened individual containers of UHT milk are exempt from the leftover prohibition. Service of leftovers to populations meeting the definition of a highly susceptible population is prohibited. Sandwiches may only be retained for the next meal period scheduled during the current day's operation. If sandwiches were prepared for the dinner meal, their retention is authorized in support of the "midnight" meal, but the sandwiches should not be retained beyond that period. Sandwiches prepared for the "midnight" meal may be retained for the next day's breakfast but must be discarded if not consumed during that meal. Sandwiches retained for an additional meal must be held at prescribed temperatures and must be monitored throughout the retention period to ensure compliance. Refer to the "Note" in Item 20 regarding retention of unopened and unused operational ration tray-packs that were heated.

Applicable publication sections:

9-502.11* (C) Frozen and refrigerated foods, management (authorized UHT milk re-service) 9-502.14* Leftover foods

Tac-Item 26. Protection from ice used as coolant; food contact with water/ice. One of the provisions contained within this grouping is *critical*. Noncompliance occurs when ice previously used as a coolant is subsequently added to food, such as a beverage, or a packaged food is placed in direct contact with the ice and the type of food packaging is insufficient to prevent water intrusion through the packaging material. Noncompliance also occurs when unpackaged foods that do not meet the criteria specified in paragraphs 3-303.12(C) and (D) are placed in direct contact with ice or water.

Applicable publication sections:

3-303.11* Ice used as exterior coolant, prohibited as ingredient

3-303.12 Storage or display of food in contact with water or ice

c. Utensils and equipment.

Tac-Item 27. Thermometers provided and accurate. Thermometers provide a means for assessing active managerial control associated with the temperature of TCS foods. Compliance is achieved when individual temperature measuring devices (for example, thermocouple or bi-metallic stem thermometers) are present and properly scaled for the range of use to measure food, water, or ambient air temperatures. Food thermometers must be calibrated at an appropriate frequency to ensure accuracy. The inspector should compare temperature measurements taken from their own calibrated thermometer and those measurements attained from thermometers used in the operation when assessing accuracy compliance. Food thermometers should be accessible for use during cooking and warewashing.

Applicable publication sections:

4-203.11 Temperature measuring devices, food-accuracy

4-203.12 Temperature measuring devices, ambient air and water—accuracy

4-204-112 Temperature measuring devices—functionality

4-302.12 Food temperature measuring devices

4-302.13 (A) Temperature measuring devices, manual Warewashing—availability

4-502.11 (B) Good repair and calibration

Tac-Item 28*. Food-contact surfaces cleaned and sanitized. All of the provisions assessed within this item grouping are *critical*. Compliance is based on direct observations of food contact surfaces of equipment and utensils; observations of cleaning and sanitizing procedures; discussion of cleaning and sanitizing procedures with the PIC or other assigned food workers; and actual measurements/readings of chemical sanitizer concentration and/or hot water sanitizing temperature using test strips and calibrated thermometers, as appropriate. There should be an overall assessment of the food-contact surfaces of equipment and utensils, both in clean storage and in use, to determine compliance. This item must be marked "noncompliant" when the available methods of cleaning and sanitizing food-contact surfaces of equipment and utensils are ineffective. Cleanliness of cooking and baking equipment (for example, griddle tops, waffle irons, and oven interior) presents a low risk when compared to other food-contact surfaces; therefore, it is assessed along with cleanliness of nonfood contact surfaces using <u>Item 41</u>. Compliance regarding proper use of warewashing equipment and warewashing procedures is assessed in <u>Item 6</u>.

Applicable publication sections:

4-501.111* Manual warewashing equipment, hot water sanitization temperatures

4-501.112 (C) Mechanical warewashing equipment, hot water sanitization temperatures—[cited using 4-703.11(B)]

<u>4-501.114</u>* Manual and mechanical warewashing equipment, chemical sanitization—temperature, pH, concentration and hardness

4-501.115* Manual warewashing equipment, chemical sanitization using detergent-sanitizers

4-601.11* (A) Equipment, food-contact surfaces, and utensils

4-602.11* Equipment food-contact surfaces and utensils—frequency

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4-702.11* Before use after cleaning
4-703.11* Hot water and chemical methods
5-101.14* Steam
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Tac-Item 29. *Utensils and equipment properly dried, stored, handled.* An assessment is made of the overall storage practices and handling of cleaned and sanitized equipment and utensils. Equipment must be air-dried prior to storage. Drainboards or drying racks must be free from environmental contamination (for example, soil, dust, rain) when items are being dried or stored. Proper maintenance and use of insulated food containers is assessed using *Item 24*.

Applicable publication sections:

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4-901.11 Equipment and utensils, air-drying required
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4-903.11 (A) & (B) Equipment, utensils, linens, and single-service and single-use articles—storing multi-use equipment and utensils

4-903.12 Prohibitions—storage location

4-904.11 Kitchenware and tableware—preventing contamination

4-904.12 Soiled and clean tableware

Tac-Item 30. Equipment and utensils: good repair/operational; authorized materials. Some of the provisions contained within this grouping are *critical*. Equipment and utensils must be appropriate for use in food service and must remain in good repair. Food service equipment and utensils that have a national stock number and are listed as items contained within approved U.S. military field feeding systems will meet the requirements within this item grouping as long as the equipment remains serviceable. Tactical food service equipment from coalition military partners and commercial food service equipment from foreign manufacturers may not meet the requirements of this publication and require evaluation and approval by the regulatory authority prior to use. Equipment such as food thermometers must be properly used and in proper adjustment/calibration.

Applicable publication sections:

<u>9-102.10</u> Food, equipment, and facilities, management [general information; this item is not debitable]

9-402.10 Good repair and operation (equipment and utensils) [general information; this item is not debitable]

Further supported by:

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4-101.11* Characteristics—materials for construction and repair
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4-101.12 Cast iron, use limitations

4-101.13 Lead, use limitation

4-101.14* Copper use limitation

4-101.15* Galvanized metal, use limitation

4-101.17 Wood, use limitation

4-101.18 Nonstick coatings, use limitation

4-101.19 Nonfood-contact surfaces

4-101.110 Paint or other coatings, application

4-101.111 Sealing compounds—characteristics

4-101.112 Plastic, use prohibition

4-102.11* Characteristics—single-service and single-use

4-201.11 Equipment and utensils—durability and strength

4-201.12* Food temperature measuring devices

4-201.13 Sealing compounds—durability, installation and application

4-202.11* Food-contact surfaces—cleanability

4-202.12 CIP equipment

4-202.13 "V" threads, use limitation

4-202.14 Hot oil filtering equipment

4-202.15 Can openers

4-202.16 Nonfood-contact surfaces

4-202.17 Kick plates, removable

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4-204.12 Equipment openings, closures and deflectors
4-204.13* Dispensing equipment, protection of equipment and food
4-204.15 Bearings and gear boxes, leakproof
4-204.16 Beverage tubing, separation
4-204.17 Ice units, separation of drains
4-204.18 Condenser unit, separation
4-204.122 Case lot handling apparatuses, moveability
4-205.11 Equipment and utensil, approval
4-205.12 Equipment and utensil, compliance measures
4-205.13 Overseas food operations
4-302.11 Utensils, consumer self-service
4-501.11 Good repair and proper adjustment—equipment
4-501.12 Cutting surfaces
4-501.13 Microwave ovens
4-502.11 (A) & (C) Good repair and calibration—utensils and temperature and pressure measuring devices
4-603.11 Dry cleaning—methods
4-902.11 Food-contact surfaces—lubricating and reassembling
4-902.12 Equipment—lubricating and reassembling
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Tac-Item 31. Cleaning: nonfood-contact surfaces; cooking & baking equipment. Observations are made to determine if the frequency of cleaning is adequate to prevent accumulations of food debris or build-up of food residues (for example, grease or burnt food) on the food-contact surface of cooking and baking equipment (for example, griddle tops, waffle irons, and oven interior) and on nonfood-contact surfaces of equipment (for example, floor or shelves inside walk-in refrigeration/freezer units).

Applicable publication sections:

9-401.11 Cleaning, frequency and methods

Further supported by:

- 4-601.11 (B) & (C) Equipment, food-contact surfaces, nonfood-contact surfaces, and utensils
- 4-602.12 Cooking and baking equipment
- 4-602.13 Nonfood contact surfaces

Tac-Item 32. Single-use/single-service items: properly stored and used. One of the provisions contained within this grouping is *critical*. Single-use/single-service items are not designed to be cleaned and re-used; therefore, they must be properly stored and protected to prevent their possible contamination. Tactical feeding operations do not have suitable facilities for cleaning, sanitizing, air drying, and storing multi-use tableware; therefore, single-use articles are required.

Applicable publication sections:

- 4-502.12* Single-service and single-use articles, required use
- 4-502.13 Single-service and single-use articles—use limitations
- 4-903.11 (A) & (C) Equipment, utensils, linens and single-service and single-use articles—storing single-use/single service articles
- 4-903.12 Prohibitions
- 4-904.11 Kitchenware and tableware—preventing contamination

Tac-Item 33. Wiping cloths; properly used and stored; sponge prohibition. Reusable wiping cloths are appropriate for cleaning and sanitizing food-contact surfaces and the tables and chairs in dining areas, but must be laundered daily using an approved laundry system/service. Wiping cloths used for food-contact surfaces must be separate from the cloths used for dining areas. Wiping cloths that are used throughout the day must be stored in a sanitizing solution between uses. The solutions should be reasonably clean (that is, free from food debris or grease film) and must be maintained at the proper sanitizer concentration (4-501.114). Solutions exceeding the

recommended sanitizer concentrations are assessed using <u>Item 14</u>, <u>Toxic substances properly identified</u>, <u>stored</u>, <u>and used</u>. Sponges, if present, are not to be used in contact with clean/sanitized food-contact surfaces.

Applicable publication sections:

- 3-304.14 Wiping cloths, use limitation
- 4-101.16 Sponges, use limitation
- 4-901.12 Wiping cloths, air-drying location

d. Water.

Tac-Item 34*. *Potable water: supplied and used; approved source; quality.* All violations contained within this item grouping are reported as *critical*. Compliance determination is based on water supplied from an approved potable source and water analyses results. Assessment regarding appropriate use of field-packaged water is included under this item. Issues involving bottled water manufactured by a commercial bottling facility are assessed using *Item 15*.

Applicable publication sections:

- 9-102.11* (C) Minimum operational requirements—adequate water supply
- 9-301.11* Approved system
- 9-303.11* Drinking water quality, standards

Further supported by:

5-101.13* Bottled and packaged drinking water

Tac-Item 35. Plumbing and bulk storage: approved system or storage container; no cross-connections; inspected/maintained. Some of the provisions contained within this grouping are critical. With the exception of commercial bottled water, all water supplied in a deployment setting is considered field water regardless if stored in bulk or distributed through a plumbed system. For fixed plumbing systems, a determination must be made regarding the source/approval of the installed system, including the equipment and devices connected to the potable water supply. For nonplumbed or partially plumbed systems, an assessment of the storage tanks and connecting hoses is required. Further assess the layout of the establishment and the water distribution system to determine if there are any points at which the potable water supply is subject to contamination or if the system is in disrepair. Bulk storage tanks for potable water must be approved and should have accompanying documentation regarding periodic inspections and super-chlorination as prescribed by local public health/preventive medicine or theater policy.

Applicable publication sections:

- 9-304.11 Bulk water, storage container
- 9-304.12* Pipes and hoses, connections

Further supported by:

- 5-101.12* System flushing and disinfection
- 5-102.12* Nondrinking water
- 5-104.11 System—distribution, delivery, and retention
- <u>5-104.12</u> Alternative water supply (delivery system)
- 5-201.11* Approved-materials
- 5-202.11* Approved system and cleanable fixtures
- 5-202.13* Backflow prevention, air gap
- 5-202.14* Backflow prevention device, design standard
- 5-202.15 Conditioning device, design
- 5-203.14* Backflow prevention device, when required
- 5-203.15 Backflow prevention device, carbonator
- 5-204.12 Backflow prevention device, location
- 5-204.13 Conditioning device, location
- 5-205.12* Prohibiting a cross-connection
- 5-205.13 Scheduling inspection and service for a water system device
- 5-205.14* Water reservoir of fogging devices, cleaning

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5-205.15* System maintained in good repair
5-205.16 Water conditioning device, replacing cartridges and filters
5-301.11* Approved—materials, mobile water tank and mobile food establishment water tank
5-302.12 Inspection and cleaning port, protected and secured
5-302.13 "V" type threads, use limitation
5-302.14 Tank vent, protected
5-302.15 Inlet and outlet, sloped to drain
5-302.16* Hose, construction and identification
5-303.11* Filter, compressed air
5-303.12 Protective cover or device
5-304.11* System flushing and sanitization—operation and maintenance
5-304.12 Using a pump and hoses, backflow prevention
5-304.13 Protecting inlet, outlet and hose fitting
5-304.14 Tank, pump and hoses, dedication
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Tac-Item 36. Sufficient quantity of potable water to support food operations and sanitation. A sufficient quantity of potable water must be supplied to support food preparation, sanitation, and hygiene activities. Examine bulk potable water containers and potable water supplied to handwashing facilities. When availability of potable water is limited, use of operational rations, such as individual (MREs) or tray-type rations (UGR-H&S), should be maximized. Issues regarding water quality (potability) are marked using <u>Item 34</u>.

Applicable publication sections:

9-302.11 Capacity (water)

Tac-Item 37*. Chlorine residual (nonbottled/packaged water): present and monitored. All of the provisions contained within this grouping are critical. Tactical food operations are ultimately responsible for monitoring chlorine residual of bulk water used in the operation. Food operation managers are required to conduct daily monitoring of chlorine residuals in bulk potable water containers and in plumbed water supplied to the food operation. Food operators are responsible for rechlorinating the water in assigned water trailers or other bulk potable water storage containers when levels fall below the minimum prescribed level. To verify test kits are on hand and personnel are knowledgeable in proper testing procedures, ask the PIC to demonstrate how the personnel test the chlorine residual. Inspection personnel must also have a test kit (or chlorine test strips) readily available to measure trace levels of FAC in the event a kit is not available at the food operation. In some cases, the unit field sanitation team is tasked to conduct daily monitoring and rechlorination of water at the food operation. In this case, the inspector must confer with the field sanitation team to verify daily monitoring is conducted. Regardless of "who" conducts the monitoring and rechlorination, a violation is marked when test kits/strips are not readily available or cannot adequately measure the appropriate FAC range; personnel do not properly conduct chlorine testing or do not interpret the data properly; or when FAC does not meet the minimum prescribed requirements.

Applicable publication sections:

- 9-303.12* Chlorine residual, requirements
- 9-303.13* Chlorine residual monitoring
 - e. Health and hygiene.

Tac-Item 38. *Ill employee: reporting, restriction and exclusion.* Five of the six provisions assessed within this item grouping are reported as *critical*. If noncompliance is based <u>solely</u> on violation of Section 2-401.12 (Discharges from the Eyes, Nose, and Mouth), score the item as *noncritical*. Discharges from the eyes, nose, or mouth are generally associated with heavy coughing, sneezing, runny nose, or tearing eyes due to allergies or illness. When the inspector observes cooks or KPs not washing their hands after coughing, sneezing, or wiping their nose or eyes, paragraph 2-301.14(C) is violated and is marked using *Item 41*. Compliance under this item grouping is based on the following:

- A. Direct observations of food workers and KPs. Cooks and KPs must not be sick or experiencing symptoms that require reporting such that the individual must be excluded or restricted from working with food or food equipment. 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 this publication. This item should be marked "noncompliant" when—
- 1. The inspector observes a food service worker or KP with specific reportable symptoms (subparagraph 2-201.11(A)(1)); or
- 2. The inspector becomes aware that employee food service worker 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 or exclude the individual as required by this publication (§ 2-201.12) and (§2-201.13); or
- 3. The inspector becomes aware that the PIC has not notified the regulatory authority that one of their food service workers is jaundiced or has been diagnosed with an illness due to a pathogen as specified under subparagraphs 2-201.11 (A)(2)(a)-(e) of the publication.
- 4. There are individuals working in the food operation that have been diagnosed with Norovirus, HAV, shigellosis, *STEC*, or typhoid fever; or with active symptoms of vomiting and/or diarrhea; or working with food, food contact equipment, utensils, or single-service articles with an open, uncovered infected wound or pustule, or with a sore throat with a fever. 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.
- 5. There is evidence that restrictions or exclusions are removed without written medical documentation from a health practitioner or approval from the regulatory authority as specified in Section 2-201.13.
- B. Cooks and KPs have a responsibility to report an illness or infected wound to the PIC and the PIC must exclude or restrict the worker, as appropriate. Failure of an assigned food-worker to report and failure of the PIC to exclude or restrict ill or infected workers is debited under this item grouping, but requires further investigation for possible violations involving training and duties of the PIC (see Item 46, paragraph C). When an assigned food worker is ill or has a wound that appears infected and the individual states he or she was never informed of their reporting responsibilities, the inspector must assess whether training/counseling was provided and must record any violations regarding the absence of training under Item 46.

Applicable publication sections:

2-201.11* (A), (B), (C), & (E) Responsibility of person in charge, food employees, and conditional employees 2-201.11* (D) & (F) Responsibility of person in charge, food employees, and conditional employees—responsibility of the PIC to exclude or restrict

2-201.12* Exclusions and restrictions

2-201.13* Removal, adjustment, or retention of exclusions and restrictions

2-401.12 Discharges from the eyes, nose, and mouth

9-103.11* Health and medical screening

Tac-Item 39. Eating, drinking and tobacco use in food prep and service areas; proper tasting procedures. Compliance is based on direct observations. Provision compliance occurs when food employees are observed drinking from a closed beverage container subsequently stored on a nonfood-contact surface and separate from exposed food, clean equipment, and unwrapped single-service and single-use articles. Use of a tactical hydration system that is worn by the individual is appropriate as long as the sipping tube is secured to prevent contact with food and there is no leakage from the tube opening.

Applicable publication sections:

2-401.11 Eating, drinking, or using tobacco

3-301.12* Preventing contamination when tasting

Tac-Item 40. Personal cleanliness: clothing, hair restraint, jewelry. Observation of food service personnel for clean outer clothing, effective hair restraints, prohibited jewelry, and the condition or protection of fingernails must be made. Although operating in a field setting, cooks and KPs must wear military uniforms that are free of heavy soil and residues acquired from handling fuel and other petroleum products. When the tactical situation permits,

cooks should wear a clean uniform every day and should minimize wearing tactical gear that may present a safety issue or potentially contaminate food during preparation or service. Assessments regarding proper handwashing are marked using *Item 41*; assessments regarding use of camouflage paint are marked using *Item 42*.

Applicable publication sections:

- 2-302.11 Maintenance—fingernails
- 2-303.11 Prohibition—jewelry
- 2-304.11 Clean condition—outer clothing
- 2-402.11 Effectiveness—hair restraints
- 9-601.11 (C) Camouflage paint and food employee uniforms (clothing)

Tac-Item 41. Hands clean and properly washed. Some of the provisions contained within this grouping are *critical*. Inspections should be conducted during active meal preparation and service. This item is considered compliant when food workers are observed using proper handwashing techniques at appropriate times and places. This item is considered noncompliant when hand antiseptics are used by cooks and KPs (in the sanitation center) in lieu of handwashing and when food preparation sinks and warewashing sinks are used for washing hands. Violations involving cooks or KPs wearing camouflage paint on their hands during food-related operations are marked using <u>Item 42</u>.

Applicable publication sections:

- 2-301.11* Clean condition—hands and arms
- 2-301.12* Cleaning procedure
- 2-301.14* When to wash
- 2-301.15 Where to wash
- 2-301.16 Hand antiseptics

Tac-Item 42. Camouflage paint and toxic coatings on hands, arms, and face. Noncompliance associated with the use of camouflage paint or other toxic skin coatings, such as insect repellent, by food workers is based on the type of subsistence being prepared/served. When the tactical situation, as determined by the commander, requires food workers to wear camouflage paint, insect repellents, and tactical gear during food preparation and service, an alternate feeding plan incorporating the use of individual or tray-type (heat-and-serve) operational rations should be employed. When conditions require food workers to wear camouflage paint on their hands, arms, and face during service of food, compliance is achieved by wearing disposable gloves and properly changing gloves between tasks and there is no indication of cross-contamination of food. Violations associated with improper glove use are marked using Item 44. Noncompliance in this item is noted when an alternate feeding plan is not incorporated (A-type rations are being prepared), and camouflage paint is worn by food workers during food preparation, regardless of glove use.

Applicable publication sections:

9-601.11 (A) Camouflage paint and food employee uniforms

Tac-Item 43*. Bare hand/arm contact with food. The primary provision assessed within this item grouping is generally reported as *critical*, with the exception of paragraph 3-301.11(C), which is designated as a *swing* item. Deployment food service is identified as supporting a highly susceptible population due to potential impact on mission readiness. Compliance for this item occurs when cooks and KPs are observed using suitable utensils or gloves to prevent bare hand contact with RTE foods. Guidance provided in ¶ 9-204.12(C) regarding disposable glove use is also used to assess the situation. This item is marked "noncompliant" if one person is observed touching RTE food with his or her bare hands. Restrictions for bare-hand contact do not apply when handling whole fruit that has an outer skin intended to be removed by the consumer. The *swing* violation is rated *critical* under paragraph 3-301.11(C) when the food-handler is processing food that is not in an RTE form and the food-handler has unprotected cuts/wounds on exposed hands or forearms. When the *swing* provision is assessed as *noncritical*, the inspector must count the item grouping as *noncritical* when the inspection is scored. Violations associated with improper glove use are marked using *Item 44*.

Applicable publication sections:

3-301.11* Preventing contamination from hands

Tac-Item 44. Disposable gloves used properly. The observation of food preparation activities and disposable glove use by individuals who prepare or serve food is necessary. If misused, gloves may serve as a source of crosscontamination. Disposable gloves must be appropriate for use with food. Review the package label to ensure powdered gloves are approved for use with food. Glove use is mandatory when RTE foods are being handled, waterless handwashing (hand antiseptics) is the only means available to "clean" hands, or camouflage paint is worn during food service. Look for proper glove exchange and for handwashing between glove changes. The use of gloves when camouflage paint is worn during food preparation and service and during cleaning and sanitizing activities is assessed using Item 42; violations involving bare-hand contact with RTE food are marked using Item 43.

