

FDA VOLUNTARY NATIONAL RETAIL FOOD REGULATORY PROGRAM STANDARDS

Self-Assessment & Verification Audit
Workshop
Waltham, MA
April 2-4, 2024



Welcome Instructors

- Mary Leong, RFS
- Steve Nattrass, RFS
- Tom Nerney, RFS
- Valerie Potopsingh, RFS
- Mike Touhey, RFS



Tell Us About You

- Name
- Jurisdiction/Location
- Experience in Retail Program Standards
 - Years enrolled
 - Standards your jurisdiction meets or working toward
 - New enrollee



Standards as a Program Framework

- Standards provide:
 - A guide to design and management of a retail food program
 - A program foundation
 - A tool to evaluate the effectiveness of food safety interventions

Current Environment State & Local Retail Food Programs



- Diminishing Resources (NEHA reports 10% reduction of work force for State and local health agency since 2007)
- Competing Program Priorities
- Retail Food Safety Risk Assessment Needed
- "Outputs" rather than "Outcomes" used to measure "Program Effectiveness"
- Program Performance Measures not clearly identified
- No mechanism for conducting FTE "cost-benefit" justification



State & Local Retail Food Programs

As resource capacities are diminishing, the size of the foodservice industry is rapidly increasing

The National Restaurant Association statistics on the increased number of restaurants nationally:

1972 – 491,000 Restaurants

2020 - > 1,000,000 Restaurants

The Food Marketing Institute 2020 report:

> 250,000 Retail Food Stores

~ 300 to 500 Establishments for each Retail Food Safety Inspection Officer



THESE FORCES MAY LEAD TO:

- Disincentive on the part of regulatory programs to devote resources for initiatives designed to enhance program effectiveness
- Lack of uniformity in Food Codes not viewed as a critical performance issue
- Lack of resources to properly train and standardize regulatory health officials
- Insufficient time for inspections leads to less regulatory focus on foodborne illness risk factors

THESE FORCES CAN LEAD TO:



- Regulatory retail food program quality assurance processes focused on Outputs rather than Outcomes
- Review of compliance protocols lacking to ensure due process and fairness to the industry
- Insufficient resources presents challenges to the formation of committees, task forces, etc., that provide a forum for industry input
- Industry permit fees often based on increases in inspection loads rather than services provided



Summary Identify Program Needs to Address

- A "holistic approach" (FSMA) to retail food safety
- Method for setting food safety priorities using a riskbased performance measurement
- Identification of program areas where an agency can have the greatest impact on retail food safety
- Wider application of effective FBI risk factor intervention strategies



Summary Identify Program Needs To Address

- Information to justify program budgets and FTEs
- Incentives for innovations in program implementation and administration
- Avenues for improving industry and consumer confidence





- STANDARD 1 REGULATORY FOUNDATION
- STANDARD 2 TRAINED REGULATORY STAFF
- STANDARD 3 INSPECTION PROGRAM BASED ON HACCP PRINCIPLES
- STANDARD 4 UNIFORM INSPECTION PROGRAM
- STANDARD 5 FOOD BORNE ILLNESS RESPONSE
- STANDARD 6 COMPLIANCE & ENFORCEMENT
- STANDARD 7 INDUSTRY & COMMUNITY RELATIONS
- STANDARD 8 PROGRAM RESOURCES
- STANDARD 9 PROGRAM ASSESSMENT

Retail Food Program Standards Web Site



http://www.fda.gov/retailprogramstandards

Voluntary National Retail Food Regulatory Program Standards



Voluntary National Retail Food Regulatory Program Standards

The Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) define what constitutes a highly effective and responsive program for the regulation of foodservice and retail food establishments.

They begin by providing a foundation and system upon which all regulatory programs can build through a continuous improvement process. The Retail Program Standards encourage regulatory agencies to improve and build upon existing programs. Further, they 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. In support of this goal, FDA works cooperatively with our state, local, territorial and tribal partners using a risk-based approach to leverage limited resources. The Retail Program Standards represent an important component of a comprehensive strategic approach to help ensure the safety and security of the food supply at the retail level.

→ |

2022 Retail Program Standards and Worksheets

If you have questions about the Retail Program Standards, please contact an <u>FDA Retail</u> <u>Food Specialist</u>.

Content current as of:

01/12/2023

Regulated Product(s)

Food & Beverages

Voluntary National Retail Food Regulatory Program Standards



Voluntary National Retail Food Regulatory Program Standards - November 2019



"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.

OMB Control No. 0910-0621 Expiration Date: 09-30-2023 See additional PRA statement

Paperwork Reduction Act of 1995 (PDF - 100KB)

Table of Contents

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Overview of the Retail Program Standards

- Introduction to the Standards (PDF: 72KB)
- Program Standards Definitions (PDF: 52KB)

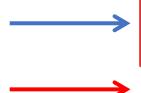
Voluntary National Retail Food Regulatory Program Standards



Overview of the Retail Program Standards

- Introduction to the Standards (PDF: 72KB)
- Program Standards Definitions (PDF: 52KB)

Information about Enrolling and Participating in the Retail Program Standards



The U.S. Food and Drug Administration (FDA) is issuing a statement clarifying that Verification Audits conducted as part of the 2019 version of the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) may be conducted either virtually or on-site. A change will be made within the "instructions for Completing the Program Self-Assessment and Verification Audit Form" for each of the nine standards. The words "on-site visit" will be replaced with the words "Verification Audit", which is a defined term within the VNRFRPS. This editorial change is being made by the FDA outside of the normal Conference for Food Protection (CFP) cycle. Additionally, language will be added to the section entitled "Verifying the Self-Assessment" section of the Administrative Procedures document for clarification purposes.



- Clearinghouse Work Group Questions and Answers for implemented 2019 standards (PDF: 692KB) August 2021
- Clearinghouse Fact Sheet (PDF: 557KB)
- Administrative Procedures (PDF: 145KB)
- FDA National Registry Report (FDA Form 3958) (PDF: 1.19MB)
- Self Assessment/Audit Verification Summary and Gap Analysis Tool (XLS: 106KB)
 This tool is a secondary means of collecting information associated with the
 VNRFRPS and the existing PDF versions are the official 508 compliant version of
 the worksheets.



Standard 1: Regulatory Foundation

- Standard 1 (PDF: 90KB)
- Standard 1 Self-Assessment and Verification Audit Form (PDF: 776KB)
- Standard 1 Self-Assessment Instructions and Worksheet for Part I (PDF: 387KB)
- Standard 1 Self-Assessment Instructions and Worksheet for Part II (PDF: 1.1MB)
- Standard 1 Self-Assessment Instructions and Worksheet for Part III (PDF: 234KB)
- Standard 1 Verification Audit Instructions and Worksheet for Part I (PDF: 720KB)
- Standard 1 Verification Audit Instructions and Worksheet for Part II (PDF: 687KB)
- Standard 1 Verification Audit Instructions and Worksheet for Part III (PDF: 683KB)

Voluntary National Retail Food Regulatory Program Standards

Standard 8: Program Support and Resources

- Standard 8 (PDF: 111KB)
- Standard 8 Self-Assessment and Verification Audit Form (PDF: 883KB)
- Standard 8 Self-Assessment Instructions and Worksheet (PDF: 706KB)
- Standard 8 Staffing Level (FTE to Inspection Ratio) Assessment Workbook
 Instruction Guide ☑
- Standard 8 Staffing Level (FTE to Inspection Ratio) Assessment Workbook

Standard 9: Program Assessment

- Standard 9 (PDF: 92KB)
- Standard 9 Self-Assessment and Verification Audit Form (PDF: 214KB)

Other Important Documents

- Summary of Changes (PDF: 65KB)
 - Voluntary National Retail Food Regulatory Program Standards Compiled (PDF: 2.07MB)



Retail Food Program Standards Web Site

http://www.fda.gov/retailprogramstandards

This document provides an overview of the similarities between the Retail Program Standards and the PHAB accreditation process and details the connections between the criteria that apply within each initiative. The detailed crosswalk provides specific examples of where documentation generated when implementing the Retail Program Standards can be used to satisfy documentation requirements associated with the accreditation process. This document will assist those who pursue conformance with the Retail Program Standards and PHAB Accreditation concurrently, without duplicating resources or effort.





Retail Food Protection Page

http://www.fda.gov/RetailFoodProtection

Retail Food Protection

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Retail Food Protection

Listing of Retail Food Protection Information and Resources

FDA Food Code

Food Defense & Emergency Response for Retail Food

Retail Food Industry/Regulatory Assistance & Training

Retail Food Risk Factor Study

Standardization of Retail

Retail Food Safety Initiative

schools, and correctional facilities.

FDA strives to promote the application of science-based food safety principles in retail and

foodservice settings to minimize the incidence of foodborne illness.



A Cooperative Program

More than 3,000 state, local and tribal agencies have primary responsibility to regulate the retail food and foodservice industries in the United States. They are responsible for the inspection and oversight of over 1 million food establishments - restaurants and grocery stores, as well as vending machines, cafeterias, and other outlets in health-care facilities, schools, and correctional facilities.



Retail Food Protection Page

http://www.fda.gov/RetailFoodProtection



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	Email Address	Subscribe
inbox.		



https://www.fda.gov/food/retail-food-protection/fda-food-code

FDA Food Code



FDA Food Code

Food Code 2022

Food Code 2017

Food Code 2013

Food Code 2009

Food Code 2005

Food Code 2001

Food Code 1999

Food Code 1997

The U. S. Food and Drug Administration (FDA) publishes the Food Code, a model that assists food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry (restaurants and grocery stores and institutions such as nursing homes). Local, state, tribal, and federal regulators use the FDA Food Code as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy.

Between 1993 and 2001, the Food Code was issued in its current format, every two years. With the support of the Conference for Food Protection (CFP), FDA decided to move to a four-year interval between complete Food Code editions. During the interim period between full editions, FDA may publish a Food Code Supplement that updates, modifies, or clarifies certain provisions. The 2005 Food Code was the first full edition published on the new four-year interval, and it was followed by the Supplement to the 2005 Food Code, which was published in 2007. The 2022 Food Code is the most recent full edition published by FDA.

Content current as of:

Regulated Product(s)
Food & Beverages

Topic(s) Retail Food Protection Food & Beverage Safety



https://www.fda.gov/food/retail-food-protection/retail-food-industryregulatoryassistance-training

Retail Food Industry/Regulatory Assistance & Training



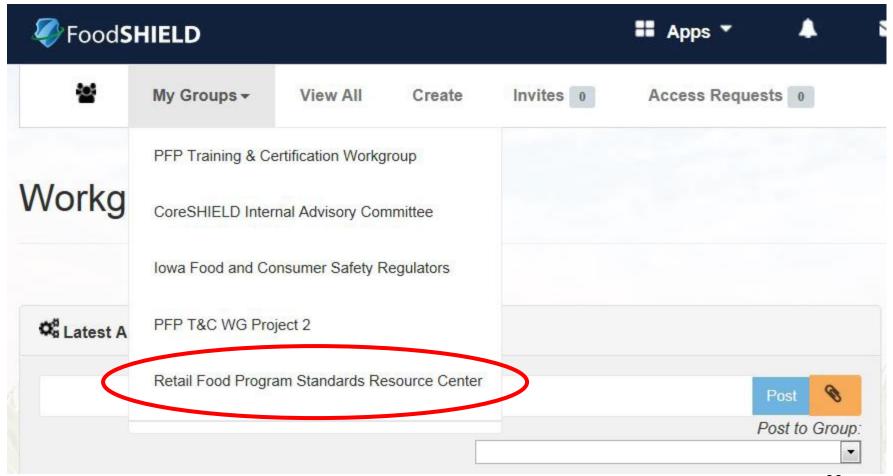
Topics on this page:

- Time and Temperature Control for Safety
- Preventing Cross-Contamination
- Employee Health
- Plan Review at Retail Food Establishments
- · Special Processes as Retail
- Labeling
- HACCP
- Retail Food Protection Industry Educational Materials
- Information about the Risk Factor Study
- Free Training Provided by the Food and Drug Administration
- Other Information
- · General Retail Resources



FoodSHIELD Retail Food Program Standards Resource Center

http://www.FoodShield.org



PROGRAM STANDARDS RESOURCES QUESTIONS





Self-Assessment & Verification Audit Workshop Objectives

- Participants should be able to:
 - ➤ Define the core requirements for each of the nine Program Standards
 - ➤ Describe the self-assessment and verification audit process for each of the nine Program Standards
 - Assess retail food regulatory program information to determine compliance with the core criteria in each of the nine Program Standards



Self-Assessment & Verification Audit Workshop Format

- Participants will be split into breakout groups
- After each Standard presentation, each breakout group will complete a series of questions / scenarios, approximately 20-30 minutes will be allocated for each Standard
- Each breakout group will identify a spokesperson (rotate for each Standard)



Self-Assessment & Verification Audit Workshop Format

- After each breakout, we will discuss the answers in the large group
- Questions and scenarios have been divided into three categories
 - > INFORMATION
 - > APPLICATION
 - > INTERPRETATION



Self-Assessment & Verification Audit Workshop Format

- The workshop is divided into two parts:
 - Self-Assessment Process for each Standard
 * This will also cover the verification audit process for Standards 3, 4, 5, 7, 8, 9 because the criteria for review is the same
 - Verification Audit Process for Standards 1, 2, and 6

WORKSHOP FORMAT & EXPECTATIONS QUESTIONS





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

Retail Food Program Standards Web Site



http://www.fda.gov/retailprogramstandards

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2022 Retail Program Standards and Worksheets

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Content current as of: 04/11/2023

Regulated Product(s) Food & Beverages

Retail Food Program Standards Web Site



http://www.fda.gov/retailprogramstandards

Voluntary National Retail Food Regulatory Program Standards

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Overview of the Retail Program Standards

- Introduction to the Standards (PDF: 213B)
- Program Standards Definitions (PDF: 182KB)

Information about Enrolling and Participating in the Retail Program Standards

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- Retail Program Standards Reference System
- Clearinghouse Work Group Questions and Answers for implemented 2022 standards (PDF: 760KB) April 2023
- Clearinghouse Fact Sheet (PDF: 557KB)
- Administrative Procedures (PDF: 1449KB)
- Retail Program Standards Timeline (PDF: 165KB)
- FDA National Registry Report (FDA Form 3958) (PDF: 1.19MB)
- Self Assessment/Audit Verification Summary and Gap Analysis Tool (XLS: 105KB)
 This tool is a secondary means of collecting information associated with the
 VNRFRPS and the existing PDF versions are the official 508 compliant version of
 the worksheets.



Administrative Procedures



Overview of the Process

- Self-assessment completed and reported to FDA
- Verification Audit requested and conducted on Standards the jurisdiction indicates as having met
- Reporting Program Standards status using the Form FDA 3958, Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report submitted to the FDA Retail Food Specialist

Administrative Procedures

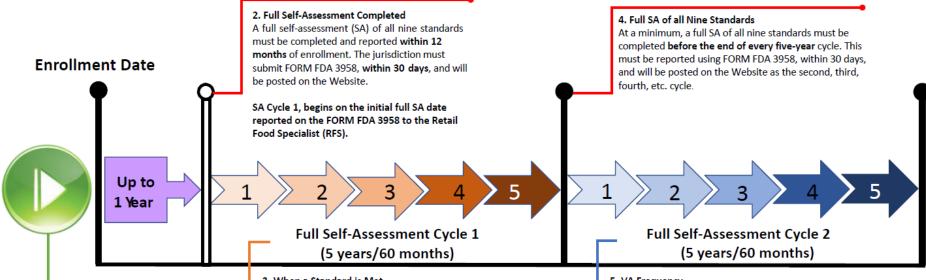


Overview of the Process



Retail Program Standards Timeline

This standard timeline represents information from the Administrative Procedures Manual only. Questions should be referred to your Retail Food Specialist (RFS). This document was last updated in June 2022.



1. Enrollment Period

Jurisdiction submits FORM FDA 3958 to enroll in Program Standards (PS). This is the date of enrollment. Info is posted on the Retail PS Website (Website).

3. When a Standard is Met

If a standard has been claimed as met during either a full SA of all nine standards, or during an SA update of one or more individual standards, the jurisdiction must request a verification audit (VA) within three months of the completion of the SA or SA update. The VA must be completed within six months of the SA or SA update. When a standard is met, it must be reported using FORM FDA 3958, within 30 days, and will be posted on the Website.

5. VA Frequency

VA's shall be conducted at the following frequency: 1.After the initial SA (conducted within 12 months of enrollment), if the jurisdiction claims conformance with one or more Standards; and 2.After each subsequent full SA (conducted every 60 months), if the jurisdiction claims conformance with one or more Standards.

Any standards that were met (verified by a successful audit) in the previous full SA must be self-assessed again as part of the five-year full SA, and the VA must be done again for any Standard reported as met, regardless of the date the VA was reported from the previous full SA.

Administrative Procedures Self-Assessments



- Self-assessment within 12 months of enrollment & every 60 months thereafter to:
 - Compare program elements to relevant criteria in the Standards;
 - Determine if supporting records are maintained

Administrative Procedures, Page AP-3

Administrative Procedures Self-Assessments



- The most recent version of the Retail Food Program
 Standards must be used when completing a required self-assessment.
- If a jurisdiction is updating a current self-assessment, it can either use the version of the Standards effective when the current self-assessment was completed or the current version of the Standards, at the jurisdiction's discretion.

Administrative Procedures, Page AP-4

Administrative Procedures Verification Audits



- The jurisdiction must request a Verification Audit(VA) within 3 months of the completion of the Full Self-Assessment of all Nine Standards (SA9) or Self-Assessment update in which one or more of standard is met.
- The verification audit should be completed within 6 months of the SA9 or Self-Assessment Update.
 - May be conducted either virtually or on-site.
 - Administrative Procedures, Page AP-4-5

Administrative Procedures Who can perform an Audit?



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

Administrative Procedures, Page AP-4

Administrative Procedures Reporting



- Complete and submit a Form FDA 3958 to the appropriate FDA Retail Food Specialist within 30 days following a Self-Assessment, Self-Assessment Update, and any Verification Audit
- The latest version of this form is available on the FDA Retail Program Standards website:
 - https://www.fda.gov/food/voluntary-national-retail-foodregulatory-program-standards/voluntary-national-retailfood-regulatory-program-standards-august-2022

Administrative Procedures National Registry Report FDA Form 3958



Voluntary National		ug Administrati d Regulator	ion ry Prog	ram Standards		OMB N Expirat (See P	Approved Number 0910-0821 tion Date: 09/30/2023 Nublic Reporting Burde tient on page 2.)
Information about the Jun Name of Jurisdiction Reporting	risdiction						
This Information							
	City				State	*	ZIP Code
Contact Person for Jurisdiction	Title for Co	ontact Person			Phone		er for Jurisdiction's ot Person
Website Link for Jurisdiction							
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Inst	structions for Completing FDA National Registry	Report - Form 3958
		submitted to the appropriate FDA Regional Retail Food Specialist n of the self-assessment, self-assessment update, or verification audi
	e Listing of Jurisdictions Enrolled in the Voluntary Nation ta contained in this report.	nal Retail Food Regulatory Program Standards will be updated using
may	ay be completed online and submitted electronically to the	sion to the appropriate Retail Food Specialist. Alternatively, this form the appropriate Retail Food Specialist. A listing of Retail Food the Standards website (www.fda.gov/RetailProgramStandards).
Part	art 1: Information about the Jurisdiction	
1.	Enter the jurisdiction name, and the jurisdiction addre	PSS.
	Program Standards correspondence will be sent.	ct person for this jurisdiction. This is the individual to whom Retail
	Enter the jurisdiction's website address.	
4.	Indicate if the jurisdiction is willing to serve as an aud	litor for another jurisdiction.
Part	art 2: Information about Enrollment	
	 Select the first box to indicate that the jurisdiction is a 	
	the Voluntary National Retail Food Regulatory Progra	
	updating this information please select the relevant s	
4.	 If the first three options are not applicable, select "Oti 	her" and provide additional information.
Part	rt 3: Information about Self-Assessment Findings and V	erification Audit Findings
1.	1. Enter the date that the self-assessment was complete	ed.
2.	that is checked, do not enter a date unless the self-as	rds were met, as determined by the self-assessment. For each box ssessment date for that Standard is different than the date that the ent update was completed for Standard X after the self-assessment
3.		icate which Standards were met, as verified by a verification audit, ed to indicate the date that the verification audit was completed for
Part	rt 4: Permission to Publish Information on FDA's Websit	e
1.		orm will be published on FDA's Listing of Jurisdictions Enrolled in the Standards. Check the appropriate box(es) to indicate what information
Afte	ter completing Parts 1-4, the Program Manager must:	
1.	 Enter the name of the Authorized Individual. This may this information. 	y be the Program Manager or another individual authorized to submit
2.	2. Provide the signature of the Authorized Individual for	the reporting jurisdiction.
	a. If the form is completed electronically, click the sig	
	 b. If the form is completed by hand, sign your name i 	n the signature box.
3.	Enter the date that the form is signed.	
=		
		ments of the Paperwork Reduction Act of 1995.
		FORM TO THE PRA STAFF ADDRESS BELOW.*
5	collection of information is estimated to average 12 minutes p	work Reduction Act of 1995: The public reporting burden time for this ser response, including the time to review instructions, search existing data review the collection of information. Send comments regarding this burden ding suggestions for reducing this burden, to:
	Department of Health and Human Services Do not Food and Drug Administration	send your completed form to the PRA Staff email address to the left.
	Office of Operations	"An agency may not conduct or sponsor, and a person is not
1	Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov	required to respond to, a collection of information unless it displays a currently valid OMB number."
500	RM FDA 3958 (10/18)	Page 2 of 2

Administrative Procedures Retail Program Standards



 Additional information related to the VNRFRPS can be found at:

https://www.fda.gov/retailprogramstandards

 Announcements related to RFFM, and upcoming events (training & seminars) as well as the last listing of enrolled jurisdictions.

Listing of Jurisdictions Enrolled in the Retail Program Standards



Who is enrolled?

<u>Listing of Jurisdictions Enrolled in the Voluntary National Retail Food Regulatory</u>

<u>Program Standards</u> provides information about jurisdictions that have enrolled in the Retail Program Standards. The information is updated on a quarterly basis to reflect new enrollments, as well as to recognize achievements made by current enrollees. If you have questions about the enrollment information on this page, please contact retailfoodprotectionteam@fda.hhs.gov.

Supporting Materials

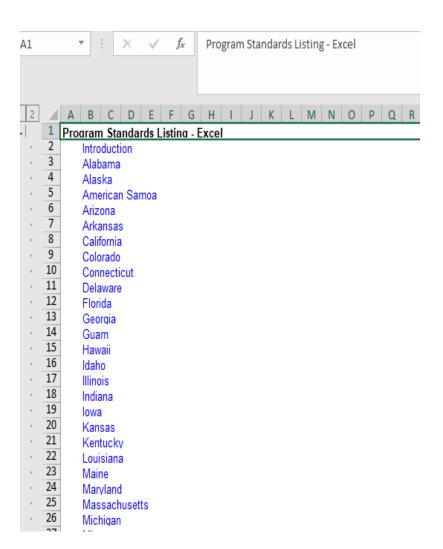
Links to Other Standards

Courses, Workshops & Events

Funding and Grants

Listing of Jurisdictions Enrolled in the Retail Program Standards





Listing of Jurisdictions Enrolled in the Retail Program Standards



Alaska

Last Updated: 4/1/2022 8:11:48 PM

Standards Achieved [as determined by a Self-Assessment (SA) and Verification Audit (VA)] for Alaska

Enrolled Agency Name	Enrollment Date	Self- Assessment Period	Self- Assessment Completed	Achieved Conformance with Standard 1	Achieved Conformance with Standard 2	Achieved Conformance with Standard 3	Achieved Conformance with Standard 4	Achieved Conformance with Standard 5	Achieved Conformance with Standard 6	Achieved Conformance with Standard 7	Achieved Conformance with Standard 8	Achieved Conformance with Standard 9
Alaska Food Safety and Sanitation Program, ADEC	1/3/2006	1	3/5/2007							SA (3/5/2007) VA (6/12/2007)		SA (3/5/2007) VA (6/12/2007)
		2	6/25/2012			SA (6/25/2012) VA (11/1/2013)				SA (6/25/2012) VA (11/7/2013)		SA (6/25/2012) VA (4/1/2013)
		3	8/31/2017			SA (8/31/2017)				SA (8/31/2017)		SA (8/31/2017)
		4	2/6/2020			SA (2/6/2020)	SA (2/6/2020)	SA (2/6/2020)		SA (2/6/2020) VA (8/27/2020)		
Municipality of Anchorage Health Department	2/7/2001	1	12/31/2002	SA (12/31/2002)	SA (12/31/2002) VA (10/25/2006)					SA (12/31/2002) VA (7/1/2007)		SA (12/31/2002) VA (7/1/2007)
		2	3/31/2015		SA (3/31/2015) VA (10/25/2006)					SA (3/31/2015) VA (3/7/2006)		
		3	2/7/2020							SA (2/7/2020)		
	A		A									



(Page AP-5 Administrative Procedures Manual)

- Initial Steps to take with a Non-Conforming Audit
 - Contact Retail Food Specialist within 10 business days of the close of the audit
 - Discuss steps necessary to reconcile discrepancies and establish a correction plan; or
 - Establish a corrective action plan to retain information on web listing; or
 - Remove any incorrect self reported data from web listing



(Page AP-6 Administrative Procedures Manual)

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



(Page AP-6 Administrative Procedures Manual)

- Requesting Assistance from the Clearinghouse:
 - Written request from jurisdiction within 30 days of close of audit;
 - Explanation of issues in dispute;
 - Include a copy of the verification audit report;
 - Jurisdiction can include supporting information relevant to the results of the self-assessment or verification audit
 - Clearinghouse informs auditor of request. Auditor may submit written materials



(Page AP-6 Administrative Procedures Manual)

- Clearinghouse Assistance Process:
 - Sets date/time to hear facts from each side via conference call.
 - Both the jurisdiction and auditor will be given an opportunity to speak in support of materials submitted.
 - Clearinghouse may ask question of both sides.
 - Clearinghouse will deliberate in private before rendering a decision



(Pages AP-6-7 Administrative Procedures Manual)

- Clearinghouse Decisions:
 - Provides a written response to both the jurisdiction and the auditor within 10 business days of the conference call.
 - Clearinghouse panel decision is final

Administrative Procedures When is a Verification Audit Required?



(Page AP-4 Administrative Procedures Manual)

- Verification audits shall be conducted at the following frequency:
 - After the initial self-assessment (conducted within 12 months of enrollment), if the jurisdiction claims conformance with one or more Standards; and
 - After each subsequent self-assessment (conducted every 60 months), if the jurisdiction claims conformance with one or more Standards.



Participant Manual

Administrative Procedures Questions 1 and 2 Page 38

Administrative Procedures Self-Assessments



- Self-assessment within 12 months of enrollment & every 60 months thereafter to:
 - Compare program elements to relevant criteria in the Standards;
 - Determine if supporting records are maintained

Administrative Procedures, Page AP-3



Participant Manual

Administrative Procedures Question 3 Page 38

Administrative Procedures Self-Assessments



- The most recent version of the Retail Food Program
 Standards must be used when completing a required self-assessment.
- If a jurisdiction is updating a current self-assessment, it can either use the version of the Standards effective when the current self-assessment was completed or the current version of the Standards, at the jurisdiction's discretion.

Administrative Procedures, Page AP-4



Participant Manual

Administrative Procedures Question 4 Page 38

Administrative Procedures Verification Audits



- The jurisdiction must request a Verification Audit(VA) within 3 months of the completion of the Full Self-Assessment of all Nine Standards (SA9) or Self-Assessment update in which one or more of standard is met.
- The verification audit should be completed within 6 months of the SA9 or Self-Assessment Update.
 - May be conducted either virtually or on-site.
 - Administrative Procedures, Page AP-4-5



Participant Manual

Administrative Procedures Question 5 Page 39

Administrative Procedures Who can perform an Audit?



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

Administrative Procedures, Page AP-4



Participant Manual

Administrative Procedures Question 6 Page 39



(Pages AP-5 thru AP-7 Administrative Procedures Manual)

- Contact Retail Food Specialist within 10 business days of the close of the audit
- Request Assistance from the Clearinghouse



Participant Manual

Administrative Procedures Question 7 Page 39

Administrative Procedures When is a Verification Audit Required?



(Page AP-4 Administrative Procedures Manual)

- Verification audits shall be conducted at the following frequency:
 - After the initial self-assessment (conducted within 12 months of enrollment), if the jurisdiction claims conformance with one or more Standards; and
 - After each subsequent self-assessment (conducted every 60 months), if the jurisdiction claims conformance with one or more Standards.

