

# **FDA Procedures for Standardization of Retail Food Safety Inspection Officers**

**U.S. Public Health Service**



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## **Procedures Manual**

*Updated to the 2013 FDA Food Code and  
The Supplement to the 2013 Food Code*

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**U.S. Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
College Park, MD 20740**

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## Chapter

# 1 Purpose and Definitions

## Parts

1-1 INTRODUCTION

1-2 DEFINITIONS

1-1 INTRODUCTION

### *Subparts*

**1-101 Background**

**1-102 Introduction**

**1-103 Purpose**

**1-104 Scope**

### **1-101 Background.**

Under the authority of the Public Health Service Act as amended, the U.S. Food and Drug Administration (FDA) has a responsibility to provide assistance to state and local retail food protection programs [42 USC 243]. FDA provides assistance to federal agency retail food protection programs under authority of the Economy Act [31 USC 1535]. Assistance provided to federal, state, and local governmental bodies is also pursuant to FDA's authorities and responsibilities under the Federal Food, Drug, and Cosmetic Act [21 USC 301].

Historically, FDA has met this responsibility by offering a variety of training opportunities and technical assistance based on model codes addressing recommended sanitation and food safety criteria for retail food and foodservice establishments. Providing the model FDA *Food Code* and model code interpretations and opinions is the mechanism through which FDA, as a lead federal food protection agency, promotes uniform implementation of national food regulatory policy among federal, state, tribal, and local agencies that have primary responsibility for retail food

safety oversight or regulation. To ensure greater uniformity, FDA recommends that regulatory jurisdictions adopt the model FDA *Food Code* as law or regulation.

## **1-102 Introduction.**

The main goal of a national food safety program is the reduction and prevention of foodborne illness. To that end, FDA provides several pathways, one of which is the STANDARDIZATION of retail food inspection personnel. This process provides regulatory personnel with the opportunity to subject their knowledge and skills related to the Code's provisions to a uniform system of measurement. The process and criteria for demonstrating proficiency in the required performance areas are described in the *FDA Procedures for Standardization of Retail Food Safety Inspection Officers*.

The procedures are based on the FDA *Food Code* and are updated to reflect current *Food Code* provisions and to include a more refined focus on **FOODBORNE ILLNESS RISK FACTORS**, **FOOD CODE INTERVENTIONS**, and application of the principles of Hazard Analysis and Critical Control Point (HACCP).

It is critical that food safety personnel become standardized through this process to ensure that retail foods are safe, unadulterated, and honestly presented throughout the United States. A **CERTIFICATE OF STANDARDIZATION** as an **FDA STANDARDIZED FOOD SAFETY INSPECTION OFFICER** is issued to all **CANDIDATES** who successfully complete the **STANDARDIZATION** process.

## **1-103 Purpose.**

The purpose of the FDA **STANDARDIZATION** procedure is to promote uniformity of regulatory retail food inspections among federal, state, local and tribal agencies. In addition, it is used to reduce the risk of foodborne illness based on a science-based interpretation of the *Food Code* and effective principles to achieve compliance. The application of the **STANDARDIZATION** procedure will ensure that the **CANDIDATE** recognizes **FOODBORNE ILLNESS RISK FACTORS**, **FOOD CODE INTERVENTIONS**, and **GOOD RETAIL PRACTICES**. The procedure will confirm that the **CANDIDATE** can achieve practical and immediate correction of **Out of Compliance (OOC)** **FOODBORNE ILLNESS** risk factors during the inspection, can effectively communicate with the establishment's staff, can understand and apply HACCP principles and use necessary inspection equipment in a risk-based, real-time regulatory inspection.

This procedure is not intended to provide basic training to individual **CANDIDATES** but rather is intended to confirm a high level of knowledge,

understanding and application of food safety principles.

The CANDIDATE shall meet all the requirements of the procedure in order to be standardized by FDA. Chapter 2 of the procedure describes the qualifications required of the CANDIDATE; Chapter 3 describes the field requirements; and Chapter 4 describes the communication requirements to convey the purpose and findings of the inspection as well as achieve corrective action and compliance. A template for a RISK-BASED STANDARDIZATION INSPECTION can be found in Annex 6.

The template (Annex 6-2) provides a list of recommended inspection activities for both standardization CANDIDATES and regulatory inspectors. Both types of inspection should contain aspects of evaluation/auditing and education/training for short term and long term correction of violations. The primary focus of either type of inspection should be on provisions of the *Food Code* that directly eliminate, prevent or reduce to an acceptable level, hazards associated with foodborne illness or injury or on provisions that support or facilitate them. The 2009 *Food Code* designates these provisions as Priority and Priority Foundation Items, respectively. Earlier versions of the *Food Code* referred to critical and non-critical items.

CANDIDATES who are successful in achieving STANDARDIZATION by FDA are expected to use the procedure to train or standardize other inspectors within their regulatory agency in a manner that is consistent with routine regulatory inspections.

### **1-104 Scope.**

The procedures in this manual describe the process used by the FDA STANDARD in standardizing qualified food safety inspection personnel in retail food establishment inspection techniques based on the FDA *Food Code*. Successful completion of the process results in STANDARDIZATION as a FDA STANDARDIZED FOOD SAFETY INSPECTION OFFICER.

The STANDARDIZATION process encompasses both auditing the performance of the CANDIDATE and training to improve the performance of the CANDIDATE. The FDA STANDARD evaluates the APPLICANT's understanding and application of the *Food Code* provisions during inspections of food establishments. In addition, the FDA STANDARD evaluates the inspection technique used by the applicant, and he or she imparts knowledge during the STANDARDIZATION exercise to assist the CANDIDATE with becoming more proficient in the understanding and application of the *FOOD CODE AND RISK-BASED INSPECTION* technique. The STANDARD will discuss, explain and correct interpretations and marking of the inspection report after each inspection. The STANDARD may also take the opportunity through "teaching moments" during the inspection to point out examples that illustrate new

Code provisions, interpretations or industry changes.

The procedures used in the STANDARDIZATION process are intended as a template for a regulatory inspection conducted by federal, state, local and tribal governing bodies that directly regulate food establishments at the retail level. The process of questioning to clarify procedures and methods helps understanding of operations before and after the inspection and is especially useful during foodborne outbreak investigations.

## **1-2 DEFINITIONS**

### ***Subpart***

#### **1-201 Applicability and Terms Defined**

#### **1-201 Applicability and Terms Defined.**

- (A) Terms defined in this document appear in SMALL CAPS and are defined in (B) below. These definitions apply in the interpretation and application of this procedure.
- (B) Terms Defined:
  - (1) “**APPLICANT**” means an employee of FDA, state, or other regulatory authority who applies for STANDARDIZATION or re-STANDARDIZATION and is recommended to the FDA for STANDARDIZATION or re-STANDARDIZATION by the person’s supervisor.
  - (2) “**CANDIDATE**” means a regulatory officer whose duties include the inspection of retail food and foodservice establishments, may also include STANDARDIZATION of other Food Safety Inspection Officers, and is:
    - (a) An APPLICANT who successfully completes the eligibility requirements for initial STANDARDIZATION, or
    - (b) An FDA STANDARDIZED FOOD SAFETY INSPECTION OFFICER who is applying for re-STANDARDIZATION.
  - (3) “**CERTIFICATE**” means the official document issued by FDA to a STANDARDIZED FOOD SAFETY INSPECTION OFFICER.
  - (4) “**CRITICAL CONTROL POINT (CCP)**” means a point or

procedure in a specific food system where loss of control may result in an unacceptable health risk.

- (5) **“CRITICAL LIMIT (CL)”** means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a CRITICAL CONTROL POINT to minimize the risk that the identified food safety hazard may occur.
- (6) **“FOODBORNE ILLNESS RISK FACTORS”** means improper practices or procedures which are most frequently identified by epidemiologic investigation as a cause of foodborne illness or injury at the retail level:
- Improper holding temperatures;
  - Inadequate cooking;
  - Contaminated equipment;
  - Unsafe source; and
  - Poor personal hygiene.
- (7) **“GOOD RETAIL PRACTICES (GRP)”** means the preventive measures that include practices and procedures which effectively control the introduction of pathogens, chemicals, and physical objects into food. GOOD RETAIL PRACTICES are prerequisites to instituting a HACCP plan or RISK CONTROL PLAN and are not addressed by the FOOD CODE INTERVENTIONS or FOODBORNE ILLNESS RISK FACTORS.
- (8) **“INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST (ICSSL)”** means an FDA publication of shellfish dealers, domestic and foreign, who have been certified by a state or foreign authority as meeting the public health control measures specified in the National Shellfish Sanitation Program (NSSP).
- (9) **“FOOD CODE INTERVENTIONS”** means the preventive measures identified in the FDA *Food Code* to protect consumer health:
- Management’s demonstration of knowledge;
  - Employee health controls;
  - Controlling hands as a vehicle of contamination;
  - Time/temperature parameters for controlling pathogens; and
  - Consumer advisory.

- (10) “RISK-BASED INSPECTION”** means a food establishment inspection approach that utilizes the technical skills and attributes identified in the five performance areas, **FOODBORNE ILLNESS RISK FACTORS** and **FOOD CODE INTERVENTIONS**, Good Retail Practices, Application of HACCP, Inspection Equipment, and Communication as specified in Subpart 3-102 with particular emphasis on **FOOD CODE INTERVENTIONS** and **FOODBORNE ILLNESS RISK FACTORS**.
- (11) “RISK CONTROL PLAN (RCP)”** means a mutually agreed upon written plan (between the **CANDIDATE** and the management of the food establishment) that describes a management system for control of **FOODBORNE ILLNESS RISK FACTORS**. The plan delineates necessary records, responsible personnel, what needs to be controlled, and how it will be controlled.
- (12) “STANDARD”** means a person employed by FDA who is responsible for standardizing a **CANDIDATE**. This person shall be standardized by the National **STANDARD** or designee from FDA’s Center for Food Safety and Applied Nutrition (**CFSAN**). The **STANDARD** represents the FDA position on all issues during the **STANDARDIZATION** process.
- (13) “STANDARDIZATION”** means the process whereby a **CANDIDATE** demonstrates the knowledge and skills to satisfy requirements for a **STANDARDIZED FOOD SAFETY INSPECTION OFFICER** as stated in this procedure
- (14) “STANDARDIZED FOOD SAFETY INSPECTION OFFICER”** means a person who has been standardized by FDA and has successfully met all requirements for **STANDARDIZATION**.

Chapter

# 2 Qualifying for Standardization

Part

2-1 PREREQUISITE TRAINING AND EXPERIENCE

2-1 PREREQUISITE TRAINING AND EXPERIENCE

*Subparts*

**2-101 Objective**

**2-102 Eligibility**

**2-101 Objective.**

This chapter explains the prerequisite training and experience requirements for CANDIDATES to qualify for FDA STANDARDIZATION. In order for FDA to engage in the process of field inspections for the purpose of STANDARDIZATION, the CANDIDATE must qualify by fulfilling the training and experience requirements specified in this chapter. These eligibility requirements only apply to first time APPLICANTS for FDA STANDARDIZATION. Once standardized, CANDIDATES for re-STANDARDIZATION only need to meet the STANDARDIZATION maintenance requirements (see Section 3-403).

**2-102 Eligibility.**

(A) APPLICANTS for initial FDA STANDARDIZATION must:

- (1) Be routinely engaged in retail food protection program work;
- (2) Have job responsibility for conducting food safety training and/or STANDARDIZATION of other regulatory personnel;

- (3) Have successfully completed the “pre” and “post” curriculum coursework for new hires cited in Trained Regulatory Staff (Standard 2) in the Draft Voluntary National Retail Food Regulatory Program Standards<sup>1</sup> through ORA-U on-line training<sup>2</sup>.
  - a) Evidence of completion of equivalent training and experience for any of these courses may be verified by the STANDARD.
  - b) CANDIDATES can demonstrate equivalency by showing that the course objectives for each course meet 80% of the ORA-U training objectives and evidence of successful completion is provided; and
- (4) Have fulfilled one or more of the following prerequisites:
  - a) At least one year of full time experience in retail food establishment inspections within the past three years; or
  - b) At least 100 retail food establishment inspections performed within the past three years, such as regulatory, training, or consultation inspections.
- (5) Have successfully completed, for re-STANDARDIZATION, within the preceding two years at least 20 contact hours of training in the application of food science and related studies such as microbiology, epidemiology, regulations, plan review or Hazard Analysis and Critical Control Point (HACCP) principles.

<sup>1</sup> Draft Voluntary National Retail Food Regulatory Program Standards, available at <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm>

<sup>2</sup> ORA-U On-Line Training, available at <http://www.fda.gov/Training/ForStateLocalTribalRegulators/default.htm>

Chapter

# 3

## Standardization: Field Requirements and Administration

Parts

- 3-1 SCOPE
- 3-2 INSPECTION EQUIPMENT REQUIREMENTS
- 3-3 INSPECTIONS
- 3-4 FDA STANDARDIZATION
- 3-5 STANDARDIZATION RENEWAL
- 3-6 TERMINATION OF FIELD EXERCISE OR  
STANDARDIZATION SUSPENSION OR REVOCATION
- 3-7 APPEALS

### 3-1 SCOPE

*Subparts*

- 3-101 Objective
- 3-102 Performance Areas
- 3-103 Methodology

#### **3-101 Objective.**

This chapter explains the field requirements leading to FDA STANDARDIZATION.

#### **3-102 Performance Areas.**

The following areas of performance shall be addressed by the CANDIDATE during the food establishment inspections and evaluated by the

STANDARD:

**(A) FOODBORNE ILLNESS RISK FACTORS and FOOD CODE INTERVENTIONS:**

The CANDIDATE shall demonstrate knowledge of current FDA *Food Code* provisions related to FOOD CODE INTERVENTIONS and FOODBORNE ILLNESS RISK FACTORS and the ability to interpret and apply them.

**(B) GOOD RETAIL PRACTICES:**

The CANDIDATE shall demonstrate knowledge of current FDA *Food Code* provisions related to GOOD RETAIL PRACTICES and the ability to interpret and apply them.

**(C) Application of HACCP Principles:**

The CANDIDATE shall demonstrate the ability to verify compliance with an existing HACCP plan and apply HACCP principles in the development of flow charts and RISK CONTROL PLANS (RCPS). In the absence of a HACCP Plan, the CANDIDATE shall demonstrate the ability to apply all seven HACCP principles to the inspection process.

**(D) Inspection Equipment:**

The CANDIDATE shall be equipped and familiar with inspection equipment essential to each food establishment inspection. During the inspection, the CANDIDATE shall demonstrate knowledge of proper use of essential inspection equipment.

**(E) Communication:**

The CANDIDATE shall demonstrate the ability to effectively communicate with the person in charge and food employees during all phases of the inspection and explain significant inspection findings to the person in charge at the conclusion of the inspection.

**3-103 Methodology.**

**(A) Initial STANDARDIZATION:**

The FDA STANDARD and the CANDIDATE shall conduct eight joint field inspections of food establishments (including at least one with a HACCP plan) selected by the STANDARD. The food establishments selected for inspection during STANDARDIZATION

should be in risk categories 2, 3, or 4 as described in Annex 5 of the *Food Code* and shall include the observation of such processes as cooking, cooling, hot/cold holding, reheating, and complex food preparation. All eight inspections for initial STANDARDIZATION should be completed within a reasonable period of time, not to exceed 12 months.

**(B) Re-STANDARDIZATION:**

The FDA STANDARD and the CANDIDATE will conduct six joint field inspections of food establishments (including at least one with a HACCP Plan) selected by the STANDARD. The food establishments selected for inspection during re-STANDARDIZATION should be in risk category 2, 3, or 4 as described in Annex 5 of the *Food Code*. All six inspections for re-STANDARDIZATION should be completed within a reasonable period of time, not to exceed three years.

**(C) Options of the STANDARD:**

The STANDARD has the option of adjusting the time period, type of facility selected, and methodology for inspection at any time to enhance the effectiveness of the STANDARDIZATION process.

**(D) Performance Evaluation Methods:**

The performance of the CANDIDATE shall be evaluated by the FDA STANDARD using the methods outlined in Table 1:

**Table 1. Summary of Evaluation Methods for Each Performance Area.**

<b>PERFORMANCE AREA</b>	<b>INITIAL STANDARDIZATION<sup>1</sup></b>	<b>RE-STANDARDIZATION<sup>2</sup></b>
<b>FOODBORNE ILLNESS RISK FACTORS and FOOD CODE INTERVENTIONS</b>	Joint Inspections	Joint Inspections
<b>GOOD RETAIL PRACTICES</b>	Joint Inspections	Joint Inspections
<b>Application of HACCP Principles</b>	<ul style="list-style-type: none"> <li>• RISK CONTROL PLAN;</li> <li>• Process Flow Charts;</li> <li>• Verification of existing HACCP Plan; and</li> <li>• Orally communicates the Seven Principles of HACCP.</li> </ul>	<ul style="list-style-type: none"> <li>• RISK CONTROL PLAN;</li> <li>• Process Flow Charts (optional); and</li> <li>• Verification of existing HACCP Plan.</li> </ul>
<b>Inspection Equipment</b>	Field Observations	Field Observations
<b>Communication</b>	Field Observations	Field Observations

- NOTE:**
1. All of the initial STANDARDIZATION requirements are to be completed during a total of 8 joint inspections with the FDA STANDARD, over a period not to exceed 12 months.
  2. The re-STANDARDIZATION requirements are to be completed during a total of 6 joint inspections with the FDA STANDARD over a period not to exceed 3 years.

## **3-2 INSPECTION EQUIPMENT REQUIREMENTS**

### *Subparts*

#### **3-201 Equipment Use**

#### **3-202 Equipment List**

#### **3-201 Equipment Use.**

Specific inspection equipment is required to effectively and accurately conduct an inspection and evaluate risk factors that contribute to foodborne illness in retail food operations. The CANDIDATE shall be evaluated on the proper use of the inspection equipment during all inspections [refer to Subpart 3-302(C)]. Even though some equipment is listed as optional, it may be essential for some food establishment inspections, depending on the circumstances (FDA *Food Code*, Annex 5).

#### **3-202 Equipment List.**

(A) The following is a list of the essential equipment recommended to evaluate a retail food or foodservice operation:

- (1) Necessary inspection forms and administrative materials;
- (2) Head cover: baseball cap, hair net, or equivalent;
- (3) Thermocouple temperature measuring device;
- (4) Maximum registering thermometer or temperature-sensitive tape for verifying hot water warewashing final rinse temperature;
- (5) Chemical test kit for different chemical sanitizer types;
- (6) Flashlight; and
- (7) Alcohol swabs.

(B) The following is a list of optional equipment recommended to evaluate a retail food or foodservice operation:

- (1) Light meter;
- (2) Pressure gauge;
- (3) Measuring tape;
- (4) Time-temperature data logger;
- (5) pH meter;
- (6) Water activity meter;
- (7) Camera; and
- (8) Lab coat or equivalent protection to cover street clothes.

## **3-3 INSPECTIONS**

### *Subparts*

#### **3-301 Field Exercise**

#### **3-302 Performance Criteria**

#### **3-303 Assessment – Level of Agreement with Performance Criteria**

### **3-301 Field Exercise.**

#### **(A) Roles:**

##### **(1) Role of the CANDIDATE.**

During all joint field food establishment inspections, the CANDIDATE shall take the lead. The CANDIDATE shall make introductions and determine who the person in charge is at the beginning of each inspection.

The CANDIDATE shall record all observations and inspection data collected during the inspection. For the purpose of tracking temperature patterns, it is recommended that the CANDIDATE perform a preliminary survey of food temperatures early in each inspection.

At various times during the field exercise the CANDIDATE shall be directed to perform specific tasks, such as explaining code requirements, citing FDA *Food Code* provisions, calibrating inspection equipment, and preparing flow charts or reviewing HACCP records to demonstrate proficiency in each area.

##### **(2) Role of the STANDARD.**

FDA STANDARDIZATION is not a joint training exercise. It is an assessment with an auditing and training component. The role of the STANDARD is to confirm the CANDIDATE's ability to conduct a routine inspection in realistic timeframes recognizing the **FOODBORNE ILLNESS RISK FACTORS** that most frequently contribute to foodborne illness, the **FOOD CODE INTERVENTIONS** that prevent foodborne illness, and **GOOD RETAIL PRACTICES**. The STANDARD will also confirm that the CANDIDATE can achieve immediate correction of Out of Compliance (OOC) risk factors, practically apply HACCP principles, demonstrate effective communication skills and correctly use inspection equipment.

The STANDARD's role is primarily to observe the CANDIDATE during the performance of a routine inspection and evaluate his/her performance during the STANDARDIZATION exercise. The STANDARD may offer procedural guidance to instruct the CANDIDATE to focus on specific performance areas or demonstrate specific technical skills during the course of the exercise. The STANDARD will provide constructive corrective action in the interest of STANDARDIZATION as appropriate throughout the exercise.

The STANDARD will ensure that the CANDIDATE is briefed prior to beginning the exercise on expectations before and during the exercise. Areas that will be covered include the following:

- The need for the CANDIDATE to contact the jurisdiction in the work area for permission to conduct inspections, if necessary
- An understanding that the STANDARDIZATION exercise will be based on the requirements in the current version of the *FDA Food Code* and most recent version of the *Standardization Procedures*
- Calibrating thermocouples and thermometers before the STANDARDIZATION exercise
- Having all inspection equipment and clothing [lab coat (optional), closed toed shoes, hat or hair net, etc.].
- Selecting food establishments in risk category 2, 3, or 4 as described in ANNEX 5 of the *Food Code*
- Conducting RISK-BASED INSPECTIONS which emphasizes the evaluation of **FOODBORNE ILLNESS RISK FACTORS** and **FOOD CODE INTERVENTIONS** but also demonstrates knowledge and application of GRPs
- Taking final cooking temperatures of all types of animal food cooked in the establishment when possible
- Achieving corrective action for Out of Compliance (OOC) **FOODBORNE ILLNESS RISK FACTORS** before leaving the facility
- Developing a **RISK CONTROL PLAN** with management/person-in-charge
- Preparing three food preparation process flow diagrams based on observed practices (one for each of the three food preparation processes)
- Explaining the seven HACCP principles.
- Citing the *Food Code* requirements for any OOC **FOODBORNE ILLNESS RISK FACTORS** or **FOOD CODE INTERVENTIONS** on the inspection report
- Using appropriate inspection equipment
- Demonstrating effective communication skills

- Conducting an inspection as closely as possible to a real-time regulatory inspection by the end of the exercise

**(B) Performance Areas:**

The STANDARD will evaluate the CANDIDATE's ability to conduct a RISK-BASED INSPECTION and apply *Food Code* requirements and principles in the following performance areas: (a more detailed guide to the concepts considered under each performance area is found in Annex 6 of this procedure).

- (1) **FOODBORNE ILLNESS RISK FACTORS and FOOD CODE INTERVENTIONS** – utilize an approach that effectively identifies high risk operations and behaviors in the food establishment and focuses an inspection on determining the compliance status of those related **FOODBORNE ILLNESS RISK FACTORS** and/or **FOOD CODE INTERVENTIONS**.;
- (2) **GOOD RETAIL PRACTICES** – demonstrates knowledge of the *Food Code* by recognizing and properly citing the provisions of the Code not designated as **FOODBORNE ILLNESS RISK FACTORS** and **FOOD CODE INTERVENTIONS**;
- (3) **Application of HACCP (Hazard Analysis and Critical Control Point) principles** – demonstrates the ability to verify compliance with an existing HACCP plan and apply HACCP principles in the development of flow charts and **RISK CONTROL PLANS (RCPs)**. In the absence of a HACCP plan, the CANDIDATE shall demonstrate the ability to apply all seven HACCP principles to the inspection process;
- (4) **Inspection equipment** – the CANDIDATE shall be equipped and familiar with inspection equipment essential to each food establishment inspection. During the inspection, the CANDIDATE shall demonstrate knowledge of proper use of essential inspection equipment; and
- (5) **Communication** – the CANDIDATE shall demonstrate the ability to effectively communicate with the person in charge and food employees and explain significant inspection findings to the person in charge at the conclusion of the inspection.

**(C) Determining Code Citations:**

The STANDARD will make the final determination of the *Food Code* citation for any observed violations.

**(D) Comparison of Findings:**

Following each inspection, the CANDIDATE and STANDARD will compare findings to determine any disagreements for **FOODBORNE ILLNESS RISK FACTORS, FOOD CODE INTERVENTIONS and GOOD RETAIL PRACTICES.**

At the conclusion of the field exercise, the STANDARD shall tabulate and review the CANDIDATE’S inspection results and other observations to determine if the CANDIDATE has successfully completed the requirements for STANDARDIZATION (See Table 2). The checklist for STANDARDIZATION performance areas (Annex 6-1) can be used as an aid in this determination.

**(E) Termination of the Exercise/Inspection.**

When the STANDARD terminates the STANDARDIZATION exercise before completing the eight (initial) or six (re-STANDARDIZATION) inspections because of the CANDIDATE’S inability to meet (or the likelihood of not meeting) the performance criteria, the STANDARD will work with the CANDIDATE and his/her supervisor to develop an action plan to help the CANDIDATE meet the performance criteria.

**3-302 Performance Criteria.**

To be standardized by FDA, a CANDIDATE shall meet the following criteria for each performance area:

**(A) **FOODBORNE ILLNESS RISK FACTORS and FOOD CODE INTERVENTIONS and GOOD RETAIL PRACTICES:****

**(1) **Inspection Report:****

At the conclusion of each RISK-BASED INSPECTION, the CANDIDATE shall complete the FDA STANDARDIZATION Inspection Report (Annex 2, Section 1), based on observations and data collected during the inspection. The CANDIDATE shall determine which items on the inspection report form were in or out of compliance, not observed, and/or not applicable based on the observations.