Applicable publication sections:

3-304.15 Gloves, use limitations

9-204.12 (C) Handwashing facilities (waterless handwashing and glove use)

9-601.11 (B) Camouflage paint and food employee uniforms (use of gloves)

f. Supervision and Training

Tac-Item 45*. *PIC present and demonstrates knowledge.* The inspection must occur when the tactical kitchen is in active operation. The primary provisions assessed in this grouping are *critical*, with the exception of 2-102.11(C), which is a *swing* item. A *critical* violation occurs when a qualified PIC is not present during periods when food is being prepared or served, or when Warewashing activities are occurring. The designated PIC must meet the requirements in 2-102.12 by having the authority to supervise and direct the actions of the food employees. Mark this item "noncompliant" if any **one** of the following items is found:

- A. A designated PIC is not present when the tactical kitchen or food sanitation center are in operation. The violation remains noncompliant, but is marked corrected onsite if a qualified PIC returns to the operation during the inspection. A "qualified" PIC is a person who possesses a valid food safety certification and has "supervisory" or "management" authority to direct the actions of the cooks and KPs.
- B. The designated PIC does not have a food safety certificate from an accredited program as specified in 2-102.20 or the certificate has expired. Certificates are generally valid for 5 years, depending on the certifying source.
- C. A critical violation regarding failure to demonstrate knowledge may also be awarded based on observations combined with questioning. Two conditions in Section 2-102.11 [paragraphs (A) and (C)] are used in combination to assess the PIC's ability to demonstrate knowledge even when a valid food safety certificate is on file. Paragraphs (A) and (C) are *swing* violations. When multiple critical violations are observed during an inspection, the inspector should ask the PIC to discuss or demonstrate proper procedures relevant to the critical violations. Questions should be open-ended to evaluate the PIC's understanding of the associated health effects that may result from the violations. The inspector should ask a sufficient number of questions to allow the inspector to make an informed decision concerning the PIC's knowledge of this publication's requirements and of general public health principles as they apply to the operation. The dialogue should be extensive enough to reveal whether or not the PIC's knowledge will enable him/her to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented. The PIC's inability to correctly respond to the inspector's questions coupled with one or more critical violations is indicative of failure to demonstrate knowledge.

Applicable publication sections:

<u>2-101.11</u>* Assignment

2-102.11* Demonstration

[2-102.12 Certified food protection manager – a violation of this provision results in a violation of 2-101.11(A)]

Tac-Item 46. *PIC and employees: duties; training.* This item is "fully compliant" when the following criteria are met:

- A. Duties of the PIC. Violations associated with food temperature controls, cook hygienic practices, food equipment sanitation, and other operational controls are indicators that the PIC is not actively supervising the activities within the food operation. 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.
- B. Training. Compliance is demonstrated by presenting evidence (a record per 2-505.11) such as a curriculum/outline and attendance rosters documenting that each cook and personnel assigned in an additional duty capacity have completed appropriate training specified in \P 2-501.11(A) and 2-503.13(B). Training for cooks, nutritional care specialists, culinary specialists, and other similar job series in which the individual prepares or serves food must also include employee illness reporting responsibilities as specified in \P 2-201.11(A). Training records may include unexpired Food Safety Manager Certification or a training syllabus and attendance roster that contains the required information specified in \P 2-505.11(C).
- C. A *critical* violation may exist if there is evidence to support that food service personnel were never trained or counseled regarding their requirement to report or disclose health information such as reportable illnesses and infections as specified in Section 2-201.11(A) **and** there is no record of such training or counseling. Evidence may be in the form of a training record containing a training outline that includes discussion of reportable illnesses and health conditions, or a counseling record such as the *Conditional Employee or Food Employee Reporting Agreement*, or other general counseling document. A violation involving an ill employee who should have been restricted or excluded, has an infected wound or skin infection, or has discharges from the eye, nose, or mouth, is debited using *Item 38*.

Applicable publication sections:

- 2-103.11 Person in charge—duties
- 2-201.11* (A) Responsibility of person in charge, food employees, and conditional employees
- <u>2-501.11</u> Training requirements
- 2-502.11 (Supervisor) requirements and renewal
- 2-503.11 General requirements
- 2-505.11 Documentation, retention and presentation
- <u>8-304.11</u> Responsibilities of the food manager

Tac-Items 47 – 49. Other findings. This item is used to distinguish deficiencies not otherwise addressed in *Items 1-46* on the inspection report. Before checking this item, review the Applicable Publication Sections that are listed for *Items 1-46*. Violations noted under *Items 47-49* should be identified by provision number and described with detailed observations in the *Remarks* section of the inspection form. Appendix C provides a list of debitable provisions. Multiple deficiencies documented under "other findings" should only be counted as one violation when the critical and noncritical *Number and Type of Violations* are tallied for page 1 of the report. Refer to the *Item 51* description provided in Section II of this appendix for examples of other findings.

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APPENDIX F

FORMS AND TEMPERATURE GUIDES

F-1. Required forms

- a. The following forms are required for use by public health personnel to document facility risk assessments and sanitation inspections.
 - (1) DD Form 2972, Food Facility Risk Assessment Survey
 - (2) DD Form 2973, Food Operation Inspection Report
 - (3) DD Form 2974, Tactical Kitchen Food Sanitation Inspection
- *b*. Required forms are published and available in electronic format through the DOD Issuances Web site located at http://www.esd.whs.mil/Directives/forms/dd2500 2999/.
- c. Automated forms that are programmed in DOEHRS-IH and correspond to the DD Forms specified in paragraph a. of this section are recognized as official forms.

F-2. Optional forms

- a. The following forms provide a model format for documenting employee requirements and submitting applications to operate temporary food establishments. Use of these forms is optional.
- (1) DD Form 2970, *Application for Temporary Food Establishments*, is recommended for use by the food operation manager or the nonappropriated fund organization (for example, AAFES, NEX, MCX, MWR) that is sponsoring the food vendor when requesting permission to operate a temporary food establishment.
- (2) DD Form 2971, Conditional Employee or Food Employee Reporting Agreement, is recommended for use by the food establishment manager during initial training with new food employees to document acknowledgement of medical reporting responsibilities as stated in ¶ 2-103.11(N). The reporting agreement is designed to assist those responsible for managing employees in order to prevent foodborne disease. The document specifies that the PIC 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 PIC.
- (3) DD Form 2975, *Temporary Food Event Coordinator's Application*, is recommended for use by designated event coordinators when two or more temporary food establishments will be included at the venue.
 - b. Optional forms may be modified to conform with local policies and procedures.

F-3. Temperature guides

Tables F-1 and F-2 summarize the minimum required cooking and reheating temperatures of the listed foods, respectively.

Table F-1. Summary chart for minimum food cooking temperatures and holding times

Food	Minimum Temperature and Holding Time at the Specified Temperature ¹	
Cooked fruits and vegetables	135°F (57°C); 15 seconds	
 Raw Eggs prepared for immediate service Commercially Raised Game Animals and Exotic Species of Game Animals Fish, Pork cutlets/chops, and Meat not otherwise specified in this chart or in ¶ 3-401.11(B) 	145°F (63°C); 15 seconds	
Pork Roast	145°F (63°C); 4 minutes	
 Raw Eggs not prepared for immediate service (e.g., scrambled bulk, quiche, pre-cracked or "pooled") Comminuted Commercially Raised Game Animals and Exotic Species of Game Animals Comminuted Fish and Meats Injected Meats 	158°F (70°C); < 1 second, or 155°F (68°C); 15 seconds, or 150°F (66°C); 1 minute, or 145°F (63°C); 3 minutes	
 Poultry Baluts Stuffed Fish; Stuffed Meat; Stuffed Pasta; Stuffed Poultry; Stuffed Ratites Stuffing Containing Fish, Meat, Poultry, or Ratites Wild Game Animals 	165°F (74°C); 15 seconds	
Food Cooked in a Microwave Oven	165°F (74°C); Hold for 2 minutes after removing from microwave oven	
¹ Summarized from § <u>3-401.11</u>		

Table F-2. Summary chart for minimum food reheating temperatures and holding times

Food	Minimum Temperature	Minimum Holding Time at the Specified Temperature	Maximum Time to Reach Minimum Temperature
Any TCS food (advanced prepared or leftover) that is cooked, cooled, and reheated: ¶¶ 3-403.11(A) and (D)	165°F (74°C)	15 seconds	2 hours
Any TCS food (advanced prepared or leftover) that is reheated in a microwave oven: ¶¶ 3-403.11(B) and (D)	165°F (74°C)	and hold for 2 minutes after reheating	2 hours
RTE TCS food that is taken from a commercially processed, hermetically sealed container or intact package: ¶¶ 3-403.11(C) and (D)	135°F (57°C)	No time specified	2 hours
Unsliced portions of meat roasts cooked as specified under ¶ 3-401.11(B): ¶ 3-403.11(E)	Same oven parameters and minimum time and temperature conditions as specified under ¶ 3-401.11(B); or Minimum and maximum time and temperature conditions listed in this chart for ¶¶ 3-403.11(A) and (D).		Not applicable
			onditions listed in this

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APPENDIX G

PUBLIC HEALTH REASONS AND ASSESSMENT GUIDANCE

Responsibility	<u>2-101.11</u>	Assignment
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Designation of a PIC 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 as they occur.

In cases where a food establishment has several departments on the premises (for example, a commissary with deli, seafood, and produce departments), it may be unnecessary from a food safety standpoint to staff each department with a separate PIC 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 PIC for multiple departments or the entire facility can oversee these operations and be ready to take corrective actions if necessary.

Food establishment managers for small food venues (for example, coffee shops, sandwich shop, and operations generally characterized as "fast food" or "take out only") can easily serve as the PIC if their administrative duties do not preclude them from observing all aspects of the food operation throughout the day. As a food establishment increases in size and complexity, employees become more dispersed throughout the operation and are assigned distinct functions, such as food receipt and storage, food preparation, food serving, waste management, and warewashing, A single PIC may not have the ability to supervise the full range of activities, or may not have the authority to direct the actions of employees in different areas. This is very common in dining facilities where food service and dining attendants are managed under separate contracts: Food receipt, storage, preparation, and service are conducted by active military personnel or food service contract, and a separate dining attendant contract may manage dining room activities, warewashing, general facility sanitation, and solid waste. Under these circumstances the food establishment manager may serve as the overall PIC, but other supervisory-level individuals are designated as the PIC for their respective areas.

The designated PIC who is knowledgeable about foodborne disease prevention, 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 PIC can demonstrate competency. Many aspects of the food operation itself will reflect the competency of that person. Applying knowledge is a key component of active managerial controls in a food operation. A critical violation of "knowledge" is evident when multiple critical or noncritical violations are observed during the inspection. This may occur despite the PIC having Food Protection Manager certification. Active managerial controls involve consistent observances by the PIC and timely and appropriate corrective actions for critical and noncritical violations associated with employee food handling practices and the sanitary condition of facilities and equipment. The discovery of multiple violations during an inspection, or the frequent reoccurrence of the same or similar violations observed during consecutive inspections indicates ineffective active managerial controls, which may be attributed to a lack of knowledge or understanding of food safety principles by the PIC.

A dialogue with the PIC 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 honestly represented.

An in-depth discussion between the inspector and the PIC is necessary to distinguish if there is simply a failure of the PIC to perform his "duties" or there is a true failure in "knowledge." Focus the discussion on violations that are discovered during the inspection. The topics presented in \P 2-102.11(C) serve as a guide for assessing knowledge; assessments must be relevant to the operation—

- query the PIC's knowledge regarding appropriate controls associated with observed violations;
- observe the PIC's ability to readily administer or direct proper procedures or actions to correct the violation without receiving specific guidance from the inspector;
- assess the PIC's ability to communicate the potential public health consequences associated with the
 observed violations.

A critical violation for "knowledge" under these circumstances cannot be corrected onsite and can only be demonstrated through observance of proper food safety practices (that is, active managerial controls) during the next inspection.

Guidance for paragraph (C)(17) of the provision: 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 RTE food is a Code requirement.

	<u>2-102.12</u>	Certified Food Protection Manager
Also refer to the public health reasons for § 2-101.11		

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 CDC 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:

- Size and scope of the operation;
- Hours of operation;
- Types of foods sold or served;
- Extent to which food is prepared onsite;
- Number of staff;
- Type of population served (for example, highly susceptible or not); and
- Number of meals served.

<u>2-102.20</u>	Food Protection Manager Certification
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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 CFP completed work on its *Standards for Accreditation of Food Protection Manager Certification Programs* found at: http://www.foodprotect.org/food-protection-manager-certification/. In 2002 the Conference entered into a cooperative agreement with the 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 FDA, in his address before the 2004 biennial meeting of the CFP, 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 throughcertification 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."

*The ANSI-CFP Accreditation Program list of accredited organizations utilizing the CFP Standards may be viewed on-line by going to:

 $\underline{https://www.ansica.org/wwwversion2/outside/ALL directoryListing.asp?menuID=8\&prgID=8\&status=4\\$

** Accredited program does not refer to training functions or educational programs.

Duties	<u>2-103.11</u>	Person in Charge
NOTE: Additional responsibilities of the PIC or food establishment manager are specified under the following		

NOTE: Additional responsibilities of the PIC or food establishment manager are specified under the following provisions:

- <u>8-304.11</u>—Responsibilities
- 8-402.12—Self-evaluations
- 8-404.11—Imminent health hazards; ceasing operations
- 8-405.11 and 8-406.11—Correcting violations
- <u>8-8.g.</u>—Food establishment manager

A primary responsibility of the PIC 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 PIC 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 PIC 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. [Note: This is not a common practice on DOD installations.] Upon delivery, all food must be appropriately stored in a safe and secure manner within the food establishment. For example, TCS 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. References for the DOD Food Defense Program are provided at Appendix A of this publication.

Food allergy is an increasing food safety and public health issue, affecting approximately 4 percent of the U.S. population, or 12 million Americans.

An important duty of the PIC is to make sure that any required temperatures are achieved or maintained when foods are cooked, cooled or held in a food establishment. By making it a duty of the PIC to ensure that employees are monitoring food temperatures to verify the critical temperature limits, the likelihood of temperature abuse is reduced. This includes oversight of temperature monitoring to ensure: 1) that animal foods are being cooked to the required minimum temperatures to prevent the survival of pathogens that may be present (2-103.11(F)); 2) that cooked foods are being cooled rapidly to ensure that the growth of bacterial pathogens and toxin production is prevented (2-103.11(G)); and 3) that foods that require temperature control for safety are being held at temperatures that adequately prevent pathogen growth and toxin production (new 2-103.11(H)).

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 CFP passed Issue 2008-III-006 which provided that food allergy awareness should be a food safety training duty of the PIC. Accordingly, the PIC'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 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 DD Form 2971, "Conditional Employees or Food Employees Reporting Agreement," 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 DD Form 2971;
- 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 Appendix G, 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 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.

The food establishment manager or designated PICs are ultimately responsible for observing the daily activities within the food operation, recognizing conditions and procedures that are in violation of prescribed standards set forth in the TSFC or the operation's approved HACCP Plan, initiating corrective actions to mitigate conditions that present a critical hazard, and following through on corrective actions to resolve nonconforming conditions and practices.

(Also refer to the 2013 FDA Food Code, Annex 4 – Management of Food Safety Practices, section 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. For that reason the specified agents 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 (for example, 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 HAV (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, Escherichia coli (*E. coli*) O157:H7 or other STEC, *Shigella* spp. infection, or NTS.

Diagnosis with typhoid fever or HAV 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 HAV 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, HAV, 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 Appendix). 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 HSP) and restrictions (for non-HSP facilities) depending on the agent involved (See section 2-201.12, <u>Table #2</u>). 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, <u>Table #3</u>). 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 an 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 an 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 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 (ADA), 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 Web site, 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.

<u>2-201</u>	Infected Food Employees and Conditional Employees Practical Applications of Using Subpart 2-201
<u>2-201.20</u>	Medical Screening Criteria

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 PIC 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 PIC 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	2-201.11	Responsibility of the Person in Charge, Food
Symptoms and Diagnosis	<u>2-201.11</u>	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 PIC 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 PIC. The PIC 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 PIC 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 PIC 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 PIC 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 ADA. 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 PIC 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 § 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 §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 PIC. The symptoms listed in the Code cover the common symptoms experienced by persons suffering from the pathogens identified by the 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.

The symptoms of vomiting, diarrhea, or jaundice_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 to 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 PIC. 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 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 food establishment manager and the PIC 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 Typhoid fever (caused by *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 Typhoid fever (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 Typhoid fever (caused by *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 ADA⁴.

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

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⁴ Whether or not the employee in question is an individual with an ADA disability, Food Code exclusions or restrictions must be removed when requirements for removal under § 2-201.13 of the Code are met.

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 (for example, Crohns disease), 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 the 2013 FDA Food Code, Annex 2 that relate to this section of the Code or contact the EEOC. See the EEOC'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.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 food establishment manager to convey to applicants and employees the importance of notifying the PIC of changes in their health status. Once notified, the PIC 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 ADA, 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 Web site 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/pdfs/pathogens-by-food-handlers-508c.pdf.

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. Nonfoodborne 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*-- [*1. Kauffmann-White scheme for designation of Salmonella serotypes]

Sapoviruses

Shigella species

Staphylococcus aureus

Streptococcus pyogenes

Taenia solium - cysticercosis

Vibrio cholera

Yersinia enterocolitica

The Six Listed Pathogens:

The CDC has designated the six 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 19^{th} Edition of Control of Communicable Diseases Manual, the CDC Web site, and the FDA Bad Bug Book, 2^{nd} 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 ribonucleic acid polymerase (RNA), nonenveloped viruses. They are a genetically diverse group classified into at least five genogroups, designated as GI through GV, which are further subdivided 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 RTE 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 (that is, diarrhea or vomiting) are critical for norovirus control.

Incubation Period: In volunteer studies, the range is 10 to 50 hours. In foodborne norovirus outbreaks, the median incubation period is 33 hours.

Symptoms and Complications: Acute-onset of vomiting, watery nonbloody 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 percent 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 (NTS): 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 NTS, prompts the PIC to exclude food employees with diagnosis of NTS, and provides conditions for reinstatement of a food employee who provides to the PIC written medical documentation from a health practitioner that states the food employee is free from NTS, and where appropriate, approval from the regulatory authority.

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 CDC accounted for 49 percent 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 percent 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 percent), 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 percent) 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 (for example, 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, (that is, 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 percent 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: 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 CDC.

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 percent 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 (for example, 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 percent of untreated typhoid fever patients will discharge bacilli for 3 months after onset of symptoms, and 2 to 5 percent become permanent carriers.

SHIGA TOXIN-PRODUCING ESCHERICHIA *COLI*: *E. coli* O157:H7 is the most commonly identified serotype of 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 (that is, bloody diarrhea) or hemolytic uremic syndrome (HUS). Infections with STEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and HUS or thrombotic thrombocytopenic purpura. [Note: "enterohemorrhagic *E. coli*" (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 (for example, hemorrhagic colitis, HUS). About 3 to 7 percent 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 four 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: 8 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 to 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 percent among hospitalized cases. Other complications can also occur, such as reactive arthritis, intestinal perforation, and HUS.

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.

<u>HEPATITIS A</u> **VIRUS:** HAV is a 27-nanometer picornavirus (positive strand RNA, non-enveloped virus). The HAV 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 percent 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 percent 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 to 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 percent 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 to 30 days (range 15 to 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 (that is, hepatitis A); onset of illness is usually abrupt. In young adults, 76 to 97 percent have symptoms and 40 to 70 percent are jaundiced. Jaundice generally occurs 5 to 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 tests. The disease varies in severity from a mild illness to a fulminant hepatitis, ranging from 1 to 2 weeks to several months in duration. In up to 10 to 15 percent 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 to 0.3 percent and can reach 1.8 percent 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 (10⁶ to 10⁸/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, 1 to 2 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, or HAV.

Which employees who report exposure are restricted?

 Employees who work in a food establishment serving an HSP facility, except those employees who are exposed to NTS.

Why don't employees who are exposed to NTS need to be restricted?

For those employees who are exposed toNTS, 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, including care of a child, 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 HAV?

- 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.
 - o For norovirus, 48 hours after the most recent exposure.
 - o For Shigella spp., 3 days after the most recent exposure.
 - o For E. coli O157:H7 or other STEC, 3 days after the most recent exposure.
 - o For typhoid fever (S. Typhi), 14 days after the most recent exposure.
 - o 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:
 - o For norovirus, symptomatic period plus 48 hours.
 - o For Shigella spp., symptomatic period plus 3 days.
 - o For E. coli O157:H7 or other STEC, symptomatic period plus 3 days.
 - o For typhoid fever (S. Typhi), symptomatic period plus 14 days.
 - o 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 an 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.

	<u>2-201.12</u>	Exclusions and Restrictions ⁵

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 PIC 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 HAV, 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 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, in this Appendix).

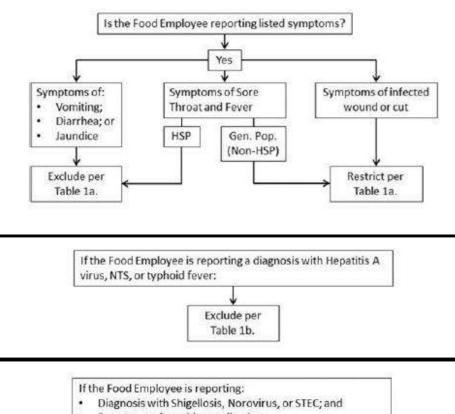
The degree of risk for a food employee or conditional employee who is diagnosed with an infection but asymptomatic with regard to symptoms, to transmit a foodborne pathogen decreases with the resolution of symptoms. This risk decreases even further for those employees that are diagnosed with a listed 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, <u>Table #2</u>).

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 nonhighly 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 the 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.

⁵ In order to comply with Title I of the ADA, 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 this Appendix, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Appendix. When faced with an apparent conflict between ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. EEOC.

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



Symptoms of vomiting or diarrhea

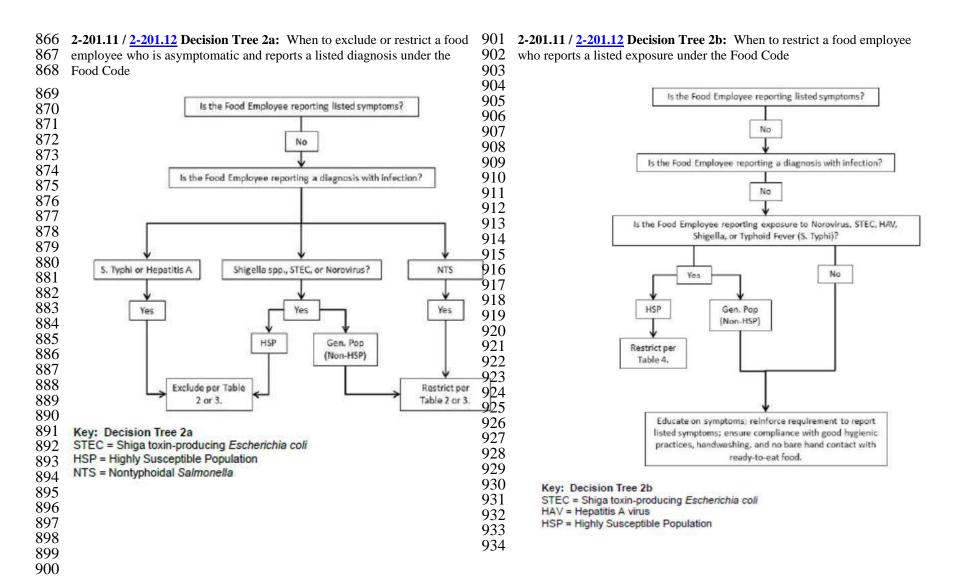
Exclude per Table 1b.

Key: Decision Tree 1

STEC = Shiga toxin-producing Escherichia coli

HSP = Highly Susceptible Population

NTS = Nontyphoidal Salmonella



935 2-201.12 Table 1a: Summary of Requirements for Symptomatic Food Employees

Food employees and conditional employees shall report symptoms immediately to the PIC.

