

2017

Self-Assessment and Audit Manual

U.S. Department of Health and Human Services

Food and Drug Administration Center for Food Safety and Applied Nutrition College Park, MD 20740

INTRODUCTION

Achieving national uniformity among regulatory programs responsible for retail food protection in the United States has long been a subject of debate among the industry, regulators and consumers. Adoption of the *FDA Food Code* at the state, local and tribal level has been a keystone in the effort to promote greater uniformity. However, a missing piece has been a set of widely recognized standards for regulatory programs that administer the *Food Code*. To meet this need FDA has developed the "Voluntary National Retail Food Regulatory Program Standards" (Retail Program Standards) through ideas and input from federal, state, and local regulatory officials, industry, trade and professional associations, academia and consumers on what constitutes a highly effective and responsive retail food regulatory program.

In March of 1996, the FDA hosted a meeting to explore ways in which its retail food protection program could be improved. Participants in the meeting included FDA Retail Food Specialists, FDA headquarters personnel, state and local regulatory officials from the six FDA regions, the president of the Association of Food & Drug Officials, and industry representatives. Following that meeting, FDA established a National Retail Food Team comprised of the Regional Retail Food Specialists, CFSAN personnel and other FDA personnel directly involved in retail food protection. A Retail Food Program Steering Committee was established and tasked with leading the team to respond to the direction given by the participants in the meeting, i.e. providing national leadership, being equal partners, being responsive, providing communication and promoting uniformity.

The Steering Committee was charged with developing a five-year operational plan for FDA's retail food program. The Steering Committee was also charged with ensuring the operational plan was in keeping with the goals and mission of the President's Food Safety Initiative. FDA solicited input from the regulatory community, industry and consumers in developing the plan. The resulting Operational Plan charted the future of the National Retail Food Program and prompted a reassessment of the respective roles of all stakeholders and how best to achieve program uniformity.

From the goals established in that first Operational Plan, two basic principles emerged on which to build a new foundation for the retail program:

- Promote active managerial control of the risk factors most commonly associated with foodborne illness in food establishments, and
- Establish a recommended framework for retail food regulatory programs within which the active managerial control of the risk factors can best be realized.

These principles led to the drafting of standards that encourage voluntary participation by the regulatory agencies at the state, local, and tribal level. The Program Standards were developed with input obtained through a series of meetings over a two-year period including: the 1996 stakeholders meeting, FDA Regional Seminars, meetings with state officials hosted by the Retail Food Specialists, and six Grassroots Meetings held around the country in 1997. Valuable input from industry associations, associations of regulatory officials, and others was also obtained. The Retail Program Standards were

provided to the Conference for Food Protection for further input and to achieve broad consensus among all stakeholders.

In developing the Retail Program Standards, FDA recognized that the ultimate goal of all retail food regulatory programs is to reduce or eliminate the occurrence of illnesses and deaths from food produced at the retail level and that there are different approaches toward achieving that goal. Federal, state, local, and tribal agencies continue to employ a variety of mechanisms with differing levels of sophistication in their attempt to ensure food safety at retail.

While the Retail Program Standards represent the effective, focused food safety program to which we ultimately aspire, they begin by providing a foundation and system upon which all regulatory programs can build through a continuous improvement process. The Standards encourage regulatory agencies to improve and build upon existing programs. Further, the Standards provide a framework designed to accommodate both traditional and emerging approaches to food safety. The Retail Program Standards are intended to reinforce proper sanitation (good retail practices) and operational and environmental prerequisite programs while encouraging regulatory agencies and industry to focus on the factors that cause and contribute to foodborne illness, with the ultimate goal of reducing the occurrence of those factors.

PURPOSE

The Retail Program Standards serve as a guide to regulatory retail food program managers in the design and management of a retail food regulatory program and provide a means of recognition for those programs that meet these standards. Program managers and administrators may establish additional requirements to meet individual program needs.

The Retail Program Standards are designed to help food regulatory programs enhance the services they provide to the public. When applied in the intended manner, the Program Standards should:

- Identify program areas where an agency can have the greatest impact on retail food safety
- Promote wider application of effective risk-factor intervention strategies
- Assist in identifying program areas most in need of additional attention
- Provide information needed to justify maintenance or increase in program budgets
- Lead to innovations in program implementation and administration
- Improve industry and consumer confidence in food protection programs by enhancing uniformity within and between regulatory agencies

Each Standard has one or more corresponding worksheets, forms and guidance documents. Regulatory agencies may use existing, available records or may choose to develop and use alternate forms and worksheets that capture the same information.

SCOPE

The Retail Program Standards apply to the operation and management of a retail food regulatory program that is focused on the reduction of risk factors known to cause or contribute to foodborne illness and to the promotion of active managerial control of these risk factors. The results of a self-

assessment against the Standards may be used to evaluate the effectiveness of food safety interventions implemented within a jurisdiction. The Standards also provide a procedure for establishing a database on the occurrence of risk factors that may be used to track the results of regulatory and industry efforts over time.

HISTORY

The Retail Program Standards were pilot tested in each of the five FDA regions in 1999. Each regulatory participant reported the results at the 2000 Conference for Food Protection. Improvements to the Standards were incorporated into the January 2001 version based on input from the pilot participants. Further refinements to the Standards were made in subsequent drafts leading up to the endorsement of the March 2002 version of the Retail Program Standards by the 2002 Conference for Food Protection. Subsequent changes and enhancements have been made following concurrence of the stakeholders at the biennial meetings of the Conference for Food Protection.

In maintaining these standards, FDA intends to allow for and encourage new and innovative approaches to the reduction of factors that are known to cause foodborne illness. Program managers and other health professionals participating in this voluntary program who have demonstrated means or methods other than those described here may submit those to FDA for consideration and inclusion in the Retail Program Standards. Improvements to future versions of the Standards will be made through a process that includes the Conference for Food Protection to allow for constant program enhancement and promotion of national uniformity.

IMPACT ON PROGRAM RESOURCES

During pilot testing of the Retail Program Standards in 1998, some jurisdictions reported that the self-assessment process was time consuming and could significantly impact an agency's resources. Collection, analysis, and management of information for the database Occurrence of Risk Factor Studies were of special concern. However, participating jurisdictions also indicated that the resource commitment was worthwhile and that the results of the self-assessment were expected to benefit their retail food protection program. Advance planning is recommended before beginning the data collection process in order to use resources efficiently. In addition, changes to the Standards now allow jurisdictions to use routine inspection data for analysis on the occurrence of risk factors, significantly reducing the resource requirements for separate data collection.

It is further recommended that jurisdictions not attempt to make program enhancements during the self-assessment process. A better approach is to use the self-assessment to identify program needs and then establish program priorities and plans to address those needs as resources become available.

COMMENTS AND INQUIRIES

To promote uniform and reasonable application of these Standards, interested persons are invited to submit comments and inquiries to their FDA Regional Retail Food Specialist or to the Retail Food Protection Team in the FDA Center for Food Safety and Applied Nutrition at: retailfoodprotectionteam@fda.hhs.gov.

Administrative Procedures for Participation in the Voluntary National Retail Food Regulatory Program Standards

Table of Contents

OVERVIEW OF THE PROGRAM STANDARDS	2
PURPOSE OF THIS DOCUMENT	
ENROLLING IN THE PROGRAM STANDARDS	
MAINTENANCE IN THE PROGRAM STANDARDS	
CONDUCTING THE SELF-ASSESSMENT	
VERIFYING THE SELF-ASSESSMENT	4
REPORTING THE RESULTS OF SELF-ASSESSMENTS AND VERIFICATION AUDITS TO FDA	
DISPUTE RESOLUTION PROCESS FOR NON-CONFIRMING AUDITS	6
RETAIL FOOD PROGRAM STANDARDS CLEARINGHOUSE CONTACT	8

Administrative Procedures for Participation in the Voluntary National Retail Food Regulatory Program Standards

Overview of the Program Standards

The purpose of the *Voluntary National Retail Food Regulatory Program Standards* (hereafter referred to as the Retail Program Standards) is to establish best practices for regulatory programs that license and inspect foodservice and retail food establishments. Jurisdictions are encouraged to use the Retail Program Standards to improve program management and to implement best practices that enhance the quality of public health services provided to stakeholders. Effective use of the Retail Program Standards will enable a jurisdiction to make lasting programmatic improvements to their retail food protection program.

Purpose of this Document

This document describes the general procedures for enrolling in the Program Standards, remaining in active participant in the Program Standards, and resolving issues associated with the interpretation and application of the Program Standards. This document is divided into the following sections:

- 1. Enrollment in the Retail Program Standards
- 2. Maintenance in the Program Standards
 - a. Self-assessment of a retail food regulatory program against the criteria in each of the 9 Program Standards;
 - b. Confirmation of the accuracy of the Self-Assessment and demonstration of an enrolled jurisdiction's progress in reducing the occurrence of foodborne illness risk factors;
 - c. Reporting to FDA the status of the self-assessment and verification audit; and
- 3. Dispute resolution process for non-confirming audits.

For additional information, the reader may refer to the FDA website for more detailed documentation on the Program Standards. Detailed information along with the most recent version of the Program Standards can be found on the following website: http://www.fda.gov/RetailProgramStandards.

Enrolling in the Program Standards

Enrollment in the Retail Program Standards conveys an eligible jurisdiction's intent to actively use the Retail Program Standards as a tool to assess and improve its retail food regulatory program.

Government agencies and organizations responsible for regulation or oversight of the food establishments that sell, serve or vend food directly to the public are eligible to enroll in the Retail Program Standards.

A jurisdiction initiates the enrollment process by notifying their FDA Regional Retail Food Specialist of its intent to enroll in the Retail Program Standards. To enroll, a jurisdiction must complete and sign the related sections on the *FDA National Registry Report* (FDA Form 3958) and submit these forms to the FDA Regional Specialist.

Upon submission of the completed enrollment form, FDA will add the jurisdiction to its on-line <u>Listing</u> of <u>Jurisdictions Enrolled in the Voluntary National Retail Food Regulatory Program Standards</u>. The listing is organized by State and contains basic information about the jurisdiction, the key contact person, and the Retail Program Standards milestones achieved by the jurisdiction.

Maintenance in the Retail Program Standards

FDA encourages enrolled jurisdictions to actively participate in the Retail Program Standards. Active participation means that a jurisdiction takes action to:

- 1. Periodically assess its program using the criteria in the nine Retail Program Standards;
- 2. Have its self-assessment verified by an independent audit (for Standards that the jurisdiction reports meeting); and
- 3. Report the status of the program self-assessment and verification audit to FDA.

Conducting the Self-Assessment

Description of the Self-Assessment

The Self-Assessment is an internal review by program management to determine if the existing retail food protection program conforms to the criteria in the Retail Program Standards.

Frequency of the Self-Assessment

A self-assessment against the criteria in each of the nine (9) Retail Program Standards shall be completed at the following frequency:

- 1. Within 12 months of the date of enrollment; and
- 2. Following the initial self-assessment, the complete self-assessment cycle must be repeated at a minimum every 60 months.

A jurisdiction may, and is encouraged to, complete a self-assessment update at any time during the 60-month interval to reflect the most current information on its program accomplishments as reflected by comparison against one or more of the individual Standards.

Required Documents for the Self-Assessment

The most recent version of the Retail Program Standards must be used when completing a required self-assessment.

A self-assessment update can be made using the version of the Retail Program Standards effective at the jurisdiction's previous required self-assessment or a more recent version of the Retail Program Standards, at the jurisdiction's discretion.

Individuals conducting a self-assessment are encouraged to use the provided worksheets to complete the self-assessment. These worksheets are designed to assist the assessor in identifying and recording program accomplishments and gaps, and to document the location of quality records and source documents.

Documents containing equivalent summary information can be used in lieu of the provided worksheets.

Documenting the Assessment of Individual Standards

To support a determination that a Retail Program Standard has been met, a jurisdiction shall retain documents used during the self-assessment and have them available for use during the verification audit, including:

- 1. Complete the corresponding worksheets. Alternatively, provide documents containing equivalent summary information for that Standard in preparation of the verification audit; and
- 2. Establish, identify, and maintain quality records specified as requirements in each of the Retail Program Standards. The quality records must be maintained in such a manner that an auditor can be provided information necessary to verify that a Standard's criteria have been met.

If a self-assessment indicates that the jurisdiction does not meet a Standard, the jurisdiction should identify any deficiencies in meeting the Standards criteria.

Verifying the Self-Assessment

Description of the Verification Audit

The Verification Audit is a systematic, independent examination by an external party to confirm the accuracy of the Self-Assessment that claims one or more Standard(s) as met.

A verification audit may be conducted by an authorized city, county, district, state, federal, tribal or other third party person who has no responsibilities for the day-to-day operations of the jurisdiction requesting the verification audit. The auditor shall complete the verification audit.

Frequency of the Verification Audit

The program manager, or a designated representative, must request a verification audit within three (3) months of the completion of the self-assessment or self-assessment update in which one

or more Standard(s) is claimed as met. The verification audit must be completed within six (6) months of that self-assessment or self-assessment update.

Verification audits shall be conducted at the following frequency:

- 1. After the initial self-assessment (conducted within 12 months of enrollment), if the jurisdiction claims conformance with one or more Standards; and
- 2. After each subsequent self-assessment (conducted every 60 months), if the jurisdiction claims conformance with one or more Standards.

Selecting an Auditor

The jurisdiction is responsible for arranging for an individual to conduct the verification audit. If the jurisdiction is unable to arrange for an individual to serve as an auditor, the jurisdiction should contact their FDA Regional Retail Food Specialist for further guidance.

Role of the Auditor during the Verification Audit During the verification audit, the auditor will:

- 1. Review the quality records and confirm that the self-assessment accurately reflects the program's achievement status with each criterion for the version of the Retail Program Standards that was used when completing the self-assessment or a self-assessment update;
- 2. Determine if the quality records specified as requirements in each of the Retail Program Standards have been established, identified, and maintained. If the quality records for a specific program element provide inadequate information upon which to make a determination of conformance with the Standard or to enable a verification audit, that Standard is not met: and
- 3. In instances where the auditor determines that the jurisdiction does not conform with the Standard(s), review the reasons for the non-conforming finding with the Program Manager and identify the elements necessary for the jurisdiction to meet the Standard.

The auditor will convey the results of the verification audit by providing a written report to the jurisdiction. The written report shall consist of the *Self-Assessment and Verification Audit Form* for each Standard that is audited. The form must clearly indicate whether the verification audit confirms or disputes the Self-Assessment's findings with regard to conformance for each individual Standard. If the auditor disputes the findings from the Self-Assessment, the auditor must provide written comments on the *Self-Assessment and Verification Audit Form* to support the auditor's findings.

Reporting the Results of Self-Assessments and Verification Audits to FDA

<u>Timeframe for Reporting Results from a Self-Assessment or Verification Audit</u>

The program manager, or a designated representative, must report the status of the self-assessment, self-assessment update, and the verification audit to their FDA Regional Retail Food

Specialist:

- 1. within 30 days following a self-assessment (regardless of whether any Standard(s) are claimed as met);
- 2. within 30 days following a self-assessment update (only if the achievement status for a Standard has changed); and
- 3. within 30 days following any verification audit.

Method for Reporting Results from a Self-Assessment or Verification Audit Reports must be submitted on the FDA National Registry Report (FDA Form 3958).

Report forms should be marked to show attainment of each applicable Standards achieved at the time of submission. Dates showing current attainment for each Standard should be recorded on each submission in order to accurately reflect the program's history. All applicable Standards should be marked with their most recent attainment dates to ensure that accurate information is posted on the *Listing of Jurisdictions Enrolled in the Voluntary National Retail Food Regulatory Program Standards*.

Dispute Resolution Process for Non-Confirming Audits

Under the Standards process, the auditor acts as the verifier of facts. The auditor certifies the accuracy of a jurisdiction's assessment of its conformance with the Retail Program Standards. In the event that a jurisdiction disagrees with the auditor's findings at the end of a verification audit, the following is the process for resolving such differences.

Report Results of a Non-Confirming Audit

- 1. If a verification audit does not confirm the results of a self-assessment for one or more of the Standards, it is the jurisdiction's responsibility to contact their FDA Regional Retail Food Specialist within ten business days of the close of the audit. The jurisdiction and the FDA Regional Retail Food Specialist must discuss the steps necessary to reconcile any discrepancies and to establish a correction plan if it wishes to retain the self-reported information on the national web listing or to remove any incorrect self-reported data.
- 2. An action plan and timeline for correcting any element deficiencies must be developed by the jurisdiction. The plan should include specific milestones to ensure that the full criteria can be met by an established target date, not to exceed one year. The jurisdiction must review the plan and timeline with the FDA Regional Retail Food Specialist.
- 3. The results of the jurisdiction's self-assessment remain on the <u>Listing of Jurisdictions</u> <u>Enrolled in the Voluntary National Retail Food Regulatory Program Standards</u> during the correction period identified in the Action Plan.
- 4. If the jurisdiction does not wish to institute an action plan with milestones for correcting deficiencies, the listing will be changed to reflect the results of the verification audit. The jurisdiction can then work without time constraints to meet any non-confirmed standards

and submit a new *FDA National Registry Report* (FDA Form 3958) when the standard is achieved.

Dispute Resolution

FDA has established a Retail Food Program Standards Clearinghouse (Clearinghouse). The Clearinghouse is composed of:

- Two FDA Regional Retail Food Specialists;
- One member of the FDA Center of Food Safety and Applied Nutrition Retail Food Policy Team;
- One representative from the Conference for Food Protection Program Standards Committee; and
- Representatives from five jurisdictions enrolled in the Standards.

The Clearinghouse was established to answer questions about the Standards and to give interpretations based on the existing Standards language. The Clearinghouse is also available to assist in resolving differences that arise as a result of a verification audit.

Written Request for Assistance

- 1. A jurisdiction seeking the assistance of the Clearinghouse must submit a request in writing to the Clearinghouse. Contact information for the Standards Clearinghouse is provided below. The request must include an explanation of the issues in dispute or interpretations in question, and a copy of the verification audit report. The jurisdiction may include any supporting information relevant to the results of the self-assessment or verification audit. The written request must be made within 30 calendar days of the close of the audit.
- 2. The Clearinghouse Chair will inform the auditor of the jurisdictions request. The auditor may also supply additional written materials within 30 calendar days from the time they are notified.

Assistance Process

- 1. The Clearinghouse will set a date and time to hear the facts from each side via conference call.
- 2. The jurisdiction and the auditor will be provided the opportunity to speak in support of the materials they submitted in writing. Clearinghouse members may ask questions of each side.
- 3. The Clearinghouse will then confer in private before providing clarification on the issue.

Decisions

- 1. After conferring in private, the Clearinghouse will provide a written response to the jurisdiction and the auditor within 10 business days following the conference call.
- 2. The interpretation of the Clearinghouse panel is final.

Retail Food Program Standards Clearinghouse Contact

Robert Sudler, Jr. MS, CP-FS

Consumer Safety Officer FDA/CFSAN/Office of Food Safety Retail Food Protection Staff / Retail Food Policy Team 5001 Campus Drive Mail Stop HFS-320, Room 3B-018 College Park, MD. 20740

Phone: 240-402-1943 Fax: 301-436-2672

E-Mail: robert.sudler@fda.hhs.gov

STANDARD 1 REGULATORY FOUNDATION

Table of Contents

REQUIREMENT SUMMARY
A. FDA Food Code Interventions and Risk Factor Control Measures
B. Good Retail Practices
C. Compliance and Enforcement
OUTCOME
DOCUMENTATION

STANDARD 1 REGULATORY FOUNDATION

This standard applies to the regulatory foundation used by a retail food program. Regulatory foundation includes any statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that governs the operation of a retail food establishment.

Requirement Summary

The regulatory foundation includes provisions for:

- 1. The public health interventions contained in the current published edition of the *Food Code* or one of the two most recent previous editions of the *Food Code*;
- 2. Control measures for the risk factors known to contribute to foodborne illness;
- 3. Good Retail Practices (GRP's) at least as stringent as the *Food Code* edition as specified in 1 above; and
- 4. Compliance and enforcement at least as stringent as the selected provisions from *Food Code* and Annex 1 of the *Food Code* edition as specified in 1 above.

Description of Requirement

A. Food Code Interventions and Risk Factor Control Measures

The regulatory foundation contains provisions that are at least as stringent as the public health interventions and the provisions that control risk factors known to contribute to foodborne illness contained in the current published edition of the *Food Code* or one of the two most recent previous editions of the *Food Code*. Jurisdictions that meet Standard 1 but who may become noncompliant due to the release of a new edition of the *Food Code* are considered to continue meeting the Standard for a period of two years from the release date of the new *Food Code* edition in order to complete the process of updating its regulations.

To meet this element of the Standard, regulations must have a corresponding requirement for the *Food Code* sections as listed and summarized in the *Standard 1: Self-Assessment Worksheet for Part I*, from #1 "Demonstration of Knowledge" through #11 "Highly Susceptible Populations." For initial listing, the regulatory foundation must contain at least 9 of the 11 interventions and risk factor controls. In order to meet fully the requirements of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third audit.

B. Good Retail Practices

The regulations contain provisions that address Good Retail Practices that are at least as stringent as those described in the edition of the *Food Code* as specified in A. To meet this element of the Standard, regulations must have a corresponding requirement for 95 percent of the *Food Code* sections as listed and summarized in the *Standard 1: Self-Assessment Worksheet for Part II*, from #12 "Personnel" through #37 "Variance for Smoking."

C.Compliance and Enforcement

The regulations contain provisions that address Compliance and Enforcement requirements that are at least as stringent as those contained in the edition of the *Food Code* as specified in A. To meet this element of the Standard, regulations must have a corresponding requirement for each of the *Food Code* sections as listed in the *Standard 1: Self-Assessment Worksheet for Part III*, items 1 through 12; except item 12 pertaining to "Legal Remedies," where only one of the sections pertaining to criminal, injunctive, or civil penalties is required.

Outcome

The desired outcome of this standard is the adoption of a sound, science-based regulatory foundation for the public health program and the uniform regulation of industry.

Documentation

The quality records needed for this standard include:

- 1. The statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of a retail food establishment; and
- 2. The completed Standard 1: Program Self-Assessment and Verification Audit Form.
- 3. The completed *Standard 1: Self-Assessment Worksheet* for:
 - Part I *Food Code* Intervention and Risk Factor Controls
 - Part II Good Retail Practices
 - Part III Compliance and Enforcement

INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

STANDARD 1 - REGULATORY FOUNDATION

Program Self-Assessment and Verification Audit Form

The Standard 1: Program Self-Assessment and Verification Audit Form is designed to document the findings from the self-assessment and the verification audit process. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standard 1 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self-Assessment

Jurisdictions conducting a self-assessment of the Regulatory Foundation component must indicate on the form if each of the listed Standard 1 criteria are met. These responses are recorded under the column "Jurisdiction's Self-Assessment."

Jurisdictions are not obligated to use this form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 1 criteria listed on this form are available for review.

The Standard 1: Program Self-Assessment and Verification Audit Form is divided into four sections:

- 1. Assessment of the Program's Regulatory Foundation;
- 2. Food Code Interventions and Risk Factors;
- 3. Good Retail Practices; and
- 4. Compliance and Enforcement.

The self-assessor must review each Standard 1 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 1: Program Self-Assessment and Verification Audit Form*.

If a review of the jurisdiction's source documents does not confirm that the Standard 1 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction's Self-Assessment" column of the *Standard 1: Program Self-Assessment and Verification Audit Form*. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 1: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction must provide the auditor with their completed *Standard 1: Program Self-Assessment and Verification Audit Form* and any worksheets or documents used to support and demonstrate that the Standard 1 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 1: Program Self-Assessment and Verification Audit Form.* The self-assessor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 1 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 1 criteria.

Documenting the Findings from the Verification Audit

The self-assessor must provide their completed *Standard 1: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 1: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "NO" box under the "Auditor's Verification" column on the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any Standard 1 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on page one of the *Standard 1: Program Self-Assessment and Verification Audit Form.* The auditor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 2 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 1 criteria if the auditor does not confirm the self-assessment findings.

Standard 1: Regulatory Foundation Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the Self-Assessment:
Self-Assessor's Title:
Jurisdiction Name:
Jurisdiction Address:
Phone: FAX: E-mail:
Date the Standard 1 Self-Assessment was Completed:
Self-Assessment indicates that the Jurisdiction MEETS the Standard 1 criteria: YES NO
I affirm that the information represented in the Self-Assessment of Standard 1 is true and correct
Signature of the Self-Assessor:
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VENITION AUDIT SUMMARY
Printed Name of the Person who conducted the Verification Audit:
Verification Auditor's Title:
Auditor's Jurisdiction Name:
Auditor's Jurisdiction Address:
Phone: FAX: E-mail:
Date the Verification Audit of Standard 1 was Completed:
Verification Audit indicates that the Jurisdiction MEETS the Standard 1 criteria: YES
I affirm that the information represented in the Verification Audit of Standard 1 is true and correct
Signature of the Verification Auditor:
Signature of the Verification Auditor:

Standard 1: Regulatory Foundation Program Self-Assessment and Verification Audit Form

	Auditor's Verification	If no, auditor is to specify why criterion is not met							
		ON.							
		YES							
	Jurisdiction's Self-Assessment	Self-Assessor's General Comments	uo						
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		YES	ory Fot				tors		
Jurisdiction Name:	Criteria		1. Assessment of the Program's Regulatory Foundation	a) The jurisdiction has documentation that it has performed a side-by-side comparison of its prevailing statutes, regulations, rules, and other pertinent requirements against the current published edition of the FDA Food Code or one of the two most recent previous editions of the FDA Food Code.	b) The jurisdiction's side-by-side comparison includes an assessment of major Food Code Interventions and Risk Factors, Good Retail Practices, and Compliance/ Enforcement Administrative requirements	c) The regulatory foundation assessment clearly identifies the jurisdiction's corresponding requirement to the applicable <i>Code</i> section. The assessment provides a determination as to whether a specific provision in the jurisdiction's regulation meets the intent of the corresponding <i>FDA Food Code</i> section.	2. Food Code Interventions and Risk Factors	a) The jurisdiction's initial Food Code assessment indicates that the agency's regulatory requirements contain at least 9 of the 11 FDA Food Code intervention and risk factor controls. By the third verification audit the jurisdiction's assessment indicates that the agency's regulatory requirements contain all 11 of the FDA Food Code intervention and risk factor controls.	Part I - Self-Assessment Worksheet Part I - Verification Audit Worksheet

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Criteria		Ť	Jurisdiction's Self-Assessment			Auditor's Verification
	YES	O _N	Self-Assessor's General Comments	YES	ON ON	If no, auditor is to specify why criterion is not met
b) The jurisdiction's Food Code assessment indicates that the agency has a corresponding requirement for ALL FDA Food Code provisions related to the interventions and risk factor controls.						
NOTE: Auditor's random selection of Food Code Intervention and Risk Factor Control Sections confirms the jurisdiction's assessment that a corresponding requirement is contained in the agency's rules, regulations, ordinances, code, or statutes.						
3. Good Retail Practices						
a) The jurisdiction's Food Code assessment indicates that regulatory requirements contain at least 95 percent of the FDA <i>Food Code</i> Good Retail Practices Sections.						
NOTE: Auditor's random selection of Good Retail Practices Code Sections confirms the jurisdiction's assessment that a corresponding requirement is contained in the agency's code or statutes. Documentation from:						
Part II - Self-Assessment Worksheet Part II - Verification Audit Worksheet						
4. Compliance and Enforcement	-					
a) The jurisdiction's Food Code assessment indicates that regulatory requirements contain ALL the FDA Food Code Compliance and Enforcement Sections identified in the Standard.	[[[[
NOTE: Auditor's random selection of Compliance and Enforcement Code Sections confirms the jurisdiction's assessment that a corresponding requirement is contained in the agency's code or statutes. Documentation from:						
Part III - Self Assessment Worksheet Part III - Verification Audit Worksheet						

Standard 1: Regulatory Foundation Program Self-Assessment and Verification Audit Form

Gener	General Notes Pertaining to the Program Self-Assessment or the Verification Audit	

DEFINITIONS

The following definitions apply in the interpretation and application of these Standards.

- 1. **Active Managerial Control** The purposeful incorporation of specific actions or procedures by industry management into the operation of a business to attain control over foodborne illness risk factors.
- 2. **Auditor** Any authorized city, county, district, state, federal, tribal or other third party person who has no responsibilities for the day-to-day operations of that jurisdiction and is charged with conducting a verification audit, which confirms the accuracy of the self-assessment.
- 3. **Baseline Survey** See Risk Factor Study.
- 4. **Candidate** A regulatory officer whose duties include the inspection of retail food establishments.
- 5. **Compliance and Enforcement** Compliance includes all voluntary or involuntary conformity with provisions set forth by the regulatory authority to safeguard public health and ensure that food is safe. Enforcement includes any legal and/or administrative procedures taken by the regulatory authority to gain compliance.
- 6. **Confirmed Foodborne Disease Outbreak** means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiologic analysis implicates the food as the source of the illness or epidemiological analysis alone implicates the food as the source of the illness.
- 7. **Direct Regulatory Authority** (**DRA**) The organizational level of government that is immediately responsible for the management of the retail program. This may be at the city, county, district, state, federal, territorial, or tribal level.
- 8. **Enforcement Actions** Actions taken by the regulatory authority such as, but not limited to, warning letters, revocation or suspension of permit, court actions, monetary fines, hold orders, destruction of food, etc., to correct a violation found during an inspection.
- 9. **Follow-up Inspection** An inspection conducted after the initial routine inspection to confirm the correction of a violation(s).
- 10. **Food Code Interventions** the preventive measures to protect consumer health stated below:
 - 1. management's demonstration of knowledge;
 - 2. employee health controls;
 - 3. controlling hands as a vehicle of contamination;
 - 4. time / temperature parameters for controlling pathogens; and
 - 5. consumer advisory.
- 11. **Food-Related Injury** Means an injury from ingesting food containing a physical hazard such as bone, glass, or wood.
- 12. **Foodborne Disease Outbreak** The occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.
- 13. **Good Retail Practices** (**GRP's**) Preventive measures that include practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that are prerequisites to instituting a HACCP or Risk Control Plan and are not addressed by the *FDA Food Code* interventions or risk factors.
- 14. **Hazard** A biological, chemical or physical property that may cause food to be unsafe for

- human consumption.
- 15. **National Registry of Retail Food Protection Programs (National Registry) A** listing of retail food safety programs that have voluntarily enrolled as participants in the *Voluntary National Retail Food Regulatory Program Standards*.
- 16. **Person in charge (PIC)** The individual present at a food establishment who is responsible for the operation at the time of inspection.
- 17. **Program Element** One of the program areas for which a National Standard has been established such as regulations, training, inspection system, quality assurance, foodborne illness investigation, compliance and enforcement, industry and consumer relations, and program resources.
- 18. **Program Manager** The individual responsible for the oversight and management of a retail food regulatory program.
- 19. **Quality Records** Documentation of specific elements of program compliance with the National Standards as specified in each Standard.
- 20. **Risk Control Plan (RCP)** a concisely written management plan developed by the retail or food service operator with input from the health inspector that describes a management system for controlling specific out-of-control risk factors.
- 21. **Risk Factors** the improper employee behaviors or improper practices or procedures in retail food and food service establishments stated below which are most frequently identified by epidemiological investigation as contributing to foodborne illness or injury:
 - 1. improper holding temperature;
 - 2. inadequate cooking;
 - 3. contaminated equipment;
 - 4. food from unsafe source; and
 - 5. poor personal hygiene.
- 22) **Risk Factor Study** (formerly Baseline Survey) A study on the occurrence of foodborne illness risk factors within institutional, foodservice, restaurants, and retail food facility types under a jurisdiction's regulatory authority. Criteria for a Risk Factor Study are detailed in Standard 9, including at a minimum:
 - 1. Data Collection, analysis, and a written report;
 - 2. A collection instrument with data items pertaining to the five foodborne illness risk factors;
 - 3. A collection instrument that uses the convention of IN, OUT, NA and NO to document observations;
 - 4. All facility types identified by FDA's national study that are under the jurisdiction's regulatory authority; and
 - 5. Studies subsequent to the initial study repeated at 5-year intervals.
- 23) **Routine Inspection A** full review and evaluation of a food establishment's operations and facilities to assess its compliance with Food Safety Law, at a planned frequency determined by the regulatory authority. This does not include re-inspections and other follow-up or special investigations.
- 24) **Self-Assessment** An internal review by program management to determine whether the existing retail food safety program meets the *Voluntary National Retail Food Regulatory Program Standards*.
- 25) **Self-Assessment Update** Comparison of one or more program elements against the *Voluntary National Retail Food Regulatory Program Standards* between the required 60-month periodic

- self-assessment.
- 26) **Standardization Inspection** An inspection used to demonstrate a candidate's knowledge, communication skills, and ability to identify violations of all regulatory requirements and to develop a risk control plan for identified, uncontrolled risk factors.
- 27) **Suspect Foodborne Outbreak** Means an incident in which two or more persons experience a similar illness after ingestion of a common food or eating at a common food establishment/gathering.
- 28) **Trainer** An individual who has successfully completed the following training elements as outlined in Steps 1 3, Standard 2, and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.
 - 1. Satisfactory completion of the prerequisite curriculum;
 - 2. Completion of a field training process similar to that contained in Appendix B-2; and
 - 3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum.
- 29) **Training Standard** An individual who has successfully completed the following training elements AND standardization elements in Standard 2 and is recognized by the program manager as having the field experience and communication skills necessary to train new employees. The training and standardization elements include:
 - 1. Satisfactory completion of the prerequisite curriculum;
 - 2. Completion of a field training process similar to that contained in Appendix B-2;
 - 3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum;
 - 4. Successful completion of a standardization process based on a minimum of eight inspections that includes development of HACCP flow charts, completion of a risk control plan, and verification of a HACCP plan, similar to the FDA standardization procedures;
 - 5. Completion of a minimum of 20 contact hours of continuing education in food safety every 36 months after the initial training is completed as outlined in Standard 2; and
 - 6. Standardization maintained every three (3) years as outlined in Standard 2.
- 30) **Verification Audit** A systematic, independent examination by an external party to confirm the accuracy of the Self-Assessment.