**(2) **CANDIDATE Scoring:****

The STANDARD shall grade each FDA STANDARDIZATION Inspection Report (Annex 2, Section 1), by circling each incorrectly marked item and discussing these items with the CANDIDATE after each inspection. The STANDARD may mark an item “S” to reflect a disagreement in a case where the

CANDIDATE has the opportunity to make an observation or take a measurement and fails to do so, and intervention by the STANDARD would alert the CANDIDATE of the missed opportunity. A scoring of “S” should be used in instances such as when there is an opportunity to take a cooking temperature of a hamburger, but the CANDIDATE does not take the temperature and subsequently marks 18 (B) as NO. The STANDARD’s scoring of an item as “S” represents a disagreement between the CANDIDATE and the STANDARD.

At the conclusion of each inspection, the STANDARD shall determine the number of disagreements on items and record that number in the chart provided in Annex 5. At the completion of the final inspection, the STANDARD shall total the number of disagreements for all food establishments inspected.

- (a) To satisfy the “FOODBORNE ILLNESS RISK FACTORS and FOOD CODE INTERVENTIONS” performance area, the CANDIDATE shall not disagree with the STANDARD on more than 12 items in any one establishment in this section of the STANDARDIZATION Inspection Report and have an average score of at least 90%.
- (b) To satisfy the “GOOD RETAIL PRACTICES” performance area, the CANDIDATE shall not disagree with the STANDARD on more than 5 items in any one establishment in this section of the STANDARDIZATION Inspection Report and have an average score of at least 85%.

**(B) Application of HACCP Principles:**

During the food establishment inspections, the CANDIDATE shall demonstrate the proper inspection approach for food establishments with pre-existing HACCP plans and those without HACCP plans. Each Candidate shall demonstrate an understanding of HACCP by:

- (1) **Flow Charts:** (Required for initial STANDARDIZATIONS; optional for re-STANDARDIZATIONS)

- (a) **Preparing Process Flow Charts:**

During the joint inspections, the STANDARD shall select a total of three food preparation processes for the CANDIDATE to describe on a flow chart, to include:

- (i) Process 1 – “No Cook Step”
- (ii) Process 2 – “Same Day Service”

**(iii) Process 3 – “Complex Food Preparation”**

The CANDIDATE shall develop each flow chart using information gained through actual observations of operational steps during an inspection. Information gained through discussions with the person in charge and/or food employees should be used to substitute for a lack of actual observations, i.e. when operational steps in the process do not occur during the inspection. On each flow chart, the CANDIDATE shall identify the hazards, each CRITICAL CONTROL POINT, and the CRITICAL LIMITS. The CANDIDATE shall indicate the CRITICAL LIMITS as stated by the FDA *Food Code* and by the establishment (if the establishment’s CRITICAL LIMITS differ from those in the *Food Code*). In addition, the CANDIDATE shall also indicate to the STANDARD any CRITICAL CONTROL POINTS that the establishment did not control.

**(b) Requirements:**

The STANDARD shall grade the three flow charts based on the correct identification of hazards, CRITICAL CONTROL POINTS, and the CRITICAL LIMITS. To satisfy this requirement, the three flow charts may contain no more than two errors or omissions. The FDA Retail HACCP Manual entitled, *Managing Food Safety: A Regulator’s Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems*, and the current edition of the FDA *Food Code* will be the reference documents for this exercise.

**(2) RISK CONTROL PLAN: (Required for both initial STANDARDIZATION and re-STANDARDIZATION)**

**(a) Developing a RISK CONTROL PLAN:**

During at least one of the joint inspections, the STANDARD will select a CRITICAL CONTROL POINT that the CANDIDATE has determined is not in compliance with CRITICAL LIMITS set by the FDA *Food Code*. The CANDIDATE shall complete Annex 3-1, in order to demonstrate a clear understanding of the observation, process used, associated hazards, CRITICAL LIMITS, and corrective actions that are being targeted for a RISK CONTROL PLAN. The CANDIDATE shall guide the person in charge in developing a RISK CONTROL PLAN. The RISK CONTROL PLAN should stress simple control measures that can be integrated into the daily routine of the food

establishment. The plan should be brief and address the following points:

- (i) Specific observation(s) noted during inspection
- (ii) Applicable code violation(s) (optional)
- (iii) FOODBORNE ILLNESS RISK FACTOR to be controlled
- (iv) Hazard (most common, significant);
- (v) What must be achieved to gain compliance in the future;
- (vi) How active managerial control will be achieved (Who is responsible for the control, what monitoring and record keeping is required, who is responsible for monitoring and completing records, what corrective actions should be taken when deviations are noted, and how long the plan is to continue); and
- (vii) How the results of implementing the RISK CONTROL PLAN will be communicated back to the inspector.

**(b) Requirements:**

To satisfy the requirements, all seven points (i through vii) shall be addressed in the RISK CONTROL PLAN. The CANDIDATE is not required to ask the person in charge to commit to implementation of the RISK CONTROL PLAN (Annex 3, Section 1).

**(3) HACCP Plans: (Required for both initial STANDARDIZATION and re-STANDARDIZATION)**

**(a) Verification of HACCP Plans:**

During the joint inspections, the CANDIDATE shall select at least one food establishment to inspect that has implemented a HACCP Plan. The CANDIDATE shall demonstrate the ability to verify that the HACCP Plan is properly implemented by reviewing the food establishment's monitoring procedures and record keeping, verifying that the CRITICAL LIMITS are met, and substantiating that corrective actions are taken when the CRITICAL LIMITS are not met. The STANDARD shall select at least one CRITICAL CONTROL POINT for the CANDIDATE to verify.

The CANDIDATE shall review the records for the selected CRITICAL CONTROL POINT(S) for three specific 24 hour periods, which shall include records for the current day, if possible, and two additional days selected at random. Based on this review, the CANDIDATE shall make the

following determinations regarding monitoring, record keeping, and the performance of corrective action for a total of nine HACCP Plan record answers (Annex 4, Chart 2):

- (i) Required monitoring was performed on the three selected dates;
- (ii) Accurate and consistent records appear for the three selected dates; and
- (iii) Corrective action was documented in accordance with the plan when CRITICAL LIMITS were not met on each of the three selected dates (CANDIDATE shall select the three days of records through discussions with the establishment's management. One of the days selected must be the current day).

**(b) HACCP Principles (For initial STANDARDIZATION only):**

The CANDIDATE shall orally communicate to the STANDARD the HACCP principles and how they would apply to the food establishment's operation.

**(c) Requirement:**

The CANDIDATE shall document the findings on the HACCP Plan Verification Summary Chart (Annex 4, Section 2, Chart 2). To satisfy this requirement, the CANDIDATE and the STANDARD shall be in agreement with at least eight out of the nine answers on the HACCP Plan Verification Summary Chart.

**(C) Inspection Equipment:**

The CANDIDATE shall have essential equipment (listed in 3-202) available for use during each inspection and shall demonstrate knowledge of necessary equipment to conduct food establishment inspections. The CANDIDATE shall know how to properly use and maintain the equipment. Specifically, the CANDIDATE shall demonstrate that the temperature measuring device is accurate at 0°C (32°F) and 100°C (212°F).

**(D) Communication:**

In accordance with Chapter 4 of this procedure, the CANDIDATE shall take the lead in communicating with industry personnel during each of the inspections in three areas:

- (1) Introduction;
- (2) Open Dialogue and Discussion with the Person in Charge;  
and
- (3) Exit Conference.

During the inspections, the CANDIDATE shall demonstrate by example the concepts of food safety such as seeking immediate, appropriate correction of risk factors, eliciting responses about employee health, washing hands at the appropriate place and time, and wearing the proper inspection apparel. The STANDARD shall observe and evaluate the CANDIDATE by focusing attention on communication skills that relay to the person in charge, the compliance status and any observations, concerns, and alternatives for compliance. Satisfactory performance is achieved if this information is conveyed in a way that is understood, accepted, and acted upon. The STANDARD can assess this using the checklist in ANNEX 6-1 and the Template in ANNEX 6-2.

### **3-303 Assessment - Level of Agreement with Performance Criteria.**

- (A) Chart 3 in Annex 5 of this procedure can be used to tally the number of disagreements on the items between the STANDARD and the CANDIDATE in the “FOODBORNE ILLNESS RISK FACTORS and FOOD CODE INTERVENTIONS” and “GOOD RETAIL PRACTICES” sections of the STANDARDIZATION Inspection Report.
- (B) **Criteria for Success:**
  - (1) To achieve STANDARDIZATION, the CANDIDATE shall meet minimum requirements for the three (3) Performance Areas described in 3-302 (A) and (B). The CANDIDATE may receive a “Needs Improvement” classification in the “Equipment” and “Communication” Performance Areas and still be standardized.
  - (2) When one or both of these Performance Areas is classified as “Needs Improvement,” the CANDIDATE and the CANDIDATE’S supervisor shall be notified that the “Needs Improvement” area must be satisfactorily addressed before re-STANDARDIZATION is granted. Prior to re-STANDARDIZATION, the CANDIDATE’S supervisor must notify the STANDARD that the area(s) of concern have been addressed.

**Table 2. SUMMARY OF LEVEL OF AGREEMENT REQUIRED FOR EACH PERFORMANCE AREA.**

<b>PERFORMANCE AREA</b>	<b>LEVEL OF AGREEMENT</b>
<b>FOODBORNE ILLNESS RISK FACTORS and FOOD CODE INTERVENTIONS</b>	<ul style="list-style-type: none"> <li>• <b>No more than 12 disagreements</b> in any one food establishment and an <b>average score of 90%</b> for all inspections in the STANDARDIZATION. (Minimum of 80= No more than 12 disagreements out of a total of 62 items)</li> </ul>
<b>GOOD RETAIL PRACTICES</b>	<ul style="list-style-type: none"> <li>• <b>No more than five disagreements</b> in any one food establishment and an <b>average score of 85%</b> for all inspections in the STANDARDIZATION. (Minimum of 80 = No more than five disagreements out of a total of 27 items)</li> </ul>
<b>Application of HACCP Principles</b>	<ul style="list-style-type: none"> <li>• <b>3 Process Flow Charts:</b> (optional for re-STANDARDIZATION) Maximum of two errors or omissions [3-302(B)(1)]</li> <li>• <b>1 RISK CONTROL PLAN:</b> four parts accurately addressed [3-302(B)(2)]</li> <li>• <b>1 HACCP Plan Verification:</b> Correctly review documentation records on three different dates for a food establishment with a HACCP Plan [3-302(B)(3)] with agreement on at least eight out of the nine answers on Chart 2 (Annex 4, Section 2)</li> </ul> <p><b>Knowledge of HACCP principles:</b> Accurately lists the seven principles and explains how each applies to a food establishment (initial STANDARDIZATION only)</p>
<b>Inspection Equipment**</b>	<ul style="list-style-type: none"> <li>• CANDIDATE has equipment from the essential equipment list</li> <li>• CANDIDATE demonstrates knowledge and use of essential equipment</li> </ul> <p>(Rate as Satisfactory or Needs Improvement)</p>
<b>Communication**</b>	<p><b>Observations of:</b></p> <ul style="list-style-type: none"> <li>• Introductions to person in charge (4-102)</li> <li>• Fact finding questions through interview with person in charge (4-103)</li> <li>• CANDIDATE setting an example [4-102(B)]</li> <li>• Exit conference with person in charge (4-104)</li> </ul> <p>(Rate as Satisfactory or Needs Improvement)</p>
<p>** Performance Areas deemed in need of improvement shall be satisfactorily addressed before re-STANDARDIZATION.</p>	

## **3-4 FDA STANDARDIZATION**

### *Subparts*

#### **3-401 CERTIFICATE Issuance**

#### **3-402 STANDARDIZATION Expiration**

#### **3-403 STANDARDIZATION Maintenance**

#### **3-401 CERTIFICATE Issuance.**

Upon achieving the required level of agreement with the STANDARD, the CANDIDATE is awarded the CERTIFICATE of an FDA STANDARDIZED FOOD SAFETY INSPECTION OFFICER. A CERTIFICATE recognizing the accomplishment is forwarded to the CANDIDATE and notification is sent to the CANDIDATE'S supervisor within 60 days.

#### **3-402 STANDARDIZATION Expiration.**

STANDARDIZATION is valid for a period of three years. The date that STANDARDIZATION is issued and the date that it expires appear on the CERTIFICATE issued by the STANDARD.

#### **3-403 STANDARDIZATION Maintenance.**

- (A) Official records of all STANDARDIZATIONS in retail food inspection shall be maintained by the STANDARD for at least three years.
- (B) STANDARDIZATION shall be maintained in good standing for the three-year period when the STANDARDIZED FOOD SAFETY INSPECTION OFFICER:
  - (1) Each year, attends the annual Retail Food Protection Seminar held in the STANDARDIZED FOOD SAFETY INSPECTION OFFICER'S FDA region;
  - (2) Continuing Education and Training – Each CANDIDATE that is standardized will accumulate 20 contact hours of continuing education every 36 months after initial STANDARDIZATION is completed. The CANDIDATE qualifies for one contact hour for each hour's participation in any of the following activities:
    - (a) Professional symposiums/college courses,
    - (b) Workshops, and
    - (c) Food-related training provided by government agencies;

- (3) Annually conducts and documents STANDARDIZATION exercises, in accordance with this document, with at least five other retail food program inspection personnel; and
- (4) Annually accomplishes and documents at least one of the following activities:
  - (a) Assists at least five retail food establishments in the development of RISK CONTROL PLANS (RCP). The STANDARDIZED FOOD SAFETY INSPECTION OFFICER shall submit a report describing the outcome of the RCP to the STANDARD, or
  - (b) Conducts or coordinates and documents to the STANDARD at least five training courses related to the retail food protection program, or
  - (c) Performs and documents to the STANDARD any combination of training courses or RISK CONTROL PLANS that equals five.
- (C) Upon written request by the STANDARDIZED FOOD SAFETY INSPECTION OFFICER, the requirements listed in Paragraph 3-403(B) may be adjusted by the STANDARD due to special situations or circumstances.

## **3-5 STANDARDIZATION RENEWAL**

### *Subparts*

#### **3-501 Requirements**

#### **3-502 Expired STANDARDIZATION**

### **3-501 Requirements.**

In order to renew a person's STANDARDIZATION, the STANDARD and the STANDARDIZED FOOD SAFETY INSPECTION OFFICER shall conduct six STANDARDIZATION inspections, as described in Part 3-3 and Chapter 4. A person's STANDARDIZATION may not be extended beyond the expiration date unless the person successfully fulfills the criteria described in Part 3-3 and Chapter 4 and has complied with the STANDARDIZATION maintenance criteria listed in Part 3-4.

### **3-502 Expired STANDARDIZATION.**

If a person's STANDARDIZATION expires and is not renewed and the person subsequently reapplies for STANDARDIZATION, the person shall apply in writing to the STANDARD for re-STANDARDIZATION giving the reasons why the person is qualified and should be re-STANDARDIZED. The person shall submit a nomination form signed by the person's program supervisor. The STANDARD shall respond in writing to the program supervisor advising whether or not FDA will proceed with re-STANDARDIZATION and the conditions under which STANDARDIZATION renewal may be accomplished.

## **3-6 TERMINATION OF THE FIELD EXERCISE OR STANDARDIZATION SUSPENSION OR REVOCATION**

### *Subparts*

#### **3-601 Termination of Field Exercise**

#### **3-602 STANDARDIZATION Suspension or Revocation**

#### **3-603 Request for Re-STANDARDIZATION After Termination, Suspension, or Revocation**

### **3-601 Termination of Field Exercise.**

- (A) The STANDARD has the option to terminate the field exercise at any time during the STANDARDIZATION procedure if the CANDIDATE is not properly prepared to achieve the required level of agreement.
  
- (B) The STANDARD shall notify the CANDIDATE and the CANDIDATE's supervisor in writing with the reasons for termination of the field exercise. The STANDARD may offer the CANDIDATE and his/her supervisor the opportunity to develop a follow-up action plan designed to prepare the CANDIDATE for a successful STANDARDIZATION exercise. The CANDIDATE and his/her supervisor may choose to pursue this avenue or not. If the CANDIDATE declines the option described in paragraph (B) above or fails the completed field exercise, the STANDARD shall document the results of the field exercise, with the reasons for termination of the field exercise. This information shall be forwarded to the CANDIDATE's supervisor and a copy shall be placed in the FDA file. All evidence and conclusions reached by the Agency shall be documented in writing by the STANDARD and shall be kept for 3 years in accordance with the Freedom of Information Act.

### **3-602 STANDARDIZATION Suspension or Revocation.**

- (A) When a STANDARDIZED FOOD SAFETY INSPECTION OFFICER fails to fulfill the required maintenance activities described in Part 3-4, the STANDARD shall consult with the STANDARDIZED FOOD SAFETY INSPECTION OFFICER to fully examine the reasons for the failure.
- (B) Before suspension or revocation, the STANDARD shall consult with other appropriate personnel in the STANDARDIZED FOOD SAFETY INSPECTION OFFICER's agency and within FDA including: the Center for Food Safety and Applied Nutrition (CFSAN), Retail Food-Cooperative Programs Coordination Staff, Retail Food Protection Team (RFPT); and the Office of Regulatory Affairs (ORA), Division of Federal-State Relations (DFSR).
- (C) The STANDARD, the RFPT, and the DFSR shall reach a decision as to whether:
  - (1) No action should be taken;
  - (2) A warning letter should be sent to the STANDARDIZED FOOD SAFETY INSPECTION OFFICER and the person's supervisor or agency;
  - (3) The STANDARDIZATION should be suspended temporarily, with notice regarding conditions required for reinstatement; or
  - (4) The STANDARDIZATION should be revoked.
- (D) The STANDARD shall notify the STANDARDIZED FOOD SAFETY INSPECTION OFFICER and the supervisor of the STANDARDIZED FOOD SAFETY INSPECTION OFFICER, in writing, of the Agency's decision.
- (E) All evidence and conclusions reached by the Agency shall be documented in writing by the STANDARD and shall be kept for 3 years in accordance with the Freedom of Information Act.

### **3-603 Requests for Re-STANDARDIZATION after Termination, Suspension, or Revocation.**

CANDIDATES may apply for another opportunity to become standardized when an unsuccessful field exercise is terminated by the STANDARD or a STANDARDIZATION suspension or revocation occurs. Before reapplying, CANDIDATES should improve their skills and areas of weakness.

## **3-7 APPEALS**

### *Subparts*

#### **3-701 Appeals Board Members**

#### **3-702 Filing an Appeal**

#### **3-703 Appeals Board Meeting**

#### **3-704 Hearings**

#### **3-701 Appeals Board Members.**

Representatives from the following organizations will comprise the STANDARDIZATION Appeals Board (Appeals Board):

- (A) An FDA Regional Food Specialist (other than the involved STANDARD);
- (B) A Retail Food Protection Team representative; and
- (C) An Office of Partnerships representative.

#### **3-702 Filing an Appeal.**

The CANDIDATE, after being notified of the CANDIDATE'S failure to successfully achieve STANDARDIZATION or re-STANDARDIZATION, may appeal the decision. Should the CANDIDATE elect to submit an appeal, this action must be initiated within thirty days of the date of the written notification of the termination, suspension, or revocation.

#### **3-703 Appeals Board Meeting.**

Upon receipt of a CANDIDATE'S appeal by the FDA, a meeting of the Appeals Board will be held to determine if the argument regarding the failed STANDARDIZATION process is worthy of being heard.

#### **3-704 Hearings.**

##### **(A) Preliminary Hearing:**

If the appeal is not convincing, the decision of the FDA STANDARD to terminate the field exercise will stand. If the Appeals Board determines that the CANDIDATE'S argument holds merit, the CANDIDATE and the FDA STANDARD shall be notified in writing that a hearing will be held, including a date and time for the hearing.

**(B) Hearing Procedure:**

At the hearing, the following procedure will be followed:

- (1) The CANDIDATE will present the CANDIDATE'S argument for reversing the STANDARD'S decision;
- (2) The Appeals Board will have the opportunity to question the action or conduct of the CANDIDATE and the STANDARD; and
- (3) The Appeals Board will make a decision regarding the FDA STANDARD'S decision. The Appeals Board decision will be either to let the decision stand or to consider conducting an additional standardization exercise.

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# 4

# Communication Skills

## Part

### 4-1 APPLICATION

### 4-1 APPLICATION

#### *Subparts*

#### **4-101 Objective**

#### **4-102 Introduction**

#### **4-103 Dialogue and Discussion with the Person in Charge**

#### **4-104 Exit Conference**

#### **4-101 Objective.**

Skillful communication is essential to the inspection process in order to effectuate needed changes by the person in charge. This chapter highlights the importance of communication skills during an inspection. Activities and responsibilities involved in a retail food inspection program require a person to speak and to listen effectively.

Many different types of communication skills and approaches are necessary and valuable during the inspection process. The CANDIDATE shall be required to take the lead in communicating with industry personnel during all inspections and the STANDARD shall evaluate the CANDIDATE'S communication skills.

#### **4-102 Introduction.**

(A) The CANDIDATE shall be required to make all introductions. A complete introduction consists of:

- (1) Introducing all persons participating in the inspection;
- (2) Presenting credentials or identification;

- (3) Describing the purpose and flow of the inspection;
- (4) Identifying and explaining to the person in charge that it will be necessary to ask questions about the operation during the inspection; and
- (5) Explaining that this is not intended as a regulatory inspection and that there will be no written report left at the end of the inspection; however, significant findings will be brought to the attention of the person in charge. Where required by the jurisdiction, a regulatory inspection can also be made and a report left with the person in charge.

(B) In addition to verbal and written communication, the CANDIDATE shall also use the inspection process to communicate and demonstrate food safety concepts by example. Activities such as immediate correction of risk factors, focusing inspection activities on **FOODBORNE ILLNESS** risk factors and **FOOD CODE** interventions, proper handwashing, sanitizing thermometers before probing foods, and wearing the proper inspection apparel should be used to reinforce spoken and written communications.

#### **4-103 Dialogue and Discussion with the Person in Charge.**

The CANDIDATE shall have a discussion with the person in charge to determine:

- (A) If a HACCP plan exists, and if so, whether the person in charge understands the principles of the HACCP plan and is ensuring that the employees are effectively using the plan;
- (B) What training is provided for employees and managers that is relevant to applying the **FOOD CODE INTERVENTIONS** and controlling **FOODBORNE ILLNESS RISK FACTORS**;
- (C) Specific responses to key employee health related activities; and
- (D) What Potentially Hazardous Foods/Time-Temperature Control for Safety Foods are on the menu and what production activities are ongoing at the time of inspection.

#### **4-104 Exit Conference.**

At the exit conference, the CANDIDATE shall clearly:

- (A) Convey and discuss in detail with the person in charge the inspection findings including:
  - (1) The compliance status of the food establishment describing each significant violative condition and, where appropriate, acceptable compliance alternatives,
  - (2) The response and plans of the person in charge for correcting violations, including a RISK CONTROL PLAN, and
  - (3) Corrective actions observed during the inspection. Such proactive food safety measures should be commended; however, the CANDIDATE should use this as an opportunity to explain what might have happened if an inspection had not occurred and the corrective action had not been identified.
- (B) Explain the public health significance of the **FOODBORNE ILLNESS RISK FACTORS** and **FOOD CODE INTERVENTIONS, GOOD RETAIL PRACTICES**, and the **CRITICAL CONTROL POINTS** which do not meet the **CRITICAL LIMITS** as established in the *FDA Food Code*; and
- (C) Demonstrate the ability to discuss and resolve issues that the person in charge might not agree with or clearly understand in a courteous and professional manner.

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**ANNEX 1**

**FDA STANDARDIZATION NOMINATION FORM**

**TO: FDA REGIONAL FOOD AND DRUG DIRECTOR**

**FROM:** \_\_\_\_\_

**SUBJECT: REQUEST FOR FDA STANDARDIZATION**

**DATE:** \_\_\_\_\_

**APPLICANT INFORMATION**

<b>Candidate's Name:</b>		<b>Title:</b>	
<b>Office Telephone Number:</b>		<b>Home Telephone Number:</b>	
<b>Office Fax Number:</b>	<b>Office Email Address:</b>	<b>Agency:</b>	
<b>Office Address:</b>	<b>City:</b>	<b>State:</b>	<b>Zip:</b>
<b>Home Address:</b>	<b>City:</b>	<b>State:</b>	<b>Zip:</b>

**BACKGROUND INFORMATION**

<b>Length of Service With Agency:</b>

<b>Present Duties / Date Assigned:</b>

**FDA STANDARDIZATION NOMINATION FORM**

<b>Prior Retail Food Safety Experience:</b>	<b>Dates:</b>

<b>Formal Education/ Training Background:</b>

<b>Continuing Education:</b> (List hours of education with course titles/dates, within the last 2 years) Note: 20 contact hours minimum to qualify for nomination.

<b>Other Prerequisites Completed:</b>

**SUPERVISOR'S SIGNATURE** (Confirming request for nomination):

**NAME (Print):** \_\_\_\_\_

**NAME (Signature):** \_\_\_\_\_ **Date:** \_\_\_\_\_

**TITLE:** \_\_\_\_\_

## ANNEX 2-1

### FDA STANDARDIZATION INSPECTION REPORT

Establishment Name:		Type of Facility:	
Physical Address:		Person in Charge:	
City:	State:	Zip:	County:
Inspection Time In:	Inspection Time Out:	Date:	Candidate's Name:
Agency:	Standard's Name:	Person Completing Form: (circle one) Candidate OR Standard	

#### Foodborne Illness Risk Factors

Food from Unsafe Sources  
 Improper Holding Temperatures  
 Poor Personal Hygiene  
 Inadequate Cooking Temperatures  
 Contaminated Equipment/ Cross-Contamination

#### Food Code Interventions

Demonstration of Knowledge  
 Hands as a Vehicle of Contamination  
 Employee Health  
 Time/Temperature Relationships  
 Consumer Advisory

For each item, indicate one of the following for **OBSERVATIONAL STATUS**:

IN – Item found in compliance  
 OUT – Item found out of compliance

NO – Not observed  
 NA – Not applicable

The Standard may mark an item “S” to reflect a disagreement in a case where the Candidate has the opportunity to make an observation or take a measurement and fails to do so, and intervention by the Standard would alert the Candidate to the missed opportunity.