The PIC 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). <i>Exceptions:</i> If diagnosed with Norovirus, <i>Shigella</i> 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). <u>Exceptions</u> : 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	2-201.12(B)(1) if the onset occurred within the last 7 • Food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or • Food employee provides medical documentation	
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

939 Key: Table 1a

940 RA = Regulatory Authority

941 STEC = Shiga toxin-producing Escherichia coli

942 HAV = Hepatitis A virus 943

HSP = Highly Susceptible Population

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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 PIC.

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- The PIC shall notify the RA when a food employee is jaundiced or reports a listed diagnosis.
- The PIC 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
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)	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. Serving an HSP facility: 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed in No. 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

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2-201.12 Table 1b (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?
Norovirus	EXCLUDE Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	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. Serving an HSP facility: 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed in No. 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
Shigella spp.	exclude Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	 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. Serving an HSP facility: 2-201.13(A)(3)(b): Remains excluded until meeting the requirements in No. 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 PIC.

- The PIC shall notify the RA when a food employee reports a listed diagnosis.
- The PIC 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	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	Yes
2-201.11 (A)(3)) Nontyphoidal	RESTRICT	RESTRICT	2-201.13)(C)(2) (also see Table 1b). When approval is obtained from the RA 2-201.13(G), and:	Yes
Salmonella	2-201.12(G)	2-201.12(G)	 Food employee provides medical documentation, that states the food employee is freeof a nontyphoidal Salmonella infection 	165
			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)). 	

967 **2-201.12 Table 2** (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. 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 listed 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 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
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

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970 **2-201.12 Table 2** (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?
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
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

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RA = Regulatory Authority STEC = Shiga toxin-producing *Escherichia coli*

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HAV = Hepatitis A virus
HSP = Highly Susceptible Population
NTS = Nontyphoidal Salmonella 975

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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 PIC.

- The PIC shall notify the RA when a food employee reports a listed diagnosis.
- The PIC 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)). 	

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985 **2-201.12 Table 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

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RA = Regulatory Authority STEC = Shiga toxin-producing *Escherichia coli* 988

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HAV = Hepatitis A virus
HSP = Highly Susceptible Population
NTS = Nontyphoidal *Salmonella* 990

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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 PIC.

- The PIC 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
- PIC shall reinforce and ensure compliance with good hygienic practices, symptom reporting requirements, proper handwashing and no bare hand contact 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

continued

1001 **2-201.12 Table 4** (continued)

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?
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
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

1002 Key: Table 4

HSP = Highly Susceptible Population BHC = Bare Hand Contact 1003

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RTE = Ready-To-Eat
GHP = Good Manufacturing Practices 1006

STEC = Shiga toxin-producing Escherichia coli 1007

2-201.12 Exclusion and Restrictions (continued)

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 percent 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 NTS.

Upon being notified of the history of exposure, the PIC 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 PIC 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 PIC.

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 nonfood 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.



Food employees diagnosed with Norovirus, HAV, *Shigella* spp., *E. coli* O157:H7 or other STEC, NTS and symptomatic with diarrhea, vomiting, or jaundice, are excluded under subparagraph 2-201.12 (A)(2) or

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⁶ In order to comply with Title I of the ADA, 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 this Appendix, § 2-201.11. However, it is not possible to explain all relevant aspects of the ADA within this Appendix. When faced with an apparent conflict between the ADA and the Food Code's exclusion and restriction requirements, employers should contact the U.S. EEOC.

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 PIC 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 PIC 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 PIC 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).

In a food establishment that serves an HSP, 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 an HSP 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 HAV 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 HAV 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 HAV has a mild form of hepatitis A without jaundice. Food employees diagnosed with an anicteric infection with the HAV 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 HAV 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 American Public Helath Association-published recommendations in the "Control of Communicable Diseases Manual."

Hands and Arms	<u>2-301.11</u>	Clean Condition
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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.

2-30	1.12	Cleaning Procedure
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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 EEOC has agreed that this requirement for thorough handwashing can be met through reasonable accommodation in accordance with the ADA. 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 "subungual 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 rest room 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, (that is, $> 10^4$ 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 RTE food is necessary.

<u>2-301.13</u>	Special Handwash Procedures
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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 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.

<u>2-301.14</u>	When to Wash
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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.

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. (See also the public health reason for § 6-301.12 Hand Drying Provisions.)

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.

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 percent reduction. The FDA bases the 5-log reduction on the Association of Official Analytical Chemists 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 RTE 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 over-the-counter (OTC) 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; 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 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 for "Health Care Antiseptic Drug Products for OTC Human Use; Proposed Rule." This tentative final monograph, 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.

As a Food Additive

To be subject to regulation under the food additive provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), 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 "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/IngredientsPackagingLabeling/GRAS/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 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/ingredientspackaginglabeling/packagingfcs/notifications/default.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 <u>2-302.11</u>	Maintenance
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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	<u>2-303.11</u>	Prohibition
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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 ADA. The PIC 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 (for example, an Internet search using the term "medical alert jewelry" leads to numerous suppliers).

An additional hazard associated with jewelry, to include embedded nail jewelry and glue-on nail extensions, 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.

Although the Code provision only restricts jewelry worn on the hands and wrists, the PIC holds primary responsibility for evaluating the need to remove other jewelry that present a hazard to food or the employee. Examples include facial jewelry other unsecured jewelry, such as necklaces. Food employees may contaminate their hands when they touch facial jewelry, ear rings, or tongue rings. Exposed necklaces can injure the food employee if caught on food processing equipment. Title 21, CFR, Part 117.10, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, specifies in subparagraph (b)(4) that food managers "shall take all reasonable measures and precautions to ensure...[worker] cleanliness by...Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand."

Outer Clothing 2-304

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	<u>2-401.11</u>	Eating, Drinking, or Using Tobacco
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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. Suitable containers include water bottle with cap and sports bottle or drink cup with a lid and straw.

<u>2-401.12</u>	Discharges from the Eyes, Nose, and Mouth
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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	<u>2-402.11</u>	Effectiveness
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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.

Facial hair such as mustaches, goatees, beards, sideburns, and eyebrows, and exposed body hair on arms, chest, back or neck that protrudes from clothing may become dislodged and fall into food or onto food-contact surfaces. There are no standards that specify how long hair must be in order to require a restraint. However, facial hair that is less than one quarter inch in length presents a low risk of becoming dislodged. The PIC should evaluate each situation, when presented, and determine the need for a restraint. Recommended practices for hair management include, but are not limited to—

- Grooming to reduce the length of the exposed hair.
- Use of specialized net restraints (for example, sleeve net or beard net (snood)).
- Wearing a closed collar shirt.
- Prohibiting the wear of sleeveless clothing/uniforms. Shirts should have one-half or three-quarter length sleeves.

Animals	<u>2-403.11</u>	Handling Prohibition
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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.

Training	<u>2-501.11</u>	Training Requirements
	<u>2-502.11</u>	(Supervisor) Requirements and Renewal
	Subpart 2-503	Food Employee Training
	Subpart <u>2-504</u>	Other Personnel Requiring Training

Epidemiological outbreak data are used to identify the five major risk factors that contribute to foodborne illnesses in the United States. Because four of the five major risk factors are related to employee behaviors and food preparation practices, it is essential that all food employees understand the risks and controls as they apply to their food operation. One of the key public health interventions identified by the FDA to protect the public from foodborne illness is through the "demonstration of knowledge." Demonstration of knowledge is a requirement for all designated food establishment PICs. However, all individuals who work with food that is made available to the general public have the responsibility for ensuring the food is protected from conditions that could lead to a foodborne illness.

Foods that are not considered time or temperature controlled for safety are not potentially hazardous due to their inability to support pathogenic microbial growth. However, these non-TCS foods can become contaminated when they are unpackaged (for example, popcorn, nacho chips with cheese, and soft pretzels) and improperly handled by a sick employee (for example, Norovirus transmission); exposed to improperly stored toxic materials; or contaminated from pest infestations.

Within the restaurant industry employees are characterized as very transient due to the high turnover rate experienced within individual establishments each year. As a result the knowledge and depth of the employee's food safety experience and understanding are very limited. Basic food-handler's training is designed to provide the inexperienced food employee with a general awareness and understanding of basic food safety risks and the principles of protection that must be practiced to protect public health. This knowledge is reinforced each year through refresher training.

Food managers and supervisory level food employees are typically less transient in their profession and are likely to have more experience and knowledge than a basic food employee. Attaining certification as a Food Protection Manager requires an in-depth understanding of food pathogens, food safety principles, hygiene and health, food equipment, pests, physical facilities, and sanitation. The examination mechanism that results in Food Protection Manager Certification provides assurance that the individual has the demonstrated capacity to oversee all aspects of food safety. Due to the extent of knowledge required for certification, certified individuals are not required to complete annual refresher training; knowledge is validated every 5 years during recertification.

Members of military units or civilian organizations who prepare food in support of an organizational function that is not open to the general public are not classified as "food employees." The installation's public health regulatory authority should establish local policy and procedures as a guide for tenant organizations when engaging in these types of functions.

	<u>2-601.11</u>	Clean-up of Vomiting and Diarrheal Events
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This is a new provision introduced in the 2013 FDA Food Code under Part 2-5, § 2-501.11. It was renumbered under Part 2-6, § 2-601.11 in the TSFC due to previous assignment by DOD for Part 2-5 to address training.

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 percent of all foodborne gastroenteritis outbreaks. The 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 than 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 onsite. 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 RTE food items served to consumers.

The Food Code specifies that the PIC 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 PIC 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 PIC, Food Employees, and Conditional Employees for more information about appropriate employee health policies.

Condition	<u>3-101.11</u>	Safe, Unadulterated, and Honestly Presented
Sources	<u>3-201.11</u>	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 FFDCA. 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.

Military regulation AR 40-657/NAVSUP 4355.4H/MCO P10110.31H, Veterinary/Medical Food Safety, Quality Assurance and Laboratory Services, requires all foods procured in support of military installations and operations to come from a sanitarily-approved source or be otherwise exempt. The Veterinary Service evaluates commercial food manufacturers and suppliers for sanitary conditions and other food protection measures.

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.

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. Freezing for a specified time/temperature combination 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 or other information should accompany the product to advise as to whether the product was frozen properly. When documentation or labeling is absent from the food manufacturer to indicate the fish was previously frozen, the food establishment bears the responsibility for freezing the fish on premises before offering it for consumption in a raw or undercooked form.

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 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 the Glossary 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 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 younger 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 § 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/ucm0 58962.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 RTE, 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 (also known as "cold pasteurization") to reduce foodborne pathogens, including *E. 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 CFR (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 CFR (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 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 comingling 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, at http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7700.1Rev1.pdf.

Labeling for Raw Shell Eggs

The 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/FSIS review and approval, and appropriately affixing the labels to their products.

Refer also to public health reason for § 3-602.11 Food Labels.

3-201.12	Food in a Hermetically Sealed Container
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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 *C. botulinum*, an organism whose spores (that is, survival stages for nongrowth 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 *E. coli*, *Salmonella* spp., and *Lm*, 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 Web site 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 noncommercial 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 body of water.

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.

<u>3-201.15</u>	Molluscan Shellfish
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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; 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 *Lm* 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 dependent upon either the month of the year or the average monthly maximum air temperature 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 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 eurotoxic shellfish poisoning 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 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. Amnesic shellfish poisoning 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 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. The 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 are essential to keep risks to a minimum.

	<u>3-201.16</u>	Wild Mushrooms
Refer also to the public health reason for §§ 3-101.11 and 3-201.11.		

Although the FDA Food Code has established conditions for the use of wild mushrooms, the decision was made by DOD to prohibit the use and sale of wild mushrooms based on the following public health reasons—

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 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.

3 201 17	Cama Animala
<u>3-201.17</u>	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.

3-201.18 Fresh Fruits and Vegetables

The use of unprocessed human feces as fertilizer (a.k.a., "night soil") is a risky practice as it may contain many disease-causing organisms and other contaminants. Use of untreated human waste as a fertilizer is not an acceptable agricultural practice in the U.S. based on EPA regulations and Federal codes, which require treatment plants to treat human waste at least once before it can be applied to any land. In developing nations, however, the practice of using untreated human waste as fertilizer is widespread. Common parasitic worm infections, such as ascariasis, in these countries are linked to night soil, because their eggs are in feces.

Wastewater treatment plants are designed to remove as many contaminants as possible from the water and then discharge the water as effluent. Sewage sludge is the leftover solid waste generated from the treatment process. Although sewage sludge is typically treated to remove some of the contaminants, not all are removed. Sewage sludge regularly tests positive for a host of heavy metals, flame retardants, polycyclic aromatic hydrocarbons, pharmaceuticals, phthalates, dioxins, and a host of other chemicals and organisms. Of the thousands of contaminants that have been found in sludge, the U.S. government regulates only 10 of them (nine heavy metals and fecal coliform).*

Serving food products, primarily root crops, grown in or on soils where human waste is used as a fertilizer is prohibited due to potential absorption of contaminants by the crop. Root crops include potatoes, carrots, turnips and rutabagas, and similar crops where the edible portion is buried beneath the soil or in direct contact with the soil. Nonroot crops grown using night soil may be authorized for use when evaluated and approved by appropriate Federal, state, or DOD veterinary inspectors.

*Food Safety News, Sewage Sludge as a Fertilizer: Safe? http://www.foodsafetynews.com/2010/10/sewage-sludge-as-fertilizer-safe/

Specifications for Receiving	<u>3-202.11</u>	Temperature
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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. The 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 45°F (7.2°C).

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.

<u>3-202.12</u>	Additives
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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

 $\underline{\text{http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ThresholdRegulationExemptions/ucm0936}}{85.\text{htm.}}$

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. "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).
- (iv) "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.
- (v) "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 Inapplicability and limited applicability, (4) A hearing on an order for relabeling, 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.

<u>3-202.14</u>	Eggs and Milk Products, Pasteurized
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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 TCS 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.

<u>3-202.15</u>	Package Integrity
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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 *C. 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, that is, 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. Damaged packaging is both a food safety and food defense issue.

	<u>3-202.16</u>	Ice
Refer also to public health reason for § 4-503.11, Maintenance of ice machines		

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.

<u>3-202.17</u>	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.

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.

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 (highly susceptible populations)		

Original Containers and Records 3-203.11	Molluscan Shellfish, Original Container
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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 § 3-202.17 must be recorded on a log sheet to correlate with the date of sale of the consumer sized containers.

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 HAV 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	<u>3-301.11</u>	Preventing Contamination from Hands
Refer to the public health reasons for §§ 2-301.11, 2-301.12, and 2-301.14.		

In November 1999, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) concluded that bare hand contact with RTE 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 RTE 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 RTE foods via hand contact with RTE 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 HAV. 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 RTE food to be about 10 percent 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, RTE food, thorough handwashing is important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the food.

If an RTE 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 RTE toppings to a pizza dough or adding vegetables to a raw meat dish before cooking), 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 RTE foods. The exception specifically targets bare hand contact with RTE 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 RTE 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 RTE 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.

3-301.11(E)	Prior Approval for Food Employees to Touch Ready-to-Eat Food with Bare Hands
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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. Most of these outbreaks involve enteric (that is, 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 (that is, 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 RTE food (that is, 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.

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 RTE 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 §§ 2-201.11 – 2-201.13 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,** (that is., 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 § 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,** (that is, that food employees and conditional employees report their health status as specified in § 2-201.11); ill food employees are restricted or excluded as specified in § 2-201.12; and the exclusions and restrictions are removed as specified in § 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 person in charge recognizes that the hazard being addressed is the possible contamination of RTE food by viral and parasitic as well as bacterial pathogens that are transferred from employees' hands.

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⁷ 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.

(2) The RTE 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 RTE food is precluded.

For example, identify 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 RTE food using bare hands.

Another example could be a food employee who is responsible solely for assembling a variety of RTE 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 (for example, 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 RTE 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	5-307. 11	Packaged and Unpackaged Food – Protection
Contamination		Separation, Packaging, and Segregation

It is important to separate foods in an RTE 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 RTE 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 RTE foods or commercially processed bulk-pack food that is packaged onsite 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.

2 202 12	Food Storage Containers, Identified with Common
<u>3-302.12</u>	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.

3-30	/ ₁ . • •	Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes
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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 Salmonella-free and is an RTE food. The pasteurized product should be substituted in a recipe that requires raw or undercooked eggs.

	<u>3-302.14</u>	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 the FDA Food Code's 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.

<u>3-302.15</u>	Washing Fruits and Vegetables
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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 § 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 bacterial pathogens are internalized, they 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 § 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 FF&V 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 RTE without further washing. The label should also state if further washing is recommended or necessary. Precut or prewashed produce in open bags should <u>not</u> be washed before use. After being cut, certain produce such as melons, leafy greens and tomatoes are considered TCS food requiring TCS 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/IndustryandRegulatoryAssistanceandTraining Resources/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 FF&V producers was issued jointly by the 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

 $\underline{\text{http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064574.htm.}$

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 (for example, 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:

 $\underline{http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm}.$

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 Web site 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	3-303.11	Ice Used as Exterior Coolant, Prohibited as
Ice Used as a Coolant	<u>5-305.11</u>	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. Food contamination may also occur when potentially contaminated ice is used to cool hot leftovers or advanced prepared foods, to chill individually packaged beverages or RTE food by placing them in direct contact with the ice, or pre-chilling insulated food containers.

	3-303.12	Storage or Display of Food in Contact with Ice and Water
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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
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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.

	<u>3-304.12</u>	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 RTE food or to minimize contact with food that is not in an RTE form. Onsite 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.

Storing in-use utensils in a sanitizing solution between uses is ineffective and may ultimately result in contamination of the food due to the following conditions:

- Food debris remaining on the utensil when placed in the sanitizing solution will rapidly consume the active antimicrobial agent in the solution, thus requiring frequent replacement of the sanitizing solution. Other than measuring the residual concentration of the chemical sanitizer, there is no reliable method for determining when a used sanitizing solution should be changed. The appearance of visible debris in the solution is not a good indicator and is almost certain to occur the first time the soiled utensil is placed in the solution. Additionally, the efficacy of the sanitizing agent requires physical removal of food debris and oily residues from the utensil in order for the active chemical agent to reach the utensil surface and destroy the microbial contaminants.
- Microbial contaminants from food residues will rapidly multiply when the active sanitizing agent in solution is neutralized from the presence of food debris and the temperature of the solution is below 135°F.
- Preparing a sanitizing solution at a concentration that exceeds the allowable limit for the chemical sanitizing agent is not an acceptable practice. Exceeding allowable chemical concentrations violates the criteria set forth in 40 CFR 180.940 as specified in § 7-204.11 and could result in a chemical intoxication when toxic residues are transferred from the utensil to the food.

See also the public health reason for § 3-304.14 Wiping Cloths.

<u>3-304.13</u>	Linens and Napkins, Use Limitation
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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.

	<u>3-304.14</u>	Wiping Cloths, Use Limitation
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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.

	<u>3-304.15</u>	Gloves, Use Limitation
Refer to the public health reason for § 3-304.11		

Gloves used in touching RTE 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 RTE 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 RTE foods could contaminate the food.

Natural Rubber Latex (NRL) Gloves

NRL 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 FDA Food Code, Annex 2, § 3-304.15). Reactions can be mild such as sneezing or severe anaphylactic shock. For this reason the military services have decided to prohibit using single-use gloves made of latex during food preparation. Alternatives to latex include synthetic rubber or nonlatex materials, such as neoprene, nitrile, or vinyl.

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.
 - 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..."
 OSHA addresses gloves in 29 CFR 1910.138, Hand Protection (SubPart Number I, 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.

Powdered Gloves

The recommended discontinued use of powdered gloves by DOD began in 2002, following several incidents involving anthrax contaminated mail and subsequent incidents where the presence of an unknown white powder-like substance was observed in the work place and feared to be due to a deliberate anthrax contamination. This recommended practice was applied in the 2015 edition of the TSFC and remains as a recommendation in the current edition.

Section 4-102.11 discusses the required characteristics of single-use articles and specifies the material may not allow migration of deleterious substances. When a food establishment elects to purchase powdered disposable gloves, care must be taken to ensure the glove is approved for use with food. The "powder" must be an approved food additive. Gloves that are approved for use with food generally contain corn starch. Gloves that are not approved for use with food contain talcum powder or other chemicals that are not approved food additives. Disposable gloves approved for use with food will indicate "Approved for Use with Food," "Approved for Food Handling," or other similar marking on the packaging.

	<u>3-304.16</u>	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.

Returned food containers that have deep or excessive cuts or abrasions on the food contact surface should not be retained for future use. Food particles may become lodged in the crevices and may not be adequately removed during cleaning and sanitizing.

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 TCS foods. Equipment must be designed to prevent the contamination by the consumer.

Preventing Contamination from	<u>3-305.11</u>	Food Storage
the Premises	<u>3-305.12</u>	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
<u>5-505.15</u>	Food, Original Container

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended TCS 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, TCS foods are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

3-30	<u>)5.14</u>	Food Preparation
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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	3-306.11	Food Display
Consumers	<u> </u>	2 0 0 d 2 2 p 2 d j

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.

3-30	<u>6.12</u>	Condiments, Protection
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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.

	<u>3-306.13</u>	Consumer Self-Service Operations
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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 RTE 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. Food employee training should include food safety related to customer self-serve operations. Wait staff, hostesses or

other "food employees" who do not typically oversee these activities may not have adequate training to properly monitor customer self-serve food bars.

Bean sprouts that are displayed in produce areas for consumer self-service are TCS foods and appropriate refrigeration must be maintained. However, they are not considered RTE since they are intended to be washed by the consumer before consumption.

3-306.14 Returned Food and Re-Service or Sale	
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Food can serve as a means of person-to-person transmission of disease agents such as HAV and Norovirus. Any unpackaged foods, even bakery goods in a bread basket that are not TCS 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. Unpackaged food that has been in the possession of a consumer, but was not eaten must be discarded as food waste.

	<u>3-306.15</u>	Dispensing of Milk, Cream, and Nondairy Products
See also the public health reasons for §§ 3-501.16 (Cold Holding) and 4-204.13 (Dispensing Equipment)		

Bulk milk generally packaged as a volume greater than 1 gallon, must be stored under refrigeration and dispensed as specified under § 4-204.13 to protect against contamination.

A "working" container of milk that was transferred from a bulk package to a small dispenser (for example, container volume of 1 gallon or less) and is intended for consumer self-service will enter the temperature danger zone multiple times throughout the day and is subject to contamination by the consumer. Milk remaining in these containers at the end of the meal period must be discarded as specified in ¶ 3-306.13(E). When dispensing containers are not returned to a cold holding unit or placed in ice between uses, time as a public health control must be employed and the product discarded when it reaches the 4-hour or 6-hour retention period as specified under § 3-501.19.

Preventing Contamination from	3-307.11	Miscellaneous Sources of Contamination
Other Sources	<u>3-307.11</u>	Wiscenaneous 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 cannot anticipate all the diverse means by which food can become contaminated after receipt.

Cooking	<u>3-401.11</u>	Raw Animal Foods
	<u>3-401.12</u>	Microwave Cooking
	<u>3-401.13</u>	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 130°F (54.4°C) is the same lethality attained as if it were cooked for 4 minutes after it has reached 145°F (62.8°C). 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-log10 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 <a href="http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/95-035-035

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; and 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 145°F (63°C), 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 ¶ 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, http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/95-033F Appendix A.htm)

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 degrees 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 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 (for example, 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 an RTE 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 (for example, 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 155°F (68°C) 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 155°F (68°C), 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 *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 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 165°F (74°C) or above for 15 seconds yield greater than a 7D reduction.