Submit by Email

Print Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Voluntary National Retail Food Regulatory Program Standards FDA NATIONAL REGISTRY REPORT

Form Approved OMB Number 0910-0621 Expiration Date: xx/xx/xxxx (See Public Reporting Burden Statement on page 2.)

1. Information about the J	urisdiction					
Name of Jurisdiction Reporting This Information	Address					
	City			State		ZIP Code
Contact Person for Jurisdiction	Title for Co	ontact Person		Pł		l er for Jurisdiction's act Person
E-Mail Address for Jurisdiction's Co	ontact Person					
				Jurisdic		g to serve as an auditor er jurisdiction:
Website Link for Jurisdiction					☐ Yes	s No
2. Information about Enrol	lment		Enrolli	ment Date	(DD/MM/Y)	/YY)
Please enroll this juri		_				
Update Results for the			of Enrolled Jurisdiction ssessment.	ıs		
Other - Please explain		Jen-A	ssessment.			
		- Eindings o	nd Varification Aug	lit Eindin	200	
3. Information about Self-A	1226221116111					
Completion Date for Self-Assess	sment		Self-Assessmer	nt**		fication Audit***
Instructions for Completing this	Saction	Program Standard Number	Program Standard (Mark all that app		(Mark all t	tion Audit Confirmed that apply and enter the confirmed for each)
** If the jurisdiction's self-assessme	ent indicates	1				
conformance with any Standards, the applicable Standards. Only en		2				
if it differs from that of the self-asse		3				
completion date (i.e. a self-assessi	ment update	4				
was conducted) *** If the jurisdiction's verification a	udit	5				
confirms conformance with any Sta		6				
please mark the applicable Standa indicate the completion date.	aras <u>ana</u>	7				
**** All dates should be entered in	the	8				
MM/DD/YYYY format.		9				
4. Permission to Publish II	nformation	on the FDA	Website			
Permission is granted to publish the Regulatory <i>Program Standards:</i>	e following info	rmation in the	Listing of Jurisdictions Er	nrolled in th	ne Voluntary	National Retail Food
Enrollment information		Self-asses	ssment findings	Verific	cation audit	findings
Authorized Individual (Printed) Ti	tle		Signature			Date (mm/dd/yyyy)

Instructions for Completing FDA National Registry Report - Form 3958

The FDA National Registry Report must be completed and submitted to the appropriate FDA Regional Retail Food Specialist (Retail Food Specialist) within 30 days following completion of the self-assessment, self-assessment update, or verification audit. The *Listing of Jurisdictions Enrolled in the Voluntary National Retail Food Regulatory Program Standards* will be updated using data contained in this report.

This form may be completed online and printed for submission to the appropriate Retail Food Specialist. Alternatively, this form may be completed online and submitted electronically to the appropriate Retail Food Specialist. A listing of Retail Food Specialists, by state, can be found on FDA's Retail Program Standards website (www.fda.gov/RetailProgramStandards).

Part 1: Information about the Jurisdiction

- 1. Enter the jurisdiction name, and the jurisdiction address.
- 2. Enter the name and contact information for the contact person for this jurisdiction. This is the individual to whom Retail Program Standards correspondence will be sent.
- 3. Enter the jurisdiction's website address.
- 4. Indicate if the jurisdiction is willing to serve as an auditor for another jurisdiction.

Part 2: Information about Enrollment

- 1. Select the first box to indicate that the jurisdiction is a new enrollee. Please also enter the enrollment date.
- 2. Select the second box to indicate that you would like to remove this jurisdiction from the *Listing of Jurisdictions Enrolled in the Voluntary National Retail Food Regulatory Program Standards.*
- 3. Select the third box to indicate that you are updating the findings from your self-assessment or verification audit. If you are updating this information please select the relevant self-assessment.
- 4. If the first three options are not applicable, select "Other" and provide additional information.

Part 3: Information about Self-Assessment Findings and Verification Audit Findings

- 1. Enter the date that the self-assessment was completed.
- 2. Check the applicable boxes to indicate which Standards were met, as determined by the self-assessment. For each box that is checked, do not enter a date *unless* the self-assessment date for that Standard is different than the date that the self-assessment was completed (i.e. a self-assessment update was completed for Standard X after the self-assessment was completed.)
- 3. Check the applicable boxes in the third column to indicate which Standards were met, as verified by a verification audit. For each box that is checked, a date should be entered to indicate the date that the verification audit was completed for that Standard.

Part 4: Permission to Publish Information on FDA's Website

1. With your permission, information submitted on this form will be published on FDA's Listing of Jurisdictions Enrolled in the Voluntary National Retail Food Regulatory Program Standards. Check the appropriate box(es) to indicate what information FDA may publish on the website.

After completing Parts 1-4, the Program Manager must:

- 1. Enter the name of the Authorized Individual. This may be the Program Manager or another individual authorized to submit this information.
- 2. Provide the signature of the Authorized Individual for the reporting jurisdiction.
 - a. If the form is completed electronically, click the signature box to provide an electronic signature.
 - b. If the form is completed by hand, sign your name in the signature box.
- 3. Enter the date that the form is signed.

FOR INTERNAL FDA USE ONLY (To	be completed by FDA Regional Retail Food Specialist)	
The Listing of Enrolled Jurisdictions should reflect the fol	llowing changes:	
	om Listing of Enrolled Jurisdictions (please attach an explanation)	
New/Updated Jurisdiction Contact Information	New/Updated Jurisdiction Website Address	
Updated Results for the indicated Self-Assessment	ent Period	
Reviewed By	Submitted By	

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

This section applies only to the requirements of the Paperwork Reduction Act of 1995: The public reporting burden time for this collection of information is estimated to average 12 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov Do not send your completed form to the PRA Staff email address to the left.

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

STANDARD 1 - REGULATORY FOUNDATION

Part I – *Food Code* Interventions and Risk Factor Controls

STEP 1 – Review Food Code Interventions and Risk Factor Controls

The jurisdiction's regulatory foundation must contain requirements that are at least as stringent as the public health interventions/risk factor provisions contained in the *FDA Food Code*. Part I of the *Standard 1: Self-Assessment Worksheet*, included at the end of these instructions, contains 11 public health interventions and risk factor controls:

- 1. Demonstration of Knowledge
- 2. Employee Health
- 3. Consumer Advisory
- 4. Approved Source
- 5. Time/Temperature
- 6. Protection from Contamination
- 7. Control of Hands as a Vehicle of Contamination
- 8. Good Hygienic Practices
- 9. Chemical
- 10. Conformance with Approved Procedures
- 11. Highly Susceptible Populations

To meet any one of the 11 elements described above, the self-assessment must indicate that the jurisdiction's regulatory requirements address each *Food Code* section listed under that element.

STEP 2 - Conduct the Self-Assessment for Part I

The self-assessor must compare the jurisdiction's code, regulation or ordinance with the *Food Code* sections grouped under each of the 11 public health interventions and risk factor control measures listed in Part I of the *Standard 1: Self-Assessment Worksheet*. For each *Food Code* section, the self-assessor must:

- Record the corresponding jurisdiction requirement; and
- Document his/her determination:
 - If **Full Intent** of the *Food Code* section is met, place an "X" in the appropriate column.
 - If **Partial Intent** of the *Food Code* section is met, identify language that is not included with the jurisdiction's requirement. Indicate whether the language is addressed in another jurisdiction statute, ordinance, or regulatory requirement.
 - If **No corresponding regulation exists**, indicate "No Compliance" in the appropriate column and provide any information that may explain why it is not part of the jurisdiction's current requirements.

STEP 3 – Document the Self-Assessment Results for Part I

A summary table is provided in Part I of the *Standard 1: Self-Assessment Worksheet* to document the results of the self-assessment for each of the 11 public health intervention and risk factor control measures. For each public health intervention and risk factor control measure, the self-assessor must record the findings from the self-assessment. If each *Food Code* section listed under an Intervention/Risk Factor has a check in the "Full Intent is Met" column, the Standard criteria is met. Place an "X" in the Self-Assessment Results "YES" column.

If any of the *Food Code* sections are missing, or the jurisdiction's regulatory requirements only partially meet the intent of the language, place an "X" in the Self-Assessment Results "NO" column for that intervention/risk factor control measure.

At the bottom of Part I of the *Standard 1: Self-Assessment Worksheet*, the self-assessor must record the jurisdiction's name and the number of interventions/risk factors that are met. For initial participation and listing purposes, the jurisdiction's self-assessment must indicate conformance with at least 9 of the 11 intervention/risk factor categories. By the third verification audit, the jurisdiction must meet 11 of the 11 intervention/risk factor control categories in order to meet the Standard 1 criteria.

Examples of documents that may be reviewed:

- The jurisdiction's statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of its food establishments
- Version of the *Food Code* that was used for the self-assessment
- Completed Standard 1: Self-Assessment Worksheet
 - * Part I Food Code Interventions and Risk Factor Controls
- ➤ If applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

Standard 1: Regulatory Foundation Self-Assessment Worksheet

PART I – 2017 Food Code: Interventions and Risk Factor Controls

SECTION 1 – DEMONSTRATION OF KNOWLEDGE

NO Compliance with the Food Code section is NOT Met (Indicate the Situation)				
Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)				
YES Full Intent is Met				
Jurisdiction's Corresponding Code Section, Rule, etc.				
Food Code Section	2-101.11 – Assignment	2-102.11 – Demonstration	2-102.12 – Certified Food Protection Manager	2-103.11 – Person in Charge
ltem No.	1 2-2	2 2	3 2	4 2

SECTION 2 – EMPLOYEE HEALTH

		Jurisdiction's	YES	<u>Partial Compliance</u>	ON	
ltem No.	Food Code Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)	
5	2-201.11 – Responsibility of Permit Holder, Person in Charge, and Conditional Employees					

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
9	2-201.12 – Exclusions and Restrictions				
7	2-201.13 – Removal, Adjustment, or Retention of Exclusions and Restrictions				
∞	2-501.11 – Clean-up of Vomiting and Diarrheal Events				

SECTION 3 – CONSUMER ADVISORY

ON	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)	
Partial Compliance	List what is not covered (Additional sheets can be used for explanations and comments)	
YES	Full Intent is Met	
Jurisdiction's	Corresponding Code Section, Rule, etc.	
	Food Code Section	3-603.11 – Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens
	ltem No.	9 8

SECTION 4 – APPROVED SOURCE

		Jurisdiction's	YES	<u>Partial Compliance</u>	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
10	3-201.11 – Compliance with Food Law				
11	3-201.12 – Food in a Hermetically Sealed Container				
12	3-201.13 – Fluid Milk and Milk Products				
13	3-202.13 – Eggs				
41	3-202.14 – Eggs and Milk Products, Pasteurized				
15	5-101.13 – Bottled Drinking Water				
16	3-201.14 – Fish				
17	3-201.15 – Molluscan Shellfish				
	-				

Voluntary National Retail Food Regulatory Program Standards - January 2017

ltem No.	Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent	List what is not covered (Additional sheets can be used for	NOT Met
81	3-201.16 – Wild Mushrooms			explanations and comments)	(Halacate the Shaation)
19	3-201.17 – Game Animals				
50	3-101.11 – Safe, Unadulterated, and Honestly Presented				
21	3-202.11 – Temperature				
22	3-202.15 – Package Integrity				
23	3-202.18 – Shellstock Identification				
24	3-203.12 – Shellstock, Maintaining Identification				
25	3-402.11 – Parasite Destruction				

		Jurisdiction's	YES	Partial Compliance	<u>ON</u>
ltem No.	Food Code Section		Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
26	3-402.12 – Records, Creation, and Retention				
27	27 3-202.110 – Juice Treated				

SECTION 5 – TIME/TEMPERATURE

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
28	3-401.11 – Raw Animal Foods				
29	3-401.12 – Microwave Cooking				
30	3-401.14 – Non-Continuous Cooking of Raw Animal Foods				
31	3-403.11 – Reheating for Hot Holding				

SECTION 5 – TIME/TEMPERATURE

		Jurisdiction's	YES	<u>Partial Compliance</u>	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
32	3-501.14 – Cooling				
33	3-501.15 – Cooling Method				
34	3-501.16 – Time/Temperature Control for Safety Food, Hot and Cold Holding				
35	3-501.17 – Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking				
36	3-501.18 – Ready-to-Eat, Time/Temperature Control for Safety Food, Disposition				
37	3-501.19 – Time as a Public Health Control				

SECTION 6 – PROTECTION FROM CONTAMINATION

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
38	3-301.12 – Preventing Contamination When Tasting				
39	3-302.11 – Packaged/Unpackaged Food – Separation, Packaging, and Segregation				
40	3-304.11 – Food Contact with Equipment and Utensils				
41	3-306.14 – Returned Food and Re-Service of Food				
42	3-701.11 – Discarding or Reconditioning Unsafe, Adulterated,or Contaminated Food				
43	4-201.12 – Food Temperature Measuring Devices				
44	4-501.111 – Manual Warewashing Equipment, Hot Water Sanitization Temperatures				
45	4-501.112 – Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures				

		Jurisdiction's	YES	Partial Compliance	<u>ON</u>
ltem No.	Food Code Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
46	4-501.113 – Mechanical Warewashing Equipment, Sanitization Pressure				
47	4-501.114 – Manual and Mechanical Warewashing Equipment, Chemical Sanitization – Temperature, pH, Concentration, and Hardness				
48	4-501.115 – Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers				
49	4-601.11 – Equipment, Food-Contact Surfaces, Non Food-Contact Surfaces, and Utensils				
20	4-602.11 - Equipment Food-Contact Surfaces and Utensils				
51	4-602.12 – Cooking and Baking Equipment				
52	4-702.11 – Before Use After Cleaning				
53	4-703.11 – Hot Water and Chemical				

SECTION 7 – CONTROL OF HANDS AS A VEHICLE OF CONTAMINATION

		Jurisdiction's	YES	Partial Compliance	<u>NO</u>
Item No.	Food Code Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
54	2-301.11 – Clean Condition				
55	2-301.12 – Cleaning Procedure				
56	2-301.14 – When to Wash				
57	2-301.15 – Where to Wash				
58	2-301.16 – Hand Antiseptics				
59	3-301.11 – Preventing Contamination from Hands				
09	5-203.11 – Handwashing Sinks (<i>Numbers/</i> <i>Capacities)</i>				
61	5-204.11 – Handwashing Sinks <i>(Location/</i> Placement)				

SECTION 7 – CONTROL OF HANDS AS A VEHICLE OF CONTAMINATION

NO Compliance with the Food Code section is NOT Met (Indicate the Situation)					
List what is not covered t (Additional sheets can be used for explanations and comments)					
YES Full Intent is Met					
Jurisdiction's Corresponding Code Section, Rule, etc.					
Food Code Section	5-205.11 – Using a Handwashing Sink	6-301.11 – Handwashing Cleanser, Availability	6-301.12 – Hand Drying Provision	6-301.13 – Handwashing Aids and Devices, Use Restrictions	6-501.18 – Cleaning of Plumbing Fixtures
ltem No.	62 5-	63 6	64	9 9	9 99

SECTION 8 – GOOD HYGIENIC PRACTICES

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	_	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
29	67 2-401.11 - Eating, Drinking, or Using Tobacco				

		2,40;+1;	YES	Partial Compliance	ON
Item No.	n Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
89	2-401.12 – Discharges from the Eyes, Nose, and Mouth				
69	2-401.13 - Bandage, Finger Cot, Stall				
SEC	SECTION 9 – CHEMICAL				
		Jurisdiction's	YES	Partial Compliance	<u>ON</u>
Item No.	Food Code Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
02	3-202.12 – Additives				
7.1	3-302.14 – Protection from Unapproved Additives				
72	7-207.11 – Restriction and Storage				
73	7-207.12 – Refrigerated Medicines, Storage				
74	7-208.11 – Storage (First Aid Supplies)				

Voluntary National Retail Food Regulatory Program Standards – January 2017

		Jurisdiction's	YES	Partial Compliance	ŌN
Item No.	Food Code Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
75	7-209.11 – Storage (Personal Care Items)				
9/	7-101.11 – Identifying Information, Prominence				
77	7-102.11 – Common Name				
78	7-201.11 – Separation				
62	7-202.11 – Restriction				
80	7-202.12 – Conditions of Use				
81	7-203.11 – Poisonous or Toxic Material Containers				
82	7-204.11 – Sanitizers, Criteria				

NO Compliance with the Food Code section is NOT Met (Indicate the Situation)								
Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)								
YES Full Intent is Met								
Jurisdiction's Corresponding Code Section, Rule, etc.								
Food Code Section	7-204.12 – Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria	7-204.13 – Boiler Water Additives, Criteria	7-204.14 – Drying Agents, Criteria	7-205.11 – Incidental Food Contact, Criteria	7-206.11 – Restricted Use Pesticides, Criteria	7-206.12 – Rodent Bait Stations	7-206.13 – Tracking Powders, Pest Control and Monitoring	7-301.11 – Separation (Retail Sale)
ltem No.	83 St	84 7-	85 7-	98 7-	87 7-	88 7-	-7 W 89	-2 06

SECTION 10 – CONFORMANCE WITH APPROVED PROCEDURES

Item No.		Jurisdiction's	YES	Partial Compliance	ON
	Food Code Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the <i>Food Code</i> section is NOT Met (Indicate the Situation)
91 3-404.	91 3-404.11 – Treating Juice				
92 3-502.	92 3-502.11 – Variance Requirement				
93 3-502.1 Variano	3-502.12 – Reduced Oxygen Packaging Without a Variance, Criteria				

SECTION 11 - HIGHLY SUSCEPTIBLE POPULATIONS

				:	
		Jurisdiction's	YES	Partial Compliance	ON.
Item No.	n Section	Corresponding Code Section,	Full	List what is not covered (Additional sheets can be used for	Compliance with the Food Code section is NOT Met
			is Met	explanations and comments)	(Indicate the Situation)
94	3-801.11 – Pasteurized Foods, Prohibited Reservice, and Prohibited Foods				

Standard 1: Regulatory Foundation Self-Assessment Worksheet

Part I – 2017 Food Code: Interventions and Risk Factor Controls Self-Assessment Results

Food		YES	ON O	
Code Section	Section Description	Standard Standard Criteria Criteria Met Not Met	Standard Criteria Not Met	Self-Assessor's General Comments
-	Demonstration of Knowledge			
2	Employee Health			
ю	Consumer Advisory			
4	Approved Sources			
5	Time/Temperature			
9	Protection from Contamination			
7	Control of Hands as a Vehicle of Contamination			
80	Good Hygienic Practices			
6	Chemical			
10	Conformance with Approve Procedures			
11	Highly Susceptible Populations			

indicates conformance with $\frac{}{(\# \, \mathrm{Met})}$ out of the 11 Intervention/Risk Factor Categories (regulatory agency) Assessment of

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

STANDARD 1 - REGULATORY FOUNDATION

Part II – Good Retail Practices

STEP 1 – Review Good Retail Practices

The jurisdiction's regulatory foundation must have corresponding requirements for 95 percent of the FDA Food Code sections listed in Part II – Good Retail Practices of the *Standard 1: Self-Assessment Worksheet*. This worksheet is included at the end of these instructions. Part II of the *Standard 1: Self-Assessment Worksheet* contains several categories, beginning with #12 "Personnel" through #36 "Presence of Insects / Rodents Minimized, Outer Openings Protected, etc."

STEP 2 - Conduct the Self-Assessment for Part II

The self-assessor must compare the jurisdiction's code, regulation or ordinance with the corresponding *Food Code* section for each of the Good Retail Practices (GRPs) provision listed in Part II of the *Standard 1: Self-Assessment Worksheet*. For each *Food Code* section:

- Record the corresponding jurisdiction requirement; and
- Document his/her determination:
 - If **Full Intent** of the *Food Code* section is met, place an "X" in the appropriate column.
 - If **Partial Intent** of the *Food Code* section is met, identify language that is not included with the jurisdiction's requirement. Indicate whether the language is addressed in another jurisdiction statute, ordinance, or regulatory requirement.
 - If **No corresponding regulation exists**, indicate "No Compliance" in the appropriate column and provide any information that may explain why it is not part of the jurisdiction's current requirements.

STEP 3 – Document the Self-Assessment Results for Part II

The summary table is provided at the end of Part II on the *Standard 1: Self-Assessment Worksheet* to document the results of the self-assessment for the Good Retail Practices *Food Code* provisions. For each Good Retail Practice category, the self-assessor will record the total number of *Food Code* sections for which the jurisdiction's regulations have a corresponding requirement. This number is obtained from the totals documented at the end of each of the Good Retail Practice categories.

At the bottom of Part II of the *Standard 1: Self-Assessment Worksheet*, record the number of Good Retail Practices that are met. Divide the total number of provisions met (last line of table) by 247 and multiple by 100 to determine the percentage of the Good Retail Practices provisions contained in the jurisdiction's code or regulation. A percentage equal to or greater than 95% meets the Regulatory Foundation for Sections 12 - 36.

Examples of documents that may be reviewed

- The jurisdiction's statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of its food establishments
- ➤ Version of the *FDA Food Code* that was used for the self-assessment
- Completed Standard 1: Self-Assessment Worksheet
 * Part II Good Retail Practices
- ➤ If applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

Standard 1: Regulatory Foundation Self-Assessment Worksheet

Part II - 2017 Food Code: Good Retail Practices

SECTION 12 – PERSONNEL

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
-	2-302.11 - Maintenance				
2	2-303.11 - Prohibition				
n	2-301.11 - Clean Condition				
4	4 2-402.11 - Effectiveness				
5	6-301.14 - Handwashing Signage				
T(TOTAL NUMBER OF SECTION 12 PROVISIONS MARKED "YES";	ISIONS MARKED "YE		(Section 12 has a total of 5 provisions)	

SECTION 13 – FOOD & FOOD PROTECTION

		Jurisdiction's	YES	Partial Compliance	NO
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
9	6 3-202.16 - Ice				
7	3-202.17 - Shucked Shellfish, Packaging and Identification				

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
∞	3-202.19 - Shellstock, Condition				
6	3-203.11 - Molluscan Shellfish, Original Container				
10	3-302.12 - Food Storage Containers, Identified with Common Name of Food				
-	3-302.13 - Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes				
12	3-305.13 - Vended Time/Temperature Control for Safety Food, Original Container				
13	3-601.11 - Standards of Identity				
14	3-601.12 - Honestly Presented				
15	3-602.11 - Food Labels				
16	3-602.12 - Other Forms of Information				

		Jurisdiction's	YES	<u>Partial Compliance</u>	ON
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent (/ Is Met	Full List what is not covered. It what is not covered. Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
17	17 6-404.11 - Segregation and Location				
	TOTAL NUMBER OF SECTION 13 PROVISIONS MARKED "YES":	TSIONS MARKED "YES	S.:	(Section 13 has a total of 12 provisions)	

SECTION 14 - PLANT FOOD COOKING FOR HOT HOLDING

		Jurisdiction's	YES	Partial Compliance	ON
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	Full List what is not covered. Intent (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
18	3-401.13 - Plant Food Cooking for Hot Holding				

SECTION 15 - PROTECTION FROM CONTAMINATION

		Jurisdiction's	YES	Partial Compliance	NO
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
19	3-302.15 - Washing Fruits and Vegetables				
20	3-303.11 - Ice Used as Exterior Coolant, Prohibited as Ingredient				
21	3-302.12 - Storage or Display of Food In Contact with Water and Ice				
22	3-304.11 - Food Contact with Equipment and Utensils				
23	3-305.11 - Food Storage				
24	3-305.12 - Food Storage, Prohibited Areas				
25	3-305.14 - Food Preparation				
26	3-306.11 - Food Display				
27	3-306.12 - Condiments, Protection				

ltem	Food Code	Jurisdiction's Corresponding	YES Full	Partial Compliance List what is not covered.	ON
V	Section	Code Section, Rule, Etc.	Intent Is Met	(Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
28	3-306.13 - Consumer Self-Service Operations				
29	3-307.11 - Miscellaneous Sources of Contamination				·
TOT	TOTAL NUMBER OF SECTION 15 PROVISIONS MARKED "YES":	VISIONS MARKED "YI	ES:	(Section 15 has a total of 11 provisions)	
SEC	SECTION 16 – FACILITIES / METHODS TO CONTROL PRODUCT TEMPERATURE	THODS TO CONTR	OL PR	ODUCT TEMPERATURE	
		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
30	3-501.11 - Frozen Food				
31	4-301.11 - Cooling, Heating, and Holding Capacities				
TOT	TOTAL NUMBER OF SECTION 16 PROVISIONS MARKED "YES":	VISIONS MARKED "YI	ES:	(Section 16 has a total of 2 provisions)	

SECTION 17 – TIME / TEMPERATURE CONTROL FOR SAFETY FOOD - PROPERLY THAWED

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	_	Full Intent Is Met	Full List what is not covered. Intent (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
32	3-501.12 - Time / Temperature Control for Safety Food, Slacking				
33	3-501.13 - Thawing				
TOT	TOTAL NUMBER OF SECTION 17 PROVISIONS MARKED "YES":	ISIONS MARKED "YE		(Section 17 has a total of 2 provisions)	

SECTION 18 – DISPENSING OF FOOD / UTENSILS PROPERLY STORED

			YES	Partial Compliance	ON
Item No.	Food Code Section	Jurisdiction s Corresponding Code Section, Rule, Etc.	Full Intent Is Met	Full List what is not covered. ntent (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
34	3-304.12 - In-Use Utensils, Between-use Storage				
35	4-204.13 - Dispensing equipment, Protection of Equipment and Food				
36	4-204.14 - Vending Machine Vending Stage Closure				

SECTION 19 - THERMOMETERS PROVIDED AND CONSPICUOUS

		Jurisdiction's	YES	<u>Partial Compliance</u>	ON.	
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)	
37	4-203.11 - Temperature Measuring Devices					
38	4-203.12 - Temperature Measuring Devices, Ambient Air and Water					
39	4-204.112 - Temperature Measuring Devices					
40	4-302.12 - Food Temperature Measuring Devices					
TOT	TOTAL NUMBER OF SECTION 19 PROVISIONS MARKED "YES":	VISIONS MARKED "YE	ES":	(Section 19 has a total of 4 provisions)		i

SECTION 20 – FOOD AND NONFOOD CONTACT SURFACES: DESIGNED, CONSTRUCTED, MAINTAINED, INSTALLED, LOCATED, OPERATED, CLEANABLE

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
41	3-304.16 - Using Clean Tableware for Second Portions and Refills				
42	3-304.17 - Refilling Returnables				
43	4-101.11 - Characteristics				
44	4-101.12 - Cast Iron, Use Limitation				
45	4-101.13 - Lead, Use Limitation (In Ceramic, China, and Crystal)				
46	4-101.14 - Copper, Use Limitation				
47	4-101.15 - Galvanized Metal, Use Limitation				

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section		Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
48	4-101.17 - Wood, Use Limitation				
49	4-101.18 - Nonstick Coatings, Use Limitation				
50	4-101.19 - Nonfood-Contact Surfaces				
51	4-102.11 - Characteristics				
52	4-201.11 - Equipment and Utensils				
53	4-202.11 - Food-Contact Surfaces				
54	4-202.12 - CIP Equipment				
55	4-202.13 - "V" Threads, Use Limitation				
26	4-202.14 - Hot Oil Filtering Equipment				

		Jurisdiction's	YES	Partial Compliance	ŌN
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
57	4-202.15 - Can Openers				
58	4-202.16 - Nonfood-Contact Surfaces				
59	4-202.17 - Kick Plates, Removable				
09	4-204.12 - Equipment Openings, Closures, and Deflectors				
61	4-204.15 - Bearings and Gear Boxes, Leakproof				
62	4-204.16 - Beverage Tubing, Separation				
63	4-204.17 - Ice Units, Separation of Drains				
94	4-204.18 - Condenser Unit, Separation				
65	4-204.19 - Can Openers on Vending Machines				

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
99	4-204.110 - Molluscan Shellfish Tanks				
29	4-204.111 - Vending Machines, Automatic Shutoff				
89	4-204.121 - Vending Machines, Liquid Waste Products				
69	4-204.122 - Case Lot Handling Equipment, Moveability				
70	4-204.123 - Vending Doors and Openings				
71	4-302.11 - Utensils, Consumer Self-Service				
72	4-401.11 - Equipment, Clothes Washers and Dryers and Storage Cabinets, Contamination Prevention				
73	4-402.11 - Fixed Equipment, Spacing or Sealing				
74	4-402.12 - Fixed Equipment, Elevation or Sealing				

		Jurisdiction's	YES	<u>Partial Compliance</u>	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
75	4-501.11 - Good Repair and Proper Adjustment				
92	4-501.12 - Cutting Surfaces				
77	4-501.13 - Microwave Ovens				
78	4-502.11 - Good Repair and Calibration				
79	4-601.11(B - C) - Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, Utensils				
80	4-602.13 - Nonfood-Contact Surfaces				
81	4-604.11 - Dry Cleaning				
82	4-902.11 - Food-Contact Surfaces				

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	Full List what is not covered. ntent (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
83	4-902.12 - Equipment				

TOTAL NUMBER OF SECTION 20 PROVISIONS MARKED "YES": [[Section 20 has a total of 43 provisions)

SECTION 21 - WAREWASHING FACILITY: DESIGNED CONSTRUCTED, INSTALLED, LOCATED, OPERATED, CLEANABLE, USED

		Jurisdiction's	YES	Partial Compliance	NO
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
84	4-303.11 - Cleaning Agents and Sanitizer, Availability				
85	4-203.13 - Pressure Measuring Devices, Mechanical Warewashing Equipment				
98	4-204.113 - Warewashing Machine, Data Plate Operating Specifications				
87	4-204.114 - Warewashing Machines, Temperature, Measuring Devices				
88	4-204.115 - Warewashing Machines, Temperature, Measuring Devices				

		Jurisdiction's	YES	<u>Partial Compliance</u>	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
88	4-204.116 - Manual Warewashing Equipment, Heaters and Baskets				
06	4-204.117 - Warewashing Machines, Automatic Dispensing of Detergents and Sanitizer s				
91	4-204.118 - Warewashing Machines, Flow Pressure Device				
92	4-204.119 - Warewashing Sinks and Drainboards, Self-Draining				
93	4-204.120 - Equipment Compartments, Drainage				
94	4-301.12 - Manual Warewashing, Sink Compartment Requirements				
95	4-301.13 - Drainboards				
96	4-302.13 - Temperature Measuring Devices, Manual Warewashing				
26	4-302.14 - Sanitizing Solutions, Testing Devices				

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
86	4-501.14 - Warewashing Equipment, Cleaning Frequency				
66	4-501.15 - Warewashing Machines, Manufacturer's Operating Instructions				
100	4-501.16 - Warewashing Sinks, Use Limitation				
101	4-501.17 - Warewashing Equipment, Cleaning Agents				
102	4-501.18 - Warewashing Equipment, Clean Solutions				
103	4-501.19 - Manual Warewashing Equipment, Wash Solution Temperature				
104	4-501.110 - Mechanical Warewashing Equipment, Wash Solution Temperature				
105	4-501.116 - Warewashing Equipment, Determining Chemical Sanitizer Concentration				
106	4-603.12 - Precleaning				