#### ABBREVIATIONS

**“CCP” means** Critical Control Point  
**“CL” means** Critical Limit  
**“GRP” means** Good Retail Practice  
**“HACCP” means** Hazard Analysis and Critical Control Point  
**“HSP” means** Highly Susceptible Population  
**“ICSSL” means** Interstate Certified Shellfish Shippers List  
**“TCS Food” means** Time/Temperature Control for Safety Food  
**“RTE” means** Ready-to-Eat

**FOODBORNE ILLNESS RISK FACTORS AND *FOOD CODE* INTERVENTIONS**

**Supervision**

**STATUS**

- |                      |   |
|----------------------|---|
|                      | <b>1. Person in charge present, demonstrates knowledge, and performs duties</b>                     |
| <b>IN OUT</b>        | A. Assignment – PIC   |
| <b>IN OUT</b>        | B. Demonstration  |
| <b>IN OUT</b>        | C. Duties of PIC  |
| <b>IN OUT<br/>NA</b> | <b>2. Certified Food Protection Manager – Establishment has a Certified Food Protection Manager</b> |

**Employee Health**

- |               |   |
|---------------|---|
| <b>IN OUT</b> | <b>3. Management, food employee and conditional employee; Knowledge, responsibilities and reporting</b> |
| <b>IN OUT</b> | <b>4. Proper use of restriction and exclusion and reporting</b>   |
| <b>IN OUT</b> | <b>5. Clean-up of Vomiting and Diarrheal Events</b>   |

**Good Hygienic Practices**

- |                      |  |
|----------------------|--|
| <b>IN OUT<br/>NO</b> | <b>6. Proper eating, tasting, drinking, or tobacco use</b> |
| <b>IN OUT<br/>NO</b> | <b>7. No discharge from eyes, nose, and mouth</b>          |

**Preventing Contamination by Hands**

- |                         |   |
|-------------------------|---|
| <b>IN OUT<br/>NO</b>    | <b>8. Hands clean &amp; properly washed</b>   |
| <b>IN OUT<br/>NA NO</b> | <b>9. No bare hand contact with RTE foods or a pre-approved alternative procedure properly followed</b> |
|                         | <b>10. Adequate handwashing sinks properly supplied and accessible</b>                                  |
| <b>IN OUT</b>           | A. Adequate handwashing sinks conveniently located and accessible for employees                         |

**IN OUT** B. Handwashing sinks supplied with hand cleanser/sanitary towels/hand drying devices/signage

**Approved Source**

**11. Food obtained from approved source**

**IN OUT** A. All food from regulated food processing plants/no home prepared or canned foods/standards for eggs, milk, juice

**IN OUT**  
**NA NO** B. All Molluscan shellfish from ICSSL listed sources/no recreationally caught shellfish received or sold/all fish commercially caught/raised or approved by the Regulatory Authority

**IN OUT**  
**NA NO** C. Game animals and wild mushrooms approved by regulatory authority

**IN OUT**  
**NA NO** **12. Food received at proper temperature**

**IN OUT** **13. Food in good condition, safe, and unadulterated**

**14. Required records available: shellstock tags, parasite destruction**

**IN OUT**  
**NA NO** A. Written documentation of parasite destruction maintained for 90 days for fish products that are intended for raw or undercooked consumption

**IN OUT**  
**NA NO** B. Shellstock tags maintained for 90 days in chronological order

**Protection from Contamination**

**15. Food separated and protected**

**IN OUT**  
**NA NO** A. Separating raw animal foods from raw RTE food and separating raw animal food from cooked RTE food

**IN OUT**  
**NA NO** B. Raw animal foods separated from each other during storage, preparation, holding, and display

**IN OUT** C. Food protected from environmental contamination

**IN OUT**  
**NA** **16. Food-contact surfaces: cleaned and sanitized**

**17. Proper disposition of returned, previously served, reconditioned, and unsafe food**

**IN OUT**

A. After being served or sold to a consumer, food is not reserved

**IN OUT**

B. Discarding or reconditioning unsafe, adulterated, or contaminated Food

**Time/Temperature Control for Safety(TCS Food)**

**18. Proper cooking time & temperatures**

**IN OUT  
NA NO**

A. Raw eggs broken on request and prepared for immediate service cooked to 63°C (145°F) for 15 seconds

**IN OUT  
NA NO**

B. Comminuted fish, meat, game animals commercially raised for food and raw eggs not prepared for immediate service and comminuted meat on a child's menu cooked to 68°C (155°F) for 15 seconds or the time/temperature relationship specified in the chart in the Food Code.

**IN OUT  
NA NO**

C. Whole meat roast, including beef, corned beef, lamb, pork, cured pork roasts and formed roasts, cooked to 54°C (130°F) for 112 minutes or as chart specifies and according to oven parameters per chart

**IN OUT  
NA NO**

D. Ratites and injected meats or mechanically tenderized meats cooked to 68°C (155°F) for 15 seconds or the time/temperature relationship specified in the chart in the Food Code.

**IN OUT  
NA NO**

E. Poultry; baluts; stuffed fish/meat/poultry/ratites/pasta or stuffing containing fish, meat, poultry, or ratites; cooked to 74°C (165°F) for 15 seconds

**IN OUT  
NA NO**

F. Wild game animals cooked to 74°C (165°F) for 15 seconds

**IN OUT  
NA NO**

G. Whole-muscle, intact beef steaks cooked to surface temperature of 3°C (145°F) on top and bottom and a cooked color changes is achieved on all external surfaces.

**IN OUT  
NA NO**

H. Raw animal foods rotated, stirred, covered, and heated to 74°C (165°F) in microwave. Food stands for 2 minutes after cooking.

**IN OUT  
NA NO**

I. All other raw animal foods cooked to 63°C (145°F) for 15 seconds

**IN OUT  
NA NO**

J. Raw animal foods cooked, using a non-continuous-cooking process, cooked to the time/temperature requirements specified for the particular raw animal food.

**19. Proper reheating procedures for hot holding**

**IN OUT  
NA NO**

A. TCS Food that is cooked and cooled on premises is rapidly reheated within 2 hours to 74°C (165°F) or above for 15 seconds for hot holding

**IN OUT  
NA NO**

B. Food reheated to 74°C (165°F) or above in microwave for hot holding

**IN OUT  
NA NO**

C. Commercially processed, RTE food reheated to 57°C (135°F) or above for hot holding

**IN OUT  
NA NO**

D. Remaining unsliced portions of roasts reheated for hot holding using minimum over parameters

**20. Proper cooling time & temperatures**

**IN OUT  
NA NO**

A. Cooked TCS Food cooled from 57°C (135°F) to 21°C (70°F) within 2 hours and from 57°C (135°F) to 5°C (41°F) or below in hours

**IN OUT  
NA NO**

B. TCS Food prepared from ambient temperature and/or pre-chilled ingredients) cooled to 5°C (41°F) or below in 4 hours

**IN OUT  
NA NO**

C. Foods (milk/shellfish) received at a temperature according to law cooled to 5°C (41°F) or below in 4 hours

**IN OUT  
NA NO**

D. Immediately upon receiving, raw eggs placed under refrigeration that maintains ambient air temperature of 7°C (45°F)

**21. Proper hot holding temperatures**

**IN OUT  
NA NO**

A. TCS Food maintained at 57°C (135°F) or above, except during preparation, cooking, or cooling, or when time is used as a public health control

**IN OUT  
NA NO**

B. Whole meat roasts held at a temperature of 54°C (130°F) or above

**22. Proper cold holding temperatures**

**IN OUT  
NA**

A. TCS Food maintained at 5°C (41°F) or below, except during preparation, cooking, cooling, or when time is used as a public health control

**IN OUT  
NA NO**

B. Untreated raw eggs stored in 7°C (45°F) ambient air temperature

**23. Proper date marking & disposition**

IN OUT  
NA NO

A. Date marking for RTE, TCS Food prepared on-site or opened commercial container held for more than 24 hours

IN OUT  
NA NO

B. Discarding RTE, TCS Food prepared on-site or opened commercial container held at  $\leq 5^{\circ}\text{C}$  ( $41^{\circ}\text{F}$ ) for  $\leq 7$  days

IN OUT  
NA NO

**24. Time as a public health control: procedures & records**

**Consumer Advisory**

IN OUT  
NA

**25. Consumer advisory provided for raw or undercooked animal foods**

**Highly Susceptible Populations**

**26. Pasteurized foods used; prohibited foods not offered**

IN OUT  
NA

A. Prepackaged juice/beverage containing juice with a warning label [21 CFR, Section 101.17 (g)] not served

IN OUT  
NA

B. Using pasteurized eggs in recipes if eggs are to be undercooked; or are combined unless: cooked to order & immediately served; used immediately before baking and thoroughly cooked; or prepared under a HACCP plan controlling *Salmonella* Enteritidis

IN OUT  
NA

C. Raw or partially cooked animal food and raw seed sprouts not served

IN OUT  
NA

D. Foods not re-served under certain conditions

**Chemical**

IN OUT  
NA

**27. Food additives: approved and properly used**

**28. Toxic substances properly identified, stored, and used**

IN OUT

A. Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items properly identified, stored, and used

IN OUT  
NA

B. Poisonous or toxic materials held for retail sale properly stored

**Conformance with Approved Procedures**

**29. Compliance with variance, specialized process, ROP Criteria & HACCP plan**

**IN OUT  
NA**

A. Reduced Oxygen Packaging (ROP) as specified in 3-502.12 permitted without a variance under certain specified conditions in accordance with a required HACCP plan or without a required HACCP Plan

**IN OUT  
NA**

B. Operating in accordance with approved variance and/or HACCP plan as required

**IN OUT  
NA**

C. When packaged in a food establishment, juice is treated under a HACCP plan to reduce pathogens or labeled as specified in the Food Code

**Score: Number of disagreements for Intervention/Risk Factors \_\_\_\_\_**

**GOOD RETAIL PRACTICES (GRPs)**

**Safe Food and Water**

**IN OUT  
NA**

**30. Pasteurized eggs used where required**

**IN OUT**

**31. Water and ice from approved source**

**IN OUT  
NA**

**32. Variance obtained for specialized processing methods**

**Food Temperature Control**

**IN OUT**

**33. Proper cooling methods used; adequate equipment for temperature control**

**IN OUT  
NA NO**

**34. Plant food properly cooked for hot holding**

**IN OUT  
NA NO**

**35. Approved thawing methods used**

**IN OUT**

**36. Thermometers provided & accurate**

**Food Identification**

IN OUT            37. Food properly labeled; original container

**Prevention of Food Contamination**

IN OUT            38. Insects, rodents, & animals not present

IN OUT            39. Contamination prevented during food preparation, storage & display

IN OUT            40. Personal cleanliness

IN OUT            41. Wiping cloths: properly used & stored

IN OUT            42. Washing fruits & vegetables

**Proper Use of Utensils**

IN OUT            43. In-use utensils: properly stored

IN OUT            44. Utensils, equipment & linens: properly stored, dried, & handled

IN OUT            45. Single-use/single-service articles: properly stored & used

IN OUT            46. Slash-resistant and cloth gloves used properly

**Utensils, Equipment and Vending**

IN OUT            47. Food & non-food contact surfaces cleanable, properly designed, constructed, & used

IN OUT            48. Warewashing facilities: installed, maintained, & used; test strips

IN OUT            49. Non-food contact surfaces clean

**Physical Facilities**

IN OUT            50. Hot & cold water available; adequate pressure

IN OUT            51. Plumbing installed; proper backflow devices

IN OUT            52. Sewage & waste water properly disposed

IN OUT            53. Toilet facilities: properly constructed, supplied, & cleaned

IN OUT            54. Garbage & refuse properly disposed; facilities maintained

**IN OUT**

**55. Physical facilities installed, maintained, & clean**

**IN OUT**

**56. Adequate ventilation & lighting; designated areas used**

**Score:**

**Number of disagreements for Good Retail Practices**

\_\_\_\_\_

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**REPORT MARKING INSTRUCTIONS WITH 2013 *FOOD CODE***  
**REFERENCES**

The following provides guidance to the CANDIDATE on marking the form.

**Compliance Status**

For each item on the form, indicate one of the following for **COMPLIANCE STATUS**

IN - Item found in compliance

NO - Not observed

OUT - Item found out of compliance

NA - Not applicable

Where no option occurs for marking NO or NA, these have been removed from the Marking Instructions.

The STANDARD may mark an item “S” to reflect a disagreement in a case where the CANDIDATE has the opportunity to make an observation or take a measurement and fails to do so, and intervention by the STANDARD would alert the CANDIDATE to the missed opportunity.

***The Reliance of Statements made by the Person In Charge in Determining Compliance with the Provisions of the Food Code***

The FDA Procedures for Standardization of Food Safety Inspection Officers stresses open communication between the CANDIDATE and Person in Charge and food employees. To be an effective communicator, the CANDIDATE is expected to ask questions relative to the flow of food through the establishment, preparation and cooking procedures, as well as employee health and normal everyday operation of the facility. Responses to questions give the CANDIDATE a better idea of the **FOODBORNE ILLNESS RISK FACTORS** that could be present in the establishment and allows for better budgeting of time while conducting the inspection. In addition, comments made by these individuals can often be used to support or augment direct observations and, in some very limited cases, can be used as the sole basis for determining compliance with provisions of the *Food Code*.

By assessing **FOODBORNE ILLNESS RISK FACTORS** that are suspected of being uncontrolled at times other than the inspection (i.e., before or after the inspection), time can be better spent on troubleshooting problems and bringing the **FOODBORNE ILLNESS RISK FACTORS** back under control through proper intervention strategies. The CANDIDATE is expected to relay deficiencies in the operation to the Person in Charge so that on-site and long-term corrective action can be initiated.

**Guidelines for Using Statements Made by the Person in Charge or Food Employees to Determine Compliance**  
**(Further guidance is provided in the Marking Instructions)**

- **Marking IN and OUT of Compliance**

Generally, a mark of OUT must be based on actual observations noted in the establishment at the time of the inspection. Regulatory action must be based on evidence gathered during an inspection and not based solely on a Person in Charge's incorrect answer to a question asked by the CANDIDATE. For instance, the Person in Charge tells the inspector, "I slice ham using my bare hands." This would most definitely be an item for discussion with management but would not, in and of itself, justify a mark of OUT for no bare contact with RTE food. In this case, the CANDIDATE must actually observe a food employee touching ready-to-eat food with his or her bare hands before marking OUT of compliance.

There are some items on the inspection report for which the CANDIDATE may rely solely on discussions with management or food employees to determine the compliance status. These items relate to policies, including those that relate to the establishment's employee health policy and also those that address Part 3-8 of the *Food Code* (highly susceptible populations).

Frequently, observations are made while a food is undergoing a process, i.e. cooling and reheating, when the CANDIDATE must ask the Person in Charge or food employees questions to support or augment actual observations made. For instance, if a food item is observed cooling in a walk-in cooler and a temperature check reveals a temperature greater than 41°F, questions should be asked regarding the length of time the food has been cooling to properly determine compliance with the time/temp requirements of the *Food Code*. Also, this information is vital to determine the most appropriate on-site corrective action.

- **Marking Not Observed (NO) or Not Applicable (NA)**

In order to fully complete the inspection form as required, the CANDIDATE should question the Person in Charge and food employees, as appropriate, concerning the types of food served and food preparation processes conducted in the establishment even at times when the inspector is not there. For instance, if thawing is not actually observed, the CANDIDATE should ask questions about whether or not thawing is actually conducted in the establishment **at any time** to properly mark thawing as either NO or NA.

## FOODBORNE ILLNESS RISK FACTORS AND *FOOD CODE* INTERVENTIONS

### Supervision

#### STATUS

#### **1. Person in charge present, demonstrates knowledge, and performs duties**

This item must be marked IN or OUT of compliance. The person in charge (PIC) has three assigned responsibilities - Presence; Demonstration of Knowledge; and Duties.

#### IN OUT

#### **A. Assignment – PIC**

Person in charge is present. This item is marked OUT of compliance if there is no PIC per - ¶¶ 2-101.11 (A) and (B).

NA  
NO

**Do Not Mark** this item NA  
**Do Not Mark** this item NO

2-101.11 Assignment <sup>(PF)</sup>

#### IN OUT

#### **B. Demonstration**

This item must be marked IN or OUT of compliance. The PIC has three options for demonstrating knowledge.

This item is marked IN compliance if the PIC meets at least **one** of the options. The three options for demonstration of knowledge allowed by the Food Code are:

1. Certification by an accredited program as specified in ¶ 2-102.20 (A).
2. Complying with this Code by having no violations of Priority items during the current inspection; or
3. Correct responses to the CANDIDATE's questions regarding public health practices and principles applicable to the operation. The inspector should assess this item by asking open-ended questions to evaluate the PIC's knowledge in each of the areas enumerated in Subparagraphs 2-102.11 (C) (1) and (4-16). Questions can be asked during the initial interview, menu review, or throughout the inspection as appropriate. The CANDIDATE should ask a sufficient number of questions to enable the inspector to make an informed decision concerning the PIC's knowledge of the Code requirements and public health principles as they apply to the operation. The dialogue should be extensive enough to reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce food that are safe, wholesome, unadulterated, and accurately represented.

NA

**Do Not Mark** this item NA

**NO**                    **Do Not Mark** this item NO

2-102.11 (A) - (B) and (C) (1) and (4-16) Demonstration <sup>(PF)</sup>  
2-102.20 (A) Food Protection Manager Certification (Non-Debitable)

**NOTE 1:** “Incorrect” responses to questions regarding public health practices and Principles [except for Subparagraphs 2-102.11 (C) (2) (3), which are captured under Item 3], in and of themselves, are not sufficient for marking other items on this inspection form OUT. For instance, if the PIC does not know the *Food Code* requirement for cooling, yet no actual OUT of compliance observations are made with regard to cooling during the inspection, then OUT of compliance cannot be marked for Item 20.

**IN OUT**            **C. Duties of PIC**

This item must be marked IN or OUT of compliance based on the interaction and observation with the PIC and food employees. The CANDIDATE needs to determine the systems or controls the PIC has put into practice regarding oversight and/or routine monitoring of the Duties listed in § 2-103.11. This is accomplished by 1) discussion with the PIC, and 2) verified through observation that the systems or controls are actually being implemented. This concept is commonly referred to as Active Managerial Control.

This item is marked OUT of compliance when there is a pattern of non-compliance and obvious failure by the PIC to ensure employees are complying with the duties listed in § 2-103.11. Since marking this item out of compliance requires judgment, it is important that this item not be marked for an isolated incident, but rather for an overall evaluation of the PIC's ability to ensure compliance with the duties described in § 2-103.11.

**NA**                    **Do Not Mark** this item NA

**NO**                    **Do Not Mark** this item NO

2-103.11 (A-N) and (P) Person in Charge - Duties <sup>(PF)</sup>

**IN OUT**            **2. Certified Food Protection Manager – Establishment has a Certified Food Protection Manager**

This item is marked IN compliance if an establishment employee, with management and supervisory responsibility, has a Food Protection Manager Certification from an accredited program<sup>1</sup>, such as specified in

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<sup>1</sup> **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.

Accredited program examples –Prometric, Serv-Safe, National Registry, 360Training

2-102.20 (B). This item is marked OUT of compliance if the establishment has no Certified Food Protection Manager.

**NA** This item maybe marked NA if certified food protection manager is not required based on determination that the establishment poses minimal risk of causing, or contributing to foodborne illness due to the nature of the operation and extent of food preparation.

**NO** **Do not Mark** this item NO

2-102.12 (A) and (B) Certified Food Protection Manager <sup>(C)</sup>  
2-102.20 (B) Food Protection Manager Certification <sup>(C)</sup> (Non-debitable)

### **Employee Health**

**NOTE 2:** One may rely solely on discussions, questions, and documentation to determine the compliance status of this item.

**IN OUT** **3. Management, food employee and conditional employee; knowledge, responsibilities and reporting**

This item must be marked IN or OUT of compliance.

This item is marked IN compliance when the following criteria are met:

- The PIC is aware of his or her responsibility to inform food employees and conditional employees of their responsibility to report information about their health and activities as they relate to diseases that are transmissible through food (i.e., certain symptoms and diagnosis) to the person in charge and for the PIC to report to the regulatory authority as specified under ¶ 2-103.11 (O) and ¶¶ 2-201.11 (A) - (C), and (E); and
- The PIC provides documentation or otherwise satisfactorily demonstrates during the inspection, that all food employees and conditional employees are informed of their responsibility to report to management information about their health and activities as it relates to diseases that are transmissible through food, as specified under ¶ 2-201.11 (A). Satisfactory compliance may be documented by completion of Form 1-B, Conditional Employees or Food Employees Reporting Agreement, in Annex 7 of the *Food Code* for each employee or other similar state or local form containing the same information; or
- In lieu of Form 1-B, compliance may be demonstrated by:
  - a) Presenting evidence such as a curriculum and attendance rosters documenting that each employee has completed a training program

which includes all the information required on Form 1-B regarding their reporting responsibilities; or

- b) Implementation of an employee health policy which includes a system of employee notification using a combination of training, signs, pocket cards, or other means to convey all of the required information on Form 1-B to all food employees and conditional employees. A signed acknowledgement by the employee should be part of any employee health policy.

The Regulatory Authority is encouraged to establish a policy of selecting one employee at random during each inspection and requesting the PIC verify, by one of the previously listed methods, that the selected employee has been informed of his or her responsibility to report symptoms, exposures, and diagnosed illnesses to management. The PIC is not expected to quote symptoms and diseases from memory, but should be able to locate that information on Form 1-B or similar documents used to demonstrate compliance.

Additional information is provided in Annex 3 of the Public Health Reasons for Subpart 2-201, including a number of questions, which may be used as a reference to assist the Regulatory Authority in determining compliance with this item.

**NA**  
**NO**

**Do Not Mark** this item NA  
**Do Not Mark** this item NO

2-102.11 (C) (2) - (3) and (17) Demonstration <sup>(PF)</sup>

2-103.11 (O) Person in Charge, Duties <sup>(PF)</sup>

2-201.11 (A), (B), (C), and (E) Responsibility of Permit Holder, Person in Charge and Conditional Employees <sup>(P, PF)</sup>

**IN OUT**

**4. Proper use of restriction and exclusion and reporting**

This item must be marked IN or OUT of compliance. Compliance must be based on first hand observations or information and cannot be based solely on responses from the PIC to questions regarding hypothetical situations or knowledge of the Food Code.

This item is marked IN compliance when the following criteria are observed at the time of the inspection:

- There are no ill food/conditional employees.
- There are no food/conditional employees experiencing symptoms, with or without a diagnosis, that require reporting, or reason for the PIC to exclude or restrict an employee.
- A food employee has been excluded/restricted and will return to work restricted/unrestricted as specified in §2-201.13 or a conditional employee is allowed to return to work as a food employee.

This item is marked OUT of compliance when:

- The inspector observes a working employee with a reportable symptom specified in Subparagraph 2-201.11 (A) (1); or
- The inspector becomes aware that an employee has reported information about his or her health and activities as it relates to diseases that are transmissible through food and the PIC has not acted to restrict/exclude a food/conditional employee as required by § 2-201.12; and 2-201.13 or
- The inspector becomes aware that the PIC has not notified the Regulatory Authority that an employee is jaundiced or diagnosed with an illness due to a pathogen as specified under Subparagraph 2-201.11 (A) (2) (a) - (f); or
- There are food employees working in the food establishment that have been diagnosed with an illness, exposed to, or is the suspected source of a confirmed disease outbreak as specified in Subparagraphs 2-201.11 (A) (2-5); or
- A food employee with an active sore throat with fever is working in a food establishment that exclusively serves a highly susceptible population, as specified in ¶ 2-201.12 (H). Food employees with a sore throat and fever must be restricted when working in facilities not serving a HSP.

**NA**  
**NO**

**Do Not Mark** this item NA

**Do Not Mark** this item NO

2-201.11 (D) and (F) Responsibility of the Person in Charge to exclude or restrict and the responsibility of the Food Employees and Conditional Employees to Comply with Exclusions and Restrictions <sup>(P)</sup>

2-201.12 Exclusions & Restrictions <sup>(P)</sup>

2-201.13 Removal, Adjustment, or Retention of Exclusions & Restrictions <sup>(P)</sup>

**IN OUT**

**5. Clean-up of Vomiting and Diarrheal Events**

This item must be marked IN or OUT of compliance.

This item is marked IN compliance when the food establishment demonstrates they have established procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the food establishment. Refer to the Public Health Reasons (§ 2-501.11 Clean-up of Vomiting and Diarrheal Events) for suggested recommendations as to what the food establishment can include within their plan (this is not an exhaustive list).

This item is marked OUT of compliance if the food establishment cannot demonstrate they have established 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.

**NA  
NO**

**Do Not Mark** this item NA

**Do Not Mark** this item NO

2-501.11 Clean-up of Vomiting and Diarrheal Events <sup>(PF)</sup>

**Good Hygienic Practices**

**IN OUT**

**6. Proper eating, tasting, drinking, or tobacco use**

This item should be marked IN or OUT of compliance based on direct observation of the appropriate hygienic practices of food employees.

