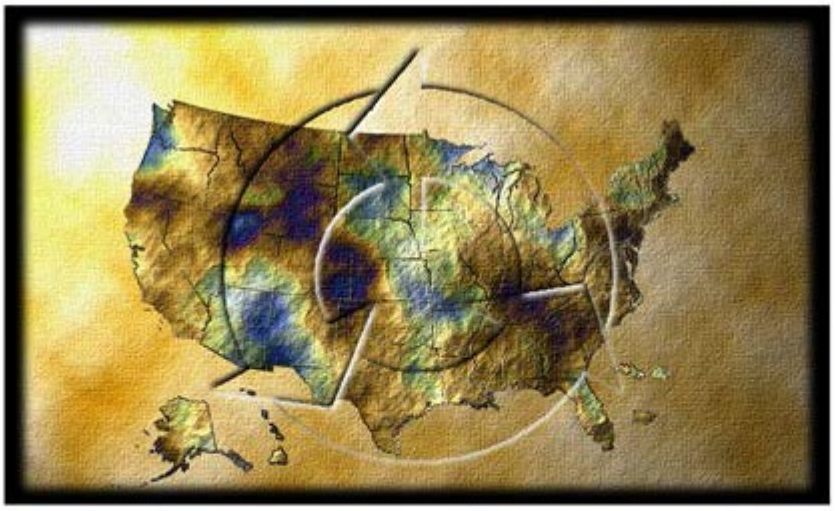
Voluntary National Retail Food Regulatory Program Standards



"Standards of Excellence for Continual Improvement"

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

2022
Administrative Procedures

U.S. Department of Health and Human Services

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

PAPERWORK REDUCTION ACT OF 1995

This document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The time required to complete this information collection is estimated to average 94.29 annual hours per recordkeeper for each enrolled jurisdiction to complete the management tasks for recordkeeping for self-assessment, risk factor study, and verification audit. FDA estimates a total of 30 minutes annually for each enrolled jurisdiction to complete the following: FDA Form 3598, ``FDA National Registry Report," and "Documentation of Successful Completion – Field Training Process" forms. FDA's recordkeeping and reporting burden estimate includes time required for a state, local, or tribal agency to review the instructions in the Program Standards, compile information from existing sources, and create any records recommended in the Program Standards that are not already kept in the normal course of the agency's usual and customary activities. Worksheets are provided to assist in this compilation. Send comments regarding this burden estimate or suggestions for reducing this burden to: Office of Food Safety, Retail Food Protection Staff, (HFS-320), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0621 (expires 09-30-2023).

COMMENTS AND INQUIRIES

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

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

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

Overview of the Program Standards

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

Purpose of this Document

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

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

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

Enrolling in the Program Standards

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

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

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

Upon submission of the completed enrollment form, FDA will add the jurisdiction to its on-line *Listing of Jurisdictions Enrolled in the Voluntary National Retail Food Regulatory Program Standards* at https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/listing-jurisdictions-enrolled-voluntary-national-retail-food-regulatory-program-standards. The listing is organized by State and contains basic information about the jurisdiction, the key contact person, and the Retail Program Standards milestones achieved by the jurisdiction.

Maintenance in the Retail Program Standards

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

1. Periodically assess its program using the criteria in the nine Retail Program Standards;

2. Have its self-assessment verified by an independent audit (for Standards that the jurisdiction reports meeting); and

3. Report the status of the program self-assessment and verification audit to FDA.

Conducting the Self-Assessment

Description of the Self-Assessment

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

Frequency of the Self-Assessment

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

1. Within 12 months of the date of enrollment; and

2. Following the initial self-assessment, the complete self-assessment cycle must be repeated at a minimum every 60 months.

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

Required Documents for the Self-Assessment

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

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

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

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

Documenting the Assessment of Individual Standards

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

1. Complete the corresponding worksheets. Alternatively, provide documents containing equivalent summary information for that Standard in preparation of the verification audit; and

2. Establish, identify, and maintain quality records specified as requirements in each of the Retail Program Standards. The quality records must be maintained in such a manner that an auditor can be provided information necessary to verify that a Standard's criteria have been met.

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

Verifying the Self-Assessment

Description of the Verification Audit

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

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

Frequency of the Verification Audit

The program manager, or a designated representative, must request a verification audit within three (3) months of the completion of the self-assessment or self-assessment update in which one or more Standard(s) is claimed as met. The verification audit must be completed within six (6) months of that self-assessment or self-assessment update.

Verification audits shall be conducted at the following frequency:

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

2. After each subsequent self-assessment (conducted every 60 months) if the jurisdiction claims conformance with one or more Standards.

Selecting an Auditor

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

Role of the Auditor during the Verification Audit

During the verification audit, the auditor will:

1. Review the quality records and confirm that the self-assessment accurately reflects the program's achievement status with each criterion for the version of the Retail Program Standards that was used when completing the self-assessment or a self-assessment update;

2. Determine if the quality records specified as requirements in each of the Retail Program Standards have been established, identified, and maintained. If the quality records for a

specific program element provide inadequate information upon which to make a determination of conformance with the Standard or to enable a verification audit, that Standard is not met; and

3. In instances where the auditor determines that the jurisdiction does not conform with the Standard(s), review the reasons for the non-conforming finding with the Program Manager and identify the elements necessary for the jurisdiction to meet the Standard.

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

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

Timeframe for Reporting Results from a Self-Assessment or Verification Audit
The program manager, or a designated representative, must report the status of the self- assessment, self-assessment update, and the verification audit to their FDA Retail Food Specialist:

1. within 30 days following a self-assessment (regardless of whether any Standard(s) are claimed as met);

2. within 30 days following a self-assessment update (only if the achievement status for a Standard has changed); and

3. within 30 days following any verification audit.

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

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

Dispute Resolution Process for Non-Conforming Audits

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

Report Results of a Non-Conforming Audit

1. If a verification audit does not confirm the results of a self-assessment for one or more of the Standards, it is the jurisdiction's responsibility to contact their FDA Retail Food Specialist within ten business days of the close of the audit. The jurisdiction and the FDA Retail Food Specialist must discuss the steps necessary to reconcile any discrepancies and to establish a correction plan if

it wishes to retain the self-reported information on the national web listing or to remove any incorrect self-reported data.

2. An action plan and timeline for correcting any element deficiencies must be developed by the jurisdiction. The plan should include specific milestones to ensure that the full criteria can be met by an established target date, not to exceed one year. The jurisdiction must review the plan and timeline with the FDA Retail Food Specialist.

3. The results of the jurisdiction's self-assessment remain on the *Listing of Jurisdictions Enrolled in the Voluntary National Retail Food Regulatory Program Standards* during the correction period identified in the Action Plan.

4. If the jurisdiction does not wish to institute an action plan with milestones for correcting deficiencies, the listing will be changed to reflect the results of the verification audit. The jurisdiction can then work without time constraints to meet any non-confirmed standards and submit a new *FDA National Registry Report* (FDA Form 3958) when the standard is achieved.

Dispute Resolution

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

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

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

Written Request for Assistance

1. A jurisdiction seeking the assistance of the Clearinghouse must submit a request in writing to the Clearinghouse. Contact information for the Standards Clearinghouse is provided below. The request must include an explanation of the issues in dispute or interpretations in question, and a copy of the verification audit report. The jurisdiction may include any supporting information relevant to the results of the self-assessment or verification audit. The written request must be made within 30 calendar days of the close of the audit.

2. The Clearinghouse Chair will inform the auditor of the jurisdictions request. The auditor may also supply additional written materials within 30 calendar days from the time they are notified.

Assistance Process

1. The Clearinghouse will set a date and time to hear the facts from each side via conference call.

2. The jurisdiction and the auditor will be provided the opportunity to speak in support of the materials they submitted in writing. Clearinghouse members may ask questions of each side.

3. The Clearinghouse will then confer in private before providing clarification on the issue.

Decisions

1. After conferring in private, the Clearinghouse will provide a written response to the jurisdiction and the auditor within 10 business days following the conference call.

2. The interpretation of the Clearinghouse panel is final.

Retail Food Program Standards Clearinghouse Contact

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

Phone: 240-402-1943
Fax: 301-436-2672
E-Mail: robert.sudler@fda.hhs.gov

Submit by Email | Print Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Voluntary National Retail Food Regulatory Program Standards

FDA NATIONAL REGISTRY REPORT

Form Approved
OMB Number 0910-0621
Expiration Date: 09/30/2023
(See Public Reporting Burden Statement on page 2.)

1. Information about the Jurisdiction

Name of Jurisdiction Reporting This Information	Address		
	City	State	ZIP Code
Contact Person for Jurisdiction	Title for Contact Person	Phone Number for Jurisdiction's Contact Person	
Website Link for Jurisdiction		Jurisdiction is willing to serve as an auditor for another jurisdiction: ☐ Yes ☐ No	
E-Mail Address for Jurisdiction's Contact Person			

2. Information about Enrollment

Enrollment Date (DD/MM/YYYY)

☐ **Please enroll this jurisdiction in the Retail Program Standards**

☐ **Please remove this jurisdiction from the *Listing of Enrolled Jurisdictions***

☐ **Update Results for the** **Self-Assessment.**

☐ **Other - Please explain**

3. Information about Self-Assessment Findings and Verification Audit Findings

Completion Date for Self-Assessment

Instructions for Completing this Section
*** If the jurisdiction's self-assessment indicates conformance with any Standards, please mark the applicable Standards. Only enter a date if it differs from that of the self-assessment completion date (i.e. a self-assessment update was conducted)*
**** If the jurisdiction's verification audit confirms conformance with any Standards, please mark the applicable Standards **and** indicate the completion date.*
***** All dates should be entered in the MM/DD/YYYY format.*

Program Standard Number	**Self-Assessment**** Program Standard Met *(Mark all that apply)*	**Verification Audit***** Verification Audit Confirmed *(Mark all that apply and enter the date confirmed for each)*
1	☐	☐
2	☐	☐
3	☐	☐
4	☐	☐
5	☐	☐
6	☐	☐
7	☐	☐
8	☐	☐
9	☐	☐

4. Permission to Publish Information on the FDA Website

Permission is granted to publish the following information in the *Listing of Jurisdictions Enrolled in the Voluntary National Retail Food* Regulatory *Program Standards:*

☐ Enrollment information ☐ Self-assessment findings ☐ Verification audit findings

Authorized Individual *(Printed)*	Title	Date *(mm/dd/yyyy)*

Instructions for Completing FDA National Registry Report - Form 3958

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

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

Part 1: Information about the Jurisdiction

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

Part 2: Information about Enrollment

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

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

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

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

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

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

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

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

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

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

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Do not send your completed form to the PRA Staff email address to the left.

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