Children's Menu

The 2013 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 (for example, "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 *E. coli* O157:H7.

As an added measure of protection, the TSFC includes elementary school-age children (12 years and younger) under the restrictions of an HSP when the food service setting is a custodial care facility such as a school, youth center, or similar operation primarily servicing young children. Children are at relatively high risk for infection with *E. coli* O157:H7. It is possibly the leading cause of acute kidney failure and HUS in children (CDC 1993). Infection with *E. coli* O157:H7 can result with mild to severe symptoms such as: nonbloody 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 percent of patients that are infected with *E. coli* O157:H7 develop HUS (CDC 1993). 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 (CDC 1993). The CDC has reported the following *E. coli* 0157:H7 infection rates per 100,000 by age range: 8.2 for young children 1 to 9 years old and 3.0 for older children 10 to 20 years old (Buzby 2001)

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 2 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." (Heddelson and Doores 1993).

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 RTE 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 Noncontinuous 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 noncontinuous 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 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://www.access.gpo.gov/nara/cfr/waisidx_08/9cfr381_08.html).

The maximum 1-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* (*C. 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 *C. perfringens*, *C. 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 *C. botulinum*, *C. perfringens*, and *Bacillus cereus* (*B. cereus*), if present. The concern is the generation of a large

number of vegetative cells of *C. perfringens* and/or *C. botulinum* before the final cooking stage. For *C. 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 *C. 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 noncontinuous cooking process. Section 3-401.14 requires that animal foods cooked by a noncontinuous 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 noncontinuous cooking in an undercooked or raw state. In other words, animal foods cooked using a noncontinuous 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 noncontinuous 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 RTE 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 noncontinuous 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	<u>3-402.11</u>	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	<u>3-403.11</u>	Reheating for Hot Holding
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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 *C. 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 RTE 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, RTE, 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 reasons for § 3-401.12.

	<u>3-404.11</u>	Treating Juice
Refer to the public health reason for § 3-801.11		

Temperature and Time Control	<u>3-501.11</u>	Frozen Food
	3-501.12	Time/Temperature Control for Safety Food, Slacking
	<u>3-501.13</u>	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 an 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, (for example, 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 312

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 41°F 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 TCS foods has been consistently identified as one of the leading contributing factors to foodborne illness. During slow cooling, TCS foods are subject to the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation temperatures, 70°F to 125°F (21°C to 52°C), 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 135°F to 41°F or 45°F in 6 hours, with cooling from 135°F 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 135°F to 70°F in 1 hour, in which case 5 hours remain for cooling from 70°F to 41°F or 45°F. Conversely, if cooling from 135°F to 41°F or 45°F is achieved in 6 hours, but the initial cooling to 70°F 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 *C. perfringens* or *B. cereus* should be killed or inactivated. However, under substandard sanitary conditions, other pathogens such as *Salmonella* or *Lm* 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 <u>not</u> 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 TCS food after cooling. Hard-boiled eggs may be cooled in drinking water but are considered to be a TCS 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 Inapplicability and limited applicability, (4) A hearing on an order for relabeling, 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 RTE products includes a heat treatment or cooking step to eliminate pathogenic and spoilage microorganisms. However, this heat treatment does not eliminate spores of *C. botulinum* and *C. perfringens* and other spore-forming bacteria. Furthermore, these organisms can thrive in the warm product since other competing organisms have been eliminated. Nonrefrigerated, 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 CDC suggested viable counts of 105 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 106 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 104 *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 104 *C. perfringens* (spores) per gram on raw product, it is possible that there may be more than 104 vegetative *C. perfringens* per gram in the product if it is improperly cooled after cooking.
- 3. Based on the CDC recommended upper limit of 105 which should not be exceeded, it was determined that a limit of no more than 1 log10 growth of *C. perfringens* would be appropriate to ensure that there would be no more than 105 *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 log10 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, *Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)*, which can be found at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/95-033F_Appendix%20B.htm, is that product must be cooled from 130°F to 80°F in 1.5 hours and from 80°F 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 sporeforming organisms can grow rapidly.

The former USDA guideline of cooling from 120°F 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 120°F, 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 120°F 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 130°F to 80°F in 5 hours and from 80°F 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 135°F to 70°F in 2 hours and from 135°F 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 CFP, at its 2000 meeting, recommended that FSIS and FDA ask the NACMCF to review the data on safe cooling times for cooked, TCS foods. The review would include data from a study, submitted to the CFP, showing that cooling of a meat product from 130°F 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 130°F 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.
- The study was done only on ground beef and may not be applicable to other meat and poultry or to other TCS 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.

	<u>3-501.15</u>	Cooling Methods
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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 (that is, 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.

<u>3-501.16</u>	Time/Temperature Control for Safety Food, Hot and Cold Holding
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Bacterial growth and/or toxin production can occur if TCS food remains in the temperature "Danger Zone" of 41° F to 135° F (5° C to 57° C) 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 TCS 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 TCS 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 Lm is the basis for the list of cold holding temperature and time combinations in ¶ 3-501.17(A). The list addresses time, in addition to temperature, as a control for the growth of Lm in refrigerated, RTE, TCS 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 41°F for 7 days and 45°F 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/RiskAssessment SafetyAssessment/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 RTE 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, RTE, TCS food, prepared and packaged in a food processing plant and held in a food establishment. Data from the risk assessment revealed a significant reduction in the projected cases of listeriosis when refrigerated storage is limited to 41°F. Based on these data and conclusions from the risk assessment, FDA continues to recommend that food establishments limit the cold storage of TCS foods, RTE foods to a maximum temperature of 41°F.

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 45°F (7°C). 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 50°F (10°C) and above but can be inhibited at lower temperatures (for example, 46°F (8°C), 45°F (7°C), and 39°F (4°C)). Based on this research and USDA's temperature requirement during transport, FDA implemented regulations that establish a maximum ambient air temperature of 45°F (7°C) 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.

The TSFC prescribes a maximum storage temperature of 41°F for shell eggs once received at a food establishment regulated by the military services. This decision was based on the known practice of food establishments frequently storing other TCS foods (for example, dairy products) in refrigeration units where eggs are stored. Applying a single refrigeration standard at all facilities reduces the likeliness of TCS foods being held at improper temperatures.

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 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 (for example, 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 *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 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 *C. perfringens* and *B. 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 126°F (52°C). 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 120°F (49°C) than at 126°F (52°C). Studies also suggest that temperatures that preclude the growth of *C. perfringens* also preclude the growth of *B. cereus*.

The 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 CFP meeting, FDA believes that maintaining food at a temperature of 135°F (57°C) 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.

	<u>3-501.17</u>	Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking
	<u>3-501.18</u>	Ready-to-Eat, Time/Temperature Control for Safety Food, Disposition
Refer to 2013 FDA Food Code, Anne	ex 7, Chart 4-C	

"Date marking" as addressed in the provision is intended to apply when foods are prepared in the food establishment or bulk RTE foods packaged by a food processing plant are opened at the food establishment. For foods prepared by the food establishment and held for more than 24 hours, the date marking identifies the date the product was prepared and the date in which the product must be consumed by or discarded. For bulk foods packaged by a food processing plant, the date marking is applied by the food establishment when the bulk product is first opened for use. Commercially packaged products that are delivered to the food establishment are required to have shelf codes printed on the packaging IAW DOD food contractual requirements.

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as *Lm*, 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 RTE foods.

Based on a predictive growth curve modeling program for Lm, RTE, TCS 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 Lm to multiply, before freezing and after thawing. TCS 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/RiskAssessment SafetyAssessment/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 RTE foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

In examining these closely, FDA showed that five factors are important in measuring the public health impact to consumers from foodborne listeriosis. These factors are: (1) amounts and frequency of consumption of an RTE food; (2) frequency and levels of Lm in an RTE 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 RTE foods were ranked according to their relative risk of contamination and growth of *Lm*. 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 CFP 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 *Lm*. 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 117. 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 (for example, sorbate, benzoates), to prevent the growth of *Lm*. There are estimates that 85 percent 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 *Lm*. Based on their wide use within this segment of the industry and their effectiveness at inhibiting the growth of *Lm*, 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

List of Hard Cheeses Exempt from Date Marking			List of Semi-Soft Cheeses Exempt from Date Marking	
Asadero	Gex blue veined	Reggiano	Asiago soft	Manchego
Abertam	Gloucester	Sapsago	Battelmatt	Monterey
Appenzeller	Gjetost	Sassenage blue	Bellelay blue	Muenster
Asiago medium or	Gruyere	veined	veined	Oka
old	Herve	Stilton blue veined	Blue	Port du Salut
Bra	Lapland	Swiss	Brick	Provolone
Cheddar	Lorraine	Tignard blue veined	Camosum	Queso de Bola
Christalinna	Oaxaca	Vize	Chantelle	Queso de la Tierra
Colby	Parmesan	Wensleydale blue	Edam	Robbiole
Cotija Anejo	Pecorino	veined	Fontina	Roquefort blue
Cotija	Queso Anejo		Gorgonzola <i>blue</i>	veined
Coon	Queso Chihuahua		veined	Samsoe
Derby	Queso de Prensa		Gouda	Tilsiter
Emmentaller	Romanello		Havarti	Trappist
English Dairy	Romano		Konigskase	
			Limburger	
			Milano	

In December, 1999, FDA issued an exemption from date marking for certain types of hard and semi-soft cheeses based on the presence of several factors that may control the growth of *Lm*. 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.

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 *Lm* 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 *Lm* 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 onsite, in a food establishment, such as ceviche.

Shellstock

Although *Lm* 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 *Lm* to harmful levels when the product is held under refrigeration at retail. Therefore, shellstock are exempt from date marking.

USDA-regulated products

Date marking provisions of the Food Code do not apply to shelf stable RTE meat and poultry products. Shelf stable RTE 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, or combination of moisture-protein ratio 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 RTE 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 RTE fermented products that need refrigeration. Bologna is a cooked, perishable sausage and there are other salamis (for example, 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-TCS 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 supersede 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 (outside of military installations), 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.

Veterinary food safety and food quality standards for DOD restrict the use of commercially packaged food that has reached its use-by, expiration, or similar date marking. DOD policy exceptions for food in OCONUS locations, food manufactured in CONUS and shipped to an overseas location, and food supporting Naval operations. Other situations in which a shelf-code extension is requested are evaluated on a case-by-case basis by the regulatory authority. (Refer to the public health reason for § 3-503.11.)

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 individual consumer packages.

Advanced prepared and pre-prepared foods

See also public health reasons for § 3-401.14 Noncontinuous Cooking of Raw Animal Foods, § 3-502.12 Reduced Oxygen Packaging (Cook-Chill and Sous-Vide), and § 3-502.13 Freezing TCS Foods.

The terms "advanced" prepared and "pre-prepared" are often used synonymously to characterize foods that are partially or fully prepared more than 24 hours in advance of its intended service period. Raw meat and poultry that is being marinated is considered to be a "pre-prepared" food that requires further processing (that is, cooking) prior to being served. Fully cooked foods that were intended to be served during the current day's meal schedule, but were never placed on a serving line due to fewer than expected customers or deliberate over-production are also managed as an "advanced prepared" food.

3-501.19 Using Time as a Public Health Control

The 2000 CFP meeting recommended that FDA ask the NACMCF to review the Food Code provision that addresses using time alone as a public health control, § 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 § 3-501.19 allows TCS 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 41°F (5°C) when initially removed from temperature control, and as long as the food temperature does not exceed 70°F (21°C). 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, Lm is a primary organism of concern. Even while food is held at refrigeration temperatures, the growth potential of Lm warrants concern for TCS foods RTE foods. Although the FDA and USDA have a zero tolerance for Lm in RTE food, conditions are permitted in the Food Code that would allow Lm cells 1 log of growth (3.3 generations). Salmonella is also a concern especially with products containing eggs. However, Lm 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 41°F or 45°F then transferred to an ambient temperature of 75°F for 4 hours, the growth rate of *Lm* 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 68°F and 70°F in egg and milk products confirmed slow *Lm* growth at room temperatures.

Using the USDA Pathogen Modeling Program (PMP) and assuming the optimum conditions of pH 6.8, 0.5 percent NaCl, 0.0 percent nitrite, *Lm* 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 TCS 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 4 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 *C. perfringens* and *B. 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 (10⁵⁻⁷ 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 Lm, 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 *Lm* 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 September 2003 Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods, the Food Code allows TCS 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 TPHC 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. *C. 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, five 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 percent of items are held above 45°F (Figure 1). The data also show that by the time the product arrives at the home, 98 percent 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 percent 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.

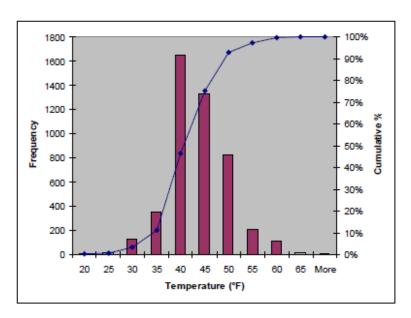


Figure 1. Temperatures of refrigerated products at retail (Audits International).

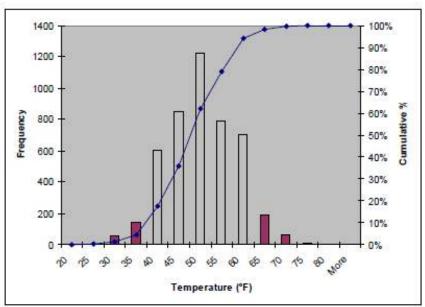


Figure 2. Product temperatures after transport to the home (Audits International).

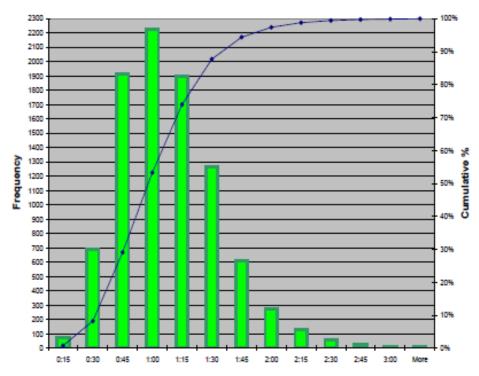


Figure 3. Times reported for transport of grocery items from the retail outlet to the home (Audits International).

The Safety of the TPHC 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 4 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 6 hours. For foods warming from refrigeration to ambient temperatures, the data from the Audits International study outlined above, along with simulations from the USDA 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 *B. cereus* (vegetative), *E.coli*, *Lm*, 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 *C. 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.

3-501.110 Leftovers,	Conditions for Retention
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Refer to the public health reasons for §§ 3-403.11, Reheating, 3-501.14 Cooling, and 3-501.17 & 3-501.18 Date Marking and Disposition

Non-TCS foods do not promote the growth of pathogenic microorganisms. Non-TCS foods that were offered for consumer self-service may be retained and reserved as long as the food was protected from contamination. Paragraph 3-306.14(B) requires protection of the non-TCS food from contamination between uses and infers contamination control must be assured when handled (or exposed) to the self-serve customer—see public health reasons for § 3-306.14 regarding the risk of pathogen transmission to non-TCS foods that are unprotected and subject to consumer exposure and handling. When food particles and liquids from TCS food is comingled with a non-TCS food, the product is considered contaminated and must be disposed. The quantity of TCS food contaminating the non-TCS item combined with the absence of temperature controls during holding/storage may be sufficient to allow the growth of pathogenic microorganisms to unsafe levels.

Hot TCS food that is prepared by the food establishment, held for service, cooled and reheated, and cold TCS food that is prepared, chilled, and held for service may become contaminated by the food handler or unsanitary equipment and may be subject to conditions that promote the growth of harmful microorganisms in the food. Toxigenic bacteria (for example, *Staphylococcus aureus*) and spore forming bacteria (for example, *C. perfringens, C. botulinum, and B. cereus*) present the greatest risk to consumers since reheating leftover foods will not destroy the toxins and improper cooling may result in activation of bacterial spores.

Highly processed foods such as salads prepared by hand (for example, mayonnaise-based macaroni, potato, or chicken salad) that are prepared by the food establishment present the highest risk for contamination with *Staphylococcus* bacteria and opportunities for spore-forming bacteria growth due to inadequate temperature controls during preparation and cooling. Hot foods such as stews, soups, whole roasts, and other large or dense products that are improperly cooled can promote regrowth of harmful bacteria.

Specialized Processing Methods	<u>3-502.11</u>	Variance Requirement
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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 PIC 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 § 8-103.11.

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.

Variances to prescribed TSFC standards are reviewed by DOD public health regulators. The food establishment bears primary responsibility for preparing the variance request and coordinating the laboratory analysis needed as a validation that food will remain safe under the variance procedure. Technical review of the variance request may occur at the installation level, but may require elevation through the public health technical support chain to the military component's Public Health Center or designated subject matter expert.

Once a variance has been approved by the regulatory authority, the food establishment is expected to meet the requirements and procedures delineated in the variance. The regulatory authority inspects the food establishment using the variance criteria and cites nonconformances to the variance document as inspection violations. Some variance criteria may be more restrictive than the published standards of the TSFC. A violation is cited when the variance criteria is not adhered to regardless if the observed condition remains within an acceptable Food Code standard.

3-502.12	Reduced Oxygen Packaging Without a Variance,
	Criteria

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 percent at sea level), including vacuum packaging,, modified atmosphere packaging, controlled atmosphere packaging, cook-chill processing, and sous vide. 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 percent. 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 $41^{\circ}F$ ($5^{\circ}C$) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but nonproteolytic *C. botulinum* and *Lm* are able to multiply well below $41^{\circ}F$ ($5^{\circ}C$). For this reason, *C. botulinum* and *Lm* are the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

ROP 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 Lm without a variance. Paragraph 3-502.12 (B) identifies an ROP method with secondary barriers that will control C. botulinum and Lm when used in conjunction with a food storage temperature of $41^{\circ}F$ ($5^{\circ}C$) 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 *Lm* in ROP foods because:

- C. botulinum will not produce toxin below an aw of 0.91, and the minimum aw for growth of Lm is 0.92.
- *C. botulinum* will not produce toxin when the pH is 4.6 or below and *Lm* 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 41°F (5°C).

Other intrinsic or extrinsic factors can also control the growth and/or toxin production of C. botulinum and Lm.

Foods that are not TCS foods should not support the growth of *C. botulinum* and *Lm*. Therefore, the ROP HACCP requirements of §§ 3-502.11 or 3-502.12 apply only to TCS foods.

ROP with One Barrier (Cook-Chill and Sous Vide)

Some foods may not have secondary barriers to prevent the growth of C. botulinum and Lm, 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 an ROP process, time/temperature becomes the critical controlling factor for growth of C. botulinum and Lm. Nonproteolytic C. botulinum spores are able to germinate and produce toxin at temperatures down to $38^{\circ}F$ ($3^{\circ}C$). Therefore, holding ROP foods at $38^{\circ}F$ ($3^{\circ}C$) or less should prevent the formation of C. botulinum toxin. Lm is able to grow, although very slowly, at temperatures down to $30^{\circ}F$ ($-1^{\circ}C$). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In \P 3-502.12(D), cookchill 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 subparagraph (D)(2)(e) of the provision.

These time-temperature combinations will provide equivalent food safety protection without need for a variance. (Lm 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 *Lm* 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 34°F (1°C) or 41°F (5°C) 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.

ROP with Cheese

Cheeses, as identified in \P 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 41°F (5°C) 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 *Lm* under modified atmosphere conditions.

ROP with Fish

Unfrozen raw fish and other seafood are specifically excluded from ROP at retail because of these products' natural association with nonproteolytic *C. botulinum* (primarily type E) which grows at 37-38°F (3°C). ROP of fish and seafood that are frozen before, during, and after the ROP packaging process does not present this hazard.

HACCP Plans with ROP

A HACCP plan is essential when using ROP processing procedures. *C. botulinum* and *Lm* 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 § 3-502.12 (the criteria specified in 3-502.12(D) combined with holding the product at 41°F (5°C) 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 § 3-502.11) provide evidence that the ROP methodology intended for use is safe.

The Relationship Between Time and ROP

Time is also a factor that must be considered in ROP at retail. The use of date labels on vacuum, modified atmosphere, and controlled atmosphere packaging 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 34°F (1°C) or less for 30 days or 41°F (5°C) 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.

Paragraph 3-502.12 (F) exempts refrigerated, ROP foods that are always removed from the package within 48 hours of packaging from the requirements in § 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.

	3-502.13	Freezing Foods
Also see public health reasons for § 3-502.12 ROP (Cook-Chill and Sous Vide) and 3-501.14 Cooling		

Surplus within a food establishment should not be a common occurrence. Inventory management and projecting daily headcounts are key factors that help to preclude surplus. Food establishments experiencing a surplus food situation should apply various measures to reduce the surplus, such as adjust pending deliveries and procurements, modifying the projected menu for the week to incorporate surplus items, cross-leveling items with other food establishments, or donating to an approved charitable organization.

Food surplus ultimately creates a problem with shelf life. When a food establishment is experiencing a surplus situation for foods that are packaged by a food processing plant and would like to freeze the product to extend the shelf life, Army Veterinary Services or Air Force Public Health must be contacted for approval to verify product quality and to determine the new "use-by" date.

Frozen shelf life for food advanced prepared by the food establishment is limited to 45 days, in part, as an inventory management control, but mostly to protect food quality. Preparing and freezing foods requires stick controls for

ensuring foods are cooked and held at proper temperatures and are rapidly cooled to preclude the growth of sporeforming and toxigenic bacteria.

Leftover foods removed from a serving line are prohibited from being frozen due to the increased potential for temperature abuse and cross-contamination that may occur as a result of frequent transitions between food prep, holding, and serving locations and handling by multiple food employees.

	<u>3-503.11</u>	Restriction for Sale
Also see public health reasons for § 3-501.17 (manufacturer's use-by dates)		

The policy for restricting sales of outdated foods has been coordinated with retail and procurement activities to ensure only the highest quality foods are sold or issued, and in keeping with those agencies best business practices.

The food establishment implements an FIFO inventory management system. A breakdown in FIFO practices may lead to violations involving outdated food. Food quality is affected when a product exceeds the manufacturer's shelf code date, which is contrary to DOD's intent to provide wholesome, quality food to consumers.

Accumate Dennescontation	<u>3-601.11</u>	Standards of Identity
Accurate Representation	<u>3-601.12</u>	Honestly Presented
Labelina	<u>3-602.11</u>	Food Labels
Labeling	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. 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 108282) 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 (that is, 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 (for example, bass, flounder, or cod), the specific species of crustacean shellfish (for example, crab, lobster, or shrimp), and the specific types of tree nuts (for example, 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 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) RTE 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 Nutrition Labeling and Education Act, 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. Part of the challenge is 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. 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 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 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* (§ 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 (that is, 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 an RTE 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 RTE 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 onsite (for example, 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 onsite 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
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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	<u>3-801.11</u>	Pasteurized Foods, Prohibited Re-Service, and Prohibited Food
Refer to the public health reason for § 3-201.11 See also public health reason for § 3-401.11, <i>Children's Menu</i> .		
See also public health feason for § 5-401.11, Chitaren's Menu.		