Voluntary National Retail Food Regulatory Program Standards – January 2017

<u>ON</u>	Compliance with FDA Food Code is not Met (Indicate the Situation)						
Partial Compliance	List what is not covered. (Additional sheets can be used for explanations and comments)						(Section 21 has a total of 28 provisions)
YES	Full Intent Is Met						ES'':
Jurisdiction's	Corresponding Code Section, Rule, Etc.						VISIONS MARKED "YI
	Food Code Section	4-603.13 - Loading of Soiled Items, Warewashing Machines	4-603.14 - Wet Cleaning	4-603.15 - Washing, Procedures for Alternative Manual Warewashing Equipment	110 4-603.16 - Rinsing Procedures	4-904.14 - Rinsing Equipment and Utensils After Cleaning and Sanitizing	TOTAL NUMBER OF SECTION 21 PROVISIONS MARKED "YES":
	ltem No.	107	108	109 <i>h</i>	110 ,	111	TOTA

Voluntary National Retail Food Regulatory Program Standards – January 2017

SECTION 22 - WIPING CLOTHS, LINENS, NAPKINS, GLOVES, SPONGES: PROPERLY USED, STORED

		Jurisdiction's	YES	Partial Compliance	NO
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
112	3-304.13 - Linens and Napkins, Use Limitation				
113	3-304.14 - Wiping Cloths, Use Limitation				
114	3-304.15 - Gloves, Use Limitation				
115	4-101.16 - Sponges, Use Limitation				
116	4-801.11 - Clean Linens				
117	4-802.11 - Specifications				
118	4-803.11 - Storage of Soiled Linens				
119	4-803.12 - Mechanical Washing				
120	4-901.12 - Wiping Cloths, Air Drying Locations				

		Jurisdiction's	YES	Partial Compliance	ON
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	Full List what is not covered. Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
121	121 4-903.12 - Equipment				
TOT	TOTAL NUMBER OF SECTION 22 PROVISIONS MARKED "YES";	ISIONS MARKED "YE	ES:	(Section 22 has a total of 10 provisions)	

SECTION 23 – STORAGE, HANDLING OF CLEAN EQUIPMENT, UTENSILS

		Jurisdiction's	YES	Partial Compliance	<u>NO</u>
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
122	4-901.11 - Equipment and Utensils, Air- Drying Required				
123	4-903.11 - Equipment, Utensils, Linens, and Single-Service and Single-Use Articles				
124	4-903.12 - Prohibitions				
125	4-904.11 - Kitchenware and Tableware				
126	126 4-904.12 - Soiled and Clean Tableware				

		Jurisdiction's	YES	Partial Compliance	ON
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	-ull List what is not covered. tent (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
127	127 4-904.13 - Preset Tableware				
TOT_{ℓ}	TOTAL NUMBER OF SECTION 23 PROVISIONS MARKED "YES"	TSIONS MARKED "YE		(Section 23 has a total of 6 provisions)	

SECTION 24 - SINGLE-SERVICE / SINGLE-USE ARTICLES: STORAGE, DISPENSING, USE, NO REUSE

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	Full List what is not covered. Intent (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
128	4-502.12 - Single-Service and Single-Use Articles, Required Use				
129	4-502.13 - Single-Service and Single-Use Articles, Use Limitation				
130	130 4-502.14 - Shells, Use Limitation				
TOT	TOTAL NUMBER OF SECTION 24 PROVISIONS MARKED "YES";	TSIONS MARKED "YI	ES":	(Section 24 has a total of 3 provisions)	

SECTION 25 – SAFE WATER SOURCE, HOT AND COLD UNDER PRESSURE, ADEQUATE QUANTITY

		Jurisdiction's	YES	<u>Partial Compliance</u>	ON
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
131	5-101.11 - Approved System				
132	5-102.11 - Standards				
133	5-102.12 - Nondrinking Water				
134	5-102.13 - Sampling				
135	5-102.14 - Sample Report				
136	5-103.11 - Capacity				
137	5-103.12 - Pressure				
138	5-104.11 - System				
139	5-104.12 - Alternative Water Supply				
TOT	TOTAL NUMBER OF SECTION 25 PROVISIONS MARKED "YES":	VISIONS MARKED "YF	ES'':	(Section 25 has a total of 9 provisions)	

SECTION 26 - PLUMBING: INSTALLED, MAINTAINED

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
140	5-101.12 - System Flushing and Disinfection				
141	5-201.11 - Approved				
142	5-202.11 - Approved System and Cleanable Fixtures				
143	5-202.12 - Handwashing Facility, Installation				
144	5-202.15 - Conditioning Device, Location				
145	5-203.13 - Service Sink				
146	5-204.13 - Conditioning Device, Location				
147	5-205.13 - Scheduling Inspection and Service for a Water System Device				
148	5-205.14 - Water Reservoir of Fogging Devices, Cleaning				

		Jurisdiction's	YES	Partial Compliance	NO
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
149	5-205.15 - System Maintained in Good Repair				
150	5-301.11 - Approved				
151	5-302.11 - Enclosed System, Sloped to Drain				
152	5-302.12 - Inspection and Cleaning Port, Protected and Secured				
153	5-302.13 - "V" Type Threads, Use Limitation				
154	5-302.14 - Tank Vent, Protected				
155	5-302.15 - Inlet and Outlet, Sloped to Drain				
156	5-302.16 - Hose, Construction and Identification				
157	5-303.11 - Filter, Compressed Air				
158	5-303.12 - Protective Cover or Device				

Voluntary National Retail Food Regulatory Program Standards – January 2017

		Jurisdiction's	YES	Partial Compliance	ON
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
159	5-303.13 - Mobile Food Establishment Tank Inlet				
160	5-304.11 - System Flushing and Disinfection				
161	5-304.12 - Using a Pump and Hoses, Backflow Prevention				
162	5-304.13 - Protecting Inlet, Outlet, and Hose Fitting				
163	5-304.14 - Tank, Pump, and Hoses, Dedication				

[(Section 26 has a total of 24 provisions) TOTAL NUMBER OF SECTION 26 PROVISIONS MARKED "YES":

SECTION 27 – CROSS CONNECTION, BACK SIPHONAGE, BACKFLOW PREVENTION

		Jurisdiction's	YES	Partial Compliance	ON
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
164	5-202.13 - Backflow Prevention, Air Gap				
165	5-202.14 - Backflow Prevention Device, Design Standard				
166	5-203.14 - Backflow Prevention Device, When Required				
167	5-203.15 - Backflow Prevention Device, Carbonator				
168	5-204.12 - Backflow Prevention Device, Location				
169	5-205.12 - Prohibiting a Cross Connection				
TOT_{ℓ}	TOTAL NUMBER OF SECTION 27 PROVISIONS MARKED "YES":	TSIONS MARKED "YE	.S.:	(Section 27 has a total of 6 provisions)	

SECTION 28 – TOILET FACILITIES: CONVENIENT, ACCESSIBLE, DESIGNED, INSTALLED

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	Full List what is not covered. Intent (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
170	170 5-203.12 - Toilets and Urinals				
171	171 6-402.11 - Convenience and Accessibility				
TOT	TOTAL NUMBER OF SECTION 28 PROVISIONS MARKED "YES":	TSIONS MARKED "YE	S.:	(Section 28 has a total of 2 provisions)	

SECTION 29 - TOILET ROOMS ENCLOSED, SELF CLOSING DOORS; FIXTURES GOOD REPAIR,

TE RECEPTACLES	
CLEAN PROPER WASTE RECEPTACI	
こ	

Item Food Code Section Corresponding Code Section. Full List what is not covered. List what is not covered. Code Section. Rule, Etc. Is Met Full List what is not covered. Code Section. Intent Is Meditional sheets can be used for explanations and comments) Compliance with FDA Food Code is not (Indicate the Situation) 173 6-202.14 - Toilet Rooms, Enclosed Image: Intent Room Receptable Rooms, Enclosed Image: Intent Rooms, Enclosed I			Jurisdiction's	YES	Partial Compliance	ON
172 Covered Covered 173 Govered Covered 174 G-202.14 - Toilet Rooms, Enclosed Covered 174 G-302.11 - Toilet Tissue Availability Covered 175 G-501.19 - Closing Toilet Room Doors Covered	ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.			Compliance with FDA Food Code is not Met (Indicate the Situation)
173 6-202.14 - Toilet Rooms, Enclosed □ 174 6-302.11 - Toilet Tissue Availability □ 175 6-501.19 - Closing Toilet Room Doors □	172					
174 6-302.11 - Toilet Tissue Availability	173	6-202.14 - Toilet Rooms, Enclosed				
175 6-501.19 - Closing Toilet Room Doors						
	175	6-501.19 - Closing Toilet Room Doors				

SECTION 30 – SEWAGE AND WATER WASTE DISPOSAL

			VEC	Daytial Compliance	Q
ltem No.	Food Code Section	Jurisdiction's Corresponding Code Section, Rule, Etc.		List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
176	5-401.11 - Capacity and Drainage				
177	5-402.11 - Backflow Prevention				
178	5-402.12 - Grease Trap				
179	5-402.13 - Conveying Sewage				
180	5-402.14 - Removing Mobile Food Establishment Wastes				
181	4-502.15 - Flushing a Waste Retention Tank				
182	5-403.11 - Approved Sewage Disposal System				
183	5-403.12 - Other Liquid Wastes and Rainwater				
TOT	TOTAL NUMBER OF SECTION 30 PROVISIONS MARKED "YES":	/ISIONS MARKED "YE	:.S::	(Section 30 has a total of 8 provisions)	

SECTION 31 - GARBAGE AND REFUSE DISPOSAL - CONTAINERS OR RECEPTACLES: COVERED, ADEQAUTE NUMBER, INSECT / RODENT PROOF, FREQUENCY OF REMOVAL, CLEAN, AREA PROPERLY CONSTRUCTED, NECCESSARY IMPLEMENTS, SUPPLIES

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
184	5-501.11 - Outdoor Storage Surface				
185	5-501.12 - Outdoor Enclosure				
186	5-501.13 – Receptacles				
187	5-501.14 – Receptacles in Vending Machines				
188	5-501.15 – Outside Receptacles				
189	5-501.16 – Storage Areas, Rooms, and Receptacles, Capacity and Availability				
190	5-501.18 – Geaning Implements and Supplies				
191	5-501.19 – Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units Location				
192	5-501.110 – Storing Refuse, Recyclables, and Returnables				

		Jurisdiction's	YES	Partial Compliance	ON
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
193	5-501.111 – Areas, Enclosures, and Receptacles, Good Repair				
194	5-501.112 –Outside Storage Prohibitions				
195	5-501.113 –Covering Receptacles				
196	5-501.114 – Using Drain Plugs				
197	5-501.115 – Maintaining Refuse Areas and Enclosures				
198	5-501.116 – Cleaning Receptacles				
199	5-502.11 – Frequency				
200	5-502.12 – Receptacles or Vehicles				
201	5-503.11 – Community or Individual Facility				

		Jurisdiction's	YES	<u>Partial Compliance</u>	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	Full List what is not covered. Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
202	6-202.110 - Outside Refuse Areas, Curbed and Graded to Drain				

(Section 31 has a total of 19 provisions) TOTAL NUMBER OF SECTION 31 PROVISIONS MARKED "YES":

SECTION 32 - PHYSICAL FACILITY, FLOORS, WALLS, CEILINGS: DESIGNED, CONSTRUCTED, MAINTAINED, CLEAN

Compliance with FDA Food Code is not Met (Indicate the Situation) 9 (Additional sheets can be used for explanations List what is not covered. Partial Compliance and comments) Intent Is Met YES Full Corresponding Code Section, Jurisdiction's Rule, Etc. 6-201.12 - Floors, Walls, and Ceilings, Utility Lines 6-201.13 - Floors and Wall Junctures, Coved, and Enclosed or Sealed 6-201.11 - Floors, Walls, and Ceilings 6-101.11 - Surface Characteristics 6-102.11 - Surface Characteristics Food Code Section Item No. 204 205 203 206 207

		Jurisdiction's	YES	Partial Compliance	ON
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
208	6-201.14 - Floor Carpeting, Restrictions and Installation				
209	6-201.15 - Floor Covering, Mats and Duckboards				
210	6-201.16 - Wall and Ceiling Coverings and Coatings				
211	6-201.17 - Walls and Ceilings, Attachments				
212	6-201.18 - Walls and Ceilings, Studs, Joists, and Rafters				
213	6-202.17 - Outdoor Food Vending Areas, Overhead Protection				
214	6-202.18 - Outdoor Servicing Areas, Overhead Protection				
215	6-501.11 - Repairing				
216	6-501.12 - Cleaning, Frequency and Restrictions				

		Jurisdiction's	YES	Partial Compliance	NO
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	Full List what is not covered. ntent (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
217	6-501.13 - Cleaning Floors, Dustless Methods				
218	6-501.17 - Absorbent Materials on Floors, Use Limitation				
TOT	TOTAL NUMBER OF SECTION 32 PROVISIONS MARKED "YES":	ISIONS MARKED "YE	S.::	(Section 32 has a total of 16 provisions)	

SECTION 33 - LIGHTING, VENTILATION, DRESSING ROOMS / DESIGNATED AREAS MAINTAINED

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
219	4-202.18 - Ventilation Hood Systems, Filters				
220	4-204.11 - Ventilation Hood Systems, Drip Preventions				
221	4-301.14 - Ventilation Hood Systems, Adequacy				
222	6-202.11 - Light Bulbs, Protective Shielding				

		Jurisdiction's	YES	Partial Compliance	ON
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
223	6-202.12 - Heating, Ventilating, Air Conditioning System Vents				
224	6-303.11 - Intensity				
225	6-304.11 - Mechanical				
226	6-305.11 - Designation				
227	6-403.11 - Designated Areas				
228	6-501.14 - Cleaning Ventilation Systems, Nuisance and Discharge Prohibition				
229	6-501.110 - Using Dressing Rooms and Lockers				
TOT	TOTAL NUMBER OF SECTION 33 PROVISIONS MARKED "YES":	VISIONS MARKED "YI	ES'':	(Section 33 has a total of 11 provisions)	

SECTION 34 - PREMISES MAINTAINED FREE OF LITTER, UNNECESSARY ARTICLES, CLEANING AND MAINTENANCE **EQUIPMENT PROPERLY STORED**

Partial Compliance	List what is not covered. (Additional sheets can be used for explanations and comments)						(Section 34 has a total of 5 provisions)
YES	Full Intent (A						3":
							YE
Jurisdiction's	Corresponding Code Section, Rule, Etc.						VISIONS MARKED "
Jurisdiction's	Food Code Code Section Section Rule, Etc.	6-202.19 - Outdoor Walking and Driving Surfaces, Graded to Drain	6-501.15 - Cleaning Maintenance Tools, Preventing Contamination	6-501.16 - Drying Mops	6-501.113 - Storing Maintenance Tools	6-501.114 - Maintaining Premises, Unnecessary Items and Litter	TOTAL NUMBER OF SECTION 34 PROVISIONS MARKED "YES":

SECTION 35 - COMPLETE SEPARATION FROM LIVING / SLEEPING QUARTERS; LAUNDRY

tem Food Code Corresp No. Section Code S Rule Rule 235 4-301.15 - Clothes Washers and Dryers	Jurisdiction's Corresponding Code Section, Rule, Etc. Is Me	Full List what is not covered. Additional sheets can be used for explanations and comments)	NO Compliance with FDA Food Code is not Met (Indicate the Situation)

		Jurisdiction's	YES	<u>Partial Compliance</u>	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	Full List what is not covered. Intent (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
236	4-401.11 - Equipment Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention				
237	237 4-803.15 - Use of Laundry Facilities				
238	6-202.11 - Private Homes and Living or Sleeping Quarters, Use Prohibition				
239	6-202.112 - Living or Sleeping Quarters, Separation				
TOT	TOTAL NUMBER OF SECTION 35 PROVISIONS MARKED "YES";	ISIONS MARKED "YE		(Section 35 has a total of 5 provisions)	

SECTION 36 – PRESENCE OF INSECTS / RODENTS MINIMIZED, OUTER OPENINGS PROTECTED, ANIMALS AS ALLOWED

		Jurisdiction's	YES	Partial Compliance	O
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	Full List what is not covered. Intent (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
240	240 2-403.11 - Handling Prohibition				
241	6-202.13 - Insect Control Device, Design and Installation				

		Jurisdiction's	YES	<u>Partial Compliance</u>	ON
ltem No.	Food Code Section	Corresponding Code Section, Rule, Etc.	Full Intent Is Met	List what is not covered. (Additional sheets can be used for explanations and comments)	Compliance with FDA Food Code is not Met (Indicate the Situation)
242	6-202.15 - Outer Openings Protected				
243	6-202.16 - Exterior Walls and Roofs, Protective Barrier				
244	6-501.111 - Controlling Pests				
245	6-501.112 - Removing Dead or Trapped Birds, Insects, Rodents, and other Pests				
246	6-501.115 - Prohibiting Animals				
TOT_{ℓ}	TOTAL NUMBER OF SECTION 36 PROVISIONS MARKED "YES":	VISIONS MARKED "YH	ES":	(Section 36 has a total of 7 provisions)	

STANDARD 1: REGULATORY FOUNDATION SELF-ASSESMENT WORKSHEET

PART II – 2017 Food Code: Good Retail Practices SELF-ASSESSMENT RESULTS

Section Number	Number of Provisions Met (Identified as "YES" on worksheet)	Section Description
12		Personnel
13		Food and Food Protection
14		Plant Cooking for Hot Holding
15		Protection from Contamination
16		Facilities / Methods to Control Product Temperature
17		Time/Temperature Control for Safety Food Properly Thawed
18		Dispensing Food / Utensils Properly Stored
19		Food Equipment
20		Food and Nonfood-Contact Surfaces
21		Warewashing Facilities; Designed, Constructed, Installed, Located, Operated, etc.
22		Wiping Cloths, Linens, Napkins, Gloves, Sponges: Properly Used, Stored
23		Storage, Handling of Clean Equipment, Utensils
24		Single-Service / Single Use Articles: Storage, Dispensing, Use, no Reuse
25		Safe Water Source, Hot and Cold Under Pressure, Adequate Quantity
26		Plumbing: Installed, Maintained
27		Cross Connection, Back Siphonage, Backflow Prevention
28		Number, Convenient, Accessible, Designed, Installed
29		Toilet Rooms Enclosed, Self-Closing Doors; Fixtures, Good Repair, Clean, etc.
30		Sewage and Waste Water Disposal
31		Garbage and Refuse Disposal - Containers or Receptacles: Covered, etc.
32		Physical Facility - Floors, Walls, Ceiling: Designed, Constructed, Maintained, etc.
33		Lighting, Ventilation, Dressing Rooms / Designated Areas Maintained
34		Premises Maintained Free of Litter, Unnecessary Articles
35		Complete Separation from Living / Sleeping Quarters; Laundry
36		Presence of Insects / Rodents Minimized, Outer Openings Protected, etc.,

	TOTAL	NUMBER	OF PRO	VISIONS	MET -	(Add	Column 2	2)
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Divide the total number of provisions met (last line of table) by 246 and multiple by 100 to determine the percentage of the Good Retail Practices provisions contained in your code regulation.

A percentage equal to or greater than 95% meets the Regulatory Foundation for Sections 12 thru 36.

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

STANDARD 1 - REGULATORY FOUNDATION

Part III – Compliance and Enforcement

STEP 1 – Review Compliance and Enforcement Administrative Provisions

Part III of the Standard 1: Self-Assessment Worksheet contains 12 Compliance and Enforcement areas within a regulatory retail food program. This worksheet is included at the end of these instructions. To meet this element of Standard 1, the jurisdiction's regulatory requirements must have a corresponding requirement for the *Food Code* sections listed in Items 1 through 11. For Item 12 pertaining to "Legal Remedies," a jurisdiction need only demonstrate that its regulatory foundation provides the authority to implement one of the legal remedies pertaining to criminal, injunctive, or civil penalties.

STEP 2 - Conduct the Self-Assessment for Part III

The self-assessor must compare the jurisdiction's code, regulation or ordinance against with the FDA Food Code Compliance and Enforcement provisions listed on the self-assessment worksheets. For each Food Code section:

- Record the corresponding jurisdiction requirement; and
- Document his/her determination:
 - If **Full Intent** of the *Food Code* section is met, place an "X" in the appropriate column.
 - If **Partial Intent** of the *Food Code* section is met, identify language that is not included with the jurisdiction's requirement. Indicate whether the language is addressed in another jurisdiction statute, ordinance, or regulatory requirement.
 - If **No corresponding regulation exists**, indicate "No Compliance" in the appropriate column and provide any information that may explain why it is not part of the jurisdiction's current requirements.

STEP 3 – Document the Self-Assessment Results for Part III

A summary table is provided at the end of Part III on the Standard 1: Self-Assessment Worksheet to document the results of the regulatory foundation self-assessment for the Compliance and Enforcement Food Code provisions. At the bottom of Part III on the Standard 1: Self-Assessment Worksheet, record the number of Compliance and Enforcement categories that are met. To meet the Standard 1, Part III criteria, the jurisdiction must have a "YES" response for all 12 of the listed Compliance and Enforcement categories.

Examples of documents that may be reviewed

- The jurisdiction's statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of its food establishments
- Version of the FDA Food Code that was used for the self-assessment
- Completed Standard 1: Self-Assessment Worksheet
 - * Part III Compliance and Enforcement
- If applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

Standard 1: Regulatory Foundation Self-Assessment Worksheet

Part III – 2013 Food Code: Compliance and Enforcement Summary

Partial ComplianceNOList what is not covered (Additional sheets can be used for explanations and comments)Compliance with the Food Code section is NOT Met (Indicate the Situation)						
YES Full (A is Met						
Jurisdiction's Corresponding Code Section, Rule, etc.						
Food Code Section	Hold orders, Embargo, and Destruction of Food 8-901.10 – Conditions Warranting Remedy	Hold orders, Embargo, and Destruction of Food 8-903.10 – Hold Order, Justifying Conditions and Removal of Food	Hold orders, Embargo, and Destruction of Food 8-903.30 – Hold Order, Contents	Permit / License Required; Right to Deny 8-301.11 – Prerequisite for Operation	Permit / License Required; Right to Deny 8-304.20 – Permits Not Transferable	Plan Review / Pre-operational inspections 8-201.11 – When Plans are Required
ltem No.	1a 8	1b 8 8 8	ار ت 8	2a 88	2b 88	<u>Q</u> ∞

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance <u>with</u> the <i>Food Code</i> section is NOT Met (Indicate the Situation)
4	Inspection Authority / Right to Access 8-402.20 – Refusal, Notification of Right to Access, and Final Request for Access				
5a	Information Authority; Restriction / Exclusion of Employees 8-501.10 – Obtaining Information: Personal History of Illness, Medical Examination, and Specimen Analysis				
5b					
5c	Information Authority; Restriction / Exclusion of Employees 8-501.30 – Restriction or Exclusion Order: Warning or Hearing Not Required, Information Required in Order				
9	Authority to Require HACCP Plans 8-201.13 – When a HACCP Plan is Required				
7a	Granting of Variances 8-103.10 – Modifications and Waivers				
76	Granting of Variances 8-103.11 – Documentation of Proposed Variance and Justification				
7c	Granting of Variances 8-103.12 – Conformance with Approved Procedures				

		Jurisdiction's	YES	Partial Compliance	ON
Item No.	Food Code Section	Corresponding Code Section, Rule, etc.	Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance <u>with</u> the <i>Food Code</i> section is NOT Met (Indicate the Situation)
7д	Jurisdiction Does NOT Issue Variances (Variances Prohibited) Variances Prohibited				
8a	Timely Correction of Critical Violations 8-405.11 – Timely Correction				
8b	Timely Correction of Critical Violations 8-405.20 – Verification and Documentation of Correction				
80	Timely Correction of Critical Violations 8-406.11 – Time Frame for Correction				
9a	Imminent Health Hazard (Summary of Suspension) 8-404.12 – Resumption of Operations				
q6	Imminent Health Hazard (Summary of Suspension) 8-904.10 – Conditions Warranting Action				
10a	License Suspension / Revocation 8-905.10 – Response to Notice of Hearing or Request for Hearing, Basis and Time Frame				

<u>ON</u>	Compliance <u>with</u> the <i>Food Code</i> section is NOT Met (Indicate the Situation)					
Partial Compliance	List what is not covered (Additional sheets can be used for explanations and comments)					
YES	Full Intent is Met					
Jurisdiction's	Corresponding Code Section, Rule, etc.					
	Food Code Section	License Suspension / Revocation 8-905.20 - Response to Notice of Hearing or Request for Hearing, Required Form and Contents	Institution of Proceedings 8-910.10 - Institution of Proceedings	Criminal Penalties 8-911.10 - Authorities, Methods, Fines and Sentences	12b 8-912.10 - Petitions for Injunction	Civil Penalties Provided 8-913.10 - Petitions, Penalties and Continuing Violations
	ltem No.	10b 8	11 8	12a 8	12b 8	12c 8

NOTE:

- 1. Meeting the Standard #1 criteria for the "Compliance and Enforcement" component requires a "Yes" for all *Food Code* Sections listed in Items 1 through 11.

 2. For Item 12 pertaining to legal remedies, the jurisdiction needs to demonstrate a corresponding regulatory requirement for only one of the sections pertaining to criminal, injunctive, or civil penalties.

Standard 1: Regulatory Foundation Self-Assessment Worksheet

Part III – Compliance and Enforcement Self-Assessment Results

Self-Assessor's General Comments													ith out of the 12 Compliance and Enforcement Categories
Standard Criteria is not Met													indicates conformance with
YES Standard Criteria is Met													cates conf
Compliance and Enforcement Program Description	Hold Orders, Embargo, and Destruction of Food	Permit / License Required; Right to Deny	Plan Review / Pre-operational Inspections	Inspection Authority / Right to Access	Information Authority; Restriction / Exclusion of Employees	Authority to Require HACCP Plans	Granting of Variances / Variances Prohibited	Timely Correction of Critical Violations	Imminent Health Hazard (Summary of Suspension)	License Suspension / Revocation	Highly Susceptible Populations	Legal Remedies	
Compliance and Enforcement Area	1 1	2 P	<u>Б</u>	4	5 0	9	7 (8 I) 6	10 I	11 F	12 I	Assessment of

out of the 12 Compliance and Enforcement Categories	(# Met)
ssessment of indicates conform	(Regulatory Agency)

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

STANDARD 1 - REGULATORY FOUNDATION

Part I – *Food Code* Interventions and Risk Factor Controls

STEP 1 – Confirm Completion of the Self-Assessment for the Program's Regulatory Foundation The jurisdiction's review of its food code against the *Food Code* should include documentation that a that a side-by-side comparison of its prevailing statutes, regulations, rules, and other pertinent requirements was completed. If a jurisdiction adopted the current published edition or one of the two most recent editions of the *Food Code* by reference, a side-by-side comparison of the language is not necessary. Adoption by reference meets the criteria of the Standard.

The jurisdiction's side-by-side comparison must include an assessment of the following items:

- 1. The major *Food Code* Public Health Intervention and Risk Factor control measures;
- 2. Good Retail Practices;
- 3. Compliance and Enforcement administrative requirements.

The side-by-side comparison should clearly identify the jurisdiction's corresponding requirements to the applicable *Food Code* section.

STEP 2 – Determine Food Code Interventions and Risk Factor Controls Sections to Review

The verification auditor must randomly select *Food Code* sections to review. The auditor should only review public health interventions and risk factor control categories that the jurisdiction reported as meeting on Part I of their *Standard 1: Self-Assessment Worksheet*. Part I of the jurisdiction's *Standard 1: Self-Assessment Worksheet* contains 93 *Food Code* sections pertaining to Public Health Interventions and Risk Factor Controls. Each of *these* Food Code sections has been assigned a number from 1 to 93.

For Part I, the verification auditor must randomly select 15 *Food Code* sections for the review. A list of random numbers can be obtained from the following web link: www.randomizer.org. Using the jurisdiction's *Standard 1: Self-Assessment Worksheet*, the verification auditor must identify the *Food Code* sections that correspond to the randomly selected numbers recorded on the verification audit worksheet. This worksheet is included at the end of these instructions.

The auditor should only review those *Food Code* sections that the jurisdiction indicates were met. If a Public Health Intervention or Risk Factor Control *Food Code* section is selected that the jurisdiction indicated was not met, the verification auditor should select a substitute *Food Code* section to review.

STEP 3 – Confirm Findings for *Food Code* Interventions and Risk Factor Controls

The auditor must review the randomly selected regulatory requirements. The auditor must compare the language in each of the selected jurisdiction code sections to verify that it is at least as stringent

as the corresponding *Food Code* section language. The language may be more stringent, but not less stringent. Record an "X" in the appropriate box on the *Standard 1: Verification Audit Worksheet* based on the determination.

Yes - Full Intent is Met

or

No - Full Intent is not Met

In instances where the verification auditor has determined that the jurisdiction's language does not meet the criterion, an explanation must be provided on the *Standard 1: Verification Audit Worksheet*. Record the explanation under the column "If No, Auditor is to specify why the criterion is not met."

STEP 4 – Document the Verification Audit Results for Part I

Part I of the *Standard 1: Self-Assessment Worksheet*, included at the end of these instructions, contains 11 public health interventions and risk factor controls:

- 1. Demonstration of Knowledge
- 2. Employee Health
- 3. Consumer Advisory
- 4. Approved Source
- 5. Time/Temperature
- 6. Protection from Contamination
- 7. Control of Hands as a Vehicle of Contamination
- 8. Good Hygienic Practices
- 9. Chemical
- 10. Conformance with Approved Procedures
- 11. Highly Susceptible Population

To meet any one of the 11 public health intervention and risk factor controls identified under the self-assessment process, the self-assessment must indicate that the jurisdiction's regulatory requirements address all *Food Code* sections listed for that area. For initial listing, the jurisdiction's regulatory foundation must contain at least 9 of the 11 public health interventions and risk factor controls. In order to fully meet the requirement of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third verification audit cycle.

If four or more of the 15 selected code sections reviewed during the audit process do not meet the stringency of language criteria, the Standard 1, Part I element fails to meet the criteria, and no further sampling is necessary. If one, two or three of the 15 selected code sections do not meet the stringency of the language criteria but the jurisdiction continues to meet the required number of interventions and risk factor controls to meet the Standard, then randomly select an additional 15 *Food Code* sections. No more than three total disagreements are acceptable in the thirty (30) Code sections drawn for comparison in order for the audit to confirm the Part I element of Standard 1 as met. In addition, at least 9 out of the 11 interventions and risk factor controls must still be met at the end of the first audit after the disagreements are taken into account, and the jurisdiction must meet 11 out of the 11 interventions and risk factor controls by the third regular audit in order to meet the Standard 1 criteria.

Examples of documents that may be reviewed:

- The jurisdiction's statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of its food establishments
- ➤ Version of the *FDA Food Code* that was used for the self-assessment
- ➤ Completed *Standard 1: Self-Assessment Worksheet*, Part I *Food Code* Interventions and Risk Factor Controls
- ➤ If applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

Standard 1: Regulatory Foundation Verification Audit Worksheet

Part I – Food Code Interventions and Risk Factor Controls

Part I - Interventions and Risk Factors

If no, auditor must specify why criterion is not met															
NO Full Intent is not Met															
YES Full Intent is Met															
Jurisdiction's Corresponding Code Section, Rule, etc.															
Corresponding Food Code Chapter from Part I Interventions and Risk Factors Self-Assessment Worksheet															
Randomly Selected Number															
Number of Sections Reviewed	1	2	8	4	5	9	7	8	6	10	11	12	13	14	15

NOTES

- 1. If there is Agreement that ALL 15 selected code sections meet the stringency of the language criteria in the FDA Food Code, proceed to Part II.
 - 2. If one, two or three of the 15 selected code sections do not meet the stringency of the language criteria in the FDA Food Code, then complete the Supplemental Part I Section of the Worksheet by randomly selecting another 15 Interventions and Risk Factor code sections to review.
- If four or more of the 15 selected code sections do not meet the stringency of the language criteria in the FDA Food Code, then the jurisdiction does not meet the Standard 1 criteria for Food Code Interventions and Risk Factors.