This item is marked IN compliance when a food employee is observed drinking from a closed beverage container subsequently stored on a non-food contact surface and separate from exposed food, clean equipment, and unwrapped single-service and single-use articles.

This item is marked OUT of compliance when food employees are observed improperly tasting food, eating, drinking, or smoking, or there is supporting evidence of these activities taking place in non-designated areas of the establishment. An open container of liquid in the kitchen preparation area does not necessarily constitute marking this item OUT. Further discussion with a food employee or the PIC may be needed to determine if the liquid, if labeled, is used as an ingredient in food or may be an employee beverage that is consumed in another designated area. If the liquid is an open beverage that is consumed in a designated area, it must still be stored in a manner to prevent the contamination of food, equipment, utensils, linens and single-service/single-use articles.

**NA**

**Do Not Mark** this item NA

**NO** This item may be marked NO only in the RARE case when no food workers are present at the time of inspection.

2-401.11 Eating, Drinking or Using Tobacco <sup>(C)</sup>

3-301.12 Preventing Contamination When Tasting <sup>(P)</sup>

**IN OUT** **7. No discharge from eyes, nose, and mouth**

This item should be marked IN or OUT of compliance based on direct observation of food employees.

This item is marked IN compliance when no food employees are observed having persistent sneezing, coughing, or a runny nose that causes discharge from the eyes, nose or mouth.

This item is marked OUT of compliance when a food employee has persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose or mouth, subjecting food and food-contact surfaces to potential contamination.

**NA** **Do Not Mark** this item NA

**NO** This item may be marked NO only in the RARE case when no food workers are present at the time of inspection.

2-401.12 Discharges from the Eyes, Nose, and Mouth <sup>(C)</sup>

### **Preventing Contamination by Hands**

**IN OUT** **8. Hands clean & properly washed**

**NOTE 3:** This section (Preventing Contamination by Hands) is to be marked based on actual observations only.

This item should be marked IN or OUT of compliance.

This item marked IN compliance when employees are observed using proper handwashing techniques at appropriate times and places. Hands are not required to be washed between each change of gloves if there is no change in the task being performed and there are no activities which could potentially result in cross contamination.

**NA** **Do Not Mark** this item NA

**NO** This item may be marked NO only in the RARE case when food workers are not present at the time of inspection. If no food workers are present, but the PIC accompanies the inspector on the inspection and touches food,

clean equipment, or utensils without washing his/her hands, this item is marked OUT.

2-301.11 Clean Condition-Hands and Arms <sup>(P)</sup>

2-301.12 Cleaning Procedure <sup>(P)</sup>

2-301.14 When to Wash <sup>(P)</sup>

2-301.15 Where to Wash <sup>(PF)</sup>

2-301.16 Hand Antiseptics <sup>(PF)</sup>

**IN OUT**

**9. No bare hand contact with RTE food or a pre-approved alternate properly followed**

This item should be marked IN or OUT of compliance.

This item is marked IN compliance when food employees are observed using suitable utensils or gloves to prevent bare hand (or arm) contact with ready-to-eat food or if the food employee contacts exposed RTE food with bare hands at the time the RTE food is being added as an ingredient to a food that:

- contains a raw animal food and is to be cooked in the food establishment to heat all parts of the food to the minimum temperatures specified in ¶¶ 3-401.11 (A) - (B) or §3-401.12; or
- does not contain a raw animal food but is to be cooked in the food establishment to heat all parts of the food to a temperature of at least 145°F

This item is also marked IN compliance when food employees are observed properly following a pre-approved alternative procedure to no bare hand contact.

This item is marked OUT of compliance if one food employee is observed handling ready-to-eat food with their bare hands in the absence of a prior approval and written procedures for bare hand contact. Refer to Subparagraph 3-301.11 (E) (1) - (7) for a listing of conditions that must be met in order to receive prior approval by the Regulatory Authority. Bare hand contact by food employees serving a Highly Susceptible Population is prohibited and no alternative to bare hand contact is allowed. This item is also marked OUT when food employees contact exposed RTE food with bare hands at the time the RTE food is being added as an ingredient to a food that is not properly heat treated as specified in Subparagraphs 3-301.11 (D) (1) - (2).

**NA**

This item may be marked NA if the establishment provides only packaged or bulk food items that are not ready-to-eat.

**NO**

This item may be marked NO if the establishments prepares ready-to-eat food, but no food preparation occurs at the time of inspection.

3-301.11 Preventing Contamination from Hands <sup>(P, PF, C)</sup>

3-801.11 (D) Pasteurized Foods, Prohibited Re-Service, and Prohibited Food <sup>(P)</sup>

**10. Adequate handwashing sinks properly supplied and accessible**

**IN OUT**

**A. Adequate handwashing sinks conveniently located and accessible**

This item must be marked IN or OUT of compliance based on the direct observation of conveniently located handwashing sinks, for use by food employees, in food preparation, food dispensing and warewashing areas as well as in or immediately adjacent to toilet rooms.

This item is marked OUT of compliance if a handwashing sink is not accessible to food employees who are working in food preparation, food dispensing and warewashing areas, is blocked by portable equipment or stacked full of soiled utensils or other items, or is unavailable for regular employee use.

**NA  
NO**

**Do Not Mark** this item NA  
**Do Not Mark** this item NO

- 5-202.12 Handwashing Sink, Installation <sup>(PF, C)</sup>
- 5-203.11 Handwashing Sinks - Numbers and Capacities <sup>(PF)</sup>
- 5-204.11 Handwashing Sinks - Location and Placement <sup>(PF)</sup>
- 5-205.11 Using a Handwashing Sink - Operation and Maintenance <sup>(PF)</sup>

**IN OUT**

**B. Handwashing sinks supplied with hand cleanser/sanitary towels/hand drying devices/ signage**

This item must be marked IN or OUT of compliance based on the direct observation of properly equipped handwashing sinks for food employee use.

This item is marked OUT of compliance when handwashing sinks are not stocked with soap, hand drying provisions or equipped with the required signage.

**NA  
NO**

**Do Not Mark** this item NA  
**Do Not Mark** this item NO

- 6-301.11 Handwashing Cleanser, Availability <sup>(PF)</sup>
- 6-301.12 Hand Drying Provision <sup>(PF)</sup>
- 6-301.13 Handwashing Aids and Devices, Use Restrictions <sup>(C)</sup>
- 6-301.14 Handwashing Signage <sup>(C)</sup>

**Approved Source**

**11. Food obtained from approved source**

**IN OUT**

**A. All food from regulated food processing plants/no home prepared or canned food/standards for eggs, milk, juice**

This item must be marked IN or OUT of compliance based on direct observation of food products, food labels and packaging, water analyses, and discussion with the PIC or other food employees.

This item is marked IN compliance when the regulatory authority is able to determine approved food sources. A review of supplier names, shipment invoices, buyer specification plans, proof of regulatory permit/licensure of a food source, etc. can be used to document approved food sources. Milk and milk products must comply with Grade A Standards.

This item is marked OUT of compliance when an approved food source cannot be determined.

**NA  
NO**

**Do Not Mark** this item NA

**Do Not Mark** this item NO

3-201.11 Compliance with Food Law <sup>(P, PF, C)</sup>

3-201.12 Food in a Hermetically Sealed Container <sup>(P)</sup>

3-201.13 Fluid Milk and Milk Products <sup>(P)</sup>

3-202.13 Eggs <sup>(P)</sup>

3-202.14 Eggs and Milk Products, Pasteurized <sup>(P)</sup>

3-202.110 Juice Treated - Commercially Processed <sup>(P, PF)</sup>

5-101.13 Bottled Drinking Water <sup>(P)</sup>

**IN OUT      B. All molluscan shellfish from ICSSL listed sources/no recreationally caught shellfish received or sold/all fish commercially caught/raised or approved by the Regulatory Authority.**

This item is should be marked IN or OUT of compliance based on direct observation of molluscan shellfish or fish, labels and packaging, and discussion with the PIC or other food employees.

This item is marked IN compliance when the regulatory authority is able to determine approved food sources. A review of supplier names, shipment invoices, buyer specification plans, molluscan shellfish tags, proof of regulatory permit/licensure of a food source, etc. can be used to document approved food sources.

This item is marked OUT of compliance when an approved food source cannot be determined.

**NA**            This item may be marked NA if molluscan shellfish or fish, are not used or offered for sale or service in the establishment.

**NO**            This item may be marked NO if molluscan shellfish or fish, are served or sold periodically in the establishment, but are not present at the time of the inspection and you are unable to determine prior compliance through tags, invoices or purchase records.

3-201.14 Fish <sup>(P)</sup>

3-201.15 Molluscan Shellfish <sup>(P)</sup>

**IN OUT      C. Game animals and wild mushrooms approved by regulatory Authority**

**NOTE 4:** The 2013 Food Code prohibits the sale of wild mushrooms unless a food establishment gets approval from the Regulatory authority.

This item should be marked IN or OUT of compliance based on direct observation of food products, food labels and packaging, and discussion with the PIC or other food employees.

This item is marked IN compliance when the regulatory authority is able to determine approved food sources. A review of supplier names, shipment invoices, buyer specification plans, and proof of regulatory permit/licensure of a food source, etc. can be used to document approved food sources.

This item is marked OUT of compliance when an approved food source cannot be determined.

**NA**            This item may be marked NA if game animals or wild mushrooms are not used or offered for sale or service in the establishment.

**NO** This item may be marked NO if game animals or wild mushrooms are served or sold periodically in the establishment, but are not present at the time of inspection or you are unable to determine prior compliance through invoices or purchase records.

3-201.16 Wild Mushrooms <sup>(P)</sup>  
3-201.17 Game Animals <sup>(P, C)</sup>

**IN OUT 12. Food received at proper temperature**

This item should be marked IN or OUT of compliance based on actual food temperature measurements of TCS food being received.

This item is marked IN compliance when food is received and found at proper temperatures during the inspection (i.e. catered meal for child care center arrives during the inspection and the regulatory authority verifies receiving temperature).

This item is marked OUT of compliance if food is received and accepted, but an actual food temperature measurement of a TCS food by the regulatory authority at the time of delivery exceeds the temperature specifications for receiving as prescribed by the Code.

**NA** This item may be marked NA when the establishment receives only non-TCS food and that are not frozen

**NO** This item may be marked NO if the establishment does receive TCS food, but TCS food is not received at the time of inspection.

3-202.11 Temperature <sup>(P, PF)</sup>

**IN OUT 13. Food in good condition, safe, and unadulterated**

This item must be marked IN or OUT of compliance based on direct observation of the integrity of product packaging, wholesomeness, and signs of adulteration.

This item is marked IN compliance when a dent in a canned food has not compromised the hermetic seal; cuts made in outer cardboard packaging during opening of the case do not enter the inner product packaging; the true appearance, color, or quality of a food is not misrepresented; and food is honestly presented.

This item is marked OUT of compliance when the integrity of food packaging has been compromised or the true appearance, color, or quality of a food has been intentionally altered, or the food is not honestly presented.

**NA** Do Not Mark this item NA  
**NO** Do Not Mark this item NO

3-101.11 Safe, Unadulterated, and Honestly Presented <sup>(P)</sup>  
3-202.15 Package Integrity <sup>(PF)</sup>

**14. Required records available: shellstock tags, parasite destruction**

**IN OUT** **A. Written documentation of parasite destruction maintained for 90 days for fish products that are intended for raw or undercooked consumption**

This item should be marked IN or OUT of compliance based on direct observation of fish in storage, and records of freezing of fish for parasite destruction.

This item is marked IN compliance if the permit holder provides a statement from the 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 permit holder when fish are frozen for parasite destruction on the premises.

This item is marked OUT of compliance when no records of freezing of fish for parasite destruction are available.

**NA** This item may be marked NA when no raw, raw-marinated, or undercooked fish are sold or served in RTE form or the only fish sold as raw, raw-marinated are tuna species (such as Yellowfin, Southern and Northern Bluefin and Bigeye), molluscan shellfish, fish eggs removed from their skein and rinsed, or aquacultured fish such as salmon that are exempted from freezing because they are fed formulated feed that does not contain live parasites infective to that fish.

**NO** This item may be marked NO when raw, raw-marinated or undercooked fish are sold periodically in the establishment, but are not present at the time of the inspection and prior compliance through tags, invoices, or purchase records cannot be verified.

3-402.11 Parasite Destruction <sup>(P, C)</sup>  
3-402.12 Records, Creation and Retention <sup>(PF)</sup>

**IN OUT** **B. Shellstock tags maintained for 90 days and in chronological order**

This item should be marked IN or OUT of compliance based on direct observation of shellstock tags.

This item is marked OUT of compliance if shellstock tags are not available or are incomplete, when no date is recorded on the tag or label to

indicate the last day the shellstock was sold or served, when tags or labels are not maintained in chronological order correlated to the date that is recorded on the tag or label, or when there is evidence of commingling of shellstock.

**NA** This item may be marked NA when shellstock are not sold or served in the establishment.

**NO** This item may be marked NO when shellstock are sold or served in the establishment, but are not present at the time of the inspection and prior compliance through tags, invoices, buyer specifications, or purchase records cannot be verified.

3-202.18 Shellstock Identification <sup>(PF, C)</sup>

3-203.12 Shellstock, Maintaining Identification <sup>(PF)</sup>

### **Protection from Contamination**

#### **15. Food separated & protected**

**IN OUT** **A. Separating raw animal food from raw RTE food and separating Raw animal food from cooked RTE food**

This item should be marked IN or OUT of compliance based on direct observation of food storage and food handling practices.

This item is marked IN compliance when frozen, sealed/intact commercially packaged raw animal food stored or displayed with or above frozen, sealed/intact commercially packaged RTE food.

This item is marked OUT of compliance when raw animal food is not separated from raw or cooked RTE food.

**NA** This item may be marked NA when raw animal food s are not prepared/served in the establishment or if only prepackaged raw animal foods are sold. This item may be marked NA when there are no raw animal foods used in the facility and only prepackaged foods are sold.

**NO** This item may be marked NO when raw animal foods are prepared/served in the establishment, but are are not present at the time of the inspection. This item is marked NO when raw animal foods are used or served seasonally and you are unable to determine compliance.

3-302.11 (A) (1) Packaged and Unpackaged Food - Separation, Packaging and Segregation <sup>(P)</sup>

**IN OUT**

**B. Raw animal food separated from each other during storage, preparation, holding, and display**

This item should be marked IN or OUT of compliance based on direct observation of food storage and food handling practices.

This item is marked OUT of compliance when raw animal food are subject to potential contamination by other raw animal food; or raw animal food are observed not separated by type based on minimum cook temperatures by spacing or placing in separate containers.

**NA**

This item may be marked NA when raw animal foods are not prepared or served, when only one species of raw animal food is prepared/served, or when only prepackaged raw animal foods are sold in the establishment.

**NO**

This item is marked NO when raw animal foods are prepared/served/or sold in the establishment, but are not present at the time of the inspection.

3-302.11 (A) (2) Packaged and Unpackaged Food - Separation, Packaging and Segregation <sup>(P)</sup>

**IN OUT**

**C. Food protected from environmental contamination**

This item must be marked IN or OUT of compliance based on direct observations of food storage and food handling practices.

This item is marked OUT of compliance if food is not packaged or covered during storage (unless in the process of cooling); or food is in contact with soiled equipment and utensils; or single-use gloves used for more than one task.

**NA**

**Do not Mark** this item NA

**NO**

**Do not Mark** this item NO

3-302.11 (A) (3-8) Packaged and Unpackaged Food-Separation, Packaging and Segregation <sup>(C)</sup>

3-304.11 Food Contact with Equipment and Utensils <sup>(P)</sup>

3-304.15 (A) Gloves, Use Limitation <sup>(P)</sup>

3-306.13 (A) Consumer Self - Service Operations <sup>(P)</sup>

**IN OUT**

**16. Food-contact surfaces: cleaned & sanitized**

**NOTE 5:** This item will require some judgment to be used when marking it IN or OUT of compliance. You must provide notes concerning the reason it is marked OUT of compliance.

This item should be marked IN or OUT of compliance based on direct observation of food-contact surfaces of equipment and utensils; actual measurements/readings of chemical sanitizer concentration, hot water sanitizing temperature, pH, hardness, water pressure, etc. using test strips,

heat-sensitive tapes, and equipment gauges; observations of cleaning and sanitizing procedures; and discussion of cleaning and sanitizing procedures and frequency with the PIC or other food employees.

This item is marked IN compliance when manual and/or mechanical methods of cleaning and sanitizing are effective, and performed at the prescribed frequency. There should be an overall assessment of the food-contact surfaces of equipment and utensils in clean storage and in use to determine compliance. For example, this item is not marked OUT of compliance based on one visibly soiled utensil, such as a plate or knife or if one sanitizer container is without sanitizer.

This item is marked OUT of compliance if observations are made that support a pattern of noncompliance with this item, when manual and/or mechanical methods of cleaning and sanitizing food-contact surfaces of equipment and utensils are ineffective, or if one multiuse piece of equipment such as a slicer or can opener is visibly soiled and being used at the time of the inspection. This item is also marked OUT of compliance if it is observed that equipment or utensils that have come into contact with a major food allergen such as fish was not cleaned and sanitized prior to use for other types of raw animal food.

**NA** This item may be marked NA only when cleaning and sanitizing of equipment and utensils is not required (such as when only prepackaged food is sold).

**NO** **Do Not Mark** this item NO

4-501.111 Manual Warewashing Equipment, Hot Water Sanitization Temperatures <sup>(P)</sup>

4-501.112 Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures <sup>(PF)</sup>

4-501.113 Mechanical Warewashing Equipment, Sanitization Pressure <sup>(C)</sup>

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration and Hardness <sup>(P, PF)</sup>

4-501.115 Manual Warewashing Equipment, Chemical Sanitization Using Detergent - Sanitizers <sup>(C)</sup>

4-601.11 (A) Equipment, Food - Contact Surfaces, Nonfood Contact surfaces and Utensils <sup>(PF)</sup>

4-602.11 Equipment Food - Contact Surfaces and Utensils - Frequency <sup>(P, C)</sup>

4-602.12 Cooking and Baking Equipment <sup>(C)</sup>

4-702.11 Before Use After Cleaning <sup>(P)</sup>

4-703.11 Hot Water and Chemical - Methods <sup>(P)</sup>

**17. Proper disposition of returned, previously served, reconditioned and unsafe food**

**IN OUT      A. After being served or sold to a consumer, food is not reserved**

This item must be marked IN or OUT of compliance.

This item is marked OUT of compliance if previously served unwrapped, unprotected food is observed being re-served.

**NA            Do Not Mark** this item NA  
**NO            Do Not Mark** this item NO

3-306.14 Returned Food and Re-Service of Food <sup>(P)</sup>

**IN OUT      B. Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food**

This item must be marked IN or OUT of compliance.

This item is marked OUT of compliance if food is found unsafe, adulterated, not honestly presented, from an unapproved source, or ready-to-eat food is contaminated by employees and is not discarded or reconditioned according to an approved procedure.

**NA            Do Not Mark** this item NA  
**NO            Do Not Mark** this item NO

3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food <sup>(P)</sup>

**Time/Temperature Control for Safety (TCS Food)**

**18. Proper cooking time & temperatures**

**NOTE 6:** The cooking temperatures of foods must be measured to determine compliance or noncompliance. Do not rely upon discussions with managers or cooks to make a determination of compliance or noncompliance. The temperature of raw animal food in each species cooked during the inspection should be taken. For instance, if the establishment 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. Both IN and OUT of compliance temperatures should be recorded. Also, refer to cooking chart below. If a roast of any type is cooked (in any manner other than the pre-heated oven parameters) it would be marked under 18C.

**IN OUT      A. Raw Eggs broken on request and prepared for immediate service cooked to 63°C (145°F) for 15 seconds**

This item should be marked IN or OUT of compliance based on actual cooking temperature measurements using a calibrated food temperature measuring device.

This item is marked IN compliance if a food item meets the time/temperature requirements for cooking, or if a food is cooked below the required temperature but the establishment has an approved consumer advisory or an approved variance with a HACCP plan for that food item (record the temperature and document the reason it is IN compliance).

This item is marked OUT of compliance if a food item does not meet the time/temperature requirements for cooking and the determination is made that the employee doing the cooking intends to serve the product before completing the cooking process unless requested undercooked by the consumer.

**NA**            This item may be marked NA when raw eggs are not cooked or used in the establishment (including raw eggs not used in recipes).

**NO**            This item may be marked NO when raw eggs are cooked or used in the establishment, but you are unable to determine the cooking temperature or they are not cooked at the time of inspection. The inspection should be arranged at an optimum time for measuring at least one cooked item.

3-401.11 (A) (1) Raw Animal Foods <sup>(P)</sup>

**IN OUT**

**B. Comminuted fish, meat, game animals commercially raised for food, and raw eggs not prepared for immediate service and comminuted meat on a child's menu cooked to 68°C (155°F) for 15 seconds or the time/temperature relationship specified in the chart in the Food Code**

This item should be marked IN or OUT of compliance based on actual cooking temperature measurements using a calibrated food temperature measuring device.

This item is marked IN compliance if a food item meets the time/temperature requirements for cooking, or if a food is cooked below the required temperature but the establishment has an approved consumer advisory or an approved variance with a HACCP plan for that food item (record the temperature and document the reason it is IN compliance).

This item is marked OUT of compliance if a food item does not meet the time/temperature requirements for cooking and the determination is made that the employee doing the cooking intends to serve the product before completing the cooking process. Undercooked comminuted meat, with a consumer advisory, on a child's menu is marked OUT of compliance.

**NA**

This item may be marked NA if comminuted fish, meat, commercially raised game animal, and raw eggs (not prepared for immediate service) are not cooked in the establishment.

**NO**

This item may be marked NO when one or more types of comminuted fish, meat, commercially raised game animal, or raw eggs (not prepared for immediate service) are cooked in the establishment, but you are unable to determine the cooking temperature of any of them or they are not cooked at the time of inspection. The inspection should be arranged at an optimum time for measuring at least one cooked item.

3-401.11 (A) (2) and (D) (2) Raw Animal Food <sup>(P, PF)</sup>

**IN OUT**

**C. Whole meat roasts, including beef, corned beef, lamb, pork, cured pork roasts and formed roasts, cooked to 54°C (130°F) for 112 minutes, or as chart specifies and according to oven parameter per chart.**

This item should be marked IN or OUT of compliance based on actual cooking temperature measurements obtained using a calibrated food temperature measuring device. This item is marked IN compliance if a food item meets the time/temperature requirements for cooking, or if a food is cooked below the required temperature but the establishment has an approved consumer advisory or an approved variance with a HACCP plan for that food item (record the temperature and document the reason it is IN compliance).

This item is marked OUT of compliance if a food item does not meet the time/temperature requirements for cooking and the determination is made that the employee doing the cooking intends to serve the product before completing the cooking process.

**NA** This item may be marked NA when meat roasts or formed roasts are not cooked in the establishment.

**NO** This item may be marked NO when one or more meat roasts or formed roasts are cooked in the establishment, but they are not cooked at the time of inspection. The inspection should be arranged at an optimum time for measuring at least one cooked item.

3-401.11 (B) (1) and (2) Raw Animal Foods <sup>(P, PF)</sup>

**IN OUT** **D. Ratites and injected meat or mechanically tenderized meats cooked to 68°C (155°F) for 15 seconds or the time/temperature relationship specified in the corresponding chart in the Food Code**

This item should be marked IN or OUT of compliance based on actual cooking temperature measurements using a calibrated food temperature measuring device.

This item is marked IN compliance if a food item meets the time/temperature requirements for cooking, or if a food is cooked below the required temperature but the establishment has an approved consumer advisory or an approved variance with a HACCP plan for that food item (record the temperature and document the reason it is IN compliance).

This item is marked OUT of compliance if a food item does not meet the time/temperature requirements for cooking and the determination is made that the employee doing the cooking intends to serve the product before completing the cooking process.

**NA** This item may be marked NA when none of the food items are cooked in the establishment

**NO** This item may be marked NO when one or more of the food items are cooked in the establishment, but you are unable to determine the cooking temperature of any of them.

3-401.11 (A) (2) Raw Animal Foods <sup>(P)</sup>

**IN OUT E. Poultry, baluts; stuffed fish/meat/poultry/ratites/pasta or stuffing containing fish, meat, poultry, or ratites cooked to 74°C (165°F) for 15 seconds**

This item should be marked IN or OUT of compliance based on actual cooking temperature measurements using a calibrated food temperature measuring device.

This item is marked IN compliance if a food item meets the time/temperature requirements for cooking, or if a food is cooked below the required temperature but the establishment has an approved consumer advisory or an approved variance with a HACCP plan for that food item (record the temperature and document the reason it is IN compliance).

This item is marked OUT of compliance if a food item does not meet the time/temperature requirements for cooking and the determination is made that the employee doing the cooking intends to serve the product before completing the cooking process.

**NA** This item may be marked NA when none of the food items are cooked in the establishment.

**NO** This item may be marked NO when one or more of the food items are cooked in the establishment but you are unable to determine the cooking temperature of any of them. The inspection should be arranged at an optimum time for measuring at least one cooked item.

3-401.11 (A) (3) Raw Animal Foods <sup>(P)</sup>

**IN OUT F. Wild game animals cooked to 74°C (165°F) for 15 seconds**

This item should be marked IN or OUT of compliance based on actual cooking temperature measurements using a calibrated food temperature measuring device.

This item is marked IN compliance if a food item meets the time/temperature requirements for cooking, or if a food is cooked below the required temperature but the establishment has an approved consumer advisory or an approved variance with a HACCP plan for that food item (record the temperature and document the reason it is IN compliance).

This item is marked OUT of compliance if a food item does not meet the time/temperature requirements for cooking and the determination is made that the employee doing the cooking intends to serve the product before completing the cooking process.