The Code provisions that relate to HSPs 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 HSPs 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 HSPs, 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 *E. 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 onsite 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 onsite in a facility for service to an HSP.

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 an HSP. Persons providing pureed meals to HSPs 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 HSPs 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 Web site, 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, 8-103.11, 8-103-.12, 8-201.14, and 8-304.11) is applicable to all Code provisions, variance requests related to the preparation of food for HSPs 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 an HSP 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 HSPs. 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
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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 nontemperature 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 (that is, 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.

3-901.10	Donation of Excess Food to Local Relief Organizations
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Department of Defense Directive 6400.04E delineates the responsibilities and collaborative associations for providing safe food under DOD food protection programs. Federal law⁸ encourages the donation of excess "apparently wholesome" food by Federal agencies and their contractors, and they limit criminal and civil liability associated with such donations. "Apparently wholesome foods" are foods that meet all quality and labeling standards imposed by Federal, state, and local laws and regulations even though the food may not be readily marketable due to appearance, age, freshness, grade, size, surplus or other conditions.

Food donation programs serve the dual purpose of providing sustenance to needy populations while furthering efforts towards meeting DOD sustainability initiatives such as Army Net Zero Waste and Federal solid waste diversion goals.

Multiuse	<u>4-101.11</u>	Characteristics
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Multiuse equipment is subject to deterioration because of its nature (that is, 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
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Equipment and utensils constructed of cast iron meet the requirement of durability as intended in § 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.

4 404 40	T T T T + 14 41
4.101 13	Lead, Use Limitation
4-101.13	Leau, OSC Ellintation

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.

⁸ Public Law 110-247, Federal Food Donation Act of 2008, 5 June 2008; Public Law 104-210, Bill Emerson Good Samaritan Food Donation Act, 42 U.S.C. 1791, 1 October 1996.

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 ppm, 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.

<u>4-101.14</u>	Copper, Use Limitation
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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 three 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 brewer's yeast, and fermented. The use of copper equipment during the pre-fermentation 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 (that is, 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 nontoxic, 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 a report on zinc in fruit punch: 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. Examples of authorized surfaces for sponge use include the exterior of refrigerators, stoves, and other cooking equipment where food is not expected to come into contact; floors and walls; and dining room chairs.

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.

When used, hard woods require cleaning and sanitizing between uses and must be periodically reconditioned (for example, sanded) to remove cuts and scratches. Application of food-grade protective oil is authorized to seal the wood surface.

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.

4-101.110 Paint of Other Coatings, Application

Paint and other coatings that have not been approved for use on food contact surfaces may result in toxic chemicals and heavy metals to leach into foods that come in contact with the coatings. Unapproved coatings used on food splash zone may not be tolerant to the high levels of heat or moisture produced in those areas and are subject to deterioration. Deteriorated coatings may crack and peel resulting in uncleanable surfaces, and loose particles may flake off onto food or food contact surfaces.

4-101.111 Sealing Compounds

Food debris may become lodged in sealing compounds that become gummy or sticky when exposed to high heat or high moisture environments. Additionally, non-elastic compounds or compounds that are prone to shrinking over time will develop cracks or gaps within the seal. These conditions are conducive for pests by creating opportunities for access, harborage, and food.

4-101.112 Plastic, Use Prohibition

Approved food equipment and utensils undergo durability testing to ensure material safety, design, construction, and product performance. Soft plastic containers that are not intended for multi-use may not meet the material characteristics specified in § 4-101.11.

4-101.113 Pallet Use

Use of pallets as dunnage in dry food storage areas or walk-in refrigerators is not ideal as it tends to create conditions suitable for pests. Pallets constructed using soft wood such as pine readily absorbs moisture and are not easily cleanable. Additionally, the design of pallets makes it difficult to clean food debris and spilled liquids beneath them.

Pallet use should be restricted to warehousing operations where bulk packaged foods are protected by an over-pack and pallets are frequently and easily moved.

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 cannot 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.

	<u>4-201.12</u>	Food Temperature Measuring Devices
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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 (for example, mercury, may contaminate food or utensils).

	<u>4-201.13</u>	Sealing Compounds
Refer to public health reason for § 4-101.111		

Cleanability 4-202.	Food-Contact Surfaces
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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.

<u>4-202.12</u>	Clean in Place (CIP) Equipment
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Certain types of equipment are designed to be 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 (that is, 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.

	<u>4-202.13</u>	"V" Threads, Use Limitation
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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
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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
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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.

4-20	<u>2.16</u>	Nonfood-Contact Surfaces
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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. Temperature criteria presented in the TSFC reflect the Fahrenheit value first, followed by the Celsius equivalent.

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 $\pm 1.5^{\circ}$ C requirement is more stringent than the 3°F previously required since $\pm 1.5^{\circ}$ is equivalent to $\pm 2.7^{\circ}$ 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 $68^{\circ}F$ ($20^{\circ}C$). The device must be accurate to specifications within that use range.

4-203.13	Pressure Measuring Devices, Mechanical
4-203.13	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.
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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.

	<u>4-204.12</u>	Equipment Openings, Closures and Deflectors
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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
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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 TCS 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 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
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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
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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.

<u>4-204.16</u>	Beverage Tubing, Separation
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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.

	<u>4-204.17</u>	Ice Units, Separation of Drains
Refer to public health reason for § 4-204.16 Beverage Tubing Separation		oing Separation

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. This design feature was previously accepted by NSF/ANSI, but is now prohibited in new equipment. Existing equipment that does not meet the current NSF/ANSI design criteria should be replaced upon reaching its life cycle model or when it becomes unserviceable.

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
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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.

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.

	<u>4-204.110</u>	Molluscan Shellfish Tanks
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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.

<u>4-204.111</u>	Vending Machines, Automatic Shutoff
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Failure to store TCS 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.

4-20	<u>04.112</u>	Temperature Measuring Devices
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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 TCS 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 TCS 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 TCS 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 (that is, 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
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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
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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 M. Devices
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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 successive rising temperatures causes the surface of the item being washed to reach the required 160°F (71°C) 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.

<u>4-204.116</u>	Manual Warewashing Equipment, Heaters and Baskets
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Hot water sanitization is accomplished in water of not less than 171°F (77°C) 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
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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.

<u>4-204.118</u>	Warewashing Machines, Flow Pressure Device
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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 § 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 (iron pipe size) 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.

<u>4-204.121</u>	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
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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
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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.

	4-204.124	Mechanical Warewashing Equipment, Heating Device
Refer to public health reason for § 4-204.116		

The hot water capacity of a food establishment must be designed to sustain warewashing activities during peak demand periods. Dishwashing machines are designed either for hot water sanitizing or chemical sanitizing. Hot water sanitizing machines are not designed with a chemical backup system—see public health reason for § 4-205.14.

Food establishments located in a multi-use building with competing hot water demands may not be able to adequately sustain proper mechanical warewashing temperatures without the support of a booster heater. Additionally, an older food establishment supporting a growing customer base may not be capable of sustaining sanitizing temperatures during peak demand. Providing a booster heater assures compliance for mechanical hot water sanitizing and is more feasible for the food establishment than frequently monitoring sanitizing rinse temperatures and delaying warewashing activities until adequate hot water becomes available.

Acceptability	4-205.10	Food Equipment, Certification and Classification
	<u>4-205.11</u>	Equipment and Utensil, Approval
	4-205.12	Equipment and Utensil, Compliance Measures
	<u>4-205.13</u>	Overseas Food Operations

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.

The organizations listed in the TSFC provisions are recognized by DOD for classifying and/or certifying equipment and utensils that are used in food service as safe and meeting the material and design characteristics presented in Parts 4-1 and 4-2 of the Food Code. Foreign brand equipment that does not hold similar food industry safety certification must be evaluated prior to purchase to ensure cleanability, durability, physical and electrical safety, and safety of the materials used for construction.

Local modification of food equipment may void the manufacturer's warranty. Furthermore, modification of equipment may create a new food safety risk associated with materials, equipment cleanability, or equipment function; therefore, previous certifications (for example, the NSF listing) will be voided. Modified equipment must undergo re-certification for approval. Attaching one certified piece of equipment to another piece of equipment that is also certified does not qualify the combined unit as "certified."

4-205.14	Mechanical Warewashing Equipment,
4-205.14	Modification

Dish machines are designed to provide either hot water sanitizing or chemical sanitizing, but generally not both. Most commercial dishwashers manufactured in the U.S. are certified by NSF International as meeting the requisite performance standards for food safety when installed and operated according to the manufacturer's instructions. Modifications made to a dish machine that are not specified by the manufacturer as approved alternatives may alter the mechanical functioning or performance of the machine. For this reason both the equipment warranty and the NSF certification are voided as a result of the modification.

Chemical sanitizing systems that are manufactured as independent systems, separate from the dish machine, are intended for installation onto hot water-supplied dish machines as an emergency backup when hot water sanitizing temperatures cannot be achieved. These independent systems may have been certified by NSF International; however, certification applies only to the independent system. Placing an NSF-certified device onto an NSF-certified dish machine does not make the modified dish machine NSF-certified. Modification of a dish machine through installation of an emergency chemical sanitizing system requires submission of a variance request to the regulatory authority, which then requires a new assessment of the combined system by an approved certifying agency. The assessment must show that modifications made to the dish machine to accommodate the new system have not compromised performance of the dishwasher and the installed system meets its performance standards by activating and dispensing a sufficient volume of chemical sanitizer each time there is a hot water deficit.

When a dish machine containing an add-on chemical sanitizer system and the combined system is certified by NSF, the certification applies only to the specified Make and Model of the dish machine that was evaluated. Installation of the chemical sanitizer system on a different make or model machine from the same manufacturer requires a new certification.

In accordance with the variance requirements specified under Subpart 8-103, a written procedure must be in place at the food establishment when an emergency chemical sanitizer system is installed through an approved variance. The written procedure must provide sufficient detail to ensure the system is properly monitored and used. Administrative controls may include monitoring dish machine temperatures to ensure the chemical sanitizer activates during periods of hot water deficit. This is especially important if the modified dish machine is not

equipped with an audible alarm or other control mechanism to signal chemical activation. Other controls include use of appropriate chemical sanitizer specified for the machine, refilling the chemical dispenser, proper loading of equipment and utensils in dish racks to ensure all surfaces achieve contact with the sanitizing agent, and verification of the sanitizer residual on the food contact surface.

	<u>4-205.15</u>	Warewashing Machine, Prohibition
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Residential (home-style) dish machines compared to commercial (industrial) grade machine lack the durability and, in many cases, the capacity to properly support high-volume food operations. Dishwashing machines must be suitable for the size of the operation. Suitability includes accommodating volume and size of equipment and utensils being washed, attaining and maintaining appropriate wash, rinse, and sanitizing temperatures, and proper drying capability or drainboard accommodations.

Use of residential type dish machines is appropriate in select applications involving small sizes and low volumes of soiled food equipment. Facilities generally appropriate for using a residential dish machine include training kitchens in Youth Centers, small customer-use kitchens located in guest lodging facilities, and small day care operations. In all cases, the residential dish machine must meet NSF/ANSI Standard 184.

Equipment	4-301.11	Cooling, Heating, and Holding Capacities
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The ability of equipment to cool, heat, and maintain TCS 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.
Refer also to the public health reason for § 4-603.16		

The three compartment requirement allows for proper execution of the three-step manual warewashing procedure. If properly used, the three 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 three 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.

Use of a sink with fewer than three compartments to conduct manual warewashing operations requires an approved variance from the regulatory authority, which must include a written procedure that will be followed by the food establishment.

<u>4-301.13</u>	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
Refer also to the public health reason for § 4-204.11		

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.

	<u>4-301.15</u>	Clothes Washers and Dryers
Refer also to the public health reason for § 4-401.11		

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.

Utensils, Temperature Measuring Devices, and Testing Devices	4-302.11	Utensils, Consumer Self-Service
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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 TCS food.

4	4-302.12	Food Temperature Measuring Devices
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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 PIC 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
4-302.13	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 $71^{\circ}\text{C}(160^{\circ}\text{F})$. 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 $71^{\circ}\text{C}(160^{\circ}\text{F})$. 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 $71^{\circ}\text{C}(160^{\circ}\text{F})$.

4-302.14 Sanitizing Solutions, Testing Devices	
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Testing devices to measure the concentration of sanitizing solutions are required for two 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.

<u>4-303.11</u> Cl	Cleaning Agents and Sanitizers, Availability
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If the appropriate cleaning agents and sanitizers are not on hand at all times they may not be available when needed to clean and sanitize equipment and utensils. It is also important that the cleaning agents and sanitizers be on hand, even at times where warewashing may not be in progress, so that their suitability can be verified by the regulatory authority and, if needed, by personnel who are responsible for servicing the equipment.

Location	<u>4-401.11</u>	Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention
Locuiton	4-401.12	Ice Machines

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.

Ice machines should not be located in outdoor areas or close proximity to exterior doors subject to contamination from blowing dust/dirt; splash zones adjacent to warewashing activities, food prep sinks, or handwashing sinks; or in close proximity to other potential sources of contamination from spraying, dripping, or splashing.

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 (that is, items being laundered could become contaminated from the surrounding area if the washer and dryer are not properly located).

Installation	<u>4-402.11</u>	Fixed Equipment, Spacing or Sealing
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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
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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.

quipment	<u>4-501.11</u>	Good Repair and Proper Adjustment
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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 TCS 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.

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. Minimum recommended cleaning activities include draining dish machines and cleaning the screens and inside surfaces after each meal and at the conclusion of the business 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 if the sink is not properly cleaned and sanitized immediately after conducting these food or custodial tasks.

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 (43°C), the performance of the detergent may be adversely affected (for example, animal fats that may be present on the dirty dishes would not be dissolved).

4-501.110	Mechanical Warewashing Equipment, Wash
<u>4-501.110</u>	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
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If the temperature during the hot water sanitizing step is less than 171°F (77°C), 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
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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 of the equipment or utensil being sanitized must reach at least $160^{\circ}F$ ($71^{\circ}C$) as measured by an irreversible registering temperature measuring device to affect sanitization. When the sanitizing rinse temperature exceeds $194^{\circ}F$ ($90^{\circ}C$) 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 $165^{\circ}F$ ($74^{\circ}C$) for a stationary rack, single temperature machine, and $180^{\circ}F$ ($82^{\circ}C$) for other machines are based on the sanitizing rinse contact time required to achieve the $160^{\circ}F$ ($71^{\circ}C$) 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
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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 § 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 quaternary ammonia compounds) are not included on the label, that the solutions meet the standards required in the Code.

With respect to chemical sanitization, § 4-501.114 addresses the proper use conditions for the sanitizing solution, (that is, chemical concentration range, pH, and temperature <u>minimum</u> levels) and, with respect to quaternary ammonia compounds, 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, \P 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, § 7-204.11 would be violated.

To summarize, a sanitizing solution that is too weak would be a violation of § 4-501.114. A solution that is too strong would be a violation of § 7-204.11. Section 7-202.12 would not be violated due to the existence of § 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 onsite 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 onsite generated solutions and \S 4-703.11 requires that the conditions of use yields sanitization as defined in \P 1-201.10(B) (that is, a 5 log (99.999 percent) reduction).

Because EPA does not require registration of solutions generated and used onsite, 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 (for example, concentration, temperature, contact time, pH, and other applicable factors). These data should be available onsite in the food establishment.

Any data used to validate efficacy of onsite 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/good-laboratory-practices-standards-compliance-monitoring-program.) According to the Web site, "EPA's Good Laboratory Practice Standards compliance monitoring program ensures the quality and integrity of test data submitted to the Agency in support of a pesticide product registration under Federal Insecticide, Fungicide, and Rodenticide Act (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 ongoing basis by confirming that the concentration, temperature, and pH of the sanitizing solutions comply with \P 4-501.114(A) using acceptable test methods and equipment.

The manufacturer should provide methods (for example, test strips, kits, etc.) to verify that the equipment consistently generates a solution onsite at the necessary concentration to achieve sanitization.

Devices can be used for years to produce chemicals intended for the washing of fruits and vegetables, (for example, hypochlorous acid, ozone, and chlorine dioxide). Other devices that are capable of producing hard food contact surface cleaning and sanitizing solutions onsite (for example, 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 onsite 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 FIFRA section 2(q)(1) and section 12, 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 onsite 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.

	4-5111	Manual Warewashing Equipment, Chemical Sanitization using Detergent-Sanitizers
See also the public health reason for § 4-301.12 Manual warewashing, sink compartment requirements		

Some chemical sanitizers are not compatible with detergents when a two-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
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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.

The active ingredient of chlorine bleach is sodium hypochlorite, which is an effective oxidizing agent and broad spectrum disinfectant. When chlorine is added to water, hypochlorous acid and hypochlorite ions are produced. Hypochlorous acid is the compound that kills or inactivates microbes by causing proteins to lose their structure. Water pH is an extremely important factor in determining the effectiveness of the hypochlorous acid. A neutral pH (7.2 - 7.4) is ideal and as pH rises, the hypochlorous acid becomes less effective.

Sodium hypochlorite decomposes over time and the rate of decomposition increases with exposure to elevated temperatures (above 70°F/21°C). A high chlorine concentration also affects the decomposition rate. For example, a 16 percent solution degrades within a few minutes and a 3 percent solution can last for months. Decomposition occurs regardless if the product's container is open or remains sealed. Some manufacturers compensate for the increased rate of dissipation during the summer production period by increasing the base strength of the sodium hypochlorite compared to winter production. Because of these variables, users must not rely solely on the base concentration specified on the manufacturer's label and must not assume the desired disinfecting concentration will be achieved when using the prescribed formula for preparing a sanitizing solution.

Plain (unscented) liquid "household" bleach must be diluted to the appropriate concentration prior to use as a surface antimicrobial agent. Gel or "splashless" bleach products are not authorized for preparing sanitizing solutions. Prior to 2011, U.S. bleach manufacturers formulated household bleach with a base strength between 5.25 and 6.15 percent. Although these products are still available, some U.S. bleach manufactures (for example, Clorox®) now use a base strength of 8.25 percent. Products manufactured outside the U.S. will vary in strength, typically between

3 and 10 percent. For this reason it is important to always refer to the manufacturer's label to identify the product's base strength before preparing a dilute solution for sanitizing tasks. Verify the concentration using an appropriate test kit or test paper each time a new solution is prepared.

Utensils and Temperature and Pressure Measuring Devices	4-502.11	Good Repair and Calibration
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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
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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.

<u>4-502.13</u>	Single-Service and Single-Use Articles, Use Limitation
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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
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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.

Ice Machines	<u>4-503.11</u>	Maintenance of Ice Machines
	4-503.12	Operation, Restrictions
Refer also to public health reason for § 3-202.16, Ice		

Ice machines are subject to contamination from improper control of condensation drain lines (for example, discharging directly into a sewage drain without maintaining an air gap), unsanitized ice scoops, unhygienic personnel handling ice, and other environmental sources. Over time, the interior of ice bins become unsanitary due to development of mold/mildew and mineral buildup, which can harbor bacteria.

Preventing contamination of potable ice produced in the food establishment requires three basic controls—

<u>Location</u>: Locate ice machines in areas that are not subjected to environmental sources of contamination such as splashing from warewashing activities or food preparation, or aerosolized soil particles (for example, dust or dirt).

<u>Access</u>: Only food employees should retrieve ice from ice bins that are not self-dispensing. A sanitized utensil must be used to retrieve ice.

<u>Cleaning</u>: Periodic cleaning of ice machine bins is an essential function of the food establishment to prevent mineral and mold/mildew buildup. Cleaning frequency will vary and should be scheduled before there are visible signs of buildup inside the bin or on the condensing unit. The food establishment should consult with the ice machine manufacturer for recommended cleaning procedures.

Quality assurance testing may be conducted by the regulatory authority to assess the sanitary condition of ice bins. Sample analysis should be conducted using the heterotrophic plate count method as the bacteriological quality indicator for the ice machine. All ice machines must be supplied from a potable water source. On DOD installations the potable water should maintain a trace residual of free available chlorine; therefore, it is expected that a well maintained ice machine will yield a heterotrophic plate count value less than 200 colony forming units per milliliter (CFU/mL) of sample. Test results above 500 CFU/mL indicate insufficient sanitary controls and must be investigated. If subsequent sampling yields similar results, the ice machine should be emptied, cleaned, and sanitized. Monitoring for other contamination indicators such as Total Coliform or *E. coli* is only required when there is concern regarding water quality of the potable water source or there is a suspected cross-connection between the ice machine and sanitary sewer.

Objective 4-60	<u>01.11</u>	Equipment, Food-Contact Surfaces, Nonfood- Contact Surfaces, and Utensils
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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	<u>4-602.11</u>	Equipment Food-Contact Surfaces and Utensils
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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 TCS 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 4 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 TCS 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 (for example, 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 PIC 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 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). The 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 CFP 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 the 2013 FDA Food Code, Annex 4 - Management of Food Safety Principles for Food Allergens as Food Safety Hazards.

4-602.12 Cooking and Bakin	ng Equipment
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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
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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	<u>4-603.11</u>	Dry Cleaning
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Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not TCS foods. Under some circumstances, attempts at wet cleaning may create microbiological concerns.

<u>4-603.12</u>	Precleaning
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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.

<u>4-603.13</u>	Loading of Soiled Items, Warewashing Machines
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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
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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 (that is, 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
4-003.13	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.

4-603.18 Steel Wool Prohibition

Steel wool fibers are very friable and may become lodged in the small folds/crevices of equipment and utensils, creating a physical food safety hazard. Woven brass and plastic or synthetic pads are more durable.

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	<u>4-703.11</u>	Hot Water, Chemical, and Steam
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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 160°F (71°C), 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 Sections 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.

Table 4-2 presented under § 4-501.114 of the TSFC allows application of a chorine sanitizer at concentrations below 100 ppm when the solution temperature and water pH are maintained at the levels specified in the table. The prime disinfecting agent in a chlorine bleach solution is hypochlorous acid (see public health reason for § 4-501.200). Hypochlorous acid is most effective as a disinfectant at a pH level below 7.5. The rate of decomposition reactions in chlorine increases as the solution becomes more alkaline (that is, higher pH). When the pH is above 7.5, hypochlorite ions dominate over the hypochlorous acid, which decreases the effectiveness of the disinfecting

properties. Therefore, a higher water (or solution) temperature is required to increase the disinfecting properties when the pH is above 8.0. Chlorine solutions that are prepared and placed in a bottle or bucket for application throughout the day using spray or swabbing/wiping methods are generally unable to remain at the prescribed solution temperatures specified in Table 4-2. For this reason, use of a chlorine concentration that is less than 100 ppm is limited to applications involving complete immersion of the equipment or utensil in the sanitizing solution.

The active ingredient in some chemical sanitizers can become bound to the fabric (or neutralized) when the sanitizer is applied using a swabbing or wiping method. It is assumed that the required concentration of a sanitizing solution that was properly prepared will be transferred from the bucket by the cloth to the surface being sanitized. However, research has shown that this is not always the case. Ionic bonds are formed when quaternary ammonium is used with cotton or viscose cloth (Gibb, 2016). As much as 40 percent of quaternary ammonium chloride, the active ingredient in quaternary ammonium sanitizers, can become bound to cloth fibers, thus rendering the sanitizing process ineffective. Factors such as the type of fabric, length of time the cloth is stored in the sanitizing solution, and the concentration and volume of the solution will affect "quat binding." A similar effect may occur when chlorine bleach sanitizer is applied using a wiping cloth. Due to the potential for sanitizer binding with the wiping cloth, food workers should apply chemical test paper directly to the cloth containing the sanitizing solution to verify the concentration of the active ingredient released by the cloth.

