Voluntary National Retail Food Regulatory Program Standards



"Standards of Excellence for Continual Improvement"

Developed and recommended by the U.S. Food and Drug Administration with input from federal, state, and local regulatory officials, industry, trade associations, academia, and consumers.

2024

U.S. Department of Health and Human Services

Food and Drug Administration Human Foods Program College Park, MD 20740

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INTRODUCTION TO THE STANDARDS

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 Retail Food Specialist or to the Office of Retail Food Protection: retailfoodprotectionteam@fda.hhs.gov.

Voluntary National Retail Food Regulatory Program Standards

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 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 in restaurants, retail food stores, health care facilities, and K-12 schools under a jurisdiction's regulatory authority.
- 23) **Routine Inspection** A full review and evaluation of a food establishment's operations and facilities to assess its compliance with the jurisdiction's laws, statutes, ordinances, and regulations, 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.

STANDARD 1 – REGULATORY FOUNDATION

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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 control measures for the RISK FACTORS known to contribute to foodborne illness and public health interventions contained in the current published edition of the *FDA Food Code* or one of the two most recent previous editions of the *FDA Food Code*;
- 2. GOOD RETAIL PRACTICES (GRP'S) at least as stringent as the *FDA Food Code* edition as specified in 1 above; and
- 3. COMPLIANCE AND ENFORCEMENT at least as stringent as the selected provisions from *FDA Food Code* and Annex 1 of the *FDA Food Code* edition as specified in 1 above.

If a jurisdiction adopted the current published edition or one of the two most recent editions of the *FDA Food Code* by reference, a side-by-side comparison of the language is not necessary. Adoption by reference meets the criteria of the Standard.

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 *FDA Food Code* or one of the two most recent previous editions of the *FDA Food Code*. Jurisdictions that meet Standard 1 but who may become noncompliant due to the release of a new edition of the *FDA Food Code* are considered to continue meeting the Standard for a period of two years from the release date of the new *FDA 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 all elements of 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 *FDA Food Code* as specified in A. To meet this element of the Standard, regulations must have a corresponding requirement for 95 percent of the *FDA Food Code* sections as listed and summarized in the *Standard 1: Self-Assessment Worksheet for Part II*, from #12 "Personnel" through #36 "Presence of Insects / Rodents Minimized, Outer Openings Protected, etc."

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 *FDA Food Code* as specified in A. To meet this element of the Standard, regulations must have a corresponding requirement for each of the *FDA 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. For Item 7d, jurisdictions that do not issue variances defaults to a "yes, full intent is met".

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

STANDARD 1 – REGULATORY FOUNDATION INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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 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 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 (Indicate YES/NO):						
I affirm that the information represented in the Self-Assessment of Standar	d 1 is true and correct.					
Signature of the Self-Assessor:						
VERIFICATION AUD	OIT 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 (Indicate YES/NO):						
I affirm that the information represented in the Verification Audit of Standard 1 is true and correct.						
Signature of the Verification Auditor:						

STANDARD 1 – REGULATORY FOUNDATION PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

Jurisdiction Name:

Criteria	Element	Jurisdiction's Self- Assessment YES	Jurisdiction's Self- Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Assessment of the Program's Regulatory Foundation	a) The jurisdiction has documentation of its side-by-side comparison of its statutes, regulations, rules, and other pertinent requirements against the current published edition of the <i>FDA Food Code</i> or one of the two most recent previous editions of the <i>FDA Food Code</i> .						
1. Assessment of the Program's Regulatory Foundation	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.						
1. Assessment of the Program's Regulatory Foundation	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.						

Criteria	Element	Jurisdiction's Self- Assessment YES	Jurisdiction's Self- Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
2. Food Code Interventions and Risk Factors	a) The jurisdiction's initial 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. 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. Documentation from: Part I - Self-Assessment Worksheet Part I - Verification Audit Worksheet						

Criteria	Element	Jurisdiction's Self- Assessment YES	Jurisdiction's Self- Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
3. Good Retail Practices	a) The jurisdiction's code assessment indicates that regulatory requirements contain at least 95 percent of the FDA Food Code 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						

Criteria	Element	Jurisdiction's Self- Assessment YES	Jurisdiction's Self- Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
4. Compliance and Enforcement	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			M CEL E A CORCOMENTE OR A			

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

STANDARD 1 – REGULATORY FOUNDATION INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELFASSESSMENT

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 *FDA Food Code* section listed under that element.

NOTE: If a jurisdiction adopted the current published edition or one of the two most recent editions of the FDA Food Code by reference, a side-by-side comparison of the language is not necessary. Adoption by reference meets the criteria of the Standard.

STEP 2 - Conduct the Self-Assessment for Part I

The self-assessor must compare the jurisdiction's code, regulation or ordinance with the *FDA 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 *FDA Food Code* section, the self-assessor must:

- Record the corresponding jurisdiction requirement; and
- Document his/her determination:
 - If **full intent** of the *FDA Food Code* section is met, place an "X" in the appropriate column.
 - If **partial intent** of the *FDA 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: Regulatory Foundation 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 *FDA 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: Regulatory Foundation 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 nine 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 *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; and
- ➤ 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 – Food Code: Interventions and Risk Factor Controls

SECTION 1 – DEMONSTRATION OF KNOWLEDGE

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

SECTION 2 – EMPLOYEE HEALTH

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

	FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
6.	2-201.12 – Exclusions and Restrictions				
7.	2-201.13 – Removal, Adjustment, or Retention of Exclusions and Restrictions				
8.	2-501.11— Clean-up of Vomiting and Diarrheal Events				

SECTION 3 – CONSUMER ADVISORY

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

SECTION 4 – APPROVED SOURCE

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code 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				
14. 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				
18. 3-201.16 – Wild Mushrooms				
19. 3-201.17 – Game Animals				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
20. 3-101.11 – Safe, Unadulterated, and Honestly Presented				
21. 3-202.11 – Temperature				
22. 3-202.15 – Package Integrity				
23. 3-202.18 – Molluscan Shellfish, Packaging and Identification				
24. 3-203.12 – Molluscan Shellfish, Maintaining Identification				
25. 3-402.11 – Parasite Destruction				
26. 3-402.12 – Records, Creation, and Retention				
27. 3-202.110 – Juice Treated				

SECTION 5 – TIME/TEMPERATURE

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code 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. 3-401.15 - Manufacturer Cooking Instructions				
32. 3-403.11 – Reheating for Hot Holding				
33. 3-501.14 – Cooling				
34. 3-501.15 – Cooling Method				
35. 3-501.16 – Time/Temperature Control for Safety Food, Hot and Cold Holding				
36. 3-501.17 – Ready-to-Eat, Time/Temperature Control for Safety Food, Date Marking				
37. 3-501.18 – Ready-to-Eat, Time/Temperature Control for Safety Food, Disposition				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
38. 3-501.19 – Time as a Public Health Control				

SECTION 6 – PROTECTION FROM CONTAMINATION

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
39. 3-301.12 – Preventing Contamination When Tasting				
40. 3-302.11 — Packaged/Unpackaged Food — Separation, Packaging, and Segregation				
41. 3-304.11 – Food Contact with Equipment and Utensils				
42. 3-306.14 – Returned Food and Re-Service of Food				
43. 3-701.11 – Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food				
44. 4-201.12 – Food Temperature Measuring Devices				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
45. 4-501.111 – Manual Warewashing Equipment, Hot Water Sanitization Temperatures				
46. 4-501.112 – Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures				
47. 4-501.113 – Mechanical Warewashing Equipment, Sanitization Pressure				
48. 4-501.114 – Manual and Mechanical Warewashing Equipment, Chemical Sanitization – Temperature, pH, Concentration, and Hardness				
49. 4-501.115 – Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers				
50. 4-601.11 – Equipment, Food- Contact Surfaces, Non-Food- Contact Surfaces, and Utensils				
51. 4-602.11 - Equipment Food- Contact Surfaces and Utensils				
52. 4-602.12 — Cooking and Baking Equipment				
53. 4-702.11 – Before Use After Cleaning				
54. 4-703.11 – Hot Water and Chemical				

SECTION 7 – CONTROL OF HANDS AS A VEHICLE OF CONTAMINATION

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
55. 2-301.11 – Clean Condition				
56. 2-301.12 – Cleaning Procedure				
57. 2-301.14 – When to Wash				
58. 2-301.15 – Where to Wash				
59. 2-301.16 – Hand Antiseptics				
60. 3-301.11 – Preventing Contamination from Hands				
61. 5-203.11 – Handwashing Sinks (Numbers/ Capacities)				
62. 5-204.11 – Handwashing Sinks (Location/ Placement)				
63. 5-205.11 – Using a Handwashing Sink				
64. 6-301.11 – Handwashing Cleanser, Availability				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
65. 6-301.12 – Hand Drying Provision				
66. 6-301.13 – Handwashing Aids and Devices, Use Restrictions				
67. 6-501.18 – Cleaning of Plumbing Fixtures				

SECTION 8 – GOOD HYGIENIC PRACTICES

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
68. 2-401.11 - Eating, Drinking, or Using Tobacco				
69. 2-401.12 – Discharges from the Eyes, Nose, and Mouth				
70. 2-401.13 - Bandage, Finger Cot, Stall				

SECTION 9 – CHEMICAL

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
71. 3-202.12 – Additives				
72. 3-302.14 – Protection from Unapproved Additives				
73. 7-207.11 – Restriction and Storage				
74. 7-207.12 – Refrigerated Medicines, Storage				
75. 7-208.11 – Storage (First Aid Supplies)				
76. 7-209.11 – Storage (Personal Care Items)				
77. 7-101.11 – Identifying Information, Prominence				
78. 7-102.11 – Common Name				
79. 7-201.11 – Separation				
80. 7-202.11 – Restriction				
81. 7-202.12 – Conditions of Use				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
82. 7-203.11 – Poisonous or Toxic Material Containers				
83. 7-204.11 – Sanitizers, Criteria				
84. 7-204.12 – Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria				
85. 7-204.13 – Boiler Water Additives, Criteria				
86. 7-204.14 – Drying Agents, Criteria				
87. 7-205.11 – Incidental Food Contact, Criteria				
88. 7-206.11 – Restricted Use Pesticides, Criteria				
89. 7-206.12 – Rodent Bait Stations				
90. 7-206.13 – Tracking Powders, Pest Control and Monitoring				
91. 7-301.11 – Separation (Retail Sale)				

SECTION 10 – CONFORMANCE WITH APPROVED PROCEDURES

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
92. 3-404.11 – Treating Juice				
93. 3-502.11 – Variance Requirement				
94. 3-502.12 – Reduced Oxygen Packaging Without a Variance, Criteria				

SECTION 11 – HIGHLY SUSCEPTIBLE POPULATIONS

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
95. 3-801.11 – Pasteurized Foods, Prohibited Reservice, and Prohibited Foods				

STANDARD 1 – REGULATORY FOUNDATION SELF-ASSESSMENT WORKSHEET

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

FDA Food Code Section and Description	YES Standard Criteria Met	NO Standard Criteria Not Met	Self-Assessor's General Comments
1. Demonstration of Knowledge			
2. Employee Health			
3. Consumer Advisory			
4. Approved Sources			
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 Approve Procedures			
11. Highly Susceptible Populations			

Assessment of		indicates conformance with	out of the 11 Intervention/Risk Factor
Categories	(regulatory agency)	(# M	et)

STANDARD 1 – REGULATORY FOUNDATION INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

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."

NOTE: If a jurisdiction adopted the current published edition or one of the two most recent editions of the FDA Food Code by reference, a side-by-side comparison of the language is not necessary. Adoption by reference meets the criteria of the Standard.