PROGRAM STANDARDS ADMINISTRATIVE PROCEDURES QUESTIONS





Standard 3 Inspection Program Based on HACCP Principles

Preparing for the Self Assessment or Verification Audit



FDA

Source Documents

- Copy of Program Standard 3
- Clearinghouse Interpretations
- Standard 3 Self-Assessment and Verification Audit Form
- The jurisdiction's inspection form
- Regulatory reference/guidance document that accompanies the inspection form
- Inspector's training or operating manual that details the use of the inspection form and/or other documents that demonstrate implementation of policies



Preparing for the Standard 3 Self-Assessment

Forms and Worksheets

http://www.fda.gov/retailprogramstandards



Standard 3: Inspection Program Based on HACCP Principles

- Standard 3 (PDF 78KB)
- Standard 3 Self-Assessment and Verification Audit Form (PDF 334KB)



Standard 3 Inspection Program Based on HACCP Principles

Conducting the Self-Assessment or Verification Audit

(Pages 3-4 thru 3-10, Standards Manual)

PROGRAM SELF-ASSESSMENT SUMMARY

(Page 3-7, Program Standards Manual)

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 Standard 3 is true and correct.
Signature of the Self-Assessor:
VERIFICATION AUDIT SUMMARY
Printed Name of the Person who conducted the Verification Audit:
Verification Auditor's Title:
Auditor's Jurisdiction Name:
Auditor's Jurisdiction Address:
Phone:
FAX:
E-mail:
Date the Verification Audit of Standard 3 was Completed:
Verification Audit indicates that the Jurisdiction MEETS the Standard
3 criteria (indicate YES/NO):
I affirm that the information represented in the Verification Audit of Standard 3 is true and correct
Signature of the Verification Auditor:



(Page 3-8 thru 3-10, Program Standards Manual)

Jurisdiction Name:

Criteria	Element	Ī	urisdiction'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 pecify why criterion is not met
1. Inspection Form Design	a) The jurisdiction's inspection form identifies foodborne illness risk factor and Food Code interventions							
1. Inspection Form Design	b) The jurisdiction's inspection form documents actual observations using th 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 establishment into at least 3 categories based on their potential and inherent food safety risks.							
2. Risk Assignment Categories	b) Documentation is provided of performed interventions, action, or activities designed to improve control of foodborne illness risk factors.							
3. Inspection Frequency	a) The jurisdiction's inspection frequency is based on the assigned risk categories.							

(Page 3-8 thru 3-10, Program Standards Manual)

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. Verification and Validation of HACCP Plans	a) The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the Code.						

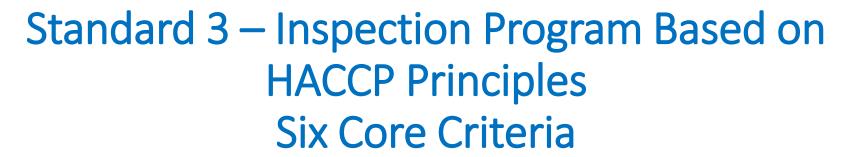
(Page 3-8 thru 3-10, Program Standards Manual)

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



Standard 3 – Inspection Program Based on HACCP Principles

 Inspection program focuses on status of risk factors, determine and documents compliance, and targets immediate and long-term correction of outof-control risk factors through active managerial control





(Page 3-2, Program Standards Manual)

- Inspection Form Design
- Risk Assessment Categories
- Inspection Frequency
- Corrective Action Policy
- Variance Request Policy
- Verification and Validation of HACCP Plan Policy

Standard 3 – Inspection Program Based on HACCP Principles Step 1: Inspection Form Design



(Page 3-8, Program Standards Manual)

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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	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.						
2. Risk Assignment Categories	b) Documentation is provided of performed interventions, action, or activities designed to improve control of foodborne illness risk factors.						
3. Inspection Frequency	The jurisdiction's inspection frequency is based on the assigned risk categories.						





- Inspection form prominently identifies foodborne illness risk factors
 - Food from Unsafe Sources
 - Poor Personal Hygiene
 - Inadequate Cooking
 - Improper Holding/Time-Temperature Controls
 - Contaminated Equipment/Protection from Contamination





- Inspection form prominently identifies public health interventions
 - Demonstration of Knowledge
 - Implementation of Employee Health Policies
 - Prevention of Hands as a Vehicle of Contamination
 - Time-Temperature Relationships
 - Consumer Advisory





 Inspection form documents the IN, OUT, Not Observed, and Not Applicable Status for foodborne illness risk factors and public health interventions





- Inspection form documents compliance and enforcement activities
 - On-site corrective actions written on inspection report
 - Blank fields for entering compliance action in electronic inspection system (EIS)
 - Canned statements in EIS
 - Planned follow-up inspections

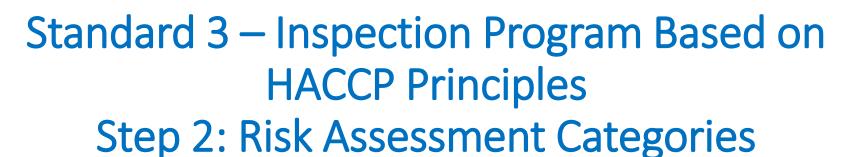
Standard 3 – Inspection Program Based on HACCP Principles Step 2: Risk Assessment Categories



(Page 3-8, Program Standards Manual)

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. 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.						
2. Risk Assignment Categories	b) Documentation is provided of performed interventions, action, or activities designed to improve control of foodborne illness risk factors.						
3. Inspection Frequency	The jurisdiction's inspection frequency is based on the assigned risk categories.						





- Must have a written process for grouping establishments into at least three (3) risk categories based on inherent food safety risks
 - Each establishment must be assigned to a category
 - The design of the process and criteria is at the jurisdiction's discretion





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 Step 3: Inspection Frequency

(Page 3-8, Program Standards Manual)

				N.T.	
J	uriso	lici	tion	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. 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.						
2. Risk Assignment Categories	b) Documentation is provided of performed interventions, action, or activities designed to improve control of foodborne illness risk						
3. Inspection Frequency	The jurisdiction's inspection frequency is based on the assigned risk categories.						





- Determine whether routine inspection frequency is consistent with the jurisdiction's established risk categories
 - Higher risk category should be assigned a routine inspection frequency greater than establishments in a lower risk category
 - No requirement for a minimum routine inspection frequency



Step 4: Written and Implemented Corrective Action Policy

(Page 3-9, Program Standards Manual)

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. Verification and Validation of HACCP Plans	a) The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the Code.						

Step 4a: Review Written & Implemented Corrective Action Policy

(Page 3-2 and 3-3, Program Standards Manual)

- Review written policy that requires inspectors to obtain on-site corrective actions, appropriate to the type of violation, for foodborne illness risk factors and public health interventions
 - Destruction of Food Extreme Temp. Abuse
 - Embargo/Destruction of Foods from Unapproved Sources
 - Accelerate cooling of foods when cooling time limits can still be met
 - Initiate use of gloves, tongs, or utensils to prevent bare hand contact with ready-to-eat foods
 - Reheating when small deviations for hot holding have occurred



Step 4b: Review Written & Implemented Long-Term Corrective Action Policy

(Page 3-2 and 3-3, Program Standards Manual)

- Review written policy that requires inspectors to discuss with operators' various options for long term control of repeated risk factor violations
 - Use of Risk Control Plans
 - Development of Standard Operating Procedures
 - Menu or Product Formulation Modifications
 - Development of Buyer Specifications
 - Training and/or Consultation Inspections

Step 4c: Review Written & Implemented Follow-up on Risk Factor Violations

(Page 3-2, Program Standards Manual)

- Review written policy that requires follow-up activities subsequent to violations of foodborne illness risk factors
 - Policy left up to the discretion of the jurisdiction
 - Policies should be specific to events or circumstances which trigger follow-up action
 - Policies must give clear direction as to the appropriate follow-up activity
 - Determine method used to communicate policy to inspection staff

Standard 3 – Inspection Program Based on HACCP Principles Step 5: Variance Requests



(Page 3-9, Program Standards Manual)

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. Verification and Validation of HACCP Plans	a) The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the Code.						





Step 5: Variance Requests

(Page 3-3, Program Standards Manual)

- Review written policy addressing code variance requests related to risk factors and interventions
 - Specify the information required
 - Justification for the variance
 - Identify when a HACCP Plan is required
 - Outline criteria for approving variances
 - Dis-allowing variance requests IS acceptable





Step 5: Review Variance Requests Policy

- This element may be met if:
 - A written policy exists describing the policy and the required information to be addressed by the requestor;
 OR
 - No variance requests related to foodborne illness risk factors or interventions have been received



Step 6: Verification and Validation of HACCP Plans

(Page 3-9, Program Standards Manual)

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. Verification and Validation of HACCP Plans	a) The jurisdiction has a written and implemented policy for the verification and validation of HACCP plans, when a HACCP plan is required by the Code.						

Standard 3 – Inspection Program Based on HACCP Principles Step 6: Review Verification & Validation of HACCP



Step 6: Review Verification & Validation of HACCP Plans Policy

- Review written policy for validating and verifying HACCP Plans when a plan is required by the jurisdiction's rule or regulation
 - Designate frequency for verification inspections
 - Identify critical areas of the HACCP Plan to be reviewed during the inspection
 - Frequency for validation of the HACCP Plan

Standard 3 – Inspection Program Based on HACCP Principles Step 6: Review Verification & Validation of HACCP Plans Policy

FDA

- This element may be met if:
 - A written policy containing the required element exists;
 OR
 - There are no facilities under the jurisdiction's authority performing operations requiring HACCP Plan





Jurisdiction demonstrates conformance with ALL the criteria contained in six inspection program categories

Standard 3 – Inspection Program Based FDA on HACCP Principles **Verification Audit Results**

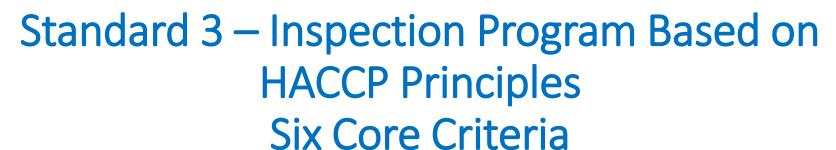


Jurisdiction Name:

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. Inspection Form Design	The jurisdiction's inspection form identifies foodborne illness risk factors and Food Code interventions	X			X		
1. Inspection Form Design	b) The jurisdiction's inspection form documents actual observations using the convention (IN, OUT, NO, and NA).	X			X		
1. Inspection Form Design	c) The jurisdiction's inspection form documents compliance and enforcement activities.	X			X		
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.	X			X		
2. Risk Assignment Categories	b) Documentation is provided of performed interventions, action, or activities designed to improve control of foodborne illness risk factors.	X			X		
3. Inspection Frequency	The jurisdiction's inspection frequency is based on the assigned risk categories.	X			X		



Standard 3 Question 1





- Inspection Form Design
- Risk Assessment Categories
- Inspection Frequency
- Corrective Action Policy
- Variance Request Policy
- Verification and Validation of HACCP Plan Policy



Standard 3 Question 2





- Clearly identifies risk factors and interventions
- Uses marking conventions IN, OUT, NO, NA
- Inspection form documents compliance and enforcement activities



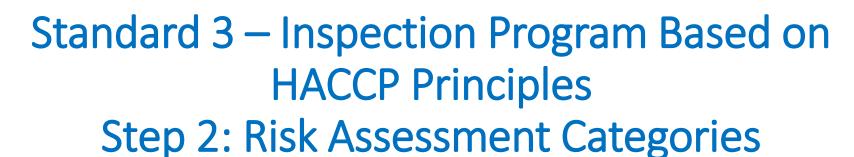
Standard 3 Question 3



- Inspection form documents the IN, OUT, Not Observed, and Not Applicable status for foodborne illness risk factors and public health interventions
 - Compliance status using an automated system may not default to an IN-compliance choice
 - Some items can be set up to only accept an IN or OUT compliance status selection



Standard 3 Question 4





 Must have a written process for grouping establishments into at least three (3) risk categories based on inherent food safety risks



Standard 3 Question 5





- Determine whether routine inspection frequency is consistent with the jurisdiction's established risk categories
 - Higher risk category should be assigned a routine inspection frequency greater than establishments in a lower risk category
 - No requirement for a minimum routine inspection frequency



Standard 3 Question 6

Step 4: Review Written & Implemented Corrective Action Policy

(Page 3-2 and 3-3, Program Standards Manual)

Written policies that require:

- On-site corrective actions, appropriate to the type of violation, for foodborne illness risk factors and public health interventions
- Inspectors to discuss with operators' various options for long-term control of repeated risk factor violations
- Follow-up activities subsequent to violations of foodborne illness risk factors



Standard 3 Question 7



Standard 3 – Inspection Program Based on **HACCP Principles Step 5: Variance Requests**

(Page 3-3, Program Standards Manual)

- Review written policy addressing code variance requests related to risk factors and interventions
 - Specify the information required
 - Justification for the variance
 - Identify when a HACCP Plan is required
 - Outline criteria for approving variances
 - Dis-allowing variance requests IS acceptable

STANDARD 3 SELF-ASSESSMENT OR VERIFICATION AUDIT PROCESS QUESTIONS





Standard 7 Industry & Community Relations



Conducting the Standard 7 Self-Assessment

- Copy of Program Standard 7
- Clearinghouse Interpretations
- Standard 7: Self-Assessment and Verification Audit Form
- The jurisdiction's records of meetings or other forums conducted to support industry consumer relations
- The jurisdiction's records or examples of educational outreach



Preparing for the Standard 7 Self-Assessment

Forms and Worksheets

http://www.fda.gov/retailprogramstandards



Standard 7: Industry and Community Relations

- Standard 7 (PDF 98KB)
- Standard 7 Self-Assessment and Verification Audit Form (PDF 814KB)
- Standard 7 Self-Assessment Instructions and Worksheet (PDF 137KB)



Standard 7 Industry & Community Relations

Preparing for the Self Assessment or Verification Audit

Standard 7 – Industry and Community Relations FDA Two Core Criteria



(Pages 7-2, Program Standards Manual)

- Industry and Consumer Interaction
- Educational Outreach

Standard 7 – Industry and Community Relations FDA **Element 1: Industry and Consumer Interaction**



(Page 7-7, Program Standards Manual)

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.						

Standard 7 – Industry and Community Relations



The jurisdiction documents:

- Participation in forums that foster communication and information exchange among regulators, industry, and consumers
- Outreach activities that provide education information on food safety

Standard 7 – Industry and Community Relations DA **Element 1: Industry and Consumer Interaction**

(Pages 7-9 and 7-10, Program Standards Manual)

Jurisdiction sponsors or participates in activities within its regulated community such as

- Food safety task forces
- Advisory boards or committees
- Other forums on food safety strategies and interventions
- Offers of participation must be extended to industry and consumer representatives
- Use of social media to obtain input on the program

Standard 7 – Industry and Community Relations DA **Element 1: Industry and Consumer Interaction**

(Pages 7-11, Program Standards Manual)

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 FDA **Element 2: Educational Outreach**



(Pages 7-7, Program Standards Manual)

	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				
2. Educational	activities focus on increasing				
Outreach	awareness of foodborne illness risk				
	factors and control methods to prevent				
	foodborne illness and may include				
	industry recognition programs, web				
	sites, newsletters, Fight BAC				
	campaigns, food safety month				
	activities, food worker training and				
	use of oral culture learner materials.				
	industry recognition programs, web sites, newsletters, Fight BAC campaigns, food safety month activities, food worker training and				

Standard 7 – Industry and Community Relations DA **Element 2: Educational Outreach**



(Pages 7-10, Program Standards Manual)

- Target groups encompass industry, consumer groups, media, elected officials
- Activities that increase awareness of risk factors and control methods to prevent foodborne illness
 - > Industry recognition programs
 - Web sites, newsletters
 - Social Media
 - Food safety month
 - Food worker training
 - Posting inspection information on website

Standard 7 – Industry and Community Relations DA **Element 2: Educational Outreach**

(Pages 7-10, Program Standards Manual)

Food Safety Bulletin Example



Standard 7 – Industry and Community Relations FDA **Element 2: Educational Outreach**

(Pages 7-10, Program Standards Manual)

Food Safety Web Site Example



Standard 7 – Industry and Community Relations Element 2: Educational Outreach Self-Assessment Worksheet

(Pages 7-12, Program Standards Manual)

PART II-Educational Outreach

Dates	Summary of Activities

Τр

FDA

Standard 7 – Industry and Community Relations Verification Audit Results

(Pages 7-7, Program Standards Manual)

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, web sites, newsletters, Fight BAC campaigns, food safety month activities, food worker training and use of oral culture learner materials.	X			X		



Participant Manual

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Standard 7 – Industry and Community Relations FDA Two Core Criteria



(Pages 7-2, Program Standards Manual)

- Industry and Consumer Interaction
- Educational Outreach



Participant Manual

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Standard 7 – Industry and Community Relations DA **Element 1: Industry and Consumer Interaction**



(Pages 7-9 and 7-10, Program Standards Manual)

Jurisdiction sponsors or participates in activities within its regulated community such as

- Food safety task forces
- Advisory boards or committees
- Other forums on food safety strategies and interventions
- Offers of participation must be extended to industry and consumer representatives
- Use of social media to obtain input on the program



Participant Manual

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(Pages 7-2, Program Standards Manual)

YES, if Each year the jurisdiction:

- Sponsors or participates in at least one regulatory, industry, consumer forum that has direct impact on their regulatory retail food program
- Sponsors, conducts, or participates in at least one educational outreach activity

STANDARD 7 SELF-ASSESSMENT OR VERIFICATION AUDIT PROCESS QUESTIONS





Standard 5 Foodborne Illness & Food Defense Preparedness and Response

Preparing for the Self Assessment or Verification Audit



FDA

- Copy of Program Standard 5
- Clearinghouse Interpretations
- Standard 5 Self-Assessment and Verification Audit Form
- The jurisdiction's manuals, procedures, directives, and/or inter-agency correspondence related to foodborne illness/food defense investigations
- MOUs and or cooperative agreements the jurisdiction has in place with other agencies that identifies specific roles/responsibilities related to foodborne illness/food defense investigations



FDA

- Foodborne illness/food defense complaint log or database
- The jurisdiction's guidance for collecting information on suspected foods; case history forms; lab notification for samples; and list of materials included in the agency's Foodborne Illness Investigation Kit
- Documentation of foodborne illness/food defense investigation staff training
- Description of the support services that will be provided by each laboratory and the types of food adulterants that can be identified





- Contact lists identifying specific laboratories based on the type of suspected pathogens or adulterants (biological, chemical, and radiological agents)
- Contact lists identifying specific laboratories for food, environmental, and clinical sample analyses
- Written traceback procedures or description of the jurisdiction's role in tracebacks
- Written recall procedures or description of the jurisdiction's role during product recalls



Preparing for the Standard 5 Self-Assessment

- Written protocol for developing and disseminating information to the media and public
- Annual trend analysis report that covers the nine categories described in the Standard 5 criteria



Preparing for the Standard 5 Self-Assessment

Forms and Worksheets

http://www.fda.gov/retailprogramstandards



Standard 5: Foodborne Illness and Food Defense Preparedness and Response

- Standard 5 (PDF 109KB)
- Standard 5 Self-Assessment and Verification Audit Form (PDF 972KB)



Standard 5 Foodborne Illness & Food Defense Preparedness and Response

Conducting the Self Assessment or Verification Audit



Standard 5 – Foodborne Illness & Food Defense Preparedness and Response

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.

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Seven Core Criteria

(Page 5-8, Program Standards Manual)

- Investigative Procedures
 - Written Operating Procedure
 - Document/Responding to Complaints/Incidences
 - Complaint/Incident Investigation Procedures
- Reporting Procedures
- Laboratory Support Documentation
- Trace-back Procedures
- Recalls
- Media Management
- Data Review and Analysis

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response NEARS – Voluntary Participation Encouraged

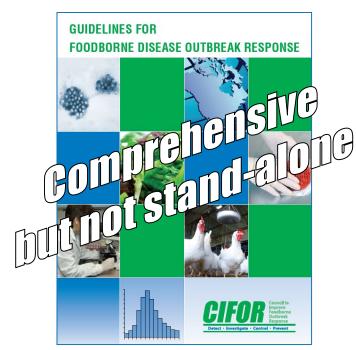
(Page 5-4 and 5-5, Program Standards Manual)

- CDC National Environmental Assessment Reporting System (NEARS)
- NEARS is designed to provide a comprehensive approach to foodborne outbreak investigation and response
- Data source to measure the impact of food safety program to further cause and prevention research
- 23 states and 23 local HDs enrolled

http://www.cdc.gov/nceh/ehs/nears

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Available Resource – CIFOR Toolkit

- Description of major functions in outbreak response,
- Specific practices to improve outbreak response, and
- Performance indicators to determine effectiveness of activities.
- Does not provide instructions for implementing any recommendation.
- Toolkit available <u>www.CIFOR.us</u>





(Page 5-9 thru 5-11, Program Standards Manual)

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. Investigation Procedures	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. Investigation 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.						

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 1: Investigative Procedures (a – c)

(Page 5-2, Program Standards Manual)

- a. Written procedures for response & investigation, identifying roles & responsibilities
- b. Maintain contact lists
- c. Written procedures or MOUs depts./programs/ agencies

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 1: Investigative Procedures (d – f)

(Page 5-2, Program Standards Manual)

- d. Database or log of complaints
- e. Procedure for complaint disposition or referral
- f. Disposition/Action/Follow up conducted within 24 hrs. for food-related illness or injury complaints proper linkage to file

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 1: Investigative Procedures (g – i)

(Page 5-2 and 5-3, Program Standards Manual)

- g. Procedures/guidance for collecting information on suspect food(s)/procedures during investigations
- Procedures for immediate notification of law enforcement official when intentional food contamination incidences are suspected
- i. Procedure for complaint referrals to other agencies having jurisdiction

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 2: Reporting Procedures (a – b)

(Page 5-11 and 5-12, Program Standards Manual)

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

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 2: Reporting Procedures (a – b)

(Page 5-2, Program Standards Manual)

- a. Contributing Factors identified in each on-site investigation report
- b. Report shared with state epi and CDC
 - Required for all "confirmed foodborne disease outbreaks"

Standard 5 – Foodborne Illness & Food Defense FDA Preparedness and Response

Step 3: Laboratory Support Documentation (a – b)

(Page 5-12, Program Standards Manual)

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).						

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 3: Laboratory Support Documentation (a – b)

(Page 5-3, Program Standards Manual)

- a. Written description or MOU of capabilities
 - In-house or external
 - Pathogens, agents, adulterants that can be identified
 - Environmental, food, clinical analysis
- b. Network is established when the state or local lab has limitations in-house

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 4: Trace-back Procedures (a)

(Page 5-13, Program Standards Manual)

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 traceback 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.						

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 4: Trace-back Procedures (a)

(Page 5-3, Program Standards Manual)

Written trace-back procedures for implicated foods should include:

- Description of coordinated involvement of appropriate agencies
- Identification of a coordinator
- Report sharing with involved agencies & CDC



Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 5: Recalls (a-c)

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 traceback 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.						

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 5: Recalls (a – c)

(Page 5-3 and 5-4, Program Standards Manual)

- a. Established recall procedure based on illness/injury investigation
- b. If jurisdiction initiates recalls, written procedures equivalent to 21 CFR, Part 7
- c. Written policies/procedures for verifying the effectiveness of recall actions by firms (effectiveness checks)

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 5: Recalls (b) – Summary 21 CFR Part 7

State coordinated recall procedures should include:

- Process for determining the hazard posed by a product and relative risk to public
- Process for working with the industry on development of voluntary recall notices / obtaining distribution points
- Coordinating/Conducting Effectiveness Checks
- Roles/Responsibilities (regulatory staff; industry involved with recall & media PIOs)

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 6: Media Management (a)

(Page 5-14, Program Standards Manual)

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.						

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 6: Media Management (a)

Written policy and procedure that:

- ➤ Identifies a media person (Public Information Officer)
- ➤ Defines protocol for providing information to the public
- Addresses coordination/cooperation with other agencies involved in the investigation

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 7: Data Review and Analysis (a – c)

(Page 5-14 thru 5-16, Program Standards Manual)

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	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.						
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) Multiple complaints on the same establishment;						
7. Data Review and Analysis	 Multiple complaints on the same establishment type; 						
7. Data Review and Analysis	Multiple complaints implicating the same food;						

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 7: Data Review and Analysis (a)

(Page 5-4, Program Standards Manual)

- a. Annual review of the complaint log/data base to identify trends in:
 - Food products
 - Food processes
 - Contributing factors

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 7: Data Review and Analysis (b)

(Page 5-4, Program Standards Manual)

- b. Identify Multiple Complaints...
 - On the same establishment
 - Same establishment type
 - Implicating same food
 - 4. Associated with similar food preparation processes

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 7: Data Review and Analysis (b)

(Page 5-4, Program Standards Manual)

b. Data Review cont'd

- Laboratory-confirmed or epi-linked food- related outbreaks
- 6. Foodborne disease outbreaks and suspect foodborne disease outbreaks
- 7. Contributing factors most often identified
- 8. Complaints involving real & alleged threats of intentional food contamination
- 9. Complaints involving the same agent (or any complaints of unusual agents)

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 7: Data Review and Analysis (c)

(Page 5-4, Program Standards Manual)

c. If no outbreak investigation conducted within last 12 months, a mock foodborne illness/defense exercise must be conducted.

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Self-Assessment/Verification Audit Criteria

(Page 5-5, Program Standards Manual)

Jurisdiction demonstrates conformance with ALL seven criteria contained in the foodborne illness and food defense preparedness and response categories

Standard 5 – Foodborne Illness & Food Defense FDA Preparedness and Response Verification Audit Results

(Page 5-9 thru 5-16, Program Standards Manual)

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. Investigation Procedures	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.)	X			X		
1. Investigation 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.	X			X		



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Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Seven Core Criteria

(Page 5-8, Program Standards Manual)

- Investigative Procedures
 - Written Operating Procedure
 - Document/Responding to Complaints/Incidences
 - Complaint/Incident Investigation Procedures
- Reporting Procedures
- Laboratory Support Documentation
- Trace-back Procedures
- Recalls
- Media Management
- Data Review and Analysis



Standard 5
Question 2
Page 26

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 1: Investigative Procedures (a – c)

(Page 5-2, Program Standards Manual)

- a. Written procedures for response & investigation, identifying roles & responsibilities
- b. Maintain contact lists
- c. Written procedures or MOUs depts./programs/ agencies

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 1: Investigative Procedures (d – f)

(Page 5-2, Program Standards Manual)

- d. Database or log of complaints
- e. Procedure for complaint disposition or referral
- f. Disposition/Action/Follow conducted within 24 hrs. for food-related illness or injury complaints
 proper linkage to file

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 1: Investigative Procedures (g – i)

(Page 5-2 and 5-3, Program Standards Manual)

- g. Procedures/guidance for collecting information on suspect food(s)/procedures during investigations
- Procedures for immediate notification of law enforcement official when intentional food contamination incidences are suspected
- i. Procedure for complaint referrals to other agencies having jurisdiction



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Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 2: Reporting Procedures (a – b)

(Page 5-2, Program Standards Manual)

- a. Contributing Factors identified in each on-site investigation report
- b. Report shared with state epi and CDC
 - Required for all "confirmed foodborne disease outbreaks"



Standard 5
Question 4
Page 26

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 3: Laboratory Support Documentation (a – b)

(Page 5-3, Program Standards Manual)

- a. Written description or MOU of capabilities
 - In-house or external
 - Pathogens, agents, adulterants that can be identified
 - Environmental, food, clinical analysis
- b. Network is established when the state or local lab has limitations in-house



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Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 4: Trace-back Procedures (a)

(Page 5-3, Program Standards Manual)

Written trace-back procedures for implicated foods should include:

- Description of coordinated involvement of appropriate agencies
- Identification of a coordinator
- Report sharing with involved agencies & CDC



Standard 5
Question 6
Page 26

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 5: Recalls (a – c)

(Page 5-3 and 5-4, Program Standards Manual)

- a. Established recall procedure based on illness/injury investigation
- b. If jurisdiction initiates recalls, written procedures equivalent to 21 CFR, Part 7
- c. Written policies/procedures for verifying the effectiveness of recall actions by firms (effectiveness checks)



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Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 5: Recalls (b) – Summary 21 CFR Part 7

State coordinated recall procedures should include:

- Process for determining the hazard posed by a product and relative risk to public
- Process for working with the industry on development of voluntary recall notices / obtaining distribution points
- Coordinating/Conducting Effectiveness Checks
- Roles/Responsibilities (regulatory staff; industry involved with recall & media PIOs)



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Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 7: Data Review and Analysis (b)

(Page 5-4, Program Standards Manual)

- b. Identify Multiple Complaints...
 - On the same establishment
 - Same establishment type
 - Implicating same food
 - 4. Associated with similar food preparation processes

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 7: Data Review and Analysis (b)

(Page 5-4, Program Standards Manual)

- b. Identify Multiple Complaints...
 - 5. Laboratory-confirmed or epi-linked food- related outbreaks
 - 6. Foodborne disease outbreaks and suspect foodborne disease outbreaks
 - 7. Contributing factors most often identified
 - 8. Complaints involving real & alleged threats of intention food contamination
 - 9. Complaints involving the same agent (or any complaints of unusual agents)



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www.fda.gov

Standard 5 – Foodborne Illness & Food Defense Preparedness and Response Step 7: Data Review and Analysis (c)

(Page 5-4, Program Standards Manual)

c. If no outbreak investigation conducted within last 12 months, a mock foodborne illness/defense exercise must be conducted.