Standard 1: Regulatory Foundation Verification Audit Worksheet

Supplement to Part I - Food Code Interventions and Risk Factor Controls

Part I – Interventions and Risk Factors

If no, auditor must specify why criterion is not met															
NO Full Intent is not Met															
YES Full Intent is Met															
Jurisdiction's Corresponding Code Section, Rule, etc.															
Corresponding Food Code Chapter from Part I Interventions and Risk Factors Self-Assessment Worksheet															
Randomly Selected Number															
Number of Sections Reviewed	1	2	8	4	5	9	7	8	6	10	11	12	13	14	15

NOTES

1. If more than three of the 30 total selected code sections do not meet the stringency of the language criteria in the FDA Food Code, then the jurisdiction does not meet the Standard 1 criteria for Food Code Interventions and Risk Factors.

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

STANDARD 1 - REGULATORY FOUNDATION

Part II – Good Retail Practices

STEP 1 – Review the Self-Assessment conducted for Good Retail Practices

To meet the Standard 1 criteria for Good Retail Practices, a jurisdiction's regulations must have a corresponding requirement for 95 percent of the *Food Code* sections listed in Part II of the Self-Assessment Worksheet. The auditor must examine the jurisdiction's Standard 1: Self-Assessment Worksheet to verify that an assessment has been made for each of the 246 Good Retail Food Practices *Food Code* sections. The auditor must determine if the jurisdiction identified at least 234 *Food Code* sections (95%) that meet the criteria for stringency of language compared to the *Food Code*.

STEP 2 – Determine Good Retail Practices Sections to Review

The verification auditor must randomly select 13 *Food Code* sections as part of the Part II review process for Good Retail Practices. A list of random numbers can be obtained from the "Randomizer" web link: www.randomizer.org. Using the jurisdiction's self-assessment worksheet, the verification auditor must identify the *Food Code* sections that correspond to the randomly selected numbers recorded on the Part II - Good Retail Practices Verification Audit Worksheet. The worksheet is included at the end of the instructions.

The auditor should only review those *Food Code* sections that the jurisdiction indicated were met. If a Good Retail Practice *Food Code* section is selected that the jurisdiction indicated was not met, the verification auditor should select a substitute *Food Code* section to review.

STEP 3 – Confirm Findings for Good Retail Practices

The auditor must review the randomly selected *Food Code* sections. The auditor must compare the language in each of the selected jurisdiction food code sections to verify that it is at least as stringent as the corresponding *FDA Food Code* section language. The language may be more stringent, but not less stringent. Record an "X" in the appropriate box based on the determination.

Yes - Full Intent is Met

or

No - Full Intent is not Met

In instances where the verification auditor determined that the jurisdiction's language does not meet the criterion, an explanation must be provided on the Verification Audit Worksheet. The auditor must record the explanation under the column "If No, Auditor is to specify why the criterion is not met."

STEP 4 - Document the Verification Audit Results for Part I

To meet the Part II – Good Retail Practices element of Standard 1, the jurisdiction's regulatory requirements must have a corresponding requirement for 95 percent of the *FDA Food Code* sections listed in Part II of the *Standard 1: Self-Assessment Worksheet*.

If four or more of the 13 selected *Food Code* sections do not meet the stringency of language criteria, the Part II element fails to meet the criteria, and no further sampling is necessary. If one, two or three of the 13 selected food code sections do not meet the stringency of the language criteria, then the auditor must randomly select an additional 13 *Food Code* sections. No more than three total disagreements are acceptable in the twenty-six (26) food code sections drawn for comparison in order for the audit to confirm that the Part II element of Standard 1 was met.

Examples of documents that may be reviewed:

- The jurisdiction's statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that govern the operation of its food establishments
- ➤ Version of the *Food Code* that was used for the self-assessment
- Completed Standard 1: Self-Assessment Worksheet
 - * Part II Good Retail Practices
- ➤ If applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

Standard 1: Regulatory Foundation Verification Audit Worksheet

Part II - Good Retail Practices

If no, auditor must specify why criterion is not met													
NO Full Intent is not Met													
YES Full Intent is Met													
Jurisdiction's Corresponding Code Section, Rule, etc.													
Corresponding Food Code Chapter from Part II Good Retail Practices Self-Assessment Worksheet													
Randomly Selected Number													
Number of Sections Reviewed	1	2	3	4	5	9	7	8	6	10	11	12	13

NOTE

- 1. If there is agreement that ALL 13 selected code sections meet the stringency of the language criteria in the FDA Food Code, proceed to Part III.
- 2. If one, two or three of the 13 selected code sections do not meet the stringency of the language criteria in the FDA Food Code, then complete the Supplemental Part II section of the worksheet by randomly selecting another 13 Good Retail Food Practices code sections to review.
- 3. If four or more of the 13 selected code sections do not meet the stringency of the language criteria in the Food Code, then the jurisdiction does not meet the Standard 1 criteria for Part II Good Retail Food Practices.

Standard 1: Regulatory Foundation Verification Audit Worksheet

Supplement to Part II - Good Retail Practices

If no, auditor must specify why criterion is not met													
NO Full Intent is not Met													
YES Full Intent is Met													
Jurisdiction's Corresponding Code Section, Rule, etc.													
Corresponding Food Code Chapter from Part I Interventions and Risk Factors Self-Assessment Worksheet													
Randomly Selected Number													
Number of Sections Reviewed	_	2	3	4	5	9	7	8	6	10	11	12	13

NOTES

1. If more than three of the 26 total selected code sections do not meet the stringency of the language criteria in the Food Code, then the jurisdiction does not meet the Standard 1 criteria for Good Retail Practices.

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

STANDARD 1 - REGULATORY FOUNDATION

Part III - Compliance and Enforcement

STEP 1 – Review the Self-Assessment conducted for Compliance and Enforcement Food Code provisions

The jurisdiction's self-assessment of their Compliance and Enforcement provisions must indicate that it has a corresponding regulatory requirement for the *Food Code* sections listed in Items 1 through 12 on Part III of the *Standard 1: Self-Assessment Worksheet*. For Items 1 through 11, a jurisdiction must demonstrate its regulations have a corresponding provision or language for all the *Food Code* sections listed. For Item 12, a jurisdiction need only demonstrate that its regulatory foundation provides the authority to implement one of the following three *Food Code* legal remedies pertaining to criminal, injunctive, or civil penalties:

8-911.10 – Authorities, Methods, Fines and Sentences

8-912.10 – Petitions for Injunction

8-913.10 – Petitions, Penalties and Continuing Violations

STEP 2 – Determine Food Code Compliance and Enforcement Sections to Review

The verification auditor must randomly select five Compliance and Enforcement areas for the review process. A list of random numbers can be obtained from the "Randomizer" web link: www.randomizer. org. Using Part III of the jurisdiction's *Standard 1: Self-Assessment Worksheet*, the verification auditor will identify the *Food Code* sections that correspond to the randomly selected number recorded on Part III of the *Standard 1: Verification Audit Worksheet*. This worksheet is included at the end of these instructions.

When conducting a verification audit, the auditor will randomly select 5 of the 11 compliance and enforcement areas to review. For each selected area, the jurisdiction must demonstrate its regulations have a corresponding provision(s) or language for each *Food Code* section listed under that area.

In the case of Item 12, pertaining to "Legal Remedies", three *Food Code* sections comprise this Compliance and Enforcement area. A jurisdiction must demonstrate a corresponding regulatory requirement for one one of the *Food Code* sections pertaining to criminal, injunctive, or civil penalties.

STEP 3 – Confirm Findings for *Food Code* Compliance and Enforcement Sections

The auditor must review the randomly selected *Food Code* sections. The auditor must compare the language in each of the selected jurisdiction code sections to verify that it is at least as stringent as the corresponding *Food Code* section language. The language may be more stringent, but not less stringent. Record an "X" in the appropriate box based on the determination.

Yes - Full Intent is Met

or

No - Full Intent is not Met

In instances where the verification auditor determined that the jurisdiction's language does not meet the criterion, an explanation must be provided on the Verification Audit Worksheet. The auditor must record the explanation under the column "If No, Auditor is to specify why the criterion is not met."

Examples of documents that may be reviewed:

- The jurisdiction's statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that govern the operation of its food establishments
- ➤ Version of the *FDA Food Code* that was used for the self-assessment
- Completed Standard 1: Self-Assessment Worksheet, Part III Compliance and Enforcement
- ➤ If applicable, documents discussing or comparing code provisions excepted if adoption was made by reference with exceptions.

Summary for the Standard 1 – Regulatory Foundation Verification Audit

At the conclusion of the verification audit process, the jurisdiction's Verification Audit Worksheet must indicate that it meets the criteria in all three Parts of the Standard in order to fully meet the Standard I requirement.

Part 1: Control of Foodborne Illness Public Health Interventions and Risk Factor Controls

Part II: Good Retail Practices

Part III: Compliance and Enforcement Administrative Provisions

Standard 1: Regulatory Foundation Verification Audit Worksheet

Part III – Compliance and Enforcement

If no, auditor must specify why criterion is not met										
NO Full Intent is not Met										
YES Full Intent is Met										
Jurisdiction's Corresponding Code Section, Rule, etc.										
Corresponding Food Code Chapter from Part III Compliance and Enforcement Self-Assessment Worksheet										
Randomly Selected Number										
Number of Sections Reviewed	-	1	2		٣		4		5	

NOTE

- 1. Some Compliance and Enforcement Areas contain multiple Food Code Sections. List all the pertinent Food Code Sections listed on the Self-Assessment Worksheet for each of the Compliance and Enforcement areas that are randomly selected.
- legal remedies, the jurisdiction needs to demonstrate a corresponding regulatory requirement for only one of the sections pertaining to criminal, injunctive, or civil penalties. If there is agreement that ALL code sections within the 5 selected "Compliance and Enforcement" components meet the stringency of the language criteria in the FDA Food Code, the Meeting the Standard 1 criteria for the "Compliance and Enforcement" component requires a "Yes" for all Food Code sections listed in Items 1 through 11. For Item 12 pertaining to
- Standard 1 criteria is met for Part III.
 - If one or more of the code sections within the 5 selected "Compliance and Enforcement" components do not meet the stringency of the language criteria in the FDA Food Code, the the jurisdiction does not meet the Standard 1 criteria for Part III. 4.

STANDARD 2 TRAINED REGULATORY STAFF

Table of Contents

REQUIREMENT SUMMARY	2
DESCRIPTION OF REQUIREMENT.	
Step 1: Pre-Inspection Curriculum	
Step 2: Initial Field Training and Experience	
Step 3: Independent Inspections and Completion of ALL Curriculum Elements	
Step 4: Food Safety Inspection Officer – Field Standardization	
Step 5: Continuing Education and Training	
OUTCOME	
DOCUMENTATION	9

STANDARD 2 TRAINED REGULATORY STAFF

This Standard applies to the essential elements of a training program for regulatory staff.

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1

Completion of curriculum courses designated as "Pre" in Appendix B-1 prior to conducting and independent routine inspections.

STEP 2

Completion of the following:

- A minimum of 25 joint field training inspections (or a sufficient number of joint inspections determined by the trainer and verified through written documentation that the FSIO has demonstrated all performance elements and competencies to conduct independent inspections of retail food establishments); and
- Successful completion of the jurisdiction's FSIO Field Training Plan similar to the process outlined in *Appendix B-2: Conference for Food Protection (CFP) Field Training Manual.*

STEP 3

Completion of the following:

- A minimum of 25 independent inspections; and
- Remaining course curriculum (designated as "post" courses) outlined in *Appendix B-1:* Curriculum for Retail Food Safety Inspection Officers.

STEP 4

Completion of a standardization process similar to the FDA standardization procedures.

STEP 5

Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 18 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months after the initial 18 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a "Pre" in Appendix B-1, for the following curriculum areas:

- 1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
- 2. Public Health Principles;
- 3. Food Microbiology; and
- 4. Communication Skills.

There are two options for demonstrating successful completion of the pre-inspection curriculum.

OPTION 1: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- FDA ORA U pre-requisite courses identified as "Pre" in Appendix B-1; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances.

Note: The estimated contact time for completion of the FDA ORA U pre-requisite ("Pre") courses is 42 hours.

OPTION 2: Completion of the pre-inspection curriculum may be demonstrated by successful completion of the following:

- Successful completion of courses deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the FDA ORA U prerequisite (Pre") courses; and
- Training on the jurisdiction's prevailing statutes, regulations, and/or ordinances; and
- Successful passing of one of the four written examination options (described later in this Standard) for determining if a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at: http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm121831.htm

Note: While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:

- Logs/records that are completed based on sign-in sheets; or
- Information validated from the certificate at the time-of-issuance; or
- A college transcript with a passing grade or other indication of successful completion of the course; or
- Automated attendance records, such as those currently kept by some professional associations and state agencies, or

• Other accurate verification of actual attendance.

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORA U courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

- 1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or
- 2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or
- 3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or
- 4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

Note: Written examinations are part of a training process, not a standardization/certification process. The examinations listed are not to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements (Steps 1-3) of this Standard. The 25 joint field inspections are to be comprised of both "demonstration" (trainer led) and "training" (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, a lower minimum number of joint field training inspections can be established for that FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan in Appendix B-2, to support the exception.

Note: The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."

Demonstration inspections are those in which the jurisdiction's trainer takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead and their inspection performance is assessed and critiqued by the trainer. The jurisdiction's trainer is

responsible for determining the appropriate combination of demonstration and training inspections based on the candidate's food safety knowledge and performance during the joint field inspections.

The joint field inspections must be conducted using a field training process and forms similar to ones presented in the *CFP Field Training Manual* included as Appendix B-2. The *CFP Field Training Manual* consists of a training plan and log, trainer's worksheets, and procedures that may be incorporated into any jurisdiction's retail food training program. It is a national model upon which jurisdictions can design basic field training and provides a method for FSIOs to demonstrate competencies needed to conduct independent inspections of retail food, restaurant and institutional foodservice establishments.

Jurisdictions are not required to use the forms or worksheets provided in the *CFP Field Training Manual*. Equivalent forms or training processes can be developed. To meet the intent of the Standard, documentation must be maintained that confirms FSIOs are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments.

Note: The CFP Field Training Manual is designed as a training approach providing a structure for continuous feedback between the FSIO and trainer on specific knowledge, skills, and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.

- The CFP Field Training Manual is <u>NOT</u> intended to be used for certification or licensure purposes.
- The CFP Field Training Manual is NOT intended to be used by regulatory jurisdictions for administrative purposes such as job classifications, promotions, or disciplinary actions.

FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2013 *FDA Food Code*). The jurisdiction's trainer/food program manager can determine if the FSIO is ready to conduct independent inspections of risk category 1 establishments (as defined in Appendix B-3) at any time during the training process.

Note: The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can in lieu of the 25 joint field inspections:

- Include a signed statement or affidavit in the employee's training file explaining the background or experience that justifies a waiver of this requirement; and
- The supervisor/training officer must observe experienced FSIOs conduct inspections to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.

Step 3: Independent Inspections and Completion of ALL Curriculum Elements

Within 18 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following six curricula areas, must be completed within this 18 month time frame.

- 1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the prerequisite curriculum outlined in Step 1);
- 2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
- 3. Communication skills (Step 1);
- 4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
- 5. Epidemiology;
- 6. Hazard Analysis Critical Control Points (HACCP);
- 7. Allergen Management
- 8. Emergency Management

All courses for each of the curriculum areas must be successfully completed within 18 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

Note: The estimated contact time for completion of the FDA ORA U "post" courses is 26 hours. The term "post" refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation "Pre" associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses listed under each curriculum area <u>OR</u> by completing courses, deemed by the regulatory jurisdiction's food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA website: http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm121831.htm

Step 4: Food Safety Inspection Officer – Field Standardization

Within 18 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." The jurisdiction's "training standard" must have met all the requirements for conducting field standardizations as presented in the definition section of these Standards. The standardization procedures shall determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

- 1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
- 2. Good Retail Practices:
- 3. Application of HACCP;
- 4. Inspection equipment; and
- 5. Communication.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Note: The field standardization and continuing standardization (re-standardization) criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol <u>must</u> include the five performance areas outlined above in Step 4.

It is highly beneficial to use the FDA Food Code, standardization forms and procedures even when a jurisdiction has adopted modifications to the Food Code. Usually regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA's standardization procedures are based on a minimum of 8 inspections. However to meet Standard 2, a minimum of 4 standardization inspections must be conducted.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel versed in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate

consistent evaluation of all candidates.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors, and communicates vital information about the inspection in a way that can be received, understood and acted upon by retail food management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard 2 criteria within the 18 month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5: Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (18 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer.

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

- 1. Attendance at FDA Regional seminars / technical conferences;
- 2. Professional symposiums / college courses;
- 3. Food-related training provided by government agencies (e.g., USDA, State, local);
- 4. Food safety related conferences and workshops; and
- 5. Distance learning opportunities that pertain to food safety, such as:
 - Web based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
 - Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

- 6. Delivering presentations at professional conferences;
- 7. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
- 8. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period¹.

Note: Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.

A maximum of four (4) contact hours may be accrued for:

9. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read
 including completion of self-assessment quizzes that accompany journal articles, written
 summaries of key points/findings presented in technical publications, and/or written book
 reports.

Note: The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, maintains the training records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses.

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);

- 2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
- 3. Certificates or other documentation of successful completion of a field training process similar to that presented in Appendix B-2. **NOTE:** The CFP Field Training Manual is available for the Conference for Food Protection web site: http://www.foodprotect.org/ and is located under the icon titled "Conference Developed Guides and Documents."
- 4. Certificates or other records showing proof of satisfactory standardization (Step 4);
- 5. Contact hour certificates or other records for continuing education (Step 5);
- 6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successful completed the training and education steps outlined in this Standard.
- 7. Date of hire records or assignment to the retail food program; and
- 8. Summary record of employees' compliance with the Standard.

The Standard 2: Program Self-Assessment and Verification Audit Form is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

STANDARD 2 – TRAINED REGULATORY STAFF

Program Self-Assessment & Verification Audit Form

The *Standard 2: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 2. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 2 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self Assessment

Jurisdictions conducting a self-assessment of the "Trained Regulatory Staff" component of their retail food protection program must indicate on the form if each of the Standard 2criterion is met. These responses are recorded under the column, "Jurisdiction's Self-Assessment."

Jurisdictions are not obligated to use the form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 2 criteria listed are available for review.

The self-assessor will review each Standard 2 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 2: Program Self-Assessment and Verification Audit Form*.

If a review of the jurisdiction's source documents does not confirm that the Standard 2 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction's Self-Assessment" column of the *Standard 2: Program Self-Assessment and Verification Audit Form*. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 2: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed Program Self-Assessment and Verification Audit Form and any documents used to support and demonstrate that the Standard 2 criteria have been met.

Once all the Standard 2 criteria have been reviewed and staff training records documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 2: Program Self-Assessment and Verification Audit Form.* The self-assessor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 2 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 2 criteria.

Documenting the Findings from the Verification Audit

The jurisdiction requesting the verification audit must provide their completed *Standard 2: Program Self-Assessment and Verification Audit Form* to the auditor for review. Auditors must indicate on the *Standard 2: Program Self-Assessment and Verification Audit Form* if each of the criterion were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings.

To meet the Standard criteria, the jurisdiction must have demonstrated that 90% of their staff assigned responsibilities for retail food and/or foodservice inspections successfully completed the training curriculum, field training, field standardization, and continuing education requirements.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any Standard 2 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 2: Program Self-Assessment and Verification Audit Form.* The auditor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 2 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 2 criteria if the auditor does not confirm the self-assessment findings.

Standard 2: Trained Regulatory Staff Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the	icted the Self-Assessment:	
Self-Assessor's Title:		
Jurisdiction Name:		
Jurisdiction Address:		
Phone:	FAX:	E-mail:
Date the Standard 2 Self-Assessment was Completed:	as Completed:	
Self-Assessment indicates that the Juri	Self-Assessment indicates that the Jurisdiction MEETS the Standard 2 criteria: YES 🗌 NO [
I affirm that the information represente	I affirm that the information represented in the Self-Assessment of Standard 2 is true and correct	
Signature of the Self-Assessor:		
	VERIFICATION AUDIT SUMMARY	Z.
Printed Name of the Person who conducted the	ıcted the Verification Audit:	
Verification Auditor's Title:		
Auditor's Jurisdiction Name:		
Auditor's Jurisdiction Address:		
Phone:	FAX:	E-mail:
Date the Verification Audit of Standard 2 was Completed:	d 2 was Completed:	
Verification Audit indicates that the Ju	Verification Audit indicates that the Jurisdiction MEETS the Standard 2 criteria: YES 🔲 💮	NO
I affirm that the information represente	I affirm that the information represented in the Verification Audit of Standard 2 is true and correct	
Signature of the Verification Auditor:		

Standard 2: Trained Regulatory Staff Program Self-Assessment and Verification Audit Form

Jurisdiction Name:

	Juris	diction	Jurisdiction's Self-Assessment		Aud	Auditor's Verification
Criteria	YES	NO	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
1. Employee Training Records						
a) The jurisdiction maintains a written training record for each employee that includes the date or hire or assignment to the agency's retail food protection program.						
b) The jurisdiction written training record provides documentation that each employee has completed the Standard 2 prerequisite ("Pre") training curriculum PRIOR to conducting independent retail food or foodservice inspections.						
2. Initial Field Training						
a) The jurisdiction maintains a written training record that provides confirmation that each employee completed a minimum of 25 joint field training inspections of retail food and/or foodservice establishments (if less than 25 joint field training inspections are performed, written documentation on file that FSIO has successfully demonstrated all required inspection competencies) PRIOR to conducting retail food or foodservice inspections.						

	Juris	diction	Jurisdiction's Self-Assessment		Auc	Auditor's Verification
	YES	NO	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
b) The jurisdiction maintains a written training record that provides confirmation that each employee successfully completed a field training process similar to that contained in the CFP Field Training Manual provided in Appendix B-2, Standard 2, PRIOR to conducting independent inspections of retail food and/or foodservice establishments.						
3. Independent Inspections / Completion of A	ALL Curr	iculun	ALL Curriculum Requirements			
a) The jurisdiction maintains a written training record that provides confirmation that each employee completed a minimum of 25 independent retail food and/or foodservice inspections PRIOR to field standardization.						
b) The jurisdiction's written training record provides documentation that each employee has completed ALL aspects of the Standard #2 training curriculum ("Pre") and ("Post") courses prior to field standardization.						
4. Field Standardization						
a) The jurisdiction maintains a written training record that provides documentation that each employee successfully completed a Standardization process similar to the FDA Procedures for Standardization within 18 months of hire or assignment to the retail food protection program.						

	Juris	sdiction	Jurisdiction's Self-Assessment		Auc	Auditor's Verification
Criteria	YES	NO	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
a) The jurisdiction maintains a written training record that provides documentation that each standardized employee has maintained their standardization by performing a minimum of 4 joint inspections with a "training standard" every 3 years.						
5. Continuing Education and Training						
a) The jurisdiction maintains a written training record that provides document that each employee conducting retail food and/or foodservice inspections has accumulated 20 hours of continuing education every 36 months after the initial training (18) months is completed.						

Standard 2: Trained Regulatory Staff Program Self-Assessment and Verification Audit Form

GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT					
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INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

STANDARD 2 – TRAINED REGULATORY STAFF

STEP 1 – Document Employee Training Records

The jurisdiction should document and retain a training record for each employee. The training record must include the date of hire or assignment to the retail food program. The *Standard 2: Self-Assessment Worksheet* may be used by the jurisdiction as a training record. The worksheet is included at the end of these instructions. In lieu of the Standard 2 Self-Assessment Worksheet, other manual forms or automated records may be used by the jurisdiction to retain training records related to the self-assessment as long as the information required in the Standard 2 criteria is documented in some manner.

STEP 2 – Document Employees Completion of Pre-Requisite "Pre" Training Curriculum

Standard 2 requires the FSIO to complete the pre-requisite coursework listed in Appendix B-1 prior to conducting independent inspections of retail food establishments. The program areas covered in the pre-requisite coursework include training on prevailing statutes, regulations, ordinances; public health principles; communication skills, and microbiology. The date each employee fully completed the Standard 2 pre-requisite curriculum must be ecorded on the Standard 2 Self-Assessment Worksheet.

STEP 3 – Document Employees Completion of Initial Field Training

Standard 2 requires a minimum of 25 joint field training inspections to be conducted with a trainer who has successfully completed all the Standard 2 training elements (Steps 1 – 3). The joint field training inspections must be completed prior to conducting independent inspections of retail food establishments. The joint field inspections must be conducted using a field training process, established by the jurisdiction, similar to the one presented in the *CFP Field Training Manual*. The *CFP Field Training Manual* is included as Appendix B-2. The date each employee completed the Standard 2 field training requirement must be recorded on the Standard 2 Self-Assessment Worksheet.

STEP 4 – Document Employees Completion of Independent Inspections / All Curriculum Requirements

Standard 2 requires a minimum of 25 independent retail food establishment inspections to be conducted by employees in various establishment types. These independent inspections must be completed prior to field standardization. In addition, all "Post" curriculum courses identified in Appendix B-1 must be successfully completed for FSIOs to be eligible for the Field Standardization Assessment. The date each employee completed 25 independent inspections AND the Standard 2 "Post" curriculum training requirement must be recorded on the Standard 2 Self-Assessment Worksheet.

STEP 5 – Document Employees Completion of Field Standardization

Within 18 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections

with a "training standard" using a process similar to the "FDA Standardization Procedures." The procedure used for standardization does not have to be identical to the *FDA Procedures for Standardization of Retail Food Inspection/Training Officers*. However, it must include a determination of the the following:

- 1. The inspector's ability to apply the knowledge and skills obtained from the training curriculum; and
- 2. The inspector's ability in the following five performance areas:
 - Conducting risk-based inspections (i.e. primary focus on the risk factors that contribute to foodborne illness).
 - Recognizing good retail practice requirements,
 - > Applying HACCP principles to the inspection process,
 - Demonstrating knowledge and use of essential inspection equipment, and
 - > Communicating in an effective manner.

NOTE: For new hires or employees newly assigned to the retail food protection program, the date recorded in the "Completion of Field Standardization" column must be within 18 months of the date recorded in the "Date of Hire or Assignment to the Retail Food Protection Program."

For experienced employees, however, the completion date for standardization may be in excess of 18 months of their date of hire. This is because the jurisdiction may not have been standardizing their retail food protection program staff prior to enrollment in the Program Standards. Keep in mind that the Standard 2 language was written to establish a training and standardization process for new employees. As long as the experienced FSIO has successfully completed standardization at the time of the self-assessment the Standard 2criteria is met.

The date each employee successfully completes field standardization must be recorded on the *Standard 2: Self-Assessment Worksheet*.

STEP 6 – Document Employee Continuing Education and Training

Each employee must accumulate 20 contact hours of continuing education training every 36 months. For employees newly hired or newly reassigned to the retail food program, the 36 month period does not begin until after the first 18 months of training. For existing employees, the 36 month period does not begin until a jurisdiction enrolls as a participant in the Standards. The date each employee accumulated 20 contact hours of continuing education within the 36 months of their most current standardization/restandardization cycle must be recorded on the Standard 2 Self-Assessment Worksheet.

STEP 7 – Document the Self-Assessment Results

The self-assessor must document if each of the listed employees met the Standard 2 criteria. The self-assessors response should be recorded in the Self-Assessment Worksheet under the column "Meets the Standard 2 Criteria YES or NO." A jurisdiction meets the Standard 2 criteria if ninety percent (90%) of the retail food program inspection staff fulfilled all the training and standardization requirements within the specified time frames.

Standard 2: Trained Regulatory Staff Training Record for Each Employee **Self-Assessment Worksheet**

	Meets the Standard 2 Criteria YES or No												
	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)												
	Completion of Field Standardization* (within 18 months of hire or assignment to the Retail Food Program)												
equired)	Completion of a Minimum 25 Independent Inspections AND "Post" Curriculum Courses* (within 18 months of hire or assignment to the Retail Food Program												
(* indicates completion date required)	Completion of a Minimum of 25 Joint Field Training Inspections* AND Successful completion of a field training process similar to the CFP Field Training Manual in Appendix B-2 Completion of a Minimum Animum Jament Inspections (within 18 months of hire resistance or assignment to the Retail Food Program												
(* ji	Completion of Training Pre-requisite ("Pre") Curriculum* (Prior to conducting independent inspections)												
	Date of Hire or Assignment to the Retail Food Program												
	Employee Name												
	No.	1	2	3	4	2	9	7	8	6	10	11	12

NOTE:

- 1. Ninety percent (90%) of the staff must meet each training element for the Jurisdiction to meet Standard 2 Trained Regulatory Staff.
- 2. Based on the documentation from this worksheet, record your findings for each of the items on the Standard 2: Program Self-Assessment and Verification Audit Form.

ADDITIONAL STANDARD 2 SELF-ASSESSMENT WORKSHEET (if needed)

Standard 2: Trained Regulatory Staff Training Record for Each Employee Self-Assessment Worksheet

NOTE:

- 1. Ninety percent (90%) of the staff must meet each training element for the Jurisdiction to meet Standard 2 Trained Regulatory Staff.

 2. Based on the documentation from this worksheet, record your findings for each of the items on the Standard 2: Program Self-Assessment and
 - Verification Audit Form.

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

STANDARD 2 – TRAINED REGULATORY STAFF

STEP 1 – Verify Employees Training Records

The jurisdiction should document and retain a training record for each employee. The training record must include the date of hire or assignment to the retail food program. The Standard 2 Self-Assessment Worksheet may be used by the jurisdiction as a training record. The worksheet is included at the end of these instructions. In lieu of the Standard 2 Self-Assessment Worksheet, other manual forms or automated records may be used by the jurisdiction to retain training records related to the self-assessment as long as the information required in the Standard 2 criteria is documented in some manner.

STEP 2 – Verify Jurisdiction's Worksheet Percentage Calculation

Review the jurisdiction's Standard 2 Self-Assessment Worksheet, or equivalent documentation, to determine if the results of the jurisdiction's self-assessment indicate that ninety percent (90%) of the retail food program staff successfully completed all the Standard 2 training and standardization elements within the required time frames. If audit calculations result in a percentage that is less than 90%, the auditor can conclude that the jurisdiction does not meet the Standard 2 criteria. If this conclusion is reached, the audit process for Standard 2 is completed. There is no need to randomly select and review individual employee training records.

STEP 3 – Determine the Number of Employee Training Records to Review

If the jurisdiction used the Standard 2: Self-Assessment Worksheet, the employees will be listed in numerical order. The verification auditor must use a random selection method to determine which employees' training records will be reviewed. Employees should be eliminated from the random selection process if they meet one of the following criteria:

- 1. The employee has been employed or worked in the retail food program for less than 18 months; or
- 2. The employee is no longer assigned to the retail food program; or
- 3. The self-assessor indicated on the Self-Assessment Worksheet that the employee did not meet each Standard 2 element.

The number of training records that must be randomly selected is based on the number of employees conducting retail food establishment inspections. Use the chart below to determine the number of employee training records to review.

Number of Employees	Number of Files to Select
5 or less	All
20 or less	5
21 or more	25 percent

STEP 4 – Obtain Random Numbers

A list of random numbers can be obtained from the following web site: www.randomizer.org
Record the random numbers generated from the web site (or from an alternate random number selection process) on the Standard 2 Verification Audit Worksheet. The worksheet is included at the end of these instructions.

STEP 5 – Select Employee Training Records to Review

Using the jurisdiction's Standard 2 Self-Assessment Worksheet, or equivalent documentation, the verification auditor must identify the employee training records that correspond to the randomly selected numbers recorded on the Standard 2 Verification Audit Worksheet. Record the employee's name adjacent to the corresponding random number on the Standard 2 Verification Audit Worksheet.

Only those employees' training records that the jurisdiction reports as meeting all the Standard 2 training and standardization elements are to be reviewed. If an employee is randomly selected but the jurisdiction indicated that employee does not meet the Standard 2 criteria, the verification auditor should randomly select a substitute employee training record to review.

STEP 6 – Verify Documentation of the Completion of the Standard Training Criteria

The verification auditor must review the training file for each of the randomly selected employees to confirm completion of the following items:

- coursework related to the Standard 2 Pre-requisite ("Pre") curriculum;
- ➤ a minimum of 25 joint field training inspection, including documentation that confirms Food Safety Inspection Officers (FSIOs) are trained on, and have demonstrated, the performance element competencies needed to conduct independent inspections of retail food and/or foodservice establishments;
- ➤ a minimum of 25 independent inspections and ALL the Standard 2 ("Post") curriculum requirements;
- Field standardization within 18 months of hire or re-standardization every three years after initial standardization, and
- ➤ 20 hours of food safety related continuing education every three years

NOTE: For new hires or employees newly assigned to the retail food protection program, the date recorded in the "Completion of Field Standardization" column must be within 18 months of the date recorded in the "Date of Hire or Assignment to the Retail Food Protection Program."