STEP 2 - Conduct the Self-Assessment for Part II

The self-assessor must compare the jurisdiction's code, regulation, or ordinance with the corresponding FDA 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 FDA Food Code section:

- Record the corresponding jurisdiction requirement; and
- Document his/her determination:
 - If **full intent** of the FDA Food Code section is met, place an "X" in the appropriate column.
 - If **partial intent** of the *FDA 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 *FDA 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 246 and multiply 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; and
- > 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 - Food Code: Good Retail Practices

SECTION 12 – PERSONNEL

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
1. 2-302.11 - Maintenance				
2. 2-303.11 - Prohibition				
3. 2-304.11 - Clean Condition				
4. 2-402.11 - Effectiveness				
5. 6-301.14 - Handwashing Signage				

TOTAL NUMBER OF SECTION 12 PROVISIONS MARKED "YES ______ (Section 12 has a total of 5 provisions)

SECTION 13 – FOOD & FOOD PROTECTION

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
6. 3-202.16 - Ice				
7. 3-202.17 - Shellstock, Condition				
8. 3-202.18 - Molluscan Shellfish, Packaging and Identification				
9. 3-203.11 - Molluscan Shellfish, Original Container				
10. 3-302.12 - Food Storage Containers, Identified with Common Name of Food				
11. 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				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
14. 3-601.12 - Honestly Presented				
15. 3-602.11 - Food Labels				
16. 3-602.12 - Other Forms of Information				
17. 6-404.11 - Segregation and Location				

TOTAL NUMBER OF SECTION 13 PROVISIONS MARKED "YES	(Section 13 has a total of 12 provisions
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SECTION 14 – PLANT FOOD COOKING FOR HOT HOLDING

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

TOTAL NUMBER OF SECTION 14 PROVISIONS MARKED "YES ______ (Section 14 has a total of 1 provisions)

SECTION 15 – PROTECTION FROM CONTAMINATION

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section 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. 3-303.12 - 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				
28. 3-306.13 - Consumer Self- Service Operations				
29. 3-307.11 - Miscellaneous Sources of Contamination				

TOTAL NUMBER OF SECTION 15 PROVISIONS MARKED "YES ______ (Section 15 has a total of 11 provisions)

SECTION 16 – FACILITIES / METHODS TO CONTROL PRODUCT TEMPERATURE

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
30. 3-501.11 - Frozen Food				
31. 4-301.11 - Cooling, Heating, and Holding Capacities				

TOTAL NUMBER OF SECTION 16 PROVISIONS MARKED "YES (S	Section 16 has a total o	f 2 provisions)
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SECTION 17 – TIME / TEMPERATURE CONTROL FOR SAFETY FOOD - PROPERLY THAWED

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
32. 3-501.12 - Time / Temperature Control for Safety Food, Slacking				
33. 3-501.13 - Thawing				

TOTAL NUMBER OF SECTION 17 PROVISIONS MARKED "YES (Section 17 has a total of 2 provision)	ΓAL NUMBER OF SECTION 17 PROVISIONS MARKED "YES (Se	Section 17 has a total o	f 2 provisions
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SECTION 18 – DISPENSING OF FOOD / UTENSILS PROPERLY STORED

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section 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				

TOTAL NUMBER OF SECTION 18 PROVISIONS MARKED "YES	(Section 18 has a total of 3 provision.	S
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SECTION 19 – THERMOMETERS PROVIDED AND CONSPICUOUS

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
37. 4-203.11 - Temperature Measuring Devices, Food				
38. 4-203.12 - Temperature Measuring Devices, Ambient Air and Water				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
39. 4-204.112 - Temperature Measuring Devices				
40. 4-302.12 - Food Temperature Measuring Devices				

TOTAL NUMBER OF SECTION 19 PROVISIONS MARKED "YES ______ (Section 19 has a total of 4 provisions)

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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section 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				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
45. 4-101.13 – Lead, Use Limitation				
46. 4-101.14 - Copper, Use Limitation				
47. 4-101.15 - Galvanized Metal, Use Limitation				
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				
56. 4-202.14 - Hot Oil Filtering Equipment				
57. 4-202.15 - Can Openers				_

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
58. 4-202.16 - Nonfood-Contact Surfaces				
59. 4-202.17 - Kick Plates, Removable				
60. 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				
64. 4-204.18 - Condenser Unit, Separation				
65. 4-204.19 - Can Openers on Vending Machines				
66. 4-204.110 - Molluscan Shellfish Tanks				
67. 4-204.111 - Vending Machines, Automatic Shutoff				
68. 4-204.121 - Vending Machines, Liquid Waste Products				
69. 4-204.122 - Case Lot Handling Apparatuses, Moveability				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
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				
75. 4-501.11 - Good Repair and Proper Adjustment				
76. 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				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
81. 4-603.11 - Dry Cleaning				
82. 4-902.11 - Food-Contact Surfaces				
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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section 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				
86. 4-204.113 - Warewashing Machine, Data Plate Operating Specifications				
87. 4-204.114 - Warewashing Machines, Internal Baffles				

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FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
88. 4-204.115 - Warewashing Machines, Temperature, Measuring Devices				
89. 4-204.116 - Manual Warewashing Equipment, Heaters and Baskets				
90. 4-204.117 - Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers				
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				
97. 4-302.14 - Sanitizing Solutions, Testing Devices				
98. 4-501.14 - Warewashing Equipment, Cleaning Frequency				

	Tuniadisticula		Partial Compliance	NO
FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	List what is not covered (Additional sheets can be used for explanations and comments)	Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
99. 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				
107. 4-603.13 - Loading of Soiled Items, Warewashing Machines				
108. 4-603.14 - Wet Cleaning				
109. 4-603.15 - Washing, Procedures for Alternative Manual Warewashing Equipment				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
110. 4-603.16 - Rinsing Procedures				
111. 4-904.14 - Rinsing Equipment and Utensils After Cleaning and Sanitizing				

TOTAL NUMBER OF SECTION 21 PROVISIONS MARKED "YES ______ (Section 21 has a total of 28 provisions)

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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section 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				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
118. 4-803.11 - Storage of Soiled Linens				
119. 4-803.12 - Mechanical Washing				
120. 4-901.12 - Wiping Cloths, Air Drying Locations				
121. 4-902.12 - Equipment				

TOTAL NUMBER OF SECTION 22 PROVISIONS MARKED "YES	(Section 22 has a total of 10 provisions)
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SECTION 23 – STORAGE, HANDLING OF CLEAN EQUIPMENT, UTENSILS

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section 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				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
125. 4-904.11 - Kitchenware and Tableware				
126. 4-904.12 - Soiled and Clean Tableware				
127. 4-904.13 - Preset Tableware				

TOTAL NUMBER OF SECTION 23 PROVISIONS MARKED "YES ______ (Section 23 has a total of 6 provisions)

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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section 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. 4-502.14 - Shells, Use Limitation				

TOTAL NUMBER OF SECTION 24 PROVISIONS MARKED "YES ______ (Section 24 has a total of 3 provisions)

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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section 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				

TOTAL NUMBER OF SECTION 25 PROVISIONS MARKED "YES ______ (Section 25 has a total of 9 provisions)

SECTION 26 – PLUMBING: INSTALLED, MAINTAINED

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section 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 Sink, 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				
149. 5-205.15 - System Maintained in Good Repair				
150. 5-301.11 - Approved				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
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				
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				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
163. 5-304.14 - Tank, Pump, and Hoses, Dedication				

TOTAL NUMBER OF SECTION 26 PROVISIONS MARKED "YES	(Section 26 has a total of	f 24 provisions	ĭ
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SECTION 27 – CROSS CONNECTION, BACK SIPHONAGE, BACKFLOW PREVENTION

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
5-202.13 - Backflow Prevention, Air Gap				
5-202.14 - Backflow Prevention Device, Design Standard				
5-203.14 - Backflow Prevention Device, When Required				
5-203.15 - Backflow Prevention Device, Carbonator				
5-204.12 - Backflow Prevention Device, Location				
5-205.12 - Prohibiting a Cross Connection				

TOTAL NUMBER OF SECTION 27 PROVISIONS MARKED "YES ______ (Section 27 has a total of 6 provisions)

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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
170. 5-203.12 - Toilets and Urinals				
171. 6-402.11 - Convenience and Accessibility				

TOTAL NUMBER OF SECTION 28 PROVISIONS MARKED "Y	Y ES (Section 28 has a	a total of 2 provisions)
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SECTION 29 – TOILET ROOMS ENCLOSED, SELF-CLOSING DOORS; FIXTURES GOOD REPAIR, CLEAN PROPER WASTE RECEPTACLES

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
172. 5-501.17 - Toilet Room Receptacle, Covered				
173. 6-202.14 - Toilet Rooms, Enclosed				
174. 6-302.11 - Toilet Tissue Availability				
175. 6-501.19 - Closing Toilet Room Doors				

TOTAL NUMBER OF SECTION 29 PROVISIONS MARKED "YES (Section 29 has a total of 4 provision)

SECTION 30 – SEWAGE AND WATER WASTE DISPOSAL

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section 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. 5-402.15 - Flushing a Waste Retention Tank				
182. 5-403.11 - Approved Sewage Disposal System				
183. 5-403.12 - Other Liquid Wastes and Rainwater				

TOTAL NUMBER OF SECTION 30 PROVISIONS MARKED "YES	(Section 30 has a total of 8 provisions
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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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section 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 – Cleaning 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				
193. 5-501.111 – Areas, Enclosures, and Receptacles, Good Repair				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
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				
202. 6-202.110 - Outside Refuse Areas, Curbed and Graded to Drain				

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

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

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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
214. 6-202.18 - Outdoor Servicing Areas, Overhead Protection				
215. 6-501.11 - Repairing				
216. 6-501.12 - Cleaning, Frequency and Restrictions				
217. 6-501.13 - Cleaning Floors, Dustless Methods				
218. 6-501.17 - Absorbent Materials on Floors, Use Limitation				

TOTAL NUMBER OF SECTION 32 PROVISIONS MARKED "YES ______ (Section 32 has a total of 16 provisions)

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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
219. 4-202.18 - Ventilation Hood Systems, Filters				
220. 4-204.11 - Ventilation Hood Systems, Drip Prevention				
221. 4-301.14 - Ventilation Hood Systems, Adequacy				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
222. 6-202.11 - Light Bulbs, Protective Shielding				
223. 6-303.11 - Intensity				
224. 6-304.11 - Mechanical				
225. 6-305.11 - Designation				
226. 6-403.11 - Designated Areas				
227. 6-501.14 - Cleaning Ventilation Systems, Nuisance and Discharge Prohibition				
228. 6-501.110 - Using Dressing Rooms and Lockers				
229. 6-202.12 - Heating, Ventilating, Air Conditioning System Vents				

TOTAL NUMBER OF SECTION 33 PROVISIONS MARKED "YES ______ (Section 33 has a total of 11 provisions)

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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
230. 6-202.19 - Outdoor Walking and Driving Surfaces, Graded to Drain				
231. 6-501.15 - Cleaning Maintenance Tools, Preventing Contamination				
232. 6-501.16 - Drying Mops				
233. 6-501.113 - Storing Maintenance Tools				
234. 6-501.114 - Maintaining Premises, Unnecessary Items and Litter				

TOTAL NUMBER OF SECTION 34 PROVISIONS MARKED "YES ______ (Section 34 has a total of 5 provisions)

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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
235. 4-301.15 - Clothes Washers and Dryers				
236. 4-401.11 - Equipment Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
237. 4-803.13 - Use of Laundry Facilities				
238. 6-202.111 - Private Homes and Living or Sleeping Quarters, Use Prohibition				
239. 6-202.112 - Living or Sleeping Quarters, Separation				

TOTAL NUMBER OF SECTION 35 PROVISIONS MARKED "YES ______ (Section 35 has a total of 5 provisions)

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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	<u>YES</u> Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
240. 2-403.11 - Handling Prohibition				
241. 6-202.13 - Insect Control Device, Design and Installation				
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				

TOTAL NUMBER OF SECTION 36 PROVISIONS MARKED "YES ______ (Section 36 has a total of 7 provisions)

STANDARD 1 – REGULATORY FOUNDATION SELF-ASSESMENT WORKSHEET

PART II - 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		Thermometers Provided and Conspicuous	
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		Toilet Facilities: Convenient, Accessible, Designed, Installed	
29		Toilet Rooms Enclosed, Self-Closing Doors; Fixtures, Good Repair, Clean, etc.	
30		Sewage and Wastewater Disposal	
31		Garbage and Refuse Disposal - Containers or Receptacles: Covered, etc.	
32		Physical Facility - Floors, Walls, Ceiling: Designed, Constructed, Maintained,	
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 PROVISIONS MET (Add Column 2):	
Divide the total number of provisions met (last line of table) by 246 and multiply by 10	
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.