**NA** This item may be marked NA when wild game animals are not cooked in the establishment.

**NO** This item may be marked NO when wild game animals are cooked in the establishment, but you are unable to determine the cooking temperature of any of them or are not cooked at the time of inspection. The inspection should be arranged at an optimum time for measuring at least one cooked item.

3-401.11 (A) (3) Raw Animal Foods <sup>(P)</sup>

**IN OUT** **G. Whole-muscle, intact beef steaks cooked to surface temperature of 63°C (145°F) on top and bottom and a cooked color change is achieved on all external surfaces**

This item should be marked IN or OUT of compliance based on actual cooking temperature measurements using a calibrated food temperature measuring device.

This item is marked IN compliance if a food item meets the time/temperature requirements for cooking, or if a food is cooked below the required temperature but the establishment has an approved consumer advisory or an approved variance with a HACCP plan for that food item (record the temperature and document the reason it is IN compliance).

This item is marked OUT of compliance if a food item does not meet the time/temperature requirements for cooking and the determination is made that the employee doing the cooking intends to serve the product before completing the cooking process.

**NA** This item may be marked NA when whole-muscle, intact beef steaks are not cooked in the establishment, or undercooked steaks are not offered.

**NO** This item may be marked NO when whole-muscle, intact beef steaks are cooked in the establishment, but you are unable to determine the cooking temperature. The inspection should be arranged at an optimum time for measuring at least one cooked item.

3-401.11 (C) (3) Raw Animal Foods <sup>(P)</sup>

**IN OUT** **H. Raw animal foods rotated, stirred, covered, and heated to 74°C (165°F) in a microwave. Food stands for 2 minutes after cooking**

This item should be marked IN or OUT of compliance based on actual cooking temperature measurements using a calibrated food temperature measuring device.

This item is marked IN compliance if a food item meets the time / temperature requirements for cooking, or if a food is cooked below the required temperature but the establishment has an approved consumer

advisory or an approved variance with a HACCP plan for that food item (record the temperature and document the reason it is IN compliance).

This item is marked OUT of compliance if a food item does not meet the time/temperature requirements for cooking and the determination is made that the employee doing the cooking intends to serve the product before completing the cooking process.

**NA** This item may be marked NA when the establishment does not cook raw animal foods in the microwave.

**NO** This item may be marked NO when the establishment does cook raw animal foods in the microwave, but you are unable to determine the cooking temperature of any item at the time of inspection. The inspection should be arranged at an optimum time for measuring at least one cooked item.

3-401.12 Microwave Cooking <sup>(P, C)</sup>

**IN OUT** **I. All other raw animal foods cooked to 63°C (145°F) for 15 seconds**

This item should be marked IN or OUT of compliance based on actual cooking temperature measurements using a calibrated food temperature measuring device.

This item is marked IN compliance if a food item meets the time/temperature requirements for cooking, or if a food is cooked below the required temperature but the establishment has an approved consumer advisory or an approved variance with a HACCP plan for that food item (record the temperature and document the reason it is IN compliance).

This item is marked OUT of compliance if a food item does not meet the time/temperature requirements for cooking and the determination is made that the employee doing the cooking intends to serve the product before completing the cooking process unless requested undercooked by the consumer.

**NA** This item may be marked NA when no other raw animal foods are cooked in the establishment.

**NO** This item may be marked NO when other raw animal foods are cooked in the establishment, but you are unable to determine the cooking temperature of any of them. The inspection should be arranged at an optimum time for measuring at least one cooked item.

3-401.11 (A) (1) (b) Raw Animal Foods <sup>(P)</sup>

**IN OUT**      **J. Raw animal foods cooked, using a non-continuous cooking process, cooked to the time/temperature requirements specified for the particular raw animal food**

This item should be marked IN or OUT of compliance based on actual cooking temperature measurements using a calibrated food temperature measuring device.

This item is marked IN compliance if a food item meets the requirements for non-continuous cooking process as specified in Section 3-401.14. The establishment must have written procedures and have obtained prior approval from the regulatory authority. Procedures are available for review upon request describing how the foods are prepared and stored after initial heating but prior to cooking for sale or service in order for this item to be IN compliance.

This item is marked OUT of compliance if a food item does not meet the time/temperature requirements for cooking and the determination is made that the employee doing the cooking intends to serve the product before completing the cooking process. This item is also marked OUT of compliance if written procedures describing how the foods are prepared and stored after initial heating but prior to cooking for sale or service are not available for review.

**NA**              This item may be marked NA when the establishment does not cook raw animal foods, using a non-continuous cooking process.

**NO**              This item may be marked NO when the establishment does cook raw animal foods, using a non-continuous cooking process, but you are unable to determine the cooking temperature of any of them. The inspection should be arranged at an optimum time for measuring at least one cooked item.

3-401.14 Non-Continuous Cooking of Raw Animal Foods <sup>(P, PF)</sup>

**Internal Cooking Temperature Specifications (add chart from ANNEX 7)**

<b>145°F for 15 seconds</b>	Raw eggs cooked for immediate service Fish, except as listed below	Meat, except as listed in the next 2 rows Commercially raised game animals, rabbits
<b>155°F for 15 seconds:</b>	Ratites (Ostrich, Rhea and Emu) Injected or mechanically tenderized meats Raw eggs not for immediate service	Comminuted meat, fish, or commercially raised game animals
<b>165°F for 15 seconds:</b>	Wild game animals Poultry	Stuffed fish, meat, pork, ratites, poultry, & pasta Stuffing containing fish, meat, ratites & poultry
<b>Whole Meat Roasts</b> Refer to cooking charts in the <i>Food Code</i> ¶ 3-401.11(B)		

**19. Proper reheating procedures for hot holding**

**NOTE 7:** The reheating temperatures of food must be taken to determine compliance or noncompliance. Do not rely solely upon discussions with managers or cooks to determine compliance or noncompliance. Temperatures IN and OUT of compliance should be recorded.

**IN OUT      A. TCS food that is cooked and cooled on premises is rapidly reheated within 2 hours to 74°C (165°F) or above for 15 seconds for hot holding**

This item should be marked IN or OUT of compliance based on actual temperature measurements of food upon completion of the reheating process and prior to being placed in hot holding using a calibrated food temperature measuring device.

This item is marked OUT of compliance if a food item is not reheated to the required temperature and/or within two hours prior to hot holding.

**NA**      This item may be marked NA when a TCS food is not held over for a second service and/or reheating for hot holding is not performed in the establishment.

**NO**      This item may be marked NO when a TCS food is held over for a second service and is reheated for hot holding, but is not reheated for hot holding at the time of inspection.

3-403.11 (A) and (D) Reheating for Hot Holding <sup>(P)</sup>

**IN OUT**

**B. Food reheated to 74°C (165°F) or above in microwave for hot holding**

This item should be marked IN or OUT of compliance based on actual temperature measurements of food upon completion of the reheating process and prior to being placed in hot holding using a calibrated food temperature measuring device. The food must be stirred, covered and allowed to stand covered for two minutes after reheating.

This item is marked OUT of compliance if a food item is not reheated to the required temperatures and/or within two hours prior to hot holding.

**NA**

This item may be marked NA when the establishment does not use a microwave to reheat TCS food for hot holding.

**NO**

This item may be marked NO when the establishment does use a microwave to reheat TCS food for hot holding, but you are unable to determine the reheating temperature of any of them.

3-403.11 (B) Reheating for Hot Holding <sup>(P)</sup>

**IN OUT**

**C. Commercially processed, RTE food reheated to 57°C (135°F) or above for hot holding**

This item should be marked IN or OUT of compliance based on actual temperature measurements of food upon completion of the reheating process and prior to being placed in hot holding using a calibrated food temperature measuring device.

This item is marked OUT of compliance if the items are not reheated to the required temperature and/or within two hours prior to hot holding.

**NA**

This item may be marked NA when commercially processed ready-to-eat food is not reheated for hot holding in the establishment.

**NO**

This item may be marked NO when commercially processed ready-to-eat food is reheated for hot holding in the establishment, but you were unable to determine the reheat temperature.

3-403.11 (C) Reheating for Hot Holding <sup>(P)</sup>

**IN OUT      D. Remaining unsliced portions of roasts reheated for hot holding using minimum oven parameters**

This item should be marked IN or OUT of compliance based on actual temperature measurements of food upon completion of the reheating process and prior to being placed in hot holding using a calibrated food temperature measuring device.

This item is marked OUT of compliance if the items are not reheated to the required time/temperature as specified in Section 3-403.11 (E).

**NA**            This item may be marked NA when remaining unsliced portions of roasts are not used or reheated in the establishment.

**NO**            This item may be marked NO when the establishment does reheat remaining unsliced portions of roasts for hot holding, but you were unable to determine the reheat time/temperature at the time of inspection.

3-403.11 (E) Reheating for Hot Holding

**20. Proper cooling time & temperatures**

**NOTE 8:** Cooked TCS 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. For example, if an establishment cools chili from 135°F to 70°F in 1.5 hours; they have 4.5 hours to get it from 70°F to 41°F or less. There are two critical limits that must be met with cooling. Discussions with the person in charge along with observations should be used to determine compliance. For instance, during a discussion the person in charge says a food product was cooled overnight in the walk-in cooler. The product is checked and the temperature is 50°F. Eight hours have elapsed from closing to opening. This item should be marked OUT because the product did not cool from 135°F to 70°F within two hours and from 135°F to 41°F or less within a total of 6 hours. Because the entire cooling process is difficult to observe during an inspection, at the onset of the inspection a determination of whether food is currently being cooled should be made. If cooling is taking place temperatures should be taken to make a determination of whether proper cooling is possible with procedures being used. Temperatures IN and OUT of compliance should be recorded.

**IN OUT      A. Cooked TCS food cooled from 57°C (135°F) to 21°C (70°F) within 2 hours and from 57°C (135°F) to 5°C (41°F) or below in 6 hours**

This item should be marked IN or OUT of compliance based on actual temperatures of TCS food in the cooling process. The basis for determining IN or OUT of compliance can also be supported through discussion and/or record review which would provide the inspector reliable data of the “start time” for cooling from 135°F. See above NOTE for an example of using actual temperature and discussion with the PIC in

determining OUT of compliance without actually being at the establishment during the entire cooling of TCS food process, from start to finish.

**NA** This item may be marked NA when cooked TCS food is not cooled in the establishment.

**NO** This item may be marked NO when cooked TCS food is cooled in the establishment, but cooling was not taking place at the time of the inspection or the temperature and time parameters could not be determined during the length of the inspection.

3-501.14 (A) Cooling <sup>(P)</sup>

**IN OUT** **B. TCS Food prepared from ambient temperature and/or pre-chilled ingredients cooled to 5°C (41°F) or below in 4 hours**

This item should be marked IN or OUT of compliance based on actual temperatures of TCS food in the cooling process. The basis for determining IN or OUT of compliance can also be supported through discussion and/or record review which would provide the inspector reliable data of the “start time” for cooling. See above NOTE for an example of using actual temperature and discussion with the PIC in determining OUT of compliance without actually being at the establishment during the entire cooling of TCS food process, from start to finish.

**NA** This item may be marked NA when the establishment does not cool TCS food from ambient temperature or pre-chilled ingredients.

**NO** 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.

3-501.14 (B) Cooling <sup>(P)</sup>

**IN OUT** **C. Food (milk/shellfish) received at a temperature according to law cooled to 5°C (41°F) or below in 4 hours**

**NOTE 9:** If one product is found out of temperature the item is marked out of compliance.

This item should be marked IN or OUT of compliance based on actual temperatures of TCS food in the cooling process. The basis for determining IN or OUT of compliance can also be supported through discussion and/or record review which would provide the inspector reliable data of the “start time” for cooling. See above NOTE for an example of using actual temperature and discussion with the PIC in

determining OUT of compliance without actually being at the establishment during the entire cooling of TCS food process, from start to finish.

**NA** This item may be marked NA when the establishment does **not** receive shellstock or milk.

**NO** This item may be marked NO when the establishment does receive shellstock, milk, or other products that have a transport temperature above 41°F, but you are not there to observe the actual receipt.

3-501.14 (C) Cooling <sup>(P)</sup>

**IN OUT** **D. Immediately upon receiving, raw eggs placed under refrigeration that maintains ambient air temperature of 7°C (45°F)**

**NOTE 10:** If raw eggs are immediately placed under refrigeration capable of maintaining an ambient air temperature of 45°F, satisfactory compliance is achieved. Federal regulations require that raw eggs be transported and stored at 45°F or lower ambient air temperature - cooling time does not apply to this item.

This item should be marked IN or OUT of compliance based on actual observation of raw eggs being placed into a refrigeration unit maintaining an ambient air temperature of 45°F.

**NA** This item may be marked NA when the establishment does not receive raw eggs.

**NO** This item may be marked NO when raw eggs are received by the establishment, but you are not there to observe the actual receipt and immediate disposition.

3-501.14 (D) Cooling <sup>(P)</sup>

## **21. Proper hot holding temperatures**

**NOTE 11:** Temperatures of IN compliance and OUT of compliance food items should be recorded.

**IN OUT** **A. TCS food maintained at 57°C (135°F) or above, except during preparation, cooking, or cooling, or when time is used as a public health control**

This item should be marked IN or OUT of compliance based on actual food temperature measurements using a calibrated food temperature measuring device.

This item is marked IN compliance when the regulatory authority determines that, of the TCS food temperature measurements taken during

the inspection, no hot holding temperatures are less than prescribed by the Code.

This item is marked OUT of compliance if one TCS food is found out of temperature, unless Time as a Public Health Control (TPHC) is used for that TCS food.

**NA** This item may be marked NA when the establishment does not hot hold TCS food.

**NO** This item may be marked NO when the establishment does not hot hold TCS food, but TCS food is not being hot held at the time of inspection. Inspections should be conducted during a time when hot holding temperatures can be taken.

3-501.16 (A) (1) Time/Temperature Control for Safety (TCS) Food Hot and Cold Holding <sup>(P)</sup>

**IN OUT** **B. Whole meat roasts held at a temperature of 54°C (130°F) or above**

This item should be marked IN or OUT of compliance based on actual food temperature measurements using a calibrated food temperature measuring device.

This item is marked IN compliance when the regulatory authority determines that, of the TCS food temperature measurements taken during the inspection, no hot holding temperatures are less than prescribed by the Code.

This item is marked OUT of compliance if one TCS food is found out of temperature, unless Time as a Public Health Control (TPHC) is used for that TCS Food.

**NA** This item may be marked NA if whole meat roasts are not cooked and hot held in the establishment.

**NO** This item may be marked NO when whole meat roasts are cooked and hot held in the establishment, but were not being hot held at the time of inspection. Inspections should be conducted during a time when hot holding temperatures can be taken.

3-501.16 (A) (1) Time/Temperature Control for Safety (TCS) Food Hot and Cold Holding <sup>(P)</sup>

## 22. Proper cold holding temperatures

**NOTE 12:** Temperatures IN compliance and OUT of compliance should be recorded.

**IN OUT      A. TCS food maintained at 5°C (41°F) or below, except during preparation, cooking, cooling, or when time is used as a public health control (TPHC)**

This item should be marked IN or OUT of compliance based on actual food temperature measurements using a calibrated food temperature measuring device. Discussions should be made with the PIC to determine if a food is in the process of cooling, TPHC is used, or there is an approved method to render a food so that it is not TCS food.

This item is marked IN compliance when the regulatory authority determines that, of the TCS food temperature measurements taken during the inspection, no cold holding temperatures are greater than prescribed by the Code.

This item is marked OUT of compliance if one TCS food is found out of temperature, with supportive evidence, unless TPHC is used for that TCS food.

**NA**            This item may be marked NA when the establishment does not cold hold TCS food.

**NO**            **Do not mark** this item NO

3-501.16 (A) (2) Time/Temperature Control for Safety (TCS) Food Hot and Cold Holding <sup>(P)</sup>

**IN OUT      B. Untreated raw eggs stored in 7°C (45°F) ambient air temperature**

This item should be marked IN or OUT of compliance based on actual ambient refrigerated equipment temperature measurements using a calibrated temperature measuring device.

This item is marked IN compliance when the ambient temperature inside the refrigerated equipment is at or below 45°F.

This item is marked OUT of compliance when the ambient temperature inside the refrigerated equipment is above 45°F.

**NA**            This item may be marked NA when the establishment does not receive raw eggs.

**NO**            This item may be marked NO only when raw eggs are received by the establishment, but are not present at the time of the inspection.

3-501.16 (B) Time/Temperature Control for Safety (TCS) Food Hot and Cold Holding <sup>(P)</sup>

**23. Proper date marking & disposition**

**IN OUT      A. Date marking for RTE, TCS food prepared on-site or opened commercial container held for more than 24 hours**

This item should be marked IN or OUT of compliance.

This item is marked IN compliance when there is a system in place for date marking all food that is required to be date marked and is verified through observation. If date marking applies to the establishment, the PIC should be asked to describe the methods used to identify product shelf-life or “consume-by” dating. The regulatory authority must be aware of food products that are listed as exempt from date marking.

**NA**      This item may be marked N.A. when there is no ready-to-eat, TCS food prepared on-premise and held, or commercial containers of ready-to-eat, TCS food opened and held, over 24 hours in the establishment.

**NO**      This item may be marked NO when the establishment does handle ready-to-eat foods requiring date marking, but no foods requiring date marking are present at the time of inspection.

3-501.17 Ready-to-Eat, Time/Temperature Control for Safety (TCS Food) Date Marking <sup>(PF)</sup>

**IN OUT      B. Discarding RTE, TCS food prepared on-site or opened commercial container held at ≤5°C (41°F) for ≤ 7 days**

This item should be marked IN or OUT of compliance.

This item is marked IN compliance when food is all within date marked time limits or food is observed being discarded within date marked time limits.

This item is marked OUT of compliance when date marked food exceeds the time limit or date-marking is not done.

**NA**      This item may be marked NA when, ready-to-eat, TCS food prepared on-premises is not held for more than 24 hours or when opened commercial containers of, ready-to-eat, TCS food are not held for more than 24 hours in the establishment.

**NO** This item may be marked NO when the establishment does handle ready-to-eat foods requiring date marking, but no foods requiring date marking are present at the time of inspection.

3-501.18 Ready-to-Eat Time/Temperature Control for Safety (TCS) Food Disposition <sup>(P)</sup>

**IN OUT 24. Time as a public health control: procedures & records**

This item should be marked IN or OUT of compliance based on direct observations, record review, a discussion with the PIC, and the review of any standard operating procedures to determine if the intent of the Code for use of TPHC is met. This provision only applies if it is the actual intention or conscious decision by the Person in Charge (PIC) to store TCS food out of temperature control using TPHC; otherwise, it may be a cold or hot holding issue.

This item is marked IN compliance if there is a written procedure at the food establishment that identifies the types of food products that will be held using time only, describes the procedure for how TPHC will be implemented, and if applicable delineates how food items previously cooked and cooled before time is used, are properly cooled; and food items (marked or identified) do not exceed the 4-hour limit at any temperature or 6-hour limit at 70°F or less.

This item is marked OUT of compliance when the food manager implies use of TPHC but does not have an effective mechanism for indicating the point in time when the food is removed from temperature control to the 4 or 6-hour discard time, or a written procedure or an effective mechanism for using TPHC is not present at the establishment.

**NA** This item may be marked NA when the establishment does not use time as a public health control.

**NO** This item may be marked NO when the establishment uses time as a public health control, but is not using this practice at the time of inspection.

3-501.19 Time as a Public Health Control <sup>(P, PF, C)</sup>

**Consumer Advisory**

**IN OUT 25. Consumer advisory provided for raw or undercooked animal foods**

This item should be marked IN or OUT of compliance based on a thorough review of the posted, written and special/daily menus with the PIC to determine if untreated eggs, meats, fish, or poultry may be used as

an ingredient in or ordered as a raw, raw-marinated, partially cooked, or undercooked food. The advisory also applies to shellstock offered for sale from a retail service case.

This item is marked IN compliance when raw or undercooked animal foods are served or sold and the establishment provides an advisory that meets the intent of the Food Code for both the disclosure and reminder components.

This item is marked OUT of compliance when raw or undercooked animal foods are served or sold and there is no consumer advisory, the food item is not disclosed, or there is no reminder statement. The consumer advisory does not exempt the requirement for freezing for parasite control.

**NA** This item may be marked NA when a food establishment does not serve a ready-to-eat food that necessitates an advisory, i.e., an animal food that is raw, undercooked, or not otherwise processed to eliminate pathogens.

**NO** **Do Not Mark** this item NO

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens <sup>(PF)</sup>

### **Highly Susceptible Populations**

#### **26. Pasteurized foods used; prohibited food not offered**

**NOTE 13:** Discussions with the person in charge and employees regarding whether or not certain foods are served or certain practices occur in the establishment, along with observations should be used to determine compliance. Violations of bare hand contact by food employees serving a Highly Susceptible Population ¶ 3-801.11 (D) is marked under Item #9.

**IN OUT** **A. Prepackaged juice/beverage containing juice with a warning label [21 CFR, Section 101.17 (g)] not served**

This item should be marked IN or OUT of compliance based on direct observations and discussions with the PIC and food employees regarding whether or not certain foods are served or certain practices occur in an establishment serving a highly susceptible population.

This item is marked IN compliance if only treated/pasteurized juices/juice beverages are served.

**NA** This item may be marked NA if a highly susceptible population is not served.

**NO** **Do Not Mark** this item NO

3-801.11 (A) Pasteurized Foods, Prohibited Re-service, and Prohibited Food <sup>(P, C)</sup>

**IN OUT**      **B. Using pasteurized eggs in recipes if eggs are to be undercooked; or are combined unless: cooked to order and immediately served; used immediately before baking and thoroughly cooked; or prepared under a HACCP plan controlling *Salmonella* Enteritidis**

This item should be marked IN or OUT of compliance, based on direct observations and discussions with the PIC and food employees regarding whether or not certain foods are served or certain practices occur in an establishment serving a highly susceptible population.

This item is marked IN compliance when only pasteurized eggs are used in foods/recipes containing undercooked eggs and recipes in which more than one egg is combined, unless there is a cook step or HACCP plan to control *Salmonella* Enteritidis.

**NA**            This item may be marked NA if the establishment does not serve a highly susceptible population.

**NO**            **Do Not Mark** this item NO

3-801.11 (B) and (E) Pasteurized Foods, Prohibited Re-service and Prohibited Food <sup>(P)</sup>

**IN OUT**      **C. Raw or partially cooked animal food and raw seed sprouts not served**

This item should be marked IN or OUT of compliance, based on direct observations and discussions with the PIC and food employees regarding whether or not certain foods are served or certain practices occur in an establishment serving a highly susceptible population.

This item is marked IN compliance if no raw or partially cooked animal foods or raw seed sprouts are served.

**NA**            This item may be marked NA if the establishment does not serve a highly susceptible population.

**NO**            **Do Not Mark** this item NO

3-801.11 (C) Pasteurized Foods, Prohibited Re-service, and Prohibited Food <sup>(P)</sup>

**IN OUT**      **D. Food not re-served under certain conditions**

This item should be marked IN or OUT of compliance based on direct

observations and discussions with the PIC and food employees regarding whether or not certain foods are served or certain practices occur in an establishment serving a highly susceptible population.

This item is marked IN compliance if no unopened packaged food is re-served following service to patients in medical isolation or quarantine or protective environment, also IN if packages of FOOD from any patients, clients, or other CONSUMERS are not re-served to PERSONS in protective environment isolation.

**NA** This item may be marked NA if the establishment does not serve a highly susceptible population.

**.NO** **Do Not Mark** this item NO

3-801.11 (G) Pasteurized Foods, Prohibited Re-service, and Prohibited Food <sup>(C)</sup>

### Chemical

**IN OUT** **27. Food additives: approved & properly used**

This item should be marked IN or OUT of compliance based on direct observations of food ingredients in storage and listed as product ingredients supplemented by discussion with the PIC.

This item is marked IN compliance if approved food and color additives are on site and used properly or if sulfites are on the premises, and they are not applied to fresh fruits/vegetables for raw consumption. Approved food additives are listed and have threshold limits in accordance with the CFRs and do not apply to food additives that are considered Generally Recognized as Safe (GRAS), such as salt, pepper, etc.

This item is marked OUT of compliance if unapproved additives are found on the premises or approved additives are improperly used, such as sulfites being applied to fresh fruits or vegetables.

**NA** This item may be marked NA if the food establishment does not use any food additives or sulfites on the premises.

**NO** **Do Not Mark** this item NO

3-202.12 Additives <sup>(P)</sup>

3-302.14 Protection from Unapproved Additives <sup>(P)</sup>

## 28. Toxic Substances Properly Identified, Stored, and Used

IN OUT

### A. Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items properly identified, stored, and used

This item must be marked IN or OUT of compliance based on direct observations of labeling, storage, reconstitution, and application of bulk and working containers of cleaning agents and sanitizers, personal care items, first aid supplies, medicines, pesticides, and potential toxic and poisonous substances.

This item is marked IN compliance when bulk and working containers of cleaning agents and sanitizers are labeled; sanitizing solutions are not exceeding the maximum concentrations; personal care items, first aid supplies, medicines, and chemicals are stored separate from and not above food, equipment, utensils, linens, and single-service and single-use articles; and restricted use pesticides are applied only by or under the supervision of a certified applicator.

This item is marked OUT of compliance if a cleaning agent or sanitizer is not properly identified and stored, if a sanitizing solution has a higher concentration than prescribed, or if medicines and first aid kits are improperly labeled and stored.