For experienced employees, however, the completion date for standardization may be in excess of 18 months of their date of hire. This is because the jurisdiction may not have been standardizing their retail food protection program staff prior to enrollment in the Program Standards. Keep in mind that the Standard 2 language was written to establish a training and standardization process for new employees. As long as the experienced FSIO has successfully completed standardization at the time of the self-assessment the Standard 2 criteria is met.

STEP 7 – Making a Determination Based on the Results of the Audit

For each employee training file reviewed, the verification auditor must mark the appropriate box on the Standard 2 Verification Audit Worksheet. The auditor must indicate "YES –Standard 2 criteria are met" or "NO" – Standard 2 criteria is not met." If the verification auditor determines an employee training record did not meet the Standard 2 criteria, an explanation must be provided noting any deficiencies. A jurisdiction meets the Standard 2 criteria if ninety percent (90%) of the retail food program inspection staff fulfilled all the training and standardization requirements within the specified time frames.

Standard 2: Trained Regulatory Staff Verification Audit Worksheet

If NO, auditor is to specify why criterion is not met															
No Met															
Yes Standard 2 Criteria are Met															
Employee Name															
Randomly Selected Number															
No.	-	7	ĸ	4	2	9	7	8	6	10	11	12	13	14	15

NOTE:

- 1. All randomly selected employee training records must contain documentation that the Standard 2 training and standardization elements have been successfully completed.
 - 2. Based on the documentation from this worksheet, record your determination for each of the items on the jurisdiction's Standard 2: Program Self-Assessment and Verification Audit Form.

ADDITIONAL STANDARD 2 VERIFICATION AUDIT WORKSHEET (if needed)

Standard 2: Trained Regulatory Staff Verification Audit Worksheet

If NO, auditor is to specify why criterion is not met															
No Standard 2 Criteria are Not Met															
Yes Standard 2 Criteria are Met															
Employee Name															
Randomly Selected Number	1	2	3	4	5	9	7	8	6	10	11	12	13	14	15

NOTE:

- 1. All randomly selected employee training records must contain documentation that the Standard 2 training and standardization elements have been successfully completed.
 - 2. Based on the documentation from this worksheet, record your determination for each of the items on the jurisdiction's Standard 2: Program Self-Assessment and Verification Audit Form.

Program Standard #2

APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officers

For state, local & tribal regulators to register on-line for free access to web courses, go to: http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm120925.htm

Pre-requisite ("Pre") curriculum courses

(to be completed during the 25 joint inspection period AND prior to conducting any independent inspections)

PUBLIC HEALTH PRINCIPLES

1. Public Health Principles (90) FDA36

MICROBIOLOGY

Food Microbiological Control (series):

- 1. Overview of Microbiology (60) MIC01
- 2. Gram-Negative Rods (60) MIC02
- 3. Gram-Positive Rods & Cocci (90) MIC03
- 4. Foodborne Viruses (60) MIC04
- 5. Foodborne Parasites (90) MIC05
- 6. Mid-Series Exam (30) MIC16
- 7. Controlling Growth Factors (90) MIC06
- 8. Control by Refrigeration & Freezing (60) MIC07
- 9. Control by Thermal Processing (90) MIC08
- 10. Control by Pasteurization (90) MIC09
- 11. Aseptic Sampling (90) MIC13
- 12. Cleaning & Sanitizing (90) MIC15

PREVAILING STATUTES, REGULATIONS, ORDINANCES

- 1. Basic Food Law for State Regulators (60) FDA35
- 2. Basics of Inspection: Beginning an Inspection (90) FDA38
- 3. Basics of Inspection: Issues & Observations (90) FDA39
- 4. An Introduction to Food Security Awareness (60) FD251 (ORA U internet site)
- 5. FDA Food Code

NOTE: Specific state/local laws & regulations to be addressed by each jurisdiction

COMMUNICATION SKILLS

1. Communication Skills for Regulators (Course can be accessed through (http://www.accessdata.fda.gov/ORAU/CommRegulators/)

Curriculum ("Post") courses

(to be completed any time prior to Food Code Standardization AND within 18 months of hire or assignment to the regulatory retail food program)

MICROBIOLOGY

Food Microbiological Control (series):

- 1. Control by Retorting (90) MIC10
- 2. Technology-Based Food Processes (120) MIC11
- 3. Natural Toxins (90) MIC12

HACCP

Basics of HACCP (series):

- 1. Overview of HACCP (60) FDA16
- 2. Prerequisite Programs & Preliminary Steps (60) FDA17
- 3. The Principles (60) FDA18

ALLERGENMANAGEMENT

1. Food Allergens (60) FD252 (Course can be accessed through http://class.ucanr.edu/)

EPIDEMIOLOGY

Foodborne Illness Investigations (series):

1. Collecting Surveillance Data (90) FI01

Voluntary National Retail Food Regulatory Program Standards – January 2017

- 2. Beginning the Investigation (90) FI02
- 3. Expanding the Investigation (90) FI03
- 4. Conducting a Food Hazard Review (90) FI04
- 5. Epidemiological Statistics (90) FI05
- 6. Final Report (30) FI06

EMERGENCY MANAGEMENT

FEMA – Incident Command System and National Incident Management System: Course available from FEMA web link. – http://training.fema.gov/IS/NIMS.asp

- 1. IS-100.a, Introduction to Incident Command System, (180) ICS-100 or IS-100 for FDA
- 2. IS-200.a, ICS for Single Resources and Initial Action Incidents, (180) ICS-200
- 3. IS-700.a, NIMS an Introduction, (180) ICS 700

() Average time in minutes required to take the course, 60 minutes equals .1 CEU, 90-120 minutes equals .2 CEUs Estimated total hours for "Pre" courses are 42 hours.

Estimated total hours for "Post" courses are 26 hours.

Estimated total hours for completion of all Program Standard #2 coursework are 68 hours

Program Standard #2 APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officers

"Application" Courses and "Hands-On" Training

To provide application and transfer of web instruction to the FSIO's work environment, a jurisdiction's training program (inclusive of both classroom instruction *and* field training inspections) for staff newly hired or newly assigned to the retail food protection program must include a minimum of eighty percent (80%) of the learning objectives contained in the ORA U course *FD170: Application of Inspection and Investigation Techniques*. A jurisdiction may use any one of the following options to address learning objectives not covered in their existing training programs.

- 1. FD170: Application of Inspection and Investigation Techniques (available at www.insti.org/).
- 2. Courses and/or field training exercises developed by regulatory jurisdictions or other entities that contain learning objectives and exercises equivalent to Option 1 above.
- 3. Discussions, questions and exercises (conducted in the office or during the 25 joint inspections) that contain learning objectives and exercises equivalent to Option 1 above.

The learning objectives for the ORA U course FD170: Application of Inspection and Investigation Techniques are included below:

FD170: Application of Inspection and Investigation Techniques

Applying Knowledge and Principles to the Real World of Inspection and Investigation of Food Establishments

Learning Objectives: Upon completion of this course, participants will be able to:

- 1. Explain prerequisite knowledge, skills, and abilities required for inspection and investigation.
- 2. Apply laws, codes, and guidance documents.
- 3. Select and use inspection and investigation equipment and tools.
- 4. Identify the potential hazards present in an establishment.
- 5. Identify the steps of a focused food safety inspection.
- 6. Explain different types of investigations.
- 7. Write descriptive, accurate, and unbiased reports.

APPENDIX B-2: CFP Field Training Manual

Background

The Conference for Food Protection (CFP) has progressed through multiple stages in the development of a nationally recognized model for training and standardizing regulatory Food Safety Inspection Officers (FSIO) responsible for conducting food safety inspections. Research conducted by CFP revealed that existing training and standardization programs were nearly as varied as the number of regulatory jurisdictions throughout the country. In response, a model multi-tiered approach for training and standardizing FSIOs was developed using the FDA Voluntary National Retail Food Regulatory Program Standards, Standard 2 – Trained Regulatory Staff.

This *Field Training Manual* focuses on two components of this multi-tiered approach contained in Standard 2 – the pre-requisite coursework and the field training model for preparing newly hired FSIOs or individuals newly assigned to the regulatory retail food protection program to conduct independent food safety inspections. The instructions and worksheets provided in this manual constitute a training process, *not* a certification or audit process.

The model developed through the CFP process, consists of a training plan, trainer's worksheets, and procedures that may be used by *any* regulatory retail food protection program. Jurisdictions do *not* have to be enrolled in the *FDA Voluntary National Retail Food Regulatory Program Standards* to use, and benefit from, this training structure for preparing FSIOs to conduct independent food safety inspections. This manual was developed to assist jurisdictions that do not have the available staff resources and funding necessary to develop a comprehensive training process. The training model presented in this manual can be readily integrated into existing regulatory retail food protection programs.

The work within this document represents the culmination of years of research and review by subject matter experts comprised of psychometricians and representatives from state and local regulatory retail food protection programs; industry trade associations; retail food and foodservice operations; academia; and the FDA's Office of Regulatory Affairs University (ORA U). The coursework and training process are the basis for much of the criteria that is contained in Steps 1 and 2 of *Standard 2 – Trained Regulatory Staff*, *FDA Voluntary National Retail Food Regulatory Program Standards*. This manual is a working document and improvements will be made through the CFP Committee process.

Overview of the Field Training Manual

All new employees or individuals new to the regulatory retail food protection program should complete pre-requisite coursework and a field training process similar to that presented in this document. The national research conducted by CFP has been used to identify the minimum performance element competencies needed to conduct effective regulatory retail food safety inspections. The *CFP Training Plan and Log* along with the *Field Training Worksheets* provided in this manual are based on these minimum performance element competencies.

Flexibility has been built into the process to allow regulatory jurisdictions the opportunity to customize training content and methods to represent a jurisdiction's own administrative policies, procedures, and inspection protocol. As you read through this manual, it is important to keep in mind that jurisdictions are not obligated to use the forms; equivalent forms or training processes can be developed. The ultimate objective is to ensure FSIOs are trained on, and provided an opportunity to successfully demonstrate, the performance element competencies that are a vital part of their job responsibilities.

Where to Access the Field Training Manual

A copy of the CFP Field Training Manual can be accessed from the Conference for Food Protection's website (http://www.foodprotect.org/).

APPENDIX B-3: Risk Categorization of Food Establishments 2017 FDA Food Code – Annex 5, Conducting Risk-based Inspections

Table 1

Risk Category	Description	Frequency #/Year
1	Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only pre-packaged, non time/temperature control for safety (TCS) foods. Establishments that prepare only non-TCS foods. Establishments that heat only commercially processed TCS foods for hot holding. No cooling of TCS foods. Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors.	1
2	Examples may include retail food store operations, schools not serving a highly susceptible population, and quick service operations. Most products are prepared/cooked and served immediately. May involve hot and cold holding of TCS foods after preparation or cooking. Complex preparation of TCS foods requiring cooking, cooling, and reheating for hot holding is limited to only a few TCS foods. Establishments that would otherwise be grouped in Category 3 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of active managerial control of foodborne illness risk factors is achieved and documented.	2
3	An example is a full service restaurant. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods. Variety of processes require hot and cold holding of TCS food. Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of active managerial control of foodborne illness risk factors is achieved and documented.	3
4	Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments serving a highly susceptible population or that conduct specialized processes (i.e. smoking and curing, reduced oxygen packaging for extended shelf-life).	4

STANDARD 3 INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

Table of Contents

REQUIREMENT SUMMARY	2
DESCRIPTION OF REQUIREMENT.	
OUTCOME	
DOCUMENTATION	

STANDARD 3 INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

This standard applies to the utilization of HACCP principles to control risk factors in a retail food inspection program.

Requirement Summary

An inspection program that focuses on the status of risk factors, determines and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors through active managerial control.

Description of Requirement

Program management:

- 1. Implements the use of an inspection form that is designed for:
 - a) The identification of risk factors and interventions.
 - b) Documentation of the compliance status of each risk factor and intervention (i.e. a form with notations indicating IN compliance, OUT of compliance, Not Observed, or Not Applicable for risk factors)
 - c) Documentation of all compliance and enforcement activities and
 - d) Requires the selection of IN, OUT, NO, or NA for each risk factor.
- 2. Develops and uses a process that groups food establishments into at least three categories based on potential and inherent food safety risks.
- 3. Assigns the inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk.
- 4. Develops and implements a program policy that requires:
 - a) On-site corrective actions* as appropriate to the type of violation.
 - b) Discussion of long-term control** of risk factor options, and
 - c) Follow-up activities.
- 5. Establishes and implements written polices addressing code variance requests related to risk factors and interventions.
- 6. Establishes written polices regarding the verification and validation of HACCP plans when a plan is required by the code.

Outcome

The desired outcome of this standard is a regulatory inspection system that uses HACCP principles to identify risk factors and to obtain immediate- and long-term corrective action for recurring risk factors.

Documentation

The quality records needed for this standard include:

- 1. Inspection form that requires the selection of IN, OUT, NO, or NA,
- 2. Written process used for grouping establishments based on food safety risk and the inspection frequency assigned to each category,

- 3. Policy for on-site correction and follow-up activities,
- 4. Policy for addressing code variance requests related to risk factors and interventions,
- 5. Policy for verification and validation of HACCP plans required by code, and
- 6. Policy requiring the discussion of food safety control systems with management when out of control risk factors are recorded on subsequent inspections.

*Note: **On-site** corrective action as appropriate to the violation would include such things as:

- a. Destruction of foods that have experienced extreme temperature abuse,
- b. Embargo or destruction of foods from unapproved sources,
- c. Accelerated cooling of foods when cooling time limits can still be met,
- d. Reheating when small deviations from hot holding have occurred,
- e. Continued cooking when proper cooking temperatures have not been met.
- f. Initiated use of gloves, tongs, or utensils to prevent hand contact with ready-to-eat foods, or
- g. Required hand washing when potential contamination is observed.

Note: **Long-term control of risk factors requires a commitment by managers of food establishments to develop effective monitoring and control measures or system changes to address those risk factors most often responsible for foodborne illness. Risk control plans, standard operating procedures, buyer specifications, menu modification, HACCP plans and equipment or facility modification may be discussed as options to achieve the long-term control of risk factors.

INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

STANDARD 3 – INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

Program Self-Assessment & Verification Audit Form

The Standard 3: Program Self-Assessment and Verification Audit Form is designed to document the findings from the self-assessment and the verification audit process for Standard 3. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 3 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self Assessment

Jurisdictions conducting a self-assessment of Standard 3 must indicate on the form if each of the listed criteria is met. These responses are recorded under the column "Jurisdiction's Self Assessment."

Jurisdictions are not obligated to use this form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 3 criteria listed on this form are available for review.

The Standard 3: Program Self-Assessment and Verification Audit Form is the only form a jurisdiction needs to use to record the results of their self-assessment. Standard 3 requires inspection policies to be established, written, and implemented. A policy without documentation of implementation does not meet the Standard 3 criteria.

The *Standard 3: Program Self-Assessment and Verification Audit Form* divides the Standard 3 criteria into six steps:

- 1. Inspection Form Design
 - a. The jurisdiction's inspection form identifies foodborne illness risk factors and *Food Code interventions*.
 - b. The jurisdiction's inspection form documents actual observations using the convention IN, OUT, NA, and NO.
 - c. The jurisdiction's inspection form documents compliance and enforcement activities.
- 2. Risk Assessment Categories
 - a. A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.
- 3. Inspection Frequency
 - a. The jurisdiction's inspection frequency is based on assigned risk categories.

4. Corrective Action Policy

- a. The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.
- b. The jurisdiction has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.
- c. The jurisdiction has a written and implemented policy that requires follow-up activites on foodborne illness risk factor violations.

5. Variance Request Policy

- a. The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and *Food Code* interventions.
- 6. Verification and Validation of HACCP Plan Policy
 - a. The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the *Food Code*.

The self-assessor must review each Standard 3 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 3: Program Self-Assessment and Verification Audit Form.*

If a review of the jurisdiction's source documents does not confirm that the Standard 3 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction's Self-Assessment" column of the Standard 3: Program Self-Assessment and Verification Audit Form. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 3: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed *Standard 3: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 3 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 3: Program Self-Assessment and Verification Audit Form.* The self-assessor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria.

Documenting the Findings from the Verification Audit

The jurisdiction requesting the verification audit must provide their completed *Standard 3: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 3: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings.

The jurisdiction must meet all six program performance criteria outlined in Standard 3.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any Standard 3 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 3: Program Self-Assessment and Verification Audit Form.* The auditor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 3 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 3 criteria if the auditor does not confirm the self-assessment findings.

Standard 3: Inspection Program Based On HACCP Principles Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the Self-Assessment:		
Self-Assessor's Title:		
Jurisdiction Name:		
Jurisdiction Address:		
Phone: FAX:	E-Mail:	11:
Date the Standard 3 Self-Assessment was Completed:		
Self-Assessment indicates that the Jurisdiction MEETS the Standard 3 criteria: YES	eria: YES 🗌 NO 🗌	
I affirm that the information represented in the Self-Assessment of Standard 3 is true and correct.	3 is true and correct.	
Signature of the Self-Assessor:		
VERIFICATION AUDIT SUMMARY	AUDIT SUMMARY	
Printed Name of the Person who conducted the Verification Audit:		
Verification Auditor's Title:		
Auditor's Jurisdiction Name:		
Auditor's Jurisdiction Address:		
Phone: FAX:	E-Mail:	11:
Date the Verification Audit of Standard 3 was Completed:		
Verification Audit indicates that the Jurisdiction MEETS the Standard 3 criteria: YES	riteria: YES 🗌 NO 🗌	
I affirm that the information represented in the Verification Audit of Standard 3 is true and correct.	d 3 is true and correct.	
Signature of the Verification Auditor:		

Standard 3: Inspection Program Based On HACCP Principles Program Self-Assessment and Verification Audit Form

Jurisdiction Name:

	Juris	diction	Jurisdiction's Self-Assessment		Aud	Auditor's Verification
Criteria	YES	ON	Self-Assessor's General Comments	YES	ON	If NO, Auditor is to specify why criterion is not met
1. Inspection Form Design						
 a) The jurisdiction's inspection form identifies foodborne illness risk factors and Food Code interventions. 						
b) The jurisdiction's inspection form documents actual observations using the convention IN, OUT, NA, and NO.						
c) The jurisdiction's inspection form documents compliance and enforcement activities.						
2. Risk Assessment Categories						
a) A risk assessment is used to group food establishments into at least 3 categories based on their potential and inherent food safety risks.						
3. Inspection Frequency						
a) The jurisdiction's inspection frequency is based on the assigned risk categories.						
4. Written and Implemented Corrective Action Policy	on Policy					
a) The jurisdiction has a written and implemented policy that requires on-site corrective action for foodborne illness risk factors observed to be out of compliance.						
b) The jurisdiction has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.						

Voluntary National Retail Food Regulatory Program Standards – January 2017

	Juris	diction	Jurisdiction's Self-Assessment		Aud	Auditor's Verification
Criteria	YES	ON	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
c) The jurisdiction has a written and implemented policy that requires follow-up activities on foodborne illness risk factor violations.						
5. Variance Requests						
a) The jurisdiction has a written and implemented policy on variance requests related to foodborne illness risk factors and <i>Food Code</i> interventions.						
6. Verification and Validation of HACCP Plans	ns					
a) The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the Code.						

Standard 3: Inspection Program Based On HACCP Principles Program Self-Assessment and Verification Audit Form

GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT

STANDARD 4 UNIFORM INSPECTION PROGRAM

Table of Contents

REQUIREMENT SUMMARY	2
DESCRIPTION OF REQUIREMENT.	
OUTCOME	
Documentation	Δ

STANDARD 4 UNIFORM INSPECTION PROGRAM

This standard applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies and compliance / enforcement procedures.

Requirement Summary

Program management has established a quality assurance program to ensure uniformity among regulatory staff in the interpretation and application of laws, regulations, policies, and procedures.

Description of Requirement

- 1) Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency and uniformity among the regulatory staff. The quality assurance program shall:
 - A. The quality assurance program shall assure that each inspector:
 - 1. Has required equipment and forms to conduct the inspection.
 - 2. Reviews the contents of the establishment file, including the previous inspection report, reported complaints on file, and, if applicable, required HACCP Plans or documents supporting the issuance of a variance.
 - 3. Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. Informs the supervisor when the establishment is not in the proper risk category or when the required frequency is not met.
 - 4. Provides identification as a regulatory official to the person in charge and states the purpose of the visit.
 - 5. Interprets and applies the jurisdiction's laws, rules, policies, procedures, and regulations required for conducting retail food establishment inspections.
 - 6. Uses a risk-based inspection methodology to conduct the inspection.
 - 7. Accurately determines the compliance status of each risk factor and Food Code intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).
 - 8. Obtains corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies.
 - 9. Discuss options for the long-term control of risk factors with establishment mangers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction's policies. Options may include, but are not limited to; risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans.
 - 10. Verifies correction of out-of-compliance observations identified during the previous inspection. In addition, follows through with compliance and enforcement in accordance with the jurisdiction's policies.
 - 11. Conducts an exit interview that explains the out-of-compliance observations, corrective actions, and timeframes for correction, in accordance with the jurisdiction's policies.

- 12. Provides the inspection report and, when necessary, cross-referenced documents, to the person in charge or permit holder, in accordance with the jurisdiction's policies.
- 13. Demonstrates proper sanitary practices as expected from a food service employee.
- 14. Completes the inspection form per the jurisdiction's policies (i.e. observations, public health reasons, applicable code reference, compliance dates).
- 15. Documents the compliance status of each risk factor and intervention (IN, OUT, NA, NO).
- 16. Cites the proper code provisions for risk factors and Food code interventions, in accordance with the jurisdiction's policies.
- 17. Documents corrective action for out-of-compliance risk factors and Food code interventions in accordance with the jurisdiction's policies.
- 18. Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.
- 19. Compliance or regulatory documents (i.e. exhibits, attachments, sample forms) are accurately completed, appropriately cross-referenced within the inspection report, and included with the inspection report, in accordance with the jurisdiction's policies.
- 20. Files reports and other documentation in a timely manner, in accordance with the jurisdiction's policies.
- B. The quality assurance program shall describe the actions that will be implemented when the program analysis identifies deficiencies in quality or consistency in any program element listed above in 1) (A).
- 2) The quality assurance program must achieve an overall inspection program performance rating for each of the twenty measured elements [Items1-20] of at least 75% using the self-assessment procedure and the appropriate table provided in the *Standard 4: Self-Assessment Instructions and Worksheet*.

An assessment review of each inspector's work shall be made during at least three joint on-site inspections, with a corresponding file review of at least the three most recent inspection reports of the same inspected establishments, during every self-assessment period.

[*NOTE: Staff members who are within their initial 18 months of training and have not completed all prerequisite courses, 25 joint inspections and 25 independent inspections as required in Standard 2, are exempt from the joint on-site inspections and file reviews used in the performance measurement rating calculation in the Standard 4 Self-Assessment Worksheet.]

Outcome

A quality assurance program exists that ensures uniform, high quality inspections.

Documentation

The quality records needed for this standard include:

- 1. A written procedure that describes the jurisdiction's quality assurance program that meets the criteria under the Description of Requirement section 1) (A), including corrective actions for deficiencies, and
- 2. Documentation that the program achieves a 75 percent performance rating on each element using the self-assessment procedures described above.

INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

STANDARD 4 – UNIFORM INSPECTION PROGRAM

Program Self-Assessment & Verification Audit Form

The *Standard 4: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 4 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self-Assessment

Jurisdictions conducting a self-assessment of Standard 4 must indicate on the form if each of the listed criteria is met. These responses are recorded under the column "Jurisdiction's Self Assessment."

Jurisdictions are not obligated to use this form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 4 criteria listed on this form are available for review.

The Standard 4: Self-Assessment and Verification Audit Form is divided into three steps:

- 1. A quality assurance program that:
 - a. Is described in a written document and covers all inspection personnel performing food service or retail food inspections,
 - b. Is monitored regularly and consistently as described in the written document, and
 - c. Has determined corrective actions that will be taken whenever quality and consistency problems are identified.
- 2. Demonstration of review and monitoring methods for the concepts in the twenty quality elements, and
- 3. Demonstration of program effectiveness using the provided statistical method1.

The self-assessor must review each Standard 4 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 4: Program Self-Assessment and Verification Audit Form.*

If a review of the jurisdiction's source documents does not confirm that the Standard 4 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction's Self-Assessment" column of the Standard 4 Program Self-Assessment and Verification Audit Form. The self-assessor may specify why the criteria are not met in the box provided.

¹ - This Standard criterion requires a statistical measure of the program's effectiveness. Instructions for conducting the statistical measure of program effectiveness are provided beginning on the Standard 4: Self-Assessment Worksheet

The self-assessor should review the findings on the Standard 4: Program Self-Assessment and Verification Form to ensure accuracy. The jurisdiction must provide the auditor with their completed Standard 4: Program Self-Assessment and Verification Audit Form and any documents used to support and demonstrate that the Standard 4 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the Standard 4: Program Self-Assessment and Verification Audit Form. The self-assessor must:

- Enter their contact information;
- Documents if the jurisdiction met the Standard 4 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 4 criteria.

Documenting the Findings from the Verification Audit

The jurisdiction requesting the verification audit must provide their completed *Standard 4: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 4: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any Standard 4 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 4: Program Self-Assessment and Verification Audit Form.* The auditor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 4 criteria in the appropriate box;
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 4 criteria if the auditor does not confirm the self-assessment findings.

Standard 4: Uniform Inspection Program Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Standard 4: Uniform Inspection Program Program Self-Assessment and Verification Audit Form

Criteria			Jurisdiction's Self-Assessment			Auditor's Verification
	YES	ON	Self-Assessor's General Comments	YES	ON	If NO, Auditor is to specify why criterion is not met
1. Written Quality Assurance Program Document	nt					
a. The jurisdiction has a written quality assurance program that covers all regulatory staff that conducts retail food and/ or foodservice inspections.						
b. The jurisdiction periodically conducts an analysis of the results of the quality assurance program to identify quality or consistency problems among the staff in the twenty quality elements.						
c. The jurisdiction's written quality assurance program describes corrective actions to address an individual retail food program inspector's performance quality or consistency issues when they are identified.						
2. Twenty Quality Assurance Program Elements	70					
The jurisdictions quality assurance program provides a method to review or monitor, either individually or programmatically, the concepts in the twenty quality elements. The twenty elements follow in I. through XX.						
I. The jurisdiction's quality assurance program assures that each inspector has the required equipment and forms to conduct the inspection.						
II. The jurisdiction's quality assurance program assures that each inspector reviews the contents of the establishment file, including the previous inspection report, reported complaints on file, and, if applicable, required HACCP Plans or documents supporting the issuance of a variance.						

Criteria			Jurisdiction's Self-Assessment			Auditor's Verification
	YES	ON	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
2. Twenty Quality Assurance Program Elements (contd.)	s (conte	d.)				
III. The jurisdiction's quality assurance program assures that each inspector verifies that the establishment is in the proper risk category and that the required inspection frequency is being met, Informs the supervisor when the establishment is not in the proper risk category or when frequency is not met.						
IV. The jurisdiction's quality assurance program assures that each inspector provides identification as a regulatory official to the person in charge and states the purpose of the visit.						
V. The jurisdiction's quality assurance program assures that each inspector interprets and applies the jurisdiction's laws, rules, policies, procedures, and regulations required for conducting retail food inspections.						
VI. The jurisdiction's quality assurance program assures that each inspector uses a risk-based inspection methodology to conduct the inspection.						
VII. The jurisdiction's quality assurance program assures that each inspector accurately determines the compliance status of each risk factor and Food Code intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).						
VIII. The jurisdiction's quality assurance program assures that each inspector obtains corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdictions policies.						

Criteria			Jurisdiction's Self-Assessment			Auditor's Verification
	YES	ON	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
2. Twenty Quality Assurance Program Elements (contd.)	s (cont	J.)				
IX. The jurisdiction's quality assurance program assures that each inspector discusses options for the long-term control of risk factors with establishment managers when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction's policies. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.						
X. The jurisdiction's quality assurance program assures that each inspector verifies correction of out-of-compliance observations identified during the previous inspection. In addition, follows through with compliance and enforcement in accordance with jurisdiction's policies.						
XI. The jurisdiction's quality assurance program assures that each inspector conducts an exit interview that explains the out-of-compliance observations, corrective actions, and timeframes for correction, in accordance with the jurisdiction's policies.						
XII. The jurisdiction's quality assurance program assures that each inspector provides the inspection report and, when necessary, cross-referenced documents, to the person in charge or permit holder, in accordance with the jurisdiction's policies.						
XIII. The jurisdiction's quality assurance program assures that each inspector demonstrates proper sanitary practices as expected from a food service employee.						

Criteria			Jurisdiction's Self-Assessment			Auditor's Verification
	YES	ON	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
2. Twenty Quality Assurance Program Elements (contd.)	ts (cont	d.)				
XIV. The jurisdiction's quality assurance program assures that each inspector completed the inspection form per the jurisdiction's policies (i.e., observations, public health reasons, applicable code reference, compliance dates).						
XV. The jurisdiction's quality assurance program assures that each inspector document the status of each risk factor and intervention (IN, OUT, NA, NO).						
XVI. The jurisdiction's quality assurance program assures that each inspector cites the proper code provisions for risk factors and Food Code interventions, in accordance with the jurisdiction's policies.						
XVII. The jurisdiction's quality assurance program assures that each inspector documents corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies.						
XVIII. The jurisdiction's quality assurance program assures that each inspector documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.						

Criteria		3 2	Jurisdiction's Self-Assessment			Auditor's Verification
	YES	ON	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
2. Twenty Quality Assurance Program Elements (contd.)	s (conte	(<u>-</u>				
XIX. The jurisdiction's quality assurance program assures that each inspector accurately completes compliance or regulatory documents (i.e., exhibits, attachments, sample forms), appropriately cross-references them within the inspection report, and includes them with the inspection report, in accordance with the jurisdiction's policies.						
XX. The jurisdiction's quality assurance program assures that each inspector files reports and other documentation in a timely manner, in accordance with the jurisdiction's policies.						
3. Demonstration of Program Effectiveness Usin	ng the S	tatistic	sing the Statistical Method in Standard 4: Self-Assessment Worksheet	lf-Asses	sment	Worksheet
a. The program effectiveness measure documents that 2 self-assessment field reviews were conducted for each employee performing retail food and or foodservice inspection work during the five-year self-assessment period. [New staff who have not completed Steps 1 through 3 of Standard 2 are exempt from this field measurement.]						
b. Based on the self-assessment field reviews using the statistical method described in Standard 4: Self-Assessment Worksheet, the jurisdiction's regulatory staff achieves a rate of 75% on each quality element for jurisdictions with 10 or more inspectors. For jurisdictions with less than 10 inspectors, the achievement rate meets or exceeds the Table 4-1 calculation.						

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GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT	
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INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

STANDARD 4 – UNIFORM INSPECTION PROGRAM

Using the Standard 4 Self-Assessment Worksheet

Criterion three on the *Standard 4: Self-Assessment and Verification Audit Form* requires a statistical measure of the program's effectiveness. Tables 4-1 and 4-2 on the *Standard 4: Self-Assessment Worksheet*, included at the end of these instructions, is designed to assist the jurisdiction in determining by statistical method the effectiveness of its Uniform Inspection Program and in documenting its findings. The jurisdictions are not obligated to use the worksheet. Equivalent forms or processes are acceptable provided that the statistical process and result is available for review.

Step 1 – Conduct three field reviews for each employee performing food service or retail food inspection work during the five-year self-assessment period.

The jurisdiction must conduct three field reviews with each employee performing food service or retail food inspection work during the five-year self-assessment period. Staff members who are within their initial 18 months of training and have not completed all prerequisite courses, 25 joint inspections and 25 independent inspections as required in Standard 2, are exempt from the field reviews and file reviews used in the performance measurement rating calculation in the Standard 4 Self-Assessment Worksheet.

Field reviews must be conducted by someone who has competed Steps 1-3 in Standard 2, and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.

Some of the performance elements can only be assessed after thorough a review of the establishment files. Therefore, each field review must be accompanied by a review of the establishment file. Information from the file review will help the field assessor determine if the FSIO:

- Obtained corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies;
- Discussed options for the long-term control of risk factors with establishment managers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction's policies; and
- Verified correction of out-of-compliance observations identified during the previous inspection. In addition, follows through with compliance and enforcement in accordance with the jurisdiction's administrative procedures.

The field reviews must be conducted at establishment types representative of the employee's case load. The jurisdiction should determine a method for selecting appropriate facilities for the field review process, and use that method consistently for all employees.