STANDARD 1 – REGULATORY FOUNDATION INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELFASSESSMENT

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 categories 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 *FDA Food Code* sections listed in Items 1 through 12.

In the case of Item 12, pertaining to "Legal Remedies", three *FDA Food Code* sections comprise this COMPLIANCE AND ENFORCEMENT category. A jurisdiction must demonstrate a corresponding regulatory requirement for one of the *FDA Food Code* sections pertaining to criminal, injunctive, or civil penalties. For item 7d, jurisdictions that do not issue variances defaults to a "yes, full intent is met".

NOTE: If a jurisdiction adopted the current published edition or one of the two most recent editions of the FDA Food Code by reference, a side-by-side comparison of the language is not necessary. Adoption by reference meets the criteria of the Standard.

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 *FDA Food Code* section:

- Record the corresponding jurisdiction requirement; and
- Document his/her determination:
 - If **full intent** of the FDA Food Code section is met, place an "X" in the appropriate column.
 - If **partial intent** of the *FDA 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 *FDA 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; and
- > 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 - Food Code: Compliance and Enforcement

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

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
5b. Information Authority; Restriction/Exclusion of Employees 8-501.20 – Restriction or Exclusion of Food Employee, or Summary Suspension of Permit				
5c. Information Authority; Restriction/Exclusion of Employees 8-501.30 – Restriction or Exclusion Order: Warning or Hearing Not Required, Information Required in Order				
6. Authority to Require HACCP Plans 8-201.13 – When a HACCP Plan is Required				
7a. Granting of Variances 8-103.10 – Modifications and Waivers				
7b. Granting of Variances 8-103.11 – Documentation of Proposed Variance and Justification				
7c. Granting of Variances 8-103.12 – Conformance with Approved Procedures				
7d. 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				
8c. Timely Correction of Critical Violations 8-406.11 – Time Frame for Correction				

FDA Food Code Section	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	Partial Compliance List what is not covered (Additional sheets can be used for explanations and comments)	NO Compliance with the FDA Food Code section is NOT Met (Indicate the situation)
9a. Imminent Health Hazard (Summary of Suspension) 8-404.12 – Resumption of Operations				
9b. 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				
10b. License Suspension / Revocation 8-905.20 - Response to Notice of Hearing or Request for Hearing, Required Form and Contents				
11a. Institution of Proceedings 8-910.10 - Institution of Proceedings				
12a. Criminal Penalties** 8-911.10 - Authorities, Methods, Fines and Sentences				
12b. 8-912.10 - Petitions for Injunction**				
12c. Civil Penalties Provided** 8-913.10 - Petitions, Penalties and Continuing Violations				

NOTE:

- 1. Meeting the Standard #1 criteria for the "Compliance and Enforcement" component requires a "Yes" for all FDA Food Code Sections listed in Items 1 through 11.
- 2. *For Item 7d, jurisdictions that <u>do not</u> issue variances defaults to a "yes, full intent is met".
- 3. **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 - Food Code: Compliance and Enforcement Self-Assessment Results

Compliance and Enforcement Category and Description	YES Full Intent is Met	NO Standard Criteria is not Met	Self-Assessor's General Comments
1. Hold Orders, Embargo, and Destruction of Food			
2. Permit / License Required; Right to Deny			
3. Plan Review / Pre-Operational Inspections			
4. Inspection Authority / Right to Access			
5. Information Authority; Restriction / Exclusion of Employees			
6. Authority to Require HACCP Plans			
7. Granting of Variances / Variances Prohibited			
8. Timely Correction of Critical Violations			
9. Imminent Health Hazard (Summary of Suspension)			
10. License Suspension / Revocation			
11. Institution of Proceedings			
12. Legal Remedies			

Assessment of		indicates conformance with	out of the 12 Compliance and Enforcement Categories
1-64	(Regulatory Agency)	(# Met)	

STANDARD 1 – REGULATORY FOUNDATION INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

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 code against the *FDA 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.

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 Provisions.

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

NOTE: If a jurisdiction adopted the current published edition or one of the two most recent editions of the FDA Food Code by reference, a side-by-side comparison of the language is not necessary. Adoption by reference meets the criteria of the Standard.

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

The verification AUDITOR must randomly select *FDA 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 94 *FDA Food Code* sections pertaining to Public Health Interventions and Risk Factor Controls. Each of these *FDA Food Code* sections has been assigned a number from 1 to 94.

For Part I, the verification AUDITOR must randomly select 15 FDA 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 FDA 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 *FDA 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 did not meet, the verification AUDITOR should select a substitute *FDA Food Code* section to review.

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

For each of the randomly selected regulatory requirements, the AUDITOR must compare the language in the jurisdiction's code to the corresponding *FDA Food Code* section to verify it's at least as 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 determines that the jurisdiction's language does not meet the criterion, they must explain 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 *FDA Food Code* sections listed for that area. For initial listing, the jurisdiction's regulatory foundation must contain at least nine 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 *FDA Food Code* sections. No more than three total disagreements are acceptable in the 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 nine 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; and
- ➤ 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 Control

Number of Sections Reviewed	Randomly Selected Number	Corresponding FDA Food Code Chapter from Part I Interventions and Risk Factors Self-Assessment Worksheet	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	NO Full Intent is Not Met	If no, auditor must specify why criterion is not met
1						
2						
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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.
- 3. 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 Control

Number of Sections Reviewed	Randomly Selected Number	Corresponding FDA Food Code Chapter from Part I Interventions and Risk Factors Self-Assessment Worksheet	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	NO Full Intent is Not Met	If no, auditor must specify why criterion is not met
1						
2						
3						
4						
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7						
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10						
11						
12						
13						
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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.

STANDARD 1 - REGULATORY FOUNDATION INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

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 FDA 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 FDA Food Code sections. The AUDITOR must determine if the jurisdiction identified at least 234 FDA Food Code sections (95%) that meet the criteria for stringency of language compared to the FDA Food Code.

NOTE: If a jurisdiction adopted the current published edition or one of the two most recent editions of the FDA Food Code by reference, a side-by-side comparison of the language is not necessary. Adoption by reference meets the criteria of the Standard.

STEP 2 – Determine Good Retail Practices Sections to Review

The verification AUDITOR must randomly select 13 FDA 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 FDA 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 *FDA Food Code* sections that the jurisdiction indicated were met. If a Good Retail Practice *Food Code* section is selected that the jurisdiction did not meet, the verification AUDITOR should select a substitute *FDA Food Code* section to review.

STEP 3 – Confirm Findings for Good Retail Practices

For each of the randomly selected regulatory requirements, the AUDITOR must compare the language in the jurisdiction's code to the corresponding Food Code section to verify it's at least as 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, they must explain 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 II

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 *FDA 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 *FDA Food Code* sections. No more than three total disagreements are acceptable in the 26 *FDA 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 *FDA Food Code* that was used for the SELF-ASSESSMENT;
- ➤ Completed Standard 1: Self-Assessment Worksheet Part II Good Retail Practices; and
- ➤ 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

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

NOTES

- 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 FDA 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

Number of Sections Reviewed	Randomly Selected Number	Corresponding FDA Food Code Chapter from Part II Good Retail Practices Self- Assessment Worksheet	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	NO Full Intent is Not Met	If no, auditor must specify why criterion is not met
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

NOTES

^{1.} If more than three of the 26 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 Good Retail Practices.

STANDARD 1 - REGULATORY FOUNDATION INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

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 it has a corresponding regulatory requirement for the *FDA Food Code* sections listed in Items 1 through 12 on Part III of the *Standard 1: Self-Assessment Worksheet*. For Items 1 through 12, a jurisdiction must demonstrate its regulations have a corresponding provision or language for all the *FDA Food Code* sections listed.

In the case of Item 12, pertaining to "Legal Remedies", three *FDA Food Code* sections comprise this COMPLIANCE AND ENFORCEMENT category. A jurisdiction must demonstrate a corresponding regulatory requirement for one of the *FDA Food Code* sections pertaining to criminal, injunctive, or civil penalties. For item 7d, jurisdictions that do not issue variances defaults to a "yes, full intent is met".

NOTE: If a jurisdiction adopted the current published edition or one of the two most recent editions of the FDA Food Code by reference, a side-by-side comparison of the language is not necessary. Adoption by reference meets the criteria of the Standard.

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

The verification AUDITOR must randomly select five COMPLIANCE AND ENFORCEMENT categories 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 *FDA 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 12 COMPLIANCE AND ENFORCEMENT categories to review. For each selected category, the jurisdiction must demonstrate its regulations have a corresponding provision(s) or language for each *FDA Food Code* section listed under that category, except Item 12 pertaining to "Legal Remedies," where only one of the sections pertaining to criminal, injunctive, or civil penalties is required. For Item 7d, jurisdictions that do not issue variances defaults to a "yes, full intent is met".

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

For each of the randomly selected regulatory requirements, the AUDITOR must compare the language in the jurisdiction's code to the corresponding *FDA Food Code* section to verify it's at least as 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; and
- ➤ 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

Number of Sections Reviewed	Randomly Selected Number	Corresponding FDA Food Code Chapter from Part III Compliance and Enforcement Self- Assessment Worksheet	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	NO Full Intent is Not Met	If no, auditor must specify why criterion is not met
1						
2						
3						
4						
5						

NOTES

- 1. Some Compliance and Enforcement categories contain multiple FDA Food Code Sections. List all the pertinent FDA Food Code Sections listed on the Self-Assessment Worksheet for each of the Compliance and Enforcement categories that are randomly selected.
- 2. Meeting the Standard 1 criteria for the "Compliance and Enforcement" component requires a "Yes" for all FDA Food Code sections listed in Items 1 through 11. 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. For Item 7d, jurisdictions that do not issue variances defaults to a "yes, full intent is met".
- 3. 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 Standard 1 criteria is met for Part III.
- 4. 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 jurisdiction does not meet the Standard 1 criteria for Part III.

STANDARD 2 – TRAINED REGULATORY STAFF

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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 any 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 food safety related continuing education every 36 months after initial training is completed for those conducting standardization of others, and minimum of 30 contact hours every 60 months for those not responsible for standardizing others after 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 24 months of hire or assignment to the retail food regulatory program.
- Step 5 every 36 months/60 months after the initial 24 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 LearnED 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 LearnED pre-requisite ("Pre") courses is 39 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 LearnED pre-requisite (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 FDA ORA LearnED course AND verification of successful completion is provided. The learning objectives for each of the listed FDA ORA LearnED courses are available from the web site link at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

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 LearnED 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 current version of the *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 24 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 eight curricula areas, must be completed within this 24-month time frame.