NA  
NO

**Do not Mark** this item NA

**Do Not Mark** this item NO

- 7-101.11 Identifying Information, Prominence-Original Containers <sup>(PF)</sup>
- 7-102.11 Common Name - Working Containers <sup>(PF)</sup>
- 7-201.11 Separation - Storage <sup>(P)</sup>
- 7-202.11 Restriction - Presence and Use <sup>(PF)</sup>
- 7-202.12 Conditions of Use <sup>(P, PF, C)</sup>
- 7-203.11 Poisonous or Toxic Material Containers - Prohibitions <sup>(P)</sup>
- 7-204.11 Sanitizers, Criteria - Chemicals <sup>(P)</sup>
- 7-204.12 Chemicals for Washing Fruits and Vegetables - Criteria <sup>(P)</sup>
- 7-204.13 Boiler Water Additives, Criteria <sup>(P)</sup>
- 7-204.14 Drying Agents, Criteria <sup>(P)</sup>
- 7-205.11 Incidental Food Contact, Criteria - Lubricants <sup>(P)</sup>
- 7-206.11 Restricted Use Pesticides, Criteria <sup>(P)</sup>
- 7-206.12 Rodent Bait Stations <sup>(P)</sup>
- 7-206.13 Tracking Powders, Pest Control and Monitoring <sup>(P, C)</sup>
- 7-207.11 Restriction and Storage - Medicines <sup>(P, PF)</sup>
- 7-207.12 Refrigerated Medicines, Storage <sup>(P)</sup>
- 7-208.11 Storage - First Aid Supplies <sup>(P, PF)</sup>
- 7-209.11 Storage - Other Personal Care Items (Stock and Retail Sale of Poisonous or Toxic Material) <sup>(C)</sup>

**IN OUT**

**B. Poisonous or toxic materials held for retail sale properly stored**

This item should be marked IN or OUT of compliance based on direct observations of containers of cleaning agents and sanitizers, personal care items, first aid supplies, medicines, pesticides, and potential toxic and poisonous substances being stored for retail sale.

This item is marked IN compliance when containers of cleaning agents, sanitizers, 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 on retail sale shelves.

This item is marked OUT of compliance if poisonous or toxic materials are not properly stored on retail shelves.

**NA**

This item may be marked NA if the establishment does not hold poisonous or toxic materials for retail sale.

**NO**

**Do Not Mark** this item NO

7-301.11 Separation - Storage and Display, Stock and Retail Sale <sup>(P)</sup>

**Conformance with Approved Procedures**

**29. Compliance with variance, specialized process, ROP Criteria & HACCP plan**

**IN OUT**

**A. Reduced Oxygen Packaging (ROP) as specified in § 3-502.12 permitted without a variance under certain specified conditions in accordance with a required HACCP plan or without a required HACCP plan**

This item should be marked IN or OUT of compliance based on direct observations of food preparation and storage, a discussion with the PIC to determine if there is reduced oxygen packaging (including cook chill or sous vide).

This item is marked IN compliance when observations of food operations and review of available records indicate compliance is being met and HACCP plans were submitted to the regulatory authority prior to conducting a ROP operation that conforms to procedures within § 3-502.12.

This item is marked IN compliance when ROP is conducted and a HACCP plan is not required as specified in 3-502.12 (F).

**NA**

This item may be marked NA when the food establishment does not conduct reduced oxygen packaging on the premises.

**NO**

**Do Not Mark** this item NO

3-502.12 Reduced Oxygen Packaging without a Variance, Criteria <sup>(P, PF)</sup>  
8-201.13 (B) When a HACCP Plan is Required <sup>(C)</sup>  
8-201.14 (D) Contents of a HACCP Plan <sup>(PF)</sup>

**IN OUT**

**B. Operating in accordance with approved variance and/or HACCP plan as required.**

This item should be marked IN or OUT of compliance based on discussion with the PIC to determine if specialized food processes are conducted in the establishment [i.e. smoking food, curing food, using food additives to render a food so that it is not TCS food, operating a Molluscan Shellfish life-support system, etc.] and if standard operating procedures and HACCP documentation are available for review.

This item is marked IN compliance when observations of food operations and review of available records indicate compliance is being met with regards to specialized food processes.

**NA** This item may be marked NA if the establishment is not required by the regulatory authority to have a variance or HACCP plan.

**NO** **Do Not Mark** this item NO

3-502.11 Variance Requirement <sup>(PF)</sup>

4-204.110 (B) Molluscan Shellfish Tanks <sup>(PF)</sup>

8-103.12 Conformance with required procedures <sup>(P, PF)</sup>

**IN OUT** **C. When packaged in a food establishment, juice is treated under a HACCP plan to reduce pathogens or labeled as specified in the Food Code**

This item should be marked IN or OUT of compliance based on direct observations of juice being packaged in the food establishment. A discussion with the PIC and a record review of standard operating procedures and HACCP documentation or labeling should be done to determine compliance.

This item is marked IN compliance when observations and review of available records indicate compliance is being met with regards to packaging juice at retail.

**NA** This item may be marked NA when juice is not packaged in the establishment.

**NO** **Do Not Mark** this item NO

3-404.11 Treating Juice <sup>(P, PF)</sup>

## **GOOD RETAIL PRACTICES (GRPs)**

### **Safe Food and Water**

**IN OUT** **30. Pasteurized eggs used where required**

**NA** Certain menu items use eggs as an ingredient in the preparation of RTE food such as Caesar salad, dressing, Hollandaise sauce, etc. This is verified by discussion with the PIC and food employees regarding the substitution of pasteurized egg products for raw eggs in uncooked food, unless allowed under ¶ 3-401.11 (D) (3).

3-302.13 Pasteurized Eggs, Substitute for raw Eggs for Certain Recipes <sup>(P)</sup>

**IN OUT**

**31. Water and ice from approved source**

There are two types of systems: Public Water System or Non-Public Water System. Regardless of its source, it must meet drinking water standards established by EPA and applicable state standards. If a non-public system is used as Drinking water, the water must be sampled/tested at least annually and records retained on file at the food establishment and per state regulations. Consideration must be given to the supply containers, piping, hoses, etc., connected to the approved source when water is made available for mobile and or temporary food establishment without a permanent supply or a permanent establishment with a temporary interruption of its permanent water supply.

- 3-202.16 Ice <sup>(P)</sup>
- 5-101.11 Approved System - Source <sup>(P)</sup>
- 5-102.11 Standards - Quality <sup>(P)</sup>
- 5-102.12 Nondrinking Water <sup>(P)</sup>
- 5-102.13 Sampling <sup>(PF)</sup>
- 5-102.14 Sample Report <sup>(C)</sup>
- 5-104.12 Alternative Water Supply <sup>(PF)</sup>

**IN OUT**

**32. Variance obtained for specialized processing methods**

When a Food Establishment wants to deviate from a requirement in the Code, utilizes specialized processing methods as specified in § 3-502.11 such as smoking food for preservation, curing food etc. a variance must first be obtained from the regulatory authority. Per ¶ 8-201.13 (A) (3) a HACCP plan is also required as part of the variance request.

**NA**

This item may be marked NA if the establishment is not engaged in a specialized processing methods or a process or processing method, determined by the regulatory authority, to require a variance and a HACCP plan.

- 8-103.11 Documentation of Proposed Variance and Justification <sup>(PF)</sup>

**Food Temperature Control**

**IN OUT**

**33. Proper cooling methods used; adequate equipment for temperature control**

A determination must first be made that cooling food is part of the operation. To assess whether or not the methods used facilitates cooling, as specified under § 3-501.14, a discussion with the PIC should support actual observations used in cooling food. There should be enough equipment, with sufficient capacity, to meet the operation's demand for the cooling, heating, and hot/cold holding of food requiring temperature

control. Observations must support the determination of compliance.  
Frozen food is solid to the touch.

3-501.11 Frozen Food <sup>(C)</sup>

3-501.15 Cooling Methods <sup>(PF, C)</sup>

4-301.11 Cooling, Heating and Holding Capacities - Equipment <sup>(PF)</sup>

**IN OUT      34. Plant food properly cooked for hot holding**

In determining compliance, observations must be made and an actual cooking temperature must be obtained.

**NA**            This item may be marked NA if vegetables and fruits are not cooked for hot holding in the establishment.

**NO**            This item may be marked NO when plant food is cooked for hot holding, but is not present or observed at the time of inspection.

3-401.13 Plant Food Cooking for Hot Holding <sup>(PF)</sup>

**IN OUT      35. Approved thawing methods used**

A determination must first be made that thawing of TCS food is part of the operation, including ROP fish. To assess whether or not the methods used facilitate thawing, as specified § 3-501.13, a discussion with the PIC should support the determination of compliance and level of risk imposed. The CANDIDATE should recognize that various food products, especially those destined for deep-fat frying, are often slacked (not thawed) prior to cooking.

**NA**            This item may be marked NA if TCS food is not thawed in the establishment.

**NO**            This item may be marked NO if TCS food is thawed, but thawing is not taking place during the inspection.

3-501.12 TCS Food, Slacking <sup>(C)</sup>

3-501.13 Thawing <sup>(C)</sup>

**IN OUT      36. Thermometers provided & accurate**

Thermometers provide a means for assessing active managerial control of TCS food temperatures. Determine compliance by observing the location and verifying the scaling of the temperature measuring devices used 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.

- 4-203.11 Temperature Measuring Devices, Food - Accuracy <sup>(PF)</sup>
- 4-203.12 Temperature Measuring Devices, Ambient Air and Water - Accuracy <sup>(PF)</sup>
- 4-204.112 Temperature Measuring Devices - Functionality <sup>(PF, C)</sup>
- 4-302.12 Food Temperature Measuring Devices <sup>(PF)</sup>
- 4-502.11 (B) Good Repair and Calibration <sup>(PF)</sup>

### Food Identification

**IN OUT      37. Food properly labeled; original container**

Packaged food shall conform to specific labeling laws. Food packaged within the food establishment must also conform to the appropriate labeling laws, with considerations given to accuracy as well as not being misleading. In addition, all major food allergens, if present, must be accurately declared. Working containers and bulk food, removed from original packaging, requires some level of assessment as to how recognizable the food is without labeling by its common name. Molluscan shellfish and vended TCS food must specifically be assessed based on their specific packaging and labeling requirements.

- 3-202.17 Shucked Shellfish, Packaging and Identification <sup>(PF, C)</sup>
- 3-203.11 Molluscan Shellfish, Original Container <sup>(C)</sup>
- 3-302.12 Food Storage Containers Identified with Common Name of Food <sup>(C)</sup>
- 3-305.13 Vended TCS Food, Original Container <sup>(C)</sup>
- 3-601.11 Standards of Identity <sup>(C)</sup>
- 3-601.12 Honestly Presented <sup>(C)</sup>
- 3-602.11 Food Labels <sup>(PF, C)</sup>
- 3-602.12 Other Forms of Information <sup>(C)</sup>

### Prevention of Food Contamination

**IN OUT      38. Insects, rodents, & animals not present protected**

An assessment is made through observation and discussion with the PIC for measures taken to control the presence of pests in the food establishment, including elimination of entry points and harborage areas, and removal of pests and its evidence. Insect trapping devices must not be located over food preparation areas.

- 2-403.11 Handling Prohibition - Animals <sup>(PF)</sup>
- 6-202.13 Insect Control Devices, Design and Installation <sup>(C)</sup>
- 6-202.15 Outer Openings, Protected <sup>(C)</sup>
- 6-202.16 Exterior Walls and Roofs, Protective Barrier <sup>(C)</sup>

- 6-501.111 Controlling Pests <sup>(PF, C)</sup>
- 6-501.112 Removing Dead or Trapped Birds, Insects, Rodents and Other pests <sup>(C)</sup>
- 6-501.115 Prohibiting Animals <sup>(PF)</sup>

**IN OUT      39. Contamination prevented during food preparation, storage & display**

The observation and understanding of the flow of food items from the point of receipt to the point of sale, service, or distribution is necessary to determine whether a violation exists. Food is subject to direct and indirect sources of contamination in the establishment. Sources may be related to the working environment, packaging, adequacy of storage facilities, and exposure of food on display to contamination (i.e. salad bars).

- 3-202.19 Shellstock, Condition <sup>(C)</sup>
- 3-303.11 Ice Used as Exterior Coolant, Prohibited as Ingredient <sup>(P)</sup>
- 3-303.12 Storage or Display of Food in Contact with Water or Ice <sup>(C)</sup>
- 3-304.13 Linens and Napkins, Use Limitations <sup>(C)</sup>
- 3-305.11 Food Storage - Preventing Contamination from the Premises <sup>(C)</sup>
- 3-305.12 Food Storage, Prohibited Areas <sup>(C)</sup>
- 3-305.14 Food Preparation <sup>(C)</sup>
- 3-306.11 Food Display - Preventing Contamination by Consumers <sup>(P)</sup>
- 3-306.12 Condiments, Protection <sup>(C)</sup>
- 3-306.13 (B) and (C) Consumer Self-Service Operations <sup>(PF)</sup>
- 3-307.11 Miscellaneous Sources of Contamination <sup>(C)</sup>
- 6-404.11 Segregation and Location - Distressed Merchandise <sup>(PF)</sup>

**IN OUT      40. Personal cleanliness**

Observation of food employees for clean outer clothing, effective hair restraints, prohibited jewelry, and the condition or protection of fingernails must be made.

- 2-302.11 Maintenance - Fingernails <sup>(PF)</sup>
- 2-303.11 Prohibition - Jewelry <sup>(C)</sup>
- 2-304.11 Clean Condition - Outer Clothing <sup>(C)</sup>
- 2-402.11 Effectiveness - Hair Restraints <sup>(C)</sup>

**IN OUT**

**41. Wiping cloths: properly used & stored**

Wiping cloths are to be used for a designated purpose and properly used. When stored in solution, the solutions should be free of food debris and visible soil and maintained at the proper sanitizer concentration § 4-501.114. Solutions exceeding the recommended sanitizer concentrations are marked under item #28, Toxic substances properly identified, stored, and used. Sponges, if present are not to be used in contact with clean/sanitized food- contact surfaces.

3-304.14 Wiping Cloths, Use Limitations <sup>(C)</sup>

4-101.16 Sponges, Use Limitation <sup>(C)</sup>

4-901.12 Wiping Cloths, Air Drying Location <sup>(C)</sup>

**IN OUT**

**42. Washing fruits & vegetables**

Raw fruits and vegetables are to be washed prior to their preparation or offered as RTE. Chemicals are allowed for washing fruits and vegetables, along with simply washing them in water. Chemicals that are used in the wash water for fruits and vegetables must be listed and approved with threshold limits in accordance with the CFRs. Refer to the label or labeling of the additive for adequate directions and to assure safe use. Discussion with the PIC and food employees will help determine the establishment's practice.

3-302.15 (C) Washing Fruits and Vegetable <sup>(PF, C)</sup>

7-204.12 Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria <sup>(P)</sup>

**Proper Use of Utensils**

**IN OUT**

**43. In-use utensils: properly stored**

Based on the type of operation, there are a number of methods available for storage of in-use utensils during pauses in food preparation or dispensing, such as in the food, clean and protected, under running water, or changing often enough to prevent bacterial growth etc. If stored in a container of water, the water temperature must be at least 135°F. In-use utensils may not be stored in chemical sanitizer or containers of ice between uses. Ice scoops may be stored, handles up, in an ice machine bin provided the scoop handle is not in contact with the ice.

3-304.12 In-Use Utensils, Between-Use Storage <sup>(C)</sup>

**IN OUT****44. Utensils, equipment & linens: properly stored, dried, & handled**

An assessment is made of the overall storage and handling of clean equipment and utensils, including tableware located in the various areas within an establishment, the basement, wait station, dining room, etc. Equipment must be air dried prior to storage and linens must be properly cleaned and stored.

- 4-801.11 Clean Linens <sup>(C)</sup>
- 4-802.11 Specifications <sup>(C)</sup>
- 4-803.11 Storage of Soiled Linens <sup>(C)</sup>
- 4-803.12 Mechanical Washing <sup>(C)</sup>
- 4-901.11 Equipment and Utensils, Air Drying Required <sup>(C)</sup>
- 4-903.11 (A), (B) and (D) Equipment, Utensils, Linens, and Single-Service and Single-Use Articles <sup>(C)</sup>
- 4-903.12 Prohibitions <sup>(C)</sup>
- 4-904.11 (B) Kitchenware and Tableware-Preventing Contamination <sup>(C)</sup>
- 4-904.12 Soiled and Clean Tableware <sup>(C)</sup>
- 4-904.13 Preset Tableware <sup>(C)</sup>
- 4-904.14 Rinsing Equipment and Utensils after Cleaning and Sanitizing <sup>(C)</sup>

**IN OUT****45. Single-use/single-service articles: properly stored & used**

These items are not designed to be cleaned and re-used; therefore, they must be properly stored and protected to prevent from contamination. Food establishments without facilities for cleaning and sanitizing kitchenware and tableware shall provide only single-use and single-service articles.

- 4-502.12 Single-Service and Single - Use Articles, Required Use <sup>(P)</sup>
- 4-502.13 Single-Service and Single - Use articles, Use Limitations <sup>(C)</sup>
- 4-502.14 Shells, Use Limitations <sup>(C)</sup>
- 4-903.11 (A) and (C) Equipment, Utensils, Linens, and Single-Service and Single-Use Articles - Storage <sup>(C)</sup>
- 4-903.12 Prohibitions <sup>(C)</sup>
- 4-904.11 Kitchenware and Tableware <sup>(C)</sup>

**IN OUT****46. Slash-resistant and cloth gloves properly used**

The observation of food preparation activities and glove-use by food employees is necessary. There should be a discussion with the PIC on how gloves are used, if applicable, in food preparation activities. Gloves may serve as a source of cross-contamination if misused.

- 3-304.15 (B-D) Gloves, Use Limitations <sup>(C)</sup>

## Utensils, Equipment and Vending

### **IN OUT      47. Food & non-food contact surfaces cleanable, properly designed, constructed, & used**

Equipment and utensils must be properly designed, constructed, and in good repair. Proper installation and location of equipment in the food establishment are important factors to consider for ease of cleaning in preventing accumulation of debris and attractants for insects and rodents. The components in a vending machine must be properly designed to facilitate cleaning and protect food products (equipped with automatic shutoff, etc.) from potential contamination. Equipment must be properly used and in proper adjustment, such as calibrated food thermometers.

- 3-304.16 Using Clean Tableware for Second Portions and Refills <sup>(C)</sup>
- 3-304.17 Refilling Returnables <sup>(P)</sup>
- 4-101.11 Characteristics - Materials for Construction and Repair <sup>(P, C)</sup>
- 4-101.12 Cast iron, Use Limitations <sup>(C)</sup>
- 4-101.13 Lead, Use Limitations <sup>(P, C)</sup>
- 4-101.14 Copper, Use Limitations <sup>(P)</sup>
- 4-101.15 Galvanized Metal, Use Limitations <sup>(P)</sup>
- 4-101.17 Wood, Use Limitations <sup>(C)</sup>
- 4-101.18 Nonstick Coatings, Use Limitations <sup>(C)</sup>
- 4-101.19 Nonfood-Contact Surfaces <sup>(C)</sup>
- 4-102.11 Characteristics - Single-Service and Single-Use <sup>(P, C)</sup>
- 4-201.11 Equipment and Utensils - Durability and Strength <sup>(C)</sup>
- 4-201.12 Food Temperature Measuring Devices <sup>(P)</sup>
- 4-202.11 Food-Contact Surfaces - Cleanability <sup>(PF)</sup>
- 4-202.12 CIP Equipment <sup>(PF, C)</sup>
- 4-202.13 "V" Threads, Use Limitations <sup>(C)</sup>
- 4-202.14 Hot Oil Filtering Equipment <sup>(C)</sup>
- 4-202.15 Can Openers <sup>(C)</sup>
- 4-202.16 Nonfood-Contact Surfaces <sup>(C)</sup>
- 4-202.17 Kick Plates, Removable <sup>(C)</sup>
- 4-204.12 Equipment Openings, Closure and Deflectors <sup>(C)</sup>
- 4-204.13 Dispensing Equipment, Protection of Equipment and Food <sup>(P, C)</sup>
- 4-204.14 Vending Machine, Vending Stage Closure <sup>(C)</sup>
- 4-204.15 Bearings and Gear Boxes, Leakproof <sup>(C)</sup>
- 4-204.16 Beverage Tubing, Separation <sup>(C)</sup>
- 4-204.17 Ice Units, Separation of Drains <sup>(C)</sup>
- 4-204.18 Condenser Unit, Separation <sup>(C)</sup>
- 4-204.19 Can Openers on Vending Machines <sup>(C)</sup>
- 4-204.110 (A) Molluscan Shellfish Tanks <sup>(P)</sup>
- 4-204.111 Vending Machines, Automatic Shutoff <sup>(P)</sup>
- 4-204.120 Equipment Compartments, Drainage <sup>(C)</sup>
- 4-204.121 Vending Machines, Liquid Waste Products <sup>(C)</sup>
- 4-204.122 Case Lot Handling Equipment, Moveability <sup>(C)</sup>
- 4-204.123 Vending Machine Doors and Openings <sup>(C)</sup>

- 4-302.11 Utensils, Consumer Self-Service <sup>(PF)</sup>
- 4-401.11 Equipment, Clothes Washers, Dryers and Storage Cabinets, Contamination, Prevention - Location <sup>(C)</sup>
- 4-402.11 Fixed Equipment, Spacing or Sealing-Installation <sup>(C)</sup>
- 4-402.12 Fixed Equipment, Elevation or Sealing <sup>(C)</sup>
- 4-501.11 Good Repair and Proper Adjustment - Equipment <sup>(C)</sup>
- 4-501.12 Cutting Surfaces <sup>(C)</sup>
- 4-501.13 Microwave Ovens <sup>(C)</sup>
- 4-502.11 (A) and (C) Good Repair and Calibration - Utensils, Temperature and Pressure Devices <sup>(C)</sup>
- 4-603.11 Dry Cleaning <sup>(C)</sup>
- 4-902.11 Food-Contact Surfaces - Lubricating and reassembling <sup>(C)</sup>
- 4-902.12 Equipment - Lubricating and Reassembling <sup>(C)</sup>

## IN OUT

### **48. Warewashing facilities: installed, maintained, & used; test strips**

Adequate warewashing facilities must be available and used for the cleaning and sanitization of food-contact surfaces, including the availability of means to monitor their use and the effectiveness of sanitization. For example, an irreversible registering temperature indicator is provided and readily accessible for measuring the utensil surface temperature for establishment that have a hot water mechanical warewashing operation. Cleaners and sanitizers must be available for use within the food establishment. Observation of manual and mechanical warewashing methods are made to assess the procedure for cleaning and sanitizing equipment and utensils.

- 4-203.13 Pressure Measuring Devices, Mechanical Warewashing Equipment <sup>(C)</sup>
- 4-204.113 Warewashing Machine, Data Plate Operation Specifications <sup>(C)</sup>
- 4-204.114 Warewashing Machines, Internal Baffles <sup>(C)</sup>
- 4-204.115 Warewashing Machines, Temperature Measuring Devices <sup>(PF)</sup>
- 4-204.116 Manual Warewashing Equipment, Heaters and Baskets <sup>(PF)</sup>
- 4-204.117 Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers <sup>(PF)</sup>
- 4-204.118 Warewashing Machines, Flow Pressure Device <sup>(C)</sup>
- 4-204.119 Warewashing Sinks and Drainboards, Self-Draining <sup>(C)</sup>
- 4-301.12 Manual Warewashing, Sink Compartments, Requirements <sup>(PF, C)</sup>
- 4-301.13 Drainboards <sup>(C)</sup>
- 4-302.13 Temperature Measuring Devices, Manual Warewashing <sup>(PF)</sup>
- 4-302.14 Sanitizing Solutions, Testing Devices <sup>(PF)</sup>
- 4-303.11 Cleaning Agents and Sanitizers, Availability <sup>(PF)</sup>
- 4-501.14 Warewashing Equipment, Cleaning Frequency <sup>(C)</sup>
- 4-501.15 Warewashing Machines, Manufacturers' Operation Instructions <sup>(C)</sup>
- 4-501.16 Warewashing Sinks, Use Limitations <sup>(C)</sup>
- 4-501.17 Warewashing Equipment, Cleaning Agents <sup>(PF)</sup>
- 4-501.18 Warewashing Equipment, Clean Solutions <sup>(C)</sup>
- 4-501.19 Manual Warewashing Equipment, Wash Solution Temperature <sup>(PF)</sup>
- 4-501.110 Mechanical Warewashing Equipment, Wash Solution

- Temperature <sup>(PF)</sup>
- 4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration <sup>(PF)</sup>
- 4-603.12 Pre-cleaning <sup>(C)</sup>
- 4-603.13 Loading of Soiled Items, Warewashing Machines <sup>(C)</sup>
- 4-603.14 Wet Cleaning <sup>(C)</sup>
- 4-603.15 Washing, Procedures for Alternative Manual Warewashing Equipment <sup>(C)</sup>
- 4-603.16 Rinsing Procedures <sup>(C)</sup>

**IN OUT      49. Non-food contact surfaces clean**

Observations should be made to determine if the frequency of cleaning is adequate to prevent soil accumulations on non-food-contact surfaces.

- 4-601.11 (B) and (C) Equipment, Food-Contact Surfaces, Nonfood Contact Surfaces and Utensils <sup>(C)</sup>
- 4-602.13 Nonfood Contact Surfaces <sup>(C)</sup>

**Physical Facilities**

**IN OUT      50. Hot & cold water available; adequate pressure**

Regardless of the supply system, the distribution of water to the establishment must be protected and operated according to law. Adequate pressure is to be maintained at all fixtures during peak demand including the capacity to provide hot water at peak hot water demand.