The field review process (and the accompanying file review) is intended to evaluate the quality and consistency of the program for each performance element. The following should be taken into consideration when implementing the field review process:

- This Standard is intended to ensure that inspections are of a satisfactory quality and uniformity across the entire program.
- When assessing a staff member's performance during the field review process, perfection is not required to demonstrate successful achievement of a performance element.
- Table 4-2 is intended to document the results of the field review process for the
 purpose of determining if a jurisdiction has achieved conformance with Standard 4.
 Table 4-2 is not intended as a mechanism for providing feedback to staff on their
 performance during the field review process. Therefore, jurisdictions are encouraged
 to incorporate the performance elements from Standard 4 into a field review tool so
 that staff can be provided with meaningful feedback that improves the quality and
 uniformity of their inspections.
- Jurisdictions may assess additional jurisdiction-specific performance elements during the field review process. However, for the purposes of determining conformance with Standard 4, additional jurisdiction-specific performance elements may not be included in the calculation used for Table 4-1 or 4-2.

Step 2 – Confirm that three field reviews have been conducted for each employee performing foodservice or retail food inspection work during the five-year self-assessment period.

Table 4-2 of the *Standard 4: Self-Assessment Worksheet* is used to document the field inspections and to analyze statistically the program's overall effectiveness. The jurisdiction conducts at least three field inspections with each inspector who conducts food service or retail food inspections during each five-year self-assessment period.

Table 4-2 must be completed with at least twelve field inspections. Jurisdictions with less than four inspectors must complete additional field inspections with each inspector in order to reach a total of twelve inspections. For example, a jurisdiction with three inspectors would need to:

Complete four inspections each inspector.

Step 3 – Use Table 4-2 to enter the results from the two field reviews for each Food Safety Inspection Officer (FSIO)

- In the first column of Table 4-2, identify each FSIO by name or by a code.
- In the Establishment ID column, identify the two establishments included in the field reviews for each FSIO.
- In the "DATE" column, record the dates of the field visit and file review.
- Items 1 through 20 are the Standard 4 criteria related to the FSIOs competencies.

The self-assessor must place a check mark in the corresponding column of Table 4-2 when the activity or competency is verified.

Step 4 – Conduct calculations to Determine Program Effectiveness

JURISDICTIONS WITH TEN OR MORE INSPECTORS

For jurisdictions with ten or more inspectors conducting foodservice or retail food inspections, the self-assessor must:

- 1. Add the number of check marks in the column titled "Item 1";
- 2. Divide the total number of checks marks from Step 1 by the total number of field inspections documented in Table 4-2;
- 3. Multiply the number in Step 2 by 100; and
- 4. Repeat this process for Item 1 through Item 20.

This results in a percent achievement for each of the twenty quality elements. Each of the twenty columns must show at least a 75% achievement rate in order for the program to meet the effectiveness measure. Perform and review the calculations for each of the twenty columns.

JURISDICTIONS WITH LESS THAN TEN INSPECTORS

For jurisdictions with less than ten inspectors conducting foodservice or retail food inspections, an adjustment must be made in the statistical method to compensate for the small sample size. The self-assessor must:

- 1. Add the total number of check marks for Item 1 through Item 20;
- 2. Refer to Chart 4-1. Column three of Chart 4-1 shows the minimum number of items that must be marked "IN Compliance" to meet the effectiveness measure for Standard 4.
- 3. Complete Table 4-1 to determine if the jurisdiction achieves conformance with the effectiveness measure in Standard 4.

Step 5 - Document Results of the Uniform Program Assessment

Use the worksheet results to mark "YES" or "NO" for criteria list under " 3 – Demonstration of Program Effectiveness Using the Statistical Method in Standard 4 Self-Assessment Worksheet " on the Standard 4: Self-Assessment and Verification Audit Form.

Standard 4: Uniform Inspection Program Self-Assessment Worksheet

Chart 4-1
Method of Calculation for Jurisdictions with Less Than Ten Inspectors

# of inspectors	# inspections needed	# of items needed to be marked IN compliance in order to meet Standard 4 criteria
<4	12 minimum	200 (out of 240 possible Items)
4-9	3 per inspector	4 inspectors = 200 (out of 240 possible Items) 5 inspectors = 252 (out of 300 possible Items) 6 inspectors = 303 (out of 360 possible Items) 7 inspectors = 355 (out of 420 possible Items) 8 inspectors = 407 (out of 480 possible Items) 9 inspectors = 459 (out of 540 possible Items)

NOTE:

Period from

1. These minimum inspection program assessment criteria are comparable to the 75% IN Compliance rate for each of the ten inspection program areas for jurisdictions with 10 or more inspectors.

Example: For 6 inspectors, there will be 3 field visits per inspector = 18 visits 18 visits X 20 Items per visit = 360 Total Possible Items

Table 4-1
Calculation of Uniformity for Jurisdictions with Less Than Ten Inspectors

to

1. Number of inspectors in the jurisdiction	
2. Number of inspections used in the calculation (minimum of 12)	
3. Total number of items marked as correct during joint field visits and corresponding file reviews and recorded on Table 4-2.	
4. Total number of possible items based on the number of inspections (20 items times the # of inspections – see Chart 4-1, column 3)	
Determine conformance (YES or NO) using Chart 4-1, column 3	

Standard 4: Uniform Inspection Program Self-Assessment Worksheet

Table 4-2: Calculation of Uniformity for Jurisdictions with Ten or More Inspectors

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	ltem (20)																				
	ltem (19)																				
	Item (18)																				
	ltem (17)																				
	Item (16)																				
	ltem (15)																				
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NOTE: 1. A check mark indicates the inspector complies with the item.

Standard 4: Uniform Inspection Program Self-Assessment Worksheet

Table 4-3: Calculation of Uniformity for Jurisdictions with Ten or More Inspectors

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•	n Item Item (6) (7)			
	Item Item Item Item (1) (2) (3) (4)			
	ltem ltem (1) (2)			
		1. Number of Check Marks From Table 4-2	2. Number of Inspections Reviewed in Table 4-2	3. % IN Compliance (Row 1 ÷ Row 2)

STANDARD 5 FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

Table of Contents

REQUIREMENT SUMMARY	2
DESCRIPTION OF REQUIREMENT.	
1. Investigative Procedures	2
2. Reporting Procedures	3
3. Laboratory Support Documentation	
4. Trace-back Procedures	
5. Recalls	3
6. Media Management	4
7. Data Review and Analysis	
OUTCOME	
DOCUMENTATION	

STANDARD 5 FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate, which results in illness, injury and outbreaks.

Requirement Summary

The program has an established system to detect, collect, investigate and respond to complaints and emergencies that involve foodborne illness, injury, and intentional and unintentional food contamination.

Description of Requirement

1. Investigative Procedures

- a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and food-related injury*. The procedures clearly identify the roles, duties and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.
- b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, food-related injury* or contamination of food.
- c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties and responsibilities of each party.
- d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, food-related injury* or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.
- e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.
- f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.
- g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site investigations of food-related illness, food-related injury*, or outbreak investigations.

- h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.
- i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.

2. Reporting Procedures

- a. Possible contributing factors to the food-related illness, food-related injury* or intentional food contamination are identified in each on-site investigation report.
- b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed foodborne disease outbreaks* with CDC.

3. Laboratory Support Documentation

- a. The program has a letter of understanding, written procedures, contract or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.
- b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

4. Trace-back Procedures

a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

5. Recalls

- a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak or intentional food contamination.
- b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.

c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.

6. Media Management

a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.

7. Data Review and Analysis

- a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury* investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food-related injury*. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.
- b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:
 - 1) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* in a single establishment;
 - 2) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Disease Outbreaks* in the same establishment type;
 - 3) Foodborne Disease Outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* implicating the same food;
 - 4) Foodborne Disease outbreaks*, Suspect Foodborne Outbreaks* and Confirmed Foodborne Disease Outbreaks* associated with similar food preparation processes;
 - 5) Number of confirmed foodborne disease outbreaks*;
 - 6) Number of foodborne disease outbreaks* and suspect foodborne disease outbreaks*;
 - 7) Contributing factors most often identified;
 - 8) Number of complaints involving real and alleged threats of intentional food contamination; and
 - 9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.
- c. In the event that there have been no food-related illness or food-related injury* outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate response to an actual confirmed foodborne disease outbreak* and include on-site inspection, sample collection and analysis. A mock investigation must be completed at least once per year when no foodborne disease outbreak* investigations occur.

Note: Regulatory Programs are encouraged to also participate in the CDC National Environmental Assessment Reporting System (NEARS). NEARS is designed to provide a more

comprehensive approach to foodborne disease outbreak investigation and response and will provide a data source to measure the impact of food safety programs to further research and understand foodborne illness causes and prevention. (The following link provides additional information regarding NEARS: http://www.cdc.gov/nceh/ehs/nears/index.htm)

Outcome

A food regulatory program has a systematic approach for the detection, investigation, response, documentation and analysis of alleged food-related incidents that involve illness, injury, unintentional or deliberate food contamination.

Documentation

The quality records required to meet this standard include:

- 1. Logs or databases of alleged food-related illness and food-related injury* complaints maintained and current.
- 2. Collection forms specified in the operating procedures.
- 3. Investigation reports of alleged food-related illness, food-related injury*, or incidents. Reports are retrievable by implicated establishment name.
- 4. The written procedures, contracts or MOU's with the supporting laboratories.
- 5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event.
- 6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
- 7. Completed copies of the annual review and analysis (after 12 months of data).
- 8. Current written media policy/procedure and contact person.
- 9. The contact list for communicating with all relevant agencies.
- 10. Portions of any emergency response relevant to food safety and security.

[*Note: See the Standards Definitions for the meaning of these defined terms.]

INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

STANDARD 5 – FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

Program Self-Assessment & Verification Audit Form

The *Standard 5: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process for Standard 5. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standard 5 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self-Assessment

Jurisdictions conducting a self-assessment of Standard 5 must indicate on the form if each of the listed criteria is met. These responses are recorded under the column "Jurisdiction's Self Assessment."

Jurisdictions are not obligated to use this form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 5 criteria listed on this form are available for review.

The Standard 5: Program Self-Assessment and Verification Audit Form is the only form a jurisdiction needs to use to record the results of their self-assessment. The Standard 5: Program Self-Assessment and Verification Audit Form divides the Standard 5 criteria into seven categories:

- 1. Investigation Procedures;
 - ➤ Written Operating Procedure; Contact Lists; Cooperative Agreements;
 - Documenting and Responding to Reported Complaints/Incidences;
 - Complaint/Incident Investigation Procedures;
- 2. Reporting Procedures;
- 3. Laboratory Support Documentation;
- 4. Trace-back Procedures:
- 5. Recalls;
- 6. Media Management; and
- 7. Data Review and Analysis.

The self-assessor must review each Standard 5 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 5: Program Self-Assessment and Verification Audit Form*.

If a review of the jurisdiction's source documents does not confirm that the Standard 5 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction's Self-Assessment" column of the *Standard 5: Program Self-Assessment and Verification Audit Form.* The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 5: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed *Standard 5: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 5 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 5: Program Self-Assessment and Verification Audit Form.* The self-assessor must:

- Enter their contact information:
- Document if the jurisdiction met the Standard 5 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 5 criteria.

Documenting the Findings from the Verification Audit

The jurisdiction requesting the verification audit must provide their completed *Standard 5: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 5: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings. The jurisdiction must meet all seven program performance criteria outlined in Standard 5.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any Standard 5 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 5: Program Self-Assessment and Verification Audit Form.* The auditor must:

- Enter their contact information:
- Document if the jurisdiction met the Standard 5 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 5 criteria if the auditor does not confirm the self-assessment findings.

Standard 5: Foodborne Illness and Food Defense Preparedness and Response Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Self-Assessor's Title Jurisdiction Name: Jurisdiction Address: Phone: Phone: Phone: Permit: Date the Standard 5 Self-Assessment was Completed: Self-Assessment indicates that the Jurisdiction MEETS the Standard 5 criteria: YES NO NO Self-Assessor: Signature of the Self-Assessor: VERIFICATION AUDIT SUMMARY Printed Name of the Person who conducted the Verification Audit: Verification Auditor's Title: Auditor's Jurisdiction Name: Auditor's Jurisdiction Address: Phone: FAX: E-mail: NO NO NO NO NO NO NO NO NO NO
FAX: sment was Completed: the Jurisdiction MEETS the Standard 5 criteria: YES NO oresented in the Self-Assessment of Standard 5 is true and correct: VERIFICATION AUDIT SUMMARY to conducted the Verification Audit: FAX:
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r's Jurisdiction Address: FAX:
FAX:
Date the Verification Audit of Standard 5 was Completed:
Verification Audit indicates that the Jurisdiction MEETS the Standard 5 criteria: YES 🔲 NO 📋
I affirm that the information represented in the Verification Audit of Standard 5 is true and correct
Signature of the Verification Auditor:

Standard 5: Foodborne Illness and Food Defense Preparedness and Response Program Self-Assessment and Verification Audit Form

Jurisdiction Name:

	Jur	isdictio	Jurisdiction's Self-Assessment		Au	Auditor's Verification
Criteria	YES	ON	Self-Assessor's General Comments	YES	ON	If NO, Auditor is to specify why criterion is not met
1. Investigation Procedures						
a) The program has written operating procedures for responding to and/or conducting investigations of foodborne illness and food-related injury that clearly identify the roles, duties, and responsibilities of program staff and how the program interacts with other relevant departments and agencies. (The procedures may be contained in a single source document or in multiple documents.)						
b) The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illnesses, food-related injuries, or contamination of food.						
c) The program maintains a written operating procedure or a Memorandum of Understand (MOU) with the appropriate epidemiological investigation program / department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.						

	Jur	isdictio	Jurisdiction's Self-Assessment		Auc	Auditor's Verification
Criteria	YES	NO	Self-Assessor's General Comments	YES	ON	If NO, Auditor is to specify why criterion is not met
d) The program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, food-related injury, or unintentional food contamination. The final disposition for each complaint is recorded in the database or log and is filed in, or linked to, the establishment record for retrieval purposes.						
 e) Program procedures describe the disposition, action, or follow-up and reporting required for each type of complaint or referral report. 						
f) Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.						
g) The program has established procedures and guidance for collecting information on the suspect foods' preparation, storage or handling during on-site illness, food-injury, or outbreak investigations.						
h) Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.						
i) Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.						
2. Reporting Procedures						
a) Possible contributing factors to the illness, food-related injury, or intentional food contamination are identified in each on-site investigation report.						

	Jur	isdictio	Jurisdiction's Self-Assessment		Auc	Auditor's Verification
Сптепа	YES	ON	Self-Assessor's General Comments	YES	ON	If NO, Auditor is to specify why criterion is not met
b) The program shares final reports of investigations with the state epidemiologist and reports of confirmed disease outbreaks with CDC.						
3. Laboratory Support Documentation						
a) The program has a letter of understanding, written procedures, contract, or MOU acknowledging that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological, contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental, food, and/or clinical sample analyses.						
b) The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) identified in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).						
4. Trace-Back Procedures						
a) Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The trace-back provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.						

	Jur	isdictio	Jurisdiction's Self-Assessment		Auc	Auditor's Verification
Criteria	YES	ON	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
5. Recalls						
a) Program management has an established procedure to address the recall of foods implicated in an illness, outbreak, or intentional food contamination.						
b) When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR Part 7 are followed.						
c) Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.						
6. Media Management						
a) The program has a written policy and procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The protocol should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.						
7. Data Review and Analysis						
a) At least once per year, the program conducts a review of the data in the complaint log or database and the illness and food-related injury investigations to identify trends and possible contributing factors that are most likely to cause illness or injury. These periodic reviews of multiple complaints and contributing factors may suggest a need for further investigations may suggest steps for illness prevention.						

	Jur	isdictio	Jurisdiction's Self-Assessment		Auc	Auditor's Verification
Criteria	YES	ON	Self-Assessor's General Comments	YES	ON	If NO, Auditor is to specify why criterion is not met
b) The review is conducted with prevention in mind and focuses on, but is not limited to, the following: 1) Multiple complaints on the same establishment;						
2) Multiple complaints on the same establishment type;						
3) Multiple complaints implicating the same food;						
4) Multiple complaints associated with similar food preparation processes;						
5) Number of confirmed foodborne disease outbreaks;						
6) Number of foodborne disease outbreaks and suspect foodborne disease outbreaks;						
7) Contributing factors most often identified;						
8) Number of complaints involving real and alleged threats of intentional food contamination.						
9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.						
c) In the event that there have been no illness or food-related injury outbreak investigations conducted during the twelve months prior to the trend analysis, program management will plan and conduct a mock foodborne illness or food defense investigation to test program readiness. The mock investigation should simulate response to an actual illness outbreak and include on-site inspection, sample collection, and analysis. A mock investigation must be completed at least once per year when no illness outbreak investigations occur.						

Standard 5: Foodborne Illness and Food Defense Preparedness and Response Program Self-Assessment and Verification Audit Form

be answered in the affirmative in order to meet that element of the Standard. The source documents, such as the various policies and A "yes" affirmation to each statement is required to meet Standard 5. If an item contains multiple questions, then all questions must procedures, that support this summary record must be maintained in good order by the regulatory authority and must be made available upon request for purposes of a verification audit.

investigation within the twelve month period since the last trend analysis. If the jurisdiction DID conduct a foodborne illness or food defense investigation within this twelve month period, then they are not required to conduct a mock foodborne illness/food defense (NOTE: Item 7c can be marked "not applicable" (NA) if the jurisdiction DID conduct a foodborne illness or food defense

STANDARD 6 COMPLIANCE AND ENFORCEMENT

Table of Contents

REQUIREMENT SUMMARY	2
DESCRIPTION OF REQUIREMENT	
OUTCOME	
DOCUMENTATION	

STANDARD 6 COMPLIANCE AND ENFORCEMENT

This standard applies to all compliance and enforcement activities used by a jurisdiction to achieve compliance with regulations.

Requirement Summary

Compliance and enforcement activities result in follow-up actions for out-of-control risk factors and timely correction of code violations.

Description of Requirement

Compliance and enforcement encompasses all voluntary and regulatory actions taken to achieve compliance with regulations. Voluntary corrective action includes, but is not limited to, such activities as on-site corrections at time of inspection, voluntary destruction of product, risk control plans and remedial training. Enforcement action includes, but is not limited to, such activities as warning letters, re-inspection, citations, administrative fines, permit suspension and hearings. Compliance and enforcement options may vary depending on state and local law.

The program must demonstrate credible follow-up for each violation noted during an inspection, with particular emphasis being placed on risk factors that most often contribute to foodborne illness and *Food Code* interventions intended to prevent foodborne illness. The resolution of out-of-compliance risk factors and/or *Food Code* interventions must be documented in each establishment record. The essential program elements required to meet this standard are:

- 1. A written step-by-step procedure that describes how compliance and enforcement tools are to be used to achieve compliance.
- 2. Inspection report form(s) that records and quantifies the compliance status of risk factors and interventions (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).
- 3. Documentation on the establishment inspection report form or in the establishment file using the statistical method for file selection in the Supplement to Standard 6, Appendix F, where at least 80 percent of sampled establishments meet the following conditions:
 - a) The inspection and enforcement staff takes compliance and enforcement action according to the procedure (i.e. the staff follow the step-by-step compliance and enforcement procedures when violations occur), and
 - b) Resolution was successfully achieved for all out-of-control risk factors or interventions that were recorded on the selected routine inspection.

Outcome

The desired outcome of this standard is an effective compliance and enforcement program that is implemented consistently to achieve compliance with regulatory requirements.

Documentation

The quality records needed for this standard include:

- 1. A copy of the written step-by-step enforcement procedures.
- 2. Inspection form that meets the criteria.
- 3. Documentation that compliance and enforcement action was taken correctly for at least 80 percent of the sampled establishments using the *Standard 6: Establishment File Worksheet* and the *Standard 6: Self-Assessment Summary Worksheet* when out-of-control risk factors or code interventions are recorded on routine inspections.
- 4. A reference "Key" which identifies the major risk factors and *Food Code* interventions on the jurisdiction's inspection report form. [Note: A jurisdiction will not be penalized under Standard 6 for sections of the *Food Code* which have not yet been adopted.

INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

STANDARD 6 – COMPLIANCE AND ENFORCEMENT

Program Self-Assessment and Verification Audit Form

The Standard 6: Program Self-Assessment and Verification Audit Form is designed to document the findings from the self-assessment and the verification audit process for Standard 6. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 6 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self Assessment

Jurisdictions conducting a self-assessment of Standard 6 must indicate on the form if each of the criteria is met. These responses are recorded under the column "Jurisdiction's Self-Assessment."

The self-assessor must review each Standard 6 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the *Standard 6: Program Self-Assessment and Verification Audit Form.*

If a review of the jurisdiction's source documents does not confirm that the Standard 6 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction's Self-Assessment" column of the *Standard 6: Program Self-Assessment and Verification Audit Form*. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 6: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed *Standard 6: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 6 criteria have been met.

Once all the Standard 6 criteria have been reviewed and the findings from the *Standard 6: Establishment File Worksheet* and the *Standard 6: Self-Assessment Summary Worksheet* documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 6: Program Self-Assessment and Verification Audit Form.* The self-assessor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 6 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 6 criteria.

Documenting the Findings from the Verification Audit

The jurisdiction requesting the verification audit must provide their completed *Standard 6: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 6: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any Standard 6 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, audit must complete the Verification Audit Summary section located on the first page of the *Standard 6: Program Self-Assessment and Verification Audit Form.* The auditor must:

- Enter their contact information:
- Document if the jurisdiction met the Standard 6 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 6 criteria if the auditor does not confirm the self-assessment findings.

Standard 6: Compliance and Enforcement Program-Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the Self-Assessment:		
Self-Assessor's Title:		
Jurisdiction Name:		
Jurisdiction Address:		
Phone: FAX:	E-mail:	
Date the Standard 6 Self-Assessment was Completed:		
Self-Assessment indicates that the Jurisdiction MEETS the Standard 6 criteria: YES	ard 6 criteria: YES 🗌 NO 🗌	
I affirm that the information represented in the Self-Assessment of Standard 6 is true and correct Signature of the Self-Assessor:	Standard 6 is true and correct	

VERIFICATION AUDIT SUMMARY

Printed Name of the Person who conducted the	onducted the Verification Audit:	
Verification Auditor's Title:		
Auditor's Jurisdiction Name:		
Auditor's Jurisdiction Address:		
Phone:	FAX:	E-mail:
Date the Verification Audit of Standard 6 was Completed:	dard 6 was Completed:	
Verification Audit indicates that th	Verification Audit indicates that the Jurisdiction MEETS the Standard 6 criteria: YES	NO
I affirm that the information represe	I affirm that the information represented in the Verification Audit of Standard 6 is true and correct	
Signature of the Verification Auditor:	or:	

Standard 6: Compliance and Enforcement Program-Self-Assessment and Verification Audit Form

Jurisdiction Name:

	Jurisc	diction	Jurisdiction's Self-Assessment		À	Verification Audit
Criteria	YES	ON	Self-Assessor's General Comments	YES	ON	If NO, Auditor is to specify why criterion is not met
1. Compliance and Enforcement Procedure						
a) The jurisdiction has a written step-by-step compliance and enforcement procedure that describes what actions and tools (i.e. forms, documents, interventions) are to be used to achieve compliance.						
b) The jurisdiction's inspection form(s) record and quantify the compliance status of foodborne illness risk factors, <i>Food Code</i> interventions and other serious serious code violations.						
2. Assessment of Effectiveness						
a) The jurisdiction has written documentation that verifies the review of the effectiveness of the staff's implementation of the program's compliance and enforcement procedure that includes a selection of establishment files for review in accordance with the Standard criteria.						
b) The jurisdiction has written documentation verifying that at least 80% of the sampled files follow the agency's step-by-step compliance and enforcement procedures and actions were taken to resolve out-of-compliance risk factors recorded on the selected routine inspection in accordance with the Standard criteria.						

Standard 6: Compliance and Enforcement Program-Self-Assessment and Verification Audit Form

GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

STANDARD 6 – COMPLIANCE AND ENFORCEMENT

Using the Standard 6 Establishment File Worksheet

The self-assessor should have the Standard 6 self-assessment worksheets available as a reference when reading through this guidance. The following worksheets are provided at the end of these instructions:

- Standard 6: Self-Assessment Summary Worksheet
- Standard 6: Establishment File Worksheet

The *Standard 6: Self-Assessment Summary Worksheet* is designed to provide a listing of the establishments randomly selected from the jurisdiction's inventory that were reviewed as part of the self-assessment process. This worksheet provides a summary as to whether or not the inspection file/records for each of the randomly selected establishments meet the Standard 6 criteria.

The *Standard 6: Establishment File Worksheet* provides a systematic way of collecting the compliance and enforcement history for each of the randomly selected establishments. Jurisdictions do not have to use this form. However, a jurisdiction must provide documentation of the review process. The documentation must indicate if appropriate compliance and enforcement actions were taken for out-of-control risk factors and *Food Code* interventions at each establishment randomly selected for the self-assessment.

STEP 1 – Assess the Elements in the Written Compliance & Enforcement Program

To meet the criteria of Standard 6, the jurisdiction must have written step-by-step procedures outlining its compliance and enforcement process. The jurisdiction should review its compliance and enforcement policies and procedures to ensure that there is clear guidance for staff. The policies and procedures should provide steps and actions to be taken when various categories of violations occur. The policies and procedures should also provide a progression of steps to be taken when violations are not corrected within regulatory or administratively established time frames.

In addition, the jurisdiction's inspection form must use the IN compliance, OUT of compliance, Not Applicable, and Not Observed conventions to record the compliance status of the foodborne illness risk factors and the public health interventions identified in the *Food Code* to meet the requirements of Standard 6.

STEP 2 – Assess the Effectiveness of the Compliance & Enforcement Program

Randomly selected establishment files will be reviewed to determine if documented violations were resolved satisfactorily in the establishment. The results of the review will be used to assess the success of the compliance and enforcement program. This section of the self-assessment process has been broken down into the following four parts:

- **Part I** Determine the number of establishment files to review
- **Part II** Randomly select establishment files from the jurisdiction's inventory

Part III Conduct a review of each randomly selected establishment file

Part IV Determine the need to review additional randomly selected establishment files

Part I - Determine the number of establishment files to review

Jurisdictions with less than 800 total establishments must select at least 40 files for review. If a jurisdiction has less than 40 establishments in the inventory, then all files will be reviewed. Jurisdictions with 800 or more establishments must select a sample equal to 5% of the total establishments (up to a maximum of 70 files). This initial selection of sample files must be the first files reviewed.

Establishment Inventory	Number of Files to Review
Less than 800	40 establishment files
800 or more	5% of the total number of establishments (Up to a maximum of 70 files)

Part II - Randomly select establishment files from the jurisdiction's inventory Sample selection using a table of random numbers or a random number generator is preferred. This can be performed with a card file, ledger, list, or automated data system. The card file, ledger, list or automated database must be numbered or ordered in some fixed fashion so that the establishment files can be associated with the numbers selected by the random number generator.

There are many ways a jurisdiction can produce a listing of all the establishments in its inventory. The listing can be produced alphabetically; by permit number; permit date, etc. The establishment listing can be computer generated or it can be produced manually. Any method can be used as long as all the establishments are included once and only once.

When randomly selecting establishments, the self-assessor must perform the following steps:

- 1. Record the random numbers in the order they were selected under the column "Randomly Selected Numbers" on the *Standard 6: Self-Assessment Summary Worksheet*;
- 2. Identify the establishment file that corresponds to the randomly selected number recorded on the *Standard 6: Self-Assessment Summary Worksheet*; and
- 3. Record the establishment name or identification number for each of the randomly selected numbers on the *Standard 6: Self-Assessment Summary Worksheet*.

Part III - Conduct a review of each randomly selected establishment file When reviewing the compliance and enforcement history for each of the randomly selected files, the self-assessor should use a form similar to the Standard 6: Establishment File Worksheet to document their findings. This worksheet is included at the end of these instructions.

For each randomly selected establishment listed on the *Standard 6: Self Assessment Summary Worksheet*, the self-assessor must complete a separate *Standard 6: Establishment File Worksheet*.

The worksheet must document the following information:

- ➤ The name of the establishment and the permit number in the upper left hand corner of the "Establishment File Worksheet;"
- The "Start Point Inspection Date" under the heading provided. The "start-point" inspection willbe the third oldest routine inspection in the establishment's file at the time of the review if it shows a violation of one of the risk factors or public health interventions. If no risk factor or public health intervention violation is shown on that inspection, then the fourth oldest routine inspection may be used if it shows a risk factor or public health intervention violation. If no violation of a risk factor or public health intervention is documented on the third or fourth oldest routine inspection, then no "start-point" inspection exists for that establishment. Therefore, that establishment's file "does not qualify" for the self-assessment review process. If the establishment "does not qualify," the self-assessor must check the D.N.Q (did not qualify) box under the "Status of Reviewed File" and remove it from the review process. A substitute establishment file must be chosen using the second set of randomly selected numbers to replace this file.
- ➤ The Establishment File Worksheet lists ten foodborne illness risk factor and public health interventions along the top line. The self-assessor will record item numbers or other identifiers from its inspection form that correspond with each of the ten listed risk factors and public health intervention in the spaces provided adjacent the heading *Reference to local inspection items*.
 - **Note:** The self-assessor should use the *Standard 1: Self-Assessment Worksheet for Part I Inter*ventions *and Risk Factor Controls* to identify the jurisdiction's code requirements that correspond to the *Food Code* provisions included under each of the ten foodborne illness risk factor and intervention categories. If there is no corresponding local requirement for a particular foodborne illness risk factor or *Food Code* intervention, that item can be marked as "Not Applicable" in the *Reference Key*. Jurisdictions are not penalized under Standard 6 for items in the *Food Code* that have not been adopted.
- Using the *Start Point Inspection Violations* row of the worksheet, the self-assessor places an "X" under the appropriate foodborne illness risk factor or public health intervention headings if a violation was noted on the "start-point" inspection. The "X" must be entered under the appropriate heading even if the violations were corrected on site.
- For the purposes of the self-assessment, follow-up actions have been divided into three types:
 - Was on-site corrective action taken? On-site corrective action that occurs at the time of a routinely scheduled inspection;
 - Was follow-up corrective action taken? Follow-up action that occurs after the routine inspection such as re-inspection, training, risk control plans, and informal conferences;
 - Was enforcement action taken? Enforcement activities such as fines permit suspension, hearings, mandated training, restriction of operations, embargo, etc.

Completion of these three items requires a complete review of the selected establishment file. To facilitate the documentation of the file review, the self-assessor may complete the table provided at the bottom of the Establishment File Worksheet. The summary table provides a

method for defining the acronyms and notations used on the worksheet to describe the type of compliance and enforcement action taken. The self-assessor must review all the documentation in the establishment file from the "start-point" inspection forward to the current date to determine if follow-up action was taken and documented for each risk factor and public health intervention that was out of compliance on the "start-point" inspection.

- The self-assessor must review the follow-up actions for each risk factor and public health intervention violation documented on the "start-point" inspection. The self-assessor must determine if the follow-up actions complied with the jurisdiction's written procedures.
 - The self-assessor must place an "X" in the "File Meets the Standard 6 Criteria" box if:
 - O The completed Worksheet shows at least one follow-up action in each column where a foodborne illness risk factor or public health intervention violation was marked on the "start-point" inspection; and
 - o The jurisdiction's written procedure was followed.
 - The self-assessor must place an "X" in the "File Does NOT Meet the Standard 6 Criteria box." if:
 - O The completed Worksheet shows that one or more of the "start-point" violations do not have at least one follow-up activity; or
 - O The jurisdiction's written procedure was not followed for one or more follow-up activities.
- ➤ When the review for each randomly selected establishment file is completed, the self-assessor must indicate his or her findings on the Self-Assessment Summary Worksheet. Under the "Status of Reviewed File" column, the self-assessor must check one of the following boxes:
 - "YES" indicating that the reviewed file meets the Standard 6 criteria.
 - "NO" indicating that the reviewed file does not meet the Standard 6 criteria.
 - "D.N.Q." indicating that the establishment file did not qualify for the assessment and a substitute file will need to be randomly selected and reviewed.

Part IV - Determine the need to review additional randomly selected establishment files Randomly selected establishment files should be removed from the sample only if:

- The establishment has not been in business long enough to have at least three routine inspections; or
- Files in which no risk factor or public health intervention violation was documented on the "start-point" inspection.