Hot water sanitization is preferred over using chemical sanitizers because drying time is significantly reduced. (See public health reason for § 4-901.11 Air Drying.)

Steam generated from sources such as a boiler plant may contain harmful water conditioning agents that are not approved food additives IAW 21 CFR 173.310. (See public health reasons for § 7-204.13 Boiler Water Additives.)

<i>Objective</i> 4-801.11	Clean Linens
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Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness.

Frequency	<u>4-802.11</u>	Specifications
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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
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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
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Proper laundering of wiping cloths will significantly reduce the possibility that pathogenic microorganisms will be transferred to food, equipment, or utensils.

<u>4-803.13</u>	Use of Laundry Facilities
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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	
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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.

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	<u>4-902.11</u>	Food-Contact Surfaces
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Food-contact surfaces must be lubricated in a manner that does not introduce contaminants to those surfaces.

4-	l-902.12	Equipment
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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
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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
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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.

	<u>4-904.11</u>	Kitchenware and Tableware
Preventing Contamination	4-904.12	Soiled and Clean Tableware
	<u>4-904.13</u>	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.

4-9	<u>-904.14</u>	Rinsing Equipment and Utensils after Cleaning and Sanitizing
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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.

Source	<u>5-101.11</u>	Approved System
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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.

5-101.14SteamRefer to public health reasons for § 7-204.13 Boiler Water Additives, Criteria.

Quality <u>5-102.11</u> 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 only 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 (for example, 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 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 Good Agricultural Practices and safely growing, harvesting, washing, sorting, packing and distributing produce. It is available at: http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM169112.pdf.

<u>5-102.13</u> Sampling

Wells and other types of individual water supplies may become contaminated through faulty equipment or environmental contamination of groundwater. 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 cannot 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.

<u>5-103.12</u> 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 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 <u>5-201.11</u> 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	<u>5-202.11</u>	Approved System and Cleanable Fixtures
Instatiation		

Adherence to plumbing codes ensures material safety and proper installation. 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, to include 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.

<u>5-202.12</u>	Handwashing Facility, Installation
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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 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (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.

	<u>5-202.13</u>	Backflow Prevention, Air Gap
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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 backsiphonage, 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.

	<u>5-202.14</u>	Backflow Prevention Device, Design Standard
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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.

<u>5-202.15</u>	Conditioning Device, Design
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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	<u>5-203.11</u>	Handwashing Sinks
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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 §§ 2-301.14 and 2-301.15.

According to Greig et al. (July 2007)* an analysis of 816 reported outbreaks of infected worker-associated outbreaks from 1927-2006 found that over 61 percent of these outbreaks came from food service facilities and catered events, and another 11 percent 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 2006)* 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.

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.

<u>5-203.13</u>	Service Sink
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Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Wastewater 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.

	<u>5-203.14</u>	Backflow Prevention Device, When Required
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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
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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, *Backflow Preventer for Beverage Dispensing Equipment*; or ASSE Standard No. 1032, *Dual Check Valve Type Backflow Preventers for Carbonated Beverage Dispensers*, *Post Mix Type*, will prevent this occurrence, thereby reducing incidences of copper poisoning.

Location and Placement	<u>5-204.11</u>	Handwashing Sinks
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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 <u>5-205.11</u> 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. Wastewater 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 S-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.

	<u>5-205.16</u>	Water Conditioning Device, Replacing Cartridges and Filters
Refer to public health reasons for §§ <u>5-205.13</u> (inspection) and <u>5-205.15</u> (maintenance)		

<i>Materials</i> <u>5-301.11</u>	Approved
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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.

	<u>5-302.11</u>	Enclosed System, Sloped to Drain
Design and Construction	<u>5-302.12</u>	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.

<u>5-302.13</u>	"V" Type Threads, Use Limitation
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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.

<u>5-302.14</u>	Tank Vent, Protected
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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 and dirt or debris that may contaminate the water supply.

Both the inlet and outlet must be sloped to drain to prevent the pooling of possibly contaminated water or sanitizing solution.

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. A "safe" hose is one that has been tested and approved for use with drinking water.

Numbers and Capacities <u>5-303.11</u>	Filter, Compressed Air
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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.

	<u>5-303.12</u>	Protective Cover or Device
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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 (that is, 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 <u>5-304.11</u> 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.

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 percent 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 ¶ 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 ¶ 5-402.11(A).

<u>5-402.12</u>	Grease Trap
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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.

<u>5-402.13</u>	Conveying Sewage
<u>5-402.14</u>	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.

<u>5-402.15</u>	Flushing a Waste Retention Tank
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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	<u>5-403.11</u>	Approved Sewage Disposal System
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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.

<u>5-</u>	<u>-403.12</u>	Other Liquid Waste and Rainwater
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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	<u>5-501.10</u>	Indoor Storage Area
	<u>5-501.11</u>	Outdoor Storage Surface
	<u>5-501.12</u>	Outdoor Enclosure
	<u>5-501.13</u>	Receptacles
	<u>5-501.14</u>	Receptacles in Vending Machines
	<u>5-501.15</u>	Outside Receptacles
	<u>5-501.16</u>	Storage Areas, Rooms, and Receptacles, Capacity and Availability
	<u>5-501.17</u>	Toilet Room Receptacle, Covered

<u>5-501.18</u>	Cleaning Implements and Supplies
<u>5-501.19</u>	Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location
<u>5-501.110</u>	Storage Refuse, Recyclables, and Returnables
<u>5-501.111</u>	Areas, Enclosures, and Receptacles, Good Repair
<u>5-501.112</u>	Outside Storage Prohibitions
<u>5-501.113</u>	Covering Receptacles
<u>5-501.114</u>	Using Drain Plugs
<u>5-501.115</u>	Maintaining Refuse Areas and Enclosures
<u>5-501.116</u>	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	<u>5-502.11</u>	Frequency
Removai	<u>5-502.12</u>	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	<u>5-503.11</u>	Community or Individual Facility
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Alternative means of solid waste disposal must be conducted properly to prevent environmental consequences and the attraction of insects, rodents, and other pests.

Indoor Areas	<u>6-101.11</u>	Surface Characteristics
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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
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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	<u>6-201.11</u>	Floors, Walls, and Ceilings
Cieanability	<u>6-201.12</u>	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 Sealed	and Wall Junctures, Coved, and Enclosed or
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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 *Lm*.

<u>6-201.14</u>	Floor Carpeting, Restrictions and Installation
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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.

<u>6-201.15</u>	Floor Covering, Mats and Duckboards
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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.

<u>6-201.16</u>	Wall and Ceiling Coverings and Coatings
<u>6-201.17</u>	Walls and Ceilings, Attachments
<u>6-201.18</u>	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-	5-202.1 <u>1</u>	Light Bulbs, Protective Shielding
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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
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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.

<u>6-202.13</u>	Insect Control Devices, Design and Installation
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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	Toilet Rooms, Enclosed	
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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
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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 NFPA Standard 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 \P 6-202.15(C).

6-202.16	Exterior Walls and Roofs, Protective Barrier
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Walls and roofs provide a barrier to protect the interior and foods from the weather, windblown dirt and debris, and flying insects.

6	5-202.17	Outdoor Food Vending Areas, Overhead Protection
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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
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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.

<u>6-2</u>	202.19	Outdoor Walking and Driving Surfaces, Graded to Drain
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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
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If refuse areas are not graded properly, wastewater will pool and attract insects and rodents.

<u>6-202.111</u>	Private Homes and Living or Sleeping Quarters, Use Prohibited	
<u>6-202.112</u>	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.

Handwashing Sinks	<u>6-301.10</u>	Minimum Number
Refer to the public health reason for § 5-203.11		

	<u>6-301.11</u>	Handwashing Cleanser, Availability
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Hand cleanser must always be present to aid in reducing microorganisms and particulate matter found on hands.

<u>6-301.12</u>	Hand Drying Provision
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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. At the time of publishing for this edition of the TSFC, there were no hand-drying devices that meet NSF performance criteria P335 of 12-second drying time, except the air knife technology.

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. Single-use paper towels are the only approved hand drying method for food preparation handwashing sinks.

	<u>6-301.14</u>	Handwashing Signage
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A sign or poster is required in a visible location as an active reminder to food employees that they must wash their hands before returning to work.

	<u>6-301.20</u>	Disposable Towels, Waste Receptacle
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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	<u>6-302.10</u>	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	<u>6-303.11</u>	Intensity
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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	<u>6-304.11</u>	Mechanical
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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	<u>6-305.11</u>	Designation
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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	<u>6-306.10</u>	Availability
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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	<u>6-401.10</u>	Conveniently Located
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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	<u>6-402.11</u>	Convenience and Accessibility
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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	<u>6-403.11</u>	Designated Areas
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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
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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. Segregation areas or foods awaiting turn-in or disposal should be clearly marked to prevent accidental use by employees.

Refuse, Recyclables, and	6-405.10	Receptacles, Waste Handling Units, and
Returnables	<u>0-405.10</u>	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	<u>6-501.11</u>	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.

<u>6-501.12</u>	Cleaning, Frequency and Restrictions
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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 and the air handling system. 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, Using a Handwashing Sink.

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, personto-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.

ng Toilet Room Doors
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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.

<u>6-501.115</u>	Prohibiting Animals
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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 ADA (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. EEOC, 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/.

Military working dogs are not service animals and are treated differently as a result. Military working dogs may only enter the food establishment when performing official duties, which is usually on a temporary, limited time basis. Accompanying the handler during a meal break is not considered official duty. When the situation requires the military working dog to enter food preparation and food service areas, exposed foods must be covered or removed from the area to prevent potential contamination. Food contact surfaces that may have come into contact with the animal, such as clean pots and pans or dinnerware (for example, plates) that are stored on low-level shelving units and food preparation tables must be cleaned and sanitized before being used.

Original Containers	<u>7-101.11</u>	Identifying Information, Prominence
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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	<u>7-102.11</u>	Common Name
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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.

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. Appropriate physical separation may include storing toxic materials on a separate shelving unit that is spaced at a distance from food such that spillage or leaking from the toxic material cannot splash, spray, drip or spread onto food packages. Examples include locating the storage shelf on the opposite wall from food, or maintaining a minimum gap of 36 inches between shelving units.

Presence and Use	<u>7-202.11</u>	Restriction
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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 (for example, 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
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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	<u>7-203.11</u>	Poisonous or Toxic Material Containers
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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	<u>7-204.11</u>	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 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 the maximum concentrations that are considered safe for the specified application. Approved sanitizing agents are also specified in 21 CFR 178.1010, which includes the minimum required concentration based on product formulation.

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, Nonfood determinations. Because there is no EPA registration of solutions generated and used onsite, 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 onsite 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. 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 throughout all the air in a site, the gas may not be evenly distributed. This may lead to localized concentrations (for example, immediately over a three-compartment sink) that exceed OSHA limits. It is the responsibility of the food establishment manager 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 food establishment.

<u>7-204.12</u>	Chemicals for Washing Fruits and Vegetables, Criteria
<u>7-204.13</u>	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 Web site 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, 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 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 § 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 (that is, 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 onsite. 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. The 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 FFDCA. Although the petitioned use of SDBS is regulated under Section 409 of the FFDCA as a food additive, this intended use of SDBS may nevertheless be subject to regulation as a pesticide under the 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 EPA 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	<u>7-205.11</u>	Incidental Food Contact, Criteria
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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	<u>7-206.11</u>	Restricted Use Pesticides, Criteria
resucuies	<u>7-206.12</u>	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.

<u>7-206.13</u>	Tracking Powders, Pest Control and Monitoring
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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	<u>7-207.11</u>	Restriction and Storage
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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
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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	<u>7-208.11</u>	Storage
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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	<u>7-209.11</u>	Storage
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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 (Stock and Retail Sales)	<u>7-301.11</u>	Separation
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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.

	<u>8-103</u>	Variances
Refer to public health reasons for § 3-502.11		

Construction Inspection and	<u>8-201.12</u>	Contents of the Plans and Specifications
Approval	<u>8-203.10</u>	Preoperational Inspections

In conjunction with the CFP 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. 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 PIC, 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) TCS 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 PIC 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 paragraph 2-103.11(M) of this Code which requires the PIC to assure that food employees are properly trained in food safety as it relates to their assigned duties.

Unit and Organizational Functions that are not classified as Temporary Food Establishments	8-301.11	Prerequisite for Operation
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As defined in the TSFC, a food establishment is any permanent (for example, fixed), mobile, seasonal, vending machine, or temporary food service operation or retail store that is operated as a licensed business to prepare, package, serve, or vend food directly to the consumer. Examples of food establishments and components of a food establishment include restaurants, grocery stores, child care facility kitchens, food trucks, food transport vehicles, caterers, vending snack bars, and temporary food stands operated by a commercial food vendor. Although farmers markets are not classified as a food establishment, deliberate regulatory oversight is needed to ensure safe food practices are employed. All of these operations must be sanctioned by the installation commander in order to provide a service to the public on a DOD installation and assurances must be in place to protect public health.

Ultimately, the installation commander is responsible for ensuring safe food is served or dispensed at the installation and food establishments are maintained with appropriate sanitary controls. The mechanism in which this is achieved is through the inspection processes administered by public health, preventive medicine, and veterinary food safety personnel. Preoperational review of food establishments by the regulatory authority is essential to ensure food sources, facilities and equipment are suitable for the operation, and employees are properly trained to prepare and serve safe food to the public.

Private food activities occurring on the installation and intended to service individuals, small groups of individuals, or is available to the general public under limited conditions are not classified as a food establishment or temporary food establishment. Examples include food delivery vehicles responding to individual orders within the housing area, catered food supporting an office function, organizational food events in which food is prepared by organizational members, and Cottage Food operations. In general, the installation commander does not regulate these types of activities through the implementation of an ongoing surveillance plan. Instead, acceptance of food protection risk lies with the hosting commander or organizational leader.

Personnel hosting private or organizational food events are typically not trained in food safety and may have limited knowledge regarding appropriate food safety controls. An installation-level program should be established by the

regulatory authority to address oversight of events involving food, to include a home business (that is, Cottage Foods), that are not considered temporary food establishments. Establish a local policy using the guidance presented in paragraphs 8-301.11(C) and (E) for tenant units and organizations to notify the regulatory authority when planning a food event. Refer to the public health reason for Cottage Food Operations (§ 8-301.12).

Requirements to Operate	<u>8-301.12</u>	Cottage Food Operation
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Regulatory Oversight of Cottage Foods

The USDA and the FDA do not regulate Cottage Food operations. Cottage Foods are governed by state and local health regulations. The laws vary widely between states, but most have a common thread to allow production and sale of safe prepared foods to the public. Most public health jurisdictions limit the sale of Cottage Foods to individual customers, though some allow sale of specific items through retail stores and to food operations such as restaurants. At least 35 states have specific regulations which govern production and/or sale of Cottage Food.

Understanding Cottage Food Laws*

In general, foods produced under Cottage Food laws are exempt from certain licensures and codes. For this reason, only low-risk foods are allowed. Low-risk foods such as bread and cookies are foods that typically do not present a foodborne illness risk because they cannot support the growth of harmful microorganisms at unrefrigerated temperatures. High-risk foods such as meat, dairy, and eggs, readily support the growth of harmful microorganisms when held outside of safe temperature controls and present a high risk for causing foodborne illnesses.

Refrigeration serves as a good indicator of whether a food can be sold under most Cottage Food laws. If refrigeration is required, then the product is considered high-risk and not allowed as a Cottage Food. Although some baked goods contain eggs and milk as an ingredient, cooking at high temperatures makes the product safe and eliminates the need for refrigeration. However, baked items containing a cream or custard filling must be refrigerated and are considered high-risk. Products containing meat, poultry, seafood, rice, pasta, or vegetables remain high-risk after cooking and must be refrigerated.

Canned foods are another example of how cottage food laws work. Certain bacterial spores that live harmlessly in soil can remain present on vegetables even after washing. One bacteria, *C. botulinum*, produces the toxin that causes botulism, which is a deadly foodborne illness. Failure to follow proper canning procedures and controls can create conditions that allow regrowth of the toxin-producing bacteria. As long as the producer takes precautions such as cleaning utensils and canning at high temperatures, the risk of botulism is low. Additionally, the natural acid in some foods such as fruits (for example, jams) neutralizes botulism and is usually allowed under Cottage Food laws. However, canning low-acidic foods such as vegetables and meat is generally not allowed.

People who benefit from Cottage Food laws are producers who sell at farmers markets, farm stands, or other direct-to-consumer situations. Cottage Food laws vary by state, and maybe even by county, but they usually limit where and to whom producers can sell their products.

Although there are concerns among some food safety advocates regarding the increased risk of a foodborne illness outbreak resulting from Cottage Foods produced in unlicensed kitchens, the food safety risk is considered low. Cottage Food operations are usually very small, having only one or two producers. As a result they have a fair amount of oversight and control over how food is made. As long as they are producing low-risk foods, it makes little sense to impose the same strict food safety controls required by industry.

The bigger, more complex an operation becomes, the less Cottage Food laws make sense. Typically, when a producer has multiple employees, the amount of food safety oversight decreases and opportunity for mistakes-unwashed hands, unsanitized counters, spoiled ingredient--increases. If a producer is able to hire more than one employee, then that producer may be able to afford the fees and costs of complying with standard food safety regulations anyway.

Additionally, Cottage Food laws make less sense when producers are selling mostly to strangers. If a consumer buys food from a neighbor or friend, then that consumer presumably knows enough about the operation to make an informed decision. But buying food from a vendor at a large farmers market or stand is a bit different. Consumers can ask questions and make deductions about whether the food has been safely prepared, but they are nonetheless taking a risk. In the case of simple, low-risk foods such as baked goods, it makes sense to allow these stranger-to-stranger transactions. But when foods start requiring more safe handling precautions — like low acidic canning — allowing stranger-to-stranger transactions probably makes less sense.

Some argue that, regardless of the level of risks, it is the consumer's right to decide whether to take the risk. However, this argument is complicated by the fact that parents make most food decisions for their children, and children are the most susceptible to serious consequences, including death, from foodborne illnesses. In theory, the law tries to find a balance between parental rights and protecting the welfare of children. So, with this consideration in mind, it probably makes sense to limit Cottage Food laws to the sale of low-risk foods.

*Source: Food Safety News, When Does a Cottage Food Law Become a House Food Law? Kelly Damewood, January 27, 2014;, http://www.foodsafetynews.com/2014/01/when-does-cottage-food-law-become-a-house-food-law/#.VkYv3nm6G70

Regulatory guidance for Cottage Food operations

Although Cottage Food operations do not receive periodic sanitation inspections, the regulatory authority should provide guidance to assist the Cottage Food operator minimize potential food safety hazards. A review of the Cottage Food operator's application will identify high-risk foods and practices and identify ingredients that are known major food allergens. (See public health reason for § 3-602.11—food allergen labeling.)

Since Cottage Food operators are typically not trained food handlers, they may not be familiar with the food safety guidelines presented in the TSFC. The following guidance is a compilation of the requirements from various state regulations. These items and actions are essential controls that must be applied by the Cottage Food operator to protect public health—

Facilities and Equipment.

- Maintain facilities and supplies for hand washing during food production. This includes a sink and warm potable water, hand soap, and paper towels.
- Equipment to keep the food and ingredients at safe temperatures. At a minimum the producer must have a refrigerator which can be held at 38 to 40°F and, if appropriate, a freezer capable of operating at 0°F. Each refrigerator and freezer should have a thermometer place inside the unit where it can easily be read when the unit door is opened.
- Facilities and equipment to ensure food is cooked to proper temperature. This includes one or more food thermometers which can be used to check food temperatures after cooking and during hot or cold holding.
- Facilities and equipment for proper washing and sanitizing food equipment and utensils. Home-style
 dishwashers must be run on the hottest wash and rinse cycle available. Use the sanitize cycle when this
 feature is available for the dishwasher model and do not interrupt the cycle or open the dishwasher door
 before the cycle is complete.

Hygiene

- Cottage Food producer must not produce food when they are sick with symptoms of high fever, sore throat, experiencing a cold (heavy cough, runny nose, or sneezing), or stomach upset with loose stool or diarrhea.
 They must also not produce FOOD when they are taking care of a family member who is sick with similar symptoms.
- Animals, dogs, cats and other pets must be excluded from the kitchen during food preparation, cooking and wrapping.
- Producer must wear clean clothing and wash their hands up to the elbows with warm soapy water before handling food and whenever their hands become soiled such as when handling trash.
- Family members may assist the producer, but must follow the same hygiene requirements.

Food Production

- Clean and sanitize all cooking and food preparation surfaces before beginning operations.
- Wash FF&V under clean running water prior to slicing, pealing or slicing.
- Put FF&V on a clean towel after washing.
- Except for ingredients that make up the specified Cottage Food, ensure there are no major food allergens in the kitchen while the food is being produced.
- Follow the specified Cottage Food recipe each time the product is made.
- Check the final cooking temperatures using a food thermometer.
- · Keep a record of final cooking temperatures and the date of production for each batch of food produced.

	<u>8-304.11</u>	Prerequisite for Operation
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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 food service and retail level.

Interventions	<u>8-401.30</u>	Routine Inspection Substitution
Also refer to the public health reason for § 2-102.11 (demonstration of knowledge)		

Intervention strategies are designed to help improve the active managerial controls that are necessary in a food operation to protect public health from foodborne illnesses. Active managerial controls are the actions taken by food managers and supervisory personnel (that is, PICs) to ensure the food safety controls prescribed in the TSFC are regularly applied. An active manager (or supervisor) monitors employee practices and the sanitary condition of their facilities during all hours of operation and take prompt action to correct deviations from prescribed standards. (See also public health reasons for § 8-402.12, Food service Facility Self-evaluations)

When active managerial controls fail, it is generally due to either a lack of knowledge, or the reluctance of supervisory personnel to perform their duties as a food safety professional. Basic food handler's training and food protection manager certification are directed by the TSFC. Weaknesses in performance attributed to a lack of knowledge can be improved through topic-focused training or development of written procedures to target problematic areas in the food operation.

Application of knowledge in the day-to-day operations of the food establishment is driven by a variety of motivating factors. Food establishments that are located off of the installation and regulated by a local health department are subject to monetary penalties for inspection failures or critical violations that remain uncorrected at the conclusion of the inspection and also risk suspension of their operating license (or permit). The associated costs for critical violations, facility re-inspections, and license renewal can vary from a couple hundred dollars to several thousand dollars, thus providing motivation for food managers to adhere to food safety codes. These types of penalties are not applied to food establishments operating on military installations. As a result the regulatory authority must take other appropriate actions to help improve operational performance within the food establishment. When training, SOP development, and other consultative and support actions fail to improve managerial controls within an operation, action is taken to elevate the issues and associated public health risks to appropriate levels of leadership. CORs are responsible for ensuring compliance with contracted food operations' Performance Work Statement (PWS) and Statement of Work, as appropriate. When a contracted food establishment, such as a dining facility, is found to be noncompliant with the criteria set forth in the TSFC it is also a violation of the PWS. Contracted operations that consistently fail to meet the PWS are at risk for contract nonrenewal or early termination of contract. Sponsored operations through AAFES, NEX, MCX, and MWR are accountable to a General or Regional Manager who can also influence retention of a food establishment or change in management within the food operation. When this intermediary level of engagement fails to engage or improve performance within a food establishment, the issue should be addressed using the language of an operational risk assessment and elevated to the installation commander and the appropriate corporate level headquarters of the food establishment.