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

All courses for each of the curriculum areas must be successfully completed within 24 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 LearnED "post" courses is 31 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 FDA ORA LearnED 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 LearnED courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable FDA ORA LearnED course AND verification of successful completion can be provided. The learning objectives for each of the listed FDA ORA LearnED courses are available from the FDA website: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners.

Step 4: Food Safety Inspection Officer – Field Standardization

Within 24 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. FSIOs that do not standardize others shall complete restandardization at least every five 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 Standardization.

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 24- 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 responsible for standardizing others must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (24 months) is completed. All other FSIOs must accumulate 30 contact hours every 60 months after the initial training (24 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 FDA ORA LearnED, industry associations, universities); and
 - Satellite Broadcasts.
- 6. Foodborne Illness training referenced in the Crosswalk Requirements for Foodborne Illness Training Programs Standard 5.

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

- 1. Delivering presentations at professional conferences;
- 2. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
- 3. 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 three-year continuing education period.

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:

1. 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-assessed 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.

STANDARD 2 – TRAINED REGULATORY STAFF INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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 2 criterion 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 *Standard 2: 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 an "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 Self-Assessment:	
Self-Assessor's Title:	
Jurisdiction Name:	
Jurisdiction Address:	
Phone:	
FAX:	
E-mail:	
Date the Standard 2 Self-Assessment Was Completed:	
Self-Assessment Indicates That the Jurisdiction MEETS the Standard 2	
Criteria (Indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standar	rd 2 is true and correct.
Signature of the Self-Assessor:	
VERIFICATION AU	DIT 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 2 Was Completed:	
Verification Audit Indicates That the Jurisdiction MEETS the Standard	
2 Criteria (Indicate YES/NO):	
I affirm that the information represented in the Verification Audit of Stand	ard 2 is true and correct.
Signature of the Verification Auditor:	

STANDARD 2 – TRAINED REGULATORY STAFF PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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Criteria	Element	Jurisdiction's Self- Assessment YES	Jurisdiction's Self- Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification 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 of hire or assignment to the agency's retail food protection program.						
1. Employee Training Records	b) The jurisdiction's 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.						

Criteria	Element	Jurisdiction's Self- Assessment YES	Jurisdiction's Self- Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
2. Initial Field Training	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 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.						
3. Independent Inspections / Completion of ALL Curriculum Requirements	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.						

Criteria	Element	Jurisdiction's Self- Assessment YES	Jurisdiction's Self- Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
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 24 months of hire or assignment to the retail food protection program.						
4. Field Standardization	b) The jurisdiction maintains a written training record that provides documentation that a standardized employee who is responsible for standardizing others has maintained their standardization by performing a minimum of four joint inspections with a training standard every three years. Those who are not responsible for standardizing others have maintained their standardization by performing a minimum of four joint inspections with a training standard every five years.						

Criteria	Element	Jurisdiction's Self- Assessment YES	Jurisdiction's Self- Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
5. Continuing Education and Training	a) The jurisdiction maintains a written training record that provides documentation that an employee responsible for standardizing others has 20 hours of continuing education every 36 months after the initial training (24) months is completed. All other FSIOs must complete 30 contact hours every 60 months after the initial training (24 months) is completed.						

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

STANDARD 2 – TRAINED REGULATORY STAFF INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELFASSESSMENT

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 recorded 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 24 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 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 24 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 24 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.

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

Employees responsible for standardizing others must accumulate 20 contact hours of continuing education training every 36 months. All other employees must accumulate 30 contact hours of continuing education training every 60 months. For employees newly hired or newly reassigned to the retail food program, the 36/60-month period does not begin until after the first 24 months of training. For existing employees, the 36/60-month period does not begin until a jurisdiction enrolls as a participant in the Standards. The date each employee accumulated 20/30 contact hours of continuing education within the 36/60 months of their most current standardization/re-standardization 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-assessor's 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 SELF-ASSESSMENT WORKSHEET TRAINING RECORD FOR EACH EMPLOYEE

(*indicates completion date required)

No.	Employee Name	Date of Hire or Assignment to the Retail Food Program	Completion of Training Pre- requisite ("Pre") Curriculum* (Prior to conducting independent inspections)	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 25 Independent Inspections AND "Post" Curriculum Courses* (within 24 months of hire or assignment to the Retail Food Program	Completion of Field Standardization* (within 24 months of hire or assignment to the Retail Food Program)	Does FSIO standardize others? YES or NO	Number of Education Contact Hours (Minimum of 20 contact hours every three years or 30 contact hours every five years	Meets the Standard 2 Criteria YES or NO
1									
2									
3									
4									
5									
6									
7									
8									
9									
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 finding for each of the items on the Standard 2: Program Self-Assessment and Verification Audit Form.
- 3. FSIOs responsible for standardizing others must be re-standardized every three years. All other FSIOs may be re-standardized every five years.
- 4. FSIOs who standardize others must accrue a minimum of 20 contact hours every three years. All other FSIOs must accrue a minimum of 30 contact hours every five years.

Additional Standard 2 Self-Assessment Worksheet (if needed)

STANDARD 2 – TRAINED REGULATORY STAFF SELF-ASSESSMENT WORKSHEET TRAINING RECORD FOR EACH EMPLOYEE

(*indicates completion date required)

No.	Employee Name	Date of Hire or Assignment to the Retail Food Program	Completion of Training Pre- requisite ("Pre") Curriculum* (Prior to conducting independent inspections)	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 25 Independent Inspections AND "Post" Curriculum Courses* (within 24 months of hire or assignment to the Retail Food Program	Completion of Field Standardization* (within 24 months of hire or assignment to the Retail Food Program)	Does FSIO standardize others? YES or NO	Number of Education Contact Hours (Minimum of 20 contact hours every three years or 30 contact hours every five years	Meets the Standard 2 Criteria YES or NO
1									
2									
3									
4									
5									
6									
7									
8									
9									
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 finding for each of the items on the Standard 2: Program Self-Assessment and Verification Audit Form.
- 3. FSIOs responsible for standardizing others must be re-standardized every three years. All other FSIOs may be re-standardized every five years.
- 4. FSIOs who standardize others must accrue a minimum of 20 contact hours every three years. All other FSIOs must accrue a minimum of 30 contact hours every five years.

STANDARD 2 – TRAINED REGULATORY STAFF INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

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 substituted during 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 24 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 inspections, 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 24 months of hire or re-standardization every three years after initial standardization for FSIOs standardizing others and every five years for FSIOs that do not standardize others, and
- ➤ minimum of 20 contact hours of food safety related continuing education every 36 months for FSIOs standardizing others, and minimum of 30 contact hours every 60 months for all other FSIOs after initial training is completed.

NOTE: The AUDITOR shall use the Standard 2 curriculum version in the Voluntary National Retail Food Regulatory Program Standards that was utilized at the time the FSIO completed Step 1 and 3 of the Standard.

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 24 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 24 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

No.	Randomly Selected Number	Employee Name	<u>Yes</u> Standard 2 Criteria are Met	<u>No</u> Standard 2 Criteria are Not Met	If NO, auditor is to specify why criterion is not met
1					
2					
3					
4					
5					
6					
7					
8					
9					
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

No.	Randomly Selected Number	Employee Name	Yes Standard 2 Criteria are Met	<u>No</u> Standard 2 Criteria are Not Met	If NO, auditor is to specify why criterion is not met
1					
2					
3					
4					
5					
6					
7					
8					
9					
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.

STANDARD 2 – TRAINED REGULATORY STAFF APPENDIX B-1: CURRICULUM FOR RETAIL FOOD SAFETY INSPECTION OFFICERS

The courses listed below are updated and moved across different learning management systems over time. The latest information will be posted on the FDA Program Standards Landing Page at https://www.fda.gov/food/retail-food-protection/voluntary-national-retail-food-regulatory-program-standards.

NOTE: All courses, except Emergency Management, can be found on the LearnED platform at https://fdaoted.csod.com. Important: Search for courses using the specified Course Number (ex. CC8044W) and not by keyword. Emergency Management courses are available through FEMA at http://training.fema.gov/IS/NIMS.asp.

For state, local, tribal, & territorial (SLTT) regulators to register on-line for free access to web courses, go to: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/state-local-tribal-and-territorial-regulatory-partners

Pre-requisite ("Pre") Curriculum Courses

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

PUBLIC HEALTH PRINCIPLES

Course Number	Courses
CC8026W (450)	Introduction to Public Health Principles

MICROBIOLOGY

Course Number	Courses
CC8028W (90)	Biological Hazards
CC9013W (90)	Control by Thermal Processing
CC8002W (All modules) (105)	Pasteurization
CC8035W (120)	Sampling
CC8032W (210)	Sanitation Practices
CC8024W (120)	Environmental Hazards

PREVAILING STATUTES, REGULATIONS, ORDINANCES

Course Number	Courses
CC8039W (120)	Laws, Regulations, Policies, and Procedures
CC9037W (90)	Basics of Inspection: Beginning an Inspection
CC9038W (90)	Basics of Inspection: Issues & Observations
CC8027W (90)	Food Defense
CC8001W (All modules) (180)	Plumbing Controls for Commercial Food Establishments
CC8037W (150)	Jurisdiction
CC8044W (180)	Introduction to Pest Control
FDA Food Code: Specific SLTT laws and regulations to be addressed by each jurisdiction.	NOTE: Some jurisdictions may require the FDA Food Code Course in addition to SLTT food code training.

COMMUNICATION SKILLS

Course Number	Courses
CC8011W (All modules) (60)	Communication Skills for Regulators
CC8025W (150)	Professionalism

Curriculum ("Post") Courses

(To be completed any time prior to Food Code Standardization AND within 24 months of hire or assignment to the regulatory retail food program)

MICROBIOLOGY

Course Number	Courses
CC9016W (120)	Technology-Based Food Processes

HACCP

Course Number	Courses
CC8033W (120)	HACCP

ALLERGEN MANAGEMENT

Course Number	Courses
CC8029W (90)	Allergens

EPIDEMIOLOGY

Course Number	Courses
FD9035W (All modules) (480)	Foodborne Illness Investigations

PUBLIC HEALTH PRINCIPLES

Course Number	Courses
CC8018W (120)	Integrated Food Safety System

PREVAILING STATUTES, REGULATIONS, ORDINANCES

Course Number	Courses
CC8036W (90)	Transportation
CC8038W (90)	Labeling
CC8041W (135)	Recalls
CC8042W (60)	Traceability

EMERGENCY MANAGEMENT – FEMA

Course Number	Courses		
IS-100.C, Introduction to the Incident Command System, (180) ICS-100 for FDA	Introduction to Incident Command System		
IS-200.C, Basic Incident Command System for Initial Response (180)	Basic Incident Command System for Initial Response		
IS 700.B, An Introduction to NIMS, (180) ICS-			
700	An Introduction to NIMS		

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

Estimated total hours for "Pre" courses are 39 hours.

Estimated total hours for "Post" courses are 31 hours.

Estimated total hours for completion of all Program Standard 2 coursework are 70 hours.

STANDARD 2 – TRAINED REGULATORY STAFF 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/).

STANDARD 2 – TRAINED REGULATORY STAFF APPENDIX B-3: RETAIL FOOD ESTABLISHMENT CATEGORIES

2022 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

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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 foodborne illness RISK FACTORS and FOOD CODE 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 FACTORS, and
 - c) Follow-up activities.
- 5. Establish and implement a written policy addressing code variance requests related to RISK FACTORS and interventions.
- 6. Establish a written policy regarding the validation and verification of HACCP plans when a plan is required by the code.
- 7. The jurisdiction develops and implements a program policy for conducting reviews of plans submitted by food establishments****. The policy should include a review and determination of the adequacy of facilities, equipment, and procedures based on the establishment's intended menu, volume of food, flow of food and food processes. The program policy should include documentation of all plan reviews conducted (approval, conditional, denial) or, if the regulatory program does not conduct plan review or shares responsibility for the plan review with other entities or agencies, there are agreements in place between the agencies and the process for plan review is documented.