When an establishment file is eliminated from the initial random draw, a new establishment file must be selected using the random selection methodology used for the original sample. The *Establishment File Worksheet* contains a specific page for listing the results from the randomly selected substitute establishment files. If there is a need to identify other substitute establishment files, continue to use the randomly generated numbers in the order they appear to identify the corresponding establishments from the jurisdiction's inventory. The file number and the name of the originally selected

establishment that did not qualify for the self-assessment review process must be recorded under the first column of the "Substitute Establishment" summary worksheet. This provides a direct association between the newly selected establishment file and the one it is replacing.

STEP 3 - Determine if the Standard 6 criteria are met

Standard 6 requires that 80 percent of the reviewed files adhere to the jurisdiction's written compliance and enforcement procedures. Files that "did not qualify" (D.N.Q.) for the self-assessment review are not included in the calculation for this percentage. The self-assessor must determine if 80% of the establishment files reviewed met the Standard 6 criteria.

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Number Randomly of Files Selected Selected Number	y Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
12					
13					
14					
15					
16					
17					
18					
19					
20					

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
31						
32						
33						
34						
35						
36						
37						
38						
39						
40						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
41						
42						
43						
44						
45						
46						
47						
48						
49						
50						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
51						
52						
53						
54						
55						
56						
57						
58						
59						
09						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
61						
62						
63						
64						
65						
66						
67						
68						
69						
70						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
2						
3						
4						
5						
9						
7						
8						
6						
10						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

Voluntary National Retail Food Regulatory Program Standards - January 2017

Standard 6: Compliance and Enforcement

Standard 6: Compliance and Enforcemer Establishment File Worksheet

Start Point):		Employee Health Control system or policy implemented						ions	ia:
Inspection Date (Start Point):		Demonstration of Knowledge by PIC						dditionally, written	File Does NOT Meet the Standard 6 Criteria: [
		Consumer Advisory (when required)						to pass. A	the Stan
		Contaminated Food Contact Surface & Equipment						NO Cert for the file NO Acronym / Notation	s NOT Meet
ber:	tions	Poor Personal Hygiene						Stions in or	File Doe
Permit Number:	ode Interven	Bare Hand Contact with Ready-to-Eat Food						the three que: re Followed? and notations Definitions	
	Risk Factor and $Food\ Code\ $ Interventions	Time/ Temperature Parameters not Met (Time as a Control, date marking, rapid cooling)						Note: 1. Each column in which a violation is noted must receive a yes response to one of the three questions in order for the file to pass. Additionally, written procedures must have been followed. Was the Written Procedure Followed? YES NO	eria:
Establishment Name:	I	Improper Holding Temperatures Hot & Cold						Jurisdictions d	Select One File Meets the Standard 6 Criteria:
Esta		Inadequate Cooking						olation is no followed. Definitions	One feets the S
		Unsafe Source						vhich a vi	Select One File Meet
File Number:			Reference to local inspection items	Start Point Inspection Violations	Was on-site corrective action taken?	Vas follow-up corrective action taken?	Vas enforcement action taken?	Note: 1. Each column in which a violation is r procedures must have been followed. Acronym / Definition Notation	

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

STANDARD 6 – COMPLIANCE AND ENFORCEMENT

Using the Standard 6: Verification Audit Worksheet

The auditor should have the *Standard 6: Verification Audit Worksheets* available as a reference when reading through this guidance. The following worksheet is provided at the end of these instructions:

• Standard 6: Verification Audit Worksheet

The Standard 6: Verification Audit Worksheet is designed to provide a listing of the establishments randomly selected from the jurisdiction's inventory that were reviewed as part of the self-assessment process. This worksheet provides a summary as to whether or not the inspection file/records for each of the randomly selected establishments meet the Standard 6 criteria.

The Standard 6: Establishment File Worksheet provides a systematic way of collecting the compliance and enforcement history for each of the randomly selected establishments. Jurisdictions do not have to use this form. However, a jurisdiction must provide documentation of the review process. The documentation must indicate if appropriate compliance and enforcement actions were taken for out-of control risk factors and Food Code interventions at each establishment randomly selected for the self-assessment.

STEP 1 – Verify the Elements in the Written Compliance & Enforcement Program

To meet the criteria of Standard 6, the jurisdiction must have written step-by-step procedures outlining its compliance and enforcement process. The verification auditor should review its compliance and enforcement policies and procedures to ensure that there is clear guidance for staff. The policies and procedures should provide steps and actions to be taken when various categories of violations occur. The policies and procedures should also provide a progression of steps to be taken when violations are not corrected within regulatory or administratively established time frames.

Standard 6 does not dictate a required compliance process. The jurisdiction is free to determine any actions to be taken for violations of its regulations and the progression of consequences for repeated violations. The time frames and triggers for additional actions are also left to the discretion of the jurisdiction.

In addition, to meet the requirements of Standard 6, the jurisdiction's inspection form must use the IN compliance, OUT of compliance, Not Applicable, and Not Observed conventions to record the compliance status of the foodborne illness risk factors and the public health interventions identified in the *Food Code*.

Jurisdictions that have not adopted all the recommended foodborne illness risk factors and *Food Code* interventions are not penalized under Standard 6 for these omissions.

STEP 2 – Verify the Effectiveness of the Compliance & Enforcement Program

Randomly selected establishment files must be reviewed to determine if documented violations were resolved satisfactorily. The results of the review will be used to assess the success of the compliance and enforcement program. This section of the self-assessment process has been broken down into the following four parts:

- **Part I** Verify that the jurisdiction reviewed the appropriate number of files
- **Part II** Randomly select establishment files from the jurisdiction's *Standard 6:* Self-Assessment Summary Worksheet
- Part III Verify Self-Assessment findings for each selected establishment file
- **Part IV** Verify that 80% of selected establishment files adhere to the jurisdiction's written compliance and enforcement procedures

Part I - Verify that the jurisdiction reviewed the appropriate number of files The number of establishment files a jurisdiction must review as part of the Standard 6 self-assessment process is based on the size of their establishment inventory. Jurisdictions with less than 800 total establishments must select at least 40 files for review. If a jurisdiction has less than 40 establishments in the inventory, then all files will be reviewed. Jurisdictions with 800 or more establishments must select a sample size equal to 5% of the total establishments up to a maximum of 70 files.

Establishment Inventory	Number of Files to Review for the Self-Assessment
Less than 800	40 establishment files
800 or more	5% of the total number of establishments (Up to a maximum of 70 files)

Some of the randomly selected establishment files listed on the *Standard 6: Self-Assessment Summary Worksheet* may not qualify for the self-assessment process. Deletion of an establishment from the sample of files to be reviewed as part of the self-assessment process is limited to those establishments where:

- 1. The selected establishment has not been in business long enough to have at least three regularly scheduled routine inspections; or
- 2. A review of inspection reports in the selected establishment file reveals that there were no risk factor or *Food Code* intervention violations documented on the "start-point" inspection

The jurisdiction's self-assessment process must include a listing of the substitute establishment files that were reviewed as replacements for those that did not qualify. When an establishment does not qualify for the self-assessment process, the substitute establishment must not be recorded on the *Standard 6*: *Self-Assessment Summary Worksheet*, but instead on the *Standard 6*: *Self-Assessment Summary Worksheet*. The auditor should verify this.

Part II - Randomly select establishment files from the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*

Using a table of random numbers or a random number generator is the preferred method of sample selection. The random selection will be made from the establishment files listed on the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*. The number of establishment files that must be selected for review as part of the verification audit process is indicated in the chart below.

Establishment Inventory		Number of Files to Select for the Verification Audit	
Less than 800	40 establishment files	5	
800 or more	5% of the total number of establishments (Up to a maximum of 70 files)	10	

Using the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet*, the verification auditor will identify the establishment files that correspond to the randomly selected number recorded on the *Standard 6: Verification Audit Worksheet*. The verification auditor must record the establishment name or identification number for each of the randomly selected numbers on the *Standard 6: Verification Audit Worksheet*.

The verification auditor must only review establishment files that the jurisdiction has indicated as meeting all the elements of their compliance and enforcement procedures. This will require the verification auditor to eliminate establishment files that are marked "NO" on the jurisdiction's Self-Assessment Summary Worksheet. (An "X" placed in the "NO" box indicates that the self-assessment review process determined that the inspection history documented in the establishment file did not meet, or only partially met, the Standard 6 criteria and all the elements in the jurisdiction's written compliance and enforcement procedures.)

In instances where the verification auditor has randomly selected an establishment file from the jurisdiction's *Standard 6: Self-Assessment Summary Worksheet* that did not qualify (D.N.Q.) for the self-assessment review process, the substitute establishment that the jurisdiction selected for that disqualified establishment should be used.

Note: There are two types of substitutes for the audit process, which are treated differently:

- 1. If the auditor selects an establishment that was previously failed by the self-assessor, then use the auditor-generated substitute list of random numbers to select a substitute establishment.
- 2. If the auditor selects an establishment that "did not qualify" for the original self-assessment, then use the substituted establishment that was already assigned in the original self-assessment review.

Part III - Verify Self-Assessment findings for each selected establishment file

Using the jurisdiction's written compliance and enforcement procedures, the verification auditor will review the Establishment File Worksheet for each of the establishments randomly selected for the verification audit.

The *Standard 6: Establishment File Worksheet* provides a systematic way of documenting the compliance and enforcement history for each of the randomly selected establishments. Jurisdictions do not have to use this form but must provide documentation of the review process conducted to determine whether the appropriate compliance and enforcement actions for out-of-control risk factors and *Food Code* interventions were taken for each selected establishment.

Review the inspection history in each selected file beginning with the identified "start-point" inspection and moving forward through two additional inspections. Verify that either on-site corrective action, follow-up corrective action or enforcement action occurred by the end of the third inspection for each out-of-compliance risk factor or intervention marked on the start point inspections. In addition, verify that the actions taken on each violation documented on the "start-point" inspection followed the jurisdiction's written compliance policy and procedures.

In order for an establishment file to meet the Standard 6 criteria, each column marked with a violation at the "start-point" inspection must have a subsequent indication that at least one type of follow-up action was taken and the jurisdiction's written procedures must have been followed. A single violation on the "start-point" inspection without a final resolution, either correction or compliance/enforcement activity, will result in a determination that the establishment file does not meet the Standard 6 criteria. In any instances where the auditor disagrees with the jurisdiction's self-assessment of a file, the auditor must meet with the jurisdiction's program manager or representative to gain a full understanding of the rationale used for the self-assessment determination.

The verification auditor will record his or her findings for each of the establishment files reviewed on the *Standard 6: Verification Audit Worksheet*. If the verification audit of the establishment file review indicates that the full intent of the Standard 6 criteria is met, place an "X" in the "YES" box. If full intent of the Standard 6 criteria is not met, place an "X" in the "NO" box. If the verification auditor disagrees with the jurisdiction's self-assessment decision, an explanation must be provided in the last column of the *Standard 6: Verification Audit Worksheet*. Additional sheets can be used to document the need for expanded explanations.

Part IV - Verify that 80% of selected establishment files adhere to the jurisdiction's written compliance and enforcement procedures

The criteria for Standard 6 requires that 80 percent of the files with an identified violation of a foodborne illness risk factor or a *Food Code* intervention on the "start-point" inspection adhere to the jurisdiction's written compliance and enforcement procedures. Files that "did not qualify" (D.N.Q.) for the self-assessment review are not used in the calculation of the percentage.

Legitimate differences of opinion regarding stringency of language may occur during the verification audit process. An approximate ten percent (10%) discrepancy allowance is made to accommodate potential differences in interpretations.

<u>Jurisdictions with less than 800 Establishments</u> - If two or more of the five audited establishment files rated as passing by the jurisdiction are not verified by the auditor as having met the Standard 6 criteria, the Part III element fails to meet the criteria, and no further sampling is necessary. Even if no additional disagreements are found by sampling an additional set of randomly drawn establishment files, the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Determine the need for supplemental sampling. If only one establishment file from the initial sample is determined by auditor to have not met the Standard 6 criteria, then randomly select an additional 5 establishment files. Follow the same audit process used to review the first set of establishment files. The *Standard 6: Verification Audit Worksheet* for substitute establishment files, provided on a following page, can be used to record all the information related to the supplemental sampling of establishment files.

If no additional disagreements in the review of establishment files are noted, then the jurisdiction meets the Standard 6 criteria. If one or more additional establishment files fails the audit review, then the Standard 6 criteria is not met, since the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

<u>Jurisdictions with more than 800 Establishments</u> - If three or more of the ten audited establishment files rated as passing by the jurisdiction are not verified by the auditor as having met the Standard 6 criteria, then the jurisdiction fails to meet Standard 6. Even if no additional disagreements are found by sampling an additional set of randomly drawn establishment files, the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Determine the need for supplemental sampling. If one or two establishment files from the initial sample are determined by auditor to have not met the Standard 6 criteria, then randomly select an additional 10 establishment files. Follow the same audit process used to review the first set of establishment files. The *Standard 6: Verification Audit Worksheet* for substitute establishment files, provided on a following page, can be used to record all the information related to the supplemental sampling of establishment files.

No more than a total of two of 20 establishment files drawn can be determined by the auditor as not meeting the Standard 6 criteria. If more than two establishment files fail the audit review, then the Standard 6 criteria is not met, since the dilution of agreements to disagreements will be insufficient to meet the approximate ten percent (10%) disagreement allowance.

Standard 6: Compliance and Enforcement Verification Audit Worksheet Establishment Files

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	If NO, Auditor is to specify why the establishment file does not meet all the elements contained in the jurisdiction's written compliance and enforcement procedures
-						
2						
3						
4						
5						
9						
7						
8						
6						
10						

Standard 6: Compliance and Enforcement Verification Audit Worksheet Substitute Establishment Files

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	If NO, Auditor is to specify why the establishment file does not meet all the elements contained in the jurisdiction's written compliance and enforcement procedures
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

EXPLANATION OF THE STATISTICAL MODEL FOR STANDARD 6

In this part of the self-assessment, the self-assessor or auditor will review a randomly selected sample of establishment files. The review will determine if the establishments were given adequate follow-up for documented violations. Each file will be scored as passing or failing each of four aspects. In order for the program to pass, each aspect must be found passing for at least 80 percent of the establishment files reviewed.

If the inventory of establishment files is less than 800, the self-assessor or auditor must randomly select 40 files at a minimum. If the inventory of establishment files is 800 or more, the self-assessor or auditor must randomly select 5 percent of the inventory (up to a maximum of 70).

At the smallest sample, a 90 percent performing jurisdiction would pass the standard 95.4 percent of the time using 40 files. Using 45 files, the passing rate would increase to 96.4 percent, and using 50 files it raises to 97.2 percent. Raising the minimum number of files from 20 to 40 would increase the workload by 50 percent. It would reduce the risk of failure, however, for a 90 percent performer from 12.4 percent to 7.6 percent, a 41 percent reduction. Considering the consequences of failing, it is possible that some programs with inventories much less than 800 might still wish to expand their sampling to 40 files. For purposes of the self-assessment requirements, 40 is the minimum number of files to be reviewed but a larger minimum is permitted.

The statistical task here was to determine an upper bound on the sample size in order to avoid wasted effort. The proposition that was used to decide the upper bound was to have a high rate of passage for any program that does each aspect correctly 90 percent of the time. A further proposition was that we have a low rate of passage for any program that does each aspect correctly only 70 percent of the time.

Even at the smallest sample of 40 files, a 70 percent performing program would pass the standard only 1.3 percent of the time; at 30 files the passing percent drops to 0.4 percent. Therefore, the low passing rate for 70 percent performers will be met easily by any upper bound.

For inventories of 800 or more, the standard calls for sampling 5 percent of the inventory, up to some limit. The following are the probabilities of passing the Standard for a series of sample sizes, given that the program is a 90 percent performer for each aspect in any particular file review.

Sample	Probability of passing if overall performance is 90%
20	0.876
25	0.903
30	0.924
35	0.941
40	0.954
45	0.964
50	0.972
55	0.978

Sample	Probability of passing if overall performance is 90%
60	0.983
65	0.987
70	0.990
75	0.992
80	0.994
85	0.995
90	0.996

At 70 files, a 90 percent performing program has a 99 percent chance of passing this Standard. Going further buys only tiny increments of improvement. At much higher sample sizes of around 140 files, lower performing programs significantly increase their chances of passing, a change of fortune that favors the very biggest programs. Therefore the upper limit boundary has been set at 70 files for all programs of all sizes.

STANDARD 6: COMPLIANCE AND ENFORCEMENT ESTABLISHMENT FILE WORKSHEET

	Unsafe Source	Inadequate Cooking	Improper Holding Temperatures Hot & Cold	Time/ Temperature Parameters not Met (Time as a Control, date marking, rapid cooling)	Bare Hand Contact with Ready-to-Eat Food	Poor Personal Hygiene	Contaminated Food Contact Surface & Equipment	Consumer Advisory (when required)	Demonstration of Knowledge by PIC	Employee Health Control system or policy implemented
Reference to local inspection items										
rt Point Inspection Violations										
s on-site corrective										
action taken? follow-up corrective										
action taken? enforcement action										
	_									
Note:		ı					<u>I</u>			
			_	e a yes response to one of		VEC		e to pass. A	dditionally, wri	tten
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1. Each column in			W		re Followed?	YES	NO	·	dditionally, wri	tten
1. Each column in			Jurisdictions of	Vas the Written Procedur	re Followed?	YES	NO	·	dditionally, wri	
Each column in procedures mus Acronym /		n followed.	Jurisdictions of	Vas the Written Procedur definitions of acronyms a	e Followed?	YES	NO reflect follow-	·		
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STANDARD 7 INDUSTRY AND COMMUNITY RELATIONS

Table of Contents

REQUIREMENT SUMMARY	2
DESCRIPTION OF REQUIREMENT.	
1. Industry and Consumer Interaction	
2. Educational Outreach.	
OUTCOME	

STANDARD 7 INDUSTRY AND COMMUNITY RELATIONS

This standard applies to industry and community outreach activities used by a retail food regulatory program to solicit a broad spectrum of input about a retail food regulatory program's previous, current, and future activities, communicate sound public health food safety principles, and foster and recognize community initiatives focused on the reduction of foodborne illness risk factors.

Requirement Summary

The jurisdiction documents participation in forums that foster communication and information exchange among the regulators, industry and consumer representatives.

The jurisdiction documents outreach activities that provide educational information on food safety.

Description of Requirement

1. Industry and Consumer Interaction

The jurisdiction sponsors or actively participates in forums with two-way communication such as food safety task force meetings, advisory boards, advisory committees, customer surveys, web-based meetings or forums, or other mechanisms. These forums shall present information on food safety, food safety strategies and interventions to control risk factors. Offers of participation must be extended to industry and consumer representatives.

2. Educational Outreach

Outreach encompasses industry and consumer groups as well as media and elected officials. Outreach efforts may include industry recognition programs, web sites, newsletters, FightBAC ® campaigns, food safety month activities, food worker training, school-based activities, use of oral culture learner materials, or other activities that increase awareness of the foodborne illness risk factors and control methods to prevent foodborne illness. Outreach activities may also include posting inspection information on a web site or in the press.

Agency participation in at least one activity in each of the above categories annually is sufficient to meet this standard.

Outcome

The desired outcome of this standard is enhanced communication with industry and consumers through forums designed to solicit input to improve the retail food regulatory program. A further outcome is the reduction of foodborne illness risk factors through educational outreach and cooperative efforts with stakeholders.

Documentation

The quality records needed for this standard include:

- 1. Minutes, agendas or other records documenting that forums were conducted,
- 2. For formal, recurring meetings, documents such as by-laws, charters, membership criteria and lists, frequency of meetings, roles, etc.,
- 3. Surveys, web feedback links with associated follow-up materials and review documents,
- 4. Documentation of activities designed with input from industry and consumers to improve the control of foodborne illness risk factors, or
- 5. Documentation of food safety educational efforts.

Statements of policies and procedures may suffice if activities are continuous, and documenting multiple incidents would be cumbersome, (e.g, recognition provided to establishments with exemplary records or an on-going web site).

INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

STANDARD 7 – INDUSTRY AND COMMUNITY RELATIONS

Program Self-Assessment & Verification Audit Form

The *Standard 7: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 7 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self Assessment

Jurisdictions conducting a self-assessment of Standard 7 must indicate on the form if each of the criteria is met. The self-assessor must record their findings under the column "Jurisdiction's Self Assessment."

Jurisdictions are not obligated to use the form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 7 criteria listed on the form are available for review.

The self-assessor must review each Standard 7 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the Standard 7 Program Self-Assessment and Verification Audit Form.

If a review of the jurisdiction's source documents does not confirm that the Standard 7 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction's Self-Assessment" column of the *Standard 7: Program Self-Assessment and Verification Audit Form*. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 7: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed *Standard 7: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 7 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 7: Program Self-Assessment and Verification Audit Form.* The self-assessor must:

- Enter their contact information:
- Document if the jurisdiction met the Standard 7 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 7 criteria.

Documenting the Findings from the Verification Audit

The jurisdiction requesting the verification audit must provide their completed *Standard 7: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 7: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor must place an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor must place and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any Standard 7 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 7: Program Self-Assessment and Verification Audit Form.* The auditor must:

- Enter their contact information:
- Document if the jurisdiction met the Standard 7 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 7 criteria if the auditor does not confirm the self-assessment findings.

Standard 7: Industry and Community Relations Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the	d the Self-Assessment:	
Self-Assessor's Title:		
Jurisdiction Name:		
Jurisdiction Address:		
Phone:	FAX:	E-mail:
Date the Standard 7 Self-Assessment was Completed:	Completed:	
Self-Assessment indicates that the Jurisdic	Self-Assessment indicates that the Jurisdiction MEETS the Standard 7 criteria: YES	NO
l affirm that the information represented in	I affirm that the information represented in the Self-Assessment of Standard 7 is true and correct	\$ 0
Signature of the Self-Assessor:		
	VERIFICATION AUDIT SUMMARY	AARY
Printed Name of the Person who conducted the	d the Verification Audit:	
Verification Auditor's Title:		
Auditor's Jurisdiction Name:		
Auditor's Jurisdiction Address:		
Phone:	FAX:	E-mail:
Date the Verification Audit of Standard 7 was Completed:	was Completed:	
Verification Audit indicates that the Jurisdiction MEETS the Standard 7 criteria:	diction MEETS the Standard 7 criteria: YES $\ \square$	NO
l affirm that the information represented in 1	I affirm that the information represented in the Verification Audit of Standard 7 is true and correct	ect

Signature of the Verification Auditor:

Standard 7: Industry and Community Relations Program Self-Assessment and Verification Audit Form

	Juris	diction	Jurisdiction's Self-Assessment		Λ	Verification Audit
Criteria	YES	NO	Self-Assessor's General Comments	YES	ON	If NO, Auditor is to specify why criterion is not met
1. Industry and Consumer Interaction						
a) The jurisdiction maintains written documentation confirming that the agency has sponsored or actively participated in at least one meeting/forum annually, such as food safety task forces, advisory boards / committees, customer surveys, web-based meetings or forums. Documentation confirms that offers of participation have been extended to industry and consumer representatives.						
2. Educational Outreach						
a) The jurisdiction maintains written documentation confirming that the agency has sponsored or coordinated at least one educational outreach activity annually directed at industry, consumer groups, the media, and/or elected officials. Educational outreach activities focus on increasing awareness of foodborne illness risk factors and control methods to prevent foodborne illness and may include industry recognition programs, web sites, newsletters, Fight BAC campaigns, food safety month activities, food worker training, and use of oral culture learner materials.						

Standard 7: Industry and Community Relations Program Self-Assessment and Verification Audit Form

GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

STANDARD 7 – INDUSTRY AND COMMUNITY RELATIONS

Using the Standard 7 Self-Assessment Worksheet

The *Standard 7: Self-Assessment Worksheet* is designed to assist jurisdictions with maintaining documentation and information required in the Standard 7 criteria. The *Standard 7: Self-Assessment Worksheet* is divided in two sections:

- 1. Industry and Consumer Interaction; and
- 2. Educational Outreach.

STEP 1 – Confirm Documentation of Industry and Consumer Interaction Forums

The jurisdiction must maintain written documentation confirming that the agency has sponsored or actively participated in at least one meeting/forum annually. Meetings and forums include, but are not limited to food safety task forces, advisory boards or advisory committees, customer surveys, and web based meetings or forums. Documentation also confirms that offers of participation have been extended to industry and consumers. The jurisdiction must sponsor or participate in activities within its regulated community. These activities must be documented in Part I on the *Standard 7: Self-Assessment Worksheet*. The jurisdiction can use a different form if that document captures the same information. The worksheet is included at the end of these instructions.

In order to properly document these activities, the self-assessor must:

- Enter the name of the forum/meeting under the "Forum Title" column;
- Document the names of meeting/forum participants. (The appropriate column should be used to document participants from regulatory agencies, industry, and the public). If industry or consumers were not present at a meeting, a statement should be entered that conveys that an offer to participate was extended to these groups. The jurisdiction must maintain records to show that an effort was made to gain input from the regulated community and the public. Copies of letters of invitation or email print-outs soliciting participation may be retained to substantiate the offer:
- Confirm that the dates of meetings have been recorded because it establishes that the activity took place at least once annually in the most recent five-year period of the self-assessment. If meetings are recurring such as held monthly, the jurisdiction may record "monthly" under the date column and include the inception date of the meeting/forum; and
- Document action items and program items that resulted from the meeting. These should be documented in the final column titled "Summary of Activities Related to Control of Risk Factors."

Examples of documents that may be reviewed as part of the self-assessment process

- Minutes or agendas from the forum/meeting that describe the topics covered and the participants present.
- For formal, recurring meetings, documents such as by-laws, charters, membership criteria and lists that detail the purpose of the meetings, the committee make-up, frequency of meetings, and

- roles of participants.
- ➤ Brochures that detail the purpose of the meeting and topics that were presented, or illustrate collaborative food safety efforts by regulatory, industry and/or consumers.
- Letters or printed email messages that document invitations to consumers and/or industry representatives to participate in forums/meetings.

STEP 2 – Review Documentation of Educational Outreach

To meet the standard criteria, the jurisdiction must have performed at least one educational outreach activity per year during the most recent five-year period of the self-assessment. The educational outreach activity can be focused on industry, the media, consumers and/or elected officials. The methods of outreach and a summary of the activities should be recorded in Part II of *Standard 7: Self-Assessment Worksheet*.

In order to properly document the education outreach activities, the self-assessor must:

- Record the date of the educational outreach activity under the "Date" column of the worksheet. For outreach activities that are on-going such as the quarterly issuance of a food safety bulletin or a website that posts inspection scores or other food safety information, the jurisdiction need not record each date. For documentation of this component on the worksheet the information may be listed as ongoing using a date range such as "January 1 December 31, 2013" or "Ongoing since 2008." The jurisdiction would need to include the date the activity began so it can be shown that the activities occurred over the most recent five-year period.
- Briefly describe the educational outreach initiative that was conducted on the recorded date or within the specified time frame. This should be done under the "Summary of Activities" column.

Examples of documents that may be reviewed as part of the self-assessment process:

- Food Safety Brochures or Flyers
- Completed Customer Survey Cards
- ➤ Dated pictures of Food Safety Activities such as Fight BAC events held in the community, display booths at fairs
- > Jurisdiction Websites
- Food Safety Newsletters
- Acknowledgement letters thanking members from the regulatory agency for providing food safety training in forums such as schools, churches, and civic groups
- ➤ A listing of scheduled Manager Certification courses
- Sign-in Sheets from Training or Courses offered to consumers and the regulated industry
- Minutes from meetings on food safety with elected officials
- Newspapers with printed food service facility scores
- Agendas from food safety expos

Standard 7: Industry and Community Relations Self-Assessment Worksheet

Meeting minutes, agendas, by-laws, charters, membership criteria and lists, frequency of meetings, roles, performed actions and It is necessary to maintain records of the Industry and Consumer Interaction forums and of the Educational Outreach activities over the most recent five-year period. The following chart is used to document the occurrence of those forums and activities. documentation of food safety educational efforts must be maintained by the regulatory authority.

PART I - Industry and Consumer Interaction Forums

Summary of Activities Related to Control of Risk Factors			
Meeting Dates			
Consumer Participants by Organization			
Industry Participants by Organization			
Regulatory Industry Participants by Organization			
Forum Title			

Standard 7: Industry and Community Relations Self-Assessment Worksheet

PART II - Educational Outreach

Dates	Summary of Activities

STANDARD 8 PROGRAM SUPPORT AND RESOURCES

Table of Contents

REQUIREMENT SUMMARY	
DESCRIPTION OF REQUIREMENT	
DESCRIPTION OF REQUIREMENT 1. Staffing Level	
2. Inspection Equipment	
3. Administrative Program Support	
4. Regulatory Foundation	
5. Trained Regulatory Staff	
6. Inspection Program Based on HACCP Principles	
7. Uniform Inspection Program	
8. Foodborne Illness & Food Defense Preparedness & Response	
9. Compliance & Enforcement	
10. Industry & Community Relations	
10. Industry & Community Relations	
12. Accredited Laboratory	. 4
OUTCOME	. 2
DOCUMENTATION	

STANDARD 8 PROGRAM SUPPORT AND RESOURCES

This standard applies to the program resources (budget, staff, equipment, etc.) necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors known to contribute to foodborne illness.

Requirement Summary

The program provides funding, staff and equipment necessary to accomplish compliance with the Voluntary National Retail Food Regulatory Program Standards.

Description of Requirement

The program budget provides the necessary resources to develop and maintain a retail food safety program that meets the following criteria:

1. Staffing Level

A staffing level of one full-time equivalent (FTE) devoted to food for every 280-320 inspections performed. Inspections for purposes of this calculation include routine inspections, reinspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews and other direct establishment contact time such as on-site training.

A process should exist for the regulated food establishments to be grouped into at least three categories based on food safety risk (See Standard 3). The number of inspections assigned per FTE should be adjusted within the 280 – 320 range depending upon the composition of low- to high –risk establishments in the assigned inventory. When an FTE is divided between program areas, the total number of food inspections planned for that FTE should be adjusted to compensate for the additional training time required to maintain competency in multiple program areas. An adjustment of planned inspections per FTE should also occur when food establishments are geographically dispersed due to increased travel time. Through their committee process, the Conference for Food Protection has developed an assessment tool and instruction guide as resources that can be used by a jurisdiction to calculate the FTE to inspection ration The Standard 8 – Assessment Too and Standard 8 – Assessment Workbook Instruction Guide are available for downloading from the CFP web site: www.foodprotect.org and are located under the icon titled, "Conference Developed Guides and Documents."

2. Inspection Equipment

Inspection equipment of each inspector to include head covers, thermocouples, flashlights, sanitization test kits, heat sensitive tapes or maximum registering thermometers, necessary forms and administrative materials. The following equipment must be available for use by inspectors when needed: computers, cameras, black lights, light meters, pH meters, foodborne illness investigation kits, sample collection kits, data loggers and cell phones.

3. Administrative Program Support

Equipment for administrative staff to include computers, software and/or items necessary to support the record keeping system utilized by the program. A system is in place to collect, analyze, retain and report pertinent information.

4. Regulatory Foundation

Staff and resources to adopt a sound, science-based regulatory foundation for the public health program and the uniform regulation of industry required in Standard No. 1.

5. Trained Regulatory Staff

Training and training documentation for all regulatory staff to meet the level specified in Standard No. 2.

6. Inspection Program Based on HACCP Principles

Staff to meet all of the requirements in Standard No. 3, inspection based on HACCP principles.

7. Uniform Inspection Program

Administrative and supervisory staff to administer and monitor a uniform inspection program based on HACCP principles that meet Standards No. 3 and 4.

8. Foodborne Illness & Food Defense Preparedness & Response

Staff and resources to maintain a foodborne illness investigation and response system that meets Standard No. 5.

9. Compliance & Enforcement

A program that demonstrates follow-though on all compliance and enforcement actions initiated according to the written step-by-step procedures required in Standard No. 6.

10. Industry & Community Relations

An industry and consumer relations program as specified in Standard No. 7.

11. Program Assessment

Sufficient staff and resources to conduct regular program self-assessment and risk factor surveys as specified in Standard No. 9.

12. Accredited Laboratory

Funds to provide access to accredited laboratory resources in support of the program as specified under these nine Standards.

The essential program elements required to demonstrate compliance with this standard are:

- A. Full-time equivalent (FTE) personnel to inspections accomplished ratio as described in section 1.
- B. Inspection equipment assigned or available as described in section 2.
- C. Equipment and/or supplies required for administering the program as described in Section 3.
- D. A full and accurate completion of the *Standard 8: Self-Assessment Worksheet* or equivalent whether or not those standards are met.

Outcome

The desired outcome of this standard is that resources are available to support a risk-based retail food safety program designed to reduce the risk factors known to contribute to foodborne illness.

Documentation

The quality records needed for this standard include:

- 1. Documentation of FTE to inspections ratio,
- 2. Inventory of assigned and available inspection equipment,
- 3. Documentation and demonstration of records system and adequacy of support,
- 4. The completed Standard 8 Self-Assessment Worksheet

[*NOTE: An average workload figure of 150 establishments per FTE with two inspections per year was originally recommended in the 1976 Food Service Sanitation Manual, the standard originating from a book entitled, "Administration of Community Health Services." Annex 4 of the Code since 1993 has included a recommendation that 8 to 10 hours be allocated for each establishment per year to include all the activities reflected here in the definition of an inspection. The range of 280 – 320 broadly defined inspections per FTE is consistent with these previous recommendations. A measure of resources defined as inspections per FTE rather than establishments per FTE allows for the same unit of measure to be used for any jurisdiction regardless of the frequency of routine inspections conducted among the various priority categories.]

INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

STANDARD 8 – PROGRAM SUPPORT AND RESOURCES

Program Self-Assessment & Verification Audit Form

The *Standard 8: Program Self-Assessment and Verification Audit Form* is designed to document the findings from the self-assessment and the verification audit process. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 8 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self Assessment

Jurisdictions conducting a self-assessment of Standard 8 must indicate on the form if each of the criteria is met. The self-assessor must record their findings under the column "Jurisdiction's Self Assessment."

Jurisdictions are not obligated to use the form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 8 criteria listed on the form are available for review.

The self-assessor must review each Standard 8 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the Standard 8 Program Self-Assessment and Verification Audit Form.

If a review of the jurisdiction's source documents does not confirm that the Standard 8 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction's Self-Assessment" column of the *Standard 8: Program Self-Assessment and Verification Audit Form.* The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 8: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed *Standard 8: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 8 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 8: Program Self-Assessment and Verification Audit Form.* The self-assessor must:

- Enter their contact information:
- Document if the jurisdiction met the Standard 8 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 8 criteria.

Documenting the Findings from the Verification Audit

The jurisdiction requesting the verification audit must provide their completed *Standard 8: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the Program Self-Assessment and Verification Audit Form if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 8: Program Self-Assessment and Verification Audit Form.* The auditor must:

- Enter their contact information;
- Document if the jurisdiction met the Standard 8 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 8 criteria if the auditor does not confirm the self-assessment findings.

Standard 8: Program Support and Resources Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the Self-Assessment:
Self-Assessor's Title:
Jurisdiction Name:
Jurisdiction Address:
Phone: FAX: E-mail:
Date the Standard 8 Self-Assessment was Completed:
Self-Assessment indicates that the Jurisdiction MEETS the Standard 8 criteria: YES 🔲 NO 📋
I affirm that the information represented in the Self-Assessment of Standard 8 is true and correct
Signature of the Self-Assessor:
VERIFICATION AUDIT SUMMARY
Printed Name of the Person who conducted the Verification Audit:
Verification Auditor's Title:
Auditor's Jurisdiction Name:
Auditor's Jurisdiction Address:
Phone: FAX: E-mail:
Date the Verification Audit of Standard 8 was Completed:
Verification Audit indicates that the Jurisdiction MEETS the Standard 8 criteria: YES 🔲 NO 🗌
I affirm that the information represented in the Verification Audit of Standard 8 is true and correct
Signature of the Verification Auditor:

Standard 8: Program Support and Resources Program Self-Assessment and Verification Audit Form

Jurisdiction Name:

Cuitonio	Juri	isdictio	Jurisdiction's Self-Assessment		Au	Auditor's Verification
CHELIA	YES	ON	Self-Assessor's General Comments	YES	NO	If NO, Auditor is to specify why criterion is not met
1. Staffing Level - FTE's per Inspections Performed	formed					
a) The jurisdiction has written documentation, calculations, or a program resource assessment that demonstrates a staffing level of one FTE for every 280-320 retail food program inspections performed.						
2. Inspection Equipment						
a) The jurisdiction can show through written records, equipment inventories, or actual observations that each retail food program inspector has a head cover, thermocouple, flashlight, sanitization test kit, heat sensitive tapes or maximum registering thermometer, and necessary forms and administrative materials.						
b) The jurisdiction has written procedures for obtaining the use of computers, cameras, black lights, pH meters, foodborne illness kits, sample collection kits, data loggers, and cell phones should this equipment not be part of the agency's general inventory.						
3. Administrative Program Support						
a) The jurisdiction has written documentation, calculations, or a program resource assessment that demonstrates sufficient equipment is available to support the record keeping system utilized by the program.						

Since	Jur	sdiction	Jurisdiction's Self-Assessment		Auc	Auditor's Verification
	YES	ON	Self-Assessor's General Comments	YES	NO NO	If NO, Auditor is to specify why criterion is not met
b) The jurisdiction has a system in place to collect, analyze, retain, and report pertinent information required to manage and implement the program.						
4. Program Resource Assessment		-				
a) The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing, and equipment necessary to meet Standard #1 - Regulatory Foundation.						
b) The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing, and equipment necessary to meet Standard #2 - Trained Regulatory Staff.						
c) The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing, and equipment necessary to meet Standard #3 - Inspection Program Based on HACCP Principles.						
d) The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing, and equipment necessary to meet Standard #4 - Uniform Inspection Program.						
e) The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing, and equipment necessary to meet Standard #5 - Foodborne Illness and Food Security Preparedness and Response.						
f) The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing, and equipment necessary to meet Standard #6 - Compliance and Enforcement.						
g) The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing, and equipment necessary to meet Standard #7 - Industry and Community Relations.						

Criteria	Juri	sdictio	Jurisdiction's Self-Assessment		Auc	Auditor's Verification
	YES NO	NO	Self-Assessor's General Comments	YES	YES NO	If NO, Auditor is to specify why criterion is not met
h. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing, and equipment necessary to meet Standard #9 - Program Assessment.						

Standard 8: Program Support and Resources Program Self-Assessment and Verification Audit Form

GENERAL NOTES PERTAINING TO THE PROGRAM SELF-ASSESSMENT OR THE VERIFICATION AUDIT	CF-ASSESSMENT OR THE VERIFICATION AUDIT

the Standard. The source documents, such as the various policies and procedures, that support this summary record must be maintained except h). If an item contains multiple questions, then all questions must be answered in the affirmative in order to meet that element of A "yes" affirmation to criteria 1-3 and 4 (h) is required to meet Standard 8. Disclosure and analysis only is required for criteria 4 (a/i in good order by the regulatory authority and must be made available upon request for purposes of a verification audit.

INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

STANDARD 8 – Program Support and Resources

STEP 1 – Review Staffing Level – FTE's per Inspections Performed

The jurisdiction must have written documentation, calculations, or a program resource assessment that is used to determine staffing levels for retail food inspections. The "FTE (Full-Time Equivalent) per Inspections Performed" is the measure of a program's capacity to fulfill its inspection obligations.

Full-Time Equivalent (FTE) is defined as the number of productive hours (conducting retail food inspections) contributed by one person working full-time for one year.

Determine Number of Inspections: For the purposes of this standard, "inspections" are defined as routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews, foodborne illness complaint response, final construction inspections and other direct establishment contact time such as on-site training that is performed by the field inspection staff. If the same personnel who conduct inspections of the fixed-site establishments also conduct the inspections of temporary events and mobile units, then these inspection events should also be counted as "inspections" for purposes of calculating the workload ratio.

The jurisdiction must estimate the number of on-site contacts made in a year. The **Inspection-to-FTE Ratio** is then calculated as the *total number of inspections* (*or on-site visits*) divided by the *number of FTE's*. To meet the Standard 8 criteria, the ratio must fall between 280 and 320 inspections per FTE.

The Conference for Food Protection's Program Standard Committee has designed resource tools for assisting jurisdictions with calculating the **Inspection-to-FTE** ratio:

- ➤ Standard 8 Staffing Level Assessment Workbook
- ➤ Standard 8 Staffing Level Assessment Workbook; Instruction Guide

The above resources are available on the Conference for Food Protection web site: www.foodprotect.org

STEP 2 – Review Inspectional Equipment Documentation

- Documentation for inspection equipment: The self-assessor must confirm that the jurisdiction has documentation to verify that necessary inspection equipment is provided and assigned to each inspector, including head covers, thermocouples, flashlights, sanitization test kits, heat sensitive tapes or maximum registering thermometers, necessary forms and administrative materials.
- Documentation for accessing use of additional equipment: The self-assessor must confirm that the jurisdiction has documentation for obtaining use of equipment that may not be part of standard equipment issued for inspection purposes, such as computers, cameras, black lights, light meters, pH meters, foodborne illness investigation kits, sample collection kits, data loggers and cell phones.

STEP 3 – Review Administrative Program Support Documentation

- Documentation of equipment/supplies for maintaining program records: The self-assessor must confirm that the jurisdiction has documentation that equipment and/or supplies required for administering the program, including computers, software and other items necessary to support the record keeping system utilized by the program, are available.
- System to analyze data: The self-assessor must verify that a system is in place to collect, analyze, retain and report pertinent information about the program.

STEP 4 - Program Resource Assessment

The Standard 8 self-assessment worksheet is designed to assist jurisdictions with maintaining documentation and information required for assessing funding, staffing, and equipment needs associated with Standards 1 through 7 and Standard 9. The worksheet is included with these instructions.

There is no penalty for a jurisdiction's failure to meet Standards 1 through 7 or Standard 9. Moreover, there is no penalty for failing to have the necessary funding and support under the criteria required in the Program Resource Assessment portion of the *Standard 8: Program Self-Assessment and Verification Audit Form.* The intent is for the jurisdiction to perform the assessment to determine if program resources are sufficient for each standard.

The self-assessor must document on the *Standard 8: Self-Assessment Worksheet* if the jurisdiction has sufficient funding, staff, and equipment to achieve each of the Standards listed on the worksheet. Each of the three resource areas (funding / staff / equipment) is assessed separately for each of the Standards. A check mark in the "YES" column indicates that the jurisdiction has sufficient resources. A check mark in the "NO" column indicates that the jurisdiction does not have sufficient resources. A "NO" response require an explanation as to what additional resources may be needed to assist the jurisdiction with meeting the Standard.

At the bottom of the worksheet, the self-assessor will indicate if the jurisdiction meets the Standard 8 requirements by checking either "YES" or "NO". Upon completing the worksheet, the self-assessor must sign and date it. The self-assessor must retain the worksheet with the other Standard 8 self-assessment documentation

Standard 8: Program Support and Resources Self-Assessment Worksheet

answer requires explanation. Use additional pages as needed. Disclosure and analysis only is required for Standard 1 through Standard 7, and Standard 9. Standard 8 Instructions: Do you have sufficient funds, staff, equipment, and resources to meet the following Standards? Answer "YES" or "NO" in each block. A "NO" requires a positive response to the three identified items.

**** The row at the bottom for "other shared resources" provides a place for you to identify needs that may not be easily attached to a specific Standard (i.e. copy machines, data lines).

Standard #	Funding	Staffing	Equipment	EXPLANATION - OTHER RESOURCES NEEDED
1	YES NO	YES NO	YES NO	
2	YES NO	YES NO	YES NO	
3	YES NO	YES NO	YES NO	
4	YES NO	YES NO	YES NO	
S	YES NO	YES NO	YES NO	
9	YES NO	YES NO	YES NO	
7	YES NO	YES NO	YES NO	
∞		*	* *	***
6	YES NO	YES NO	YES NO	
**** Other shared resources				

Do you meet the full-time equivalent (FTE) staff to inspection ration as required in Standard 8?

The requirements of Standard 8 are met:

| XES

Date:	
Title:	
Signature:	

Do your inspectors have the equipment provided and available as required in Standard 8? * *

^{***} Does your department have the equipment and supplies neccessary to maintain the records and reports system that supports the program as required in Standard 8?

STANDARD 9 PROGRAM ASSESSMENT

Table of Contents

REQUIREMENT SUMMARY	2
DESCRIPTION OF REQUIREMENT	2
Outcome	
Documentation	

STANDARD 9 PROGRAM ASSESSMENT

This Standard applies to the process used to measure the success of a jurisdiction's program in reducing the occurrence of foodborne illness risk factors to enhance food safety and public health in the community.

Requirement Summary

Program management must ensure that:

- 1. A RISK FACTOR STUDY on the occurrence of the five foodborne illness risk factors is conducted and repeated at least once every 60 months to measure trends in the occurrence of the risk factors;
- 2. An analysis is made of the data collected and a report on the outcomes and conclusions of the RISK FACTOR STUDY is written; and
- 3. A targeted intervention strategy designed to address the occurrence of the risk factors(s) identified in their RISK FACTOR STUDY is implemented and the effectiveness of such strategy is evaluated by subsequent RISK FACTOR STUDIES or other similar tools.

Description of Requirement

To achieve the criteria of Standard 9, a jurisdiction must ensure that:

- A. A RISK FACTOR STUDY and report on the occurrence of the five (5) foodborne illness risk factors must be completed. A RISK FACTOR STUDY serves two purposes:
 - 1. To identify risk factors most in need of priority attention in order to develop strategies to reduce their occurrence.
 - 2. To evaluate trends over time to determine whether progress is being made toward reducing the occurrence of foodborne illness risk factors. Studies designed to measure trends require analysis of data over a period of time, and no single point in time can be used to derive trend conclusions.
- B. The RISK FACTOR STUDY includes all facility categories under regulation by the jurisdiction.
 - It is recommended that a jurisdiction's first RISK FACTOR STUDY be conducted as soon as possible following its first SELF-ASSESSMENT, before programmatic changes are made. There is value in using the first study to establish a "baseline" against which future performance can be measured. Program improvements and changes may then be reflected in subsequent studies.
- C. The RISK FACTOR STUDY information is to be updated at least once every 60 months to measure trends specific to the occurrence of the five (5) foodborne illness risk factors.

The data collection and analysis may occur at various times over the 60-month period, as long as all facility categories under regulation are included in the 60-month cycle. The 60-month study update is required to maintain achievement of Standard 9. The subsequent studies and reports indicate if there has been a net change in the occurrence of the risk factors.

The four (4) facility categories are:

- 1. Health Care;
- 2. Schools (K-12);
- 3. Restaurants;
- 4. Retail Food Stores.
- D. A jurisdiction may use routine inspection data or may conduct a separate data collection in completing a RISK FACTOR STUDY. A data collection instrument similar to the FDA Model Data Collection Form using the IN, OUT, NA, and NO convention, is required.
- E. Failure to use this convention skews the data toward either IN compliance or OUT of compliance. The FDA data collection instrument is not intended as an inspection form. However, jurisdictions that have developed an inspection form using the IN, OUT, NA and NO convention may use that inspection form as a survey instrument.
 - If the jurisdiction uses a different form, the data may be difficult to compare with the data from the FDA National Foodborne Illness Risk Factor Studies or with data from other jurisdictions.
- F. A jurisdiction must ensure that a targeted intervention strategy designed to address the occurrence of the risk factor(s) identified in their Risk Factor Study is implemented and the effectiveness is evaluated by subsequent Risk Factor Studies or other similar tools. Jurisdictions are encouraged to incorporate various types of interventions such as code changes, educational and training activities, enforcement and compliance strategies, etc. The purpose of the intervention strategy is to attempt to affect improvement in reducing priority risk factor(s) occurrence rates between measurement intervals and assess their effectiveness.

Outcome

The desired outcome of this Standard is to enable managers to measure their program against national criteria and to demonstrate improvement in food safety. The process identifies program elements that may require improvement or be deserving of recognition.

Documentation

The quality records required for this standard include:

- 1. Survey reports on the occurrence of risk factors and *FDA Food Code* interventions identified in their RISK FACTOR STUDY,
- 2. Survey collection tools or inspection sheets used for the data collection,

- 3. Documentation that each facility category regulation is surveyed during the 60-month survey cycle,
- 4. Documentation of performed interventions, actions or activities designed to improve the control of risk factors,
- 5. Documentation that the effectiveness of performed interventions is evaluated.

INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

STANDARD 9 – PROGRAM ASSESSMENT

Program Self-Assessment & Verification Audit Form

The Standard 9: Program Self-Assessment and Verification Audit Form is designed to document the findings from the self-assessment and the verification audit process. The form is included at the end of these instructions. Whether one is performing a program self-assessment or conducting a verification audit, it is recommended that the form be available as a reference to the Standards 9 criteria.

Using the Program Self-Assessment and Verification Audit Form

Documenting the Findings from the Self Assessment

Jurisdictions conducting a self-assessment of the Standard 9 Program Assessment component must indicate on the form if each of the criteria is met. The self-assessor must record their findings under the column "Jurisdiction's Self Assessment."

Jurisdictions are not obligated to use the form. An equivalent form or process is acceptable provided that the results of the jurisdiction's self-assessment for the specific Standard 9 criteria listed on the form are available for review.

The self-assessor must review each Standard 9 criterion and determine if the jurisdiction's source documents confirm that the Standard criteria are met. If the criteria are met, the self-assessor must place an "X" in the "YES" box under the "Jurisdiction's Self-Assessment" column of the Standard 9: ProgramSelf-Assessment and Verification Audit Form.

If a review of the jurisdiction's source documents does not confirm that the Standard 9 criteria are met, the self-assessor must place an "X" in the "NO" box under the "Jurisdiction's Self-Assessment" column of the *Standard 9: Program Self-Assessment and Verification Audit Form*. The self-assessor may specify why the criteria are not met in the box provided.

The self-assessor should review the findings on the *Standard 9: Program Self-Assessment and Verification Form* to ensure accuracy. The jurisdiction will be required to provide the auditor with their completed *Standard 9: Program Self-Assessment and Verification Audit Form* and any documents used to support and demonstrate that the Standard 9 criteria have been met.

Once all the criteria have been reviewed and documented on the form, the self-assessor must complete the Program Self-Assessment Summary section on page one of the *Standard 9: Program Self-Assessment and Verification Audit Form.* The self-assessor must:

- Enter their contact information:
- Document if the jurisdiction met the Standard 9 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 9 criteria.

Documenting the Findings from the Verification Audit

The jurisdiction requesting the verification audit must provide their completed *Standard 9: Program Self-Assessment and Verification Audit Form* to the auditor for review. The auditor must indicate on the *Standard 9: Program Self-Assessment and Verification Audit Form* if the criteria were met.

If a review of the jurisdiction's source documents confirms the self-assessment conclusion that the Standard criteria are met, the verification auditor places an "X" in the "YES" box under the "Auditor's Verification" column of the form.

If a review of the jurisdiction's source documents does not confirm the self-assessment conclusion that the Standard criteria are met, the verification auditor places and "X" in the "NO" box under the "Auditor's Verification" column of the form. The verification auditor must specify why the criterion is not met in the box provided. Supplemental pages may be used to explain findings.

The verification auditor must discuss their findings with the program manager or their appointed representative and provide constructive feedback at the conclusion of the on-site visit. In particular, any Standard 9 criteria for which the auditor cannot confirm through a review of the self-assessment should be thoroughly discussed. Ample time should be allotted to ensure that there is a clear understanding of the reasons for the "non-conforming" finding. The auditor should be prepared to identify the elements required for the jurisdiction to meet the Standard.

Once the close out interview has been conducted, the auditor must complete the Verification Audit Summary section located on the first page of the *Standard 9: Program Self-Assessment and Verification Audit Form.* The auditor must:

- Enter their contact information:
- Document if the jurisdiction met the Standard 9 criteria in the appropriate boxes; and
- Sign the form where indicated.

It then will be up to the jurisdiction to determine its action plan and time frame for correcting any deficiencies in order to meet the Standard 9 criteria if the auditor does not confirm the self-assessment findings.

Standard 9: Program Assessment Program Self-Assessment and Verification Audit Form

PROGRAM SELF-ASSESSMENT SUMMARY

Printed Name of the Person who conducted the Self-Assessment:	
Self-Assessor's Title:	
Jurisdiction Name:	
Jurisdiction Address:	
Phone: FAX: E-mail:	
Date the Standard 9 Self-Assessment was Completed:	
Self-Assessment indicates that the Jurisdiction MEETS the Standard 9 criteria: YES NO □	
I affirm that the information represented in the Self-Assessment of Standard 9 is true and correct.	
Signature of the Self-Assessor:	
VERIFICATION AUDIT SUMMARY	
Printed Name of the Person who conducted the Verification Audit:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone: E-mail:	
Date the Verification Audit of Standard 9 was Completed:	
Verification Audit indicates that the Jurisdiction MEETS the Standard 9 criteria: YES NO	
I affirm that the information represented in the Verification Audit of Standard 9 is true and correct.	
Signature of the Verification Auditor:	

Standard 9: Program Assessment Program Self-Assessment and Verification Audit Form

Jurisdiction Name:

	Juris	diction	Jurisdiction's Self-Assessment		Aud	Auditor's Verification
Criteria	YES	NO	Self-Assessor's General Comments	YES	ON	If NO, Auditor is to specify why criterion is not met
1. Risk Factor Study						
a) A study on the occurrence of foodborne illness risk factors has been completed and includes data for each facility type regulated by the jurisdiction collected over the study cycle.						
 b) The data collection form includes items pertaining to the following Center for Disease Control and Prevention (CDC) identified contributing factors to foodborne illness. 1. Food from Unsafe Sources; 2. Improper Holding/Time and Temperature; 3. Inadequate Cooking; 4. Poor Personal Hygiene; and 5. Contaminated equipment / Protection from contamination. 						
c) The data collection form provides for marking actual observations of food practices within an establishment (IN, OUT, NO, and NA).						

ojaojia	Juris	diction	Jurisdiction's Self-Assessment		Aud	Auditor's Verification
	YES	ON	Self-Assessor's General Comments	YES	YES NO	If NO, Auditor is to specify why criterion is not met
2. Report of Analysis and Outcome						
a) A report is available that shows the results of the data collection from the jurisdiction's foodborne illness risk factor study.						
b) The report provides quantitate measurements upon which to assess the trends in the occurrence of foodborne illness risk factors over time.						

Standard 9: Program Assessment Program Self-Assessment and Verification Audit Form

Critorio	Juris	diction	Jurisdiction's Self-Assessment		Aud	Auditor's Verification
	YES	NO	Self-Assessor's General Comments	YES NO	NO	If NO, Auditor is to specify why criterion is not met
3. Intervention Strategy						
a) A targeted intervention strategy designed to address the occurrence of the risk factor(s) identified in their risk factor study is implemented and the effectiveness of such strategy is evaluated by subsequent risk factor studies.						
b) Documentation is provided of performed interventions, action, or activities designed to improve control of foodborne illness risk factors.						

Standard 9: Program Assessment Program Self-Assessment and Verification Audit Form

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APPENDIX 1: SUMMARY OF CHANGES

This summary provides a synopsis of the changes made to the 2017 edition of the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards). The primary intent of this record is to capture the nature of the changes found in the 2017 edition of the Voluntary National Retail Food Regulatory Program Standards rather than to identify every word or editing change. This record should not be relied upon as an absolute comparison that identifies each and every change.

Changes Recommended by the Conference for Food Protection (CFP)

FDA works closely with stakeholders through the biennial Conference for Food Protection (CFP) to review proposed changes to the Voluntary National Retail Food Regulatory Program Standards. Changes may be proposed by FDA, or by stakeholder groups such as academia, industry, consumer groups, and regulatory officials. CFP provides an opportunity for stakeholders to provide comments about proposed changes.

The following changes reflect the recommendations from the Conference for Food Protection, 2016 biennial meeting.

Updates to Program Standards Definitions

What changed in the Definitions?

The definition for "Training Standard" was updated to include two additional elements related to training and standardization. The training standard definition now includes two new elements addressing completion of 20 contact hours of continuing education in food safety every 36 months after the initial training is completed as outlined in Standard 2, and maintenance of standardization every three years as outlined in Standard 2

How do these changes affect your jurisdiction?

Jurisdictions will now have to meet two additional as defined in the definition of "training standard".

How will I be able to access these forms?

These forms are available on FDA's website.

Updates to Standard 2- Trained Regulatory Staff

What changed in Standard 2?

Standard 2 applies to the essential elements of a training program for regulatory staff. Under Step 4: Food Safety Inspection Officer –Field Standardization, a re-emphasis was made regarding field standardization and re-standardization criteria allowing the flexibility to adhere to the regulations and ordinances germane to the jurisdiction along with a reference to using standardization procedures similar to the FDA procedures for Standardization of Retail Food Inspection Training Officers.

How do these changes affect your jurisdiction?

Jurisdictions are encouraged to reference standardization procedures similar to those contained in the FDA Procedures for Standardization of a Retail Food Inspection Training Officer. This is intended to allow jurisdictions the flexibility to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections.

How will I be able to access and complete these forms?

These forms are available on FDA's website. Enrollees can print out the forms and complete them by hand. Alternatively, these forms can be completed electronically and saved.

<u>Updates to Standard 4 – Uniform Inspection Program</u>

What changed in Standard 4?

Standard 4 applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies and compliance/enforcement activities. The following changes reflect recommendations provided in the Uniform Inspection Program – Audit Pilot Project Report while also providing greater flexibility, improved program quality assessment and greater consistency between Program Standards 2 and 4. The changes include:

- More closely aligned Program Elements described in Program Standard No. 4 with the Performance Elements and Competencies contained in the Standard No. 2 CFP Field Training Plan for new hires or staff newly assigned to the retail food protection program. This alignment process has resulted in 20 Program Elements.
- A re-ordered listing of the Program Elements in Program Standard No. 4 to reflect the organized flow of the inspection process.
- An increase the minimum number of required field assessments (joint inspections) to maintain consistency with the current statistical model upon which Standard 4 is based.

The Instructions and Worksheet for Conducting a Self-Assessment – Trained Regulatory Staff was updated to:

- Clarify that jurisdictions may assess additional performance elements as part of their field assessment process. However, for the purposes of achieving conformance with the Standard, only the performance elements specified in the Standard will be used to assess conformance with the Standard.
- Clarify that the assessment of the performance elements is not an all-or-nothing approach. (For instance, someone that misses one risk factor out of 10 risk factors during a field assessment may still achieve an acceptable level of performance/uniformity on a particular performance element)
- Clarify that enrolled jurisdictions may wish to create a field assessment tool that enables more specific comments and feedback for the individual food safety inspection officer.
- Clarify how establishments should be selected for the field assessment process.
- Provide more specific guidance about the file review process.
- Clarify who should conduct the field assessment and associated file review.

How do these changes affect your jurisdiction?

With the change in number of Performance Elements to 20, the statistical model for Standard 4 has been updated. Previously in large jurisdictions (jurisdictions with 10 or more inspectors) the evaluation was based on direct oversight of two inspections per inspector, with respect to 10 Performance Elements. By updating the statistical model the evaluation must now be based on direct oversight of three inspections per inspector. In the same regard, the statistical model for jurisdictions with less than 10 inspectors has also been updated. A new calculation model has been included. Jurisdictions that have between four to nine inspectors will conduct three joint inspections for each inspector and for jurisdictions that have three or less inspectors it is recommended that extra oversight inspections be performed to produce a total of 12 inspections. The Program Self-Assessment and Verification Audit Form and Worksheets have been updated to reflect these changes.

How will I be able to access and complete these forms?

These forms are available on FDA's website. Enrollees can print out the forms and complete them by hand. Alternatively, these forms can be completed electronically and saved.

Updates to Standard 7: Industry and Community Relations

What changed in Standard 7?

Standard 7 applies to the Industry and Community Relations outreach activities used by a retail food regulatory program to solicit a broad spectrum of input about a retail food regulatory program's previous, current and future activities. In order to assess conformance with industry and consumer interaction for Standard 7, enrolled jurisdictions may now include additional forms of two way communications such as food safety task force meetings, advisory boards, advisory committees, customer surveys, web based meetings or forums or other mechanisms. The educational outreach component of Standard 7 now allows the usage of oral culture learner materials that increase the awareness of the foodborne illness risk factors and control methods to prevent foodborne illness.

How do these changes affect your jurisdiction?

When conducting a self-assessment of Standard 7, enrolled jurisdictions now have additional options available.

How will I be able to access and complete these forms?

These forms are available on FDA's website. Enrollees can print out the forms and complete them by hand. Alternatively, these forms can be completed electronically and saved.

Updates to the Standard 9: Program Assessment

What changed in Standard 9?

The Standard 9 criteria for an enrolled jurisdiction's risk factor study now include facility categories rather than facility types as stated in previous editions. The four categories have replaced the nine facility types. The four facility categories are:

- 1. Health Care,
- 2. Schools (K-12)
- 3. Restaurants
- 4. Retail Food Stores.

How do these changes affect your jurisdiction?

The changes to the content of the Standard 9 allow enrolled jurisdictions to select categories of facility types for their risk factor study. The data collection and analysis may occur at various times over the 60- month period, as long as all facility categories under regulation are included in the 60-month cycle. Subsequent studies and reports will indicate if there has been a net change in the occurrence of the risk factors.

How will I be able to access and complete these forms?

These forms are available on FDA's website. Enrollees can print out the forms and complete them by hand. Alternatively, these forms can be completed electronically and saved.

Other Changes made by FDA

FDA made a number of changes to the Voluntary National Retail Food Regulatory Program Standards. These changes are described below.

Standard 1: Regulatory Foundation

What changed in Standard 1?

Standard 1 applies to the regulatory foundation of a retail food regulatory program. In order to assess conformance with Standard 1, enrolled jurisdictions must compare their regulatory foundation with the provisions in the FDA Food Code. In order to facilitate this process, worksheets are provided to guide the self-assessment process and the verification audit process. These worksheets facilitate the comparison of the jurisdiction's regulatory foundation with risk factor and public health intervention provisions, good retail practice provisions, and compliance and enforcement provisions contained within the FDA Food Code.

Standard 1: Self-Assessment Worksheet for Part I was updated to reflect a recent change in the Food code. The change is as follows:

 Added Section 2-401.13 Bandages, Finger Cots, or Stall products on Wrists, Hands or Fingers

This provision was incorporated into the Food Code through a recommendation from the Conference for Food Protection, 2016 biennial meeting.

In addition, the Standard 1 Program Self-Assessment and Verification Audit Form contained a typographical error that referenced completion dates for both the Self-assessment and audit as it relates to Standard 2. The error has been fixed to reflect completion dates of the Self-Assessment and Audit for Standard 1.

How do these changes affect your jurisdiction?

When conducting a self-assessment of Standard 1, jurisdictions must compare their regulatory foundation to the current edition of the Food Code, or the two most recent previous editions. These changes impact the provisions assessed during the self-assessment process when using the current edition of the Food Code.

How will I be able to access and complete these forms?

These forms are available on FDA's website. Enrollees can print out the forms and complete them by hand. Alternatively, these forms can be completed electronically and saved.

<u>Standard 3: Inspection Program Based on HACCP Principles Program Self-Assessment and Verification Audit Form</u>

What changed in Standard 3?

Section 4 of the Standard 3 Program Self-Assessment and Verification Audit Form contained a typographical error that should have read "Written and Implemented Corrective Action Plan" as opposed to "Written and Implement Corrective Action Plan"

How do these changes affect your jurisdiction?

The changes to the program Self-Assessment and Verification Audit Form will not affect a jurisdiction's ability to accurately report program Self-Assessment and Verification Audit information.

How will I be able to access and complete these forms?

These forms are available on FDA's website. Enrollees can print out the forms and complete them by hand. Alternatively, these forms can be completed electronically and saved.

Standard 5: Foodborne Illness and Food Defense Preparedness and Response

What changed in Standard 5?

Within the data Review and Analysis section of Standard 5, Regulatory Programs are encouraged to participate in the CDC National Voluntary Information System, previously known as (NEAVIS). The name of the system has now changed to the National Environmental Assessment Reporting System (NEARS). The web link has been updated to reflect the name change and accompanying pathway accessing the page.

How do these changes affect your jurisdiction?

The change incorporated into the Standard was to include a note regarding the NEARS program. Including this note does not change the process of conducting a self-assessment or verification audit for this Standard.

How will I be able to access and complete these forms?

These forms are available on FDA's website. Enrollees can print out the forms and complete them by hand. Alternatively, these forms can be completed electronically and saved.

"The 2017 Voluntary Retail National Program Standards workbook primarily reflects an incorporation of the recently approved changes that resulted from the 2016 Conference for Food Protection held in Boise, ID and changes forwarded by the Food and Drug Administration's CFSAN, Retail Food Policy Team. In addition to these recommendations and changes from FDA, the workbook also contains editorial corrections throughout to correct for spelling, grammar and date errors from previous editions."