8-402.10	Competency of Inspectors
0-402.10	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.

8-402.12 Food service Facility, Self-evaluations

Food employees are responsible for applying appropriate food safety controls to protect public health. It is the duty of the food establishment manager and other designated supervisory level personnel to ensure that hygienic practices and food safety principles are steadily applied in the operation, which is an ongoing supervisory responsibility. Deliberate actions are taken throughout the day by the PIC to observe employee practices, operational procedures, and facility sanitation and to immediately apply corrective actions to resolve or mitigate hazardous conditions and practices that present a food safety risk.

Assessments may be informal, but must be comprehensive to ensure all aspects of the operation are equally examined and addressed. The seven major categories depicted on DD Form 2973 identify the key aspects of the food operation that must be evaluated each day: Supervision and Training; Health and Hygiene; Food Source, Identification, Condition; Contamination Protection and Prevention; Temperature Control; Utensils and Equipment; and Physical Facilities. The checklist items shown on the DD Form 2973 represent the major areas evaluated during a routine food facility inspection. When used internally by the food establishment, the checklist is designed to assist the PIC when evaluating the condition of the food operation between inspections by the regulatory authority. The goal for conducting self-evaluations is to help maintain the highest standards in our food operations.

Self-evaluation actions:

- Proper assessment of food temperatures requires actual measurement of representative foods and their holding equipment at various points in the operation. For example, representative sampling includes measurement of at least two internal food product temperatures taken from all refrigerated storage or holding units, hot holding cabinets, and hot and cold serving lines; and cooked foods are measured at the termination of the cooking process, especially for entrees containing meat or poultry. Equipment operating temperatures are verified by placing a calibrated thermometer inside of each refrigerator, freezer, and hot holding cabinet to measure the ambient air temperature.
- Evaluate employee hygiene practices such as clean clothing, hair restraints, iewelry, and handwashing:
- Verify sanitization practices and procedures by measuring the hot water sanitizing temperature for mechanical and manual warewashing. Observe mixing procedures when chemical sanitizers are prepared and verify the concentration of the prepared solution using an appropriate test paper or test kit.
- Look for damaged food equipment and areas of the physical facilities in need of repair. Initiate work orders and follow up on existing work orders.

A breakdown in PIC duties and responsibilities to self-assess and implement corrective actions becomes evident when the regulatory authority consistently finds multiple critical or noncritical violations during inspections. If not already directed by service policy, and as a strategy to help improve active managerial controls, the regulatory authority may implement a requirement for the PIC to document daily or weekly self-evaluations using DD Form 2973 or other approved documentation. Self-evaluations are not rated. The self-evaluation documents observed nonconformances to the TSFC and the actions taken by the PIC to correct the violation and prevent it from occurring in the future.

8-403.20 Inspection Ratings		8-403.20	Inspection Ratings
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A standardized system for rating Routine food operation inspections was developed to remove subjectivity and inconsistent application of previously prescribed scoring criteria. Applying a standardized scoring and rating plan ensures consistency throughout the DOD when stating the observed level of compliance. This in turn results in meaningful data when analyzing the effectiveness of the Food Protection Program at the installation, region, service component, and DOD level.

The prescribed rating verbiage—Fully-, Substantially-, Partially-, and Noncompliant—is preferred over the more ambiguous ratings of "Excellent," "Satisfactory," "Marginal," and "Unsatisfactory" because it conveys more clearly the intent of the inspection, which is to assess compliance. Some jurisdictions prefer to use a letter-grading or color-coding system when reporting the inspection rating. Military personnel readily recognize the risk potential

associated with a Green-Amber-Red status since this notation is primarily used throughout the DOD to indicate equipment or operational readiness. The A-B-C-D letter-grading system is equally recognized by the general public.

Installation commanders and the regulatory authority may choose to apply the letter-grade or color-code system in order to establish "visual" continuity with the State/local health department. Implementing a unified rating system helps consumers to easily recognize the food establishment's compliance posture regardless if subsisting on or off of the installation. At a minimum the inspection rating must include the TSFC "compliance" level presented in § 8-403.20, Table 8-4, indicating *Fully Compliant, Substantially Compliant, Partially Compliant, or Noncompliant*, and may be combined with the corresponding color-code and/or letter grade. The scoring criterion is the primary component for determining inspection ratings and must not be altered in order to align with a local health department's rating system.

Inspection ratings are only awarded for comprehensive inspections such as Pre-operational and Routine inspections. Follow-up inspections conducted following a *Noncompliant* inspection rating are a continuation of the original inspection and are intended to verify corrective actions to eliminate previously uncorrected critical conditions.

Because a comprehensive facility inspection is not conducted, the scoring table cannot be applied correctly. Follow-up inspections are assessed as *Pass* or *Fail*, regardless if new violations were found. "Pass" means all critical violations were corrected or the conditions contributing to the critical violation have been altered to mitigate the critical hazard pending a more permanent resolution (for example, equipment repair or replacement). Since the Follow-up is a continuation of the original inspection, the Follow-up inspection document is posted with the corresponding Routine inspection and the maximum inspection rating is indicated as *Partially Compliant*.

<u>8-403.50</u>	Public Information
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Regulatory documents that describe the compliance status of a regulated food establishment may be of particular interest to consumers, academia, industry, and other regulators. Certain laws may obligate government entities to make regulatory documents available to the public upon request. Proactively making these documents available to the public, by way of a Web site, may reduce the burden associated with requesting these documents, and therefore make it more likely that these documents will be accessible and reviewed by interested stakeholders.

Imminent Health Hazard	<u>8-404.11</u>	Ceasing Operations and Reporting
Imminent Heatin Hazara	<u>8-404.12</u>	Resumption of Operations

An IHH is a product, practice, circumstance, or event that presents an immediate danger to life and health. Failure to appropriately address the IHH by ceasing operations and applying prompt corrective actions is expected to directly lead to an adverse health effect among customers. Section 8-404.11 identifies key conditions that may present an IHH. In some situations, professional judgment of the PIC and regulatory authority are needed to determine whether the condition truly presents an IHH requiring cessation of the operation to promptly remediate the situation, or a critical hazard that can be mitigated with limited disruption of the operation.

An IHH is likely for the following conditions:

- Lack of potable water or extended interruption of water source. (NOTE: Suitable accommodations are
 needed to allow Handwashing and Warewashing if the food operation is not closed. A temporary, portable,
 or improvised handwashing sink should be equipped with a pump mechanism or hands-free water
 dispensing configuration to prevent recontamination of hands during and after use.)
- Inadequate amount of refrigeration capacity. Insufficient capacity means the facility lacks refrigeration storage space to manage all of the following activities safely: segregation/separation of stored foods to prevent cross-contamination; thawing; and cooling. Additionally, inadequate capacity results in overpacking refrigeration units, which may create an unsafe storage environment. For example, reduced air circulation results in unsafe food temperatures for stored products; and build-up of spilled food or residues can promote pests or lead to cross-contamination.

- Sewage backup. (NOTE: The presence of sewage odors does not present an IHH, but should be investigated further to ensure it does not lead to an IHH condition in the future.)
- Lack of hot water.
- Extended interruption of electrical power.
- Misuse of poisonous/toxic chemicals.
- On-set of an apparent food borne illness disease outbreak.
- Fire/flood and other catastrophic manmade or natural disasters.
- Failure to exclude an infectious employee.
- Gross insanitary condition.

Characterization of "gross insanitary conditions" as an IHH is challenging and somewhat subjective. Key indicators include evidence that food has been contaminated or contaminated food-contact surfaces that are in active use. For example, a facility found to have evidence of a rodent infestation presents a variety of sanitation hazards that are noncritical in most cases (§§ 6-501.111 and 6-501.112), but may present a critical hazard when there are indications that food-contact surfaces have been contaminated. The IHH occurs when food packages torn due to rodent feeding are found being used by the food operation, or rodent droppings or other indicators of contamination (for example, using a black light or surface swab test results) are found on food-contact surfaces such as racks of cooking utensils that are stored after being cleaned and sanitized, food prep tables or serving lines, or dinnerware stored on racks in the dining room.

Although the following conditions present insanitary conditions, they do not meet the defined meaning of an IHH.

- Excessive food debris and residues throughout the food establishment (for example, on floors or inside refrigerators).
- Encrusted food or grease build-up inside ovens or exhaust hoods, on griddle cooktops, or on pots/pans.

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A critical violation is a condition that if left uncorrected or is not modified to mitigate the food safety risk is expected to cause an illness or injury to consumers. *Noncritical* provisions are requirements that contribute to the assurance for providing safe food, but independently are not likely to cause a foodborne illness or injury to a consumer. Typically, in order for foodborne illness or injury to occur from noncritical violations, a succession of multiple noncritical provisions related to a single situation must be violated. This occurrence is unlikely; the TSFC standards are deliberately designed to create layers of protection to preclude criteria designated as noncritical from directly contributing to a foodborne illness or injury.

Frequent occurrence or recurrence of noncritical violations does not make the situation more likely to directly cause a foodborne illness or injury. It does, however, serve to indicate a failure in appropriate supervisory level functions. Public health regulators, who notice frequent occurrence or recurrence of noncritical, as well as critical violations, regardless of whether the violation was corrected onsite, should address these findings through an assessment of the PIC's demonstration of knowledge and the PIC's execution of prescribed duties and responsibilities. (See public health reasons for §§ 2-102.11 and 2-103.11 for knowledge and duties of the person-in-charge.)

	<u>8-501.20</u>	Restriction or Exclusion of Food Employee, or Suspension of Operation
See the public health reason discussion	on for <u>§ 2-201.12</u>	

Defined Terms	Accredited Program	Refer to ¶(3) in the definition for 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 organizations 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.

Defined Terms 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, 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 Egg Products Inspection Act.

In producing baluts, fertile duck eggs are incubated for approximately 18 days at a temperature of 108.5°F (42.5°C) 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 99°F (37°C). A balut is a TCS 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		
Defined Terms	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 food operation manager 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 (for example, refrigeration units, dressing room and toilet facilities, food equipment, water and waste systems, and pest control) might be subject to similar regulatory requirements. The Food Code is intended to apply to "food establishments."

Defined Terms	<u>Packaged</u>	Refer to public health reasons for Food Labels §3-602.11
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The definition of "packaged" was revised in $\P(2)$ to clarify when foods packaged at retail need not be labeled.

Defined Terms

TCS is defined in terms of whether or not it requires TCS 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 TCS. 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 135°F (57°C). 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 aw 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 (for example, irradiation, high pressure processing, pulsed light, ozonation);
- Combination products are prepared; or
- Other extrinsic factors (for example, packaging/atmospheres) or intrinsic factors (for example, redox potential, salt content, antimicrobials) are used to control or eliminate pathogen growth.

[Refer to the 2013 FDA Food Code definition "Time/Temperature Control for Safety Food" subparagraph (2)(b) for discussion of water activity (a_w) and pH interactions use of Tables A and B.] Before using Tables A and B as referenced in the FDA Food Code definition for "Time/Temperature Control forSafety Food" to determine whether a food requires TCS, answers to the following questions should be considered:

- Is the intent to hold the food without using time or temperature control?
 - o 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 TCS based on the definition for a TCS food?
- 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 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 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 aw 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 or 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 aw 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 Report, "Evaluation and Definition of Potentially Hazardous Foods" at

http://www.fda.gov/Food/Food/Food/ScienceResearch/SafePracticesforFoodProcesses/ucm0 94141.htm

Instructions for using the following Decision Tree and Table A and Table B [from the 2013 FDA Food Code]:

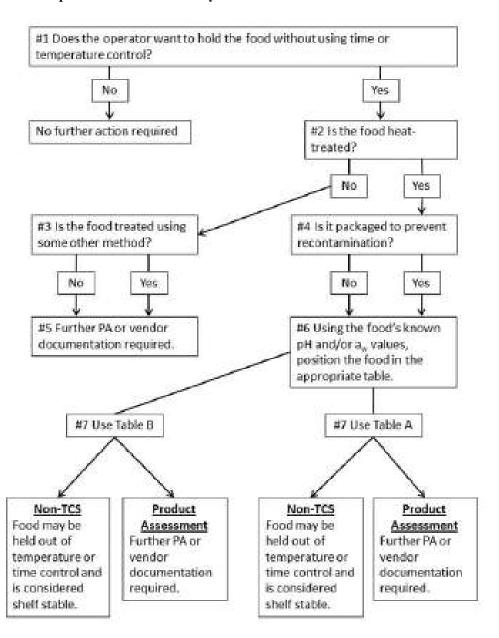
1. Does the operator want to hold the food without using time or temperature control?

- a. No Continue holding the food at ≤41°F (5°C) or ≥135°F (57°C) 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 § 3-401.11) 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 § 3-401.11, 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?
 - 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 recontamination, higher ranges of pH and/or aw 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 "aw values" that contains the aw 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 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.

TCS Food 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



TCS Food - Table A and Table B

(extracted from 2013 FDA Food Code)

Table A. Interaction of pH and aw 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
<u><</u> 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 aw for control of vegetative cells and spores in FOOD not heat-treated or heattreated but not PACKAGED

Aw 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

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GLOSSARY

Section I Acronyms

AAFES

Army/Air Force Exchange Service

ADA

Americans with Disabilities Act of 1990

AFI

Air Force Instruction

ANSI

American National Standards Institute

AR

Army Regulation

ATTP

Army Tactics Techniques and Procedures

BISSC

Baking Industry Sanitation Standards Committee

BUMEDINST

Bureau of Medicine Instruction

CDC

Centers for Disease Control and Prevention

CFP

Conference for Food Protection

CFR

Code of Federal Regulations

CFSAN

Center for Food Safety and Applied Nutrition

CIP

Clean in place

cm

centimenter(s)

CONUS Continental United States
COR Contracting Officer's Representative
COS Corrected Onsite
DA PAM Department of the Army Pamphlet
DeCA Defense Commissary Agency
DFAC Dining Facility
DOD Department of Defense
DODVSA Department of Defense Veterinary Service Activity
DOEHRS Defense Occupational and Environmental Health Readiness System
EEOC U.S. Equal Employment Opportunity Commission
EHEC Enterohemorrhagic <i>E. coli</i>
EHS-Net Environmental Health Specialist-Network
FAC Free Available Chlorine
FCC Family Child Care (homes)
FCWG (Tri-Service) Food Code Working Group
FDA Food and Drug Administration
FFDCA Federal Food, Drug, and Cosmetic Act

Tresh finds and vegetables	
FIFO First in, First Out	
FIFRA Federal Insecticide, Fungicide, and Rodenticide Act	
fpm feet per minute	
FSA Food service assistant	
FSIS Food Safety and Inspection Service	
GRAS Generally recognized as safe	
HACCP Hazard Analysis & Critical Control Point	
HAV Hepatitis A virus	
HAZCOM Hazard communication	
HSP Highly susceptible population	
HUS Hemolytic uremic syndrome	
IAW In accordance with	
IFC Insulated food container	
IFVA Installation food vulnerability assessment	
IG Immune globulin	
IgG Immunoglobulin G	

FF&V

Fresh fruits and vegetables

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National Sanitation Foundation
NSSP National Shellfish Sanitation Program
NTS Nontyphoidal Salmonella
OCONUS outside the continental United States
OMB Office of Management and Budget
OTC Over-the-counter
PA Product Assessment Required
PIC person in charge
PMP Pathogen Modeling Progrm
ppm parts per million
PSP paralytic shellfish poisoning
PWS Performance Work Statement
quats quaternary ammonia compounds
RNA ribonucleic acid
ROP reduced oxygen packaging
RTE ready to eat

NRL

NSF

Glossary

Natural rubber latex

SDBS

 ${\rm SME}$

sodium dodecylbenzenesulfonate

subject matter expert

SOP standing operating procedure
STANAG Standardization Agreement
STEC Shiga toxin-producing <i>Escherichia coli</i>
TB MED Technical Bulletin, Medical
TCS Time/temperature control for safety (food)
TPHC Time as a Public Health Control
TSFC Tri-Service Food Code
UFC Unified Facilities Criteria
UGR Unitized group ration
USAFSAM U.S. Air Force School of Aerospace Medicine
USC U.S. Code
USDA U.S. Department of Agriculture
(US) EPA U.S. Environmental Protection Agency
UHT Ultra-high temperature

Section II Terms

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"** means any substance that the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packaging, processing, preparing, transporting, or holding food; and including any source of radiation intended for any such use). †
 - (2) "Color additive" means a material which—
- (a) Is a dye, pigment, or other substance made by a process of synthesis or similar artifice or extracted, isolated, or otherwise derived from a vegetable, animal, mineral or other source; and
- (b) When added or applied to a food, is capable (alone or through reaction with other substances) of imparting color.

Adulterated

A food shall be deemed to be adulterated based on the following:

- (1) Poisonous, insanitary, etc., ingredients.
- (a) 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.
- (b) 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 the Federal Food, Drug, and Cosmetic Act; or
- (c) If it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a(a) of this title; or
 - (d) If it is or if it bears or contains—
- (i) Any food additive that is unsafe within the meaning of section 348 of the Federal Food, Drug, And Cosmetic Act; or
- (ii) A new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of the Federal Food, Drug, and Cosmetic Act; or
- (e) If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or
- (f) 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
- (g) 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
- (h) 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
- (i) 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 the Federal Food, Drug, and Cosmetic Act.

- (2) Absence, substitution, or addition of constituents.
 - (a) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or
 - (b) If any substance has been substituted wholly or in part therefor; or
 - (c) If damage or inferiority has been concealed in any manner; or
- (d) 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.
- (3) Color additives. If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of the Federal Food, Drug, and Cosmetic Act.
 - (4) Confectionery containing alcohol or nonnutritive substance. If it is confectionery, and—
- (a) 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;
- (b) 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;
- (c) 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.
- (5) 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.
 - (6) Dietary supplement or ingredient: safety.
 - (a) If it is a dietary supplement or contains a dietary ingredient that—
 - (i) Presents a significant or unreasonable risk of illness or injury under—
 - (a) Conditions of use recommended or suggested in labeling, or
- (b) If no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;
- (ii) 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;
- (iii) 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 IAW sections 554 and 556 of title 5 of the U.S. Code to affirm or withdraw the declaration; or
- (iv) Is or contains a dietary ingredient that renders it adulterated under paragraph (1)(a) 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.
- (b) Before the SECRETARY may report to a United States attorney a violation of paragraph (a)(i) 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.
 - (7) Dietary supplement: manufacturing practices.
- (a) 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 (b).

- (b) 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 IAW chapter 5 of title 5 of the U.S. Code.
- (8) 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 the Federal Food, Drug, and Cosmetic Act, 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.
- (9) Noncompliance with sanitary transportation practices. If it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations promulgated under section 350e of the Federal Food, Drug, and Cosmetic Act.

Advanced prepared[†]

A FOOD that is prepared (cooked, partially cooked, or raw) in advance. Marinating FOOD is included as "advanced preparation." Unused portions of prepared FOOD that were intended for use on the day of preparation, but were never placed on a serving line is treated as an "advanced prepared" FOOD. "Advanced prepared" FOODS are not LEFTOVERS.†

ANSI

American National Standards Institute (ANSI) is a private, nonprofit organization that administers and coordinates the U.S. voluntary standardization and conformity assessment system. *Note: For courses certified by ANSI and a CFP-recognized accrediting agency, it is only the exam that is "certified," not the course content itself.*

Approval

Cleared or accepted by the MEDICAL or REGULATORY AUTHORITY. †

Approved

Acceptable to the MEDICAL or REGULATORY AUTHORITY based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

Approved source

A sanitarily approved establishment listed in VETCOM CIR 40-1, *Worldwide Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement*; or an establishment which meets the criteria for exemption from Directory listing as defined by AR 40-657/NAVSUP 4355.4H/MCO P10110.31H and AFI 48-116, and the Department of Defense Veterinary Service Activity Food Risk Evaluation Committee. †

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.

$\mathbf{a}_{\mathbf{w}}$

Water activity which is a measure of the free moisture in a FOOD; it is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Baffle

A flow-directing or obstructing vane or panel used in a warewashing machine to direct or restrict the flow of water. †

Balut

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

A liquid for drinking, including water.

Bottled drinking water

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

Canthaxanthin

A carotenoid pigment widely distributed in nature. †

Casing

A tubular container for sausage products made of either natural or artificial (synthetic) material.

Certification number

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.

Chemically washed

A disinfection process for FF&V using an APPROVED SANITIZING agent to reduce potential hazards associated with surface microbial contamination.

Child care facility

A Nonappropriated Funded (NAF) day care center, including MWR Child, Youth, and School Services, Child Development Centers, and Child Care Centers; FCC homes; Marine Corps Community Services; the Army/Air Force Exchange Service (AAFES), and Navy Child and Youth Programs. †

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

- (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 two or more types of MEAT that have been reduced in size and combined, such as sausages made from two or more MEATS.

Conditional employee

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 ADA.

Conference for Food Protection

Biennially, the CFP brings together representatives from the food industry, government, academia, and CONSUMER organizations to identify problems, formulate recommendations, and implement practices that ensure food safety. (http://www.foodprotect.org/)

Confirmed disease outbreak

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

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.

Consumer self-service

Any area where members of the general public serve themselves without the assistance of a FOOD EMPLOYEE, for example: buffet bars, salad bars, dessert, potato, and soup bars; soft-serve ice cream, customer drink, and coffee bars. †

Contracting Officer also known as KO[†]

An individual with the authority to enter into, administer, and/or terminate contracts and make related determinations and findings.

Contracting Officer's Representative †

An individual designated by the functional activity appointed by the KO and delegated specific authority to monitor contract performance and to perform specific contract administration functions.

Cook-chill

A culinary process where food is cooked to a *just done* status. The food is immediately packaged into a plastic bag, air is expelled, and the bag is closed with a plastic or metal crimp, creating a reduced oxygen environment. The bag is immediately chilled, but not frozen, for storage and reheating at a later time. †

Corrosion-resistant material

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.

Cottage food[†]

A FOOD which is produced in a private home or residence and is not a TCS FOOD.

Counter-mounted equipment

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

Critical control point

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

Critical item[†]

- (1) "Critical item" means a provision of this standard that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental health HAZARD.
 - (2) "Critical item" is an item that is denoted in this publication with an asterisk(*).

Critical limit

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.

Cross-connection

Any physical connection or arrangement between two otherwise separate piping systems, one of which contains potable water, and the other, water of unknown or questionable safety, steam, other gases or liquids, whereby there may be a flow from one system to the other; or any actual or potential connection between a public water supply and a source of contamination or pollution.

Curtain

Refers to the heavy cloth or plastic panels used with WAREWASHING machines. **Curtains** are hung at the WAREWASHING machine openings to prevent the loss of heat and moisture from the machine without obstructing proper operation. †

Cut leafy greens

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 (that is, 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

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.

Debit, debiting, debitable[†]

The terms "debit," "debiting," and "debitable" as used in this publication refer to a Tri-Service Food Code requirement that when not properly complied with or achieved may be reported as a violation on an inspection report.