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 validation and verification of HACCP plans required by code,
- 6. Policy requiring the discussion of food safety control systems with management when out of control RISK FACTORS are recorded on subsequent inspections, and
- 7. Policy for conducting reviews of plans submitted by food establishments. The policy should include the documentation of all plan reviews conducted (approval, conditional, denial) or if plan review is conducted externally, documentation of the process (policy, contract, MOU).

*NOTE: Consideration of the elements outlined in Standard 4 will ensure a strong foundation for a quality and uniform inspection program.

**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.

****NOTE: Through their committee process, the Conference for Food Protection (CFP) has developed Plan Review for Food Establishment guidance on the CFP web site: www.foodprotect.org located under the icon titled, "Conference Developed Guides and Documents" and can be downloaded at https://www.foodprotect.org/guides-documents/plan-review-for-food-establishments-2016/.

STANDARD 3 – INSPECTION PROGRAM BASED ON HACCP PRINCIPLES INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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 activities 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. Validation and Verification of HACCP Plan Policy
 - a. The jurisdiction has a written and implemented policy for the validation and verification of HACCP plans, when a HACCP plan is required by the *Food Code*.
- 7. The jurisdiction develops and implements a program policy for conducting reviews of plans submitted by food establishments. The policy should include a review and determination of the adequacy of facilities, equipment, and procedures based on the establishment's intended menu, volume of food, flow of food, and food processes.

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

	77.121(1 5 61/11/11111
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 3 Self-Assessment Was Completed:	
Self-Assessment Indicates That the Jurisdiction MEETS the Standard 3 Criteria (Indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standar	d 3 is true and correct.
Signature of the Self-Assessor:	
VERIFICATION AUD	IT SUMMARY
VERIFICATION AUD Printed Name of the Person Who Conducted the Verification Audit:	IT SUMMARY
	IT SUMMARY
Printed Name of the Person Who Conducted the Verification Audit:	IT SUMMARY
Printed Name of the Person Who Conducted the Verification Audit: Verification Auditor's Title:	IT SUMMARY
Printed Name of the Person Who Conducted the Verification Audit: Verification Auditor's Title: Auditor's Jurisdiction Name:	IT SUMMARY
Printed Name of the Person Who Conducted the Verification Audit: Verification Auditor's Title: Auditor's Jurisdiction Name: Auditor's Jurisdiction Address:	IT SUMMARY
Printed Name of the Person Who Conducted the Verification Audit: Verification Auditor's Title: Auditor's Jurisdiction Name: Auditor's Jurisdiction Address: Phone:	IT 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:	IT 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:	IT 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 3 Was Completed: Verification Audit Indicates That the Jurisdiction MEETS the Standard	

STANDARD 3 – INSPECTION PROGRAM BASED ON HACCP PRINCIPLES PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	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						
1. Inspection Form Design	b) The jurisdiction's inspection form documents actual observations using the convention (IN, OUT, NO, and NA).						
1. Inspection Form Design	c) The jurisdiction's inspection form documents compliance and enforcement activities.						
2. Risk Assignment 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.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
4. Written and Implemented Corrective Action Policy	a) The jurisdiction has a written and implemented policy that requires on-site corrective actions for foodborne illness risk factors observed to be out of compliance.						
4. Written and Implemented Corrective Action Policy	b) The jurisdiction has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.						
4.Written and Implemented Corrective Action Policy	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 Food Code interventions.						
6. Validation and Verification of HACCP Plans	a) The jurisdiction has a written and implemented policy for the validation and verification of HACCP plans, when a HACCP plan is required by the Code.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
Implemented Policy for Conducting Plan Review	The jurisdiction has a plan review policy that requires plan review that complies with the Food Code or documentation of the process if it's done by another jurisdiction of agency.						

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

STANDARD 4 – UNIFORM INSPECTION PROGRAM

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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 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.
 - 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 option 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 24 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.

STANDARD 4 – UNIFORM INSPECTION PROGRAM INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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. An ongoing quality assurance program that:
 - a. Is described in a written document and covers all inspection personnel performing food service or retail food inspections, and
 - b. 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.

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 VERIFICATION AUDIT. 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 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 4 Self-Assessment Was Completed:	
Self-Assessment Indicates That the Jurisdiction MEETS the Standard 4 Criteria (Indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standar	d 4 is true and correct.
Signature of the Self-Assessor:	
VERIFICATION AUD	IT 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 4 Was Completed:	
Verification Audit Indicates That the Jurisdiction MEETS the Standard 4 Criteria (Indicate YES/NO):	
I affirm that the information represented in the Verification Audit of Stand	ard 4 is true and correct.
Signature of the Verification Auditor:	

STANDARD 4 – UNIFORM INSPECTION PROGRAM PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Written Quality Assurance Program Document	a. The jurisdiction has a written quality assurance program that covers all regulatory staff that conducts retail food and/ or foodservice inspections.						
1. Written Quality Assurance Program Document	b. 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 Elements	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.						
2. Twenty quality Assurance Elements	I. The jurisdiction's quality assurance program assures that each inspector has the required equipment and forms to conduct the inspection.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
2. Twenty quality Assurance Elements	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.						
2. Twenty quality Assurance Elements	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.						
2. Twenty quality Assurance Elements	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.						
2. Twenty quality Assurance Elements	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.						
2. Twenty quality Assurance Elements	VI. The jurisdiction's quality assurance program assures that each inspector uses a risk-based inspection methodology to conduct the inspection.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
2. Twenty quality Assurance Elements	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).						
2. Twenty quality Assurance Elements	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.						
2. Twenty quality Assurance Elements	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.						
2. Twenty quality Assurance Elements	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.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
2. Twenty quality Assurance Elements	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.						
2. Twenty quality Assurance Elements	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.						
2. Twenty quality Assurance Elements	XIII. The jurisdiction's quality assurance program assures that each inspector demonstrates proper sanitary practices as expected from a food service employee.						
2. Twenty quality Assurance Elements	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).						
2. Twenty quality Assurance Elements	XV. The jurisdiction's quality assurance program assures that each inspector documents the status of each risk factor and intervention (IN, OUT, NA, NO).						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
2. Twenty quality Assurance Elements	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.						
2. Twenty quality Assurance Elements	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.						
2. Twenty quality Assurance Elements	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.						
2. Twenty quality Assurance Elements	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.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
2. Twenty quality Assurance Elements	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 Using the Statistical Method in Standard 4: Self- Assessment Worksheet	a. The program effectiveness measure documents that 3 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.]						
3.Demonstration of Program Effectiveness Using the Statistical Method in Standard 4: Self-Assessment Worksheet	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.						

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

STANDARD 4 – UNIFORM INSPECTION PROGRAM INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

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 24 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 that are 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 three 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 three 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.

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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:

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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**

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

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

STANDARD 4 – UNIFORM INSPECTION PROGRAM SELF-ASSESSMENT WORKSHEET

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

										_									I _	_	_	_	
No.	Inspector ID	Establishment ID	Date	Item (1)	Item (2)	Item (3)	Item (4)	Item (5)	Item (6)	Item (7)	Item (8)	Item (9)	Item (10)	Item (11)	Item (12)	Item (13)	Item (14)	Item (15)	Item (16)	Item (17)	Item (18)	Item (19)	Item (20)
1																							
2																							
3																							
4																							
5																							
6																							
7																							
8																							
9																							
10																							
11																							
12																							
13																							
14																							
15																							
16																							
17																							
18																							
19																							
20																							

NOTE: 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

Measure	Item (1)	Item (2)	Item (3)	Item (4)	Item (5)	Item (6)	Item (7)	Item (8)	Item (9)	Item (10)	Item (11)	Item (12)	Item (13)	Item (14)	Item (15)	Item (16)	Item (17)	Item (18)	Item (19)	Item (20)
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 4 – UNIFORM INSPECTION PROGRAM INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

Step 1 – Verify the Elements in the Written Quality Assurance Program

To meet the criteria of Standard 4, the jurisdiction must have 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 should be described in a written document and cover all inspection personnel performing food service or retail food inspections. The quality assurance plan should describe corrective actions to be taken whenever quality and consistency problems are identified. The written program should also include the twenty quality elements listed in Standard 4. The verification AUDITOR should review the written quality assurance program to ensure that there is clear guidance for staff.

Standard 4 does not dictate a required procedure for the quality assurance program, only that it must be ongoing and monitored regularly as described in the written document. The jurisdiction is free to determine any actions to be taken to address quality and consistency problems as they arise. The jurisdiction may add additional quality elements beyond the twenty listed in the Standard.

Step 2 – Verify the Demonstration of Program Effectiveness.

Part I – Verify the number of inspection staff and confirm that a minimum of three field and file reviews have been conducted for each employee performing foodservice or retail food inspection work during the five-year self-assessment period and verify that the jurisdiction has a minimum of twelve total reviews.

Table 4-2 of the *Standard 4: Self-Assessment Worksheet* is used to document the field and file reviews for 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 and file reviews 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 with each inspector.

NOTE: Staff members who are within their initial 24 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.

Part II – Verify the Program Effectiveness calculation based on program size.

The completed Table 4-2 should be used to calculate Program Effectiveness based on one of two options:

• Option 1: Jurisdictions with ten or more (10+) inspectors

Verify the calculations completed on Table 4-3 meet the requirements of the Standard. Each of the twenty columns in Table 4-3 must show at least a 75% achievement in order for the program to meet the effectiveness measure.

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• Option 2: Jurisdictions with less than ten (1-9) inspectors

Verify the calculations completed on Table 4-1 meet the requirements of the Standard. Use Chart 4-1 to verify that minimum number of items to meet the effectiveness measure for Standard 4 have been met.

STANDARD 5 – FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

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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 FOODBORNE 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 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 MOUs 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: Regulatory programs are encouraged to refer to the Crosswalk - Requirements for Foodborne Illness Training Programs located on the CFP website at www.foodprotect.org under the Conference-Developed Guides and Documents tab and to also participate in the CDC National Environmental Assessment Reporting System (NEARS). The Crosswalk is a table that identifies training resources that correlate to the requirements listed in Standard 5. 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.)

STANDARD 5 – FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

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

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. Investigative Procedures;
 - ➤ Written Operating Procedure; Contact Lists; Cooperative Agreements;
 - ➤ Documenting and Responding to Reported Complaints/Incidences;
 - Complaint/Incident Investigative 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

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 5 Self-Assessment Was Completed:	
Self-Assessment Indicates That the Jurisdiction MEETS the Standard 5 Criteria (Indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standar	d 5 is true and correct.
Signature of the Self-Assessor:	
VERIFICATION AUD	OIT 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 5 Was Completed:	
Verification Audit Indicates That the Jurisdiction MEETS the Standard 5 Criteria (Indicate YES/NO):	
I affirm that the information represented in the Verification Audit of Stand	ard 5 is true and correct.
Signature of the Verification Auditor:	

STANDARD 5 – FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE PROGRAM PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1 Investigative	a) The program has written operating procedures for responding to and/or conducting investigations of foodborne illness and foodrelated 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.)						
1. Investigative Procedures	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.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Investigative Procedures	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.						
1. Investigative Procedures	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.						
1. Investigative Procedures	e) Program procedures describe the disposition, action, or follow-up and reporting required for each type of complaint or referral report.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Investigative Procedures	f) Program procedures require disposition, action or follow- up on each complaint or referral report alleging food- related illness or injury within 24 hours.						
1. Investigative Procedures	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.						
1. Investigative Procedures	h) Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.						
1. Investigative Procedures	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.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
2. Reporting Procedures	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.						
3. Laboratory Support Documentation	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).						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
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.						
5. Recalls	a) Program management has an established procedure to address the recall of foods implicated in an illness, outbreak, or intentional food contamination.						
5. Recalls	b) When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR Part 7 are followed.						
5. Recalls	c) Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
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.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
7. Data Review and Analysis	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;						
7. Data Review and Analysis	(2) Foodborne disease outbreaks, suspect foodborne outbreaks and confirmed foodborne disease outbreaks in the same establishment type;						
7. Data Review and Analysis	(3) Foodborne disease outbreaks, suspect foodborne outbreaks and confirmed foodborne disease outbreaks implicating the same food;						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
7. Data Review and Analysis	(4) Foodborne disease outbreaks, suspect foodborne outbreaks and confirmed foodborne disease outbreaks associated with similar food preparation processes;						
7. Data Review and Analysis	(5) Number of confirmed foodborne disease outbreaks						
7. Data Review and Analysis	(6) Number of foodborne disease outbreaks and suspect foodborne outbreaks;						
7. Data Review and Analysis	(7) Contributing factors most often identified;						
7. Data Review and Analysis	(8) Number of complaints involving real and alleged threats of intentional food contamination; and						
7. Data Review and Analysis	(9) Number of complaints involving the same agent and any complaints involving unusual agents when agents are identified						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
7. Data Review and Analysis*	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.						

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

A "yes" affirmation to each statement is required to meet Standard 5. If an item contains multiple questions, then all questions must be answered in the affirmative in order to meet that element of the Standard. The source documents, such as the various policies and 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.

*NOTE: Item 7c can be marked "not applicable" (NA) if the jurisdiction DID conduct a foodborne illness or food defense 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 training exercise.

STANDARD 6 – COMPLIANCE AND ENFORCEMENT

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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 encompass 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.]
- 5. A copy of the jurisdiction's established written procedures, including random sampling method used to measure the effectiveness of the COMPLIANCE AND ENFORCEMENT program.
- 6. Documentation from a statistician of equivalence to the Explanation of the Statistical Model for Standard 6.

STANDARD 6 – COMPLIANCE AND ENFORCEMENT INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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 VERIFICATION AUDIT. 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 (Indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standard	d 6 is true and correct.
Signature of the Self-Assessor:	
VERIFICATION AUD	IT 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 6 Was Completed:	
Verification Audit Indicates That the Jurisdiction MEETS the Standard	
6 Criteria (Indicate YES/NO):	
I affirm that the information represented in the Verification Audit of Standa	ard 6 is true and correct.
Signature of the Verification Auditor:	

STANDARD 6 – COMPLIANCE AND ENFORCEMENT PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

Jurisdiction Name:

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	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.						
1. Compliance and Enforcement Procedure	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 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.						

Criteria	Element	Jurisdiction's Self-Assessment YES	f-Assessment Self-Assessment Self-Assessor's Ge			Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
2. Assessment of Effectiveness	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.						

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

STANDARD 6 – COMPLIANCE AND ENFORCEMENT INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

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 establishment files or ROUTINE INSPECTIONS 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 selected establishments or ROUTINE INSPECTIONS. 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 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 – File Selection Process

In order to meet the criteria in Standard 6, jurisdictions must select files for review. There are three different methods that can be utilized for file selection, outlined as option 1, 2 and 3. Jurisdictions must select one of the three options.

- **Option 1:** Review each inspection when an FBI Risk Factor or Public Health intervention was marked out of compliance;
 - **Part I** All inspection files are selected by the jurisdiction for review
- Option 2: Using a selection method as described in this standard set forth in Parts I-II;

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*.
- **Option 3:** Using a selection method, other than those described in Option 1 and 2 above, established by the jurisdiction with written procedures that includes supporting documentation and worksheets that:
 - Part I Describe the COMPLIANCE AND ENFORCEMENT review process;
 - **Part II** Describe and include the random selection of establishment files or ROUTINE INSPECTIONS that have at least one Foodborne Illness or Public Health Intervention Violation marked OUT of compliance; and
 - **Part III** Is equivalent to the published Standard 6 statistical model for the number of inspections reviewed and the method of selection.

Determine the need to review additional randomly selected establishment files.

If using Option 2 or 3, determine the need to review additional files or inspections. Randomly selected establishment files or ROUTINE INSPECTIONS 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 - Assess the Effectiveness of the Compliance & Enforcement Program

Each jurisdiction shall measure the effectiveness of their COMPLIANCE AND ENFORCEMENT program to determine if the jurisdiction has satisfactorily resolved FBI Risk Factor and Public Health Intervention violations.

The results of the review will be used to assess the success of the COMPLIANCE AND ENFORCEMENT program. The following process are methods that jurisdictions can use for Option 1 (all files reviewed) or for Options 2-3 (randomly selected establishment files or ROUTINE INSPECTIONS).

Conduct a review of each selected inspection (Option 1), or randomly selected establishment file / ROUTINE INSPECTION (Option 2 or 3). 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 selected establishment or randomly selected establishment listed on the *Standard 6: Self-Assessment Summary Worksheet*, the self-assessor must complete a separate *Standard 6: Establishment File Worksheet*.

When using Options 1 or 2, 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 will be the third most recent 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 most recent 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 most recent 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.

When using Option 3, the worksheet must document the following information:

- The number of inspections selected which must be statistically equal to the Option 2 number of establishment files
- > 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 will be randomly selected and must have at least one out of compliance risk factor or public health intervention at the time of the review and sufficient time must have passed to evaluate follow up depending on individual jurisdictional policy, to qualify for the review. For files that do qualify (at least one out of compliance risk factor or public health intervention and sufficient time to assess follow up based on the jurisdiction's policy) the inspection should be reviewed to ensure the jurisdiction's COMPLIANCE AND ENFORCEMENT policy was followed for the inspection. Additional inspections in the establishment file may need to be reviewed to determine if the policy was followed. The self-assessor may need to go back several inspections to obtain the violation history or may need to look forward, at more recent inspections to see if a correction was made.
- > Documentation showing that the self-assessor has gone back as far as needed to ensure the policy was followed.

If no violation of a risk factor or public health intervention is documented, then no "start-point" inspection exists for that inspection. Also, if the "start-point" inspection has an out of compliance risk factor or public health intervention but there has been insufficient time based on the jurisdictional policy time frames to evaluate if COMPLIANCE AND ENFORCEMENT protocols have been followed it "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 inspection file must be chosen using the second set of randomly selected numbers to replace this file.

Self-Assessment Review Process (Using Option 1, 2, or 3):

- 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:
 - 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:
 - 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.

STEP 4 – 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.

STANDARD 6 – COMPLIANCE AND ENFORCEMENT SELF-ASSESSMENT SUMMARY AND WORKSHEET

Establishment Files

Jurisdiction Name:

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						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
28						
29						
30						
31						
32						
33						
34						
35						
36						
37						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
38						
39						
40						
41						
42						
43						
44						
45						
46						
47						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
48						
49						
50						
51						
52						
53						
54						
55						
56						
57						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
58						
59						
60						
61						
62						
63						
64						
65						
66						
67						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
68						
69						
70						

STANDARD 6 – COMPLIANCE AND ENFORCEMENT SELF-ASSESSMENT SUMMARY AND WORKSHEET

Substitute Establishment Files

Jurisdiction Name:

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						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
18						
19						
20						

STANDARD 6 – COMPLIANCE AND ENFORCEMENT ESTABLISHMENT FILE WORKSHEET

File Number: Establishment Name:				Permit Number:			Inspection Date (Start Point):				
				Risk F	actor an	d Public He	alth Intervention	ons			
	Supervision	Employee Health	Good Hygienic Practices	Preventing Contamination by Hands	Approved Source	Protection from Contamination	Time/Temperature Control for Safety	Consumer Advisory	HSP Population	Food Color Additives and Toxic Substances	Conformance with Approved Procedures
Reference to local inspection items Start Point Inspection Violations											
Was on-site corrective action taken?											
Was follow-up corrective action											
Was enforcement action taken?											
NOTE: Each column in which a followed.	violation is r	noted must	•	-			rder for the file to p		ally, written p	procedures must h	ave been
Jurisdiction's Defin	nitions of A	Acronym						110			
Acronym /Notati	ion	Definition	ons	Acronym /N	Notation	D	efinitions	Acrony	ym/Notation	De	finitions
			File I	Meets the Stan	dard 6 (Criteria:	YES	NO			

STANDARD 6 – COMPLIANCE AND ENFORCEMENT INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A VERIFICATION AUDIT

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 VERIFICATION AUDIT 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* Substitute Establishment Files 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 Review for the Self-Assessment	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.

<u>Determine the need for supplemental sampling</u>. 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 are 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.

<u>Determine the need for supplemental sampling</u>. 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 are 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

T	•	1.	4 •	TA T
. I	IIPIS	an	ction	Name:
•	WI IN	CAR.	CULUII	1 1001110.

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
1						
2						
3						
4						
5						
6						
7						

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
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						

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
18						
19						
20						

STANDARD 6 – COMPLIANCE AND ENFORCEMENT ESTABLISHMENT FILE WORKSHEET

File Number:	Number: Establishment Name:				Permit Number:			Inspection Date (Start Point):			
				Risk F	actor an	d Public He	alth Intervention	ons			
	Supervision	Employee Health	Good Hygienic Practices	Preventing Contamination by Hands	Approved Source	Protection from Contamination	Time/Temperature Control for Safety	Consumer Advisory	HSP Population	Food Color Additives and Toxic Substances	Conformance with Approved Procedures
Reference to local inspection items Start Point Inspection											
Violations Was on-site corrective action taken?											
Was follow-up corrective action											
Was enforcement action taken?											
NOTE: Each column in which a followed.	violation is r	noted must i	•	-	•		der for the file to p		ally, written p	rocedures must h	ave been
Jurisdiction's Defin	nitions of A	Acronym	s and Not	ations Used to	Reflect 1	Follow-up A	ction				
Acronym /Notation Definit		Definition	tions Acronym /Nota		Notation	tion Definitions		Acronym/Notation		Dei	finitions
	I		File I	Meets the Stan	dard 6 C	Criteria:	YES	NO		I	

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. To reduce the change 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 STANDARDIZED KEY CROSSWALK TO THE 2022 FDA FOOD CODE

This crosswalk is intended to assist jurisdictions in making comparisons with their code against the 2022 FDA Food Code. The Form 3-A Food Inspection Report Item numbers are based on the model FDA inspection form found in Annex 7 of the 2022 FDA Food Code. Completion of the crosswalk is intended to assist jurisdictions completing Standard 6 documentation which identifies major risk factors and public health interventions on the jurisdiction's inspection report form. Annex 5 contains additional information regarding the content of Form 3-A.

FBI Risk Factors and Interventions	Food Establishment Inspection Report (Form 3-A) Item Number	Applicable 2022 FDA Food Code References
Supervision		
PIC	1	2-101.11; 2-102.11(A), (B), (C)(1), (4)-(16); 2-103.11 (A) - (O), (Q)
CFPM	2	2-102.12(A)
Employee Health		
Management	3	2-102.11(C)(2), (3), (17); 2-103.11(P); 2-201.11(A), (B), (C), (E)
Restriction and Exclusion	4	2-201.11(D), (F); 2-201.12; 2-201.13
Vomit and Diarrheal events	5	2-501.11
Good Hygienic Practices		
Eating, Tasting and Drinking	6	2-401.11, 3-301.12
Discharge from eyes, nose, and mouth	7	2-401.12
Preventing Contamination by Hands		
Hands Clean and Properly Washed	8	2-301.11; 2-301.12; 2-301.14; 2-301.15; 2-301.16
No Bare Hand Contact with RTE Foods	9	3-301.11, 3-801.11(D)
Adequate handwashing sinks	10	5-202.12; 5-203.11; 5-204.11; 5-205.11; 6-301.11; 6-301.12; 6-301.13; 6-301

FBI Risk Factors and Interventions	Food Establishment Inspection Report (Form 3-A) Item Number	Applicable 2022 FDA Food Code References
Approved Source		
Food obtained from approved source	11	3-201.11-17; 3-202.13-14; 3-202.110; 5-101.13
Food Received at proper temperature	12	3-202.11
Food in good condition, safe and unadulterated	13	3-101.11, 3-202.15
Required records available, shellstock tags, parasite destruction	14	3-202.18, 3-203.12, 3-402.11, 3-402.12
Protection from Contamination		
Food Separated and Protected	15	3-302.11, 3-304.11, 3-304.15(A), 3-306.13(A)
Food Contact surfaces; cleaned and sanitized	16	4-501.111-115; 4-601.11(A); 4-602.11-12; 4-702.11; 4-703.11
Proper disposition or returned, previously served, reconditioned and unsafe food	17	3-306.14, 3-701.11
Time/Temperature Control for Safety		
Cooking	18	3-401.11; 3-401.12; 3-401.14; 3-401.15
Reheating	19	3-403.11
Cooling	20	3-501.14
Hot Holding	21	3-501.16(A)(1)
Cold Holding	22	3-501.16(A)(2), (B)
Date marking	23	3-501.17, 3-501.18
Time as Public Health Control	24	3-501.19

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FBI Risk Factors and Interventions	Food Establishment Inspection Report (Form 3-A) Item Number	Applicable 2022 FDA Food Code References
Consumer Advisory		
Consumer Advisory provided for raw/undercooked foods	25	3-603.11
HSP Populations		
Pasteurized foods used; prohibited foods not offered	26	3-801.11(A), (B), (C), (E), (G)
Food Color Additives and Toxic Substances		
Food Additives approved and properly used	27	3-202.12, 3-302.14
Toxic substances identified, stored, and used	28	7-101.11; 7-102.11; 7-201.11; 7-202.11; 7-202.12; 7-203.11; 7-204.11; 7-204.12; 7-204.13; 7-204.14; 7-205.11; 7-206.11; 7-206.12; 7-206.13; 7-207.11; 7-207.12; 7-208.11; 7-209.11; 7-301.11
Conformance with Approved Procedures		
Compliance with variance/specialized process/HACCP	29	3-404.11; 3-502.11; 3-502.12; 4-204.110(B); 8-103.12; 8-201.13; 8-201.14

NOTE:

Item numbers listed in this column refer to the item numbers within FDA's Food Establishment Inspection Report (Form 3-A, found in Annex 7).

STANDARD 6 – COMPLIANCE AND ENFORCEMENT ESTABLISHMENT FILE WORKSHEET

Based on 2022 FDA Food Code Form 3A: Food Establishment Inspection Report

File Number:	Establishment Name:					Permit Number: Ins			nspection Date (Start Point):		
				Risk I	Factor an	d Public He	alth Intervention	ons			
	Supervision	Employee Health	Good Hygienic Practices	Preventing Contamination by Hands	Approved Source	Protection from Contamination	Time/Temperature Control for Safety	Consumer Advisory	HSP Population	Food Color Additives and Toxic Substances	Conformance with Approved Procedures
Reference to local inspection items	1, 2	3, 4, 5	6, 7	8, 9, 10	11, 12, 13, 14	15, 16, 17	18, 19, 20, 21, 22, 23, 24	25	26	27, 28	29
Start Point Inspection Violations											
Was on-site corrective action taken?											
Was follow-up corrective action											
Was enforcement action taken?											
NOTE: Each column in which a followed.	violation is n	noted must	receive a ye.	s response to one	of the three	questions in or	rder for the file to p	ass. Addition	ally, written p	procedures must h	ave been
			Was th	e Written Pro	cedure F	ollowed?	YES	NO			
Jurisdiction's Defir	nitions of A	cronym	s and Not	ations Used to	Reflect 1	Follow-up A	ction				
Acronym /Notation Definitions		Acronym /	Notation	D	Definitions		Acronym/Notation		finitions		
	•			·		·		•		•	

File Meets the Standard 6 Criteria: _____ YES _____ NO

STANDARD 7 – INDUSTRY AND COMMUNITY RELATIONS

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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 activity, 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, websites, 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 website 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 website).

STANDARD 7 – INDUSTRY AND COMMUNITY RELATIONS INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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 . 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 Self-Assessment:				
Self-Assessor's Title:				
Jurisdiction Name:				
Jurisdiction Address:				
Phone:				
Fax:				
E-mail:				
Date the Standard 7 Self-Assessment Was Completed:				
Self-Assessment Indicates That the Jurisdiction MEETS the Standard 7				
Criteria (Indicate YES/NO):				
I affirm that the information represented in the Self-Assessment of Standar	d 7 is true and correct.			
Signature of the Self-Assessor:				
VERIFICATION AUD	IT 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 7 Was Completed:				
Verification Audit Indicates That the Jurisdiction MEETS the Standard				
7 Criteria (Indicate YES/NO):				
I affirm that the information represented in the Verification Audit of Standard 7 is true and correct.				
Signature of the Verification Auditor:				

STANDARD 7 – INDUSTRY AND COMMUNITY RELATIONS PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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Criteria	Element	Jurisdiction's Self- Assessment YES	Jurisdiction's Self- Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Industry and Consumer Interaction	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, webbased meetings, or forums. Documentation confirms that offers of participation have been extended to industry and consumer representatives.						
2. Educational Outreach	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, websites, newsletters, Fight BAC campaigns, food safety month activities, food worker training and use of oral culture learner materials.						

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

STANDARD 7 – INDUSTRY AND COMMUNITY RELATIONS INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELF-ASSESSMENT

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 printouts 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

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. Meeting minutes, agendas, by-laws, charters, membership criteria and lists, frequency of meetings, roles, performed actions and documentation of food safety educational efforts must be maintained by the regulatory authority.

PART I – Industry and Consumer Interaction Forums

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

STANDARD 7 – INDUSTRY AND COMMUNITY RELATIONS SELF-ASSESSMENT WORKSHEET

PART II - Educational Outreach

Dates	Summary of Activities

STANDARD 8 – PROGRAM SUPPORT AND RESOURCES

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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

NOTE: Jurisdictions can achieve conformance using one of two methods. Both methods can be accessed for downloading from the Conference for Food Protection (CFP) web site: www.foodprotect.org and located under the icon titled, "Conference Developed Guides and Documents."

Option 1: Standard 8 Staffing Level Assessment

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

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 CFP has developed an assessment tool and instruction guide as resources that can be used by a jurisdiction to calculate the FTE to inspection ratio.

Option 2: Standard 8 Staffing Level Alternative Conformance Method

Jurisdictions may access the alternative model for achieving conformance with Standard 8 from the Conference for Food Protection (CFP) web site: www.foodprotect.org and 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-through 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.

STANDARD 8 – PROGRAM SUPPORT AND RESOURCES INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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 Standard 8: 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 VERIFICATION AUDIT. 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 (Indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standard	d 8 is true and correct.
Signature of the Self-Assessor:	
VERIFICATION AU	DIT 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 (Indicate YES/NO):	
I affirm that the information represented in the Verification Audit of Standa	ard 8 is true and correct.
Signature of the Verification Auditor:	

STANDARD 8 – PROGRAM SUPPORT AND RESOURCES PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
1. Staffing Level	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 or the staffing level set by the jurisdiction. NOTE: The jurisdiction may use an alternative for determining and calculating staffing level. It should be indicated within the Self-Assessment General Comments section.						
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.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
2. Inspection Equipment	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.						
3. Administrative Program Support	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.						
4. Program Resource Assessment	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.						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
4. Program Resource Assessment	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.						
4. Program Resource Assessment	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.						
4. Program Resource Assessment	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.						
4. Program Resource Assessment	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.						
4. Program Resource Assessment	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.						

4. Program Resource Assessment 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.	Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
	Resource	conducted an assessment to determine if the agency has the budget, staffing, and equipment necessary to meet Standard #9 -						

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

NOTE: To Meet Standard 8 a "yes" affirmation to all elements under Criteria 1 - 4 is required. Answering "yes" to all elements under Criteria 1 - 3 reflects the fact that the jurisdiction has conducted an assessment of Criteria 1 - 3 and also has met all the elements under these Criteria. Answering "yes" to all elements under Criteria 4 reflects the fact that the jurisdiction has conducted an assessment of all elements under Criteria 4. For Criteria 4, as long as an assessment of each element is conducted a "yes" affirmation can be made, whether or not the jurisdiction has sufficient budget, staffing and equipment necessary to meet Standards 1 - 7, and 9. For all Criteria (1 - 4), if an item contains multiple questions, then all questions must be answered in the affirmative in order to meet that element of the Standard. The source documents, such as the various policies and 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.

STANDARD 8 – PROGRAM SUPPORT AND RESOURCES INSTRUCTIONS AND WORKSHEET FOR CONDUCTING A SELFASSESSMENT

STEP 1 – Review Staffing Level

The jurisdiction must have written documentation, calculations, or a program resource assessment that is used to determine staffing levels for retail food inspections.

Option 1: Standard 8 Staffing Level Assessment

To meet the Standard 8 criteria, a jurisdiction must 1) determine their FTE (Full-Time Equivalent) per Inspections Performed and show an **Inspection-to-FTE Ratio** between 280 and 320 inspections per FTE, or 2) show they have met the jurisdictional requirement for adequate staffing levels.

The "FTE per Inspections Performed" is the measure of a program's capacity to fulfill its inspection obligations.

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.

FTEs per Inspection Performed: 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.

Option 2: Standard 8 Staffing Level Alternative Conformance Method

For those jurisdictions interested in using the assessment tool provided as part of Issue 2020-II-018, it can be accessed on the CFP website at www.foodprotect.org:

Alternative Standard 8 Workbook 2023

The CFP's Program Standard Committee has designed the alternative tool to assist jurisdictions with calculating if jurisdictions are adequately staffed:

- ➤ Alternative S8 Workbook CFP Instructions
- ➤ Alternative S8 Workbook single document
- ➤ Alternative S8 Workbook page 1
- ➤ Alternative S8 Workbook page 2
- ➤ Alternative S8 Workbook page 3
- ➤ Alternative S8 Workbook Model 3_4 Risk Codes_2022

The above resources are available on the CFP 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

Jurisd	licti	on N	ame:

Standard #	Funding (Yes/No)	Staffing (Yes/No)	Equipment (Yes/No)	EXPLANATION – OTHER RESOURCES NEEDED
1				
2				
3				
4				
5				

Standard #	Funding (Yes/No)	Staffing (Yes/No)	Equipment (Yes/No)	EXPLANATION – OTHER RESOURCES NEEDED				
6								
7								
8		*	**	***				
9								
****Other shared resources								
*Do you meet the full time equivalent (FTE) staff to inspection ratio as required in Standard 8? **Do your inspectors have the equipment provided and available as required in Standard 8? ***Does your department have the equipment and supplies necessary to maintain the records and reports system that supports the program as required in Standard 8? File Meets the Standard 8 Criteria:YESNO								
Signature: Title:								

STANDARD 9 – PROGRAM ASSESSMENT

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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 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 a written report on the occurrence of the five foodborne illness RISK FACTORS, including the quantitative results, must be completed. A RISK FACTOR STUDY serves two purposes:
 - 1. To identify RISK FACTORS most in need of priority attention 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. A trend analysis requires at least three data points and cannot be derived using a single point in time. The jurisdiction must assess trends at their third and subsequent RISK FACTOR studies using their quantitative findings.
- 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 SURVEY 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.

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 data collection 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.

E. 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. Study reports on the occurrence of RISK FACTORS and FOOD CODE INTERVENTIONS identified in their RISK FACTOR STUDY,
- 2. Data collection tools or inspection sheets used for the data collection,
- 3. Documentation that each facility category regulated by the jurisdiction is included during the 60-month 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.

STANDARD 9 – PROGRAM ASSESSMENT INSTRUCTIONS FOR COMPLETING THE PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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 Standard 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: Program Self-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 VERIFICATION AUDIT. 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 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 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 (Indicate YES/NO):	
I affirm that the information represented in the Self-Assessment of Standard	d 9 is true and correct.
Signature of the Self-Assessor:	
VERIFICATION AUD	IT 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 9 Was Completed:	
Verification Audit Indicates That the Jurisdiction MEETS the Standard	
9 Criteria (Indicate YES/NO):	
I affirm that the information represented in the Verification Audit of Standa	ard 9 is true and correct.
Signature of the Verification Auditor:	

STANDARD 9 – PROGRAM ASSESSMENT PROGRAM SELF-ASSESSMENT AND VERIFICATION AUDIT FORM

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Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	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 category regulated by the jurisdiction collected over the study cycle.						
1. Risk Factor Study	 b) The data collection form includes items pertaining to the foodborne illness risk factors: 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. 						
1. Risk Factor Study	c) The data collection form provides for marking actual observations of food practices within an establishment (IN, OUT, NO, and NA).						

Criteria	Element	Jurisdiction's Self-Assessment YES	Jurisdiction's Self-Assessment NO	Self-Assessor's General Comments	Auditor's Verification YES	Auditor's Verification NO	If NO, Auditor is to specify why criterion is not met
2. Report of Analysis and Outcome	a) A report that shows the results of the jurisdiction's risk factor study.						
2. Report of Analysis and Outcome	b) The report provides quantitative measurements to assess the trends in the occurrence of risk factors over time.						
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 its effectiveness evaluated.						
3. Intervention Strategy	b) Documentation of performed interventions, actions, or activities designed to improve control of risk factors is provided.						

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

APPENDIX 1: SUMMARY OF CHANGES

This summary provides a synopsis of the changes made to the 2024 edition of the Voluntary National Retail Food Regulatory Program Standards. The primary intent of this record is to capture the nature of the changes found in the 2024 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. The CFP provides an opportunity for stakeholders to provide comments about proposed changes.

The following changes reflect the recommendations from the Conference for Food Protection, 2020 and 2023 biennial meetings.

Updates to Standard 2 – Amend Standard 2 curriculum to replace select courses with updates.

What changed in Standard 2?

Replacement of FD35 Basic Food Law for State Regulators with B17 Laws, Regulations, Policies and Procedures (CC8039W)

Replacement of FDA36 Public Health Principles with B23 Public Health Principles (CC8026W)

Replacement of MIC13 Aseptic Sampling with B25 Sampling (CC8035W)

Replacement of MIC15 Cleaning and Sanitizing with B26 Sanitation Practices (CC8035W)

How do these changes affect your jurisdiction?

The replacement of these courses will allow jurisdictions an alternative selection for FSIO's to complete coursework toward achieving conformance with Standard 2.

How will I be able to access and complete these forms?

The B1 Appendix - Curriculum for Retail Food Safety Inspection Officers is available on FDA's website (https://www.fda.gov/food/retail-food-protection/voluntary-national-retail-food-regulatory-program-standards).

(CFP Issue 2020-II-025)

<u>Updates to Standard 2 – Amend Standard 2 curriculum to include additional "pre" and "post" topics.</u>

What changed in Standard 2?

Addition of B8 Environmental Hazards (CC8024W) to "Post" curriculum

Addition of B12 Intergrated Food Safety System (CC8018W) to "Post" curriculum

Addition of B15 Jurisdiction (CC8037W) to "Pre" curriculum

Addition of B16 Labeling (CC8038W) to "Post" curriculum

Addition of B19 Pest Control (CC8044W) to "Pre" curriculum

Addition of B20 Plumbing (CC8001W) to the "Pre" curriculum

Addition of B22 Professionalism (CC8025W) to the "Pre" curriculum

Addition of B24 Recalls (CC8041W) to the "Post" curriculum

Addition of B27 Tracebility (CC8042W) to the "Post" curriculum

Addition of B28 Transportation (CC8026W) to the "Post" curriculum

How do these changes affect your jurisdiction?

The addition of these courses will allow jurisdictions additional course selections for FSIO's to complete coursework toward achieving conformance with Standard 2.

How will I be able to access and complete these forms?

The B1 Appendix - Curriculum for Retail Food Safety Inspection Officers is available on FDA's website (https://www.fda.gov/food/retail-food-protection/voluntary-national-retail-food-regulatory-program-standards).

(CFP Issue 2023-II-026)

Updates to Standard 2 Appendix B-1 Tracking Versions

What changed in Standard 2?

Appendix B-1: Curriculum for Retail Food Safety Inspection Officers will be posted on FDA's website with versioning history beginning with the 2024 edition. As changes are made to Appendix B1, updated and archived versions will be accessible to jurisdictions.

How do these changes affect your jurisdiction?

Jurisdictions are encouraged to reference the updated Appendix B-1 for the correct location and course number for all available courses in Standard 2.

How will I be able to access and complete these forms?

These forms are available on FDA's website.

(CFP Issue 2023-II-010)

Updates to Standard 2: Change to Re-standardization Frequency for staff not standardizing others.

What changed in Standard 2?

The frequency of re-standardization for those not responsible standardizing others will change from three years to five years. Contact hours of continuing education for those not responsible for standardizing others changed from 20 contact hours every 36 months to 30 contact hours every 60 months. There is no change to the re-standardization frequency or contact hours for those responsible for standardizing others.

How do these changes affect your jurisdiction?

FSIO's that do not standardize others now have 5 years to be re-standardized and must obtain 30 contact hours within 60 months.

How will I be able to access and complete these forms?

These forms are available on FDA's website.

(CFP Issue 2023-II-011)

Updates to Standard 3 – Edits to Description of Requirement and Self – Assessment Audit Forms

What changed in Standard 3?

The use of terms "Validation" and "Verification" in the Description of Requirements section and the Self-Assessment and Verification Audit Form has been reversed to reduce confusion and reinforce the correct usage of the terms "Validation" and "Verification".

How do these changes affect your jurisdiction?

The term "Validation" now precedes the term "Verification" with respect to the review of HACCP plans.

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.

(CFP Issue 2023-II-018)

<u>Updates to Standard 3 – Incorporation of Plan Review into Standard 3</u>

What changed in Standard 3?

A new element 7 that calls for a jurisdiction to develop and implement a program policy for conducting reviews of plans submitted by food establishments has been added to Standard 3. The policy should include a review and determination of the adequacy of facilities, equipment, and procedures based on the establishment's intended menu, volume of food, flow of food and food processes. A note has also been added to encourage jurisdictions to use the CFP developed Plan Review Guidance document.

How do these changes affect your jurisdiction?

The addition allows for a jurisdiction to address plan review of food establishments within Standard 3.

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.

(CFP Issue 2023-II-019)

<u>Updates to Standard 4 – Create Standard 4 Audit Procedures</u>

What changed in Standard 4?

Audit Procedures have been added to Standard 4 Uniform Inspection Program.

How do these changes affect your jurisdiction?

Those conducting audits on Standard 4 will now have access to clear audit instructions.

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.

(CFP Issue 2023-II-025)

Updates to Standard 5: Edits to Definitions

What changed in Standard 5?

Edits were made to several defined terms in Standard 5 including: Food Related Injury, Confirmed Foodborne Disease Outbreaks, Suspect Foodborne Outbreaks, and Foodborne Disease Outbreak. The terms were *capitalized*, and the asterisk has been removed.

How do these changes affect your jurisdiction?

The terms were previously defined in the VNRFRPS. *However*, they have been capitalized to indicate that the meaning of the term can be found in the definition section of the VNRFRPS. The change is intended to eliminate possible confusion.

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.

(CFP Issue 2023-II-026)

Updates to Standard 6: Updated Standard 6 Establishment File Worksheet Form 3A

What changed in Standard 6?

Edits were made to the Standard 6 Establishment File Worksheet according to the 2022 FDA Food Code. A recommended template was submitted as part of the 2023 CFP Program Standards Committee report.

How do these changes affect your jurisdiction?

Jurisdictions can use the Standard 6 Establishment File worksheet to assess their compliance with Standard 6.

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.

(CFP Issue 2023-II-031)

Updates to Standard 6: Updated Standardized 6 Key Crosswalk to the 2022 FDA Food Code

What changed in Standard 6?

Edits were made to the Standard 6 Standardized Key Crosswalk according to the 2022 FDA Food Code. A recommended template was submitted as part of the 2023 CFP PS Committee report.

How do these changes affect your jurisdiction?

Jurisdictions can use the Standard 6 Standardized Key Crosswalk to assess their compliance with Standard 6.

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.

(CFP Issue 2023-II-032)

Standard 8: Program Support and Resources - Audit Procedures for Alternative Model

What changed in Standard 8?

Audit Procedures have been developed for those jurisdictions using the Alternative model for determining staffing levels in Standard 8. There is additional guidance for using the alternative model for Standard 8 under the Conference Developed Guides and Documents tab on CFP's website (www.foodprotect.org)

How do these changes affect your jurisdiction?

Jurisdictions will now have audit procedures when using the alternative model to determine staffing levels within Standard 8.

How will I be able to access and complete these forms?

Jurisdictions may access an example of an alternative model for achieving conformance with the VNRFRPS Standard 8 staffing level element from the Conference for Food Protection (CFP) web site: www.foodprotect.org located under the icon titled, "Conference Developed Guides and Documents."

(CFP Issue 2023-II-034)

Other Changes made by FDA

FDA made several editorial and formatting changes to the Voluntary National Retail Food Regulatory Program Standards. These changes are described below.

Formatting Changes

Program Self-Assessment and Verification Audit Forms for all nine Standards and most of the corresponding Worksheets were reformatted to be accessible in their layout and follow a logical reading order. Font size and type, page margins, and paragraph spacing and text spacing were also reformatted to be more consistent and readable.

The 2024 Voluntary National Retail Food Regulatory Program Standards workbook primarily reflects an incorporation of the recently approved changes that resulted from the 2023 Conference for Food Protection held in Houston, TX. 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.

PAPERWORK REDUCTION ACT OF 1995

This document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The time required to complete this information collection is estimated to average 94.29 annual hours per recordkeeper for each enrolled jurisdiction to complete the management tasks for recordkeeping for self-assessment, risk factor study, and verification audit. FDA estimates a total of 30 minutes annually for each enrolled jurisdiction to complete the following: FDA Form 3958, "FDA National Registry Report," and "Documentation of Successful Completion – Field Training Process" forms. FDA's recordkeeping and reporting burden estimate includes time required for a state, local, or tribal agency to review the instructions in the Program Standards, compile information from existing sources, and create any records recommended in the Program Standards that are not already kept in the normal course of the agency's usual and customary activities. Worksheets are provided to assist in this compilation. Send comments regarding this burden estimate or suggestions for reducing this burden to: Food and Drug Administration, Office of Retail Food Protection, 5001 Campus Drive, College Park, MD 20740.

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 control number. The OMB control number for this information collection is 0910-0621 (expires 10-31-2026).

COMMENTS AND INQUIRIES

To promote uniform and reasonable application of these Standards, interested persons are invited to submit comments and inquiries to their FDA Retail Food Specialist or to the Office of Retail Food Protection: retailfoodprotectionteam@fda.hhs.gov.