- 5-103.11 Capacity - Quality and Availability <sup>(PF)</sup>
- 5-103.12 Pressure <sup>(PF)</sup>
- 5-104.11 System-Distribution, Delivery, and Retention <sup>(PF)</sup>

**IN OUT      51. Plumbing installed; proper backflow devices**

The observation of an approved plumbing system, installed and maintained, including the equipment and devices connected to the potable water supply, is necessary to determine whether a violation exists. An assessment of the layout of the establishment and the water distribution system is made to determine if there are any points at which the potable water supply is subject to contamination or is in disrepair.

- 5-101.12 System Flushing and Disinfection <sup>(P)</sup>
- 5-201.11 Approved - Materials <sup>(P)</sup>
- 5-202.11 Approved System and Cleanable Fixtures <sup>(P, C)</sup>
- 5-202.13 Backflow Prevention, Air Gap <sup>(P)</sup>
- 5-202.14 Backflow Prevention Device, Design Standard <sup>(P)</sup>
- 5-202.15 Conditioning Device, Design <sup>(C)</sup>
- 5-203.13 Service Sink <sup>(C)</sup>

- 5-203.14 Backflow Prevention Device, When Required <sup>(P)</sup>
- 5-203.15 Backflow Prevention Device, Carbonator <sup>(P)</sup>
- 5-204.12 Backflow Prevention Device, Location <sup>(C)</sup>
- 5-204.13 Conditioning Device, Location <sup>(C)</sup>
- 5-205.12 Prohibiting a Cross Connection <sup>(P, PF)</sup>
- 5-205.13 Scheduling Inspection and Service for a Water System Device <sup>(PF)</sup>
- 5-205.14 Water Reservoir of Fogging Devices, Cleaning <sup>(P)</sup>
- 5-205.15 System Maintained in Good Repair <sup>(P, C)</sup>
- 5-301.11 Approved - Materials for Mobile Water Tank and Mobile Food Establishment Water Tank <sup>(P, C)</sup>
- 5-302.11 Enclosed System, Sloped to Drain <sup>(C)</sup>
- 5-302.12 Inspection and Cleaning Port, Protected and Secured <sup>(C)</sup>
- 5-302.13 “V” Type Threads, Use Limitation <sup>(C)</sup>
- 5-302.14 Tank Vent, Protected <sup>(C)</sup>
- 5-302.15 Inlet and Outlet, Sloped to Drain <sup>(C)</sup>
- 5-302.16 Hose, Construction and Identification <sup>(P, C)</sup>
- 5-303.11 Filter, Compressed Air <sup>(P)</sup>
- 5-303.12 Protective Cover or Device <sup>(C)</sup>
- 5-303.13 Mobile Food Establishment Tank Inlet <sup>(C)</sup>
- 5-304.11 System Flushing and Sanitization - Operation and Maintenance <sup>(P)</sup>
- 5-304.12 Using a Pump and Hoses, Backflow Prevention <sup>(C)</sup>
- 5-304.13 Protecting Inlet, Outlet and Hose Fitting <sup>(C)</sup>
- 5-304.14 Tank, Pump and Hoses, Dedication <sup>(P)</sup>

**IN OUT**

**52. Sewage & waste water properly disposed**

There are two types of systems: public sewage treatment plant and an individual sewage disposal system. Observation of the establishment’s overall sewage and wastewater system is necessary to determine if a violation exists. Indications that a system is not functioning properly may include the presence of sewage back-up into the establishment or outdoors on the ground. Condensate drippage and other non-sewage wastes must be drained to a system in accordance to law, and backflow prevention, if required, must be installed between the sewage system and the drain of equipment holding food or utensils. Mobile wastewater holding tanks must also be assessed for capacity and maintenance. Mop water must be disposed of properly.

- 5-401.11 Capacity and Drainage <sup>(C)</sup>
- 5-402.11 Backflow Prevention <sup>(P)</sup>
- 5-402.12 Grease Trap <sup>(C)</sup>
- 5-402.13 Conveying Sewage <sup>(P)</sup>
- 5-402.14 Removing Mobile Food Establishment Wastes <sup>(PF)</sup>
- 5-402.15 Flushing a Waste Retention Tank <sup>(C)</sup>
- 5-403.11 Approved Sewage Disposal System <sup>(P)</sup>
- 5-403.12 Other Liquid Wastes and Rainwater <sup>(C)</sup>

**IN OUT**

**53. Toilet facilities: properly constructed, supplied, & cleaned**

A toilet facility should be assessed to determine if: it is not an attractant to insects; the number of fixtures are adequate; toilet tissue and a covered trash receptacle (ladies room only) are provided; fixtures are not being kept clean; and the door self-closes to prevent recontamination of hands.

- 5-203.12 Toilets and Urinals <sup>(C)</sup>
- 5-501.17 Toilet Room Receptacle, Covered <sup>(C)</sup>
- 6-202.14 Toilet Rooms, Enclosed <sup>(C)</sup>
- 6-302.11 Toilet Tissue, Availability <sup>(PF)</sup>
- 6-402.11 Convenience and Accessibility <sup>(C)</sup>
- 6-501.18 Cleaning of Plumbing Fixtures <sup>(C)</sup>
- 6-501.19 Closing Toilet Room Doors <sup>(C)</sup>

**IN OUT      54. Garbage & refuse properly disposed; facilities maintained**

The assessment of the refuse collection and disposal areas for proper receptacles and maintenance is necessary to determine whether a violation exists. Since refuse areas may attract and harbor insects and pests, as well as create a public health nuisance, particular attention must be paid to the maintenance of the refuse facilities and area.

- 5-501.11 Outdoor Storage Surface <sup>(C)</sup>
- 5-501.12 Outdoor Enclosure <sup>(C)</sup>
- 5-501.13 Receptacles <sup>(C)</sup>
- 5-501.14 Receptacles in Vending Machines <sup>(C)</sup>
- 5-501.15 Outside Receptacles <sup>(C)</sup>
- 5-501.16 Storage Areas, Rooms and Receptacles, Capacity and Availability <sup>(C)</sup>
- 5-501.18 Cleaning Implements and Supplies <sup>(C)</sup>
- 5-501.19 Storage Area, Redeeming Machines, Receptacles and Waste Handling Units, Location <sup>(C)</sup>
- 5-501.110 Storing Refuse, Recyclables and Returnables <sup>(C)</sup>
- 5-501.111 Area, Enclosures and Receptacles, Good Repair <sup>(C)</sup>
- 5-501.112 Outside Storage Prohibitions <sup>(C)</sup>
- 5-501.113 Covering Receptacles <sup>(C)</sup>
- 5-501.114 Using Drain Plugs <sup>(C)</sup>
- 5-501.115 Maintaining Refuse Areas and Enclosures <sup>(C)</sup>
- 5-501.116 Cleaning Receptacles <sup>(C)</sup>
- 5-502.11 Frequency - Removal <sup>(C)</sup>
- 5-502.12 Receptacles or Vehicles <sup>(C)</sup>
- 5-503.11 Community or Individual Facility <sup>(C)</sup>
- 6-202.110 Outdoor Refuse Areas, Curbed and Graded to Drain <sup>(C)</sup>

**IN OUT      55. Physical facilities installed, maintained, & clean**

Observations are made of the overall installation, conditions or practices related to the physical facility (i.e. whether they are in good repair and maintained). It is important that a general assessment is made in determining the level of compliance, such as in an isolated incident versus

a trend, and of the potential public health impact involved. Storage of maintenance tools, use of laundry facilities, (if applicable), and separate living/sleeping quarters are included in this section.

- 4-301.15 Clothes Washers and Dryers <sup>(C)</sup>
- 4-401.11 (C) Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention <sup>(C)</sup>
- 4-803.13 Use of Laundry Facilities <sup>(C)</sup>
- 6-101.11 Surface Characteristics - Indoor Areas <sup>(C)</sup>
- 6-102.11 Surface Characteristics - Outdoor Areas <sup>(C)</sup>
- 6-201.11 Floors, Walls and Ceilings - Cleanability <sup>(C)</sup>
- 6-201.12 Floors, Walls and Ceilings, Utility Lines <sup>(C)</sup>
- 6-201.13 Floor and Wall Junctures, Coved, and Enclosed or Sealed <sup>(C)</sup>
- 6-201.14 Floor Carpeting, Restrictions and Installations <sup>(C)</sup>
- 6-201.15 Floor Covering, Mats and Duckboards <sup>(C)</sup>
- 6-201.16 Walls and Ceiling Coverings and Coatings <sup>(C)</sup>
- 6-201.17 Walls and Ceilings, Attachments <sup>(C)</sup>
- 6-201.18 Walls and Ceilings, Studs, Joists and Rafters <sup>(C)</sup>
- 6-202.17 Outdoor Food Vending Areas, Overhead Protection <sup>(C)</sup>
- 6-202.18 Outdoor Servicing Areas, Overhead Protection <sup>(C)</sup>
- 6-202.19 Outdoor Walking and Driving Surfaces, Graded to Drain <sup>(C)</sup>
- 6-202.111 Private Homes and Living or Sleeping Quarters, Use Prohibition <sup>(P)</sup>
- 6-202.112 Living or Sleeping Quarters, Separation <sup>(C)</sup>
- 6-501.11 Repairing-Premises, Structures, Attachments, and Fixtures - Methods <sup>(C)</sup>
- 6-501.12 Cleaning, Frequency and restrictions <sup>(C)</sup>
- 6-501.13 Cleaning Floors, Dustless Methods <sup>(C)</sup>
- 6-501.15 Cleaning Maintenance Tools, Preventing Contamination <sup>(PF)</sup>
- 6-501.16 Drying Mops <sup>(C)</sup>
- 6-501.17 Absorbent Materials on floors, Use Limitations <sup>(C)</sup>
- 6-501.113 Storing Maintenance Tools <sup>(C)</sup>
- 6-501.114 Maintaining Premises, Unnecessary Items and Litter <sup>(C)</sup>

**IN OUT**

**56. Adequate ventilation & lighting; designated areas used**

Observations should be made to ensure that the ventilation is adequately preventing an accumulation of condensation, grease or other soil from potentially contaminating food and the surrounding environment and that lights are at an adequate light intensity, and personal belongings are properly stored to maintain clean and sanitary facility and protect food and equipment.

4-202.18 Ventilation Hood Systems, Filters <sup>(C)</sup>

4-204.11 Ventilation Hood Systems, Drip Prevention <sup>(C)</sup>

4-301.14 Ventilation Hood Systems, Adequacy <sup>(C)</sup>

6-202.11 Light Bulbs, Protective Shielding <sup>(C)</sup>

6-202.12 Heating, Ventilation, air Conditioning System Vents <sup>(C)</sup>

6-303.11 Intensity- Lighting <sup>(C)</sup>

6-304.11 Mechanical - Ventilation <sup>(C)</sup>

6-305.11 Designation - Dressing Areas and Lockers <sup>(C)</sup>

6-403.11 Designated areas - Employee Accommodations <sup>(C)</sup>

6-501.14 Cleaning Ventilation Systems, Nuisance and Discharge Prohibition <sup>(C)</sup>

6-501.110 Using Dressing Rooms and Lockers <sup>(C)</sup>

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<b>Risk Control Plan</b>			
<b>Establishment Name:</b>		<b>Type of Facility:</b>	
<b>Physical Address:</b>		<b>Person in Charge:</b>	
<b>City:</b>	<b>State:</b>	<b>Zip:</b>	<b>County:</b>
<b>Inspection Time In:</b>	<b>Inspection Time Out:</b>	<b>Date:</b>	<b>Inspector's Name:</b>
<b>Agency:</b>			

**Specific observation noted during inspection:**


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**Applicable code violation(s): - (Optional)**


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**Risk factor to be controlled:**


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**Hazard (most common, significant):**


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**What must be achieved to gain compliance in the future:**


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**How will active managerial control be achieved:**

(Who is responsible for the control, what monitoring and record keeping is required, who is responsible for monitoring and completing records, what corrective actions should be taken when deviations are noted, how long is the plan to continue)

**How will the results of implementing the RCP be communicated back to the inspector:**

As the person in charge of the \_\_\_\_\_ located at \_\_\_\_\_,  
I have voluntarily developed this risk control plan, in consultation with  
\_\_\_\_\_ and understand the provisions of this plan.

\_\_\_\_\_  
(Establishment Manager)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Regulatory Official)

\_\_\_\_\_  
(Date)

<b>Risk Control Plan</b>			
<b>Establishment Name: Hamburger Heaven</b>		<b>Type of Facility: Fast Food (risk category 3)</b>	
<b>Physical Address: 1234 Anywhere Street</b>		<b>Person in Charge: Sam Jones</b>	
<b>City: Nice</b>	<b>State: HI</b>	<b>Zip: 1111</b>	<b>County: Franklin</b>
<b>Inspection Time In: 8:00 am</b>	<b>Inspection Time Out: 1:00 pm</b>	<b>Date: 2/6/09</b>	<b>Inspector's Name: Jane Smith</b>
<b>Agency: State Health Dept.</b>			

**Specific observation noted during inspection:**

Hamburger cooked to 130°F on grill.

**Applicable code violation(s):**

3-401.11(A)(2)

**Risk factor to be controlled:**

Cooking

**Hazard (most common):**

*Salmonella; E. coli O157:H7*

**What must be achieved to gain compliance in the future:**

Continue to cook until internal temperature of 68°C (155°F) is met. Use a thin probe thermometer to check the final cooking temperature. Establish cooking procedures for ground beef.

**How will active managerial control be achieved:**

(Who is responsible for the control, what monitoring and record keeping is required, who is responsible for monitoring and completing records, what corrective actions should be taken when deviations are noted, how long is the plan to continue)

Temperature checks of hamburger patties will be taken using appropriate temperature measuring devices on the first batch of hamburgers cooked by assigned staff, i.e. chef, manager, line cook.

Sam Jones will record the temperature on his production chart.

Hamburgers with a temperature below 68°C (155°F) will be returned to the grill for further cooking to internal temperature of 68°C (155°F). Final temperature will be noted on the production chart.

**How will the results of implementing the RCP be communicated back to the inspector:**

Temperature records will be faxed to Jane Smith at xxx-xxx-xxxx each Friday for 4 weeks.

As the person in charge of the Hamburger Heaven located at 1234 Anywhere Street, I have voluntarily developed this risk control plan, in consultation with Jane Smith and understand the provisions of this plan.

Sam Jones  
(Establishment Manager)

2/6/2006  
(Date)

Jane Smith  
(Regulatory Official)

2/6/2006  
(Date)

# ANNEX 4-1

## HACCP PLAN VERIFICATION WORKSHEET

(Note: This document is for optional use only, and is not a requirement for the Standardization Procedure)

Establishment Name:		Type of Facility:	
Physical Address:		Person in Charge:	
City:	State:	Zip:	County:
Inspection Time In:	Inspection Time Out:	Date:	Candidate's Name:
Agency:	Standard's Name:	Indicate Person Filling Out Form: (circle one) Candidate's Form / Standard's Form	
Cold Holding Requirement For Jurisdiction: [5°C (41°F)_____] or [7°C (45°F)_____ ] or [5°C (41°F) and 7°C (45°F) combination:_____]			

1. Have there been any changes to the food establishment menu?

Yes \_\_\_\_\_ No \_\_\_\_\_

DESCRIBE:

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2. Was there a need to change the food establishment HACCP plan because of these menu changes?

Yes \_\_\_\_\_ No \_\_\_\_\_

3. List Critical Control Points (CCPs) and Critical Limits (CLs) identified by the establishment HACCP plan?

CCPs	CLs
_____	_____
_____	_____
_____	_____
_____	_____

4. What monitoring records for CCPs are required by the plan?

Type of Record	Monitoring Frequency	Record Location
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

5. Record compliance under 29B of the FDA Standardization Inspection Report (ANNEX 2, Section 1). Are monitoring actions performed according to the plan?

Yes\_\_\_\_\_ No\_\_\_\_\_ Describe under 29B of the FDA Standardization Inspection Report.

6. Is immediate corrective action taken and recorded when CLs established by the plan are not met?

Yes\_\_\_\_\_ No\_\_\_\_\_

DESCRIBE:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

7. Are the corrective actions the same as described in the plan?

Yes\_\_\_\_\_ No\_\_\_\_\_

DESCRIBE:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

8. Who is responsible for verification that the required records are being properly maintained?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

9. Did employees and managers demonstrate knowledge of the HACCP plan?

Yes\_\_\_\_\_ No\_\_\_\_\_

DESCRIBE:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

10. What training has been provided to support the HACCP plan?

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11. Describe examples of any documentation that the above training was accomplished?

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12. Are calibrations of equipment/thermometers performed as required by the plan?

Yes \_\_\_\_ No \_\_\_\_

DESCRIBE:

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Additional Comments:

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Person Interviewed: \_\_\_\_\_

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## ANNEX 4-2

### HACCP PLAN VERIFICATION SUMMARY

[For Subparagraph 3-302 (B)(3)]

Establishment Name:			Type of Facility:		
Physical Address:			Person in Charge:		
City:		State:		Zip:	County:
Insp. Time In:	Insp. Time Out:	Date:	Candidate's Name:		
Agency:		Standard's Name:		Indicate Person Filling Out Form: (circle one) Candidate / Standard	

<b>Chart 1: HACCP Plan Verification Summary</b>			
<b>HACCP Plan Verification Summary (circle YES or NO)</b>			
	<b>Record #1</b>	<b>Record #2</b>	<b>Record #3</b>
	<b>Current Date if Possible</b>	<b>2<sup>nd</sup> Selected Date:</b>	<b>3<sup>rd</sup> Selected Date:</b>
Required Monitoring Recorded <sup>1</sup>	YES/ NO	YES / NO	YES / NO
Accurate and Consistent <sup>2</sup>	YES / NO	YES / NO	YES /NO
Corrective Action Documented <sup>3</sup>	YES / NO	YES / NO	YES/ NO
Total # of record answers that are in Disagreement with the Standard = _____			
(This box for Completion by Standard only)			

The use of a HACCP plan by a food establishment can be verified through a review of food establishment records and investigating the following information:

1. Does the food establishment's HACCP documentation indicate that the required monitoring procedures were followed (frequency, initials, dated, etc.) on the 3 selected dates? A "YES" answer would indicate that all required monitoring was documented. If any required monitoring was not documented, a "NO" answer would be circled in this section.
2. Does the food establishment's HACCP documentation for the selected dates appear accurate and consistent with other observations? A "YES" answer would indicate that the record appears accurate and consistent. A "NO" answer would indicate that there is inaccurate or inconsistent HACCP documentation.
3. Was corrective action documented in accordance with the HACCP plan when CLs were not met on each of the 3 selected dates? A "YES" answer would indicate that corrective action was documented for each CL not met for each of the 3 selected dates. A "Yes" can also mean that no corrective action was needed. A "NO" answer would indicate any missing or inaccurate documentation of corrective action.

**SCORING FORM AND INSTRUCTIONS FOR SCORING AND DETERMINING PERFORMANCE**

The purpose of the following chart is to tally the disagreement between the Candidate's and the Standard's responses on the FDA Standardization Inspection Report (Annex 2 Section 1). The Standard determines whether the Candidate properly identified and categorized violative conditions on each of the "Foodborne Illness Risk Factors/*Food Code* Interventions" and the "Good Retail Practices (GRPs)" portions of the FDA Standardization Inspection Report. The Standard may mark an item "S" to reflect a disagreement in a case where the Candidate has the opportunity to make an observation or take a measurement and fails to do so, and intervention by the Standard would alert the Candidate to the missed opportunity.

<b>Chart 2: Performance Criteria Tally of Disagreements in Each Establishment</b>									
Candidate's Name:					Standard's Name:				
Candidate's Address:		Agency:	City:		State:	Zip:	County:		
Standard's Address:		Agency:	City:		State:	Zip:	County:		
Total Inspection Time:		Date:	Location of Standardization:						
<b>ESTABLISHMENTS</b>									
Performance Area	1	2	3	4	5	6	7	8	TOTAL (1-8) or TOTAL (1-6)
<b>Risk Factors and Public Health Interventions</b>									
<b>Good Retail Practices</b>									

## SCORING FORM AND INSTRUCTIONS FOR SCORING AND DETERMINING PERFORMANCE

### **Foodborne Illness Risk Factors and *Food Code* Interventions:**

To pass this section, the Candidate must achieve an average score of 90 percent (no more than 50 disagreements for all 8 establishments) with no more than 12 disagreements per establishment.

**Step 1.** Determine the number of disagreements per establishment and record it in the chart (Performance Criteria Tally of Disagreements).

- If the disagreements/establishment is less than 13, proceed to step 2.
- If the disagreements/establishment is equal to or greater than 13, stop inspections. Candidate fails.

**Step 2.** Total the number of disagreements on Foodborne Illness Risk Factors and *Food Code* Interventions for all the establishments.

- If the disagreements are equal to or less than 50 for 8 establishments, the Candidate passes.
- If the disagreements are greater than 50 for 8 establishments, the Candidate fails.
- If the disagreements are equal to or less than 37 for 6 establishments, the Candidate passes.
- If the disagreements are greater than 37 for 6 establishments, the Candidate fails.

### **Good Retail Practices:**

To pass this section, the Candidate must achieve an average score of 85 percent (no more than 32 disagreements for all 8 establishments) and have no more than 5 disagreements on GRPs per establishment.

**Step 1.** Determine the number of disagreements per establishment.

- If the disagreements/establishment are less than 6, proceed to step 2.
- If the disagreements/establishment are equal to or more than 6, stop inspections. Candidate fails.

**Step 2.** Total the number of disagreements on GRPs for all establishments.

- If the disagreements are less than or equal to 32 for 8 establishments, the Candidate passes.
- If the disagreements are greater than 32 for 8 establishments, the Candidate fails.
- If the disagreements are less than or equal to 24 for 6 establishments, the Candidate passes.
- If the disagreements are greater than 24 for 6 establishments, the Candidate fails.

**Application of HACCP Principles:** A "satisfactory" score is required to pass.

- Refer to Chapter 3, Table 2

### SCORING FORM (EXAMPLE #1)

<b>Chart 3a: Sample Performance Criteria Tally of Disagreements in Each Establishment</b>									
<b>PERFORMANCE CRITERIA TALLY OF DISAGREEMENTS IN EACH ESTABLISHMENT (SAMPLE)</b>									
Candidate's Name: <b>Jane Smith</b>					Standard's Name: <b>George Harris</b>				
Candidate's Address: <b>1234 Anywhere Street</b>		Agency: <b>State</b>		City: <b>Nice</b>			State: <b>HI</b>	Zip: <b>12345</b>	County: <b>Franklin</b>
Standard's Address: <b>4321 Somewhere Street</b>		Agency: <b>FDA</b>		City: <b>Washington DC</b>			State:	Zip: <b>20204</b>	County:
Total Inspection Time: <b>72 hrs</b>		Date: <b>7/25/06</b>		Location of Standardization: <b>Washington D.C.</b>					
ESTABLISHMENTS									
Performance Area	1	2	3	4	5	6	7	8	TOTAL (1-8) Total (1-6)
<b>Foodborne Illness Risk Factors and <i>Food Code</i> Interventions</b>	9	12	12	5	2	2	3	1	46
<b>Good Retail Practices</b>	3	2	2	5	3	3	2	2	22

In this example, the Candidate passes both the **FOODBORNE ILLNESS RISK FACTORS** and **FOOD CODE INTERVENTIONS** and the **GOOD RETAIL PRACTICES** portions. The number of disagreements for any one establishment did not exceed the maximum and the total number of disagreements for all the establishments also did not exceed the maximum number.

### SCORING FORM (EXAMPLE #2)

<b>Chart 3b: Sample Performance Criteria Tally of Disagreements in Each Establishment</b>									
<b>PERFORMANCE CRITERIA TALLY OF DISAGREEMENTS IN EACH ESTABLISHMENT (SAMPLE)</b>									
Candidate's Name: <b>Jane Smith</b>					Standard's Name: <b>George Harris</b>				
Candidate's Address: <b>1234 Anywhere Street</b>		Agency: <b>State</b>		City: <b>Nice</b>			State: <b>HI</b>	Zip: <b>12345</b>	County: <b>Franklin</b>
Standard's Address: <b>4321 Somewhere Street</b>		Agency: <b>FDA</b>		City: <b>Washington D.C.</b>			State:	Zip: <b>20204</b>	County:
Total Inspection Time: <b>72 hrs</b>		Date: <b>7/25/09</b>		Location of Standardization: <b>Washington D.C.</b>					
ESTABLISHMENTS									
Performance Area	1	2	3	4	5	6	7	8	TOTAL (1-8) Total (1-6)
<b>Foodborne Illness Risk Factors and <i>Food Code</i> Interventions</b>	12	12	13						
<b>Good Retail Practices</b>	5	5	4						

Here the Candidate fails the **FOODBORNE ILLNESS RISK FACTORS** and **FOOD CODE INTERVENTIONS** portion of this exercise. The Candidate was close to the maximum number of disagreements for any one establishment in the first two facilities and exceeded this maximum number of disagreements in the third establishment.