Disclosure

A written statement that clearly identifies the animal-derived FOODS which are, or can be ordered as, 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, and military directives as applicable. For example, the Overseas Environmental Baseline Guidance Document or country-specific Final Governing Standards establish drinking water standards and require water quality best management practices for installations located outside the United States. †
 - (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

A room or area designated for the storage of PACKAGED or containerized bulk FOOD that is not POTENTIALLY HAZARDOUS (TCS 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

- (1) Portable; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of EOUIPMENT 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.
- (3) Equipment which does not meet the requirements of \P (1) and (2) above can meet this definition if it is movable and weighs 30 pounds (14 kg) or less.[†]

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

The 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.

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, such as hand trucks, forklifts, dollies, pallets, racks, and skids, used for handling or storing large quantities of PACKAGED FOODS that are received from a supplier in a cased or overwrapped lot.

Exclude

To prevent a PERSON from working as an EMPLOYEE in a FOOD ESTABLISHMENT or entering a FOOD ESTABLISHMENT as an EMPLOYEE.

Facility Engineer†

Includes all military, Civilian, and contracted personnel responsible for construction, renovation, or maintenance of FOOD ESTABLISHMENTS on a military installation, camp, or compound.

Farmers market[†]

A "farmers market" means a public and recurring assembly of farmers or individuals, selling their own products directly to the GENERAL PUBLIC. Products typically include FF&V, but may also include unprocessed fish, meats, poultry, dairy products, and grains; and COTTAGE FOODS. TEMPORARY FOOD ESTABLISHMENTS that have been approved by the REGULATORY AUTHORITY may also be operated within the "farmers market."

Field food operation[†]

- (1) Tactical feeding operations carried out by military personnel primarily employing tactical feeding systems or equipment according to field feeding doctrine. Examples of "field food operations" include tactical kitchens such as the Mobile Kitchen Trailer, Containerized Kitchen, and other combat field feeding systems; field feeding sites serving from insulated food containers; or any operation involving preparation and service of operational rations, such as UNITIZED GROUP RATIONS.
- (2) Food service operations established using a tactical feeding system, for example, a FORCE PROVIDER system.
 - (3) Food service operations executed on an air frame or water vessel.
 - (4) "Field food operations" do not include FIELD FOOD SERVICE ESTABLISHMENTS.

Field food service establishment[†]

FOOD ESTABLISHMENTS that are located at a non-permanent military installation in a combat or contingency area of operations and sponsored by a NAF organization such as AAFES, NCX, MCX, or MWR.

- (1) Host nation FOOD ESTABLISHMENTS are treated as a "field food service establishment" when approved to operate on a U.S. military site (camp, base) that has public health (preventive medicine) regulatory oversight responsibility.
 - (2) "Field food service establishments" do not include FIELD FOOD OPERATIONS.

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.

Fixed food operation †

A food operation carried out in a permanent facility designed and equipped to store, prepare, and distribute food.

Food

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. Bottled water is included as a "food"; see BOTTLED DRINKING WATER.

Food and water risk assessment†

A program conducted by veterinary or public health personnel to assess FOOD operations to identify, mitigate, and minimize RISK from contamination; conducted under specific circumstances: short term deployments, for deployed forces during initial entry deployment, exercises, and other short-term operations conducted OCONUS or U.S. territories. Authority is derived from DOD Instruction 6490.03.

Foodborne disease outbreak

The occurrence of two or more cases of a similar illness resulting from the ingestion of a common FOOD.

Food-contact surface

- (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.
- (3) The term "nonfood-contact surface" means the surfaces of FOOD EQUIPMENT that do not meet the criteria specified in paragraphs (1) and (2) of this definition. For example, the outside surface of a refrigerator or stove, a dining room tabletop, a counter top where beverage dispensing units are located, and a FOOD EQUIPMENT and UTENSIL storage rack are "nonfood-contact surfaces."

Food defense †

A collective term used by the FDA, USDA, DHS, and DOD to encompass activities associated with protecting the food supply from deliberate/intentional contamination.

Food employee

- (1) An individual working with unPACKAGED FOOD, FOOD EQUIPMENT or UTENSILS, or FOOD-CONTACT SURFACES.
- (2) Individuals working in a FOOD ESTABLISHMENT and whose duties or responsibilities include receiving FOOD, conducting FOOD preparation or service, or conducting FOOD EQUIPMENT cleaning and SANITIZING. †

Food establishment

- (1) "Food establishment" means an operation that—
- (a) Stores, prepares, packages, serves, or 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 APPROVED 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 used solely for storage and distribution of food, for example, Exchange warehouses and Class I distribution points; †
- (b) An establishment, and VENDING MACHINES, that offer only prePACKAGED FOODS that are not TCS FOODS;
 - (c) A produce stand that only offers whole, uncut FF&V;
- (d) A <u>FOOD PROCESSING PLANT</u>; including those that are located on the PREMISES of a FOOD ESTABLISHMENT. For example, a COOK-CHILL operation located in a FOOD ESTABLISHMENT and that services other FOOD ESTABLISHMENTS or FOOD operations off of the installation is evaluated IAW MIL-STD-3006C.†
- (e) A kitchen in a private home, if only FOOD that is not a TCS FOOD is prepared for sale or service at a function such as a religious, charitable, or organizational bake sale, and if allowed by LAW 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;
- (f) An area where FOOD that is prepared as specified in subparagraph (3)(e) of this definition is sold or offered for human consumption;
- (g) 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. FCC homes and small Child Development Centers are subject to inspection though specific requirements in this publication are waived or amended; †
- (h) A private home that receives catered or home-delivered FOOD; and family housing, troop or guest quarters, and employee lunch rooms if food is prepared for service and consumed by the preparer or guest.
 - (i) A FARMERS MARKET;
 - (j) A COTTAGE FOOD operation; † or
- (k) A unit or organizational function in which FOOD is provided by unit or organizational members rather than a commercial FOOD vendor. †

Food manager

The overall manager of a FOOD ESTABLISHMENT. The **"food manager"** may be the individual who is overall responsible for the operation by providing administrative oversight and accountability of other individuals designated as the PERSON IN CHARGE, or may serve as the PERSON IN CHARGE of the FOOD operation.[†]

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 or a COOK-CHILL operation located in the FOOD ESTABLISHMENT that only supplies the FOOD ESTABLISHMENT and its supported facilities on the installation. †

Force provider[†]

"Force provider" is a containerized and highly deployable Army life support base camp system that utilizes tactical equipment sets and is operated by military units, a combination of military and contract personnel, or exclusively by contract personnel. By doctrine (ATP 4-45) **"force provider"** is intended to be set up/in place from 45 days to 2 years. **"Force provider"** FOOD operations are FIELD FOOD OPERATIONS.

Frozen[†]

FOOD is considered to be "**frozen**" when a product is solid to the touch on all surfaces and liquid products are congealed to the core. Products will begin to freeze at temperatures below 32°F (0°C). The temperature at which a product will become "**frozen**" and the time needed to attain a "**frozen**" state depends on the product size, density, and ingredients.

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 non-aquatic reptiles such as land snakes.
 - (3) "Game animal" does not include RATITES.

General public†

The term "general public" as applied in this publication means military personnel, their dependents, and other installation personnel, to include individuals, unaffiliated with the installation, that participate in events or activities covered by the TSFC. The term is used to differentiate individuals who are not members of a specific group or organization that is being referenced.

General use pesticide

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

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

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 system.

Hazard

A biological, chemical, or physical property that may cause an unacceptable CONSUMER health RISK.

Health practitioner

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

Hermetically sealed container

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 (HSP)

Individuals who are more likely than other people in the general population to experience foodborne disease because they—

- (1) Are immunocompromised; preschool age children (5 years old or younger), or older adults; and
- (2) Obtain 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.
- (3) "Highly susceptible population" includes, but is not limited to, military personnel, DOD Civilian personnel, or contractors operating in field or deployment operations such as training, exercises, combat, or contingency operations, and shipboard feeding. It includes any situation that puts CONSUMERS in an environment that would reduce their immune system capability due to high operational tempo, increased physical and emotional stress, and sleep deprivation, for example, military personnel undergoing Initial Entry Training.[†]

High-risk food†

Any RTE FOOD that will easily support the growth of pathogenic bacteria. "High-risk foods" are more likely to be implicated as vehicles of infectious or toxigenic organisms consumed in foodborne illness incidents.

- (1) "High-risk foods" are usually high in protein, require strict temperature control and protection from contamination and include:
- (a) Cooked meat and poultry and cooked meat/poultry products such as meat pies and pastries, pate, meat stock and gravy;
- (b) Dairy products such as milk, cream, artificial cream, custards, products containing unpasteurized milk, ripened soft and molded cheeses;
- (c) Egg products such as cooked EGGS, quiche and products containing uncooked or lightly cooked EGGS (for example, mayonnaise, mousse, home-made ice cream);
 - (d) Shellfish and other seafoods;
 - (e) Farinaceous dishes including cooked rice, pasta, couscous.
- (2) Some COTTAGE FOODS can present a "high-risk" for supporting the growth of pathogenic bacteria if not properly prepared/processed by the home producer. Examples include—
- (a) Home-preserved low-acid FOODS such as "canned" (for example, in jars) vegetables and meats (or meat products);
 - (b) Fruit and vegetable juices;
 - (c) Jams and jellies; and
 - (d) Unpasteurized honey.

Imminent health hazard

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 or illnesses, and
- (2) The nature, severity, and duration of the anticipated injury or illness.

Individual packaging

Single-use, single-serving packages of condiments, coffee whiteners, and similar products. Individual packaging does not include bulk containers, including pump containers. †

Injected

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."

Installation Commander

An individual with designated authority to be responsible for the control, operation, and maintenance of a military site. The term "installation commander" is synonymous with the term "senior commander" on Army installations. NOTE: For Army sites, the garrison commander is the senior commander's senior executive for installation activities and is responsible for the day-to-day operation and management of the installation and base support services.

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

FOOD preparation and storage UTENSILS.

Law

Applicable local, state, and Federal statutes, regulations, ordinances, and military-specific requirements.

Leftovers†

FOOD that was prepared for a specific meal and offered for service. "**Leftovers**" include unused portions remaining on the serving line.

Linens

Fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments, including cloth gloves.

Low-risk food†

An ambient-stable FOOD that is less-likely to cause a foodborne illness because it has a high acid content (pH 4.5 or lower), or low water content. "Low-risk foods" spoil due to their chemical composition (not microbiological activity). Examples of "low-risk foods" include—

- (1) Bread, biscuits, cereals, crisps and cakes (not cream cakes);
- (2) FOODS that have been preserved, for example; smoked or salted fish;
- (3) Dry goods (that is, FOODS that contain minimal amounts of moisture) such as bread, flour, biscuits;
- (4) Acidic FOODS such as pickled foods, vinegar, fruit;
- (5) Fermented products such as salami, pepperoni;
- (6) FOODS with high sugar/fat content such as jam and chocolate; and
- (7) Canned FOODS (that remain sealed).

Major food allergen

(1) "Major food allergen" are identified by the FDA and include the following items:

- (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

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 (A)(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.

Medical authority†

The commander of the medical treatment facility or tactical unit, or his/her designated representative, whose authority is above the preventive medicine-, public health-, or veterinary unit-designated representative conducting preventive medicine or veterinary inspections or audits under this publication.

Military unit[†]

The term "military unit" as it applies to the specifications for an ORGANIZATIONAL FOOD EVENT is characterized as the lowest level of command (for example, Company, Detachment, or Squadron) applicable to the military component.

Mobile food establishment†

A FOOD ESTABLISHMENT in an enclosed trailer, van, pushcart, recreational vehicle, or similar enclosed mobile FOOD units that are designed to be transported from site to site for the purpose of providing FOOD to CONSUMERS. FOOD ESTABLISHMENTS constructed on a mobile chassis that are operated in a static location for an indefinite amount of time remain classified as a "mobile food establishment." FIELD FOOD OPERATION platforms are exempted from this definition.

Molluscan shellfish

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.

Noncontinuous cooking

- (1) "Noncontinuous 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 the FOOD may be cooled and held for complete cooking at a later time prior to sale or service.
- (2) "Noncontinuous cooking" does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

Nonpublic water system

The term "nonpublic water system" as used in this publication is intended to mean a noncommunity water system such as a private well, transient, or non-transient system that is used to supply POTABLE WATER in support of a food operation.

NSF

National Sanitation Foundation. NSF International is a not-for-profit, nongovernmental organization that develops ANSI standards relative to public health considerations. The NSF, along with other accredited third-party product laboratories, tests and certifies specific food service equipment to established standards and protocols.

Organizational food event[†]

An "organizational food event," as applied in the TSFC, is an event in which FOOD is dispensed (given away or sold) under the auspices of an installation organization through an operation that is not a FOOD ESTABLISHMENT. Examples of an "organizational food event" include:

- (1) An event in which FOOD is prepared and dispensed on the installation by military personnel, Civilian employees, or their Family members to the GENERAL PUBLIC for the purpose of raising organizational funds (for example, a bake sale fundraiser).
- (2) An event internal to a MILITARY UNIT or an installation tenant organization and their Family members (for example, unit picnic or holiday party) and is not open to the GENERAL PUBLIC. Consult DODI 2000.16 for event parameters that constitute a "special event" requiring further action for food defense.
- (3) An "organizational food event" does not include private group activities such as an office potluck or a church supper in which organizational funds are used to purchase FOOD or FOOD is provided by attending members and is not otherwise open to the GENERAL PUBLIC.
 - (4) "Organizational food events" are not TEMPORARY FOOD ESTABLISHMENTS.

Outdated/expired product[†]

Indicated by the—†

- (1) "Best if used by" and "use-by" date, which means the product should retain maximum freshness, flavor, and texture if used by this date. It is not a "purchase-by" or safety date. Beyond this date, the product begins to deteriorate although it may still be edible.
 - (2) "Expiration date" is a manufacturer's best if used by date.
- (3) "Sell-by" or "pull-by" date, used to indicate when to remove the product(s) from the shelves, but there is generally still some leeway for home usage.

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.

Person

An association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency. May include, but is not limited to designated representatives from AAFES, NEX, MCX, MWR, and a KO.

Person-in-charge also known as **PIC**

The individual present at a FOOD ESTABLISHMENT who is responsible for the operation at the time of inspection and has the responsibility and authority to supervise and direct the activities of FOOD EMPLOYEES.

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.

Personal hygiene inspection[†]

The safety and sanitation inspection of an EMPLOYEE performed by the PERSON-IN-CHARGE.

pН

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

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

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 into the drainage system of the PREMISES.

Plumbing system

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

Substances that are not intended for ingestion and are included in four 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.

Potable water†

See **DRINKING WATER**

Potentially Hazardous Food

See TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

Poultry

(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

- (1) The PHYSICAL FACILITY, its contents, and the contiguous land or property under the control of the PERSON-IN-CHARGE; 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 PERSON-IN-CHARGE 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.

Preoperational

As used in this publication, the initial inspection conducted following an *Approval to Operate* a new FOOD concession or newly renovated/constructed FOOD ESTABLISHMENTS. It does not include veterinary inspections conducted to assess daily pre-production activities at commissaries.

Pre-prepared food[†]

See ADVANCED PREPARED

Primal cut

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.

Prime Vendor[†]

As used in this publication, a commercial food service supplier designated by a DOD entity as an approved direct delivery supplier.

Public water system[†]

As stated in 40 CFR 141 National Primary Drinking Water Regulations, a community or noncommunity water system designed of piped water for human consumption if such a system has at least 15 service connections or regularly serves an average of at least 25 individuals at least 60 days out of the year.

Qualified food safety instructor[†]

A PERSON, military or Civilian (unless exempt by military occupational specialty training and experience), who has successfully completed a FOOD safety or FOOD manager certification training course and examination process as specified under § 2-102.20 and has maintained his or her certification through periodic re-examination completed within the interval prescribed by the certification program.

Oualified proctor

A "qualified proctor" is the individual responsible for administering a Food Protection Manager Certification exam and maintaining the integrity of the exam process.

- (1) Proctor responsibilities may include but are not limited to:
 - (a) Registering as a proctor in order to receive exam materials or unlock a web-based examination process;
 - (b) Ensuring students are unaided during the exam process; and
 - (c) Ensuring exam questions are not printed, copied, downloaded, or otherwise reproduced.
- (2) The following individuals may serve as a "qualified proctor":
- (a) An education or learning center staff member from a military or Civilian organization whose duties include proctoring written examinations; or

(b) A military or Civilian individual designated in writing by the unit commander to proctor written examinations.

Ratite

A flightless bird such as an emu, ostrich, or rhea.

Ready-to-eat food also known as RTE 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 IAW 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 TCS 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 IAW 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.
- (j) All shelf stable military combat rations, such as MRE; heat-and-serve rations, unitized group ration-B (UGR-B); and long range patrol and survival rations.[†]
 - (k) ADVANCED PREPARED FOODS for which further cooking is not required for food safety.

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 percent at sea level); and
- (b) A process as specified in Subparagraph (1)(a) of this definition that involves a FOOD for which the HAZARDS *C. botulinum* or *Lm* 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

Solid waste not carried by water through the SEWAGE system.

Regulatory authority[†]

Qualified military or DOD Civilian medical personnel who are representing Army, Air Force, Navy, or Marine Corps preventive medicine, public health, or veterinary services; or the designated representative of the medical commander having jurisdiction over the FOOD ESTABLISHMENT.

Reminder

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

Re-service

The transfer of unused FOOD returned by a CONSUMER after the FOOD was served or sold and in the possession of the CONSUMER, to another PERSON.

Restrict

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

Any check, dirty EGG, incubator reject, inedible, leaker, or loss as defined in 9 CFR 590.

Restricted use pesticide

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

The likelihood that an adverse health effect will occur within a population as a result of a HAZARD in a FOOD.

Safe material

- (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.

Safe temperature[†]

- (1) "Safe temperature" means a temperature that complies with the hot and cold holding temperature requirements stated in \P 3-501.16(A).
- (2) TCS FOODS that are not held at a "safe temperature" are in the temperature danger zone, which promotes rapid bacterial growth that can lead to foodborne illness.

Salmonidae[†]

A family of ray-finned fish, the only living family of the order Salmoniformes. It includes salmon, trout, chars, freshwater whitefishes, and graylings. The Atlantic salmon and trout of the genus Salmo give the family and order their names: salmonids—Trout or salmon.

Sanitization

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 percent reduction, of representative disease microorganisms of public health importance. Associated terms: "sanitizer" and "sanitizing."

Sealed

Free of cracks or other openings that allow the entry or passage of moisture.

Seasonal food establishment[†]

A FOOD ESTABLISHMENT that is operational during a specific season or limited timeframe (greater than 14 days but less than 6 months) and is closed the remainder of the year. Examples of "seasonal food establishments" include a snack bar attached to an outdoor swimming pool, a recreational lakeside snack bar opened during summer months, a snack bar at a ski lift, or an ice cream or frozen desert bar near a recreation area or summer camp.

Secretary[†]

The U.S. Secretary of Health and Human Services.

Self-evaluation[†]

A FOOD safety and sanitation inspection performed by the PERSON-IN-CHARGE or other EMPLOYEE designated to conduct and record HACCP monitoring activities.

Semi-perishable food[†]

FOOD items that are canned, dried, dehydrated, or otherwise processed to the extent that such items may, under normal conditions, be stored in a nonrefrigerated space.

Service animal

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

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

Sewage

Liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

Shellfish control authority

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

Raw, in-shell MOLLUSCAN SHELLFISH.

Shiga toxin-producing *Escherichia coli* (STEC)

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 nonbloody diarrhea, to hemorrhagic colitis (that is, 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

MOLLUSCAN SHELLFISH from which one or both shells have been removed.

Single-service articles

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 waxed 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

The process of moderating the temperature of a FOOD such as allowing a FOOD to gradually increase from a temperature of $-10^{\circ}F$ ($-23^{\circ}C$) to $25^{\circ}F$ ($-4^{\circ}C$) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen FOOD such as shrimp.

Smooth

- (1) A FOOD-CONTACT SURFACE having a surface free of pits and inclusions and 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 will render it difficult to clean.

Sous-vide (pronounced sue veed, French for "under vacuum")†

A specialized reduced oxygen process 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.

Splash zone[†]

Surfaces subject to routine splash, spillage, or other FOOD soiling during normal use. "Splash zone" is an area adjacent to a FOOD zone, or surfaces that normally come in contact with FOOD.

Tableware

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

A thermometer, thermocouple, thermistor, or other device that indicates the temperature of FOOD, air, or water.

Temporary food establishment

A FOOD ESTABLISHMENT that operates for a period of no more than 14 consecutive days in conjunction with a single event or celebration. State, county, or city health departments may require a "temporary food establishment" to possess a valid permit or license, which should be considered during the APPROVAL process by the REGULAROTY AUTHORITY.

<u>Time/Temperature Control for Safety (TCS) Food</u> (previously referred to as "potentially hazardous food (PHF TCS))

- (1) "Time/temperature control for safety food" means a FOOD that requires 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). For additional information regarding FOOD requiring Product Assessment, refer to the definition for "time/temperature control for safety food" specified in the 2013 FDA Food Code, Chapter 1.
 - (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 nonrefrigerated storage and distribution;
- (c) A FOOD that because of its pH (<4.6) or a_W (<0.85) value, or interaction of a_W and pH values, is designated as a nonTCS FOOD as noted in the 2013 FDA Food Code, Chapter 1 definition for "time/temperature control for safety food";
- (d) A FOOD that is designated as Product Assessment Required (PA) as noted in the 2009 FDA Food Code, Chapter 1 definition for "time/temperature control for safety food" 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 ROP, 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 IAW 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.

Tri-Service Food Code Working Group[†]

Comprised of food sanitation and safety subject matter experts from the Air Force, Army, and Navy/Marine Corps public health organizations, and DOD Veterinary Services Activity.

Unitized group ration also known as UGR[†]

Military operational rations configured as either shelf-stable tray packs combined with other semi-perishable products (UGR-H&S, UGR-B and UGR-E), or a combination of perishable and semi-perishable FOOD items (UGR-A).

Utensil

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

A written document issued by the MEDICAL AUTHORITY that authorizes a modification or waiver of one or more requirements of this standard if, in the opinion of the REGULATORY AUTHORITY, a health HAZARD or nuisance will not result from the modification or waiver. The word "variance" as used in this publication refers only to a modification of a FOOD sanitation or safety control in the FOOD ESTABLISHMENT. †

Vending machine

A self-service device that, upon insertion of a coin, paper currency, token, card, 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

The room, enclosure, space, or area where one or more VENDING MACHINES are installed and operated; includes the storage areas and areas on the PREMISES that are used to service and maintain the VENDING MACHINES.

Warewashing

The cleaning and SANITIZING of UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT.

Whole-muscle, intact beef

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

1 March 2019

By Order of the Secretaries of the Army, the Navy, and the Air Force:

Official:

MARK A. MILLEY

General, United States Army Chief of Staff

KATHLEEN S. MILLER Administrative Assistant to the Secretary of the Army

C. FORREST/FAISON III Vice Admiral, Medical Corps

United States Navy

Chief, Bureau of Medicine and Surgery

ROBERT I. MILLER

Major General, USAF, MC, SFS Director, Medical Operations and Research

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