STANDARD 5 SELF-ASSESSMENT OR VERIFICATION AUDIT PROCESS QUESTIONS





Standard 8 Program Support and Resources

Preparing for the Self-Assessment or Verification Audit

Standard 8 – Program Support and Resources



The retail food protection program is provided the funding, staff, and equipment necessary to accomplish compliance with the *Voluntary National Retail Food Regulatory Program Standards*

Conducting the Standard 8 Self-Assessment Source Documents



- Copy of Program Standard 8
- Clearinghouse Interpretations
- Standard 8: Self-Assessment and Verification Audit Form
- Document of FTE to inspection ratios
 - Option 1: Assessment
 - Option 2: Alternative Model
- Inventory of assigned and available inspection equipment
- Documentation and demonstration of records system and adequacy of support
- The completed Standard 8 Self-Assessment Worksheet



Alternative Staffing Level Resource Conference for Food Protection

http://www.foodprotect.org/guides-documents/alternative-standard-8-workbook-2023/

Alternative Standard 8 Workbook 2023

/ Home / Guides and Documents / Details

This workbook can be used to measure current or proposed staffing levels for assessment of conformance with Standard 8.

- Alternative S8 Workbook CFP Instructions
- Alternative S8 Workbook Model_3_4 Risk Codes_2022 single document
- Alternative S8 Workbook Model_3_4 Risk Codes_2022 page 1
- Alternative S8 Workbook Model_3_4 Risk Codes_2022 page 2
- Alternative S8 Workbook Model_3_4 Risk Codes_2022 page 3

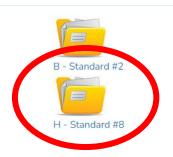
FDA

Alternative Staffing Level Resources

Program Standards Resource Center

Folders:











Model



↓† File		11 Author	11 Version	11 Date	11 11
↑ Up Folde	er				
≛ Standa	ard-8-ResourceAssessmentWorkbookBRHD.xlsx	VICTORIA TOURVILLE	11/16/2023	11/16/23	
≛ Metho	dology for Calculating the Adequacy of Staffi	Robert Custard	04/01/2023	07/10/23	w
≛ Altern	ative S8 Workbook Instructions.pdf	Deanna Copeland	07/07/23	07/07/23	>
▲ Altern	ative S8 Workbook Model_6Risk Codes_2022.xls	Deanna Copeland	07/07/23	07/07/23	
≛ Altern	ative S8 Workbook Model_3-4 Risk Codes_2022.	Deanna Copeland	06/09/2022	06/09/22	
≛ Standa	ard 8 Auditors Template Tool.docx	Cyndi Free	12/02/2020	12/02/20	W
≛ Calcul	ations of FTE.xlsx	Amber Potts	07/02/2018	07/27/20	

Showing 1 to 8 of 8 entries





http://www.fda.gov/retailprogramstandards



Standard 8: Program Support and Resources

- Standard 8 (PDF: 111KB)
- Standard 8 Self-Assessment and Verification Audit Form (PDF: 883KB)
- Standard 8 Self-Assessment Instructions and Worksheet (PDF: 706KB)
- Standard 8 Staffing Level (FTE to Inspection Ratio) Assessment Workbook
 Instruction Guide
- Standard 8 Staffing Level (FTE to Inspection Ratio) Assessment Workbook



Standard 8 Program Support and Resources

Conducting the Self-Assessment or Verification Audit

(Pages 8-1 thru 8-15, Standards Manual)

Standard 8 – Program Support and Resources Four Core Criteria



(Pages 8-2 thru 8-4, Program Standards Manual)

- Staff level per food inspections performed
- Availability of food inspection equipment
- Administrative Program Support
- Program resource (budget, staff, equipment) assessment for each Standard

Standard 8 – Program Support and Resources Step 1: Staffing Level – FTEs per Inspections Performed



(Page 8-8, Program Standards Manual)

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.						



Participant Manual

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Standard 8 - Program Support & Resources FDA **Example: Inspections-to-FTE Ratio**



(Page 8-12, Program Standards Manual)

- Assuming 40-hour work week/52 weeks 2080 Total Available
- Less 48 hrs. for Holidays
- Less 40 hrs. for Vacation Time
- Less 16 hrs. for Sick Leave
- Less 488 hrs. for Travel Time to and from facilities
- Less 24 hrs. for Personal Training
- Less 244 hrs. for Admin/Office Time

Leaving 1220 Productive Hours – FTE Conversion Factor



Participant Manual

Standard 8 Questions 3 and 4 Pages 34-35



Standard 8 - Program Support & Resources Basic Example: Calculating Current FTEs

Position	Portion of Productive Time Spent in Retail Food Inspections	Number of Employees	Total Hours Spent in Retail Food Inspection			
Three people full-time in retail food inspection	1220	X 3	= 3660			
Three inspectors devoted half-time to retail food inspection	1220/2 = 610	X 3	= 1830			
One supervisor who devotes 1/3 of time to compliance inspections	1220/3 = 407	X 1	= 407			
Total Hours Spont in Potail						
Total Hours Spent in Retail Food	5897					
Divided by Conversion Factor		1220				
Total FTE	4.8					



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Standard 8 – Program Support and Resources Basic Example: Inspections-to-FTE Ratio

Assuming 1440 Inspections

Example

1440 inspections ÷ 4.8 FTEs =

300 inspections/FTE

To meet the Standard 8 criteria the ratio must fall between

280 and 320 inspections per FTE

Standard 8 – Program Support and Resources FDA **Step 2: Inspection Equipment**

(Page 8-8, Program Standards Manual)

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	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.						
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.						

Standard 8 – Program Support and Resources Step 2: Inspection Equipment

(Page 8-8 & 8-12, Program Standards Manual)

Inspection equipment for each inspector

- head covers
- thermocouples
- flashlights
- sanitization test kits
- heat sensitive tapes
- forms & administrative material

Standard 8 – Program Support and Resources **Step 2: Inspection Equipment**

(Page 8-8 & 8-12, Program Standards Manual)

Food inspection equipment <u>AVAILABLE</u> to staff for use when needed

- computers and cameras
- black lights and light meters
- pH meters
- foodborne illness investigation kits
- sample collection kits
- data loggers
- cell phones



(Page 8-9 & 8-13, Program Standards Manual)

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. 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.						
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.						

Standard 8 – Program Support and Resources Step 3: Administrative Program Support

(Page 8-13, Program Standards Manual)

Equipment and administrative staff to ensure:

- a system to collect, analyze, retain and report pertinent information
- computers, software and/or items to support the record keeping system utilized by the program

Standard 8 – Program Support and Resources PA Step 4: Program Resource Assessment

(Page 8-9 and 8-10, Program Standards Manual)

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	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.						
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.						

Standard 8 – Program Support and Resources Step 4: Program Resource Assessment



(Page 8-9 and 8-10, Program Standards Manual)

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	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.						

Standard 8 – Program Support and Resources Step 4: Program Resource Assessment

S FDA

(Page 8-13, Program Standards Manual)

To meet the Standard 8 criteria, the jurisdiction does NOT have to meet Standards 1-7, and 9. The jurisdiction merely has to perform the assessment as to whether program resources are sufficiently available for each Standard.

Standard 8 – Program Support and Resources PA **Verification of Self-Assessment Results**

(Page 8-4, Program Standards Manual)

The essential program elements required to demonstrate compliance with this standard are:

- Full-time equivalent (FTE) personnel to inspections accomplished ratio as described in section 1.
- Inspection equipment assigned or available as described in section 2.
- Equipment and/or supplies required for administering the program as described in Section 3.
- A full and accurate completion of the Standard 8: Self-Assessment Worksheet or equivalent whether or not those standards are met.
- Budget, staffing, and equipment resource assessment conducted for each of the Standards

Standard 8 – Program Support and Resources PA **Verification of Self-Assessment Results**

(Page 8-8 thru 8-11, Program Standards Manual)

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.	X			×		
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.	×			×		



Participant Manual

Standard 8
Question 1
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Standard 8 – Program Support and Resources Four Core Criteria



(Pages 8-2 thru 8-4, Program Standards Manual)

- Staff level per food inspections performed
- Availability of food inspection equipment
- Administrative Program Support
- Program resource (budget, staff, equipment) assessment for each Standard



Participant Manual

Standard 8 Questions 6 and 7 Pages 35

Standard 8 – Program Support and Resources Step 4: Program Resource Assessment

S FDA

(Page 8-13, Program Standards Manual)

To meet the Standard 8 criteria, the jurisdiction does NOT have to meet Standards 1-7, and 9. The jurisdiction merely has to perform the assessment as to whether program resources are sufficiently available for each Standard.

STANDARD 8 SELF-ASSESSMENT OR VERIFICATION AUDIT PROCESS QUESTIONS





Standard 9 Program Assessment

Preparing for the Self-Assessment or Verification Audit



FDA

Source Documents

- Copy of Program Standard 9
- Clearinghouse Interpretations
- Standard 9: Self-Assessment and Verification Audit Form
- The jurisdiction's report documenting findings from their risk factor study
- Documentation of the jurisdiction's intervention strategy(s) to address one or more foodborne illness risk factors based on findings from their risk factor study





https://www.fda.gov/food/retail-food-protection/retail-food-risk-factor-study

Retail Food Risk Factor Study



In 1998, the FDA National Retail Food Team initiated a three-phase, 10-year study to measure the occurrence of practices and behaviors commonly identified by the Centers for Disease Control and Prevention as contributing factors in foodborne illness outbreaks.

In 2013, the FDA National Retail Food Team initiated a new, 10-year study to measure the occurrence of practices and behaviors commonly identified by the Centers for Disease Control and Prevention as contributing factors in foodborne illness outbreaks. Initial data collections began in 2013 for select restaurant facility types, followed by data collection for select institutional foodservice facility types in 2014 and select retail food store facility types in 2015. The results of the initial data collection for each of the facility types will serve as the baseline measurement from which trends will be analyzed. Two additional data collection periods for each of the facility types are planned at 3-year intervals after the initial data collection for the purposes of analyzing trends.

Backgrounders

- FDA Briefing to Food Store Stakeholders & March 2016
- FDA Briefing to Restaurant Stakeholder 🗹 June 2014
- Highlights of the 2010 Trend Analysis Report 🗹
- · Retail Food Safety Initiative



2015-2016 Occurrence Report: Report on the Occurrence of Foodborne Illness
Risk Factors in Retail Food Store Deli Departments (PDF: 1.60MB)







Forms and Worksheets

http://www.fda.gov/retailprogramstandards



Standard 9: Program Assessment

- Standard 9 (PDF 92KB)
- Standard 9 Self-Assessment and Verification Audit Form (PDF 214KB)



Standard 9 Program Assessment

Preparing for the Self-Assessment or Verification Audit

(Pages 9-2 thru 9-9, Standards Manual)



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.





(Page 9-2, Program Standards Manual)

- 1. Foodborne Illness Risk Factor Study
- 2. Risk Factor Study Report and Analysis
- 3. Intervention Strategy

Standard 9 – Program Assessment Step 1: Risk Factor Study



(Page 9-8, Program Standards Manual)

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 type regulated by the jurisdiction collected over the study cycle.						
1. Risk Factor Study	b) The data collection form includes items pertaining to the following Center for Disease Control and Prevention (CDC) identified contributing factors to foodborne illness. 1. Food from Unsafe Sources; 2. Improper Holding/Time and Temperature; 3. Inadequate Cooking; 4. Poor Personal Hygiene; and 5. Contaminated equipment / Protection from contamination.						
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).						





(Page 9-3, Program Standards Manual)

Facility Types (2016 Conference for Food Protection)

- Health Care
- Schools (K-12)
- Restaurants
- Retail Food Stores

May stagger collection over the 5 years.



Standard 9 – Program Assessment Step 1b: Study Addresses Risk Factor Areas

(Page 9-2, Program Standards Manual)

Inclusion of Foodborne Illness Risk Factor Areas

- Food from Unapproved Source
- Improper Holding/Time & Temperature
- Inadequately Cooking
- Poor Personal Hygiene
- Contamination Equipment/Protection from Contamination





(Page 9-3, Program Standards Manual)

Data Collection Form / Inspection Form — Captures Actual Observations

- IN Compliance
- OUT of Compliance
- N.O. Not Observed
- N.A. Not Applicable

Standard 9 – Program Assessment Step 2: Report of Analysis and Outcomes



(Page 9-9, Program Standards Manual)

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 is available that shows the results of the data collection from the jurisdiction's foodborne illness risk factor study.						
2. Report of Analysis and Outcome	b) The report provides quantitate measurements upon which to assess the trends in the occurrence of foodborne illness risk factors over time.						

Standard 9 – Program Assessment Step 2: Report of Analysis and Outcomes



(Page 9-2, Program Standards Manual)

Data Analysis

An analysis is made of the data collection and a report on the outcomes conclusion of the Study is written

Quantitative measurement upon which to assess trends in the occurrence of foodborne illness risk factors

Standard 9 – Program Assessment



(Page 9-2 and 9-3, Program Standards Manual)

Foodborne Illness Risk Factor Study and report within 60 months of enrollment

Updated <u>at least once every 5 years</u>

Standard 9 – Program Assessment Step 3: Intervention Strategy



(Page 9-10, Program Standards Manual)

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. Intervention Strategy	a) A targeted intervention strategy designed to address the occurrence of the risk factor(s) identified in their risk factor study is implemented and the effectiveness of such strategy is evaluated by subsequent risk factor studies.						
3. Intervention Strategy	b) Documentation is provided of performed interventions, action, or activities designed to improve control of foodborne illness risk factors.						

Standard 9 – Program Assessment Step 3: Intervention Strategy



(Page 9-3, Program Standards Manual)

Implement targeted intervention strategy that is based on data analysis.

Standard 9 – Program Assessment Verification Audit Results



(Page 9-8 thru 9-9, Program Standards Manual)

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 type regulated by the jurisdiction collected over the study cycle.	×			×		
1. Risk Factor Study	b) The data collection form includes items pertaining to the following Center for Disease Control and Prevention (CDC) identified contributing factors to foodborne illness. 1. Food from Unsafe Sources; 2. Improper Holding/Time and Temperature; 3. Inadequate Cooking; 4. Poor Personal Hygiene; and 5. Contaminated equipment / Protection from contamination.	×			×		
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).	X			X		



Participant Manual

Standard 9 Question 1

www.fda.gov





(Page 9-2, Program Standards Manual)

- 1. Foodborne Illness Risk Factor Study
- 2. Risk Factor Study Report and Analysis
- 3. Intervention Strategy



Participant Manual

Standard 9 Question 2

www.fda.gov





(Page 9-3, Program Standards Manual)

Facility Types (2016 Conference for Food Protection)

- Health Care
- Schools (K-12)
- Restaurants
- Retail Food Stores



Participant Manual

Standard 9 Question 3

www.fda.gov





(Page 9-3, Program Standards Manual)

Data Collection Form / Inspection Form — Captures Actual Observations

- IN Compliance
- OUT of Compliance
- N.O. Not Observed
- N.A. Not Applicable



Participant Manual

Standard 9 Question 4

www.fda.gov

Standard 9 – Program Assessment Step 1a: Inclusion of Facility Types



(Clearinghouse Std. 9 Question 1, pg. 111)

Standard 9 was changed based on the 2004 CFP recommendation so that a risk factor study need only be completed once every five years. In later revisions it was clarified that surveys of the various facility types can be conducted independently over the 5-year evaluation period as long as all the facility types under the jurisdiction's authority are surveyed within the recurring survey cycle. The Standard was also revised to allow regular inspection data to be used in determining the occurrence of the risk factors most in need of priority attention.

FDA currently has four industry segments that include the following facility types: Health Care (hospitals, long-term care facilities), Schools (K-12), Restaurants, Retail Food Stores (must have a deli operation). Jurisdictions must include in their study, all establishments that fall under the four industry segments for which they have regulatory oversight.



Standard 9 – Resources

Contact your Specialist. We can help!

- Discuss your goals and how they drive your study
- Discuss study design options
- Talk about sample size considerations
- Develop collection schedule
- Think about data collection policies
- Provide training
- Sample collection forms and marking instructions
- Get you access to the Retail Risk Factor Study Database

STANDARD 9 SELF-ASSESSMENT OR VERIFICATION AUDIT PROCESS QUESTIONS





Standard 4 Uniform Inspection Program

Preparing for the Self-Assessment or Verification Audit

Conducting the Standard 4 Self-Assessment



Source Documents

- Copy of Program Standard 4
- Clearinghouse Interpretations
- Table 4-2 and Table 4-3. If necessary, Table 4-1 of the Standard 4: Self-Assessment Worksheet
- The written quality assurance plan
- Schedule or list of field and file reviews
- Documents showing that the reviews occurred at the scheduled frequencies
- Analysis results/outcome reports of element review
- Descriptions of proposed follow-up actions
- Follow-up actions taken based on review

Preparing for the Standard 4 Self-Assessment



Forms and Worksheets

http://www.fda.gov/retailprogramstandards

Voluntary National Retail Food Regulatory Program Standards -August 2022



Standard 4: Uniform Inspection Program

- Standard 4 (PDF 67KB)
- Standard 4 Self-Assessment and Verification Audit Form (PDF 765KB)
- Standard 4 Self-Assessment Instructions and Worksheet (PDF 1.4MB)



Standard 4 Uniform Inspection Program

Conducting the Self-Assessment or Verification Audit



Standard 4 - Uniform Inspection Program

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



Standard 4 - Uniform Inspection Program Three Core Requirements

(Pages 4-2 thru 4-4, Standards Manual)

- Written Quality Assurance Program Document including corrective actions for deficiencies
- Twenty Quality Assurance Inspection Program Elements
- Demonstration of Program Effectiveness that the program achieves a 75 percent performance rating on each element using the appropriate Standard 4 self-assessment procedure and table

Standard 4 – Uniform Inspection Program Step 1: Written Quality Assurance Program Document



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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 periodically conducts an analysis of the results of the quality assurance program to identify quality or consistency problems among the staff in the twenty quality elements.						
1. Written Quality Assurance Program Document	c. The jurisdiction's written quality assurance program describes corrective actions to address an individual retail food program inspector's performance quality or consistency issues when they are identified.						

Standard 4 – Uniform Inspection Program Step 1a: Written Quality Assurance Program Document

- Written Quality Assurance Plan must:
 - Cover ALL retail food program inspection staff
 - Specialized Staff members who do not conduct operational inspections, (i.e., staff assigned to Plan Reviews) are not required to be covered under the QA process.

Standard 4 – Uniform Inspection Program Step 1b: Source Information Documents



- Documentation of jurisdiction review of performance levels of staff on a regular or defined schedule
 - Frequency/Review method left to jurisdiction's discretion
 - Schedule of the review process should be included in the written program
 - If no frequency schedule, alternate method must demonstrate that the program is on-going
 - Generation of reports that identify necessary follow-up and corrective actions

Standard 4 – Uniform Inspection Program Step 1c: Corrective Actions to Address



- The written program must include, in general terms, what kinds of corrective actions will be taken when performance quality or consistency issues are identified
 - Group or individual training
 - Develop/Implement Standard Operating Procedures
 - Issuance of Policy Memoranda
 - Performance Improvement Plans



(Pages 4-8 thru 4-13, Standards Manual)

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	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.						



- 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 support 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 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

- 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; OUT; Not Observed; or Not Applicable).



- 8. Obtains corrective actions for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies.
- 9. 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



- 10. 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.
- 11. Conducts an exit interview that explains the out-of-compliance observations, corrective actions, and time frames for correction, in accordance with jurisdiction's policies.



- 12. Provides the inspection report and, when necessary, cross-referenced document, to the person in charge or permit holder, in accordance with 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.



- 15. Documents the compliance status of each risk factor and intervention (IN, OUT, NO, NA).
- 16. Cites the proper code provisions for risk factors and Food Code interventions in accordance with jurisdiction's policies.
- 17. Documents corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies.



- 18. Documents that options for the long-term control of risk factors were discussed with establishment manager when the same out-of-control risk factor occurs on consecutive inspections.
- 19. Compliance or regulatory documents are accurately completed, appropriately cross-referenced with inspection report, and included with the inspection report.
- 20. Files reports and other documentation in a timely manner, in accordance with jurisdiction's policies.

Standard 4 – Uniform Inspection Program Step 3: Demonstration of Program Effectiveness



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.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.						

Standard 4 – Uniform Inspection Program Description of Performance Requirements



(Pages 4-15 thru 4-16, Standards Manual)

- Evaluation of each inspector is used to obtain an overall program performance measure
 - Assess each inspector's work during a minimum of 3 joint on-site inspections, with corresponding file review, during every SA period
 - Determine overall program performance using the appropriate statistical procedure in the Standard 4 Worksheets



Standard 4 – Uniform Inspection Program Use of Tables and Evaluation Methods

(Pages 4-15 thru 4-20, Standards Manual)

- Tables & methods provide a statistical sampling to measure the overall effectiveness of the QA program
- Two procedures for determining compliance
 - Jurisdictions with less than 10 inspectors
 (Table 4-1 and Chart 4-1)
 - Jurisdictions with 10 or more inspectors (Table 4-2)

Standard 4 – Uniform Inspection Program Ten or More Inspectors – Use Table 4-2



	Tabl	e 4-2: (Calculati	on	of L	Jnif	orn	nity	for	Jur	isdi	ctic	ns	witl	h Te	n o	r M	ore	Ins	pec	tor	s	
NI-	Inspector	D-4-	Establishment	Item																			
No.	ID	Date	ID	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)	(19)	(20)
1	044	1/8/21	3456	Х	Х	Х	X	Χ	Х	Χ	Х	Χ	X	X	Х	Х	Χ	Х	Χ	X	Х	X	X
2	044	1/8/21	7890	Х		Х	X	Χ	Х	Χ	Х	Х	X	X	X	Х	Χ	Х	Χ	X	Х	X	Х
3	044	1/8/21	1234	X	X	X	X	Χ	Х	Χ	Х	X	X	X	X	Х	Χ	Х	X	X	Х	X	X
4	171	2/3/21	5678	X	X	X	X	Х	Х	Χ	Х	X	X	X	X	Х	Χ	Х	X	X	Х	X	X
5	171	2/3/21	9012	X	X	X	X	Χ	Х	Χ	X		Х	X	X	Х	X	X	Χ	X	X	X	X
6	171	2/3/21	4567	X	Х	Χ	X	Χ	X	Χ	X	Х	Х	X	X	Χ	Χ	X	X	X	X	X	X
7	124	3/11/21	8901	X	X	X	X	Х			X		Х	X	X		X		X			X	X
8	124	3/11/21	2345	X	X		Х	Х		Χ	Х		Х	X	X	Х	X	Х	X	X	Х	X	X
9	124	3/11/21	6789	Х		Х	X	Χ			Х	Х	X	X	Х	Х	Χ		Х	Х		X	X
10	800	4/20/21	0123	Х		Х	X	Х	Χ		Χ		Х	Χ	Χ	Χ	Χ		Х	Χ		X	Х
11	800	4/20/21	0987	Х	Х	Х	X			Χ	Х		Х	X	Х	Х	Χ	Х	X	X	Х	X	X
12	800	4/20/21	6543	Х	X	X	X	Х	Х	Χ	Х	X	X	X	Х	Х	Χ	Х	X	X	Х	X	Х
13	435	5/26/21	2109	Х	Х	Х	Х	Х	Х	Х	Х	Х	X	X	Х	Х	Х	Х	Х	Х		X	Х
14	435	5/26/21	8765	Х	Х	Х	Х	Х	Х	Χ	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
15	435	5/26/21	4321	Х	Х	Х	Х	Х	Х	Х	Х	Х	X	X	Х	Х	Х	Х	Х	Х	Х	Х	Х
16	267	6/1/21	2468	Х	Х		Х			Х			Х	Х	Х	Х			Х	Х			Х
17	267	6/1/21	0246	Х	Х	Х	Х	Х			Х		Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
18	267	6/1/21	8024	Х		Х	Х	Х			Х	Х	Х	X	Х	Х	Х	Х	Х		Х	Х	Х
19	666	7/19/21	6802	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х		Х	Х	Х
20	666	7/19/21	4680	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
21	666	7/19/21	1357	Х	Х	Х	Х		Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
22	912	8/23/21	9135	Х		Х	Х	Х	Х	Х	Х		Х	Х	Х	Х		Х	Х	Х	Х	Х	Х
23	912	8/23/21	7913	Х		Х	Х	Х			Х	Х	Х	Х	Х	Х	Х		Х	Х	Х	Х	Х
24	912	8/23/21	5791	Х	Х	Х	Х	Х		Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
25	347	9/21/21	1470	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х			Х	Х
26	347	9/21/21	2581	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
27	347	9/21/21	3692	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
28	998	10/7/21	0111	Х	Х		Х	Х		Х			Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
29	998	10/7/21	2333	Х	Х	Х	Х		Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
30	998	10/7/21	4747	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	X	Х	Х	Х	Х	X	Х	Х	Х	Х



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Standard 4 – Uniform Inspection Program Ten or more inspectors – Table 4-3 Calculation



(Pages 4-15 thru 4-19, Standards Manual)

- Summary of Table 4-3 Calculation
 - Fill in check mark for each item in compliance for 3 inspections for each inspector
 - Total the number of check marks in each column
 - Divide by the total possible checks for the column and multiplied by 100
 - Must achieve 75% for each column

Standard 4 – Uniform Inspection Program Ten or More Inspectors – Use Table 4-2



	Tabl	e 4-2: (Calculati	on	of L	Jnif	orn	nity	for	Jur	isdi	ictic	ons	wit	h Te	n o	r M	ore	Ins	pec	tor	s	
Na	Inspector	Data	Establishment	Item	Item	Item	Item	Item	Item	Item	Item	Item	Item	Item	Item								
No.	ID	Date	ID	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)	(19)	(20)
1	044	1/8/21	3456	X	Х	X	X	X	X	Х	X	X	X	X	Χ	X	X	Χ	Χ	X	X	X	X
2	044	1/8/21	7890	Х		Х	X	Χ	X	Х	X	X	X	Χ	Χ	Х	X	Χ	Χ	Х	X	X	X
3	044	1/8/21	1234	Х	X	X	X	X	X	X	X	X	X	Х	X	Х	X	X	X	X	X	X	X
4	171	2/3/21	5678	X	X	X	X	X	X	X	X	X	Х	X	X	X	X	X	X	X	X	X	X
5	171	2/3/21	9012	X	X	X	X	X	Χ	X	X		Х	X	X	X	X	Χ	X	X	X	X	X
6	171	2/3/21	4567	Х	X	X	X	X	X	X	X	X	X	Х	X	Х	X	X	X	Х	X	X	X
7	124	3/11/21	8901	X	X	X	X	X			Х		Х	X	X		Х		Х			Х	X
8	124	3/11/21	2345	X	X		Х	X		X	X		Х	X	X	X	X	X	X	X	X	X	X
9	124	3/11/21	6789	Х		Х	X	X			Х	X	X	Х	X	Х	X		Х	X		Х	X
10	800	4/20/21	0123	X		Х	X	X	X		Х		Х	X	X	Х	X		Х	X		Х	X
11	800	4/20/21	0987	X	X	X	X			X	X		Х	X	X	X	X	X	X	X	X	X	X
12	800	4/20/21	6543	Х	X	X	X	Χ	X	X	X	X	X	Х	X	Х	X	X	Х	Х	X	X	X
13	435	5/26/21	2109	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		Х	X
14	435	5/26/21	8765	Х	X	X	X	X	X	X	X	X	X	Х	X	X	X	X	Х	X	X	X	X
15	435	5/26/21	4321	Х	X	X	X	Х	X	X	X	X	X	Χ	X	Х	Х	X	Х	Х	X	X	X
16	267	6/1/21	2468	Х	Х		Х			Х			Х	Х	Х	Х			Х	Х			Х
17	267	6/1/21	0246	Х	Х	X	X	X			Х		Х	Х	X	Х	X	X	X	Х	X	X	X
18	267	6/1/21	8024	Х		Х	X	Χ			Х	X	Х	Х	Х	Х	Х	Χ	Х		Х	X	X
19	666	7/19/21	6802	Х	Х	Х	X	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Χ	Х		Х	X	X
20	666	7/19/21	4680	Х	Х	X	X	X	X	X	X	X	X	Х	Х	Х	X	X	Х	Х	X	X	X
21	666	7/19/21	1357	Х	Х	Х	X		Х	Х	Х	Χ	X	Х	Х	Х	X	Χ	Х	Х	Х	X	X
22	912	8/23/21	9135	Х		Х	Х	Х	Х	Х	Х		Х	Х	Х	Х		Χ	Х	Х	Х	X	X
23	912	8/23/21	7913	Х		Х	X	X			Х	X	X	Х	Х	Х	X		Х	Х	X	X	X
24	912	8/23/21	5791	X	X	X	X	X		Χ	X	Х	Х	X	X	Х	X	X	X	X	Х	X	X
25	347	9/21/21	1470	Х	Х	Х	X	X	X	Х	X	Х	Х	Х	Х	Х	X	Х	Х			Х	X
26	347	9/21/21	2581	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
27	347	9/21/21	3692	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	X	X
28	998	10/7/21	0111	Х	Х		Х	X		Х			Х	X	Х	X	X	Х	Х	Х	Х	X	X
29	998	10/7/21	2333	Х	Х	Х	Х		Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	X	X
30	998	10/7/21	4747	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	X	X



Standard 4 – Uniform Inspection Program Ten or More Inspectors – Use Table 4-3

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)
Number of Check Marks from Table 4-2	30	24	27	30	26	20	24	28	21	30	30	30	29	28	25	30	26	24	29	30
2. Number of Inspections Reviewed in Table 4-2	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
3. % IN Compliance (Row 1÷ Row 2)	100%	80%	90%	100%	87%	67%	80%	93%	70%	100%	100%	100%	97%	93%	83%	100%	87%	80%	97%	100%





(Pages 4-18, Standards Manual)

Key points to remember

- 3 inspectors or less, use a minimum of 12 inspections.
- 4 to 9 inspectors, use three inspections each.
- Total "in compliance" checks for all items.
- Determine the number of possible check marks based on the number of inspections used (20 items X the no. of inspections).
- Determine if Standard 4 criteria is met from Chart 4-1.



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(Chart 4-1 is on Next Slide)

Standard 4 – Uniform Inspection Program Less Than 10 Inspectors – Chart 4-1



(Page 4-17, Standards Manual)

Chart 4-1

Method of Calculation for Jurisdictions with Less Than Ten Inspectors

# of inspectors	# <u>inspections</u> needed	# <u>of</u> 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:

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

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



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Standard 4 – Uniform Inspection Program Less Than 10 Inspector Calculation Exercise



No.	Inspector	Date	Establishment ID	Item		Item	Item	Item	Item (6)	Item	Item (10)	Item											
_	ID	. /- /		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)	(19)	(20)
1	044	1/8/21	3456	Х	Х	Х	Х	Х	X	Х	Х	Х	Х	Х	Х	Х	Х	Х	X	Х	Х	X	X
2	044	1/8/21	7890	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
3	044	1/8/21	1234	X	Х	X	Х	X	X	Χ	X	Χ	Χ	X	Χ	Χ	Х	Х	X	Х	X	X	X
4	171	2/3/21	5678	X	Х	X	Х	X	X	X	X	X	X	X	X	X	Х	Х	X	Х	X	X	X
5	171	2/3/21	9012	Х	Х	X	Х	X	X	X	Х		Χ	Х	Χ	Χ	Х	Х	X	Х	Х	X	X
6	171	2/3/21	4567	X	Х	X	Х	X	X	X	X	X	Χ	X	Χ	Χ	Х	Х	X	Х	X	X	X
7	124	3/11/21	8901	Х	X	X	Х	X			X		Χ	X	Χ		Х		Х			X	X
8	124	3/11/21	2345	X	Х		X	X		X	X		X	X	X	X	X	X	X	X	X	X	X
9	124	3/11/21	6789	Χ		Χ	X	Χ			X	X	Χ	Χ	X	X	X		Χ	X		Χ	X
10	800	4/20/21	0123	X		X	X	X	X		X		X	X	X	X	X		X	X		X	X
11	800	4/20/21	0987	X	Х	X	X			X	X		Х	X	Х	Х	X	X	X	X	X	X	X
12	800	4/20/21	6543	Χ	X	Χ	Χ	Χ	Χ	X	X	X	X	X	X	X	Χ	Χ	Χ	Χ	Χ	Χ	X
13	435	5/26/21	2109	X	Х	Х	Х	Х	X	X	Χ	X	Х	Χ	Х	Х	Х	Х	X	Х		Χ	X
14	435	5/26/21	8765	X	Х	X	Х	X	X	X	X	X	X	X	X	X	Х	Х	X	Х	X	X	X
15	435	5/26/21	4321	Χ	Х	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ	X
16	267	6/1/21	2468	X	X		X			X			Х	X	Х	Х			X	Х			X
17	267	6/1/21	0246	X	Х	X	Х	X			X		Х	Х	Х	Х	Х	Х	X	Х	X	Х	X
18	267	6/1/21	8024	X		Χ	X	X			X	X	X	X	X	X	X	X	X		X	Χ	X

Standard 4 – Uniform Inspection Program Answer – Less Than 10 Inspectors Exercise



(Page 4-18, Standards Manual)

Table 4-1

Calculation of Uniformity for Jurisdictions with Less Than Ten Inspectors

Period from _____01-01-2021_ to 06-01-2021

1. Number of inspectors in the jurisdiction	6
2. Number of inspections used in the calculation (minimum of 12)	18
3. Total number of items marked as correct during joint field visits and corresponding file reviews and recorded on Table 4-2.	318
4. Total number of possible items based on the number of inspections (20 items times the # of inspections – see Chart 4-1, column 3)	360
Determine conformance (YES or NO) using Chart 4-1, column 3	YES

Standard 4 – Uniform Inspection Program Self-Assessment Criteria



(Page 4-4, Standards Manual)

The quality control documentation need for this standard include:

- A written procedure that describes the jurisdiction quality assurance program that contains the 20 inspection program areas, including actions for deficiencies
- Program achieves a 75% performance rating on each of the inspection program areas, using the assessment procedure described in Standard 4

Conducting the Standard 4 Self-Assessment



Source Documents

- Copy of Program Standard 4
- Clearinghouse Interpretations
- Table 4-2 and Table 4-3. If necessary, Table 4-1 of the Standard 4: Self-Assessment Worksheet
- The written quality assurance plan
- Schedule or list of field and file reviews
- Documents showing that the reviews occurred at the scheduled frequencies
- Analysis results/outcome reports of element review
- Descriptions of proposed follow-up actions
- Follow-up actions taken based on review

Standard 4 – Uniform Inspection Program Verification Audit Results



(Pages 4-8 thru 4-14, Standards Manual)

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•	•		u	и.		•	•	-	m	•	_

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.	X			X		
1. Written Quality Assurance Program Document	b. The jurisdiction periodically conducts an analysis of the results of the quality assurance program to identify quality or consistency problems among the staff in the twenty quality elements.	Х			х		
1. Written Quality Assurance Program Document	c. The jurisdiction's written quality assurance program describes corrective actions to address an individual retail food program inspector's performance quality or consistency issues when they are identified.	X			Х		
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.	v			Х		
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.	Х			X		



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Standard 4 - Uniform Inspection Program Three Core Requirements

(Pages 4-2 thru 4-4, Standards Manual)

- Written Quality Assurance Program Document including corrective actions for deficiencies
- Twenty Quality Assurance Inspection Program Elements
- Demonstration of Program Effectiveness that the program achieves a 75 percent performance rating on each element using the appropriate Standard 4 self-assessment procedure and table



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STANDARD 4 SELF-ASSESSMENT OR VERIFICATION AUDIT PROCESS QUESTIONS





Standard 2 Trained Regulatory Staff

Preparing for the Self-Assessment



FDA

Source Documents

- Copy of Program Standard 2
- Clearinghouse Interpretations
- Listing of employees working in the retail food program and date of hire
- Records of course completion of the Standard 2 curriculum; transcripts; affidavits
- Copies of 25 joint field training inspections/independent inspections





Source Documents

- Documentation of completion of a field training process similar to that contained in Appendix B-2
- Standardization/Re-standardization certificates/letters
- Records of contact hours via database; certificates; attendance records; sign-in sheets

Preparing for the Standard 2 Self-Assessment



Forms and Worksheets

http://www.fda.gov/retailprogramstandards



Standard 2: Trained Regulatory Staff

- Standard 2 (PDF: 149KB)
- Standard 2 Self-Assessment and Verification Audit Form (PDF: 714KB)
- Standard 2 Self-Assessment Instructions and Worksheet (PDF: 674KB)
- Standard 2 Verification Audit Instructions and Worksheet (PDF: 710KB)
- Standard 2 Appendix B-1: Curriculum for Retail Food Safety Inspection Officers (PDF: 37KB)
- Standard 2 Appendix B-2: CFP Field Training Manual
- Standard 2 Appendix B-3: Establishment Categories (PDF: 1MB)



Standard 2 Trained Regulatory Staff

Preparing for the Self-Assessment

(Pages 2-11 thru 2-16, Program Standards Manual)



Standard 2 – Trained Regulatory Staff

The regulatory staff shall have the <u>knowledge</u>, <u>skills</u>, and ability to adequately perform their required duties.





(Page 2-2, Program Standards Manual)

- Step 1: Pre-Inspection Curriculum
- Step 2: Joint Field Training

 CFP Field Training Manual (Updated 2020 CFP)
- Step 3: Independent Inspections

 Completion of Curriculum (designated as "Post" courses)
- Step 4: Standardization
- Step 5: Continuing Education

Standard 2 – Trained Regulatory Staff Step 1: Employee Training Records



(Page 2-14, Program Standards Manual)

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.						





(Page 2-9 thru 2-10, Program Standards Manual)

- Maintenance of a written training record for each employee
- Documentation of completion of the Standard 2 pre-requisite curriculum prior to conducting independent inspections.

Standard 2 – Trained Regulatory Staff Step 1: Employee Training Records



(Page 2-19, Program Standards Manual)

(*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)	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)	Meets the Standard 2 Criteria YES or No
1	Billie Sims	9-21-1985	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 10-11-23	20	YES
2	Steven Owens	9-22-1995	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 12-22-23	0	YES
3	Jamie Holloway	3-6-2015	6-15-15	7-2-15	8-1-15	Re-Standardized 3-17-22	20	YES
4	Sue Scooner	11-1-2016	12-22-16	12-31-16	3-11-17	Re-Standardized 4-21-23	32	YES
5	Richard Bryan	10-22-2021	2-6-22	3-12-22	4-17-22	Standardized 1-5-23	0	YES
6	Jackson Clayton	8-8-2010	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Re-Standardized 9-21-22	20	YES
7	Joseph Pruitt	7-5-2021	11-1-21	1-12-22	8-5-22	Standardized 1-2-23	36	YES
8	Greg Washington	4-25-2017	9-26-17	10-27-17	12-3-17	Re-Standardized 9-12-23	20	YES
9	Madison Hall	4-25-2022	8-1-22	10-20-22	4-29-23	Standardized 6-24-23	24	YES
10	Joseph Rockdale	5-1-2019	10-25-19	11-11-19	12-15-19	Standardized 10-1-20	8	NO

^{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





(Pages 2-3 thru 2-4, Program Standards Manual)

Knowledge Assessment **OPTIONS**

- 1. FDA's ORA-U course/exam module, or
 - 2. Equivalent Curriculum





(Pages 2-26 thru 2-27, Appendix B-1, Program Standards Manual)

PUBLIC HEALTH PRINCIPLES

Courses	Course Number
1-Public Health Principles	FDA36 (90)

MICROBIOLOGY

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





(Pages 2-26 thru 2-27, Appendix B-1, Program Standards Manual)

PREVAILING STATUTES, REGULATIONS, ORDINANCES

THE VIEW OF STATE OF					
Courses	Course Number				
1. Basic Food Law for State Regulators	FDA35 (60)				
2. Basics of Inspection: Beginning an Inspection	FDA38 (90)				
3. Basics of Inspection: Issues & Observations	FDA39 (90)				
4. An Introduction to Food Security Awareness	FD251 (60) A PDF/READABLE VERSION at (https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/introduction-food-security-awareness) Note: Required exam is available via www.compliancewire.com.				
5. 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

Courses	Course Number
1. Communication Skills	CC8030W NOTE : Course must be accessed through LearnEd at: https://fdaoted.csod.com/





(Pages 2-3 thru 2-4, Program Standards Manual)

Equivalent Curriculum (determined by the jurisdiction)

 Course has at least 80% of the learning objectives covered in the corresponding ORA U web course,

AND

 Successful completion of a written examination (determines basic food safety knowledge). The Standard provides multiple examination options.

Standard 2 – Trained Regulatory Staff Step 1: Pre-Curriculum



(Pages 2-3 thru 2-4, Program Standards Manual)

(*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)	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)	Meets the Standard 2 Criteria YES or No
1	Billie Sims	9-21-1985	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 10-11-23	20	YES
2	Steven Owens	9-22-1995	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 12-22-23	0	YES
3	Jamie Holloway	3-6-2015	6-15-15	7-2-15	8-1-15	Re-Standardized 3-17-22	20	YES
4	Sue Scooner	11-1-2016	12-22-16	12-31-16	3-11-17	Re-Standardized 4-21-23	32	YES
5	Richard Bryan	10-22-2021	2-6-22	3-12-22	4-17-22	Standardized 1-5-23	0	YES
6	Jackson Clayton	8-8-2010	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Re-Standardized 9-21-22	20	YES
7	Joseph Pruitt	7-5-2021	11-1-21	1-12-22	8-5-22	Standardized 1-2-23	36	YES
8	Greg Washington	4-25-2017	9-26-17	10-27-17	12-3-17	Re-Standardized 9-12-23	20	YES
9	Madison Hall	4-25-2022	8-1-22	10-20-22	4-29-23	Standardized 6-24-23	24	YES
10	Joseph Rockdale	5-1-2019	10-25-19	11-11-19	12-15-19	Standardized 10-1-20	8	NO

^{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

Standard 2 – Trained Regulatory Staff Step 1: Pre-Curriculum



(Pages 2-3 thru 2-4, Program Standards Manual)

If you cannot find training records for experienced employees, have them take courses again, or ...

- If trained at your jurisdiction-
 - Find the records you can.
 - Employee can provide affidavit that they completed the training- This is NOT a waiver- it's another way to document training completion.
- If trained by a former employer-
 - Follow above process

Must document training on jurisdiction's rules/statutes

Standard 2 – Trained Regulatory Staff Step 2: Initial Field Training



(Pages 2-14 thru 2-15, Program Standards Manual)

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	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.						
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.						





(Page 2-4 thru 2-5, Program Standards Manual)

- Written documentation that employees completed a minimum of 25 joint field training inspections, OR written documentation that employees demonstrated all required inspection competencies
- Written documentation that employees successfully completed a field training process (similar to that contained in the CFP Field Training Manual)

Standard 2 – Trained Regulatory Staff CFP Model Training Plan



Conference for Food Protection (CFP) Field Training Manual for Regulatory Retail Food Safety and Inspection Officers (2020 CFP Update) | Conference-Developed Guides and Documents | Conference for Food Protection

Provides a structured approach for:

- Identifying the training content,
- Determining training methods, and
- Tracking the FSIO's progress in demonstrating performance elements and competencies specific to their job

Incorporates a variety of training methods



Standard 2 – Trained Regulatory Staff Creating a Training Plan using the CFP Field Training Manual (optional)

The manual covers four elements when developing a training plan for FSIOs:

- Determine the performance elements to be included in the training plan
- Determine the competencies for each selected performance element
- Determine need for additional performance elements and competencies
- Determine the appropriate training method for each competency



Standard 2 – Trained Regulatory Staff CFP Field Training PlanSix Inspection Training Areas

- 1. Pre-Inspection
- 2. Inspection observations and performance
- 3. Oral communication
- 4. Written communication
- 5. Professionalism
- 6. Additional inspection areas (jurisdictions can add performance elements and competencies not contained in the CFP Training Plan and Log)

Standard 2 – Trained Regulatory Staff CFP Field Training Plan and Log Coversheet



Conference for Food Protection TRAINING PLAN and LOG

Retail Food, Restaurant, and Institutional Foodservice Food Safety Inspection Officer

NOTE: The CFP Field Training Manual for Regulatory Retail Food Safety Inspection Officers (FSIOs) should be reviewed prior to using the CFP Training Plan and Log. The manual provides jurisdictions with information that will be helpful in customizing a FSIO training plan and implementing a training process that meets the specific needs of the jurisdiction.

Food Safety Inspection Officer's (FSIO) Name: Richard Bryan	Start Date of the Training Process: 10-22-18
Food Safety Inspection Officer's (FSIO) Agency: Kings County Health Department	,
Trainer's Name (if multiple trainers list all): Johnny Blanchard	Trainer's Agency: Kings County Health Department
2. Whitey Ford	Kings County Health Department
2.	
•	
•	ed all curriculum and field training elements and tail food and/or foodservice inspections
Completion Date of Pre-requisite Coursework: 2-6-19 OPTION 1: X or	OPTION 2:
Completion Date - (Performance Elements & Competencies): 3-12-1	9
Food Safety Inspection Officer's (FSIO) Signature: Richard Bryan	Trainer's or Food Program Manager's Signature: Unkery Blankard Whitey Ford

The CFP Field Training Manual for Regulatory Retail Food Safety Inspection Officers includes two components. One includes completion of pre-requisite coursework outlined in Program Standard 2 – Trained Regulatory Staff, FDA Draft Voluntary National Retail Food Regulatory Program Standards. The second component focuses on the FSIO's ability to demonstrate performance element competencies that are needed to conduct effective regulatory food safety inspections. A FSIO should successfully complete both components prior to conducting independent inspections.

PRE-REQUISITE COURSEWORK

The CFP Field Training Manual outlines the courses included in the pre-requisite curriculum and provides options for completing this component of the CFP training process. A jurisdiction can begin the field training process with FSIOs while they are still in the process of completing their pre-requisite coursework. The jurisdiction's trainers and/or food program managers are given the discretion to determine the appropriate time frame within which FSIOs are to complete pre-requisite course work during the field training process.

Standard 2 – Trained Regulatory Staff Step 2: Initial Field Training



(Pages 2-4 thru 2-5, Program Standards Manual)

(*indicates completion date required)

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)	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)	Meets the Standard 2 Criteria YES or No
Billie Sims	9-21-1985	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 10-11-23	20	YES
Steven Owens	9-22-1995	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 12-22-23	0	YES
Jamie Holloway	3-6-2015	6-15-15	7-2-15	8-1-15	Re-Standardized 3-17-22	20	YES
Sue Scooner	11-1-2016	12-22-16	12-31-16	3-11-17	Re-Standardized 4-21-23	32	YES
Richard Bryan	10-22-2021	2-6-22	3-12-22	4-17-22	Standardized 1-5-23	0	YES
Jackson Clayton	8-8-2010	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Re-Standardized 9-21-22	20	YES
Joseph Pruitt	7-5-2021	11-1-21	1-12-22	8-5-22	Standardized 1-2-23	36	YES
Greg Washington	4-25-2017	9-26-17	10-27-17	12-3-17	Re-Standardized 9-12-23	20	YES
Madison Hall	4-25-2022	8-1-22	10-20-22	4-29-23	Standardized 6-24-23	24	YES
Joseph Rockdale	5-1-2019	10-25-19	11-11-19	12-15-19	Standardized 10-1-20	8	NO
	Billie Sims Steven Owens Jamie Holloway Sue Scooner Richard Bryan Jackson Clayton Joseph Pruitt Greg Washington Madison Hall	Employee Name Assignment to the Retail Food Program Billie Sims 9-21-1985 Steven Owens 9-22-1995 Jamie Holloway 3-6-2015 Sue Scooner 11-1-2016 Richard Bryan 10-22-2021 Jackson Clayton 8-8-2010 Joseph Pruitt 7-5-2021 Greg Washington 4-25-2017 Madison Hall 4-25-2022	Employee Name Passignment to the Retail Food Program Billie Sims 9-21-1985 Previous coursework meets the standard Previous coursework meets the standard Jamie Holloway 3-6-2015 Sue Scooner 11-1-2016 Richard Bryan 10-22-2021 Jackson Clayton 8-8-2010 Previous coursework meets the standard 10-22-2021 2-6-22 Previous coursework meets the standard 11-1-2016 12-22-16 Richard Bryan 10-22-2021 11-1-21 Greg Washington 4-25-2021 Madison Hall 4-25-2022 8-1-22	Employee Name Date of Hire or Assignment to the Retail Food Program Successful completion of Training Prerequisite ("Pre") Curriculum* (Prior to conducting independent inspections) Successful completion of a field training Inspections* Successful completion of a field training Manual in Appendix B-2	Date of Hire or Assignment to the Retail Food Program Program Previous coursework meets the standard Previous coursework meets meet	Employee Name Program Program	Employee Name Part Previous coursework meets the standard Previous cou

^{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

Standard 2 – Trained Regulatory Staff Step 2: Initial Field Training



(Pages 2-4 thru 2-5, Program Standards Manual)

Documentation that employees completed at least 25 joint field training inspections, OR documentation that employees demonstrated required inspection competencies with fewer than 25.

- Mix of trainer and trainee led
- Risk Category 2, 3, 4
- Trainer is someone who has completed Steps 1-3
- Experienced staff or experienced new hires-
 - Supervisor can provide written statement or affidavit waiving joint inspections based on background and experience

Standard 2 – Trained Regulatory Staff Step 3: Independent Inspections/Post Curriculum

(Page 2-15, Program Standards Manual)

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. 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.						

Standard 2 – Trained Regulatory Staff Step 3: Independent Inspection/ Post Curriculum

(Page 2-6, Program Standards Manual)

Within 24 months of hire or assignment to the retail food protection program, the employee is to complete:

A minimum of 25 independent inspections

AND

 The "Post" curriculum coursework outlined in Appendix B-1

Standard 2 – Trained Regulatory Staff Step 3: Independent Inspection/ Post Curriculum

(Pages 2-27 thru 2-28, Appendix B-1, Program Standards Manual)

MICROBIOLOGY

Courses	Course Number
7C-Control by Retorting	MIC10 (90)
8-Technology-Based Food Processes	MIC11 (120)
9-Natural Toxins	MIC12 (90)

HACCP

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

ALLERGEN MANAGEMENT

Courses	Course Number
1. Allergens	CC8029W Course must be accessed through LearnEd at: https://fdaoted.csod.com/

Standard 2 – Trained Regulatory Staff Step 3: Independent Insp/ Post Curriculum (cont.)

(Pages 2-27 thru 2-28, Appendix B-1, Program Standards Manual)

EPIDEMIOLOGY

Courses	Course Number				
Collecting Surveillance Data	FI01 (90)				
2. Beginning the Investigation	FI02 (90)				
3. Expanding the Investigation	FI03 (90)				
4. Conducting a Food Hazard Review	FI04 (90)				
5. Epidemiological Statistics	FI05 (90)				
6. Final Report	FI06 (30)				

EMERGENCY MANAGEMENT – FEMA

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

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

Standard 2 – Trained Regulatory Staff Step 4: Field Standardization



(Page 2-16, Program Standards Manual)

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 each standardized employee has maintained their standardization by performing a minimum of 4 joint inspections with a "training standard" every 3 years.						





(Pages 2-7 thru 2-8, Program Standards Manual)

Written documentation that each employee has:

- Successfully completed a minimum of 4 joint inspections with a training standard using a process similar to the FDA Standardization procedure
- Successfully maintained their standardization status by completing a minimum of 4 joint inspections with a training standard using a process similar to the FDA Standardization procedure every 3 years

Standard 2 – Trained Regulatory Staff Step 4: Field Standardization



(Pages 2-7 thru 2-8, Program Standards Manual)

(*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)	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)	Meets the Standard 2 Criteria YES or No
1	Billie Sims	9-21-1985	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 10-11-23	20	YES
2	Steven Owens	9-22-1995	Previous coursework meets the standard	Waived, completed previous field training, records on file	Records on file:>500 independent inspections	Standardized 12-22-23	0	YES
3	Jamie Holloway	3-6-2015	6-15-15	7-2-15	8-1-15	Re-Standardized 3-17-22	20	YES
4	Sue Scooner	11-1-2016	12-22-16	12-31-16	3-11-17	Re-Standardized 4-21-23	32	YES
5	Richard Bryan	10-22-2021	2-6-22	3-12-22	4-17-22	Standardized 1-5-23	0	YES
6	Jackson Clayton	8-8-2010	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Re-Standardized 9-21-22	20	YES
7	Joseph Pruitt	7-5-2021	11-1-21	1-12-22	8-5-22	Standardized 1-2-23	36	YES
8	Greg Washington	4-25-2017	9-26-17	10-27-17	12-3-17	Re-Standardized 9-12-23	20	YES
9	Madison Hall	4-25-2022	8-1-22	10-20-22	4-29-23	Standardized 6-24-23	24	YES
10	Joseph Rockdale	5-1-2019	10-25-19	11-11-19	12-15-19	Standardized 10-1-20	8	NO

^{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

Standard 2 – Trained Regulatory Staff Step 5: Continuing Education & Training



(Page 2-16, Program Standards Manual)

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 each employee conducting retail food and/or foodservice inspections has accumulated 20 hours of continuing education every 36 months after the initial training (24 months) is completed.						





(Page 2-8 thru 2-9, Program Standards Manual)

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

 Methods for obtaining CE hours are also provided in the Program Standards Manual





(Page 2-8 thru 2-9, Program Standards Manual)

(*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)	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)	Meets the Standard 2 Criteria YES or No
1	Billie Sims	9-21-1985	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 10-11-23	20	YES
2	Steven Owens	9-22-1995	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 12-22-23	0	YES
3	Jamie Holloway	3-6-2015	6-15-15	7-2-15	8-1-15	Re-Standardized 3-17-22	20	YES
4	Sue Scooner	11-1-2016	12-22-16	12-31-16	3-11-17	Re-Standardized 4-21-23	32	YES
5	Richard Bryan	10-22-2021	2-6-22	3-12-22	4-17-22	Standardized 1-5-23	0	YES
6	Jackson Clayton	8-8-2010	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Re-Standardized 9-21-22	20	YES
7	Joseph Pruitt	7-5-2021	11-1-21	1-12-22	8-5-22	Standardized 1-2-23	36	YES
8	Greg Washington	4-25-2017	9-26-17	10-27-17	12-3-17	Re-Standardized 9-12-23	20	YES
9	Madison Hall	4-25-2022	8-1-22	10-20-22	4-29-23	Standardized 6-24-23	24	YES
10	Joseph Rockdale	5-1-2019	10-25-19	11-11-19	12-15-19	Standardized 10-1-20	8	NO

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

Standard 2 – Trained Regulatory Staff Performance Criteria



(Page 2-2, Program Standards Manual)

Ninety percent (90%) of the regulatory retail food program inspection staff shall have successfully completed:

- Steps 1-4 within 24 months of hire or assignment to the retail food program
- Step 5 every 36 months after the initial 24 months of training

Standard 2 – Trained Regulatory Staff Performance Criteria



(Page 2-2, Program Standards Manual)

(*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	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)	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)	Meets the Standard 2 Criteria YES or No
1	Billie Sims	9-21-1985	Previous coursework meets the standard	Appendix B-2 Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 10-11-23	20	YES
2	Steven Owens	9-22-1995	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 12-22-23	0	YES
3	Jamie Holloway	3-6-2015	6-15-15	7-2-15	8-1-15	Re-Standardized 3-17-22	20	YES
4	Sue Scooner	11-1-2016	12-22-16	12-31-16	3-11-17	Re-Standardized 4-21-23	32	YES
5	Richard Bryan	10-22-2021	2-6-22	3-12-22	4-17-22	Standardized 1-5-23	0	YES
6	Jackson Clayton	8-8-2010	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Re-Standardized 9-21-22	20	YES
7	Joseph Pruitt	7-5-2021	11-1-21	1-12-22	8-5-22	Standardized 1-2-23	36	YES
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9	Madison Hall	4-25-2022	8-1-22	10-20-22	4-29-23	Standardized 6.24.23	24	YES
10	Joseph Rockdale	5-1-2019	10-25-19	11-11-19	12-15-19	Standardized 10-1-20	8	NO

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

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(Page 2-2, Program Standards Manual)

- Step 1: Pre-Inspection Curriculum
- Step 2: Joint Field Training

 CFP Field Training Manual (Updated 2020 CFP)
- Step 3: Independent Inspections

 Completion of Curriculum (designated as "Post" courses)
- Step 4: Standardization
- Step 5: Continuing Education



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Standard 2 – Trained Regulatory Staff Step 1: Pre-Curriculum



(Pages 2-3 thru 2-4, Program Standards Manual)

(*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)	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)	Meets the Standard 2 Criteria YES or No
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9	Madison Hall	4-25-2022	8-1-22	10-20-22	4-29-23	Standardized 6-24-23	24	YES
10	Joseph Rockdale	5-1-2019	10-25-19	11-11-19	12-15-19	Standardized 10-1-20	8	NO

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

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(Pages 2-3 thru 2-4, Program Standards Manual)

Knowledge Assessment **OPTIONS**

- FDA's ORA-U course/exam module, or
- 2. Equivalent Curriculum



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Standard 2 – Trained Regulatory Staff Step 2: Initial Field Training



(Pages 2-4 thru 2-5, Program Standards Manual)

(*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)	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)	Meets the Standard 2 Criteria YES or No
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8	Greg Washington	4-25-2017	9-26-17	10-27-17	12-3-17	Re-Standardized 9-12-23	20	YES
9	Madison Hall	4-25-2022	8-1-22	10-20-22	4-29-23	Standardized 6-24-23	24	YES
10	Joseph Rockdale	5-1-2019	10-25-19	11-11-19	12-15-19	Standardized 10-1-20	8	NO

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

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Standard 2 – Trained Regulatory Staff Step 4: Field Standardization



(Pages 2-7 thru 2-8, Program Standards Manual)

(*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)	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)	Meets the Standard 2 Criteria YES or No
1	Billie Sims	9-21-1985	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 10-11-23	20	YES
2	Steven Owens	9-22-1995	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 12-22-23	0	YES
3	Jamie Holloway	3-6-2015	6-15-15	7-2-15	8-1-15	Re-Standardized 3-17-22	20	YES
4	Sue Scooner	11-1-2016	12-22-16	12-31-16	3-11-17	Re-Standardized 4-21-23	32	YES
5	Richard Bryan	10-22-2021	2-6-22	3-12-22	4-17-22	Standardized 1-5-23	0	YES
6	Jackson Clayton	8-8-2010	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Re-Standardized 9-21-22	20	YES
7	Joseph Pruitt	7-5-2021	11-1-21	1-12-22	8-5-22	Standardized 1-2-23	36	YES
8	Greg Washington	4-25-2017	9-26-17	10-27-17	12-3-17	Re-Standardized 9-12-23	20	YES
9	Madison Hall	4-25-2022	8-1-22	10-20-22	4-29-23	Standardized 6-24-23	24	YES
10	Joseph Rockdale	5-1-2019	10-25-19	11-11-19	12-15-19	Standardized 10-1-20	8	NO

^{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



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Standard 2 – Trained Regulatory Staff Step 5: Continuing Education & Training



(Page 2-8 thru 2-9, Program Standards Manual)

(*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)	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)	Meets the Standard 2 Criteria YES or No
1	Billie Sims	9-21-1985	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 10-11-23	20	YES
2	Steven Owens	9-22-1995	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 12-22-23	0	YES
3	Jamie Holloway	3-6-2015	6-15-15	7-2-15	8-1-15	Re-Standardized 3-17-22	20	YES
4	Sue Scooner	11-1-2016	12-22-16	12-31-16	3-11-17	Re-Standardized 4-21-23	32	YES
5	Richard Bryan	10-22-2021	2-6-22	3-12-22	4-17-22	Standardized 1-5-23	0	YES
6	Jackson Clayton	8-8-2010	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Re-Standardized 9-21-22	20	YES
7	Joseph Pruitt	7-5-2021	11-1-21	1-12-22	8-5-22	Standardized 1-2-23	36	YES
8	Greg Washington	4-25-2017	9-26-17	10-27-17	12-3-17	Re-Standardized 9-12-23	20	YES
9	Madison Hall	4-25-2022	8-1-22	10-20-22	4-29-23	Standardized 6-24-23	24	YES
10	Joseph Rockdale	5-1-2019	10-25-19	11-11-19	12-15-19	Standardized 10-1-20	8	NO

^{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



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Standard 2 – Trained Regulatory Staff Performance Criteria



(Page 2-2, Program Standards Manual)

Ninety percent (90%) of the regulatory retail food program inspection staff shall have successfully completed:

- Steps 1-4 within 24 months of hire or assignment to the retail food program
- Step 5 every 36 months after the initial 24 months of training

STANDARD 2 SELF-ASSESSMENT PROCESS QUESTIONS





Standard 1 Regulatory Foundation

Preparing for the Self-Assessment



Preparing for the Standard 1 Self-Assessment

Source Documents

- Copy of Program Standard 1
- Clearinghouse Interpretations
- Jurisdiction's Regulations/Ordinance
- Written Policies or Interpretations that carry the same weight as prevailing rules and regulations
- Copy of the current version of the FDA Food Code http://www.fda.gov/FoodCode

Preparing for the Standard 1 Self-Assessment



Forms and Worksheets

http://www.fda.gov/retailprogramstandards



Standard 1: Regulatory Foundation

- Standard 1 (PDF: 90KB)
- Standard 1 Self-Assessment and Verification Audit Form (PDF: 776KB)
- Standard 1 Self-Assessment Instructions and Worksheet for Part I (PDF: 387KB)
- Standard 1 Self-Assessment Instructions and Worksheet for Part II (PDF: 1.1MB)
- Standard 1 Self-Assessment Instructions and Worksheet for Part III (PDF: 234KB)
- Standard 1 Verification Audit Instructions and Worksheet for Part I (PDF: 720KB)
- Standard 1 Verification Audit Instructions and Worksheet for Part II (PDF: 687KB)
- Standard 1 Verification Audit Instructions and Worksheet for Part III (PDF: 683KB)



Standard 1 Regulatory Foundation

Conducting the Self-Assessment



Standard 1 Regulatory Foundation

Regulatory foundation includes any statute, regulation, rule, ordinance, or other set of prevailing set of regulatory requirements.

Standard 1 – Regulatory Foundation [DA] Four Core Requirements



(Page 1-2, Standards Manual)

- 1. Assessment of the Program's Regulatory Foundation (side-by-side comparison of the Jurisdiction's Food Code to the FDA Food Code)
- 2. Food Code Interventions and Risk Factors
- 3. Good Retail Practices
- 4. Compliance and Enforcement

Standard 1 – Regulatory Foundation Step 1: Assessment of Program's Regulatory Foundation



(Page 1-7, Standards Manual)

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 that it has performed a side-by-side comparison of its prevailing statutes, regulations, rules, and other pertinent requirements against the current published edition of the FDA Food Code or one of the two most recent previous editions of the FDA Food Code.						
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.						

Standard 1 – Regulatory Foundation Step 1: Assessment of Program's Regulatory Foundation



(Pages 1-2 and 1-3, Standards Manual)

Jurisdiction has documentation of:

- Side-by-side comparison of its requirements against the FDA Food Code
- Side-by-side comparison includes provisions for:
 - Food Code Risk Factors & Interventions
 - Good Retail Practices
 - Compliance and Enforcement
- Identifies the jurisdiction's corresponding requirement to the applicable FDA Food Code Section

Standard 1 – Regulatory Foundation Part I Worksheet: Risk Factors and Intervention

http://www.fda.gov/retailprogramstandards



Standard 1: Regulatory Foundation

- Standard 1 (PDF: 90KB)
- Standard 1 Self-Assessment and Verification Audit Form (PDF: 776KB)
- Standard 1 Self-Assessment Instructions and Worksheet for Part I (PDF: 387KB)
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- Standard 1 Verification Audit Instructions and Worksheet for Part III (PDF: 683KB)



Standard 1 Part I Interventions and Risk Factors Self-Assessment



(Pages 1-7 and 1-8, Standards Manual)

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 Food Code assessment indicates that the agency's regulatory requirements contain at least 9 of the 11 FDA Food Code intervention and risk factor controls. By the third verification audit the jurisdiction's assessment indicates that the agency's regulatory requirements contain all 11 of the FDA Food Code intervention and risk factor controls. Part I - Self-Assessment Worksheet Part I - Verification Audit Worksheet						
2. Food Code Interventions and Risk Factors	b) The jurisdiction's Food Code assessment indicates that the agency has a corresponding requirement for ALL FDA Food Code provisions related to the interventions and risk factor controls. NOTE: Auditor's random selection of Food Code Intervention and Risk Factor Control Sections confirms the jurisdiction's assessment that a corresponding requirement is contained in the agency's rules, regulations, ordinances, code, or statutes.						

Standard 1 – Regulatory Foundation Part I Worksheet: Risk Factors and Interventions



(Pages 1-13 thru 1-24, Standards Manual)

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

SECTION 1 – DEMONSTRATION OF KNOWLEDGE

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 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				

Standard 1 – Regulatory Foundation Part I Worksheet: Risk Factors and Interventions



(Page 1-13 thru 1-14, Standards Manual)

SECTION 2 - EMPLOYEE HEALTH

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 Food Code section is NOT Met (Indicate the Situation)
5. 2-201.11 – Responsibility of Permit Holder, Person in Charge, and Conditional Employees		X		
6. 2-201.12 – Exclusions and Restrictions		X		
7. 2-201.13 – Removal, Adjustment, or Retention of Exclusions and Restrictions		X		
8. 2-501.11— Clean-up of Vomiting and Diarrheal Events		X		

Standard 1 – Regulatory Foundation Part I Worksheet: Risk Factors and Interventions



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(Pages 1-25, Standards Manual)

Standard 1: Regulatory Foundation Self-Assessment Worksheet

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

Food Code Section and Description	YES Standard Criteria Met	<u>NO</u> Standard Criteria Not Met	Self-Assessor's General Comments
1. Demonstration of Knowledge	X		
2. Employee Health	X		
3. Consumer Advisory		X	No consumer advisory provision
4. Approved Sources	X		
5. Time/Temperature	X		
6. Protection from Contamination	X		
7. Control of Hands as a Vehicle of Contamination		X	Code allows for minimal bare hand contact with RTE food
8. Good Hygienic Practices	X		
9. Chemical	X		
10. Conformance with Approve Procedures	X		
11. Highly Susceptible Populations	X		

Assessment of ______indicates conformance with ____out of the 11 Intervention/Risk Factor Categories (regulatory agency) (# Met)



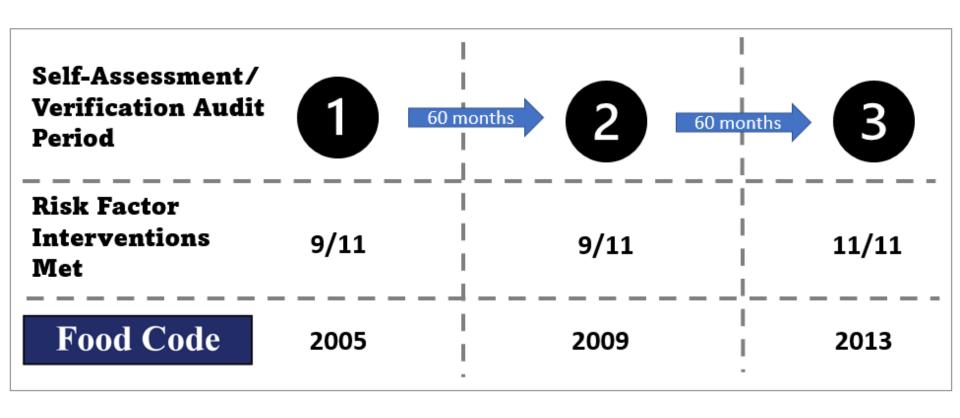
(Pages 1-2, Standards Manual)

Food Code assessment indicates that the jurisdiction's regulatory requirement contain at **least 9 of the 11** FDA Food Code Interventions and Risk Factor controls.

By the **third** verification audit, the jurisdiction's regulatory requirement must contain **ALL 11** Food Code Interventions and Risk Factors



Example 1: Would this meet Standard 1?



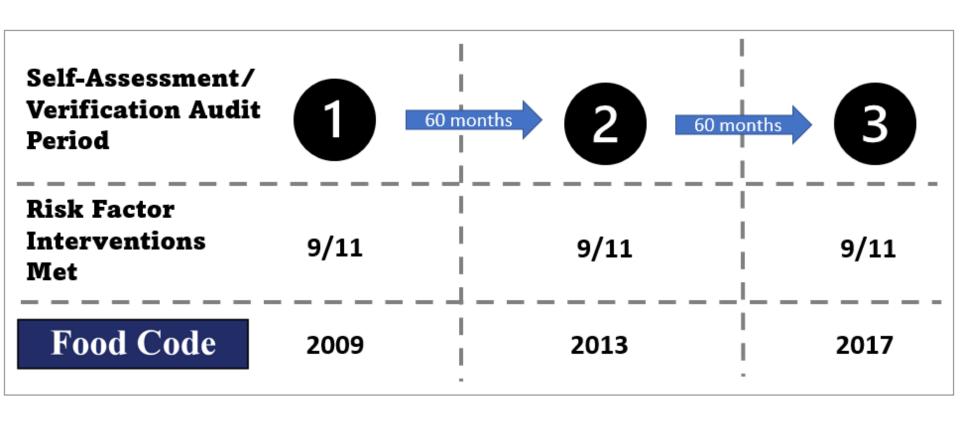


(Pages 1-2, Standards Manual)

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 that it has performed a side-by-side comparison of its prevailing statutes, regulations, rules, and other pertinent requirements against the current published edition of the FDA Food Code or one of the two most recent previous editions of the FDA Food Code.						



Example 1: Would this meet Standard 1?





Standard 1 Part II Good Retail Practices Self-Assessment Process

Standard 1 – Regulatory Foundation Good Retail Practices



(Pages 1-9, Standards Manual)

Standard 1 – Regulatory Foundation Good Retail Practices



(Page 1-2, Standards Manual)

Regulations, codes, etc. must have a corresponding requirement for **95 percent** of the *Food Code* sections listed in Standard I, Part II, Good Retail Food Practices Worksheet.

Standard 1 – Regulatory Foundation



Good Retail Practices

STANDARD 1: REGULATORY FOUNDATION SELF-ASSESMENT WORKSHEET PART II – 2017 Food Code: Good Retail Practices SELF-ASSESSMENT RESULTS

Standard 1: Regulatory Foundation Self-Assessment Worksheet

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

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) (# Met)

	Section Number	Number of Provisions Met (Identified as "YES" on worksheet)	Section Description
	12		Personnel
	13		Food and Food Protection
	14		Plant Cooking for Hot Holding
	15		Protection from Contamination
-[16		Facilities / Methods to Control Product Temperature
	17		Time/Temperature Control for Safety Food Properly Thawed
-[18		Dispensing Food / Utensils Properly Stored
_ [19		Food Equipment
	20		Food and Nonfood-Contact Surfaces
	21		Warewashing Facilities; Designed, Constructed, Installed, Located, Operated, etc.
-	22		Wiping Cloths, Linens, Napkins, Gloves, Sponges: Properly Used, Stored
$-\Box$	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
$\neg \lceil \rceil$	27		Cross Connection, Back Siphonage, Backflow Prevention
-[28		Number, Convenient, Accessible, Designed, Installed
$-\Box$	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.
$ \square$	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 100 to determine the percentage of the Good Retail Practices provisions contained in your code regulation.

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

Standard 1 – Regulatory Foundation Part II SA Worksheet: Good Retail Practices



(Pages 1-28 thru I-57, Standards Manual)

Part II - 2017 Food Code: Good Retail Practices

SECTION 12 - PERSONNEL

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 Food Code section is NOT Met (Indicate the Situation)
1. 2-302.11 - Maintenance				
2. 2-303.11 - Prohibition				
3. 2-301.11 - 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)

Standard 1 – Regulatory Foundation Part II SA Worksheet: Good Retail Practices



(Page 1-28 thru 1-57, Standards Manual)

SECTION 14 - PLANT FOOD COOKING FOR HOT HOLDING

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 Food Code section is NOT Met (Indicate the Situation)
18. 3-401.13 - Plant Food Cooking for Hot Holding				No Food Code provision

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

Standard 1 – Regulatory Foundation Part II SA Worksheet: Good Retail Practices



Section Number	Number of Provisions Met (Identified as "YES" on worksheet)	Section Description		
12	5	Personnel		
13	12	Food and Food Protection		
14	0	Plant Cooking for Hot Holding		
15	9	Protection from Contamination		
16	2	Facilities / Methods to Control Product Temperature		
17	2	Time/Temperature Control for Safety Food Properly Thawed		
18	3	Dispensing Food / Utensils Properly Stored		
19	4	Food Equipment		
20	42	Food and Nonfood-Contact Surfaces		
21	26	Warewashing Facilities; Designed, Constructed, Installed, Located, Operated, etc.		
22	10	Wiping Cloths, Linens, Napkins, Gloves, Sponges: Properly Used, Stored		
23	6	Storage, Handling of Clean Equipment, Utensils		
24	3	Single-Service / Single Use Articles: Storage, Dispensing, Use, no Reuse		
25	9	Safe Water Source, Hot and Cold Under Pressure, Adequate Quantity		
26	21	Plumbing: Installed, Maintained		
27	6	Cross Connection, Back Siphonage, Backflow Prevention		
28	2	Number, Convenient, Accessible, Designed, Installed		
29	4	Toilet Rooms Enclosed, Self-Closing Doors; Fixtures, Good Repair, Clean, etc.		
30	8	Sewage and Wastewater Disposal		
31	17	Garbage and Refuse Disposal - Containers or Receptacles: Covered, etc.		
32	16	Physical Facility - Floors, Walls, Ceiling: Designed, Constructed, Maintained,		
33	11	Lighting, Ventilation, Dressing Rooms / Designated Areas Maintained		
34	5	Premises Maintained Free of Litter, Unnecessary Articles		
35	5	Complete Separation from Living / Sleeping Quarters; Laundry		
36	6	Presence of Insects / Rodents Minimized, Outer Openings Protected, etc.,		

TOTAL NUMBER OF PROVISIONS MET (Add Column?):

Divide the total number of provisions met (last line of table) by 246 and mutuply by 100 to determine the percentage of the Good Retail Practices provisions contained in your code regulation.



Standard 1 Part III Compliance & Enforcement Self-Assessment Process

Standard 1 – Regulatory Foundation Compliance and Enforcement



(Pages 1-10, Standards Manual)

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	a) The jurisdiction's Food Code assessment indicates that regulatory requirements contain ALL the FDA Food Code Compliance and Enforcement Sections identified in the Standard. NOTE: Auditor's random selection of Compliance and Enforcement Code Sections confirms the jurisdiction's assessment that a corresponding requirement is contained in the agency's code or statutes. Documentation from: Part III - Self Assessment Worksheet Part III - Verification Audit Worksheet						

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



(Pages 1-3, Standards Manual)

Regulations, etc. contain provisions that are at least as stringent as those in the *Food Code*.

To meet this element, regulations must have a corresponding requirement for each of the *Food Code* sections listed in Standard 1, Part III, Compliance and Enforcement Worksheet, Items 1-12 (Pages 1-66 thru 1-69, Standards Manual).



(Pages 1-60 thru 1-62, Standards Manual)

Part III - 2017 Food Code: Compliance and Enforcement Summary

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 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				



(Pages 1-61, Standards Manual)

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 Food Code section is NOT Met (Indicate the Situation)
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				



(Pages 1-62, Standards Manual)

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 Food Code section is NOT Met (Indicate the Situation)
12a. Criminal Penalties 8-911.10 - Authorities, Methods, Fines and Sentences	ARS 36-601	×		
12b. 8-912.10 - Petitions for Injunction				
12c. Civil Penalties Provided 8-913.10 - Petitions, Penalties and Continuing Violations				

NOTE:

- Meeting the Standard #1 criteria for the "Compliance and Enforcement" component requires a "Yes" for all Food Code Sections listed in Items 1 through 11.
- For Item 12 pertaining to 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 SA Worksheet – Compliance & Enforcement



(Pages 1-63, Standards Manual)

Compliance and Enforcement Area 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	X		
2. Permit / License Required; Right to Deny	×		
3. Plan Review / Pre-operational Inspections	X		
4. Inspection Authority / Right to Access	×		
5. Information Authority; Restriction / Exclusion of Employees	X X X		
6. Authority to Require HACCP Plans	X		
7. Granting of Variances / Variances Prohibited	X		
8. Timely Correction of Critical Violations	X		
9. Imminent Health Hazard (Summary of Suspension)	×		
10. License Suspension / Revocation	X		
11. Highly Susceptible Populations	X		
12. Legal Remedies	X		

Assessment of _	indicates conformance with	12	out of the 12 Compliance and Enforcement C	ategories

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Standard 1 – Regulatory Foundation Verifying Results

(Pages 1-2 and 1-3, Standards Manual)

- Part I 9 out of the 11 Interventions and Risk Factor Controls must have been met (11/11 after 3rd Verification Audit)
- Part II 95% of the Good Retail Practices provisions must be included in the jurisdiction's Food Code
- Part III ALL 12 of the Compliance and Enforcement categories must have been met



Participant Manual

Standard 1
Question 1
Page 2

Standard 1 – Regulatory Foundation [DA] Four Core Requirements

(Page 1-2, Standards Manual)

- 1. Assessment of the Program's Regulatory Foundation (side-by-side comparison of the Jurisdiction's Food Code to the FDA Food Code)
- 2. Food Code Interventions and Risk Factors
- 3. Good Retail Practices
- 4. Compliance and Enforcement

Participant Manual



Standard 1
Question 2
Page 3

Standard 1 – Regulatory Foundation Part I Worksheet: Risk Factors and Interventions



(Page 1-13 thru 1-14, Standards Manual)

SECTION 2 – EMPLOYEE HEALTH

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 Food Code section is NOT Met (Indicate the Situation)
5. 2-201.11 – Responsibility of Permit Holder, Person in Charge, and Conditional Employees		X		
6. 2-201.12 – Exclusions and Restrictions		X		
7. 2-201.13 – Removal, Adjustment, or Retention of Exclusions and Restrictions		X		
8. 2-501.11— Clean-up of Vomiting and Diarrheal Events		X		

Participant Manual



Standard 1
Question 3
Page 4

Standard 1 – Regulatory Foundation Part I Worksheet: Risk Factors and Interventions



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(Pages 1-25, Standards Manual)

Standard 1: Regulatory Foundation Self-Assessment Worksheet

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

Food Code Section and Description	YES Standard Criteria Met	<u>NO</u> Standard Criteria Not Met	Self-Assessor's General Comments
1. Demonstration of Knowledge	X		
2. Employee Health	X		
3. Consumer Advisory		X	No consumer advisory provision
4. Approved Sources	X		
5. Time/Temperature	X		
6. Protection from Contamination	X		
7. Control of Hands as a Vehicle of Contamination		X	Code allows for minimal bare hand contact with RTE food
8. Good Hygienic Practices	X		
9. Chemical	X		
10. Conformance with Approve Procedures	X		
11. Highly Susceptible Populations	X		

Assessment of ______indicates conformance with ____out of the 11 Intervention/Risk Factor Categories (regulatory agency) (# Met)

Participant Manual



Standard 1
Question 4
Page 5

Standard 1 – Regulatory Foundation



Good Retail Practices

STANDARD 1: REGULATORY FOUNDATION SELF-ASSESMENT WORKSHEET PART II – 2017 Food Code: Good Retail Practices SELF-ASSESSMENT RESULTS

Number of

Provisions Met

			Number	(Identified as "YES" on worksheet)	Section Description
			12		Personnel
			13		Food and Food Protection
Standar	rd 1: Regulatory	Foundation Self-Assessment Worksheet	14		Plant Cooking for Hot Holding
Part I – 2017 Food Code: Interventions and Risk Factor Controls Self-Assessment Results			15		Protection from Contamination
YES NO			16		Facilities / Methods to Control Product Temperature
Food Code Section and Description	Standard Standard Criteria Criteria	Self-Assessor's General Comments	17		Time/Temperature Control for Safety Food Properly Thawed
	Met Not Met		18		Dispensing Food / Utensils Properly Stored
1. Demonstration of Knowledge			19		Food Equipment
2. Employee Health			20		Food and Nonfood-Contact Surfaces
3. Consumer Advisory			21		Warewashing Facilities; Designed, Constructed, Installed, Located, Operated, etc.
4. Approved Sources			22		Wiping Cloths, Linens, Napkins, Gloves, Sponges: Properly Used, Stored
			23		Storage, Handling of Clean Equipment, Utensils
5. Time/Temperature			24		Single-Service / Single Use Articles: Storage, Dispensing, Use, no Reuse
6. Protection from Contamination			25		Safe Water Source, Hot and Cold Under Pressure, Adequate Quantity
7. Control of Hands as a Vehicle of Contamination			26		Plumbing: Installed, Maintained
8. Good Hygienic Practices			27		Cross Connection, Back Siphonage, Backflow Prevention
9. Chemical			28		Number, Convenient, Accessible, Designed, Installed
			29		Toilet Rooms Enclosed, Self-Closing Doors; Fixtures, Good Repair, Clean, etc.
10. Conformance with Approve Procedures			30		Sewage and Wastewater Disposal
11. Highly Susceptible Populations			31		Garbage and Refuse Disposal - Containers or Receptacles: Covered, etc.
			32		Physical Facility - Floors, Walls, Ceiling: Designed, Constructed, Maintained,
Assessment ofindicates conformance without of the 11 Intervention/Risk Factor Categories (regulatory agency) (# Met)			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

Section

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 your code regulation.

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

TOTAL NUMBER OF PROVISIONS MET (Add Column 2):

Participant Manual



Standard 1
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Page 6

Standard 1 – Regulatory Foundation Part II SA Worksheet: Good Retail Practices



Section Number	Number of Provisions Met (Identified as "YES" on worksheet)	Section Description			
12	5	Personnel			
13	12	Food and Food Protection			
14	0	Plant Cooking for Hot Holding			
15	9	Protection from Contamination			
16	2	Facilities / Methods to Control Product Temperature			
17	2	Time/Temperature Control for Safety Food Properly Thawed			
18	3	Dispensing Food / Utensils Properly Stored			
19	4	Food Equipment			
20	42	Food and Nonfood-Contact Surfaces			
21	26	Warewashing Facilities; Designed, Constructed, Installed, Located, Operated, etc.			
22	10	Wiping Cloths, Linens, Napkins, Gloves, Sponges: Properly Used, Stored			
23	6	Storage, Handling of Clean Equipment, Utensils			
24	3	Single-Service / Single Use Articles: Storage, Dispensing, Use, no Reuse			
25	9	Safe Water Source, Hot and Cold Under Pressure, Adequate Quantity			
26	21	Plumbing: Installed, Maintained			
27	6	Cross Connection, Back Siphonage, Backflow Prevention			
28	2	Number, Convenient, Accessible, Designed, Installed			
29	4	Toilet Rooms Enclosed, Self-Closing Doors; Fixtures, Good Repair, Clean, etc.			
30	8	Sewage and Wastewater Disposal			
31	17	Garbage and Refuse Disposal - Containers or Receptacles: Covered, etc.			
32	16	Physical Facility - Floors, Walls, Ceiling: Designed, Constructed, Maintained,			
33	11	Lighting, Ventilation, Dressing Rooms / Designated Areas Maintained			
34	5	Premises Maintained Free of Litter, Unnecessary Articles			
35	5	Complete Separation from Living / Sleeping Quarters; Laundry			
36	6	Presence of Insects / Rodents Minimized, Outer Openings Protected, etc.,			

 $234 \div 246 = .951$

.951 X 100 = 95.1%

TOTAL NUMBER OF PROVISIONS MET (Add Column 2): 234

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 your code regulation. 95.1

Participant Manual



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Page 7



(Pages 1-62, Standards Manual)

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 Food Code section is NOT Met (Indicate the Situation)
12a. Criminal Penalties 8-911.10 - Authorities, Methods, Fines and Sentences	ARS 36-601	X		
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 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.



(Clearinghouse Std. 1 Question 2, pg. 15)

2. Section 8-813.10 Petitions, Penalties, and Continuing Violations

Keywords: STD-01, Regulatory foundation, compliance, enforcement, civil penalties, criminal penalties

Issue Description

Background

The Statutes in our State do not provide the State and local health jurisdictions the authority to enact or administer civil penalties. The State and local jurisdictions do, however, have provisions for criminal penalties that are equivalent to the *FDA Food Code*.

Question/Problem

Since criminal penalties are, in most instances, more punitive and stringent than civil penalties, would jurisdictions operating under the limitations of the State statute prohibiting the application of civil penalties by health authorities meet the intent of the *FDA Food Code*?

Rationale

Since criminal penalties are more stringent then civil penalties, we believe that jurisdictions that do not have authority to enact civil penalties but incorporate criminal penalties at least equivalent to the *FDA Food Code* meet the intent of Standard #1.

Response from Clearinghouse Work Group (Updated 2011)

The CFP modified Standard 1 at the 2003 Biennial meeting and the change became effective in January 2005. Standard 1 Compliance and Enforcement section now requires that only one of the three possible civil, criminal or administrative remedies is necessary to meet the intent of Standard 1.

STANDARD 1 SELF-ASSESSMENT PROCESS QUESTIONS





Standard 6 Compliance & Enforcement

Preparing for the Self-Assessment

Preparing for the Standard 6 Self-Assessment



Source Documents

- Copy of Program Standard 6
- Clearinghouse Interpretations
- Self-Assessment Verification Audit Form
- Step-by-step compliance and enforcement procedures
 - Include policies or interpretations that carry the same weight as compliance and enforcement steps
- Inspection Form
- Reference key which identifies risk factors and interventions on inspection form

Preparing for the Standard 6 Self-Assessment



Source Documents

- Documentation that compliance and enforcement action was followed for >80% of sampled establishments
- The inspection history and reports for randomly selected establishment files
- If using Option 3,
 - Written review process, including random selection, and
 - Documentation of equivalence to the "Explanation of the Statistical Model for Standard 6" from a statistician.





Forms and Worksheets

http://www.fda.gov/retailprogramstandards



Standard 6: Compliance and Enforcement

- Standard 6 (PDF: 86KB)
- Standard 6 Self-Assessment and Verification Audit Form (PDF: 826KB)
- Standard 6 Self-Assessment Instructions and Worksheet (PDF: 1.1MB)
- Standard 6 Verification Audit Instructions and Worksheet (PDF: 720KB)
- Standard 6 Explanation of Statistical Model (PDF: 87KB)
- Standard 6 Establishment File Summary (PDF: 614KB)
- Standard 6 Quick Reference Applicable Food Code Risk Factor Provisions (PDF: 123KB)



Standard 6 Compliance & Enforcement

Conducting the Self-Assessment

Standard 6 Compliance & Enforcement



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

Standard 6 – Compliance and Enforcement Main Elements



(Page 6-2, Standards Manual)

- Written step-by-step compliance and enforcement procedures
- Inspection form records / quantifies the compliance status of risk factors and Food Code interventions
- Establishment file review indicates:
 - Compliance / enforcement actions followed per the jurisdiction's written procedures
 - Resolution / correction was achieved for all out-of-control risk factors or interventions that were recorded

Standard 6 – Compliance & Enforcement Compliance & Enforcement Procedure (a)



(Page 6-7, Standards Manual)

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
a E	. Compliance nd Inforcement 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.						
a E	. Compliance nd Inforcement Procedure	b) The jurisdiction's inspection form(s) record and quantify the compliance status of foodborne illness risk factors, Food Code interventions and other serious code violations.						

Standard 6 – Compliance & Enforcement Compliance & Enforcement Procedure



(Page 6-9, Standards Manual)

Compliance and Enforcement Procedures

- Written step-by-step procedures outline the compliance and enforcement process
- Clear set of instructions that guide staff with steps/actions when various categories of violations occur
- Progression of steps taken when violations are not corrected
- Regulatory or Administrative time frames are established

Standard 6 – Compliance & Enforcement Compliance & Enforcement Procedure



(Page 6-7, Standards Manual)

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, Food Code interventions and other serious code violations.						

Standard 6 – Compliance & Enforcement Compliance & Enforcement Procedure



(Page 6-9, Standards Manual)

Jurisdiction's Inspection form must use IN, OUT, NA, NO to record the compliance status for

- Foodborne Illness Risk Factors
- Public Health Interventions

Standard 6 – Compliance & Enforcement Assessment of Effectiveness



(Page 6-7 thru 6-8, Standards Manual)

Jurisdiction Nar	n	ρ	۰

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. 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.						
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.						

Effectiveness Assessment



(Page 6-9 thru 6-13, Standards Manual)

Measure effectiveness of the compliance and enforcement program to determine if Risk Factor and Public Health Intervention violations are satisfactorily resolved per the jurisdiction's procedures

File Selection Process



(Page 6-9 thru 6-13, Standards Manual)

Three options for file selection:

- Option 1: Reviewing each inspection where a Risk Factor or Public Health intervention was marked out of compliance;
- Option 2: Using a statistical method as described in this standard set forth in Parts I-IV below;
- Option 3: Using an alternative statistical method established by the jurisdiction with written procedures that include supporting documentation and worksheets.

File Selection Process: Option 3



(Page 6-9 thru 6-13, Standards Manual)

If an alternative model is used, the jurisdiction must have written procedures, including supporting documentation and worksheets that:

- Describe the compliance and enforcement review process;
- Includes a review of the randomly selected establishments that have at least one Risk Factor or Public Health Intervention marked OUT of compliance; and
- Is equivalent to the published Standard 6 statistical model for the number of inspections revied and the method of selection.



Standard 6 – Compliance and Enforcement

Option 2: Assessment of Effectiveness (Page 6-10, Standards Manual)



Standard 6 – Using Option 2

(Page 6-9 thru 6-14, Standards Manual)

The process for selection/review of establishment files

- Determine the number of establishment files to review
- Randomly select establishment files
- Review selected establishment files against the written compliance and enforcement protocol
- Determine the need to review substitute establishment files
- Determine if Standard 6 is met



Standard 6

Question 3

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Standard 6 – Compliance and Enforcement Determining Number of Files to Review for the Self-Assessment



(Page 6-10, Standards Manual)

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)					

820 total establishments *5% = 41





Random Selection

(Page 6-9 thru 6-12, Standards Manual)

- Create inventory
 - Organize by permit number, alphabetical order
 - Assign number to each
- Use random number generator
 - Pull two unique unsorted lists
 - Range: 1 to total # of establishments
 - Number in each set: sample size

Standard 6 – Compliance and Enforcement FDA **Example Random Number Generation** www.randomizer.org



GENERATE NUMBERS

How many sets of numbers do you want to generate?	2	
How many numbers per set?	41	
	= Help	
Number range (e.g., 1-50)	1	
	820	
	* Help	
Do you wish each number in a set to remain unique?	YES	
	Help	
Do you wish to sort the numbers that are generated?	NO	
	⇒ Heip	- 27
How do you wish to view your random numbers?	Paramonto de la constanta de l	
	► Help	

Standard 6 – Compliance and Enforcement Example Random Number Generation



RESULTS

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2 Sets of 41 Unique Numbers Per Set

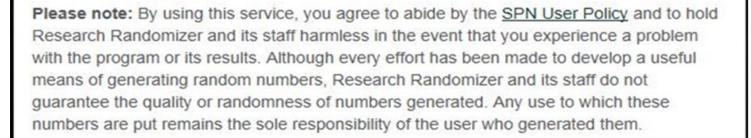
Range: From 1 to 820

Set #1

12, 274, 335, 448, 101, 174, 193, 126, 271, 121, 213, 216, 234, 5, 392, 469, 351, 33, 232, 16, 756, 651, 524, 522, 66, 750, 563, 99, 30, 142, 766, 459, 420, 243, 575, 457, 627, 708, 778, 41, 76

Set #2

20, 346, 688, 793, 421, 435, 42, 127, 140, 715, 495, 276, 624, 496, 175, 773, 369, 182, 533, 264, 458, 63, 391, 808, 426, 54, 226, 141, 639, 231, 640,, 130, 76, 338, 554, 41, 809, 593, 95, 797, 75



Standard 6 – Compliance and Enforcement FDA





(Page 6-15, Standards Manual)

Jurisdiction Name: Desert County Health Department, AZ

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
1	12	07012-Tasty Treats				
2	274	07274-Palo Verde Cafe				
3	335	07335 Cactus Flower Restaurant				
4	448	07448-Survival Foods				
5	101	07101-Desert Flavors				
6	174	07174-Rugged Mountain Foods				
7	193	07193-Sunet Dining				

STD 6 Compliance & Enforcement



Establishment File Worksheet

(Page 6-26, Standards Manual)

Fetablishment Name: Pale Verde Cafe

File Number: 2

STANDARD 6: COMPLIANCE AND ENFORCEMENT ESTABLISHMENT FILE WORKSHEET

Parmit Number: 0724 Inspection Date (Start Point):

riie Number2		staunsmin	rie Number. 2 Establishment Name. Palo verue Cate Perint Number. 0724 Inspection Date (Start Point).									
				Risk Fact	or and Food	d Code Inter	ventions					
	Unsafe Sources	Inadequate Cooking	Improper Holding Temperatures Hot & Cold	Time/ Temperature Parameters Not Met (Time as a Control, date marking, rapid cooling)	Bare Hand Contact with Ready-to-Eat Food	Poor Personal Hygiene	Contaminated Food Contact Equipment	Consumer Advisory (when required)	Demonstration of Knowledge by PIC	Employee Health Control System o Policy Implement		
Reference to local inspection items	1	2,34,5	6,7	8,11	13	14	15	NA	NA	16		
Start Point Inspection Violations												
Was on-site corrective action taken?												
Was follow-up corrective action taken?												
Was enforcement action taken?												
Note:	Note:											
1. Each column in which	h a violatio	n is noted m	ust receive a	yes response to one	of the three o	uestions in or	der for the file	to pass. Addition	ally, written proc	edures must ha		
been followed												
			Was the	Written Proced	ure Follow	ed? YE	ss	Ю				
Jurisdiction's definit	tions of ac	ronyme ar	nd notation	e used to reflect fo	ollow-up ac	tion						
Acronym /Notatio		Definition		Acronym /Notatio		Definitions		Acronym/Notatio	on D	efinitions		
					_							
RH	Re	heat to Safe	e Temp	EM		Embargo						
RCP	F	isk Control	Plan	TR	1	raining Requi	ired					
WL	w	arning Lette	er Sent	GLV	Im	Implement Glove Use						
			File Mee	ets the Standard (6 Criteria:	YE	s N	0				

Standard 6 – Standardized Key Crosswalk to the 2017 FDA Food Code

(Pages 6-37 thru 6-39 Standards Manual)

 Standard 6 – Quick Reference Applicable Food Code Risk Factor Provisions (PDF -123KB)

Standardized Key Crosswalk to the 2017 FDA Food Code

This crosswalk is intended to assist jurisdictions in making comparisons with their code against the 2017 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 2017 FDA Food Code. Completion of the crosswalk is intended to assist jurisdictions completing Standard 6 documentation which identifies major risk factors and Food Code interventions on the jurisdiction's inspection report form. Annex 5 contains additional information regarding the content of Form 3-A.

Food Establishment Inspection Report (Form 3-A)	Applicable 2017 FDA Food Code References
item number	
1	2-101.11, 2-102.11(A), (B) and (C)(1), (4)-(16), 2-103.11 (A)-
2	(P) 2-102.12(A)
3	2-102.11(C)(2), (3) and (17), 2-103.11(O), 2-201.11(A), (B), (C), and (E)
4	2-201.11(D) and (F), 2-201.12, 2-201.13
5	2-501.11
	Inspection Report (Form 3-A) Item Number 1 2

Standard 6 – Compliance and Enforcement Assessment of Effectiveness



(Page 6-10 thru 6-11, Standards Manual)

Establish Start Point Inspection

- Count back three routine inspections from the most recent one
- See if there is a Risk Factor or Intervention Violation. If not, go to the 4th.
- If none on the 4th most recent routine, DNQ.

Standard 6 – Compliance and Enforcement Did Not Qualify (D.N.Q.) Files



(Pages 6-10 thru 6-12, Standards Manual)

Two reasons for DNQ substitute for a randomly selected establishment:

- Length of business history
 - Must have three routine inspections
- No Risk Factor or Food Code Intervention Violation on "Start-Point" inspection
 - Must have RFI violation on 3rd or 4th most recent

When this happens, select a substitute establishment

Standard 6 – Compliance and Enforcement FDA





(Page 6-15, Standards Manual)

Jurisdiction Name: Desert County Health Department, AZ

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
1	12	07012-Tasty Treats			X	
2	274	07274-Palo Verde Cafe				
3	335	07335 Cactus Flower Restaurant				
4	448	07448-Survival Foods				
5	101	07101-Desert Flavors				
6	174	07174-Rugged Mountain Foods				
7	193	07193-Sunet Dining				

Standard 6 – Compliance and Enforcement Example Random Number Generation





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2 Sets of 41 Unique Numbers Per Set

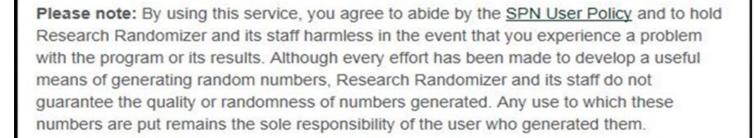
Range: From 1 to 820

Set #1

12, 274, 335, 448, 101, 174, 193, 126, 271, 121, 213, 216, 234, 5, 392, 469, 351, 33, 232, 16, 756, 651, 524, 522, 66, 750, 563, 99, 30, 142, 766, 459, 420, 243, 575, 457, 627, 708, 778, 41, 76

Set #2

20 346, 688, 793, 421, 435, 42, 127, 140, 715, 495, 276, 624, 496, 175, 773, 369, 182, 533, 264, 458, 63, 391, 808, 426, 54, 226, 141, 639, 231, 640,, 130, 76, 338, 554, 41, 809, 593, 95, 797, 75



Standard 6 – Compliance and Enforcement FDA



Substitute Establishment Files

(Pages 6-23 thru 6-25, Standards Manual)

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
1	20	07020-Survival Foods	, .			
2	346	07346-Just Hot Stuff	- 7			
3						
4						
5						
6						
7						

Determining Start Point Inspection Data



STANDARD 6: COMPLIANCE AND ENFORCEMENT ESTABLISHMENT FILE WORKSHEET

File Number: 2	ile Number: 2 Establishment Name: Palo Verde Cafe Permit Number: 0724 Inspection Date (Start Point): 07/16/2020									
				Risk Fact	or and Foo	d Code Inter	ventions			
	Unsafe Sources	Inadequate Cooking	Improper Holding Temperatures Hot & Cold	Time/ Temperature Parameters Not Met (Time as a Control, date marking, rapid cooling)	Bare Hand Contact with Ready-to-Eat Food	Poor Personal Hygiene	Contaminated Food Contact Equipment	Consumer Advisory (when required)	Demonstration of Knowledge by PIC	Employee Health Control System or Policy Implemented
Reference to local inspection items	1	2,34,5	6,7	8,11	13	14	15	NA	NA	16
Start Point Inspection Violations		х		x	х	х				
Was on-site corrective action taken?										
Was follow-up corrective action taken?										
Was enforcement action taken?										
Note: 1. Each column in which been followed	ch a violati	on is noted	ceive a	yes response to one	of the three o	questions in or	der for the file t	o pass. Addition	ally, written pro	cedures must have
			Was the	e Written Proced	ure Follow	ed? YE	SN	O		
Jurisdiction's definit	tions of a	cronyms a	nd notation	s used to reflect f	ollow-up ac	tion				
Acronym /Notatio	n	Definition	ıs	Acronym /Notatio	n	Definitions	A	Acronym/Notatio	on I	Definitions
RH	Re	eheat to Saf	e Temp	EM		Embargo				
RCP		Risk Contro	l Plan	TR	1	Training Requi	ired			
WL	v	arning Lett	er Sent	GLV	Im	plement Glov	e Use			

File Meets the Standard 6 Criteria: ____ YES ____ NO

Corrective & Enforcement Action



STANDARD 6: COMPLIANCE AND ENFORCEMENT ESTABLISHMENT FILE WORKSHEET

File Number:2	File Number: Establishment Name:Paio verde Cale Permit Number: Inspection Date (Start Point): 07/10/2020									
				Risk Fact	or and <i>Foo</i>	d Code Inter	ventions			
	Unsafe Sources	Inadequate Cooking	Improper Holding Temperatures Hot & Cold	Time/ Temperature Parameters Not Met (Time as a Control, date marking, rapid cooling)	Bare Hand Contact with Ready-to-Eat Food	Poor Personal Hygiene	Contaminated Food Contact Equipment	Consumer Advisory (when required)	Demonstration of Knowledge by PIC	Employee Health Control System or Policy Implemented
Reference to local inspection items	1	2,34,5	6,7	8,11	13	14	15	NA	NA	16
Start Point Inspection Violations		x		x	х	х				
Was on-site corrective action taken?		YES (R,H)		YES(R,H)	YES(GLV)					
Was follow-up corrective action taken?				YES (RCP)		YES(TR)				
Was enforcement action taken?		YES(WL)								
Note: 1. Each column in which been followed	ch a violatio	n is noted n	ust receive a	yes response to one	of the three o	questions in or	der for the file t	o pass. Addition	ally, written proc	edures must have
			Was the	Written Proced	ure Follow	ed? YE	sn	o		
Jurisdiction's defini	tions of ac	ronyms ar	nd notation	s used to reflect f	ollow-up ac	tion				
Acronym /Notatio	n	Definition	ıs	Acronym /Notatio	n	Definitions	A	cronym/Notatio	on I	efinitions
RH	Re	heat to Saf	e Temp	EM		Embargo				
RCP	RCP Risk Control Plan TR		1	raining Requi	ired					
WL	WL Warning Letter Sent G		GLV	Im	plement Glov	e Use				
			File Me	ets the Standard (6 Criteria:	YE	s NO			



Written Procedures or Follow Up Activity

STANDARD 6: COMPLIANCE AND ENFORCEMENT ESTABLISHMENT FILE WORKSHEET

File Number: 2	le Number: 2 Establishment Name: Palo Verde Cafe Permit Number: 0724 Inspection Date (Start Point): 07/16/2020											
	Risk Factor and Food Code Interventions											
	Unsafe Sources	Inadequate Cooking	Improper Holding Temperatures Hot & Cold	Time/ Temperature Parameters Not Met (Time as a Control, date marking, rapid cooling)	Bare Hand Contact with Ready-to-Eat Food	Poor Personal Hygiene	Contaminated Food Contact Equipment	Consumer Advisory (when required)	Demonstration of Knowledge by PIC	Employee Health Control System or Policy Implemented		
Reference to local inspection items	1	2,34,5	6,7	8,11	13	14	15	NA	NA	16		
Start Point Inspection Violations		х		x	х	х						
Was on-site corrective action taken?		YES (R,H)		YES(R,H)	YES(GLV)							
Was follow-up corrective action taken?				YES (RCP)		YES(TR)						
Was enforcement action		VEC(1411.)										

taken? Note:

Was the Written Procedure Followed? X YES NO

Jurisdiction's definitions of acronyms and notations used to reflect follow-up action

Acronym /Notation	Definitions	Acronym /Notation	Definitions	Acronym/Notation	Definitions
RH	Reheat to Safe Temp	EM	Embargo		
RCP	Risk Control Plan	TR	Training Required		
WL	Warning Letter Sent	GLV	Implement Glove Use		_

File Meets the Standard 6 Criteria: X YES NO

^{1.} Each column in which a violation is noted must receive a yes response to one of the three questions in order for the file to pass. Additionally, written procedures must have been followed

Standard 6 – Compliance and Enforcement Summary Worksheet



(Page 6-11, Standards Manual)

Jurisdiction Name: Desert County Health Department, AZ

Number of Files Selected	Randomly Selected Number	Name or ID of Establishment	Yes	No	Does Not Qualify	Self-Assessor's General Comments
1	12	07012-Tasty Treats			X	Only 2 routines
2	274	07274-Palo Verde Cafe	X			
3	335	07335 Cactus Flower Restaurant		X		Did not do RCP
4	448	07448-Survival Foods				
5	101	07101-Desert Flavors				
6	174	07174-Rugged Mountain Foods				
7	193	07193-Sunet Dining				

Standard 6 – Compliance & Enforcement



Determine if Standard 6 Criteria are Met

(Page 6-14, Standards Manual)

At least 80% of establishment files reviewed indicates:

- Staff takes compliance and enforcement action according to the jurisdiction's written procedure
- Resolution was achieved for all out-of-control risk factors and interventions recorded on the selected routine inspections



Standard 6

Question 1

Page 28

Standard 6 – Compliance and Enforcement Main Elements



(Page 6-2, Standards Manual)

- Written step-by-step compliance and enforcement procedures
- Inspection form records / quantifies the compliance status of risk factors and Food Code interventions
- Establishment file review indicates:
 - Compliance / enforcement actions followed per the jurisdiction's written procedures
 - Resolution / correction was achieved for all out-of-control risk factors or interventions that were recorded



Standard 6

Question 2

Page 28

File Selection Process



(Page 6-9 thru 6-13, Standards Manual)

Three options for file selection:

- **Option 1:** Reviewing each inspection where a FBI Risk Factor or Public Health intervention was marked out of compliance;
- Option 2: Using a statistical method as described in this standard set forth in Parts I-IV below;
- Option 3: Using an alternative statistical method established by the jurisdiction with written procedures that include supporting documentation and worksheets.



Standard 6
Question 4
Page 30

Standard 6 – Compliance and Enforcement Assessment of Effectiveness



(Page 6-10 thru 6-11, Standards Manual)

Establish Start Point Inspection

- Count back three routine inspections from the most recent
- See if there is a Risk Factor or Intervention Violation. If not, go to the 4th.
- If none on the 4th most recent routine, DNQ.



Standard 6
Question 5
Page 30

Standard 6 – Compliance and Enforcement



Did Not Qualify (D.N.Q.) Files

(Pages 6-11, Standards Manual)

Two reasons jurisdictions may delete a randomly selected establishment from the review pool:

- Length of business history
- No Risk Factor or Food Code Intervention Violation on "Start-Point" inspection

When this happens, select a substitute establishment



Standard 6
Question 6
Page 31

Standard 6 – Compliance and Enforcement Example Random Number Generation



RESULTS

PRINT

DOWNLOAD

CLOSE

2 Sets of 41 Unique Numbers Per Set

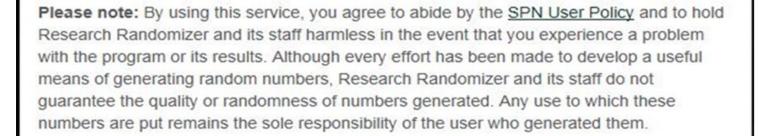
Range: From 1 to 820

Set #1

12, 274, 335, 448, 101, 174, 193, 126, 271, 121, 213, 216, 234, 5, 392, 469, 351, 33, 232, 16, 756, 651, 524, 522, 66, 750, 563, 99, 30, 142, 766, 459, 420, 243, 575, 457, 627, 708, 778, 41, 76

Set #2

20, 346, 688, 793, 421, 435, 42, 127, 140, 715, 495, 276, 624, 496, 175, 773, 369, 182, 533, 264, 458, 63, 391, 808, 426, 54, 226, 141, 639, 231, 640,, 130, 76, 338, 554, 41, 809, 593, 95, 797, 75





Standard 6

Question 7

Page 31

Non-Applicable (NA) Designations



STANDARD 6: COMPLIANCE AND ENFORCEMENT ESTABLISHMENT FILE WORKSHEET

File Number: 2 Establishment Name: Palo Verde Cafe Permit Number: 0724 Inspection Date (Start Point): 07/16/2020											
Risk Factor and Food Code Interventions											
	Unsafe Sources	Inadequate Cooking	Improper Holding Temperatures Hot & Cold	Time/ Temperature Parameters Not Met (Time as a Control, date marking, rapid cooling)	Bare Hand Contact with Ready-to-Eat Food	Poor Personal Hygiene	Contaminated Food Contact Equipment	Consumer Advisory (when required)	Demonstration of Knowledge by PIC	Employee Health Control System or Policy Implemented	
Reference to local inspection items	1	2,34,5	6,7	8,11	13	14	15	NA	NA	16	
Start Point Inspection Violations		x		х	х	х					
Was on-site corrective action taken?		YES (R,H)		YES(R,H)	YES(GLV)						
Was follow-up corrective action taken?				YES (RCP)		YES(TR)					
Was enforcement action taken?		YES(WL)									
Note: 1. Each column in which a violation is noted must receive a yes response to one of the three questions in order for the file to pass. Additionally, written procedures must have been followed Was the Written Procedure Followed? X YESNO											
Jurisdiction's definitions of acronyms and notations used to reflect follow-up action											
Acronym /Notation		Definitions		Acronym /Notation		Definitions		Acronym/Notation		Definitions	
RH	Re	Reheat to Safe Temp		EM		Embargo					
RCP	Risk Control Plan		Plan	TR		Training Required					
WL	L Warning Letter Sent		er Sent	GLV		Implement Glove Use					

File Meets the Standard 6 Criteria: X YES NO



Standard 6
Question 8
Page 32

Determining Start Point Inspection Data



STANDARD 6: COMPLIANCE AND ENFORCEMENT ESTABLISHMENT FILE WORKSHEET

Permit Number: 0724 Inspection Date (Start Point): 07/16/2020

Risk Factor and Food Code Interventions										
	Unsafe Sources	Inadequate Cooking	Improper Holding Temperatures Hot & Cold	Time/ Temperature Parameters Not Met (Time as a Control, date marking, rapid cooling)	Bare Hand Contact with Ready-to-Eat Food	Poor Personal Hygiene	Contaminated Food Contact Equipment	Consumer Advisory (when required)	Demonstration of Knowledge by PIC	Employee Health Control System or Policy Implemented
Reference to local inspection items	1	2,34,5	6,7	8,11	13	14	15	NA	NA	16
Start Point Inspection Violations		х		х	х	х				
Was on-site corrective action taken?		YES (R,H)		YES(R,H)	YES(GLV)					
Was follow-up corrective action taken?				YES (RCP)		YES(TR)				
Was enforcement action taken?		YES(WL)								
Note:										
1. Each column in which a violation is noted must receive a yes response to one of the three questions in order for the file to pass. Additionally, written procedures must have										

Jurisdiction's definitions of acronyms and notations used to reflect follow-up action

Establishment Name: Palo Verde Cafe

File Number:

been followed

Acronym /Notation	Definitions	initions Acronym /Notation Definit		Acronym/Notation	Definitions	
RH	Reheat to Safe Temp	EM	Embargo			
RCP	Risk Control Plan	TR	Training Required			
WL	Warning Letter Sent	GLV	Implement Glove Use			

Was the Written Procedure Followed? X YES NO

File Meets the Standard 6 Criteria: X YES NO



STANDARD 6 SELF-ASSESSMENT QUESTIONS





Standard 2 Trained Regulatory Staff

Preparing for the Verification Audit



Preparing for the Standard 2 Verification Audit Source Documents

- Copy of Program Standard 2
- Clearinghouse Interpretations
- Jurisdiction's Standard 2 Self-Assessment Worksheet or equivalent
- Records of course completion of the Standard 2 curriculum; transcripts; affidavits – A listing of FDA ORA U course and learning objectives are available:

<u>www.fda.gov/training-and-continuing-education/ora-university-orau</u>



Preparing for the Standard 2 Verification Audit

Source Documents

- Copies of 25 joint field training inspections/independent inspections
- Documentation of completion of a field training process similar to that contain in Appendix B-2
- Standardization/re-standardization records certificates/letters
- Records of continuing education contact hours via database; certificates; attendance records; sign-in sheets





Forms and Worksheets

http://www.fda.gov/retailprogramstandards



Standard 2: Trained Regulatory Staff

- Standard 2 (PDF: 149KB)
- Standard 2 Self-Assessment and Verification Audit Form (PDF: 714KB)
- Standard 2 Self-Assessment Instructions and Worksheet (PDF: 674KB)
- Standard 2 Verification Audit Instructions and Worksheet (PDF: 710KB)



Standard 2 Program Assessment

Preparing for the Verification Audit

(Pages 2-21 thru 2-25, Standards Manual)



Standard 2 – Trained Regulatory Staff

Regulatory staff shall have the <u>knowledge</u>, <u>skills</u>, and <u>ability</u> to adequately perform their required duties.





(Page 2-2, Program Standards Manual)

- Step 1: Pre-Inspection Curriculum
- Step 2: Joint Field Training

 CFP Field Training Manual (Updated 2020 CFP)
- Step 3: Independent Inspections

 Completion of Curriculum (designated as "Post" courses)
- Step 4: Standardization
- Step 5: Continuing Education

Standard 2 – Trained Regulatory Staff Step 1: Verify Training Records



(Page 2-21, Program Standards Manual)

(*indicates completion date required)

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)	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)	Meets the Standard 2 Criteria YES or No
Billie Sims	9-21-1985	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 10-11-23	20	YES
Steven Owens	9-22-1995	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 12-22-23	0	YES
Jamie Holloway	3-6-2015	6-15-15	7-2-15	8-1-15	Re-Standardized 3-17-22	20	YES
Sue Scooner	11-1-2016	12-22-16	12-31-16	3-11-17	Re-Standardized 4-21-23	32	YES
Richard Bryan	10-22-2021	2-6-22	3-12-22	4-17-22	Standardized 1-5-23	0	YES
Jackson Clayton	8-8-2010	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Re-Standardized 9-21-22	20	YES
Joseph Pruitt	7-5-2021	11-1-21	1-12-22	8-5-22	Standardized 1-2-23	36	YES
Greg Washington	4-25-2017	9-26-17	10-27-17	12-3-17	Re-Standardized 9-12-23	20	YES
Madison Hall	4-25-2022	8-1-22	10-20-22	4-29-23	Standardized 6-24-23	24	YES
Joseph Rockdale	5-1-2019	10-25-19	11-11-19	12-15-19	Standardized 10-1-20	8	NO
	Billie Sims Steven Owens Jamie Holloway Sue Scooner Richard Bryan Jackson Clayton Joseph Pruitt Greg Washington Madison Hall	Employee Name Assignment to the Retail Food Program Billie Sims 9-21-1985 Steven Owens 9-22-1995 Jamie Holloway 3-6-2015 Sue Scooner 11-1-2016 Richard Bryan 10-22-2021 Jackson Clayton 8-8-2010 Joseph Pruitt 7-5-2021 Greg Washington 4-25-2017 Madison Hall 4-25-2022	Employee Name Date of Hire or Assignment to the Retail Food Program Billie Sims 9-21-1985 Previous coursework meets the standard Steven Owens 9-22-1995 Previous coursework meets the standard Jamie Holloway 3-6-2015 Sue Scooner 11-1-2016 Richard Bryan 10-22-2021 Jackson Clayton 8-8-2010 Previous coursework meets the standard 12-22-16 Previous coursework meets the standard 12-22-16 11-1-2016 Richard Bryan 10-22-2021 Jackson Clayton 8-8-2010 Previous coursework meets the standard 11-1-21 Greg Washington 4-25-2021 11-1-21 Madison Hall 4-25-2022 8-1-22	Employee Name Date of Hire or Assignment to the Retail Food Program Signment to the Retail Food Program Successful completion of a field training Inspections* AND Successful completion of a field training Inspections* AND Successful completion of a field training process similar to the CFP Field Training Manual in Appendix B-2	Date of Hire or Assignment to the Retail Food Program Curriculum* (Prior to conducting independent inspections) Previous coursework meets the standard Previous meets t	Date of Hire or Assignment to the Retail Food Program Completion of Training Precisite ("Pre") Curriculum" (Prior to conducting inspections) Successful completion of a field training Manual in Appendix B-2	Employee Name Date of Hire or Assignment to the Retail Food Program Previous coursework meets the standard

^{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

Standard 2 – Trained Regulatory Staff Step 2: Verify Worksheet % Calculation



(Page 2-21, Program Standards Manual)

(*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)	Number of Education Contact Hours (Minimum of 20 Contact Hours Every 3 Years)	Meets the Standard 2 Criteria YES or No
1	Billie Sims	9-21-1985	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 10-11-23	20	YES
2	Steven Owens	9-22-1995	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Standardized 12-22-23	0	YES
3	Jamie Holloway	3-6-2015	6-15-15	7-2-15	8-1-15	Re-Standardized 3-17-22	20	YES
4	Sue Scooner	11-1-2016	12-22-16	12-31-16	3-11-17	Re-Standardized 4-21-23	32	YES
5	Richard Bryan	10-22-2021	2-6-22	3-12-22	4-17-22	Standardized 1-5-23	0	YES
6	Jackson Clayton	8-8-2010	Previous coursework meets the standard	Waived, completed previous field training; records on file	Records on file:>500 independent inspections	Re-Standardized 9-21-22	20	YES
7	Joseph Pruitt	7-5-2021	11-1-21	1-12-22	8-5-22	Standardized 1-2-23	36	YES
8	Greg Washington	4-25-2017	9-26-17	10-27-17	12-3-17	Re-Standardized 9-12-23	20	YES
9	Madison Hall	4-25-2022	8-1-22	10-20-22	4-29-23	Standardized 6-24-23	24	YES
10	Joseph Rockdale	5-1-2019	10-25-19	11-11-19	12-15-19	Standardized 10-1-20	8	NO

^{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





(Page 2-21, Program Standards Manual)

 EXAMPLE: Total # of Employees assigned to retail food program inspection responsibilities = 10

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



Standard 2 – Trained Regulatory Staff Step 4: Select Random Numbers

(Page 2-22, Program Standards Manual)

Random selection to include:

- Two sets of 5 numbers (primary and substitute sample sets).
- May obtain random numbers from: www.randomizer.org



Standard 2 – Trained Regulatory Staff Example Random Number Generation

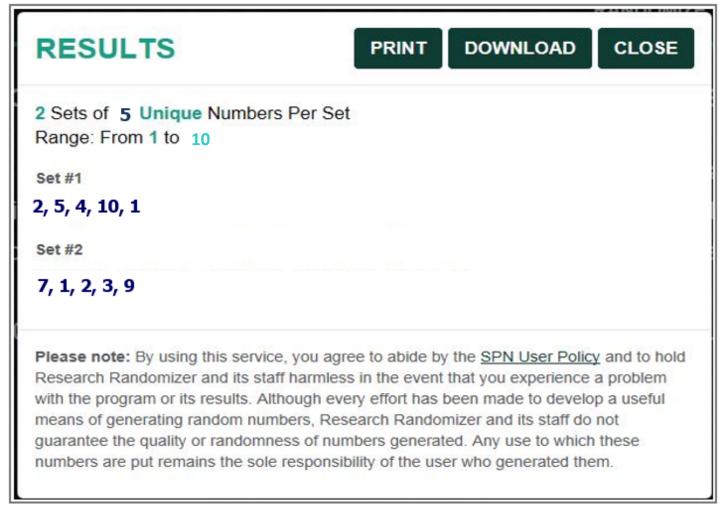
(www.randomizer.org)

RESEARCH RANDOMIZER	RANDOMIZE TUTORIAI
GENERATE NU	IMBERS
How many sets of numbers do you want to generate?	2
	Help
How many numbers per set?	5
	Help
Number range (e.g., 1-50)	1
	Help
Do you wish each number in a set to remain unique?	Yes v
	Help
Do you wish to sort the numbers that are generated?	No Y
How do you wish to view your random numbers?	Place Markers Off
Tien de yeu wish to view yeur runden manisers.	Help
	неір



Standard 2 – Trained Regulatory Staff Example Random Number Generation

(www.randomizer.org)





Standard 2 – Trained Regulatory Staff Step 5: Sampling of Employee Training Files

(Page 2-24, Program Standards Manual)

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	Steven Owens			
2	5	Richard Bryan			
3	4	Sue Scooner			
4	10	Joseph Rockdale			
5	1	Billie Sims			
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

NOTE:

- All randomly selected employee training records must contain documentation that the Standard 2 training and standardization elements have been successfully completed.
- 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 Step 5: Substitute Employee Training Files

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	Steven Owens	X		
2	5	Richard Bryan	X		
3	4	Sue Scooner	Х		
4	10	Joseph Rockdale			Jurisdiction indicated on Self-Assessment that employee has not met the Standard 2 Training and standardization elements. Randomly selected a Substitute Employee Record (Below #7- Joseph Pruitt)
- 5	1	Billie Sims	Х		
6	Sub for #4	Joseph Pruitt	Х		Substitute for Employee Record #10
	3ub 101 #4	Joseph Fruitt			Substitute for Employee necora #10
7	3ub 101 #4	озерн гини			Substitute for Employee Record #20
7 8	3ub 101 #4	лозерн Fruitt			Substitute for Employee Record #10
<u> </u>	3ub 101 #4	зоверитини			Substitute for Employee Record #10
8	3ub 101 #4	эозеритчин			Substitute for Employee Record #10
8	3ub 101 #4	лозери гтанц ————————————————————————————————————			Substitute for Employee Record #10
8 9 10	3ub 101 #4	эозеритчин			Substitute for Employee Record #20
8 9 10 11	3ub 101 #4	эозеритчиц			
8 9 10 11 12	3ub 101 #4	эозеритчин			

NOTE:

- 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 Step 6: Verification Audit Results

(Page 2-22, Program Standards Manual)

All randomly selected employee training records must contain documentation that the Standard 2 training and standardization elements have been successfully completed



Standard 2 – Trained Regulatory Staff Verification Audit Results

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	Steven Owens	х		
2	5	Richard Bryan	Х		
3	4	Sue Scooner	Х		
4	10	Joseph Rockdale			Jurisdiction indicated on Self-Assessment that employee has not met the Standard 2 Training and standardization elements. Randomly selected a Substitute Employee Record (Below #7- Joseph Pruitt)
5	1	Billie Sims	Х		
6	Sub for #4	Joseph Pruitt	х		Substitute for Employee Record #10
7					
8					
9					
10					
11					
12					
13					
14					
15					

NOTE:

- All randomly selected employee training records must contain documentation that the Standard 2 training and standardization elements have been successfully completed.
- 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.





(Page 2-23, Program Standards Manual)

Ninety percent (90%) of the regulatory retail food program inspection staff shall have successfully completed:

- Steps 1-4 within 24 months of hire or assignment to the retail food program
- Step 5 every 36 months after the initial 24 months of training



Standard 2 – Trained Regulatory Staff Verification Audit Results

Standard 2: Program Assessment
Program Self-Assessment and Verification Audit Form

		•
Jurisa	iction	Name:

Step	Criteria	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.	X			X		
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.	X			X		
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	X			X		



Participant Manual

Standard 2 Questions 7-10 Page 17

www.fda.gov

STANDARD 2 VERIFICATION AUDIT PROCESS QUESTIONS





Standard 2 Training File Review Exercise

www.fda.gov



Standard 1 Regulatory Foundation

Preparing for the Verification Audit





Source Documents

- Copy of Program Standard 1
- Clearinghouse Interpretations
- Jurisdiction's Regulations/Ordinance
- Written Policies or Interpretations that carry the same weight as prevailing rules and regulations
- Copy of the current version of the FDA Food Code

https://www.fda.gov/food/fda-food-code/food-code-2017



Preparing for the Standard 1 – Verification Audit

Source Documents

- Jurisdictions completed Standard 1: Self-Assessment and Verification Audit Form
- Jurisdiction's Standard 1 Self-Assessment
 Worksheets or other side-by-side methodology
 used for Food Code Comparison
 - Public Health Interventions & Risk Factors
 - Good Retail Practices
 - Compliance and Enforcement



Standard 1 Regulatory Foundation

Conducting the Verification Audit



Standard 1 Regulatory Foundation

Regulatory foundation includes any statute, regulation, rule, ordinance, or other set of prevailing set of regulatory requirements.

Standard 1 – Regulatory Foundation [DA] Four Core Requirements



(Page 1-2, Standards Manual)

- 1. Assessment of the Program's Regulatory Foundation (side-by-side comparison of the Jurisdiction's Food Code to the FDA Food Code)
- 2. Food Code Interventions and Risk Factors
- 3. Good Retail Practices
- 4. Compliance and Enforcement

Standard 1 – Regulatory Foundation Step 1: Assessment of Program's Regulatory Foundation



(Page 1-7, Standards Manual)

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 that it has performed a side-by-side comparison of its prevailing statutes, regulations, rules, and other pertinent requirements against the current published edition of the FDA Food Code or one of the two most recent previous editions of the FDA Food Code.						
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.						

Standard 1 – Regulatory Foundation Step 1: Assessment of Program's Regulatory Foundation



(Pages 1-2 and 1-3, Standards Manual)

Jurisdiction has documentation of:

- Side-by-side comparison of its requirements against the FDA Food Code
- Side-by-side comparison includes provisions for:
 - Food Code Risk Factors & Interventions
 - Good Retail Practices
 - Compliance and Enforcement
- Identifies the jurisdiction's corresponding requirement to the applicable FDA Food Code Section

Standard 1 – Regulatory Foundation Part I Worksheet: Risk Factors and Interventions



http://www.fda.gov/retailprogramstandards



Standard 1: Regulatory Foundation

- Standard 1 (PDF: 90KB)
- Standard 1 Self-Assessment and Verification Audit Form (PDF: 776KB)
- Standard 1 Self-Assessment Instructions and Worksheet for Part I (PDF: 387KB)
- Standard 1 Self-Assessment Instructions and Worksheet for Part II (PDF: 1.1MB)
- Standard 1 Self-Assessment Instructions and Worksheet for Part III (PDF: 234KB)
- Standard 1 Verification Audit Instructions and Worksheet for Part I (PDF: 720KB)
- Standard 1 Verification Audit Instructions and Worksheet for Part II (PDF: 687KB)
- Standard 1 Verification Audit Instructions and Worksheet for Part III (PDF: 683KB)



Standard 1 Part I Interventions and Risk Factors Verification Audit Process



Standard 1 – Regulatory Foundation Part I - Risk Factors and Interventions Verification Audit

(Pages 1-64 thru 1-65, Standards Manual)

- Total # of Provisions in Part I = 94
- Random Selection to include two sets of 15 numbers (primary and substitute sample sets)
 - May obtain random numbers from: www.randomizer.org

Participant Manual

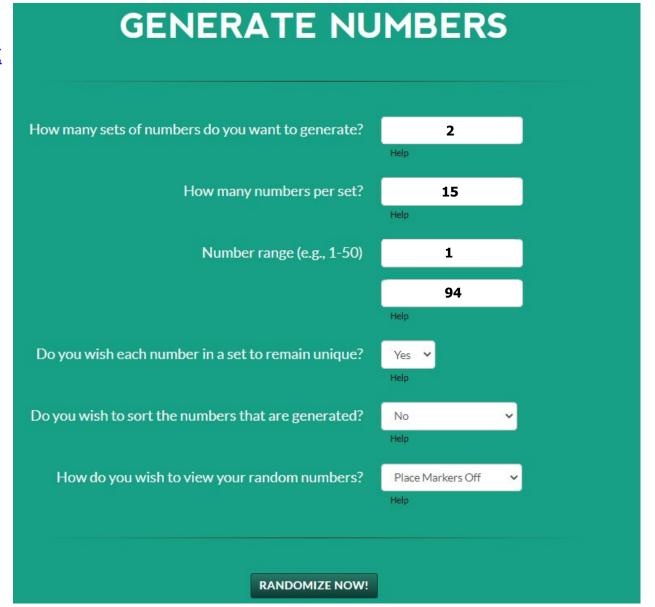


Standard 1
Question 7
Page 8

Standard 1 – Regulatory Foundation Example Random Number Generation



www.randomizer.org



Participant Manual



Standard 1
Question 8
Page 9



Standard 1 – Regulatory Foundation Example Random Number Generation



PRINT

DOWNLOAD

CLOSE

2 Sets of 15 Unique Numbers Per Set

Range: From 1 to 94

Set #1

23, 61, 18, 25, 48, 2, 14, 28, 75, 9, 45, 49, 47, 39, 94

Set #2

31, 20, 10, 46, 63, 41, 74, 57, 3, 80, 53, 93, 73, 69, 62

Please note: By using this service, you agree to abide by the <u>SPN User Policy</u> and to hold Research Randomizer and its staff harmless in the event that you experience a problem with the program or its results. Although every effort has been made to develop a useful means of generating random numbers, Research Randomizer and its staff do not guarantee the quality or randomness of numbers generated. Any use to which these numbers are put remains the sole responsibility of the user who generated them.

Standard 1 – Regulatory Foundation Part I: Risk Factors and Interventions Selection of Jurisdiction's Code Sections to Review

(Page 1-67 Standards Manual)

Part I - Interventions and Risk Factors

Number of Sections Reviewed	Randomly Selected Number	Corresponding 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	23					
2	61					
3	18					
4	25					
5	48				Set #	1
6	2					51, 18, 25, 48, 2, 14, 28, 75, 7, 45, 49, 47, 39, 9 4
7	14				25, 0	1, 10, 23, 40, 2, 14, 20, 73, 7, 43, 43, 47, 33, 34
8	28					
9	75					
10	9					
11	45					
12	49					
13	47					
14	39					
15	94					

NOTES

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

Participant Manual



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Question 9
Page 10

Standard 1 – Regulatory Foundation Part I: Risk Factors and Interventions



Selection of Jurisdiction's Code Sections to Review

Part I – Interventions and Risk Factors

(Page 1-67 Standards Manual)

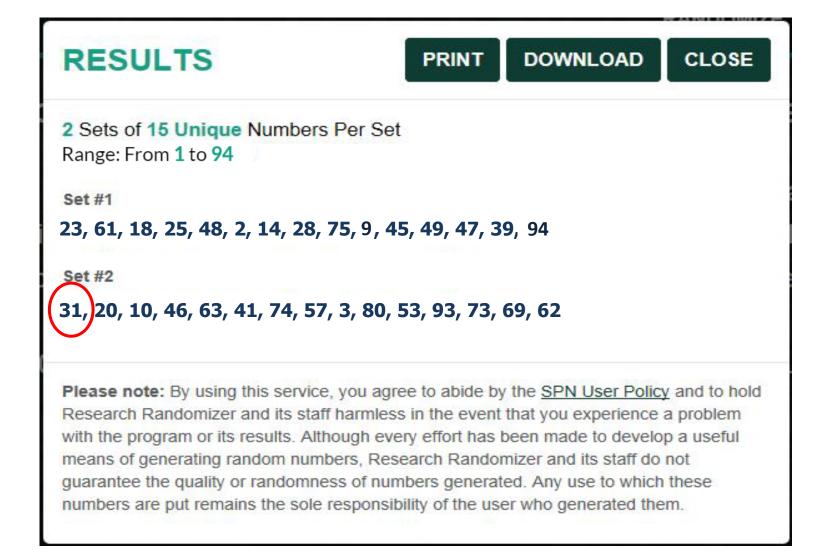
Number of Sections Reviewed	Randomly Selected Number	Corresponding Food Code Chapter from Part I Interventions and Risk Factors Self-Assessment Worksheet	Jurisdiction's Corresponding Code Section, Rule, etc.	YES Full Intent is Met	NO Full Intent is not Met	If no, auditor must specify why criterion is not met
1	23	3-202.18 Shellstock Identification	3-202.18			
2	61	5-204.11 Handwashing Sinks	5-204.11			
3	18	3-201.16 Wild Mushrooms	3-201.16			
4	25	3-402.11 Parasite Destruction	3-402.11			
5	48	4-501.115 Manual Warewashing Equipment, Chem Sanitization	4-501.115			
6	2	2-102.11 Demonstration	2-102.11			
7	14	3-202.14 Eggs and Milk Products	3-202.14			
8	28	3-401.11 Raw Animal Foods	3-401.11			
9	75	7-209.11 Storage (Personal Care Items)	7-209.11			
10	9	3-603.11 *Consumer Advisory*				
11	45	4-501.11 Mech. Warewashing Equip, Water Sanitization Temp	4-501.11			
12	49	4-601.11 Equipment, Food Contact Surfaces, Nonfood Contact Surface,	4-601.11			
13	47	4-501.114 Manual and Mech. Warewashing Equip	4-501.114			
14	39	3-302.11 Packaged/Unpackaged Food, Separation and Storage	3-302.11			
15	94	3-801.11 Pasteurized Foods	3-801.11			

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

Standard 1 – Regulatory Foundation Part I: Risk Factors and Interventions Substitute Sampling





Standard 1 – Regulatory Foundation Part I: Risk Factors and Interventions Selection of Jurisdiction's Code Sections to Review

(Page 1-67 Standards Manual)

Part I – Interventions and Risk Factors

Number of Sections Reviewed	Randomly Selected Number	Corresponding 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	23	3-202.18 Shellstock Identification	3-202.18 Shellstock Identification			
2	61	5-204.11 Handwashing Sinks	5-204.11 Handwashing Sinks			
3	18	3-201.16 Wild Mushrooms	3-201.16 Wild Mushrooms			
4	25	3-402.11 Parasite Destruction	3-402.11 Parasite Destruction			
5	48	4-501.115 Manual Warewashing Equipment, Chem Sanitization	4-501.115 Manual Warewashing Equipment, Chem Sanitization			
6	2	2-102.11 Demonstration	2-102.11 Demonstration			
7	14	3-202.14 Eggs and Milk Products	3-202.14 Eggs and Milk Products			
8	28	3-401.11 Raw Animal Foods	3-401.11 Raw Animal Foods			
9	75	7-209.11 Storage (Personal Care Items)	7-209.11 Storage (Personal Care			
10	31	3-403.11 Reheating for Hot Hold	3-403.11 Reheating for Hot Hold			
11	45	4-501.112 Mech. Warewashing Equip. Water Sanitization Temp	4-501.112 Mech. Warewashing Equip. Water Sanitization Temp			
12	49	4-601.11 Equipment Food Contact Surfaces, Nonfood Contact Surfaces	4-601.11 Equipment Food Contact Surfaces, Nonfood Contact Surfaces			
13	47	4-501.114 Manual and Mech. Warewashing Equipment	4-501.114 Manual and Mech. Warewashing Equipment			
14	39	3-302.11 Packaged/Unpackaged Food, Separation and Storage	3-302.11 Packaged/Unpackaged Food, Separation and Storage			
15	94	3-801.11 Pasteurized Foods	3-801.11 Pasteurized Foods			

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Standard 1 – Regulatory Foundation Part I: Risk Factors and Interventions Side-By-Side Review of Food Code Sections



(Page 1-67 Standards Manual)

Part I – Interventions and Risk Factors

Part I – Interventions and Risk Factors									
Number of Sections Reviewed	Randomly Selected Number	Corresponding 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	23	3-202.18 Shellstock Identification	3-202.18 Shellstock Identification						
2	61	5-204.11 Handwashing Sinks	5-204.11 Handwashing Sinks						
3	18	3-201.16 Wild Mushrooms	3-201.16 Wild Mushrooms						
4	25	3-402.11 Parasite Destruction	3-402.11 Parasite Destruction	I					
5	48	4-501.115 Manual Warewashing Equipment, Chem Sanitization	4-501.115 Manual Warewashing Equipment, Chem Sanitization						
6	2	2-102.11 Demonstration	2-102.11 Demonstration						
7	14	3-202.14 Eggs and Milk Products	3-202.14 Eggs and Milk Products						
8	28	3-401.11 Raw Animal Foods	3-401.11 Raw Animal Foods						
9	75	7-209.11 Storage (Personal Care Items)	7-209.11 Storage (Personal Care Items)						
10	31	3-403.11 Reheating for Hot Hold	3-403.11 Reheating for Hot Hold						
11	45	4-501.112 Mech. Warewashing Equip. Water Sanitization Temp	4-501.112 Mech. Warewashing Equip. Water Sanitization Temp						
12	49	4-601.11 Equipment Food Contact Surfaces, Nonfood Contact Surfaces	4-601.11 Equipment Food Contact Surfaces, Nonfood Contact Surface						
13	47	4-501.114 Manual and Mech. Warewashing Equipment	4-501.114 Manual and Mech. Warewashing Equipment						
14	39	3-302.11 Packaged/Unpackaged Food, Separation and Storage	3-302.11 Packaged/Unpackaged Food, Separation and Storage						
15	94	3-801.11 Pasteurized Foods	3-801.11 Pasteurized Foods						
						-			

Standard 1 – Regulatory Foundation Verifying Results: Risk Factors and Interventions



(Page 1-65, Standards Manual)

- If ALL 15 selected provisions pass the audit process, the jurisdiction has successfully met the Standard 1 criteria for Part I.
- If 4 or more provisions were determined not to be as stringent as the FDA Food Code, the jurisdiction's self-assessment is determined not to have met the Standard 1 criteria

Standard 1 – Regulatory Foundation Verifying Results: Risk Factors and Interventions



(Page 1-65, Standards Manual)

- If 1, 2, or 3 disagreements you must verify if they still meet the requirements.
 - If 11/11 needed, they do not pass the audit
 - If 9/11 needed, go to the summary tables

Standard 1 – Regulatory Foundation Part I Worksheet: Risk Factors and Interventions



(Page 1-25, Standards Manual)

Standard 1: Regulatory Foundation Self-Assessment Worksheet

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

Food Code Section and Description	YES Standard Criteria Met	<u>NO</u> Standard Criteria Not Met	Self-Assessor's General Comments
1. Demonstration of Knowledge	X		
2. Employee Health	X		
3. Consumer Advisory		X	No consumer advisory provision
4. Approved Sources	X		
5. Time/Temperature	X		
6. Protection from Contamination	X		
7. Control of Hands as a Vehicle of Contamination	X		
8. Good Hygienic Practices	X		
9. Chemical	X		
10. Conformance with Approve Procedures	X		
11. Highly Susceptible Populations	X		

Assessment of ______indicates conformance with _____out of the 11 Intervention/Risk Factor Categories (regulatory agency) _____(# Met)

Standard 1 – Regulatory Foundation Part I Worksheet: Risk Factors and Interventions



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(Page 1-25, Standards Manual)

Standard 1: Regulatory Foundation Self-Assessment Worksheet

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

Food Code Section and Description	YES Standard Criteria Met	NO Standard Criteria Not Met	Self-Assessor's General Comments
1. Demonstration of Knowledge	X		
2. Employee Health	X		
3. Consumer Advisory		X	No consumer advisory provision
4. Approved Sources	X		
5. Time/Temperature		X	Chicken CL – 135F for 15 seconds
6. Protection from Contamination	X		
7. Control of Hands as a Vehicle of Contamination	X		
8. Good Hygienic Practices	X		
9. Chemical	X		
10. Conformance with Approve Procedures	X		
11. Highly Susceptible Populations	X		

Assessment of ______indicates conformance with ____out of the 11 Intervention/Risk Factor Categories (regulatory agency) (# Met)

Standard 1 – Regulatory Foundation Verifying Results: Risk Factors and Interventions



(Page 1-65, Standards Manual)

- If 3 or fewer provisions do not meet the stringency language criteria, and they meet the 9/11,
 - Randomly select an additional 15 FDA Food Code provisions
 - Follow same process as used for the original 15 provisions
 - A Supplemental Part I Worksheet is provided to record findings (Page 1-68, Standards Manual)
 - If a provision is selected in the second sampling that was also selected in the original set --- select a substitute (in sequence)

Standard 1 – Regulatory Foundation Verifying Results: Risk Factors and Interventions



(Page 1-65, Standards Manual)

- No more than three total disagreements are acceptable in the 30 Code sections drawn for comparison
- AND must meet the 9/11 despite disagreements.

Standard 1 – Regulatory Foundation Part I Worksheet: Risk Factors and Interventions



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(Page 1-25, Standards Manual)

Standard 1: Regulatory Foundation Self-Assessment Worksheet

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

Food Code Section and Description	YES Standard Criteria Met	<u>NO</u> Standard Criteria Not Met	Self-Assessor's General Comments
1. Demonstration of Knowledge	X		
2. Employee Health	X		
3. Consumer Advisory		X	No consumer advisory provision
4. Approved Sources	X		
5. Time/Temperature	X		
6. Protection from Contamination	X		
7. Control of Hands as a Vehicle of Contamination		X	Code allows for minimal bare hand contact with RTE food
8. Good Hygienic Practices	X		
9. Chemical	X		
10. Conformance with Approve Procedures	X		
11. Highly Susceptible Populations	X		

Assessment of ______indicates conformance with ____out of the 11 Intervention/Risk Factor Categories (regulatory agency) (# Met)

Standard 1 – Regulatory Foundation Verifying Results: Risk Factors and Interventions



(Page 1-25, Standards Manual)

Standard 1: Regulatory Foundation Self-Assessment Worksheet

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

Food Code Section and Description	YES Standard Criteria Met	NO Standard Criteria Not Met	Self-Assessor's General Comments
1. Demonstration of Knowledge	X		
2. Employee Health	X		
3. Consumer Advisory		X	No consumer advisory provision
4. Approved Sources	X		
5. Time/Temperature		X	Chicken CL – 135F for 15 seconds
6. Protection from Contamination	X		
7. Control of Hands as a Vehicle of Contamination		X	Code allows for minimal bare hand contact with RTE food
8. Good Hygienic Practices	X		
9. Chemical	X		
10. Conformance with Approve Procedures	X		
11. Highly Susceptible Populations	X		



Standard 1 Part II Good Retail Practices Verification Audit Process

Standard 1 – Regulatory Foundation Verifying Results: Good Retail Practices Random Selection of Provisions to Review



(Pages 1-69 thru I-70, Standards Manual)

- Total # of Provisions in Part II = 246
- Random Selection to include two sets of 13 numbers (primary and substitute sample sets)
 - May obtain random numbers from:
 <u>www.randomizer.org</u>

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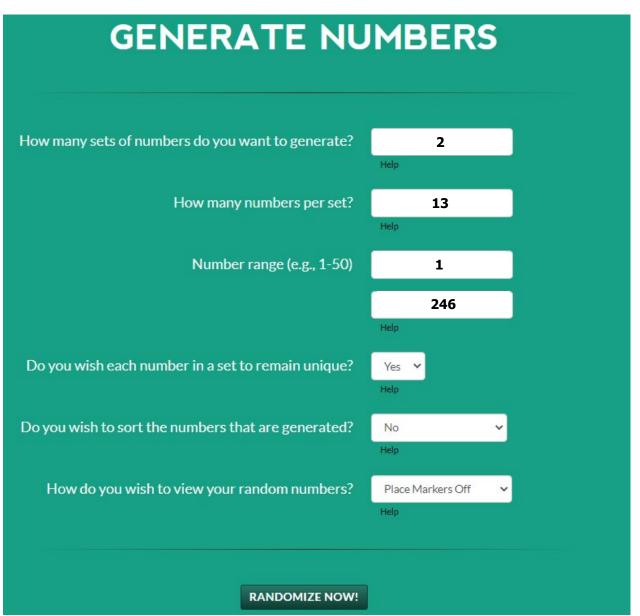


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Standard 1 – Regulatory Foundation Example Random Number Generation

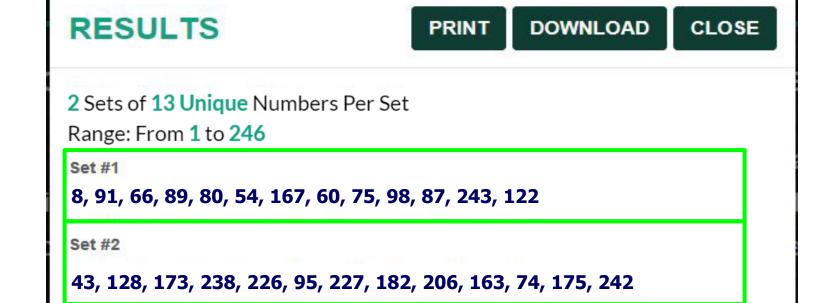


www.randomizer.org



Standard 1 – Regulatory Foundation Example Random Number Generation





Please note: By using this service, you agree to abide by the <u>SPN User Policy</u> and to hold Research Randomizer and its staff harmless in the event that you experience a problem with the program or its results. Although every effort has been made to develop a useful means of generating random numbers, Research Randomizer and its staff do not guarantee the quality or randomness of numbers generated. Any use to which these numbers are put remains the sole responsibility of the user who generated them.

Standard 1 – Regulatory Foundation Verifying Results: Good Retail Practices Random Selection of Provisions to Review



(Page 1-71, Standards Manual)

Part II - Good Retail Practices

Number of Sections Reviewed	Randomly Selected Number	Corresponding 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	8	3-202.19 Shellstock, Condition	3-202.19			
2	91	4-204.18 Warewashing Machine, Flow Pressure Device	4-204.18			
3	66	4-204.110 Molluscan Shellfish Tank				
4	89	4-204.116 Manual Warewashing	4-204.116			
5	80	4-602.13 Nonfood Contact Surf.	4-602.13			
6	54	4-202.12 CIP Equipment	4-202.12			
7	167	5-203.15 Backflow Prevention	5-203.15			
8	60	4-204.12 Equipment Openings	4-204.12			
9	75	4-501.11 Good Repair and Proper Adjustment	4-501.11			
10	98	4-501.14 Warewashing Equip., Cleaning Frequency	4-501.14			
11	87	4-204.114 Warewashing Machine, Internal Baffles	4-204.114			
12	243	6-202.16 Ext. Walls and Roofs, Protective Barrier	6-202.16			
13	122	4-901.11 Equipment and Utensils, Air Drying Req.	4-901.11			

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.
- If four or more of the 13 selected code sections do not meet the stringency of the language criteria in the Food Code, then the jurisdiction does not meet the Standard 1 criteria for Part II Good Retail Food Practices.



Standard 1 – Regulatory Foundation Example Random Number Generation



PRINT

DOWNLOAD

CLOSE

2 Sets of 13 Unique Numbers Per Set

Range: From 1 to 246

Set #1

8, 91, 66, 89, 80, 54, 167, 60, 75, 98, 87, 243, 122

Set #2

43, 128, 173, 238, 226, 95, 227, 182, 206, 163, 74, 175, 242

Please note: By using this service, you agree to abide by the <u>SPN User Policy</u> and to hold Research Randomizer and its staff harmless in the event that you experience a problem with the program or its results. Although every effort has been made to develop a useful means of generating random numbers, Research Randomizer and its staff do not guarantee the quality or randomness of numbers generated. Any use to which these numbers are put remains the sole responsibility of the user who generated them.

Standard 1 – Regulatory Foundation Verifying Results: Good Retail Practices Random Selection of Provisions to Review



(Page 1-71, Standards Manual)

Part II – Good Retail Practices

Number of Sections Reviewed	Randomly Selected Number	Corresponding 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	8	3-202.19 Shellstock, Condition	3-202.19	Х		
2	91	4-204.18 Warewashing Machine Flow Pressure Device	4-204.18	Х		
3	43	4-101.11 Characteristics	4-101.11	Х		
4	89	4-204.116 Manual Warewashing	4-204.116	Х		
5	80	4-602.13 Nonfood Contact Surf.	4-602.13	X		
6	54	4-202.12 CIP Equipment	4-202.12	х		
7	167	5-203.15 Backflow Prevention	5-203.15		Х	Only dual check valve required
8	60	4-204.12 Equipment Openings	4-204.12	Х		
9	75	4-501.11 Good Repair and Proper Adjustment	4-501.11	Х		
10	98	4-501.14 Warewashing Equip., Cleaning Frequency	4-501.14	х		
11	87	4-204.114 Warewashing Machine, Internal Baffles	4-204.114	Х		
12	243	6-202.16 Ext. Walls and Roofs, Protective Barrier	6-202.16	Х		
13	122	4-901.11 Equipment and Utensils, Air Drying Req.	4-901.11	x		

NOTES

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

Standard 1 – Regulatory Foundation Verifying Results: Good Retail Practices



(Page 1-70, Standards Manual)

 If ALL 13 selected provisions pass the audit process, the jurisdiction has successfully met the Standard 1 criteria for Part II

• If 4 or more provisions were determined not be as stringent as the FDA Food Code, the jurisdiction's self-assessment is determined not to have met the Standard 1 criteria

Standard 1 – Regulatory Foundation Verifying Results: Good Retail Practices



(Page 1-70, Standards Manual)

- If 1, 2, or 3 provisions do not meet the stringency language criteria, then randomly select an additional 13 FDA Food Code provisions
 - Follow same process as used for the original 13 provisions
 - Do not need to review their summary
 - A Supplemental Part II Worksheet is provided to record findings (Page 1-72, Standards Manual)
 - If a provision is selected in the second sampling that was also selected in the original set --- select a substitute (in sequence)

Standard 1 – Regulatory Foundation Verifying Results: Good Retail Practices



(Page 1-70, Standards Manual)

No more than **three** total disagreements are acceptable in the **26 Code sections** drawn for comparison



Standard 1 Part III Compliance & Enforcement Verification Audit Process

Standard 1 – Regulatory Foundation Verifying Results: Compliance and Enforcement



(Pages 1-73 thru 1-74, Standards Manual)

- Total # of Provisions in Part III = 12
- Random Selection to include one set of 5 numbers (only a primary set needed)
 - May obtain random numbers from: <u>www.randomizer.org</u>

Standard 1 – Regulatory Foundation Example Random Number Generation



RESULTS

PRINT

DOWNLOAD

CLOSE

1 Set of **5 Unique** Numbers

Range: From 1 to 12

Set #1

6, 4, 1, 3, 2

Please note: By using this service, you agree to abide by the <u>SPN User Policy</u> and to hold Research Randomizer and its staff harmless in the event that you experience a problem with the program or its results. Although every effort has been made to develop a useful means of generating random numbers, Research Randomizer and its staff do not guarantee the quality or randomness of numbers generated. Any use to which these numbers are put remains the sole responsibility of the user who generated them.

Standard 1 – Regulatory Foundation Verifying Results: Compliance and Enforcement



(Page 1-75, Standards Manual)

Part III – Compliance and Enforcement

Рагі III – Сотриансе ана Елиогсетені									
Number of Sections Reviewed	Randomly Selected Number	Corresponding 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	6	8-201.13 When a HACCP Plan is Required	8-201.13	х					
	Ü								
2	4	8-402.20 Refusal, Notification of Right to Access, and Final Request for Access	8-402.20	x					
	1	8-901.10 Conditions Warranting Remedy	8-901.10	x					
3		8-903.10 Hold Order, Justifying Conditions and Removal of Food	8-903.10	x					
		8-903.30 Hold Order, Contents	8-903.30	х					
		8-201.11 When Plans are Required	8-201.11	Х					
4	3								
		8-301.11 Prerequisite for Operation	8-301.11	Х					
5	2	8-304.20 Permits Not Transferable	8-304.20	х					

Standard 1 – Regulatory Foundation Verifying Results: Compliance and Enforcement



(Page 1-74, Standards Manual)

- If ALL 5 selected provisions pass the audit process,
 the jurisdictions has successfully completed Part III
- If 1 or more provisions were determined not to be as stringent as the FDA Food Code, the jurisdiction's self-assessment is determined not to have met the Standard 1 criteria
- Note: exceptions for 7 variances and 12- penalties

Standard 1 – Regulatory Foundation Verifying Results Summary



(Pages 1-2 and 1-3, Standards Manual)

- Part I 9 out of the 11 Interventions and Risk Factor Controls must have been met
 - (11/11 after 3rd Verification Audit)
- Part II 95% of the Good Retail Practices provisions must be included in the jurisdiction's Food Code
- Part III ALL 12 of the Compliance and Enforcement categories must have been met

Standard 1 – Regulatory Foundation Verifying Results



(Pages 1-7 thru 1-10, Standards Manual)

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 that it has performed a side-by-side comparison of its prevailing statutes, regulations, rules, and other pertinent requirements against the current published edition of the FDA Food Code or one of the two most recent previous editions of the FDA Food Code.	×			×		
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.	×			×		

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Standard 1 – Regulatory Foundation



(Clearinghouse Std. 1 #1 State Interpretation of When Otherwise Approved vs. Intent of *Food Code*)

Response from Clearinghouse Work Group (02-20-02)

The jurisdiction has adopted the language in Section 3-301.11 verbatim. For this specific provision, the jurisdiction is in compliance with the assessment criteria contained in Standard No. 1.

The language of Standard No. 1, in both the 'Requirement Summary' and the 'Description of Requirement' states that a jurisdiction's regulation, rule, or ordinance must have a provision as least as stringent as the specified provisions of the Food Code. According to the information provided, the jurisdiction has adopted 3-301.11 of the 1999 version verbatim.

That meets the stated requirement of Standard No. 1 for the item in question.

The language of 3-301.11 includes a phrase 'Except . . . as otherwise approved." FDA originally anticipated that jurisdictions approving alternatives to the 'no bare hands contact with ready-to-eat foods' provision would approve those alternatives that could convincingly address the hazards of fecal/oral contamination and would provide effective management controls to ensure protection of the food. This phrase was intended to allow some flexibility for innovative ideas or advancing technology that might not be foreseen. It was not anticipated that the phrase would be used as a blanket approval for 'business as usual.'

Later, FDA provided guidance in Annex 3 regarding the kinds of criteria to be used when approving alternative controls to 'no bare hand contact.' Standard No. 1 language does not include adherence to guidance or Annex 3 as a condition of meeting the Standard. While the Work Group agrees that the jurisdiction is not meeting the spirit of that provision of the Food Code, it has adopted the regulatory language necessary to protect the public health, which was the goal of Standard 1. It is in the implementation of the regulatory language where the failure occurs. This failure to meet the spirit of the Code cannot be addressed through Standard No. 1. This appears to be a gap in the Standards that was not foreseen and may well need to be addressed. The Standards will doubtless evolve over time with changes and/or additions as stakeholders gain experience and knowledge through their use.

STANDARD 1 VERIFICATION AUDIT QUESTIONS





Standard 2 Trained Regulatory Staff

Review Employee Training Files Exercise

Instructions



- 1. Employee training files and a template for Standard 2 File Review Exercise were sent to everyone yesterday afternoon.
- 2. As the auditor, you will be reviewing each employee training file to verify if it meets Standard 2 components.
- 3. Breakout will be set for 30 minutes, followed by report out please identify a spokesperson.

Note on the employee files: if a record is listed 'on file' then assume the record exists and is adequate.

Standard 2 File Review Exercise Template



Standard 2 File Review Exercise

Steps	Billie Sims	Joseph Pruitt	Richard Bryan	Steven Owens	Sue Scooner
1. "Pre"					
curriculum					
2. Joint					
inspections					
3. Independent					
Inspections					
4. Standardization					
5. 20 Contact					
Hours					
Meets (Yes/No)					

Word document provided to assist groups with their file review.





Steps	Billie Sims	Joseph Pruitt	Richard Bryan	Steven Owens	Sue Scooner
1. "Pre" curriculum	Option 2: Waiver based on REHS	Option 1: Certificates of completion	Option 1: Certificates of completion	Option 2: Affidavit	Option 1: Certificates of completion
2. Joint inspections	Affidavit	Missing	Missing	Waiver	Records 2/2/17 to 3/11/17
3. Independent Inspections	Waiver based on experience	Records 2/15/22 to 8/5/22	Missing	Waiver	Records 2/2/17 to 3/1/17
4. Standardization	Certificate 10/11/23	Certificate 1/2/23	Certificate 1/5/23	Certificate 12/22/23	Re- <u>stdz</u> due 4/21/23
5. 20 Contact Hours	20 CEs documented	36 CEs documented	Pending (due 1/4/26)	Pending (due 12/21/26)	32 CEs documented
Meets (Yes/No)	No	No	No	No	No

Billy Sims- A waiver of the pre & post curriculum training is not valid based solely on REHS credential. (Clearinghouse Std 2 #8, pg 47) **Joseph Pruitt**- Joint inspections missing.

Richard Bryan- Joint and independent inspections missing.

Steven Owens- Used Option 2 for required coursework, no documentation of passing 1 of 4 written exam options, no documentation of training on the jurisdiction's prevailing statutes, regulations and/or ordinances. (Program Standards manual pg 2-3)

Sue Scooner- Re-standardization certificate not provided.

STANDARD 2 EXERCISE QUESTIONS





Standard 1 Regulatory Foundation

Food Code Language Review Exercise

Instructions



- 1. Standard 1 Verification Audit Exercise were out yesterday afternoon (with Standard 2 exercises).
- As the auditor, you will be reviewing the selfassessor's Food Code language and doing a sideby-side comparison with the 2022 FDA Food Code.
- 3. Breakout will be set for 30 minutes, followed by report out please identify a spokesperson.

STANDARD 1 EXERCISE QUESTIONS





Standard 6 Compliance & Enforcement

Preparation for the Verification Audit

Preparing for the Standard 6 Verification Audit



Source Documents

- Copy of Program Standard 6
- Clearinghouse Interpretations
- Jurisdiction's Self-Assessment Verification Audit Form
- Inspection Form
- Step-by-step compliance and enforcement procedures
 - Include policies or interpretations that carry the same weight as compliance and enforcement steps
- Inspection Form
- Reference key which identifies risk factors and interventions on inspection form

Preparing for the Standard 6 Verification Audit



Source Documents

- Documentation that compliance and enforcement action was followed for >80% of sampled establishments
- The inspection history and reports for randomly selected establishment files
- If using Option 3,
 - Written review process, including random selection, and
 - Documentation of equivalence to the "Explanation of the Statistical Model for Standard 6" from a statistician.

Preparing for the Standard 6 Verification Audit



Forms and Worksheets

http://www.fda.gov/retailprogramstandards



Standard 6: Compliance and Enforcement

- Standard 6 (PDF: 86KB)
- Standard 6 Self-Assessment and Verification Audit Form (PDF: 826KB)
- Standard 6 Self-Assessment Instructions and Worksheet (PDF: 1.1MB)
- Standard 6 Verification Audit Instructions and Worksheet (PDF: 720KB)
- Standard 6 Explanation of Statistical Model (PDF: 87KB)
- Standard 6 Establishment File Summary (PDF: 614KB)
- Standard 6 Quick Reference Applicable Food Code Risk Factor Provisions (PDF: 123KB)



Standard 6 Compliance & Enforcement

Conducting the Verification Audit

Standard 6 Compliance & Enforcement



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

Standard 6 – Compliance and Enforcement Verify Effectiveness of Program



(Pages 6-27 thru 6-31, Standards Manual)

- Step 1: Verify the elements in the written compliance and enforcement plan
 - Written step-by-step procedure
 - How to use compliance and enforcement tools
 - Clear guidance for staff
 - Steps and actions depending on categories of violations
 - Progression when violations are not corrected w/in timeframes
 - Inspection form uses IN, OUT, NO, NA

Standard 6 – Compliance and Enforcement Verify Effectiveness of Program



(Pages 6-27 thru 6-31, Standards Manual)

- Step 2: Verify the effectiveness of the compliance and enforcement program
 - 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 Worksheet
 - PART III: Verify Self-Assessment findings for each selected establishment file
 - PART IV: Verify that 80% of selected establishment files meet the jurisdiction's written compliance and enforcement program



Standard 6—Compliance and Enforcement

Part I – Verify the jurisdiction reviewed the appropriate number of files

(Page 6-28, Standards Manual)

Standard 6 – Compliance and Enforcement Part I – Verify the jurisdiction reviewed the appropriate number of files



(Page 6-28, Standards Manual)

- Option 1: Did they review all files?
- Option 2: Did they review the number of files outlined in the table?

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)			

 Option 3: Did the review the number of files in the model outlined by their statistician?



Standard 6—Compliance and Enforcement

Part II – Randomly select establishment files from the jurisdiction's Self-Assessment Worksheet

(Page 6-29, Standards Manual)



Standard 6 – Compliance and Enforcement File Sampling for the Verification Audit

(Page 6-29, Standards Manual)

Jurisdiction's Establishment Inventory	Number of Files Included in the Jurisdiction's Self-Assessment	Number of Files to be Selected 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





(Page 6-29, Standards Manual)

Example:

- 820 establishments in the inventory.
- Self-Assessor reviewed 41 randomly selected files
- Auditor will need review 10, based on the table.

Standard 6 – Compliance and Enforcement FDA



File Sampling for the Verification Audit

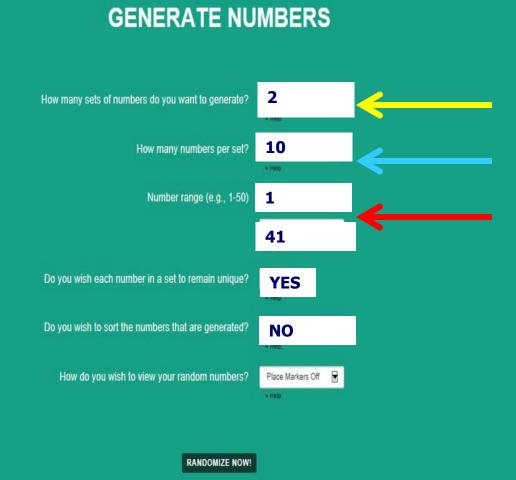
www.randomizer.org

RESULTS CLOSE DOWNLOAD PRINT **2** Sets of **10** Unique Numbers Per Set Range From 1 to 41 Set #1 15, 11, 17, 20, 3, 5, 8, 19, 22, 4 Set #2 13, 7, 21, 18, 12, 40, 36, 32, 1, 27, Please note: By using this service, you agree to abide by the SPN User Policy and to hold Research Randomizer and its staff harmless in the event that you experience a problem with the program or its results. Although every effort has been made to develop a useful means of generating random numbers, Research Randomizer and its staff do not guarantee the quality or randomness of numbers generated. Any use to which these numbers are put remains the sole responsibility of the user who generated them.

Standard 6 – Compliance and Enforcement File Sampling for the Verification Audit



www.randomizer.org



Standard 6 – Compliance and Enforcement



Part II – Conducting a Random Selection of Establishment Files for Audit

(Page 6-29, Standards Manual)

Standard 6: Compliance and Enforcement Verification Audit Worksheet Establishment Files

Jurisdiction Name: Desert County Health Department, AZ

	SELECTED	ESTABLISHMENT FILES			AUDITOR'S VERIFICATION				
Number of Files Reviewed	Randomly Selected Number	Corresponding Name or ID of Establishment Selected From the Jurisdiction's Self-Assessment Summary Worksheet	YES	NO	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 procedure				
1	15	07392-Only Turf, No Surf Meats							
2	11	07213-East Side Hospital			Selected Establishment was marked "NO" on Self-Assessment Summary Worksheet-Substitute Est-Park Place Produce				
3	17	07351-Appetizing Aromas							
4	20	07016-Desert Dogs							
5	3	07335-Cactus Flower Restaurant							
6	5	07101-Desert Flavors							
7	8	07126-Oleander Market			Establishment "DNQ" for the Std 6 review criteria. Use the jurisdiction substitute establishment "Survival Food for audit review.				
8	19	07232-Happy Feet Nursing Home							
9	22	07441-Jo-Dan's <u>Road Kill</u> Grill							
10	4	07448-Try It-You'll Like It Diner							

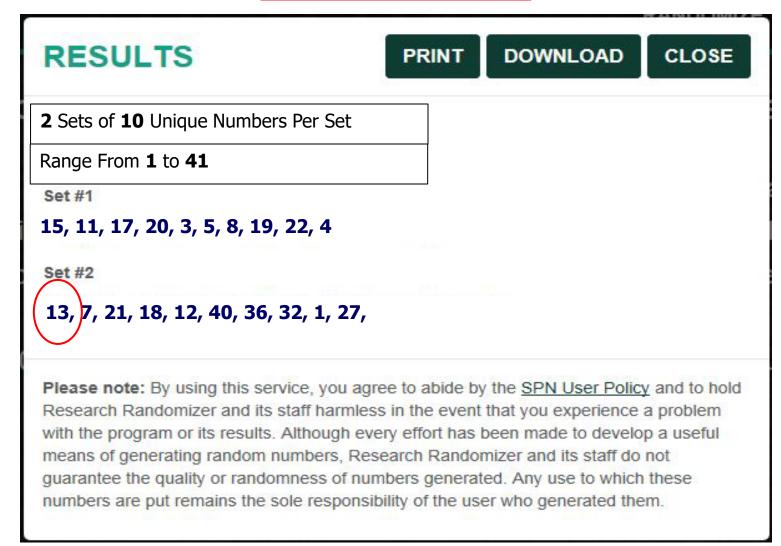
If needed, record information pertaining to substitute establishment files below

Standard 6 – Compliance and Enforcement FDA



File Sampling for the Verification Audit

www.randomizer.org



Standard 6 – Compliance and Enforcement



Part II – Conducting a Random Selection of Establishment Files for Audit

(Page 6-29, Standards Manual)

Standard 6: Compliance and Enforcement Verification Audit Worksheet Establishment Files

Jurisdiction Name: Desert County Health Department, AZ

	SELECTED	ESTABLISHMENT FILES			AUDITOR'S VERIFICATION			
Number of Files Reviewed	Randomly Selected Number	Corresponding Name or ID of Establishment Selected From the Jurisdiction's Self-Assessment Summary Worksheet	YES	NO	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 procedure			
1	2	0724 – Palo Verde Cafe						
2	11	07213-East Side Hospital			Selected Establishment was marked "NO" on Self-Assessment Summary Worksheet-Substitute Est-Park Place Produce			
3	17	07351-Appetizing Aromas						
4	20	07016-Desert Dogs						
5	3	07335-Cactus Flower Restaurant						
6	5	07101-Desert Flavors						
7	8	07126-Oleander Market			Establishment "DNQ" for the Std 6 review criteria. Use the jurisdiction substitute establishment "Survival Food for audit review.			
8	19	07232-Happy Feet Nursing Home						
9	22	07441-Jo-Dan's <u>Road Kill</u> Grill						
10	4	07448-Try It-You'll Like It Diner						
	If needed, record information pertaining to substitute establishment files below							
1	13	07234-Park Place Produce			Sub for 07213-East Side Hosp listed as "NO" on SA Summary Worksheet			
2		07020-Survival Foods			Sub for 07216-Oleander Manor listed as "DNQ" on SA Summary Worksheet			



Standard 6 – Compliance and Enforcement

Part III – Verify the Self-Assessment Findings for each Selected Establishment

Follow the Same Establishment File Review Process as Presented for the Self-Assessment

(Page 6-30, Standards Manual)

Standard 6 Compliance & Enforcement Establishment File Worksheet

FDA

(Page 6-35, Standards Manual)

STANDARD 6: COMPLIANCE AND ENFORCEMENT ESTABLISHMENT FILE WORKSHEET

0.00				Risk Fact	or and Food	d Code Inter	ventions			
	Unsafe Sources	Inadequate Cooking	Improper Holding Temperatures Hot & Cold	Time/ Temperature Parameters Not Met (Time as a Control, date marking, rapid cooling)	Bare Hand Contact with Ready-to-Eat Food	Poor Personal Hygiene	Contaminated Food Contact Equipment	Consumer Advisory (when required)	Demonstration of Knowledge by PIC	Employee Health Control System or Policy Implemented
Reference to local inspection items	1	2,34,5	6,7	8,11	13	14	15	NA	NA	NA
Start Point Inspection Violations		х		×	х	х				
Was on-site corrective action taken?		YES (R,H)		YES(R,H)	YES(GLV)					
Was follow-up corrective action taken?				YES (RCP)		YES(TR)				
Was enforcement action taken?		YES(WL)								
Note:										7,,,

Jurisdiction's definitions of acronyms and notations used to reflect follow-up action

Acronym /Notation	Definitions	Acronym /Notation	Definitions	Acronym/Notation	Definitions
RH	Reheat to Safe Temp	EM	Embargo		
RCP	Risk Control Plan	TR	Training Required		
WL	Warning Letter Sent	GLV	Implement Glove Use		

Was the Written Procedure Followed? X YES NO

File Meets the Standard 6 Criteria: X YES NO

Standard 6 – Compliance and Enforcement



Part II – Conducting a Random Selection of Establishment Files for Audit

(Page 6-32, Standards Manual)

Standard 6: Compliance and Enforcement Verification Audit Worksheet Establishment Files

Jurisdiction Name: Desert County Health Department, AZ

	SELECTED	ESTABLISHMENT FILES	AUDITOR'S VERIFICATION					
Number of Files Reviewed	Randomly Selected Number	Corresponding Name or ID of Establishment Selected From the Jurisdiction's Self-Assessment Summary Worksheet	YES	NO	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 procedure			
1	2	0724 – Palo Verde Cafe	X					
2	11	07213-East Side Hospital			Selected Establishment was marked "NO" on Self-Assessment Summary Worksheet-Substitute Est-Park Place Produce			
3	17	07351-Appetizing Aromas	x					
4	20	07016-Desert Dogs	X					
5	3	07335-Cactus Flower Restaurant	X					
6	5	07101-Desert Flavors	X					
7	8	07126-Oleander Market			Establishment "DNQ" for the Std 6 review criteria. Use the jurisdiction substitute establishment "Survival Food for audit review.			
8	19	07232-Happy Feet Nursing Home	X					
9	22	07441-Jo-Dan's <u>Road Kill</u> Grill	x					
10	4	07448-Try It-You'll Like It Diner	x					
	If needed, record information pertaining to substitute establishment files below							
1	13	07234-Park Place Produce	x		Sub for 07213-East Side Hosp listed as "NO" on SA Summary Worksheet			
2		07020-Survival Foods	x		Sub for 07216-Oleander Manor listed as "DNQ" on SA Summary Worksheet			



Standard 6 – Compliance and Enforcement

Part IV – Verify the Selected Establishment Files Adhere to the Jurisdiction's Written Compliance and Enforcement Procedures

(Pages 6-30 thru 6-31, Standards Manual)

Standard 6 – Compliance and Enforcement Verification Audit Results



(Pages 6-30 thru 6-31, Standards Manual)

Jurisdiction with Less Than 800 Establishments

The verification auditor initially randomly selects **5** establishment files to review

- If <u>ALL 5</u> establishment files pass the audit process, the jurisdiction meets the Standard 6 criteria
- If <u>2 or more</u> establishment files were determined not to meet all the compliance and enforcement criteria, the jurisdiction's self-assessment does not meet the Standard 6 criteria

Standard 6 – Compliance and Enforcement Verification Audit Results



(Pages 6-30 thru 6-31, Standards Manual)

Jurisdiction with Less Than 800 Establishments

If <u>1 establishment file</u> does not meet the Standard 6 compliance and enforcement criteria, then randomly select an additional <u>5</u> establishment files

- Follow same process as used for the original 5 files
- Verification Audit Worksheet used to record findings for establishment files (Pages 6-32 thru 6-34, Standards Manual)
- If a file is selected in the selected sampling that was also selected in the original set—select a substitute





(Pages 6-30 thru 6-31, Standards Manual)

Jurisdiction with Less Than 800 Establishments

- If **NO additional disagreements** in the review of the second set of 5 establishment files are noted, then the jurisdiction meets the Standard 6 criteria.
- If <u>1 or more</u> of the additional establishment files fails the audit review, then the Standard 6 criteria is not met. (2 or more total)

Standard 6 – Compliance and Enforcement Verification Audit Results



(Pages 6-30 thru 6-31, Standards Manual)

Jurisdiction with 800 Establishments or More

The verification auditor initially randomly selects **10** establishment files to review

- If <u>ALL 10</u> establishment files pass the audit process, the jurisdiction meets the Standard 6 criteria
- If <u>3 or more</u> establishment files were determined not to meet all the compliance and enforcement criteria, the jurisdiction's self-assessment does not meet the Standard 6 criteria





(Pages 6-30 thru 6-31, Standards Manual)

Jurisdiction with 800 Establishments or More

If **1 or 2 establishment files** do not meet the Standard 6 compliance and enforcement criteria, then randomly select an additional **10** establishment files

- Follow same process as used for the original 10 files
- Verification Audit Worksheet used to record findings for establishment files (Pages 6-32 thru 6-34, Standards Manual)
- If a file is selected in the selected sampling that was also selected in the original set --- select a substitute





(Pages 6-30 thru 6-31, Standards Manual)

Jurisdiction with 800 Establishments or More

- No more than a total of two of the 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, the Standard 6 criteria is not met

Standard 6 – Compliance and Enforcement Verification Audit Results



(Page 6-7, Standards Manual)

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

Jurisdiction Name:

Program Elements	Criteria	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.	X			X		
1. Compliance and Enforcement Procedure	b) The jurisdiction's inspection form(s) record and quantify the compliance status of foodborne illness risk factors, Food Code interventions and other serious code violations.	X			X		
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.	X			X		



Participant Manual

Standard 6

Question 9

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Standard 6 – Compliance and Enforcement File Sampling for the Verification Audit

(Page 6-28, Standards Manual)

Jurisdiction's Establishment Inventory	Number of Files Included in the Jurisdiction's Self-Assessment	Number of Files to be Selected 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



Participant Manual

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STANDARD 6 VERIFICATION AUDIT QUESTIONS