## FINAL SCORING REPORT

<b>Chart #4: Candidate's Composite Performance Score</b>			
<b>CANDIDATE'S FINAL PERFORMANCE SCORE</b>			
<b>Candidate's Name:</b>		<b>Title:</b>	
<b>Agency:</b>		<b>Office Telephone Number:</b>	
<b>Office Address:</b>		<b>City:</b>	<b>State:</b> <b>Zip:</b>
<b>Standard's Name:</b>		<b>Standard's Title:</b>	
<b>Agency:</b>	<b>Office Telephone Number:</b>	<b>Location of Standardization:</b>	
<b>Office Address:</b>		<b>City:</b>	<b>State:</b> <b>Zip:</b>
Instructions: For the following Performance Areas circle the Level of Agreement.			
<b>PERFORMANCE AREA</b>	<b>LEVEL OF AGREEMENT</b>		
A. <b>FOODBORNE ILLNESS RISK FACTORS AND <i>FOOD CODE</i> INTERVENTIONS</b>	PASSES	FAILS	
B. <b>GOOD RETAIL PRACTICES</b>	PASSES	FAILS	
C. <b>APPLICATION OF HACCP PRINCIPLES</b>	SATISFACTORY	UNSATISFACTORY	
a. <b>Process flow Charts</b>	Satisfactory	Unsatisfactory	
b. <b>Risk Control Plan</b>	Satisfactory	Unsatisfactory	
c. <b>Verification of HACCP Plans</b>	Satisfactory	Unsatisfactory	
d. <b>Statement of HACCP Principles (Initial standardization only)</b>	Satisfactory	Unsatisfactory	
D. <b>INSPECTION EQUIPMENT</b>	SATISFACTORY	NEEDS IMPROVEMENT	
E. <b>COMMUNICATION</b>	SATISFACTORY	NEEDS IMPROVEMENT	

**STANDARD'S SIGNATURE:** \_\_\_\_\_

**NAME (Print):** \_\_\_\_\_ **NAME (Signature):** \_\_\_\_\_

**Date:** \_\_\_\_\_

**CHECKLIST FOR STANDARDIZATION PERFORMANCE AREAS**

**This Checklist for Standardization Performance Areas is intended as an aid to both the Candidate for standardization and the Standard. Expectations for each of the five Performance Areas are spelled out to assist the Candidate in preparing for the exercise and to help the Standard evaluate the performance of the Candidate. Minimum requirements for standardization or re-standardization are provided in Table 2 “Summary of Level of Agreement Required for Each Performance Area.” Results should be discussed at the completion of each standardization inspection to provide feedback to the Candidate before beginning the next inspection. The checklist and comments should be used to help determine whether the Candidate completes standardization/re-standardization (see Table 2) and also to provide feedback to the Candidate about elements of the inspection process that need improvement. Columns may be used to check specific observations of the Candidate’s performance. Only one checklist should be used for the entire exercise and not a separate checklist for each inspection.**

<p><b><u>Performance Area A – Foodborne Illness Risk Factors and Food Code Interventions.</u> the Candidate shall demonstrate knowledge of current FDA Food Code provisions related to Food Code Interventions and Foodborne Illness Risk Factors which are most frequently associated with foodborne illness or injury.</b></p>		
<p>Major Performance Criteria (with examples)</p>		
<p><input type="checkbox"/> Completed the Standardization inspection exercise with no more than 12 disagreements out of a total of 62 items in any one food establishment and an average score of 90% for all inspections.</p> <p><input type="checkbox"/> Provided the correct Food Code provision for Out of Compliance Foodborne Illness Risk Factors and Food Code Interventions identified during inspection.</p> <p><input type="checkbox"/> Focused inspection on activities associated with Foodborne Illness Risk Factors and Food Code Interventions (with specific attention to handwashing, bare hand contact with RTE food, employee health, infested lesions on hands, approved sources, final cooking temperatures, cooling practices, cross contamination, cleaning and sanitization of food-contact surfaces, hot and cold holding, etc.).</p> <p><input type="checkbox"/> Verified that applicable Food Code Interventions were implemented.</p> <p><input type="checkbox"/> Was able to explain the significance of each Foodborne Illness Risk Factor and Food Code Intervention.</p> <p><input type="checkbox"/> Observed practices, behaviors and procedures.</p> <p><input type="checkbox"/> Verified control measures were in place for all Foodborne Illness Risk Factors and Food Code Interventions.</p>		
<p>Comments for Performance Area A:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>		

**Performance Area B – Good Retail Practices. The Candidate shall demonstrated knowledge of current FDA *Food Code* provisions related to Good Retail Practices and the ability to interpret and apply them.**

Major Performance Criteria (with examples)		
<input type="checkbox"/> Completed the Standardization inspection exercise with no more than 5 disagreements out of a total of 27 items in any one food establishment and an average score of 85% for all inspections. <input type="checkbox"/> Minimized but didn't ignore time and attention spent on facilities, general sanitation, Good Retail Practices. <input type="checkbox"/> Was able to explain the significance of each Good Retail Practice. <input type="checkbox"/> Observed practices, behaviors and procedures.		

Comments for Performance Area B.

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**Performance Area C – Application of HACCP. The Candidate shall demonstrate the ability to verify compliance with an existing HACCP plan and apply HACCP principles in the development of flow charts and risk control plans. In the absence of a HACCP plan, the Candidate shall demonstrate the ability to apply all HACCP principles to the inspection process.**

Major Performance Criteria (with examples).		
<input type="checkbox"/> Evaluated an existing HACCP Plan for necessary information, necessary records and compliance with the Plan. <input type="checkbox"/> Verified that the Plan contained hazards of concern, CCPs, CLs, monitoring procedures, corrective actions, verification procedures and record keeping. <input type="checkbox"/> Verified a HACCP Plan is available and used for juice packaged on-site, for ROP per 3-502.12, or for variances for smoking for preservation, curing, using food additives, other ROP, shellfish display tanks, custom processing animals, sprouting seeds, or other processing as determined by the RA. <input type="checkbox"/> Reviewed required letters of guaranty for parasite destruction, intact beef steaks. <input type="checkbox"/> Identified the three food preparation processes (no cook step, same day service and complex food preparation) used in the food facility and inspected and developed three process flow diagrams to illustrate each process (including ingredients, leftovers, CCPs, CLs, etc. with two or fewer errors to Pass. <input type="checkbox"/> Developed a Risk Control Plan based on an observed Out of Compliance Risk Factor which includes the Risk Factor, Code provision, hazards of concern, CCP, CLs, required monitoring and record keeping and person responsible, corrective action when deviations occur based on the PIC's recommendations, length of RCP, and how and when PIC communicates the results. <input type="checkbox"/> Observed practices, behaviors and procedures.		

Comments for Performance Area C:

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**Performance Area D – Inspection Equipment. The Candidate shall be equipped and familiar with inspection equipment essential to each food establishment inspection. During the inspection, the Candidate shall demonstrate knowledge of proper use of essential inspection equipment.**

Major Performance Criteria (with examples)		
<input type="checkbox"/> Possessed essential inspection equipment to conduct the standardization inspection (including inspection forms, head cover, calibrated thermocouple, maximum registering thermometer or temperature sensitive tape, chemical test kits/strips, flashlight, and alcohol swabs. <input type="checkbox"/> Was familiar with the operation of essential inspection equipment list above and optional equipment, if used (such as infrared thermometer, pH meter, water activity meter, lab grade pH strips, etc.) <input type="checkbox"/> Demonstrated proper use of equipment according to the manufacturer’s instructions and equipment’s capability (such as bi-metallic thermometer, infrared thermometer, temperature sensitive tape, chemical test strips, etc.)		
Comments for Performance Area D: _____ _____ _____ _____		

**Performance Area E – Communication. The Candidate shall demonstrate the ability to effectively communicate with the person in charge and explain significant inspection findings to the person in charge at the conclusion of the inspection.**

Major Performance Criteria (with examples)		
<input type="checkbox"/> Was able to professionally and effectively communicate with the Person in Charge and employees about the Standardization inspection and food safety issues encountered during the introduction and inspection, to better understand operations and management systems to monitor and control CCPs, to answer questions and provide other resources for needed information, to provide positive feedback if possible, to establish open dialogue, and to conduct menu reviews. <input type="checkbox"/> Used non-verbal communication techniques to convey information (setting a good example by dress, hair restraint, and demeanor; not working when ill; cleaning and sanitizing temperature measuring devices (TMDs); washing hands when entering the prep area; not contaminating food contact surfaces; using or helping to calibrate a thermometer; overcoming language or communication barriers by using drawings or demonstrations. <input type="checkbox"/> Explained the public health significance and the contribution to foodborne illness of Out of Compliance Foodborne Illness Risk Factors and <i>Food Code</i> Interventions and discussed short and long term behavior changes to achieve compliance.		
Comments for Performance Area E. _____ _____ _____ _____		

## TEMPLATE FOR CONDUCTING A RISK-BASED INSPECTION

A standardization exercise is intended to be a template for regulatory inspections conducted by federal, state, local, and tribal regulatory officials at the retail level. That is, both a Candidate's standardization and a regulatory inspection should contain education/training components and auditing/evaluating components. The focus of both types of inspections should be on the application of *Food Code* provisions related to Foodborne Illness Risk Factors and *Food Code* Interventions associated with foodborne illness but which does not ignore good retail practices. The template below provides suggested inspection activities for both standardization inspections (Stand.) and regulatory inspections (Reg.) based on the five Performance Areas (PA) identified in Subpart 3-102 of the standardization procedure.

Performance Area A – Foodborne Illness Risk Factors and *Food Code* Interventions

Performance Area B – Good Retail Practices

Performance Area C – Application of HACCP Principles

Performance Area D – Inspection Equipment

Performance Area E – Communication

### 1. PREPARING FOR AN INSPECTION

Resources and Additional information: Ref. 6, 9

#### Activity

- Contact the agency with jurisdiction in the work area for permission to conduct standardization inspections.
- Be aware of local code requirements (T/T, CA, TPHC, etc.). – Perf. Area A,B
- Calibrate thermocouples and thermometers before the standardization exercise. – Perf. Area D
- Have all essential inspection equipment, appropriate clothing. – Perf. Area D
- Choose facilities that cover risk categories 2-4 as well as food services, food stores and institutions unless exceptions are made for agencies that regulate only one type of facility. – Perf. Area C
- The Standard should explain expectations to the Candidate: scoring to accomplish standardization, conducting risk-based inspections focused on Foodborne Illness Risk Factors and *Food Code* Interventions but knowledge of GRPs, taking cooking temperatures, taking appropriate corrective actions for all OOC Foodborne Illness Risk Factors, doing a Risk Control Plan, doing 3 process flow diagrams, explaining the HACCP principles, identifying the *Food Code* provisions for any OOC Foodborne Illness Risk Factors on the inspection report, using appropriate inspection equipment, communicating effectively and conducting an inspection as closely as possible to a real-time regulatory inspection. – Perf. Area E
- Review establishment files, past inspections, repeat violations, etc. before entering when possible.

<b>2. INTRODUCTION PRIOR TO INSPECTION</b>
<b>Resources and Additional Information: Ref. 8, 9</b>
<b>Activity</b>
<ul style="list-style-type: none"> <li>• Ask to speak to the Person in Charge (PIC) and establish an open dialogue during the inspection. – Perf. Area E</li> <li>• Show identification and give a business card if possible. – Perf. Area E</li> <li>• Introduce yourself and request permission to use the facility for a standardization exercise, explaining the purpose (internal training and auditing, promoting national uniformity) and that the inspection is “off the record” with no written record left behind and no records put into the establishment’s file.- Perf. Area E</li> <li>• Explain that questions will be asked of managers and food employees to better understand the operation’s procedures.- Perf. Area E</li> <li>• Request corrective actions for all OOC Foodborne Illness Risk Factors and Food Code Interventions that contribute to foodborne illness. – Perf. Area C</li> <li>• Invite the PIC to accompany you if they have time. Otherwise, explain that any major problems will be summarized later before you leave. – Perf. Area E</li> <li>• If the PIC refuses entry, thank him/her for his/her attention and leave – do not try to convince the PIC to allow the inspection. Document the refusal for a regulatory inspection.</li> </ul>
<b>3. SET A GOOD EXAMPLE</b>
<b>Resources and Additional Information: Ref. 6, 7, 9</b>
<b>Activity</b>
<ul style="list-style-type: none"> <li>• Always wash your hands properly upon entering the work area and anytime when hands may have become contaminated. – Perf. Area E</li> <li>• Do not work if you are ill yourself. – Perf. Area E</li> <li>• Do not touch RTE food with your bare hands. – Perf. Area E</li> <li>• Clean and sanitize your thermocouple probe before taking food temperatures. – Perf. Area D</li> <li>• Make sure your thermometer is accurate. Offer to calibrate your thermometer along with the facility’s thermometer. – Perf. Area D</li> <li>• Wear clean clothes, a lab coat (optional) and effective hair restraint. – Perf. Area D</li> <li>• Do not contaminate food or equipment by setting your clip board down on work surfaces, touching things, etc. – Perf. Area D</li> <li>• Be courteous and respect the food establishment’s need to carry out their job in a timely fashion. – Perf. Area E</li> </ul>
<b>4. CONDUCTING A RISK-BASED INSPECTION</b>
<b>Resources and Additional Information: Ref. 3, 5, 6, 9</b>
<b>Activity</b>
<ul style="list-style-type: none"> <li>• Assess the level of risk of foodborne illness to the public presented by the food safety practices of the facility. – Perf. Area A</li> <li>• After identifying which processes are used in the facility (process # 1, 2 &amp;/or 3), focus attention on the CCPs and CLs for that process(s) to reduce the occurrence of Foodborne</li> </ul>

- Illness Risk Factors that contribute to foodborne illness. – Perf. Area C**
- Supplement observations by asking questions of the PIC and employees to fully understand food preparation, storage and serving/selling procedures used and the management systems in place to monitor and control the CCPs. – Perf. Area E
  - Initiate corrective actions for all “out of compliance” Foodborne Illness Risk Factors identified during the inspection to signal their importance. Short term (immediate correction) and long term (changes in procedures, practices, behaviors, monitoring, record keeping, etc.) should be considered and discussed with the responsible party or PIC. – Perf. Area A
  - Minimize but do not ignore time and attention spent on facilities, general sanitation, good retail practices, etc. – Perf. Area A, E
  - Conduct a menu or food list review. – Perf. Area A, E
  - Focus on verification of Foodborne Illness Risk Factors control measures implemented by the establishment. – Perf. Area A

**5. INITIAL WALK THROUGH**

Resources and Additional Information: Ref. 3, 5, 6, 9

**Activity**

- Ask the PIC what is occurring now – prep, set up, cooling, reheating, cooking, etc.
- Do an initial walk through to familiarize yourself with the layout of the facility (prep area, cook and serve areas, walk-in-coolers, dishwashing areas, storage, etc.) and the activities that are currently occurring. This helps you set priorities and focus the inspection. Do not begin the inspection unless you have an opportunity to record or observe something that may not be present later (i.e., get a final cooking or reheating temperature). – Perf. Area A, B, C
- Identify and prioritize activities that you want to investigate in more detail (deliveries if present, preparation, cooling, reheating, cooking, etc.). – Perf. Area A, B, C
- Ask employees to call you if you are not there when they finish cooking a food product, reheating before hot holding, etc. – Perf. Area E
- Determine which processes (Process HACCP #1, #2 &/or #3) occur in the facility to help you determine which critical control points (and risk factors) should receive focused attention. – Perf. Area C
- Do not be distracted by the PIC trying to “lead” the inspection or by out of compliance GRPs, although notes can be taken as you do the walk through. – Perf. Area B, E

**6. OBSERVATIONS**

Resources and Additional Information: Ref. 3, 5, 6, 9

**Activity**

- Focus on procedural and behavioral aspects of the operation that contribute to foodborne illness. Structures, equipment and utensils, plumbing, repairs and maintenance, cleaning, etc. can easily be observed later in the inspections. – Perf. Area A, C
- Observe when and how handwashing is done. Before starting work? Before donning gloves? After using the restroom? After touching raw meat? After handling dirty dishes before handling clean dishes? – Perf. Area A
- Observe situations where bare hand contact with RTE food may occur such as plating food

- at the grill or serving line or making sandwiches. – Perf. Area A
- Ask employees who are engaged in food preparation if you can see their hands. Then ask them if they know why you are asking (teaching moment – no infected lesions or uncovered bandages, short, clean nails, no excess jewelry, etc.). – Perf. Area A, E
- Observe products and employees behavior when deliveries are made at the time you are present. – Perf. Area A
- Take final cook temperatures of all raw animal foods served/sold. – Perf. Area A
- Observe or question cooling practices for all intended/unintended leftover PHF (TCS Food). – Perf. Area A, E
- Determine reheating practices if any (method, equipment, T/T), if any for cooled products and commercially prepared products. – Perf. Area A
- Observe product temperatures for hot and cold holding and required criteria for Time as a Public Health Control. – Perf. Area A
- Verify that *Food Code* Interventions are implemented. – Perf. Area A
- Use majority of inspection time observing practices, behaviors and procedures that contribute to Out of Compliance Foodborne Illness Risk Factors. – Perf. Area A

## 7. CORRECTIVE ACTIONS

Resources and Additional Information: Ref. 5, 7, 9

### Activity

- Request corrective actions for all OOC Foodborne Illness Risk Factors identified during the inspection to reinforce their importance. – Perf. Area A, E
- Explain why the corrective action is needed. – Perf. Area E
- Solicit ideas from the PIC as to how to accomplish the correction and/or offer alternative solutions to the OOC Foodborne Illness Risk Factors . – Perf. Area C, E
- Consider whether this may be an opportunity to do a Risk Control Plan for long term correction. – Perf. Area C
- Verify that each identified corrective action for an OOC risk factor has been accomplished (or initiated if it involves repairs, etc.) before you leave the facility. – Perf. Area C

## 8. COMMUNICATION

Resources and Additional Information: Ref. 1, 3, 8, 9

### Activity

- Questions, observations, attention will signal inspection priorities to the PIC and management. Focusing on control of Foodborne Illness Risk Factors instead of GRPs will establish this priority in their mind instead of “floors, walls and ceilings.” – Perf. Area A, E
- Communicate non-verbally as well as verbally. Set a good example with your own behavior and actions. – Perf. Area E
- “Teaching Moments” by the Standard or Regulatory Inspector can add substance and value to an inspection. When requesting a corrective action for an OOC Foodborne Illness Risk Factors , the Candidate or Inspector should explain the public health reason and offer alternatives where appropriate for the needed correction. New equipment, procedures, code provisions and interpretations can be explained as they are encountered during a standardization inspection. – Perf. Area E
- To be most effective, short and long term corrective actions should be the

- operator's/employee's idea. When their ideas are inappropriate or they have no ideas, offer options for correction.- Perf. Area A, E
- Provide helpful information to the PIC related to their operation or OOC Foodborne Illness Risk Factors that were observed during the inspection – new code requirements, current food safety issues (allergens, produce safety, employee health, food defense, etc.), websites, health department training, etc.)- Perf. Area A. E
- Share “Best Practices” or good examples of solutions to similar problems you observed elsewhere. – Perf. Area E

**9. USE OF INSPECTION EQUIPMENT**

Resources and Additional Information: Ref. 5, 7, 9

**Activity**

- Have all essential inspection equipment with you including the correct probes for your thermocouple, enough alcohol swabs, appropriate head gear, inspection forms, etc. – Perf. Area D
- Calibrate your thermocouple/thermometers before arriving and beginning the exercise. Then you are confident of your readings and can offer to calibrate yours along with the operator's during the inspection. – Perf. Area D
- Carefully clean and sanitize your thermocouple probe before use and when changing from raw to RTE foods or from one type of animal food to another. – Perf. Area D
- If you use an IR thermometer, understand its limitations (surface temperatures only, reflections can interfere, etc.) – Perf. Area D
- Do you have a way to verify the effective sanitization of hot water and chemical sanitizing warewashing machines and manual hot water and chemical warewashing equipment (160°F temperature sensitive tapes, maximum-minimum registering thermometers [glass/mercury or digital “lollipop” type], thermocouple thermometer, appropriate chemical test strips for chlorine, iodine and quaternary ammonium sanitizers). – Perf. Area D
- If you use a pH meter or water activity meter, have the appropriate buffer solutions and calibration solutions available to check your own equipment, understand how to use it, how frequently to calibrate it, etc. – Perf. Area D
- Laboratory grade pH strips are available (4 color match) but still give only an approximate pH reading (e.g., 4.0, 5.0, etc.) – Perf. Area D

**10. HACCP AND RECORD KEEPING**

Resources and Additional Information: Ref. 2, 3, 4, 5, 6, 7, 10

**Activity**

- HACCP concepts are used in several different ways during a standardization inspection. The Candidate is expected to know the seven principles of HACCP and be able to complete an exercise involving the evaluation of a HACCP plan. HACCP concepts are also addressed in other ways. – Perf. Area C
- Three flow charts for Process #1 (no cook step), Process #2 (preparation for same day service) and Process #3 (complex food preparation) are to be completed for foods identified during the Standardization exercise with hazard, CCPs and CLs shown. – Perf. Area C
- If the operator has an approved variance (e.g., sushi, curing, smoking (not cooking), use of

preservatives, live shellfish tanks, custom animal processing, sprouting seeds, or other preparation method deemed by the regulatory authority to require a variance), review the HACCP plan and records. – Perf. Area A, C

- If ROP is conducted on-site, verify that the necessary records and HACCP plan are available and maintained for 6 months. – Perf. Area A, C
- If freezing for parasite destruction in fish is done, a letter of guaranty that is company and product-specific should be available from the processor or records to show time and temperature used for freezing if done internally should be reviewed. – Perf. Area A, C
- If searing steaks for surface coloration without a consumer advisory, labeling on the container or letter of guaranty from the processor should be available for review. – Perf. Area C
- If Molluscan shellstock are served, review shellfish tags for 90 day retention, chronological order and date last sold marked on the tag. – Perf. Area B

## **11. GENERAL ASPECTS OF AN INSPECTION**

Resources and Additional Information: Ref. 3, 4, 6, 7, 9

### **Activity**

- Ask the PIC if the operator has a variance for any code provision along with a HACCP plan to support the approved variance request. – Perf. Area C, E
- Ask the PIC questions to determine whether the facility is in compliance with employee health requirements. If they do not appear to be in compliance, use this opportunity to raise their awareness about employee health issues (symptoms, diagnosis, exposure, training, conditional employees, reporting, connection between employee health, handwashing and no bare hand contact with RTE food) and provide resources or sources of information. – Perf. Area A, E
- Ask whether the facility has “specials” not listed on the menu, holiday meals, catering, parties. Also note if they use procedures or equipment not typically used. – Perf. Area E
- Note if there are management systems in place for monitoring and verifying time/temperature control, date marking, hand washing, no bare hand contact with ready-to-eat foods, time as a public health control (if used), recalls, foodborne illness outbreaks, orientation and refresher training, etc. – Perf. Area A, C, E
- Review the menu or menu board before leaving to determine if you saw all necessary operations or asked questions in cases where you were unable to observe the actual preparation. – Perf. Area A, E
- Determine if PIC is familiar with eight major allergens, their symptoms in sensitive individuals and labeling requirements for allergens. – Perf. Area A, B, E
- Observe the general level of sanitation and compliance with GRPs. – Perf. Area B

## **12. EXIT INTERVIEW**

Resources and Additional Information: Ref. 6, 7, 9

### **Activity**

- If the PIC accompanied you throughout the inspection, there is no need to review the entire inspection again before leaving. A very short review of the OOC Foodborne Illness Risk Factors and corrective actions taken or needed will be sufficient. – Perf. Area C, E
- Discussion of individual GRPs is not usually necessary unless extremely blatant. – Perf.

**Area B, E**

- **Have a list of resources available that you can provide to the PIC based on situations and questions encountered during the inspection (websites for the *Food Code*, Operator’s Manual, EEOC Restaurant Guide, Employee Health Handbook (soon to be completed), Bad Bug Book, Seafood Hazards Guide, ICSSL, Risk Factor Study, etc.). You can also offer to send them information later. – Perf. Area E**
- **Provide positive reinforce to the PIC for active managerial control, “Best Practices”, innovative methods, etc. that you observed during the inspection. – Perf. Area E**
- **Ask the PIC if there are any questions he/she would like to ask. – Perf. Area E**
- **Thank the PIC for his/her assistance and cooperation in the standardization exercise. – Perf. Area E**

**13. “Real Time” Inspection**

**Resources and Additional Information: Ref. 5, 6, 7, 9**

**Activity**

- **Inspectors doing regulatory inspections often have to work under time and resource constraints that are not considered during a standardization inspection. In order to help the Candidate better understand this transition, one or more standardization inspections should be conducted as closely as possible to a “real time” inspection. – Perf. Area A, B**
- **The time should be limited to the average time for the type of facility in the jurisdiction, including inspection, write up and exit interview with the emphasis on a risk based inspection and identification and correction of Foodborne Illness Risk Factors. – Perf. Area A, B**
- **Passing the “Foodborne Illness Risk Factors and Food Code Interventions” portion of the Inspection Report, as noted in 3-302(A) of the Standardization Procedure. – Perf. Area A**
- **Passing the “Good Retail Practices” portion of the Inspection Report, as noted in 3-302(A) of the Standardization Procedure. – Perf. Area B**

## Resources and Additional Information:

1. EEOC “How to Comply with the Americans with Disabilities Act: A Guide for Restaurant and Other Food Service Employers. Available at [http://www.eeoc.gov/facts/restaurant\\_guide.html](http://www.eeoc.gov/facts/restaurant_guide.html).
2. FDA Fish and Fisheries Products Hazards and Control Guide, Third Ed. Available at <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm2018426.htm>
3. FDA Food Code. Available at <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm>
4. FDA Food Code, Annex 3 – Public Health Reasons/Administrative Guidelines. Available at <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm>
5. FDA Food Code, Annex 4 – Management of Food Safety Practices Achieving Active Managerial Control of Foodborne Illness Risk Factors. Available at <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm>
6. FDA Food Code, Annex 5 – Conducting Risk-Based Inspections. Available at <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm>
7. FDA Managing Food Safety: A Regulator’s Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems. Available at <http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Regulators/UCM078159.pdf>.
8. FDA ORA-U Communications Course. Available at <http://www.accessdata.fda.gov/ORAU/CommRegulators/>
9. FDA Procedures for Standardization of Retail Food Safety Inspection Officers. November, 2010 <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/InspectionsQualityAssurance/ucm238920.htm>
10. National Advisory Committee on Microbiological Criteria for Foods (NACMCF). 1997. Hazard Analysis and Critical Control Point Principles and Application Guidelines. Available at <http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm>