Manufactured Food Regulatory Program Standards

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INTRODUCTION

The Food Safety Modernization Act (FSMA) mandates that the Food and Drug Administration (FDA) establish an Integrated Food Safety System (IFSS). An IFSS requires partnerships between federal, state, local, and tribal agencies to collaborate and leverage resources to ensure the protection of public health.

The Manufactured Food Regulatory Program Standards (MFRPS) is a critical component in establishing FDA's IFSS. The MFRPS (henceforth also referred to as ("program standards") establishes a uniform foundation for regulatory agencies responsible for oversight of food manufacturing plants. When fully implemented, the program standards define a set of best practices of a regulatory system.

Conformance with the program standards requires a regulatory agency to continuously assess, evaluate, and take necessary corrective actions to address gaps. MFRPS conformance will facilitate a system of mutual reliance between the FDA and other regulatory agencies and support continued improvements in regulatory manufactured food programs throughout the nation.

The program standards are comprised of ten standards that establish requirements for the critical elements of a regulatory program designed to protect the public from foodborne illness and injury. These elements include the program's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. Each standard contains a purpose statement, requirement summary, description of program elements, projected outcomes, and a list of required documentation. The program standards have corresponding self-assessment and supplemental worksheets designed to assist the regulatory program in achieving and sustaining conformance.

FDA will use the program standards as a tool to continuously improve manufactured food contracts and promote the development of a high-quality state manufactured food regulatory program which includes a process for continuous improvement based upon quality management systems. The program standards will assist both FDA and the states in fulfilling their regulatory obligations. States will be expected to develop and implement improvement plans to demonstrate that they are moving toward full implementation and to participate in FDA audits to determine level of conformance. States are encouraged to build sustainable systems including sustainability strategies and plans that will result in the standards being maintained in conformance.

The goal of the MFRPS is to implement a nationally integrated, risk-based, food safety system focused on protecting public health. The program standards establish a uniform basis for measuring and improving the performance of prevention, intervention, and response activities of manufactured food regulatory programs in the United States. The development and implementation of these program standards will help federal and state programs better direct their regulatory activities toward reducing foodborne illness hazards in food plants. Consequently, the safety and security of the United States food supply will improve as greater focus is placed on prevention.

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BACKGROUND

The food safety regulatory system in the United States is a tiered system that involves Federal, state, and local governments. The Food and Drug Administration (FDA) is responsible for ensuring that all foods moving in interstate commerce, except those under United States Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. State agencies conduct inspection and regulatory activities that help ensure food produced, processed, or sold within their jurisdictions is safe. Many state agencies also conduct food plant inspections under contract with the FDA. These inspections either are performed under the states' laws and authorities or the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or both. To maximize the use of resources among the FDA and the states, particularly when their jurisdictions overlap, their inspection programs should be equivalent in effect.

In June 2000, the Department of Health and Human Services', Office of the Inspector General (OIG) released a report of FDA's oversight of state contracts. In this report, the OIG recommended that [FDA] take steps to promote "equivalency among Federal and State food safety standards, inspection programs, and enforcement practices.[1] In response to their findings, FDA established a committee to develop a set of quality standards for manufactured food regulatory programs. The committee was comprised of officials from FDA and state agencies responsible for regulating manufactured food plants[2]. The result of the committee was the first edition of the program standards published by FDA in 2007.

In January 2011, FSMA gave the FDA authority to develop a framework to build the capacity of state and local regulatory agencies to support the IFSS model. In 2012, the FDA created the Standards Implementation Staff to give assistance, support and guidance to state programs enrolled in the MFRPS. Additionally, FDA helped establish the Manufactured Food Regulatory Program Standards (MFRPS) Alliance to create a network of state programs and assist with further development and revisions of the program standards.

In December 2011, the OIG released "Vulnerabilities in FDA's Oversight of State Food Facility Inspections". In response, the FDA stated, "Collaboration with our state partners is critical to an integrated national food safety system and is also mandated under the FDA Food Safety Modernization Act (FSMA).[3] Over the last decade, the FDA has worked to develop and implement the MFRPS which will strengthen states' food safety programs. These program standards reflect an effort in which FDA has been engaged in for many years of partnering,

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[1] *Office of Inspector General, FDA Oversight of State Food Firm Inspections: OEI-01-98-00400 (Department of Health and Human Services, 2000), p. 5.*

[2] *A building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food as defined by 21 CFR Part 110.3 (k) . Manufactured*

[3] *Office of Inspector General, Vulnerabilities in FDA's Oversight of State Food Facility Inspections: OEI-02-09-00430 (Department of Health and Human Services, 2011), p. 34.*

leveraging and empowering agencies to move the vision of a nationally integrated food safety system.

It should be noted that in the 2019 revised version of the MFRPS, definitions have been used and slightly modified from the Field Management Directive 76 titled State Contracts - Evaluation of Inspectional Performance.

DEFINITIONS

1. **Assessment:** means a systematic, independent, and documented process for obtaining objective evidence and evaluating it to determine the extent to which a requirement is met. The MFRPS assessments are conducted by FDA at approximately 18, 36, and 60 months after enrollment. Assessments after 60 months will be conducted every two years. The FDA will determine IMPLEMENTATION during each assessment. The FDA will determine CONFORMANCE at 60 months. The FDA may determine CONFORMANCE at 18 and 36 months when a standard is found to be fully implemented.

2. **Conformance or Conformity:** means the fulfillment of a requirement, specifically a State program is using and can demonstrate the use of a particular element, system, or program listed in the MFRPS.

3. **Consumer Complaints:** are complaints made by the public regarding food products, facility, practices, labeling, and any other related activities.

4. **Contact Hour:** an inspector qualifies for one contact hour of continuing education for each clock hour of participation. Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period.

5. **Critical Violations:** are violations which are directly linked to public health risk, food adulteration, and/or known contributors to foodborne illness unless otherwise defined by the State.

6. **Current and Fit-for-Use:** "current" indicates that documentation is signed and dated in accordance with program policies and procedures that meet criteria in the most current standard. "Fit-for-use" is a quality term used to indicate that a product or service fits the customer's defined purpose for that product or service. Documentation may be electronic or hard copy.

7. **Current Experienced Staff:** defined by the State program in their training plan.

8. **Document Control:** document control ensures that documents are reviewed for adequacy, approved for release by authorized personnel and distributed to and used at the location where the prescribed activity is performed.

9. **Environmental Assessment (Also called "Environmental Health Assessment"):** means an on-site food product investigation, conducted in conjunction with investigations (e.g., traceback) as needed to assess and rule out the potential that the contaminant of concern was introduced at a particular point in the distribution or production system. This is achieved by identifying contributing factors and environmental antecedents.

10. **Equivalent:** means that the State law directly references the relevant provision or regulation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or Title 21 Code of

Federal Regulations (CFR). The State program specifies the Federal statute or regulation that is incorporated into the State law, including the revision date of the State statutory provision or regulation, the date the Federal statutory provision or regulation was incorporated into the State law, and whether that statutory or regulatory provision is included in whole, in part, or modified from the original.

11. **Equivalent in Effect:** means that the State law has the same regulatory effect as the relevant FD&C Act provision or CFR regulation. A State law may have the same regulatory effect as the Federal law or regulation if either a single State law or rule has the same regulatory effect as the Federal law or regulation, or when multiple laws of that State are combined and deemed equivalent to a single Federal law or regulation. In conducting such self-assessment, the State program may need to consult with its legal counsel when a provision is determined to be Equivalent in effect.

12. **Evaluation:** means an inspection in which the ability of an inspector is assessed to determine if they are competent to complete independent inspections. Evaluations are required for GMP and each specialized inspections. The evaluation should assess an inspector's ability to:
    - Prepare for an inspection
    - Conduct an inspection
    - Follow procedures identified by the State for the specific type of inspection
    - Communicate during the inspection and on the inspection report; and
    - Assess specialized processes (as applicable).

    Appendix 4.5 Field Audit Form, a modified version of the Conference for Food Protection Audit form, or an original form created by the State which evaluates the elements listed above may be used. It is recommended that new inspectors complete evaluations and independent inspections before entering the audit cycle. However, if States use the Appendix 4.5 – Field Audit Form, the evaluations may be counted toward the total audits for that year.

13. **Field Inspection Audit:** means an inspection in which a state inspector is accompanied by a QUALIFIED AUDITOR (either FDA or State) for the purpose of assessing the quality and performance of inspections either contract or state. These inspections may be counted under 2.3.2.3 and 2.3.3.2 Field Training as evaluations and also under 4.3.2 Field Inspection Audit if Appendix 4.5 is used.

14. **Food-Related Incident:** means an unintentional or deliberate contamination, threatened or actual, of food that may occur at any point in the production system (e.g., pre-harvest production, processing, distribution) and may cause food-related illness, injury, outbreaks and HAZARDS. Examples of food related incidents include but are not limited to foodborne illness outbreaks and food tampering.

15. **Hazard:** means any biological, chemical, or physical agent in food that is reasonably likely to cause illness or injury in the absence of its control.

16. **Highly Susceptible Population:** include immuno-compromised persons, preschool age children, or older adults; and persons who obtain food at a facility that provides services such as custodial care, health care, assisted living, a child or adult day care center, kidney dialysis centers, hospital or nursing home, or nutritional or socialization services (senior citizen centers)

17. **Implementation:** means a State program has a particular element, system, or program as required in the Program Elements and documentation requirements for MFRPS.

18. **Industry Complaints:** are complaints made by Industry about inspections or inspectors.

19. **Joint Field Training Inspection:** means an inspection conducted jointly by the FDA and/or state personnel for the purposes of training or enforcement. A joint inspection may be used to provide training to a state inspector during an inspection of a firm and may either be trainer led or trainee led.

20. **Newly Hired Experienced Staff:** staff with manufactured food regulatory experience received outside the manufactured food safety program to which they are currently employed.

21. **Not Equivalent:** means there is no State law equivalent to the relevant Federal law or regulation, there is such a State law but it does not apply to the State's food plant or manufacturing establishment program, or the Federal and State laws address the same matter but are inconsistent and do not have the same regulatory effect.

22. **Outreach Activity Event:** means an outreach activity which the State program hosts, co-hosts or is an invited presenter such as seminars, workshops, conferences, trainings, or meetings that relate to food protection topics and that support communication and information exchange among regulators, industry, academia, and consumer representatives.

23. **Primary Servicing Laboratory**: means any laboratory used by the State program for ongoing or routine testing.

24. **Qualified Field Inspection Auditor:** means an individual who is recognized by the regulatory jurisdiction's food safety program manager as having field experience and communication skills necessary to audit other inspectors/investigators and who has:
    - Demonstrated the competency for basic food inspection auditing to the food safety program manager;
    - Successfully completed advanced food inspection training coursework and field training in any areas where the auditor performs advanced auditing, such as low acid foods, acidified foods, seafood HACCP, or juice inspections;
    - Been assigned this auditing responsibility; and
    - Completed the required audit training per the State program requirements.

25. **Qualified Date:** qualified date begins when an inspector has completed all basic course and field elements and has been signed off to do independent inspections. This date is used to calculate the start of the continuing education hours in 2.3.4.

26. **Qualified Field Inspection Trainer:** means an individual who is recognized by the regulatory jurisdiction's food safety program manager as having field experience and communication skills necessary to train or supervise other inspectors/investigators and who has:
    - Demonstrated the competency for basic food inspection training to the food safety program manager;
    - Successfully completed advanced food inspection training coursework and field training in any areas where the trainer performs advanced training, such as low acid foods, acidified foods, seafood HACCP, or juice inspections; and
    - Been assigned this training responsibility.
    - State program includes a definition of "qualified trainer" within their training plan.

27. **Recall Audit Checks**: are conducted by the State Agency to verify that the firm's recall was successful as defined by the State's recall procedures.

28. **Regulatory Foundation:** means laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of a food plant or manufacturing establishment.

29. **Sampling Program:** means a program in which the state collects samples as part of their manufactured food program in one or more of the sampling types as defined in the *Partnership for Food Protection's Food/Feed Testing Laboratories Best Practices Manual*[4] *(*Draft) (Final Draft 11/1/2013). The program can be based on state defined sampling frequency and does not have to be continuous or routine.

30. **Start Date:** date of newly hired into the manufactured food program or newly reassigned into the manufacturing food program as the start time for training timelines for employees.

31. **Strategic Improvement Plan:** means a type of improvement plan that includes the following information: (1) the individual element or documentation requirement of the standard that was not met, (2) improvements needed to meet the program element or documentation requirement of the standard, (3) projected completion dates for each task, (4) personnel responsible, and (5) date completed.

32. **Traceback:** [a] The method used to determine the source and scope of the product/processes associated with an outbreak and document the distribution and production chain of the product that has been implicated in a foodborne illness or

[4] Reference: PFP Food/Feed Testing Laboratories Best Practices Manual can be found: http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM404716.pdf

outbreak.[5] and [b] The process by which the origin or source of a cluster of contaminated food is identified.[6]

33. **Traceforward:** [a] once the source of an implicated food item is established, investigators may do a "traceforward" to document the distribution of all implicated lots of food from the source. This can help epidemiologists with case finding and can be used to test hypotheses about the outbreak. Traceforwards should only be used when there is a reasonable degree of confidence that the traceback correctly identified the source of the implicated product. A product recall also involves a traceforward to determine the suppliers that received the product. [b] Tracking a recalled product from the origin or source through the distribution system. [6]

34. **Verification Audit Inspection:** means an inspection in which a qualified FDA or State auditor observes a State qualified auditor performing an audit of a State inspector conducting an inspection.

[5] Reference: Multistate Foodborne Outbreak Investigations Guidelines for Improving Coordination and Communications. Glossary can be found at: http://www.cifor.us/clearinghouse/tooldetail.cfm?id=212

[6] Reference: Council to Improve Foodborne Outbreak Response (CIFOR). Guidelines for Foodborne Disease Outbreak Response, 2009. Appendix 1: Glossary which can be found at: http://www.cifor.us/documents/CIFORGuidelinesAppendices.pdf

STANDARD No. 1
Regulatory Foundation

1.1 Purpose

This standard describes the elements of the REGULATORY FOUNDATION used by a State program to regulate food plants.

1.2 Requirement Summary

The State program evaluates the scope of its legal authority and regulatory provisions to ensure the protection of manufactured food within its jurisdiction. The State program's evaluation includes a determination of how the State's REGULATORY FOUNDATION corresponds to the U.S. FDA's REGULATORY FOUNDATION.

1.3 Program Elements

1.3.1 Written Procedure for Evaluation of Legal Authority

The State program has a written procedure to evaluate the legal authority and regulatory provisions to inspect and investigate food plants, gather evidence, collect and analyze samples, and take enforcement actions. The written procedure must:

1.3.1.1 Include timeframes for a REGULATORY FOUNDATION assessment;
1.3.1.2 Describe the REGULATORY FOUNDATION assessment process, to include whenever significant changes are made to applicable Federal and/or state laws and regulations; and
1.3.1.3 Address the statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that:

1.3.1.3.1 Apply to the regulation of manufactured food;
1.3.1.3.2 Delegate authority to the State program;
1.3.1.3.3 Describe the State program's administrative procedures for rulemaking to protect public health; and
1.3.1.3.4 Identifies and lists other State or Federal agencies that have authority for any area of the REGULATORY FOUNDATION that the State program lacks.

1.3.2 REGULATORY FOUNDATION Assessment

1.3.2.1 The State program must complete Appendix 1.2 or equivalent form. The State program conducts a baseline self-assessment to determine if they are EQUIVALENT, EQUIVALENT IN EFFECT, or NOT EQUIVALENT to sections of the current Federal Food, Drug, and Cosmetic Act (FD&C Act) and Code of Federal Regulations (CFR) Title 21 specified in Appendix 1.2.

1.3.2.2 If the State program has not adopted the current version of a CFR provision the State must provide the revision date of the CFR that was adopted for each regulation.

Note: If the State program has laws and regulations pertinent to the regulation of manufactured food, for which there are no Federal provisions, these laws and regulations can also be listed in Appendix 1.2 or equivalent form.

Note: In conducting a self-assessment, the State program may need to consult with legal counsel when regarding whether a provision is EQUIVALENT IN EFFECT.

1.4 Outcome

The State program has the legal authority and regulatory provisions to protect the public health by ensuring the safety and security of the manufactured food supply within its jurisdiction. For any part of the REGULATORY FOUNDATION that the State program lacks, the State program identifies another State or Federal program with that regulatory authority to protect public health.

1.5 Documentation

The State program maintains the records listed here.

1.5.1 Written procedure for evaluation for legal authority
1.5.2 State program's written REGULATORY FOUNDATION assessment process
1.5.3 The statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that: (1) apply to the regulation of manufactured food, (2) delegate authority to the State agency, and (3) describe the State agency's administrative procedures for rulemaking to protect public health
1.5.4 Appendix 1.1 – SelfAssessment Worksheet
1.5.5 Appendix 1 - Self-Assessment Worksheet or equivalent form
1.5.6 If applicable, review by legal counsel

STANDARD No. 2
Training Program

2.1 Purpose

This standard defines the essential elements of a training program for inspectors.

2.2 Requirement Summary

The State program uses a written training plan that promotes development and demonstrates that all inspectors who will conduct manufactured food inspections complete course curriculums, field training, and continuing education to adequately perform their work.

2.3 Program Elements

2.3.1 Training Plan and Training Records

2.3.1.1 The State program uses a written training plan that ensures all inspectors receive training required to adequately perform their work assignments. The training plan includes course curriculums which provides for basic and advanced food inspection training as well as continuing education.

2.3.1.2 Appendix 2.2 or equivalent form must be used to document and summarize all training provided to inspectors.

2.3.1.3 The State program maintains a training history for active inspectors. The training history for all inactive inspectors must be kept for three years or per the state's record retention policy.

2.3.1.4 Appendix 2.3 or equivalent form must be used to document training for each inspector.

2.3.1.5 The State training record summary and individual training records must include the inspector's START DATE. Equivalent forms including electronic records may be used for required appendices.

2.3.2 Basic Food Inspection Training

The State program requires that each inspector complete a basic food inspection training curriculum that consists of coursework and field training described here.

2.3.2.1 Timeframe

The Basic Food Inspection Training course curriculum shall be successfully completed within 24 months of the inspector's START DATE with the manufactured food program.

2.3.2.2 Course Curriculum:

The Basic Food Inspection Training consists of coursework in the subject areas listed in this section.

2.3.2.2.1 Prevailing statutes, regulations, and ordinances
2.3.2.2.2 Public health principles
2.3.2.2.3 Emergency management
2.3.2.2.4 Communications skills
2.3.2.2.5 Microbiology
2.3.2.2.6 Epidemiology
2.3.2.2.7 Basics of HACCP
2.3.2.2.8 Allergen management
2.3.2.2.9 Basic food labeling
2.3.2.2.10 Food defense awareness training
2.3.2.2.11 Sampling technique and preparation

Note: States may further subdivide their basic training by identifying courses required for inspectors who only inspect non high risk warehouses. These courses must be clearly defined in the state training plan.

Note: Appendix 2.4 provides a list of available Basic Food Inspection Training Coursework that may be used to satisfy the requirements in 2.3.2.2.

2.3.2.3 Field training

2.3.2.3.1 Each inspector who will inspect general manufactured food firms must complete:
- 2.3.2.3.1.1 Ten JOINT FIELD TRAINING INSPECTION, FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER; and
- 2.3.2.3.1.2 Of the ten, two must be acceptable FIELD INSPECTION AUDITS or EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.2 Each inspector who will only inspect non high risk food warehouses must complete:
- 2.3.2.3.2.1 Five JOINT FIELD TRAINING INSPECTION, FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER; and
- 2.3.2.3.2.2 Of the five, two must be acceptable FIELD INSPECTION AUDITS or

EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.3 Inspectors who meet 2.3.2.3.2 and advance to conduct general manufactured food firms must complete:

2.3.2.3.3.1 Five additional JOINT FIELD TRAINING INSPECTIONS, FIELD INSPECTION AUDITS, or EVALUATIONS to fulfill requirements identified in 2.3.2.3.1; and

2.3.2.3.3.2 Of the five, two must be acceptable FIELD INSPECTION AUDITS or EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR.

2.3.2.3.4 JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS/EVALUATIONS are conducted in firms that are representative of the firms to be inspected by the inspector. Each inspector will complete the minimum field training requirements prior to conducting independent inspections.

2.3.3 Advanced Food Inspection Training

The State program requires each inspector who will conduct specialized food inspections to complete an advanced inspection training curriculum which consists of relevant coursework and field training as described here.

2.3.3.1 Coursework

The state program requires each inspector who will perform specialized food inspections to successfully complete the coursework specific to the type of specialized food inspections they will be performing. Specialized food inspection courses include, but not limited to:

2.3.3.1.1 Acidified foods
2.3.3.1.2 Low acid canned foods
2.3.3.1.3 Juice HACCP
2.3.3.1.4 Seafood HACCP
2.3.3.1.5 Traceback Investigations[7]
2.3.3.1.6 Foodborne Illness Investigations[7]

2.3.3.2 Field training

[7] These advanced food inspection training courses are not subject to 2.3.3.2 Field Training requirements.

The State program requires that each inspector successfully complete the following before performing independent specialized food inspections.

2.3.3.2.1 Participate in two JOINT FIELD TRAINING INSPECTIONS;

2.3.3.2.2 After successful completion of the course participate in one EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR prior to conducting independent inspections; and

2.3.3.2.3 Within one year after being released to do specialized food inspections complete a second EVALUATION or FIELD INSPECTION AUDIT that is found to be acceptable by QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR in the area of specialty.

2.3.4 Experienced Inspectors

The criterion for conducting a minimum of 10 JOINT FIELD TRAINING INSPECTIONS and/or required coursework is intended for new employees or employees new to the food safety program. For CURRENT EXPERIENCED STAFF or NEWLY HIRED EXPERIENCED STAFF, a State program's training plan shall include the following unless the state determines in their training plan that all staff will be required to complete the program elements in 2.3.2 and 2.3.3:

2.3.4.1 CURRENT EXPERIENCED STAFF

	Missing Record	Documentation in Employee Training File
2.3.4.1.1	JOINT FIELD TRAINING INSPECTIONS	Statement or affidavit explaining the background or experience that justifies a waiver of the basic or specialized JOINT FIELD TRAINING INSPECTIONS.
2.3.4.1.2	Basic Course Work	Document training records available. Create a statement or affidavit explaining the background or experience that justifies a waiver of the missing Basic Course Work.
2.3.4.1.3	Specialized Food Inspection Course Work Certificates	Statement or affidavit explaining the date and location that they have successfully completed the specialized training.

2.3.4.2 NEWLY EXPERIENCED STAFF

	Missing Record	Documentation in Employee Training File
2.3.4.2.1	JOINT FIELD TRAINING INSPECTIONS	Statement or affidavit explaining the background or experience that justifies a waiver of some or all of the basic or specialized JOINT FIELD TRAINING INSPECTIONS. Conduct two successful EVALUATION or FIELD INSPECTION AUDIT within 6 months of the Inspector's QUALIFIED DATE.
2.3.4.2.2	Basic Course Work	Document training records available. Statement or affidavit explaining the background or experience that justifies a waiver of the Basic Course Work.
2.3.4.2.3	Specialized Food Inspection Course Work Certificates	Statement or affidavit explaining the date and location that they have successfully completed the specialized training.

2.3.5 Continuing education

Within the scope of this standard, the goal of continuing education and training is to enhance the inspector's knowledge, skills, and ability to perform manufactured food inspections. The objective is to build upon the inspector's knowledge base.

2.3.5.1 Each inspector must accumulate 20 CONTACT HOURS of continuing education in food safety every 36 months.

2.3.5.2 The 36-month continuing education interval starts at the QUALIFIED DATE, when the basic training cycle is completed.

2.3.5.3 The program may establish an alternate timeframe to track continuing education as long as the alternate timeframe and how that timeframe still meets or exceeds the intent of the standard (at least 20 CONTACT HOURS every 36 months) are clearly identified in program procedures.

2.3.5.4 The inspector qualifies for CONTACT HOURS for participation in any of the following activities that are related specifically to manufactured food safety or manufactured food inspectional work:

- Attendance at national or regional seminars / technical conferences;
- Professional symposiums / college courses;
- Food-related training provided by government agencies (e.g., USDA, State, local);
- Food safety related conferences and workshops;

- Distance learning opportunities that pertain to food safety; or
- Training approved by a QUALIFIED FIELD INSPECTION TRAINER.

2.3.5.5 Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of ten (10) CONTACT HOURS may be accrued from the following activities:

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

2.3.5.6 Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of four (4) CONTACT HOURS may be accrued for reading technical publications related to manufactured food safety.

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

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

2.3.6 Coursework Sources

Basic, advanced, and continuing education coursework must be obtained from one of the sources listed here:

2.3.6.1 Training provided by a government agency (including in house training);

2.3.6.2 Distance learning, for example, satellite downlinks or web-based training[8];

[8] FDA/ORA U classroom and long distance learning courses are listed at: http://www.fda.gov/ora/training/course_ora.html

2.3.6.3 Colleges, schools, research centers, and institutes;
2.3.6.4 Food Safety Alliances recognized by FDA.

2.4 Outcome

The State program has trained inspectors with the knowledge, skills, and abilities to competently inspect, conduct investigations, gather evidence, collect samples, and take enforcement actions with manufactured food plants.

2.5 Documentation

The State program maintains the records listed here.

2.5.1 Appendix 2.1 Self-Assessment Worksheet
2.5.2 Appendix 2.2 State Training Record Summary
2.5.3 Appendix 2.3 Individual training record
2.5.4 Documents verifying successful completion of required courses
2.5.5 Course description or agendas for non-FDA courses
2.5.6 Signed statements for experienced inspectors
2.5.7 EVALUATIONS or FIELD INSPECTION AUDITS
2.5.8 Documentation for continuing education credit
2.5.9 Written Training Plan

STANDARD No. 3
Inspection Program

3.1 Purpose

This standard describes the elements of an effective inspection program for manufactured food establishments.

3.2 Requirement Summary

The State program has a manufactured food inspection system. This system provides the foundation for inspecting food firms to determine compliance with the laws administered by Federal, State, and local governments. In addition, the State program has: (1) a risk based inspection program, (2) an inspection procedure, (3) an inspection report procedure, (4) a system to respond to CONSUMER COMPLAINTS, (5) a system to resolve INDUSTRY COMPLAINTS about inspections, (6) a recall system, and (7) a sampling procedure.

3.3 Program Elements

3.3.1 Risk-based Inspection Program

The State program has an inventory of food establishments for which the State has regulatory oversight. The inventory is categorized by the risk associated with the likelihood that a food related incident will occur.

3.3.1.1 Inspections are prioritized and frequencies assigned based on established risk categories. The State program has written procedure documenting their classification criteria and inspection frequencies.

3.3.1.2 The state program must use the risk factors and classification criteria as described in:

- Appendix 3.2; or
- FD&C Act, Section 421 (a)(1); or
- Develop its own risk factor and classification criteria. If the state chooses to develop its own risk factor and classification criteria a written rationale must be provided that demonstrates how public health is protected.

3.3.2 Inspection Procedure

The State program has a written procedure for inspecting food plants that require the inspectors to:

3.3.2.1 Review the previous inspection report and CONSUMER COMPLAINTS.

3.3.2.2 Have appropriate equipment[9] and forms (if necessary). Equipment must be verified and maintained as defined by the State's standard operating procedures or manufacture's recommendations.

3.3.2.3 Make appropriate introductions, and explain the purpose and scope of the inspection.

3.3.2.4 Establish jurisdiction.

3.3.2.5 Select an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the plant is producing.

3.3.2.6 Assess employee practices critical to the safe and sanitary production and storage of food.

3.3.2.7 Properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded or otherwise in violation of applicable law.

3.3.2.8 Recognize significant violative conditions or practices, if present, and record findings consistent with State program procedures.

3.3.2.9 Distinguish between significant and insignificant observations, and isolated incidents versus trends.

3.3.2.10 Review and evaluate the appropriate records and procedures for the establishment's operation and effectively apply the information obtained from this review [during the inspection].

3.3.2.11 Collect adequate evidence and documentation to support inspection observations in accordance with State program procedures.

3.3.2.12 Verify correction of deficiencies identified during the previous inspection.

3.3.2.13 Behave professionally and demonstrate proper sanitary practices during the inspection.

3.3.2.14 Use current versions of applicable hazard guides or other guidance, to identify and evaluate the HAZARDS associated with product(s) and process(es) when conducting inspections of specialized food and processes.

3.3.2.15 Assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation when required by regulation.

3.3.2.16 When appropriate review the firm's: scheduled process; HACCP plan or necessary process controls in the absence of a HACCP plan; food safety control plan and applicable monitoring, verification and deviation or corrective action records, including those related to sanitation.

3.3.2.17 Recognize deficiencies in the firm's monitoring controls and sanitation procedures through in-plant observations.

3.3.2.18 Use suitable interviewing techniques.

3.3.2.19 Explain findings clearly and adequately throughout the inspection.

3.3.2.20 Alert the firm's person in charge when an immediate corrective action is necessary.

[9] Standard number 8, Appendix 8.3 Inspection Equipment

3.3.2.21 Answer questions and provide information in an appropriate manner.
3.3.2.22 Write findings accurately, clearly, and concisely on the State document and provide a copy to the firm's person in charge.

3.3.3 Inspection Report

The State program has a written inspection report procedure that requires inspectors to:

3.3.3.1 Submit the inspection report within designated timeframes;
3.3.3.2 Complete the inspection report form completely and accurately;
3.3.3.3 Document violations and observations clearly, legibly, and concisely; and
3.3.3.4 Follow up with corrective action, compliance and enforcement.

3.3.4 Food Recalls[10]

The State program has a food recall system with written recall procedures for:

3.3.4.1 Sharing information about recalls with relevant agencies;
3.3.4.2 Ensuring recalled products are removed promptly from the market; and
3.3.4.3 Performing RECALL AUDIT CHECKS.

3.3.5 Consumer Complaints

The State program has a system for handling CONSUMER COMPLAINTS. The system contains written procedures for:

3.3.5.1 Receiving;
3.3.5.2 Tracking;
3.3.5.3 Evaluating;
3.3.5.4 Responding to; and
3.3.5.5 Closing CONSUMER COMPLAINTS.

3.3.6 Complaints Resulting from State Program Inspection Activities

The State program has a system for handling INDUSTRY COMPLAINTS about inspections. The system contains written procedures for:

3.3.6.1 Receiving;
3.3.6.2 Evaluating; and
3.3.6.3 Responding to INDUSTRY COMPLAINTS.

[10] Reference: PFP Best Practices for Improving FDA and State Communication During Recalls can be found: http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM460013.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

3.3.7 Sampling Procedure[11]

The State program has a written sampling procedure to ensure its SAMPLING PROGRAM is carried out in a manner that is consistent with state procedure. The sampling procedures must be reflective of the types of food and samples that the state collects and must include:

3.3.7.1 Procedures that require sample collectors to:

- 3.3.7.1.1 Use the appropriate method and equipment to collect the sample.
- 3.3.7.1.2 Record sample chain of custody per state procedure.
- 3.3.7.1.3 Handle, package, and ship sample using procedures appropriate to prevent compromising condition of the sample and ensuring security of the sample.
- 3.3.7.1.4 Deliver or ship sample to the appropriate laboratory program within prescribed timeframes.

3.3.7.2 Instructions for documenting the sample collection must include the following elements when applicable the State's SAMPLING PROGRAM:

- 3.3.7.2.1 Date of Sample Collection
- 3.3.7.2.2 Product Identification Including:
  - 3.3.7.2.2.1 Name of Product
  - 3.3.7.2.2.2 Unique Manufacturing Identification references
- 3.3.7.2.3 Description of the product
- 3.3.7.2.4 Collection information including:
  - 3.3.7.2.4.1 Method of Collection
  - 3.3.7.2.4.2 Lot Sampled
  - 3.3.7.2.4.3 Lot Size
  - 3.3.7.2.4.4 Special Sample techniques if used to collect the sample
- 3.3.7.2.5 Location where sample was collected.
- 3.3.7.2.6 Name and address of responsible party, guarantor, possessor, or distributor.
- 3.3.7.2.7 Sample type
- 3.3.7.2.8 Analysis requested *if applicable*.
- 3.3.7.2.9 Product labels or specific labeling information that is collected or reproduced per state policies.

[11] Reference: PFP Food/Feed Testing Laboratories Best Practices Manual can be found: http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM404716.pdf

3.3.7.2.10 Identification of the sample with the sample number assigned by the sampler at the time of collection.

3.3.7.3 State programs are not required to have a written sampling procedure unless they collect samples. However, these programs must have a statement in lieu of sampling procedures that explains why a SAMPLING PROGRAM is not supported and how the public health is protected in the absence of such a program. An example may include: Stating that public health is protected because another state or federal agency collects samples and fulfills this need. The statement should include the name of the agency and the type of samples that it collects.

3.3.8 Records Retention

The State program must maintain records as required under Section 9.3.2.2 for the following:

3.3.8.1 Inspection reports which includes follow up activities;
3.3.8.2 Essential recall information;
3.3.8.3 CONSUMER COMPLAINTS;
3.3.8.4 INDUSTRY COMPLAINTS about inspections[12]; and
3.3.8.5 Documentation associated with sample collection.

3.4 Outcome

The State program is based on an inspection program that reduces the occurrence of foodborne illness, injury, or allergic reaction.

3.5 Documentation

The State program maintains the records listed here.

3.5.1 Appendix 3.1 Self-Assessment Worksheet
3.5.2 An inventory of food plants for which the state has regulatory oversight[13]
3.5.3 Written procedure documenting the classification criteria and inspection frequencies
3.5.4 Written rationale of the risk factor and classification criteria if a State program develops its own risk factor and classification criteria
3.5.5 Written procedures for inspecting food plants.
3.5.6 Written inspection reports procedure

[12] Records dealing with personnel actions are not subject to review during an ASSESSMENT.

[13] Refer to PFP Document Data Elements and Definitions for recommended but not required data elements for each food plant. http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM404717.pdf

3.5.7 Written inspection reports, which includes follow-up activities
3.5.8 Written procedures for food recalls
3.5.9 Essential recall information
3.5.10 Written procedures for CONSUMER COMPLAINTS
3.5.11 CONSUMER COMPLAINTS
3.5.12 Written procedures for INDUSTRY COMPLAINTS about inspections
3.5.13 INDUSTRY COMPLAINTS about inspections[14]
3.5.14 Written procedures for sampling or, in the absence of any SAMPLING PROGRAM, a statement stating how public health is protected
3.5.15 Sample collection reports
3.5.16 Documentation associated with sample collection

[14] Records dealing with personnel actions are not subject to review during an ASSESSMENT.

STANDARD No. 4
Inspection Audit Program

4.1 Purpose

This standard describes the Quality Assurance Program (QAP) and auditing procedures necessary for a State program to (1) evaluate the effectiveness and accuracy of the inspection program, inspection records, and sampling records; and (2) identify best practices used to achieve quality inspections and sample collections.

4.2 Requirement Summary

The State program has a Quality Assurance Program that conducts audits to assess the effectiveness and accuracy of its inspections and sample collections. The QAP has two components: (1) a FIELD INSPECTION AUDIT component, which is an on-site performance EVALUATION of inspections and (2) a desk audit component, which is a performance review of the written reports of inspections and sample collections.

4.3 Program Elements

4.3.1 Quality Assurance Program

The State program has a written Quality Assurance Program that contains written procedures for:

4.3.1.1 Conducting field inspection audits as described in section 4.3.2; and
4.3.1.2 Conducting inspection report audits as described in section 4.3.3; and
4.3.1.3 Conducting sample report audits as described in section 4.3.4; and
4.3.1.4 A corrective action plan as described in section 4.3.5.

4.3.2 Field Inspection Audit

QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR conducts FIELD INSPECTION AUDITS or VERIFICATION AUDIT INSPECTIONS to verify that inspections are consistently performed according to the State's written procedures described in Standard 3.

4.3.2.1 Frequency. The QAP requires a minimum of two FIELD INSPECTION AUDITS of each inspector be conducted every 36 months. Inspections selected for audits should include the highest risk firms that the inspector is trained for including specialized food inspections.
4.3.2.2 Performance is documented on Appendix 4.2 or equivalent form and Appendix 4.5 or a State audit form that meets the program elements in Standard 3, Program Element 3.3.2.

4.3.3 Inspection Report Audit

The QAP requires periodic review of inspection reports to verify that inspectional findings are obtained and reported according to established written procedure. The quality of each inspection report is audited using the performance factors listed in Appendix 4.6. An overall inspection report rating is calculated using Appendix 4.3.

4.3.3.1 The State program will review a random selection of inspection reports based on the number of inspections completed in the last 12 months using the table below:

Number of Inspections in 12 Months	Minimum Number of Reports Required	Maximum Number of Reports Required
Less than 40 reports	All	All
40 – 800 reports	40	40
More than 800 reports	5% of reports	70

4.3.3.2 Seven percent (7%) of the inspection reports reviewed must be taken from inspections that were audited.

4.3.3.3 Performance is documented on Appendices 4.6 and 4.3 or equivalent forms.

4.3.4 Sample Report Audit

If the samples are collected in conjunction with the manufactured food program, the QAP requires periodic review of sample reports. This review is to verify that samples were properly collected, identified, recorded and submitted according to established written procedure. The quality of each sample report is audited using the performance factors listed in Appendix 4.7. An overall sample report rating is calculated using Appendix 4.4.

4.3.4.1 The State program will review a random selection of sample reports based on the number of samples collected in the last 12 months using the table below:

Number of samples in 12 Months	Minimum Number of Reports Required	Maximum Number of Reports Required
Less than 40 reports	All	All
40 – 800 reports	40	40

More than 800 reports	5% of reports	70

4.3.4.2 Performance is documented on Appendices 4.7 and 4.~~4~~ or equivalent forms.

4.3.5 Corrective Action Plan

The state program has a written corrective action plan (Appendix 4.8 or equivalent form) for the inspection, sampling, and FIELD INSPECTION AUDITS that addresses action to be taken when one or more of the conditions below are met:

4.3.5.1 An individual receives an overall rating of "needs improvement";
4.3.5.2 A single performance factor for the program falls below 80%;
4.3.5.3 An overall rating for the program falls below 80%.

4.4 Outcome

The State program systematically evaluates and improves its inspection and sample collection systems to ensure that activities and information are accurate, complete, and comply with the jurisdiction's procedures and policies.

4.5 Documentation

The State program maintains the records listed here.

4.5.1 Written procedures that describe the Quality Assurance Program
4.5.2 Appendix 4.1 Self-Assessment Worksheet
4.5.3 Appendix 4.2 Summary of FIELD INSPECTION AUDIT Findings
4.5.4 Appendix 4.3 Summary of Inspection Report Audit Findings
4.5.5 Appendix 4.4 Summary of Sample Report Audit Findings
4.5.6 Appendix 4.5 FIELD INSPECTION AUDIT form or a State audit form that meets the program elements in Standard 3, Program Element 3.3.2
4.5.7 Appendix 4.6 Inspection Report Audit Form, or equivalent form
4.5.8 Appendix 4.7 Sample Report Audit Form, or equivalent form
4.5.9 Appendix 4.8 Corrective Action Plan or equivalent form.

STANDARD No. 5
Food-related Illness, Outbreak and Hazards Response

5.1 Purpose

This standard describes the food emergency response functions and related activities necessary to investigate FOOD-RELATED INCIDENTS to stop, control and prevent HAZARDS that are likely to result in a foodborne illness, injury or outbreak.

5.2 Requirement Summary

The State program has a written food emergency response program. The program describes surveillance, investigation, control measures and post response activities in collaboration with other agencies and jurisdictions for responding to reports of food-related illness, injury, outbreaks and HAZARDS, whether unintentional or deliberate, and for generating recommendations for foodborne illness prevention.

5.3 Program Elements

5.3.1 Coordination of Food-related Illness, Outbreak and Hazards Response Activities with Other Authorities

5.3.1.1 Memorandum of understanding with other state agencies: If the responsibility for state food-related illness and outbreak investigations is assigned to another state agency, a memorandum of understanding with this agency is required to fulfill the requirements of this standard.

5.3.1.2 The State program has a written procedure that:

5.3.1.2.1 Identifies and describes the roles, duties, and responsibilities of each program for the requirements in 5.3.2-5.3.5;

5.3.1.2.2 Describes agency collaboration as necessary with FDA and other appropriate local, state and federal authorities in multi-jurisdictional FOOD-RELATED INCIDENTS;

5.3.1.2.3 Designates response coordinator(s) to guide program investigation efforts in collaboration with all agencies involved;

5.3.1.2.4 Describes how all relevant agencies are notified in case of FOOD-RELATED INCIDENTS;

5.3.1.2.5 Provides guidance for notification of appropriate law enforcement agencies when intentional food contamination is suspected or threatened;

5.3.1.2.6 Describes the maintenance of a list(s) of relevant agencies and emergency contacts that is updated at least yearly.

5.3.2 Surveillance

The State program:

5.3.2.1 Uses epidemiological information from local, state, or federal agencies to detect incidents or outbreaks of foodborne illness or injury.

5.3.2.2 Maintains notifications of FOOD-RELATED INCIDENTS that are reported to the program, in a log(s) or database(s).

5.3.3 Investigation/Environmental Assessment

The State program:

5.3.3.1 Uses established procedures with recommended timeframes to investigate reports of FOOD-RELATED INCIDENTS.

5.3.3.2 Collects environmental data using established procedures similar to those found in the most current versions of "*International Association for Food Protection Procedures to Investigate a Foodborne Illnesses"* and the CIFOR *"Guidelines for Foodborne Disease Outbreak Response."*[15] .

5.3.3.3 Coordinates the TRACEBACK and TRACEFORWARD of food implicated in an illness, injury, outbreak or found to contain a HAZARD in accordance with written procedures.

5.3.3.4 Has access to laboratory support[16] for investigation of reports of FOOD-RELATED INCIDENTS.

5.3.3.5 Correlates and analyze ENVIRONMENTAL ASSESSMENT data to identify contributing factors and antecedents that led to food contamination or adulteration causing illness, injury, or outbreak.

5.3.4 Control Measures

The State program:

5.3.4.1 Mitigates and contains food-related illness, injury and HAZARDS through strategies that include industry education, enforcement and public awareness activities.

5.3.4.2 Maintains a written procedure with criteria for releasing prevention guidance and information to the public (includes identifying a media person and developing guidelines for coordinating media information with other jurisdictions).

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[15] Council to Improve Foodborne Outbreak Response (CIFOR). *Guidelines for Foodborne Disease Outbreak Response*. Atlanta: Council of State and Territorial Epidemiologists available http://cifor.us/ .

[16] Specific requirements for laboratory support are contained in Standard 10.

5.3.5 Post Response

The State program:

5.3.5.1 Maintains program investigation and ENVIRONMENTAL ASSESSMENT findings and reports.

5.3.5.2 Distributes final program investigation report(s), including an ENVIRONMENTAL ASSESSMENT if completed to relevant agencies responsible for reporting contributing factors and antecedents to CDC.

5.3.5.3 Distributes recommendations, when available, from investigation and ENVIRONMENTAL ASSESSMENT findings and reports to relevant agencies and stakeholders responsible for prevention, education and outreach.

5.4 Outcome

The State program uses a systematic approach for the detection, investigation, mitigation, documentation and analysis of FOOD-RELATED INCIDENTS to stop, control and prevent HAZARDS that are likely to result in a foodborne illness, injury or outbreak.

5.5 Documentation

The program maintains the records listed here:

5.5.1 Appendix 5.1 Self-Assessment Worksheet
5.5.2 A Memorandum of Understanding, if applicable
5.5.3 Written procedures for coordination, surveillance, ENVIRONMENTAL ASSESSMENT, control measures, and post response.
5.5.4 Records associated with coordination, surveillance, ENVIRONMENTAL ASSESSMENT, control measures, and post response.
5.5.5 A log(s) or database(s) that tracks notification of FOOD-RELATED INCIDENTS
5.5.6 Investigation/ ENVIRONMENTAL ASSESSMENT, reports and summaries

STANDARD No. 6
Compliance and Enforcement Program

6.1 Purpose

This standard describes the State agency's strategies, procedures, and actions to enforce the laws and regulations to achieve compliance and to evaluate the effectiveness of its compliance and enforcement program.

6.2 Requirement Summary

The State program has a written compliance and enforcement program, which describes its compliance strategy and procedures. The compliance and enforcement program conducts an annual review and records those actions on appendix 6.2. The State calculates an overall rating which is used to determine if compliance and enforcement procedures were followed. Results of the review are used to identify improvements and modify procedures.

6.3 Program Elements

6.3.1 Compliance and Enforcement Program

The State program has a written compliance and enforcement program that:

- 6.3.1.1 Contains compliance and enforcement strategies;
- 6.3.1.2 Describes the procedure to monitor
  - 6.3.1.2.1 CRITICAL VIOLATIONS;
  - 6.3.1.2.2 chronic violations; and
  - 6.3.1.2.3 chronic violators;
- 6.3.1.3 Uses a risk-based process to determine when a directed investigation, follow-up, or re-inspection is needed;
- 6.3.1.4 Establishes a framework for compliance and enforcement progressive actions[17]; and
- 6.3.1.5 Has a system to communicate policy and guidance to managerial and non-managerial staff.

6.3.2 Performance Review

The State program conducts a performance review of compliance and enforcement actions as defined by the State program. The State program will conduct a performance review:

[17] Compliance and Enforcement Progressive Actions may include, but are not limited to:

- Preventive actions such as promoting voluntary compliance through education program and consultation;
- Field actions such as verbal warnings, documented warnings, re-inspections, and product embargos;
- Supervisory/management actions such as warning letters or informal hearings;
- Administrative actions such as complaints and evidentiary hearings to suspend or revoke a business license; and
- Civil or criminal sanctions.

6.3.2.1 Annually;
6.3.2.2 Document on Appendix 6.2 or equivalent form to evaluate if internal compliance and enforcement actions are followed;
6.3.2.3 Use results of the review to identify improvements and modify procedures; and
6.3.2.4 Require a corrective action if performance ratings fall below 80 percent.

6.4 Outcome

The State program has a compliance and enforcement program that has written procedures to ensure that compliance actions are supported by sound judgment, adequate evidence, and appropriate documentation that is submitted in program-prescribed formats.

6.5 Documentation

The State program maintains the records listed here.

6.5.1 Appendix 6.1 Self-Assessment Worksheet
6.5.2 Written Compliance and Enforcement Program
6.5.3 Appendix 6.2 Performance Review of Enforcement Actions or equivalent form

STANDARD No. 7
Industry and Community Relations

7.1 Purpose

This standard describes the elements of industry and community outreach activities or OUTREACH ACTIVITY EVENTS developed and accomplished by the State program.

7.2 Requirement Summary

The State program participates in activities that support communication and information exchange among regulators, industry, academia, and consumer representatives. It also coordinates or participates in outreach activities or OUTREACH ACTIVITY EVENTS that provide educational information about food protection topics

7.3 Program Elements

The State program has a written procedure of the methods that will be used for communication with the food industry stakeholders and consumers. The written procedure includes how the State program will:

7.3.1 Identify the methods for communication with the food industry stakeholders and consumers.

7.3.2 Interact with industry and consumers by sponsoring or actively participating in meetings such as task forces, advisory boards, or advisory committees.

7.3.3 Tailor outreach efforts to a target population, which may include dissemination of information using electronic sources and traditional methods such as mailings. Topics of outreach efforts may include food defense, investigation strategies, regulatory requirements, violation trends, and emerging issues regarding manufactured foods. Representatives from affected food industries, consumers, academia, and other Federal, State, and local food protection agencies are invited to these meetings.

7.3.4 Document and evaluate OUTREACH ACTIVITY EVENTS using Appendix 7.2 or equivalent form. Include documents such as agendas and meeting summaries and program evaluations.

7.4 Outcome

The State program uses outreach activities or OUTREACH ACTIVITY EVENTS to inform varied populations about food protection-related issues.

7.5 Documentation

The State program maintains the records listed here.

7.5.1 Written procedure for methods used to communicate with food industry stakeholders and consumers
7.5.2 Appendix 7.1 Self-Assessment Worksheet
7.5.3 Appendix 7.2 or equivalent documentation for each OUTREACH ACTIVITY EVENT
7.5.4 Meeting summaries, agendas, or other records documenting interaction with food industry stakeholders s and consumers

STANDARD No. 8
Program Resources

8.1 Purpose

This standard describes the elements for assessing the resources (staff, equipment, and funding) needed to support a manufactured food regulatory program.

8.2 Requirement Summary

The State program conducts an assessment of resource needs for staffing, equipment, and funding for the manufactured food regulatory program.

8.3 Program Elements

8.3.1 Program Assessment
The State program completes the self-assessment to assess staffing, funding, and equipment using Appendix 8.1 or equivalent form. The administrative functions needed to support all program areas should be considered when determining program resources.

8.3.2 Staffing
The State program conducts a calculation for determining a required number of inspectors and documents on Appendix 8.2 or equivalent form. The State program has staff to inspect food plants in its establishment inventory at a frequency that is based on the plant's risk classification and the necessary inspection and travel time.

8.3.3 Equipment
A list of the equipment required for inspections and sample collections must be established and maintained by the State program using Appendix 8.3 or equivalent form.

8.4 Outcome

The State program assesses and allocates resources needed to support a manufactured food regulatory program.

8.5 Documentation

The State program maintains the records listed here:

8.5.1 Appendix 8.1 Self-Assessment Worksheet
8.5.2 Appendix 8.2 or equivalent form.
8.5.3 Appendix 8.3 or equivalent form.

STANDARD No. 9
Program Assessment

9.1 Purpose

This standard describes the process a State program uses to assess and demonstrate its CONFORMANCE with each of the program standards.

9.2 Requirement Summary

Managers conduct periodic self-assessments of the manufactured food regulatory program against the criteria established in each program standard. These self-assessments are designed to identify the strengths and weaknesses of the State programs by using the program standards.

The results of the self-assessments are used to determine areas or functions of the State program that need improvement. The results of the baseline self-assessment are used to develop a STRATEGIC IMPROVEMENT PLAN and establish timeframes for making improvements. Subsequent self-assessments are used to track progress toward meeting and maintaining CONFORMANCE with the program standards.

9.3 Program Elements

9.3.1 In the first year the State program conducts a baseline self-assessment to determine if the program meets the elements of each standard. The State program uses the Appendices and Worksheets contained herein or equivalent forms. The State program uses the results of its self-assessments to complete the Self-Assessment Summary Report (also known as Appendix 9.1).

9.3.2 The State program must:

9.3.2.1 Have a written DOCUMENT CONTROL procedure that ensures that all guidance, procedures, documents, and forms required by the standards are CURRENT AND FIT-FOR-USE.

9.3.2.1.1 All of the documents subject to this procedure can demonstrate they are CURRENT AND FIT-FOR-USE through maintenance of a master document list or other system that shows:

9.3.2.1.1.1 Documents are reviewed for accuracy.

9.3.2.1.1.2 Documents are approved for release by authorized Personnel and signed/dated with an approval or revision date.

9.3.2.1.1.3 Documents are distributed to and used at the location Where the prescribed activity is performed.

9.3.2.1 9.3.2.2 Retain records or procedures required under x.5 of each standard for the three previous years, or per the State program's record retention policy, whichever is longer. Records or procedures can be maintained either electronically or in hardcopy.

9.3.3 If the State program fails to meet any of the program elements and documentation requirements of a standard, it develops a written STRATEGIC IMPROVEMENT PLAN that includes the following information:

9.3.3.1 The individual element or documentation requirement of the standard that was not met;
9.3.3.2 Improvements needed to meet the program element or documentation requirement of the standard;
9.3.3.3 Projected completion dates for each task;
9.3.3.4 Personnel responsible, and
9.3.3.5 Date completed for each task.

9.3.4 The State program shall review and update self-assessment appendices and its STRATEGIC IMPROVEMENT PLAN at least annually.

9.3.5 The State program participates in FDA ASSESSMENTS to determine IMPLEMENTATION and CONFORMANCE to the standards. The State program addresses FDA ASSESSMENT observations and incorporates corrective actions as needed into its STRATEGIC IMPROVEMENT PLAN.

9.4 Outcome

The State program conforms to the program standards through well-defined and written evaluation activities and a process for continuous improvement.

9.5 Documentation

The State program maintains records listed here.

9.5.1 Appendix 9.1 Self-Assessment Summary Report
9.5.2 STRATEGIC IMPROVEMENT PLAN
9.5.3 DOCUMENT CONTROL procedure
9.5.4 Record retention rules, policies or procedures
9.5.5 FDA ASSESSMENT reports

STANDARD No. 10
Laboratory Support

10.1 Purpose

This standard describes the elements of laboratory support for a manufactured food regulatory program.

10.2 Requirement Summary

The State program has access to the laboratory services needed to support program functions and documents its laboratory capabilities including agreements with external laboratories.

10.3 Program Elements

10.3.1 Laboratory Support

10.3.1.1 The State program has access to a laboratory that is capable of analyzing a variety of samples including food, environmental, and clinical samples.

10.3.1.2 The State program maintains a list of services for routine and non-routine analyses such as biological HAZARD determinations.

10.3.1.3 The State program has a contract or written agreement with each PRIMARY SERVICING LABORATORY unless under the same administrative agency. If not, the contract or written agreement must be documented such as a memorandum of understanding, e-mail, or any written format but must contain the components below:

10.3.1.3.1 Define the responsibilities of each party;

10.3.1.3.2 Describe the types of testing services to be performed; and

10.3.1.3.3 Describe how exceptions to planned work will be communicated.

10.3.1.4 When a program uses a laboratory service from a non-primary servicing laboratory, there shall be documentation of the service provided; the documentation can be in a simplified format.

10.3.2 ISO Accredited Laboratories

The State program utilizes laboratories that have a current accreditation to the ISO/IEC 17025:2005 or ISO/IEC 17025:2017 standards to analyze food and environmental samples. The accreditation body of the laboratory must be a full member of the International Laboratory Accreditation Cooperation (ILAC) and a signatory to the ILAC Mutual Recognition Arrangement (MRA).

10.3.3 Non-ISO Accredited Laboratories

If state programs do not use laboratories holding accreditation to ISO/IEC 17025:2005 or ISO/IEC 17025:2017 for the analysis of food and environmental samples, then the program must utilize laboratories that have in place a quality system which incorporates the following management and technical requirements of ISO/IEC 17025:2005* or ISO/IEC 17025:2017 at a minimum:

*Note ISO/IEC 17025:2005 will be invalid after November 30, 2020 per ILAC. Future versions of the ISO/IEC 17025 standard shall be evaluated and incorporated into Standard 10, as applicable.

10.3.3.1 A documented quality system which incorporates management and technical requirements of ISO/IEC 17025:2005 or ISO/IEC 17025:2017 and associated procedures, that include but ae not limited to:

- 10.3.3.1.1 Calibration and maintenance of equipment;
- 10.3.3.1.2 Analyses are performed using validated and verified test procedures;
- 10.3.3.1.3 Documentation of sample traceability;
- 10.3.3.1.4 Documentation of analytical results and analysts performing work;
- 10.3.3.1.5 Analysts that are trained and authorized to perform technical procedures; and
- 10.3.3.1.6 Periodic audits.

10.3.3.2 A procedure that defines the activities necessary when non-conforming work occurs. The documented process must describe how quality control data are assessed to assure that test results from non-conforming work are not released. The documented process must describe how cause analysis and problem resolution are recorded.

10.3.3.3 A document control procedure that assures documents issued to personnel are current, suitable, and reviewed and approved by authorized personnel prior to release. The procedure must also assure that obsolete documents are removed from use.

10.3.3.4 A documented record keeping process that assures that records of original observations and data collection are maintained and sufficient to establish traceability of test results to sample handling and storage, to sample analysis including data collection, to equipment calibration and maintenance, and to the review of test results prior to release.

10.3.3.5 A documented process to assure that reference materials and reference cultures used are fit for purpose, are not outdated, and are traceable to a lot number or other unique identifier.

10.3.3.6 A documented process to assure that the laboratory participates in relevant and available proficiency testing activities.

10.4 Outcome

The State program has access to laboratory services described in this standard.

10.5 Documentation

The State program maintains records listed here.

10.5.1 Appendix 10.1 Self-assessment worksheet
10.5.2 Contracts or written agreements with PRIMARY SERVICING LABORATORIES
10.5.3 A list of laboratories used by the state that are non-primary servicing laboratories.
10.5.4 Documentation of services provided by PRIMARY SERVICING LABORATORIES and non-primary servicing laboratories.
10.5.5 ISO Accredited Laboratory: ISO/IEC 17025:2005 or ISO/IEC 17025:2017 Certificate and Scope of Accreditation
10.5.6 Non-ISO Accredited Laboratory Documents:
10.5.6.1 Documented Quality System
10.5.6.2 Corrective Action
10.5.6.3 Document Control
10.5.6.4 Record Keeping
10.5.6.5 Process for Ensuring Validity of Results (including but not limited to Reference Materials and or Proficiency Testing)

Appendix 1.1: Self-Assessment Worksheet

State Agency: _____

Program Elements	***Yes/No***	***If No, please explain why element is not met***
1.3.1 Written Procedure for Evaluation of Legal Authority		
Does the State Program's written procedure:		
1. *Describe the REGULATORY FOUNDATION assessment process?*		
2. *Include timeframes for conducting a REGULATORY FOUNDATION assessment; including whenever significant changes are made to applicable Federal and/or State laws and regulations?*		
3. *Address statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that:*		
a. *Apply to the regulation of manufactured food?*		
b. *Delegate authority to the State's program?*		
c. *Describe the State administrative procedures for rulemaking to protect public health?*		
d. *Identify and list other State and Federal agencies that have authority for any area of the REGULATORY FOUNDATION the State program lacks?*		
1.3.2 REGULATORY FOUNDATION Assessment		
Does the State's REGULATORY FOUNDATION assessment include:		
1. *A baseline self-assessment using Appendix 1.2 or equivalent to determine if the State is EQUIVALENT, EQUIVALENT IN EFFECT, or NOT EQUIVALENT to sections of the FD&C act and CFR as specified in Appendix 1.2?*		
2. *Revision date of the CFR that was adopted for each regulation if the State Program has not adopted the current version of a CFR provision.*		

Assessment completed by: _____ ***Date***_____

Appendix 1: Statutes and Regulations Worksheet

Instructions: *Determine if State laws and regulations are "EQUIVALENT," "EQUIVALENT IN EFFECT," or "NOT EQUIVALENT" to Federal statutes and regulations. If there is no State law or regulation that is EQUIVALENT or EQUIVALENT IN EFFECT, mark the NOT EQUIVALENT box; otherwise list the State law or regulation citation and complete the columns for either EQUIVALENT or EQUIVALENT IN EFFECT as appropriate. The Notes section shall be used in part to detail differences between State and Federal laws and regulations. If regulatory responsibility for a FD&C-CFR falls under the jurisdiction of another agency, that particular FD&C-CFR row should be left blank – with documentation provided in the notes section of which agency has the jurisdiction. Please note that to the extent that any federal statutes or regulations guided below reference FDA regulated products other than food (i.e. tobacco), such references are not intended to be within the scope of this self-assessment which relates only to human food.*

		State Citation	EQUIVALENT			EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial or Full	Review Date		
Federal Food, Drug & Cosmetic Act								
201	Definitions (f), (k), (m), and (ff)							
301	Prohibited acts (a), (b), (c), (d), (e), (f), (k), and (v)							
303*	Penalties							
304**	Seizure							
401	Definitions and standards for food							
402	Adulterated food							

		State Citation	EQUIVALENT			EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial or Full	Review Date		
403	Misbranded food (a)-(s)							
413	New dietary ingredients							
701	Regulations and hearings							
703***	Records of interstate shipments							
704	Factory inspection							

*Penalties may vary from Federal statute.

**Although the State program may not have authority for seizure, the State program could have legal authority to stop adulterated and misbranded products from moving in commerce, for example, detention, stop-sale orders, withdrawal from distribution, and embargoes.

*** This section covers records in interstate commerce. State laws should include intrastate records.

Title 21 Code of Federal Regulations: Food and Drugs								
1	General enforcement regulations (§ 1.20-1.24) and (Subpart O § 1.900-1.934)							
7	Enforcement policy (ONLY § 7.1-7.13 and § 7.40-7.59)							

		State Citation	EQUIVALENT			EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial or Full	Review Date		
70	Color additives (ONLY § 70.20-70.25)							
73	Listing of colors exempt from certification (ONLY § 73.1-§ 73.615)							
74	Listing of color additives subject to certification (ONLY § 74.101-706)							
81	General Restrictions for Provisional Color Additives for Use in Foods, Drugs, and Cosmetics							
82	Listing of certified provisionally listed colors and specifications (ONLY § 82.3-§ 82.706)							
100	General (ONLY § 100.155)							
101	Food labeling (EXCEPT § 101.69 and § 101.108)							

		State Citation	EQUIVALENT			EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial or Full	Review Date		
102	Common or usual name for nonstandardized foods (EXCEPT § 102.19)							
104	Nutritional quality guidelines for foods							
105	Foods for special dietary use							
106	Infant formula quality control procedures (EXCEPT § 106.120)							
107	Infant formula (EXCEPT § 107.200-§ 107.280)							
108	Emergency permit control (ONLY § 108.25-§ 108.35)							
109	Unavoidable contaminants in food for human consumption and food- packaging materials							

		State Citation	EQUIVALENT			EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial or Full	Review Date		
110[18]	Current good manufacturing practice in manufacturing, packing, or holding human food							
111	Current good manufacturing practice for dietary supplements							
113	Thermally processed low-acid foods packaged in hermetically sealed containers							
114	Acidified foods							
115	Shell eggs							
117	Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food							

[18] Part 110 was modernized and codified in Part 117 by the current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventative Controls for Human Food Rule (21 CFR Part 117).

		State Citation	EQUIVALENT			EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial or Full	Review Date		
118	Production, Storage, And Transportation of Shell Eggs							
120	Hazard Analysis and Critical Control Point (HACCP) systems							
123	Fish and fishery products							
129	Processing and bottling of bottled drinking water							
130	Food standards: general (EXCEPT § 130.5-6 and § 130.17)							
131	Milk and cream							
133	Cheeses and related cheese products							
135	Frozen desserts							
136	Bakery products							

		State Citation	EQUIVALENT			EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial or Full	Review Date		
137	Cereal flours and related products							
139	Macaroni and noodle products							
145	Canned fruits							
146	Canned fruit juices							
150	Fruit butters, jellies, preserves, and related products							
152	Fruit pies							
155	Canned vegetables							
156	Vegetable juices							
158	Frozen vegetables							
160	Eggs and egg products							
161	Fish and shellfish							
163	Cacao products							

		State Citation	EQUIVALENT			EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial or Full	Review Date		
164	Tree nut and peanut products							
165	Beverages							
166	Margarine							
168	Sweeteners and table syrups							
169	Food dressings and flavorings							
170	Food additives EXCEPT § 170.6, § 170.15, and § 170.17)							
172	Food additives permitted for direct addition to food for human consumption							
173	Secondary direct food additives permitted in food for human consumption							
174	Indirect food additives: general							

		State Citation	EQUIVALENT			EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial or Full	Review Date		
175	Indirect food additives: adhesives and components of coatings							
176	Indirect food additives: paper and paperboard components							
177	Indirect food additives: polymers							
178	Indirect food additives: adjuvants, production aids, and sanitizers							
180	Food additives permitted in food or in contact with food on an interim basis pending additional study							
181	Prior-sanctioned food ingredients							
182	Substances generally recognized as safe							

		State Citation	EQUIVALENT			EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial or Full	Review Date		
184	Direct food substances affirmed as generally recognized as safe							
186	Indirect food substances affirmed as generally recognized as safe							
189	Substances prohibited from use in human food							
190	Dietary supplements							

State law and regulations:

State laws and regulations used by the program to address regulatory responsibilities outside of FDA jurisdiction are listed below.

_____

_____

_____

_____

_____

Assessment completed by:_____

(NAME) **(DATE)**

Appendix 2.1: Self-Assessment Worksheet

State agency: _____

Program Elements	Yes/No	If no, please explain why element is not met
2.3.1. Training Plan and Training Records		
Does the State program:		
1. Have a written training plan that ensures all inspectors receive training required to adequately perform their work assignments?		
2. Maintain a training history for active inspectors?		
3. Maintain a history for all inactive inspectors for three years or per the state's record retention policy?		
4. Use Appendix 2.2 or equivalent form to document and summarize all training provided to inspectors?		
5. Use Appendix 2.3 or equivalent form to document training for each inspector?		
6. Training record summary and individual training records include the inspector's START DATE?		
2.3.2. Basic Food Inspection Training		
Does the State program require that each inspector:		
1. Complete all Basic Food Inspection Training coursework within 24 months of START DATE with manufactured food program?		
2. Complete the basic course curriculum in the subject areas listed in 2.3.2.2.1 – 2.3.2.2.11?		
3. Who will inspect general food manufactured food firms complete ten JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER?		
4. Who will inspect general food manufactured food firms complete two acceptable FIELD INSPECTION AUDITS or EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR?		
5. Who will inspect non high risk food warehouses complete five JOINT FIELD TRAINING INSPECTION, FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER?		

Program Elements	Yes/No	If no, please explain why element is not met
6. Who will inspect non high risk food warehouses complete two acceptable FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER?		
7. Who advances to conduct general food manufacturing firms from non-high risk food warehouses complete five additional JOINT FIELD TRAINING INSPECTIONS, FIELD INSPECTION AUDITS, or EVALUATIONS to fulfill requirements identified in 2.3.2.3.1, of which, two are representative of the general manufactured food firms?		
8. Who advances to conduct general food manufacturing firms from non-high risk food warehouses complete two additional acceptable FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER?		
9. Complete the minimum field training requirements prior to conducting independent inspections?		
2.3.3. Advanced Food Inspection Training		
Does the State program require each inspector:		
1. Who performs specialized food inspections to complete the coursework specific to the type of specialized food inspection they will be performing?		
2. Who performs specialized food inspections to participate in two JOINT FIELD TRAINING INSPECTIONS?		
3. After successful completion of the course; participate in one EVALUATION or FIELD INSPECTION AUDIT with a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR prior to conducting independent inspections?		
4. Within one year after being released to do specialized food inspections complete a second EVALUATION or FIELD INSPECTION AUDIT with a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR in the area of specialty?		
2.3.4 Experienced Inspectors		
For CURRENT EXPERIENCED STAFF or NEWLY HIRED EXPERIENCED STAFF a State program's training plan shall include the following unless the state determines in their		

Program Elements	Yes/No	If no, please explain why element is not met
training plan that all staff will be required to complete the program elements in 2.3.2 and 2.3.3:		
1. Missing basic course work, does the State program have a statement or affidavit that explains the background or experience that justifies the waiver?		
2. Missing JOINT FIELD TRAINING INSPECTIONS, does the State program have a Statement or affidavit explaining the background or experience that justifies a waiver of the basic or specialized JOINT FIELD TRAINING INSPECTIONS?		
3. Who is newly hired who had JOINT FIELD TRAINING INSPECTIONS waived, were two successful EVALUATIONS or FIELD INSPECTION AUDITS completed within 6 months of the inspector's QUALIFIED DATE?		
4. Missing specialized coursework, does the State program have a statement or affidavit explaining the date and location that the specialized training was completed?		
2.3.5 Continuing Education and Training		
1. Does each inspector conducting manufactured food inspections accumulate 20 CONTACT HOURS of continuing education every 36 months from the start of the QUALIFIED DATE?		
2. Does the state program maintain documentation for continuing education credit as outlined in 2.3.5.7?		
2.3.6 Coursework Sources		
Is all basic, advanced, and continuing education coursework obtained from sources listed in 2.3.5.1 – 2.3.5.4?		

Assessment completed by:_____

(NAME) **(DATE)**

Appendix 2.2: Inspector Training Record Summary

Instructions: This Appendix is used to document and track inspectors' training status. Enter the name of all active inspectors. Include the START DATE of employment, and record the date the inspector completed the coursework and field training for the basic and advanced curriculums. For continuing education, indicate the QUALIFIED DATE and number of CONTACT HOURS completed.

Employee name	START DATE	Basic Food Inspection Curriculum		Advanced Food Inspection Curriculum			Continuing Education	
		Course work	Field work	Area of Specialty	Course work	Field work	QUALIFIED DATE	CONTACT HOURS

Assessment completed by:_____

(NAME) **(DATE)**

Appendix 2.3: Inspector Training Record

State Agency: _____

Name of Inspector _____ **START DATE** _____

Basic Food Inspection Curriculum Coursework		
Course *Please provide the course name and location for each subject area*	**Date completed**	**Course Documentation Available for Review (Y/N)**
Prevailing statutes, regulations, and ordinances		
Public health principles		
Emergency Management		
Communication skills		
Microbiology		
Epidemiology		
Basics of HACCP		
Allergen Management		
Basic food labeling		
Food defense awareness training		
Sampling Techniques and preparation		

Appendix 2.3: Inspector Training Record (continued)

Inspector Name_____

Basic Food Inspection Curriculum Fieldwork				
JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS		**Date Completed**	**EVALUATION/AUDIT Acceptable (Y/N)**	**Documentation Available for Review (Y/N)**
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

Appendix 2.3: Inspector Training Record (continued)

Inspector Name_____

Advanced Food Inspection Curriculum Coursework		
Course *Please provide the name and location of the course.*	**Completion Date**	**Course Documentation Available For Review (Y/N)**
Acidified food		
Low acid canned food		
Juice HACCP		
Seafood HACCP		
Traceback Investigations		
Foodborne Illness Investigations		

Appendix 2.3: Inspector Training Record (continued)

Inspector Name_____

Instructions: Identify and record the type of specialized food inspection conducted for the JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS**,** *such as acidified foods, low acid canned foods, juice HACCP, or seafood HACCP.*

Advanced Food Inspection Curriculum Fieldwork				
Specialized food inspection				
JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS		**Completion Date**	**EVALUATION/AUDIT Acceptable (Y/N)**	**Documentation Available for Review (Y/N)**
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				
Specialized food inspection				
JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS		**Completion Date**	**EVALUATION/AUDIT Acceptable (Y/N)**	**Documentation Available for Review (Y/N)**
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				

Appendix 2.3: Inspector Training Record (continued)

Name of Inspector _____ QUALIFIED DATE _____

CONTINUING EDUCATION COURSEWORK *A total of 20 CONTACT HOURS required every 36 months*			
Activities in Program Element 2.3.4.4 *Maximum of 20 CONTACT HOURS*			
Type of Activity *(Provide Title and Brief Description*	**Date Completed**	**Documentation Available for Review (Y/N)**	**CONTACT HOURS Earned**
		Subtotal	
Presenting, Training, or Publishing (Program Element 2.3.4.5) *Maximum of 10 CONTACT HOURS*			
Type of Activity *(Provide Title and Brief Description*	**Date Completed**	**Documentation Available for Review (Y/N)**	**CONTACT HOURS Earned**
		Subtotal	
Reading Technical Publications (Program Element 2.3.4.6) *Maximum of 4 CONTACT HOURS*			
Type of Activity *(Provide Title and Brief Description*	**Date Completed**	**Documentation Available for Review (Y/N)**	**CONTACT HOURS Earned**
		Subtotal	
		Total CONTACT HOURS Earned	

Appendix 2.4: Curriculum Example Basic Food Inspector Training

Standard 2 requires a State program to have a documented training plan that ensures all inspectors receive training to adequately perform their work assignments. Additionally, Standard 2 identifies thirteen coursework areas for basic food inspection training and allows for coursework to be obtained from distance learning, for example satellite downlinks or web-based training such as those available from FDA Office of Regulatory Affairs University (ORAU).

*The list below is an **example** of the basic food inspection training coursework that could be used to meet section 2.3.2 Basic Food Inspection Training coursework requirements. Unless indicated below, the majority of FDA courses are available through*
http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm119016.htm

PREVAILING STATUTES, REGULATIONS, ORDINANCES

1. Basic Food Law for State Regulators (60) FDA35
2. Basics of Inspection: Beginning an Inspection (90) FDA38
3. Basics of Inspection: Issues & Observations (90) FDA39
4. An Introduction to Food Security Awareness (60) FD251 (ORA U internet site)
5. Food & Drug Law: FDA Jurisdictions, FDA01
6. Food & Drug Law: Prohibited Actions, FDA02
7. Food & Drug Law: Judicial Actions, FDA03
8. Food & Drug Law: Criminal Actions Violations, FDA04
9. Food & Drug Law: Imports & Exports, FDA05
10. Recalls of FDA Regulated Products, FDA24

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

PUBLIC HEALTH PRINCIPLES

1. Public Health Principles (90) FDA36

EMERGENCY MANAGEMENT

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

1. IS-100.a, Introduction to Incident Command System, (180) ICS-100 or IS-100 for FDA
2. IS-200.a, ICS for Single Resources and Initial Action, Incidents, (180) ICS-200
3. IS-700.a, NIMS an Introduction, (180) ICS 700
4. IS-800.b, National Response Framework – An Introduction, ICS 800

COMMUNICATION SKILLS

1. Communication Skills for Regulators (Course can be accessed through https://ifpti.absorbtraining.com/#/purchase/category/49067)

FOOD MICROBIOLOGICAL CONTROL (SERIES):

1. Overview of Microbiology (60) MIC01
2. Gram-Negative Rods (60) MIC02
3. Gram-Positive Rods & Cocci (90) MIC03
4. Foodborne Viruses (60) MIC04
5. Foodborne Parasites (90) MIC05
6. Mid-Series Exam (30) MIC16
7. Controlling Growth Factors (90) MIC06
8. Control by Refrigeration & Freezing (60) MIC07

Appendix 2.4: Curriculum Example Basic Food Inspector Training (continued)

FOOD MICROBIOLOGICAL CONTROL (SERIES):

9. Control by Thermal Processing (90) MIC08
10. Control by Pasteurization (90) MIC09
11. Control by Retorting (90) MIC10
12. Technology-Based Food Processes (120) MIC11
13. Natural Toxins (90) MIC12
14. Aseptic Sampling (90) MIC13
15. Cleaning & Sanitizing (90) MIC15

EPIDEMIOLOGY: Foodborne Illness Investigations (series):

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

HACCP: Basics of HACCP (series):

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

ALLERGEN MANAGEMENT

1. Food Allergens (60) FD252

BASIC LABELING

1. Food Labeling (60) FDA45 (Course can be accessed through https://ifpti.absorbtraining.com/#/purchase/category/49067)

FOOD DEFENSE

1. ALERT: Food Defense Awareness Training

SAMPLING TECHNIQUE

1. Aseptic Sampling (90) MIC13

Appendix 3.1: Self-Assessment Worksheet

State agency: _____

Program Elements	Yes/No	If no, please explain why element is not met
3.3.1 Risk-based inspection program		
1. Does the State program maintain an inventory of food plants for which the State has regulatory oversight?		
2. Does the State program have a written procedure documenting the classification criteria and inspection frequencies?		
3. Is the inventory categorized by the degree of risk associated with the likelihood that a food safety or defense incident will occur?		
4. Does the State program use the risk factors and classification criteria as described in 3.3.1.2?		
3.3.2 Inspection procedure		
Does the State program's inspection procedure require inspectors to:		
1. Review the previous inspection report and CONSUMER COMPLAINTS?		
2. Have appropriate forms (if necessary) and equipment[19] that has been verified and maintained as defined by the state's standard operating procedures or manufacturer's recommendations?		
3. Make appropriate introductions, and explain the purpose and scope of the inspection?		
4. Establish jurisdiction?		
5. Select appropriate product/process for the inspection (high risk products and processes)?		
6. Assess employee practices critical to the safe and sanitary production and storage of food?		
7. Properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded?		

[19] Manufactured Food Regulatory Programs Standard 8: Program Resources and appendix 8.3 Inspection Equipment

Program Elements	Yes/No	If no, please explain why element is not met
8. Recognize significant violative conditions or practices, and record findings consistent with program procedures?		
9. Distinguish between significant and insignificant observations, and isolated incidents versus trends?		
10. Review and evaluate the appropriate operational records and procedures and apply the information obtained from this review?		
11. Collect adequate evidence and documentation in accordance with program procedures to support the inspectional observations?		
12. Verify correction of deficiencies from a previous inspection?		
13. Behave professionally and demonstrate proper sanitary practices during the inspection?		
14. Use current versions of applicable hazard guides or other guidance, to identify and evaluate the HAZARDS associated with product(s) and process(es) when conducting inspections of specialized food and processes?		
15. Assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation when required by regulation?		
16. When appropriate review the firm's: scheduled process; HACCP plan or necessary process controls in the absence of a HACCP plan; food safety control plan and applicable monitoring, verification and deviation or corrective action records, including those related to sanitation.		
17. Recognize deficiencies in the firm's monitoring controls and sanitation procedures through in-plant observations?		
18. Use suitable interviewing techniques?		
19. Explain findings clearly and adequately throughout the inspection?		
20. Alert the firm's person in charge when an immediate corrective action is necessary?		
21. Answer questions and provide information in an appropriate manner?		

Program Elements	Yes/No	If no, please explain why element is not met
22. Write findings accurately, clearly, and concisely on the State document and provide a copy to firm's person in charge?		
3.3.3 Inspection reports		
Does the State program have written inspection report procedures that require inspectors to:		
1. Submit inspection report in a timely manner?		
2. Complete the inspection report form completely and accurately?		
3. Document violations and observations clearly, legibly, and concisely?		
4. Follow up with corrective action, compliance and enforcement?		
3.3.4 Food recalls		
Does the State program have a food recall system that has written procedures for:		
1. Sharing information about recalls with relevant agencies?		
2. Ensuring recalled products are removed promptly from the market?		
3. Performing RECALL AUDIT CHECKS?		
3.3.5 CONSUMER COMPLAINTS		
Does the program have procedures for receiving, tracking, evaluating, responding to, and closing CONSUMER COMPLAINTS?		
3.3.6 Industry complaints about inspections		
Does the program have procedures for receiving, evaluating, and responding to food INDUSTRY COMPLAINTS about inspections?		
3.3.7 Sampling procedure		
Does the State program's sampling procedure include:		
1. Use of appropriate method & equipment to collect the sample?		

Program Elements	Yes/No	If no, please explain why element is not met
2. Record sample chain of custody per State procedures?		
3. Appropriately handle, package, and ship sample according to procedures to prevent compromising conditions and ensure security of the sample?		
4. Deliver or ship sample to the appropriate laboratory within acceptable timeframes?		
5. Instructions for documenting the applicable sample collection information?		
a. Date of sample collection?		
b. Product identification which includes name of product and unique manufacturing identification reference?		
c. Description of product?		
d. Collection information which includes method of collection, lot sampled, lot size, and any special sampling techniques used?		
e. Location where sample was collected?		
f. Name and address of responsible party, guarantor, processor or distributor?		
g. Sample type?		
h. Analysis requested (when applicable)?		
i. Product labeling or labeling information?		
j. Identification of the sample with a sample number assigned at the time of collection?		
6. For states that do not have a SAMPLING PROGRAM, is there a statement that explains why a SAMPLING PROGRAM is not supported and how public health is protected in the absence of such a program?		
3.3.8 Records Retention		
Does the State program maintain records as required under 9.3.2.2 for the following:		
1. Inspection reports which include follow up activities?		
2. Essential recall information?		
3. CONSUMER COMPLAINTS?		

Program Elements	Yes/No	If no, please explain why element is not met
4. INDUSTRY COMPLAINTS about inspections[20]		
5. Documentation associated with sample collection?		

Assessment completed by:_____

(NAME) **(DATE)**

[20] Records dealing with personnel actions are not subject to review during an ASSESSMENT.

Appendix 3.2: Risk Classification Criteria for Food Plants

Risk management is prioritizing opportunities to reduce risk and allocate food safety efforts and resources. Policymakers must consider the entire production-to-consumption chain and all of the participants (regulators, industry, researchers, health care providers, and consumers) when deciding how to best utilize resources to maximize food safety and reduce costs.

Standard number 3 focuses on one segment of the total food safety system – inspection of food plants. Although this standard does not prescribe a classification scheme or inspection frequency, frequencies could be established through: (1) risk-based assessment of foodborne hazards, (2) ranking the public health impacts of specific hazards, (3) measurement and valuation of the benefits of reducing risk, (4) evaluation of the effectiveness and cost of risk reduction intervention options, and (5) integration of these analyses to allocate resources.

When categorizing establishments by risk, State programs may consider several factors including: (1) the type of food and ingredients, (2) processing requirements, (3) volume of product manufactured or distributed, (4) intended consumer, and (5) compliance history of the food plant. The factors may be assigned numerical values that are tabulated to rank the food plants and prioritize inspections.
Foods with microbial hazards, especially those that require stringent temperature controls, are usually deemed high risk. Other foods such as unpasteurized juices may be classified as high risk based on epidemiologic implication in foodborne disease outbreaks. In addition to microbial hazards, chemical hazards should also be evaluated.

Complex manufacturing processes with many critical control points such as commercial sterilization, acidification, dehydration, formulation control, or mandatory HACCP systems are generally considered high risk. These operations must be properly controlled to prevent, eliminate, or reduce food safety hazards to acceptable levels. Reconditioning operations including food salvage are often ranked as high risk because improper reconditioning could result in distribution of adulterated or misbranded products to consumers.

High volume manufacturers and distributors have the potential to expose more consumers to food safety hazards if product or process controls fail. When combined with other factors, they may be classified as high risk.

Many classification schemes prioritize products intended for use by HIGHLY-SUSCEPTIBLE POPULATIONS because these populations are more likely to experience foodborne illnesses compared to the general population.

Inspection or compliance history is commonly considered when establishing inspection frequencies. It is reasonable to expect those firms with a history of compliance to be inspected less frequently than those firms with a history of non-compliance. Some State programs factor the compliance history directly into the risk ranking while others use performance criteria to adjust the inspection frequency from a baseline established by other criteria.

Standard number 3 requires a State program to categorize food plants based on risk and to allocate resources and establish inspection frequencies based on that categorization. Standard number 3 does not prescribe how this must be done. State programs should document their classification system and inspection frequencies. Differences between agencies will exist for many reasons including variable resources, legislative mandates, localized industries and practices, and competing priorities.

Appendix 3.2: Risk Classification Criteria for Food Plants (continued)

The risk classification criteria listed is intended solely to assist State programs with establishing their own classification system.

Risk	**Type of processing**
High	Canning low acid foods, acidifying foods, vacuum packaging, salvaging, smoking for preservation, curing
Medium	Cooking, cooling, holding under controlled temperatures, pasteurization
Low	Temperature control not required
Risk	**Type of foods**
High	Potentially hazardous foods frequently implicated in foodborne illness (sprouts, unpasteurized juices, raw shellfish, cream-filled pastries, filled macaroni products)
Medium	Potentially hazardous foods not typically implicated in foodborne illness
Low	Non-potentially hazardous foods
Risk	**Volume of product manufactured/distributed**
Higher	High volume operations with broad distribution
Lower	Low volume operations or operations with localized distribution
Risk	**Target population**
Higher	Foods consumed by HIGHLY-SUSCEPTIBLE POPULATIONS
Lower	Foods consumed solely or primarily by the general population
Risk	**Compliance History**
Higher	Businesses with an inconsistent or poor history of compliance with food safety requirements
Lower	Businesses routinely in compliance with food safety requirements

Appendix 4.1: Self-Assessment Worksheet

State agency: _____

Program Elements	Yes/No	If no, please explain why element is not met
4.3.1 Quality Assurance		
The State program has a written Quality Assurance Program (QAP) that contains written procedures:		
1. Conducting FIELD INSPECTION AUDITS as described in section 4.3.2?		
2. Conducting inspection report audits as described in section 4.3.3?		
3. Conducting sample report audits as described in section 4.3.4?		
4. A corrective action plan as described in section 4.3.5?		
4.3.2 FIELD INSPECTION AUDITS		
Does the State program:		
1. Use a QUALIFIED TRAINER or QUALIFIED AUDITOR conduct FIELD INSPECTION AUDITS or VERIFICATION AUDIT INSPECTIONS to verify that inspections are consistently performed according State program's written inspection procedures described in Standard 3?		
2. Conduct a minimum of two FIELD INSPECTION AUDITS per inspector conducted every 36 months?		
3. Select inspections for FIELD INSPECTION AUDITS that include the highest risk firms that the inspector is trained for including specialized food inspections?		
4. Complete Appendix 4.5 or equivalent form be used to document FIELD INSPECTION AUDITS?		
5. Complete Appendix 4.2 or equivalent form document overall rating calculations of FIELD INSPECTION AUDITS?		
4.3.3 Inspection Report Audits		
Does the State program:		
1. Conduct a periodic review of inspection reports to verify that inspectional findings are obtained and reported according to established written procedure?		

Program Elements	Yes/No	If no, please explain why element is not met
2. Use a random selection of inspection reports based on the number of inspections completed in the last 12 months using the table in 4.3.3.1?		
3. Take seven percent (7%) of inspection reports reviewed from inspections that were FIELD INSPECTION AUDITS?		
4. Complete Appendix 4.6 or equivalent form to document inspection report audits?		
5. Complete Appendix 4.3 or equivalent form to document overall rating calculations of inspection report audits?		
4.3.4 Sample Report Audits		
Does the State program:		
1. Conduct a periodic review of sample reports to verify that samples were collected, identified, recorded, and submitted according to established written procedure?		
2. Use a random selection of sample reports based on the number of samples collected in the last 12 months using the table in 4.3.4.1?		
3. Complete Appendix 4.7 or equivalent form to document sample report audits?		
4. Complete Appendix 4.4 or equivalent form to document overall rating calculations of sample report audits?		
4.3.5 Corrective Action Plan		
Does the State program have a written corrective action plan (Appendix 4.8 or equivalent form) that addresses actions when one or more of the conditions below are met:		
1. An individual receives a rating of "needs improvement"?		
2. An individual performance factor for the program falls below 80%?		
3. An overall rating for the program falls below 80%?		

Assessment completed by:_____

(NAME) **(DATE)**

Appendix 4.2: Performance rating for the field inspection audits

State agency: _____ **Performance period:** _____

Performance rating (4): _____

Reviewed by: **Office:** **Date:**

Performance factors (5)	Auditor's initials and date of audit (1)																				A_t (3)	NI_t (3)
	Performance ratings (2)																					
I.1																						
I.2																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
II.7																						
II.8																						
II.9																						
II.10																						
IIA.1																						
IIA.2																						
IIA.3																						
IIA.4																						
III.1																						
III.2																						
III.3																						
III.4																						
III.5																						
III.6																						
Subtotal	*Enter the sum of the totals from all continuation sheets.*																					
Total	*Enter the final sums (subtotal + sums of (3) on this form).*																					

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

Appendix 4.2: Performance rating or the field inspection audits (continued)

State agency: _____ **Performance period:** _____

Performance factors (5)	Auditor's initials and date of audit (1)																				A_t (3)	NI_t (3)
	Performance ratings (2)																					
I.1																						
I.2																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
II.7																						
II.8																						
II.9																						
II.10																						
IIA.1																						
IIA.2																						
IIA.3																						
IIA.4																						
III.1																						
III.2																						
III.3																						
III.4																						
III.5																						
III.6																						
Total	*Enter the sums of (3).*																					

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

Appendix 4.2a: Summary of Field Inspection Audit Findings

The summary of the performance factor ratings for all FIELD INSPECTION AUDITS allows FDA and the State program to recognize trends in inspectional coverage and identify specific areas in the inspection program that may need improvement.

Appendix 4.2 is used to calculate an overall rating for the performance period and identify single performance factors rated as "needs improvement" in multiple audits. The performance factors are described in appendix 4.5. A rating below 80 percent indicates a need for improvement and requires corrective action.

INSTRUCTIONS:

(1) For each field inspection audited, record the auditor's initials and date of audit in the box.

(2) For each field inspection audited, record the rating for each performance factor listed in appendix 4.5.
A = acceptable; NI = needs improvement.

(3) Record the A_t and NI_t for each performance factor.
A_t = horizontal total of acceptable ratings.
NI_t = horizontal total of needs improvement ratings.

(4) Calculate the overall rating for the FIELD INSPECTION AUDITS.
Record the rating in the space provided in the box located at the top of Appendix 4.2.

FORMULA:

FIELD INSPECTION AUDIT performance rating =
$[\sum A_t / (\sum A_t + \sum NI_t)] \times 100$

NOTE: $\sum$ *is the statistical symbol for the sum of all numbers.*

$\sum A_t$ = vertical sum of acceptable ratings.
$\sum NI_t$ = vertical sum of needs improvement ratings.

(5) Evaluate audit ratings for a single performance factor. Use the space at the bottom of Appendix 4.2 to identify and make notes about single performance factors rated as "needs improvement" in multiple audits.

Appendix 4.3: Performance rating for inspection report audits

State agency: _____ **Performance period:** _____

Performance rating (4): _____

Reviewed by: _____ **Office:** _____ **Date:** _____

Performance factors (5)	Firm identification number and date of inspection (1)																				A_t (3)	NI_t (3)
	Performance ratings (2)																					
I.1																						
I.2																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
II.7																						
II.8																						
II.9																						
II.10																						
Subtotal	***Enter the sum of the totals from all continuation sheets.***																					
Total	***Enter the final sums (subtotal + sums of (3) on this form).***																					

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

Appendix 4.3: Performance rating for inspection report audits (continued)

State agency: _____ Performance period: _____

Performance factors (5)	Firm identification number and date of inspection (1)																				A_t (3)	NI_t (3)
	Performance ratings (2)																					
I.1																						
I.2																						
I.3																						
I.4																						
I.5																						
I.6																						
I.7																						
I.8																						
I.9																						
I.10																						
Subtotal	*Enter the sum of the totals from all continuation sheets.*																					
Total	*Enter the final sums (subtotal + sums of (3) on this form).*																					

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

Appendix 4.3a: Summary of inspection report audit findings

The summary of the performance factor ratings for all inspection report audits allows FDA and the State program to recognize trends in inspectional coverage and identify specific areas in the inspection program that may need improvement.

Appendix 4.3 is used to calculate an overall rating for the performance period and identify single performance factors rated as "needs improvement" in multiple audits. The performance factors are described in appendix 4.6. A rating below 80 percent indicates a need for improvement and requires corrective action.

INSTRUCTIONS: (1) For each inspection report audited, record the firm identification number and date of the inspection in the box.

(2) For each inspection report audited, record the rating for each performance factor listed in appendix 4.6.
A = acceptable; NI = needs improvement.

(3) Record the A_t and NI_t for each performance factor.
A_t = horizontal total of acceptable ratings.
NI_t = horizontal total of needs improvement ratings.

(4) Calculate the overall rating for the inspection report audits.
Record the rating in the space provided in the box located at the top of Appendix 4.3.

FORMULA:

Inspection report audit performance rating =
$[\sum A_t / (\sum A_t + \sum NI_t)] \times 100$

NOTE: $\sum$ *is the statistical symbol for the sum of all numbers.*

$\sum A_t$ = vertical sum of acceptable ratings.
$\sum NI_t$ = vertical sum of needs improvement ratings.

(5) Evaluate audit ratings for a single performance factor. Use the blank page of Appendix 4.3 to identify and make notes about single performance factors rated as "needs improvement" in multiple audits.

Appendix 4.4: Performance rating for the sample report audits

State agency: _____ **Performance period:** _____

Performance rating (4): _____

Reviewed by: _____ **Office:** _____ **Date:** _____

Performance factors (5)	Sample report identification number and date of sample collection (1)																				A_t (3)	NI_t (3)
	Performance ratings (2)																					
I.1																						
I.2																						
I.3																						
I.4																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
II.7																						
II.8																						
II.9																						
II.10																						
Subtotal	***Enter the sum of the totals from all continuation sheets.***																					
Total	***Enter the final sums (subtotal + sums of (3) on this form).***																					

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

Appendix 4.4: Performance rating for the sample report audits (continued)

State agency: _____ **Performance period:** _____

Performance factors (5)	Sample report identification number and date of sample collection (1)																				A_t (3)	NI_t (3)
	Performance ratings (2)																					
I.1																						
I.2																						
I.3																						
I.4																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
II.7																						
II.8																						
II.9																						
II.10																						
Total	*Enter the sums of (3).*																					

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS "NEEDS IMPROVEMENT" IN MULTIPLE AUDITS.

Appendix 4.4a: Summary of sample report audit findings

The summary of the performance factor ratings for all sample report audits allows FDA and the State program to recognize trends in inspectional coverage and identify specific areas in the inspection program that may need improvement.

Appendix 4.4 is used to calculate an overall rating for the performance period and identify single performance factors rated as "needs improvement" in multiple audits. The performance factors are described in appendix 4.7. A rating below 80 percent indicates a need for improvement and requires corrective action.

INSTRUCTIONS: (1) For each sample report audited, record the sample report identification number and date of sample collection in the box.

(2) For each sample report audited, record the rating for each performance factor listed in appendix 4.7.
A = acceptable; NI = needs improvement.

(3) Record the A_t and NI_t for each performance factor.
A_t = horizontal total of acceptable ratings.
NI_t = horizontal total of needs improvement ratings.

(4) Calculate the overall rating for the sample report audits.
Record the rating in the space provided in the box located at the top of Appendix 4.4.

FORMULA:
Sample report audit performance rating =
$[\sum A_t / (\sum A_t + \sum NI_t)] \times 100$

NOTE: $\sum$ ***is the statistical symbol for the sum of all numbers.***

$\sum$ **A_t = vertical sum of acceptable ratings.**

$\sum$ **NI_t = vertical sum of needs improvement ratings.**

(5) Evaluate audit ratings for a single performance factor. Use the space at the bottom of Appendix 4.4 to identify and make notes about single performance factors rated as "needs improvement" in multiple audits.

Appendix 4.5: Contract Audit Form (FDA 3610)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CONTRACT AUDIT

FDA AUDITOR	STATE INSPECTOR
FIRM	CFN / FEI NUMBER
FIRM ADDRESS	
PRODUCT(S) COVERED	
TIME IN TIME OUT	OVERALL RATING ☐ Acceptable ☐ Needs Improvement

NOTE: EVERY ITEM MARKED "NEEDS IMPROVEMENT" MUST BE ACCOMPANIED BY AN EXPLANATION OF WHY THE ITEM WAS JUDGED AS NEEDING IMPROVEMENT.

Overall Rating:
If three or less items are marked "needs improvement," the overall rating is "acceptable." If four or more items are marked "needs improvement," the overall rating is "needs improvement." The overall rating must be marked in the space provided in the header on the first page.

All questions must be answered "acceptable" or "needs improvement," except for section *II.A. Inspection Observations and Performance for 'HACCP-Regulated' firms*. **If the establishment is not subject to Seafood or Juice HACCP regulations, leave the scoring for these four questions blank.**

If four or more evaluated items are marked as "needs improvement," the state program manager must be notified by the appropriate FDA liaison that additional training or other performance improvement measures for then inspector being audited should be initiated. All contract inspectors who receive an overall audit score of "needs improvement" shall receive remedial training in deficient areas or as agreed upon by the FDA Project and Co-Project Officers prior to resuming contract inspection duties.

I. Preinspection Assessment

1. DID THE INSPECTOR REVIEW THE STATE'S ESTABLISHMENT FILE FOR THE PREVIOUS INSPECTION REPORT AND POSSIBLE COMPLAINTS OR ACCESS OTHER AVAILABLE RESOURCES IN PREPARATION FOR THE INSPECTION?

   ☐ Acceptable ☐ Needs Improvement

   Comments *(required for Needs Improvement)*

2. DID THE INSPECTOR HAVE THE APPROPRIATE EQUIPMENT AND FORMS TO PROPERLY CONDUCT THE INSPECTION?

☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

II. Inspection Observations and Performance

1. WAS FDA JURISDICTION ESTABLISHED?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

2. DID THE INSPECTOR SELECT AN APPROPRIATE PRODUCT FOR THE INSPECTION AND, IF NECESSARY, MAKE APPROPRIATE ADJUSTMENTS BASED ON WHAT THE FIRM WAS PRODUCING?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

3. DID THE INSPECTOR ASSESS THE EMPLOYEE PRACTICES CRITICAL TO THE SAFE PRODUCTION AND STORAGE OF FOOD?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

4. DID THE INSPECTOR PROPERLY EVALUATE THE LIKELIHOOD THAT CONDITIONS, PRACTICES, COMPONENTS, AND/OR LABELING COULD CAUSE THE PRODUCT TO BE ADULTERATED OR MISBRANDED?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

5. DID THE INSPECTOR RECOGNIZE SIGNIFICANT VIOLATIVE CONDITIONS OR PRACTICES IF PRESENT AND RECORD FINDINGS CONSISTENT WITH STATE PROCEDURES?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

6. DID THE INSPECTOR DEMONSTRATE THE ABILITY TO DISTINGUISH BETWEEN SIGNIFICANT VERSUS INSIGNIFICANT OBSERVATIONS AND ISOLATED INCIDENTS VERSUS TRENDS?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

7. DID THE INSPECTOR REVIEW AND EVALUATE THE APPROPRIATE RECORDS AND PROCEDURES FOR THIS ESTABLISHMENT'S OPERATION AND EFFECTIVELY APPLY THE INFORMATION OBTAINED FROM THIS REVIEW?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

8. DID THE INSPECTOR COLLECT ADEQUATE EVIDENCE AND DOCUMENTATION IN ACCORDANCE WITH STATE PROCEDURES GIVEN THE NATURE OF THE INSPECTIONAL FINDINGS?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

9. DID THE INSPECTOR VERIFY CORRECTION OF DEFICIENCIES IDENTIFIED DURING THE PREVIOUS STATE INSPECTION?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

10. DID THE INSPECTOR ACT IN A PROFESSIONAL MANNER AND DEMONSTRATE PROPER SANITARY PRACTICES DURING THE INSPECTION?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

II. A. Inspection Observations and Performance for 'HACCP-regulated' Facilities

Note to Auditor: These four questions apply to only firms subject to HACCP regulations. These four questions should be left blank for firms not subject to HACCP regulations.

1. DID THE INSPECTOR USE THE "FISH AND FISHER PRODUCTS HAZARDS AND CONTROLS GUIDE" OR THE "JUICE HACCP HAZARDS AND CONTROLS GUIDE," AS APPROPRIATE, TO IDENTIFY AND EVALUATE THE HAZARDS ASSOCIATED WITH THE PRODUCT AND PROCESS?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

2. DID THE INSPECTOR ASSESS THE FIRM'S IMPLEMENTATION OF SANITATION MONITORING FOR THE APPLICABLE EIGHT KEY AREAS OF SANITATION?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

3. DID THE INSPECTOR REVIEW THE FIRM'S HACCP PLAN (OR NECESSARY PROCESS CONTROLS IN THE ABSENCE OF A HACCP PLAN) AND APPLICABLE MONITORING, VERIFICATION AND CORRECTIVE ACTION RECORDS, INCLUDING THOSE RELATED TO SANITATION?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

4. DID THE INSPECTOR RECOGNIZED EFFICIENCIES IN THE FIRM'S MONITORING AND SANITATION PROCEDURES THROUGH IN-PLANT OBSERVATIONS?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

II. Oral and Written Communication

1. DID THE INSPECTOR IDENTIFY HIMSELF/HERSELF AND MAKE APPROPRIATE INTRODUCTIONS, WHICH INCLUDE EXPLAINING THE PURPOSE AND SCOPE OF THE INSPECTION?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

2. DID THE INSPECTOR USE SUITABLE INTERVIEWING TECHNIQUES?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

3. DID THE INSPECTOR EXPLAIN FINDINGS CLEARLY AND ADEQUATELY THROUGHOUT THE INSPECTION?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

4. DID THE INSPECTOR ALERT THE FIRM'S APPROPRIATE MANAGEMENT WHEN AN IMMEDIATE CORRECTIVE ACTION WAS NECESSARY?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

5. DID THE INSPECTOR ANSWER QUESTIONS AND PROVIDE INFORMATION IN AN APPROPRIATE MANNER?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

6. DID THE INSPECTOR WRITE THEIR FINDINGS ACCURATELY, CLEARLY AND CONCISELY ON THE STATE FORM/DOCUMENT LEFT WITH THE FIRM?

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

ADDITIONAL COMMENTS

SIGNATURE OF FDA AUDITOR	DATE

Appendix 4.5a: Guidance for completing the contract audit form (FDA 3610)

This document provides guidance on assigning ratings during an audit for each of the performance factors listed on the Contract Audit Form. For each performance factor examples of actions and observations that would likely result in a "needs improvement" rating are provided.

I. PRE INSPECTION ASSESSMENT

1. Did the inspector review the State's establishment file for the previous inspection report and possible complaints or access other available resources in preparation for the inspection?

References:
- State program's establishment files
- FDA compliance programs referenced in the contract

Examples of a "needs improvement" rating:

a. The inspector does not review the State's previous inspection report and follow-up on previously cited deficiencies.
b. The inspector does not review a firm's response letter that promised corrective actions after the last inspection, which was conducted by the State.
c. The inspector does not verify the firm's normal days of operation or seasonal hours.
d. The inspector does not follow-up on a consumer complaint contained in the State's establishment file.

2. Did the inspector have the appropriate equipment and forms to properly conduct the inspection?

References:
- FDA compliance programs referenced in the contract
- FDA inspection guides

Examples of a "needs improvement" rating:

a. During an inspection of a cream-filled pie manufacturer, the inspector does not have a calibrated thermometer to check the temperature of the pie.
b. During an inspection of a cooked, ready-to-eat food processor, the inspector does not have a method to test the concentration of iodine sanitizer in the hand dip station. During the inspection, the inspector does not have a flashlight to examine poorly lit raw material storage areas.

II. INSPECTION OBSERVATIONS AND PERFORMANCE

1. Was FDA jurisdiction established?

References:
- FDA Investigations Operations Manual (IOM), subchapter 432 - Documenting Interstate Shipments
- IOM, subchapter 701 – Statutory Authority

Examples of a "needs improvement" rating:

a. The inspector fails to confirm interstate movement of a product or ingredients.
b. The inspector conducts an inspection of a candy manufacturer assigned under FDA contract. He/she fails to discover that the manufacturer has not shipped product in interstate commerce in the past 24 months. This manufacturer has no ingredients or packaging components shipped interstate.

2. Did the inspector select an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the firm was producing?

References:

- FDA compliance programs referenced in the contract

Examples of a "needs improvement" rating:

a. The inspector covers only a low-risk product while the firm is producing a high-risk product on the day of the inspection.
b. The inspector does not cover a small ready-to-eat sandwich operation in a large frozen dinner processing plant.
c. While inspecting a beverage bottling plant whose primary product is institutional-sized root beer syrup, the inspector ignores a bottled water processing operation at that site.

3. Did the inspector assess the employee practices critical to the safe production and storage of food?

Examples of a "needs improvement" rating:

a. The inspector fails to evaluate the hygienic practices of employees working in a food processing area.
b. The inspector is unaware of the need for employees who are processing cooked, ready-to-eat foods to wash and sanitize their hands every time they touch an unclean surface.
c. The inspector notices that the firm has a trash bin and a reclaim bin in the same area. He/she does not, however, recognize the potential hazard. Consequently, the inspector misses an employee placing trash in the reclaim bin that contains product reintroduced into the manufacturing process.

4. Did the inspector properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded?

References:

- FDA compliance programs referenced in the contract
- NLEA inspection guide

Examples of a "needs improvement" rating:

a. The inspector fails to recognize when a firm's finished product labeling does not contain a sulfite declaration, even though the raw material does contain a sulfite declaration.
b. The inspector fails to note the significance of "back hauling" raw eggs in a tanker used to carry pasteurized ice cream mix.

c. During an inspection of a baby food manufacturer, the inspector notices a rapid moving belt is causing glass jars to rattle and shards of glass are on the belt. The inspector fails to relate that observation to a recent increase in complaints about glass in baby food.
d. The inspector fails to recognize the addition of an allergen during the production of a breaded product and fails to follow-up on the label review.

5. Did the inspector recognize significant violative conditions or practices, if present, and record findings consistent with State procedures?

Examples of a "needs improvement" rating:

a. The inspector fails to recognize that the food residues and mold growth on food contact surfaces are violations.
b. The inspector does not recognize that employees handling cooked, ready-to-eat product with soiled hands is a deficiency.
c. The inspector doesn't notice that machine parts over food contact surfaces are lubricated with automobile oil.
d. The inspector fails to recognize that condensate dripping from a freezer onto finished product may cause cross contamination.

6. Did the inspector demonstrate the ability to distinguish between significant versus insignificant observations and isolated incidents versus trends?

References:

- FDA compliance programs referenced in the contract

Examples of a "needs improvement" rating:

a. The inspector notes minor deficiencies such as chewing gum and nail polish while failing to note places where cross contamination of cooked and raw product might occur.
b. The inspector identifies record keeping deficiencies in records that are two months old. The inspector objects to these deficiencies without appropriately considering that the firm's weekly management review of the records has identified the deficiencies, which have not been repeated within the last seven weeks.
c. During an inspection of a ready-to-eat salad processor, the inspector focuses primarily on filthy, non-food contact surfaces.
d. During the inspection of a warehouse, the inspector focuses on products stored against the wall but doesn't notice several pallets of rice infested with moths.

7. Did the inspector review and evaluate the appropriate records and procedures for this establishment's operation and effectively apply the information obtained from this review?

Examples of a "needs improvement" rating:

a. During a review of the processing records, the inspector fails to detect that cooking times are outside the scheduled process.
b. The inspector fails to detect possible evidence of record falsification such as inconsistencies among different types of records, unrealistic and repetitive data, and inconsistencies in signatures.
c. Can teardown records are reviewed, but the inspector didn't realize teardown measurements were not done at appropriate intervals.

8. Did the inspector collect adequate evidence and documentation in accordance with State procedures given the nature of the inspectional findings?

Examples of a "needs improvement" rating:

a. The inspector fails to adequately document findings according to State requirements when violations are found in the firm.
b. The inspector fails to follow State requirements when collecting samples of processed food necessary to document violative conditions.
c. In an acidified food processing plant, the pH of the final product is questionable. The inspector does not, however, collect a sample of the product for pH determination.

9. Did the inspector verify correction of deficiencies identified during the previous State inspection?

Examples of a "needs improvement" rating:

a. Although significant time-temperature abuse of coconut cream pies was identified during the previous inspection, the inspector does not determine if the deficiencies were corrected.
b. In the previous inspection, the inspector reported that a private well was not equipped with a sanitary seal. During the current inspection, the manager tells the inspector that the well was repaired, and the lab results were acceptable. The inspector reviews the microbiological lab results, but does not go to the well to verify that the sanitary seal was installed.
c. The inspector fails to follow up on deficiencies from the previous inspection for cooked, ready-to-eat product because that product was not being made at the time of the inspection. Nor does the inspector review process records for the product to determine if the firm took appropriate corrective actions.

10. Did the inspector act in a professional manner and demonstrate proper sanitary practices during the inspection?

Examples of a "needs improvement" rating:

a. The inspector does not use the boot bath when entering in the firm's processing areas.
b. The inspector fails to sanitize his/her thermometer prior to probing product.
c. The inspector fails to wear protective clothing when entering an aseptic processing area.
d. The inspector wears dangling earrings, bracelets, and necklaces in the food processing areas of a baby food manufacturer.

II. A. INSPECTION OBSERVATION AND PERFORMANCE FOR 'HACCP-REQUIRED' FACILITIES

Note: Questions 1-4 are rated only when the firm is required by regulation to have a HACCP plan.

References:

- FDA compliance programs referenced in the contract
- Title 21 Code of Federal Regulations (21 CFR) parts 110, 120, 123, and 1240
- Fish and Fishery Products Hazards & Controls Guide
- HACCP Regulation for Fish & Fishery Products: Questions and Answers
- Juice HACCP Hazards and Controls Guide

Appendix 4.5a: Guidance for completing the contract audit form (FDA 3610) (continued)

1. Did the inspector use the "Fish and Fishery Products Hazards and Controls Guide" and the "Juice HACCP Hazards and Controls Guide", as appropriate, to identify and evaluate the hazards associated with the product and process?

Examples of a "needs improvement" rating:

a. In a tuna processing plant, the inspector fails to identify histamine as a hazard inherent to the incoming raw material and fails to question its absence in the firm's HACCP plan. (Failure to identify a hazard reasonably likely to occur.)
b. A firm is producing fresh, raw, refrigerated fish in Cryovac packaging. The inspector is not aware that C. botulinum is a significant hazard.
c. An inspector incorrectly identifies aquaculture drugs as a significant hazard for a secondary processor of a product that it receives from the primary processor. (Identification of a hazard not reasonably likely to occur.)
d. The inspector fails to recognize that a batter tank in a breaded shrimp processing operation is a possible CCP. (Failure to recognize an appropriate CCP.)

2. Did the inspector assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation?

Examples of a "needs improvement" rating:

a. The inspector insisted the firm perform medical check-ups for crabmeat pickers.
b. The inspector cannot determine which of the eight areas of sanitation are relevant to the firm's operations.
c. The inspector fails to inquire about the firms SSOPs and monitoring practices.

3. Did the inspector review firm's HACCP plan (or necessary process controls in the absence of a HACCP plan) and applicable monitoring, verification, and corrective action records, including those related to sanitation?

Examples of a "needs improvement" rating:

a. The inspection reveals that the firm is processing a product that requires a HACCP plan. The inspector cites the firm's failure to have a HACCP plan, but the inspector does not determine if the necessary controls were put into place without a HACCP plan.
b. Although the inspector is told that the firm uses well water, not potable water, as its source for ice, the inspector does not verify that the firm has the water tested for coliforms to ensure its safety.
c. The inspector does not ask the plant manager for records of pest control after learning that the service is contracted to a private company.
d. The inspector does not accompany the firm's sanitarian on a routine pre-operation inspection that would have given him an indicated that the sanitation and/or sanitation monitoring may be inadequate.

4. Did the inspector recognize deficiencies in the firm's monitoring and sanitation procedures through in-plant observations?

Examples of a "needs improvement" rating:

a. The inspector fails to recognize that cumulative times and temperatures for cooling, holding, and picking of cooked crabs were substantially above such times and temperatures specified in the firm's HACCP plan.
b. The inspector fails to recognize that a firm's finished product labeling does not contain a sulfite declaration even though an ingredient contains a sulfite declaration.
c. The inspector fails to recognize that the presence of food residues and mold growth on processing equipment immediately prior to processing is evidence of unsanitary conditions.
d. The inspector does not recognize that food-contact surfaces are being sanitized with a product that is not approved for use on food contact surfaces.

III. ORAL AND WRITTEN COMMUNICATION

1. Did the inspector identify himself/herself and make appropriate introductions, which include explaining the purpose and scope of the inspection?

Examples of a "needs improvement" rating:

a. The inspector fails to explain why he/she is at the firm.
b. The inspector enters through the back door and begins examining a storage area without notifying anyone at the firm.

2. Did the inspector use suitable interviewing techniques?

Examples of a "needs improvement" rating:

a. The inspector requests for information are vague; consequently, the firm provides documents that are unrelated to the inspection.
b. The firm manager is unable to respond to a request for information, because the inspector spoke in unfamiliar and confusing jargon.
c. When the plant manager's responses are evasive, the inspector does not ask follow-up questions to obtain the necessary information. Consequently, the answers to the questions are incomplete.

3. Did the inspector explain findings clearly and adequately throughout the inspection?

Examples of a "needs improvement" rating:

a. The inspector does not discuss a significant observation at the close-out meeting.
b. The inspector does not discuss with the general manager a significant deficiency observed in the processing area before going to the packing area of the cannery.
c. The inspector is vague during his discussion with the managers at the end of the inspection. Therefore, the managers are unaware of the significance of the observations and that corrective actions are needed.

Appendix 4.5a: Guidance for completing the contract audit form (FDA 3610) (continued)

4. Did the inspector alert the firm's appropriate management when an immediate corrective action was necessary?

Examples of a "needs improvement" rating:

a. The inspector fails to alert the appropriate manager that food containing undeclared FD&C Yellow #5 is being packaged, and, if shipped, could result in a health hazard.
b. The inspector didn't notify the plant manager when he saw blood dripping from boxes of boneless beef onto raw carrots.
c. The inspector documented condensate dripping from bins of ready-to-eat salad not packaged.

5. Did the inspector answer questions and provide information in an appropriate manner?

Examples of a "needs improvement" rating:

a. The inspector discusses specific information about a pending compliance action against a competitor with an employee on the processing line.
b. The inspector gives a competitor's product formula to a friendly plant manager.
c. The inspector fabricates an answer to a policy question that could lead the firm to take an inappropriate corrective action.
d. The inspector dictates an inappropriate corrective action for a deficiency.

6. Did the inspector write their findings accurately, clearly, and concisely on the State form/document left with the firm?

References:

- FDA compliance programs referenced in the contract

Examples of a "needs improvement" rating:

a. The inspector fails to write that the firm has a significant process deviation on the list of findings.
b. The inspector fails to write on the list of findings that he/she observed excreta pellets in bags of rice.
c. The list of findings shows that the "Firm did not control hazards" with no further explanation.

Appendix 4.6: Inspection Report Audit Form

MANUFACTURED FOOD REGULATORY PROGRAM STANDARDS INSPECTION REPORT AUDIT FORM	
AUDITOR:	DATE OF AUDIT: DATE OF INSPECTION:
FIRM NAME: FIRM ADDRESS:	Type of Inspection: ☐ General Food ☐ Seafood HACCP ☐ Juice HACCP ☐ LACF ☐ Acidified ☐ Other:
TOTAL NUMBER: Acceptable Needs Improvement Audit Score:	AUDIT RATING: ☐ Acceptable ☐ Needs Improvement

INSTRUCTIONS TO THE AUDITOR

All performance factors must be rated 'Acceptable' or 'Needs Improvement.' The total number of 'Acceptable' and 'Needs Improvement,' as well as the audit score and audit rating, must be recorded in the space above.

To calculate the audit score: *Audit Score = [# Acceptable/ (# Acceptable + # Needs Improvement)] x 100*.

If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement.'

I. Organization and Records of Findings

1. THE INSPECTOR SUBMITTED THE REPORT WITHIN DESIGNATED TIMEFRAMES.

   ☐ Acceptable ☐ Needs Improvement

   Comments *(required for Needs Improvement)*

2. ALL REQUIRED FIELDS ON INSPECTION REPORT OR RELATED REPORT FORMS ARE COMPLETED.

   ☐ Acceptable ☐ Needs Improvement

   Comments *(required for Needs Improvement)*

3. WRITTEN OBSERVATIONS WERE CLEAR AND CONCISE.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

4. THE INSPECTOR FOLLOWED ALL CURRENT AND APPLICABLE STATE REPORT WRITING AND INSPECTIONAL DOCUMENTATION PROCEDURES.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

5. THE INSPECTOR IDENTIFIES VIOLATIONS BASED ON STATE AND/OR FEDERAL REGULATIONS.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

6. THE INSPECTOR REVIEWS PAST INSPECTION FINDINGS AND ACTS ON REPEATED OR UNRESOLVED VIOLATIONS.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

7. THE INSPECTOR RECORDED SIGNIFICANT FINDINGS.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

8. THE INSPECTOR RECORDED THE COLLECTION OF ALL SAMPLES, EXHIBITS, PHOTOGRAPHS, OR PHOTOCOPIES TO SUPPORT FINDINGS.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

9. OBTAINS AND DOCUMENTS ON-SITE CORRECTIVE ACTION AT THE TIME OF INSPECTION AS APPROPRIATE TO THE TYPE OF VIOLATION. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
10. THE INSPECTOR FOLLOWED THROUGH AND DOCUMENTED COMPLIANCE ACTIVITIES PER STATE POLICY. ☐ Acceptable ☐ Needs improvement Comments *(required for Needs Improvement)*
General Comments
Enter any general comments or recommendations as a result of this audit.

Appendix 4.7: Sample Report Audit Form

MANUFACTURED FOOD REGULATORY PROGRAM STANDARDS SAMPLE REPORT AUDIT FORM	
AUDITOR:	DATE OF AUDIT: DATE OF INSPECTION:
FIRM NAME: FIRM ADDRESS:	DATE OF COLLECTION: SAMPLE ID #:
TOTAL NUMBER: Acceptable Needs Improvement Audit Score:	AUDIT RATING: ☐ Acceptable ☐ Needs Improvement

INSTRUCTIONS TO THE AUDITOR

All performance factors must be rated 'Acceptable' or 'Needs Improvement.' The total number of 'Acceptable' and 'Needs Improvement,' as well as the audit score and audit rating, must be recorded in the space above.

To calculate the audit score: *Audit Score = [# Acceptable/ (# Acceptable + # Needs Improvement)] x 100.*

If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement.'

I. Sample Observations and Performance

1. METHOD OF COLLECTION WAS APPROPRIATE FOR TYPE OF PRODUCT.

   ☐ Acceptable ☐ Needs improvement

   Comments *(required for Needs Improvement)*

2. RECORD SAMPLE CHAIN OF CUSTODY PER STATE PROCEDURE.

   ☐ Acceptable ☐ Needs improvement

   Comments *(required for Needs Improvement)*

3. SAMPLE WAS HANDLED, PACKAGED, AND SHIPPED TO PREVENT COMPROMISING THE CONDITION OR INTEGRITY OF THE SAMPLE, AS EVIDENCED BY ACCEPTANCE AND TESTING BY THE RECEIVING LABORATORY.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

4. SAMPLE WAS SUBMITTED WITHIN PRESCRIBED TIMEFRAMES.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

II. Sample Collection

1. DATE OF SAMPLE COLLECTION

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

2. PRODUCT IDENTIFICATION INCLUDING NAME AND MANUFACTURING REFERENCE INFORMATION WAS RECORDED. FOR ENVIRONMENTAL SAMPLES A DESCRIPTION OF THE COLLECTION POINT IS ACCEPTABLE.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

3. DESCRIPTION OF PRODUCT INCLUDING SAMPLE SIZE.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

4. COLLECTION INFORMATION, INCLUDING METHOD OF COLLECTION, LOT SAMPLED, LOT SIZE, AND ANY SPECIAL TECHNIQUES USED TO COLLECT THE SAMPLE WAS RECORDED.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

5. LOCATION WHERE SAMPLE WAS COLLECTED IS RECORDED.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

6. NAME AND ADDRESS OF MANUFACTURER, RESPONSIBLE PARTY, GUARANTOR, PROCESSOR, OR DISTRIBUTOR WERE RECORDED. FOR ENVIRONMENTAL SAMPLES THE PHYSICAL LOCATION OF THE COLLECTION SITE AND RESPONSIBLE PARTY IS ACCEPTABLE.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

7. SAMPLE TYPE (SURVEILLANCE, COMPLIANCE, INVESTIGATIONAL, OR REGULATORY) WAS RECORDED.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

8. THE TYPE OF ANALYSIS REQUESTED WAS RECORDED IF APPLICABLE. IF THE TYPE OF ANALYSIS IS NOT REQUIRED ON SAMPLE REPORT PER STATE PROCEDURES THIS ITEM IS ACCEPTABLE.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

9. PRODUCT LABELS OR LABELING INFORMATION INCLUDING IS COLLECTED OR REPRODUCED IF REQUIRED BY STATE PROCEDURES. FOR ENVIRONMENTAL SAMPLES THE DESCRIPTION OF THE LOCATION OF THE SAMPLE COLLECTION POINT IS ACCEPTABLE.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

10. THE SAMPLE IDENTIFICATION ASSIGNED BY THE SAMPLER AT THE TIME OF COLLECTION WAS REPORTED.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

General Comments
Enter any general comments or recommendations as a result of this audit.

Appendix 4.8: Corrective Action Plan

The corrective action for each deficiency reported during an audit should be described in the table below. Supporting documents should be referenced and maintained by the State program.

State agency: _____

Assessment Completed by: _____

(NAME) (DATE)

Type of audit: ☐ **FIELD INSPECTION** ☐ **INSPECTION REPORT** ☐ **SAMPLE REPORT**

Performance factor (record number from audit form)	Description of deficiency	Corrective action(s)	Date of next audit

Appendix 5.1: Self-Assessment Worksheet

State agency: _____

Program Elements	Yes/No	If no, please explain why element is not met
5.3.1 Coordination with Other Authorities		
Does the State program:		
1. Have an MOU for foodborne illness outbreak investigations, if required?		
2. Have a written procedure that identifies and describes the roles, responsibilities and duties of each program responsible for supporting foodborne illness outbreak response in requirements 5.3.1-5.3.4?		
3. Have a written procedure that describes collaborate with FDA and other agencies in multi-jurisdictional FOOD-RELATED INCIDENTS?		
4. Have a written procedure that designates a response coordinator(s) to guide program investigation efforts in collaboration with all agencies involved?		
5. Have a written procedure that notifies all relevant agencies of FOOD-RELATED INCIDENTS?		
6. Have written procedure that provides guidance for notification of appropriate law enforcement agencies when intentional food contamination is suspected or threatened?		
7. Have a written procedure that describes the maintenance of a list(s) relevant agencies and emergency contacts that is updated at least yearly?		
5.3.2 Surveillance		
Does the State program:		
1. Use epidemiological information from local, state, or federal agencies to detect incidents or outbreaks of foodborne illness or injury?		
2. Maintain notifications of FOOD-RELATED INCIDENTS that are reported to the program, in a log or database?		

Program Elements	Yes/No	If no, please explain why element is not met
5.3.3 Investigation/Environmental Assessment		
Does the State program:		
1. Use established procedures with recommended timeframes to investigate reports of FOOD-RELATED INCIDENTS?		
2. Collect ENVIRONMENTAL ASSESSMENT data using established procedures similar to those found in IAFP and CIFOR?		
3. Coordinate the TRACEBACK and TRACEFORWARD of food implicated in an illness, injury, outbreak or found to contain a HAZARD?		
4. Have access to laboratory support for investigation of reports of FOOD-RELATED INCIDENTS?		
5. Correlate and analyze ENVIRONMENTAL ASSESSMENT data to identify contributing factors and antecedents?		
5.3.4 Control Measures		
Does the State program:		
1. Mitigate and contain food-related illness, injury and HAZARDS through strategies that include industry education, enforcement and public awareness activities?		
2. Maintain a written media procedure with criteria for releasing prevention guidance and information to the public?		
5.3.5 Post Response		
Does the State program:		
1. Maintain written program investigation and ENVIRONMENTAL ASSESSMENT findings and reports?		
2. Distribute final program investigation report, including an ENVIRONMENTAL ASSESSMENT, if completed, of illness or injury implicating food to relevant agencies responsible for reporting contributing factors and antecedents to CDC?		

Program Elements	Yes/No	If no, please explain why element is not met
3. Distributes recommendations, when available, from investigation and ENVIRONMENTAL ASSESSMENT findings and reports to relevant agencies and stakeholders responsible for prevention, education and outreach.		

Assessment completed by: _____

(NAME) **(DATE)**

Appendix 6.1: Self-Assessment Worksheet

State agency: _____

Program Elements	Yes/No	If no, please explain why element is not met
6.3.1 Compliance and Enforcement Program		
Does the state have a written compliance and enforcement program that:		
1. Contains written compliance and enforcement strategies?		
2. Describes the procedure to monitor: CRITICAL VIOLATIONS, chronic violations and chronic violators?		
3. Uses a risk-based process to determine when a directed investigation, follow-up, or re-inspection is needed?		
4. Establishes a framework for compliance and enforcement progressive actions?		
5. Has a system to communicate policy and guidance to managerial and non-managerial staff?		
6.3.2 Performance Review		
Does the State program conduct a performance review:		
1. Annually?		
2. Document on Appendix 6.2, or equivalent form to evaluate if internal compliance and enforcement actions are followed?		
3. Use results of the review to identify improvements and modify procedures?		
4. Require a corrective action if performance ratings fall below 80 percent?		

Assessment completed by:_____

(NAME) **(DATE)**

Appendix 6.2: Calculation of the level of conformance to compliance procedures

State agency: _____

Rating for conformance to compliance procedures (4):

Food firm identification number (1)	Enforcement action recommended (1)	Compliance procedures followed? (2)		USE THIS SPACE TO EXPLAIN IMPROVEMENTS NEEDED TO FOLLOW COMPLIANCE PROCEDURES
Subtotal	***Enter the sum of the totals from all continuation sheets.***	**A_t =**	**NI_t =**	
Total	***Enter the final sums -- subtotal + sums of (2) -- on this form.***	**A_t =**	**NI_t =**	

Assessment completed by:_____

(NAME) **(DATE)**

Appendix 6.2: Calculation of the level of conformance to compliance procedures (continued)

Food firm identification number (1)	Enforcement action recommended (1)	Compliance procedures followed? (2)		USE THIS SPACE TO EXPLAIN IMPROVEMENTS NEEDED TO FOLLOW COMPLIANCE PROCEDURES
Total	***Enter the sums of (2).***	A_t =	NI_t =	

Appendix 6.2a: Performance Review of Enforcement Actions

Appendix 6.2 is used to record the enforcement actions recommended in the past 12 months and to calculate the State agency's rating for conformance to compliance procedures. Supporting documents should be referenced and maintained by the State agency. Please indicate if an action was taken because voluntary compliance was not achieved.

It is recommended that all cases be reviewed; otherwise, a statistical approach should be used to determine a representative number of cases. Use continuation sheets as necessary.

INSTRUCTIONS: (1) Record the food firm identification number and the recommended enforcement action.

(2) For each type of enforcement action, record the level of conformance to compliance procedures.
A = acceptable; NI = needs improvement

(3) Record the A_t and NI_t .

A_t = vertical sum of acceptable ratings.

NI_t = vertical sum of needs improvement ratings.

(4) Calculate the overall rating for the State agency's conformance to compliance procedures. Record the rating in the box located at the top of Appendix 6.2.

FORMULA:

Performance factor rating = $[A_t / (A_t + NI_t)] \times 100$

Appendix 7.1: Self-Assessment Worksheet

State agency: _____

Program Elements	Yes/No	If no, please explain why element is not met
7.3 Outreach Methods		
Does the State program have a written procedure that includes how the program will:		
1. Identify the methods that will be used for communication with the food industry stakeholders and consumers?		
2. Interact with industry and consumers by sponsoring or actively participating in meetings such as task forces, advisory boards, or advisory committees?		
3. Tailor outreach efforts to a target population and may include dissemination of information using electronic sources and traditional methods such as mailings?		
4. Document and OUTREACH ACTIVITY EVENT using Appendix 7.2 or equivalent form? Include documents such as agendas and meeting summaries and program evaluations.		

Assessment completed by:_____

(NAME) (DATE)

Appendix 7.2: Outreach Activity Event and Self-Evaluation Worksheet

State program: _____

This worksheet is completed by the State program to document OUTREACH ACTIVITY EVENTS. Attach verifying documents such as agendas and meeting summaries and program evaluations to this form.

Section I. Overview of Outreach Activity

a. Type of OUTREACH ACTIVITY EVENT (check one):

☐ Seminar ☐ Workshop ☐ Training course

☐ Other: _____

b. Subject or name of OUTREACH ACTIVITY EVENT: _____

c. Date of OUTREACH ACTIVITY EVENT: _____

d. Host organization: _____

Section II. Self-Evaluation of OUTREACH ACTIVITY EVENTS

Program Elements	Yes/No	If no, please explain.
a. The purpose and objectives were clearly defined		
b. The content of the OUTREACH ACTIVITY EVENT was consistent with the objectives		
c. The activity was tailored to a target population Identify target population:		
d. An evaluation was completed by attendees		
e. State program addressed comments from attendees in Section III of this form.		

Section III. Critique of OUTREACH ACTIVITY EVENT

Discuss what went well, what could be done better, and what more could be done to improve the OUTREACH ACTIVITY EVENT. Address comments from attendees, if available.

Assessment completed by: _____

(NAME) **(DATE)**

Appendix 8.1: Self-Assessment Worksheet

State agency: _____

Assessment completed by:_____
(NAME) (DATE)

Does the State program have sufficient funds, staff, equipment, and resources necessary to meet the program standards? Answer yes or no in each block. If no, please explain. Use additional pages as needed

Standard		Funding	Staffing	Equipment	Other resources needed
1	Regulatory Foundation				
2	Training Program				
3	Inspection Program				
4	Inspection Audit Program				
5	Food-related Illness …Outbreaks…Food Defense				
6	Compliance and Enforcement				
7	Industry and Community Relations				
8	Program Resources				
9	Program Assessment				
10	Laboratory Support				

Appendix 8.1a: Self-Assessment Worksheet Instructions

The Appendix 8.1 Self-Assessment Worksheet summarizes the State program's assessment of their resources for all ten Standards.

Instructions:

For each Standard, the State program conducts an assessment of resource needs for staffing, equipment, and funding for the manufactured food regulatory program. Answer yes or no in each block. If the response is no, please explain the additional resources needed. Use additional pages as needed.

When completing Appendix 8.1 the State program should consider the following items:

- Regulatory Foundation (Standard 1). The State program has resources to evaluate the scope of its legal authority and regulatory provisions to ensure the protection of manufactured food within its jurisdiction.

- Training Program (Standard 2). The State program has resources to implement a training plan that ensures all inspectors conducting manufactured food inspections complete course curriculums, field training, and continuing education to adequately perform their work.

- Inspection Program (Standard 3). The State program has resources to implement a risk based inspection program that reduces the occurrence of foodborne illness, injury, or allergic reactions.

- Inspection Audit Program (Standard 4**).** The State program has resources to administer and monitor the quality of its inspections and sample collections.

- Food-related Illness and Outbreaks and Food Defense Preparedness and Response (Standard 5)**.** The State program has the resources necessary to detect, investigate, mitigate, document and analyze the FOOD-RELATED INCIDENTS to stop, control and prevent HAZARDS that are likely to result in a foodborne illness, injury or outbreak.

- Compliance and Enforcement Program (Standard 6). The State program has resources to administer and monitor a compliance and enforcement program.

- Industry and Community Relations (Standard 7). The State program has resources that allow participation and assessment of outreach activities and OUTREACH ACTIVITY EVENTS.

- Program Resources (Standard 8).The State program has resources to conduct an assessment of resource needs for staffing, equipment, and funding to support a manufactured food regulatory program.

- Program Assessment (Standard 9). The State program has the resources to conduct self-assessments and develop and manage a STRATEGIC IMPROVEMENT PLAN resulting in conformance with the Manufactured Food Regulatory Program Standards and a process for continuous improvement.

- Laboratory Support (Standard 10). The State program has resources to assess laboratory services needed to support program functions.

Appendix 8.2: Calculation for determining a required number of inspectors

This appendix is <u>an example</u> of how to calculate the number of field staff required to conduct inspections[21] of food plants. The data in the following table will vary significantly based on local or regional conditions. The State program may use the risk categories and inspection frequencies found in the statement of work for the food contract as a basis for determining the required number of inspectors.

Risk category	Number in inventory	Inspection frequency	Average inspection time (includes travel) [22]	Reinspection frequency
High	1,000	12 months	7.2 hours	10%
Medium	2,000	18 months	5.7 hours	10%
Low	1,000	24 months	4.2 hours	10%

1. Calculate available annual inspection time per full time equivalent (FTE).

For example, the State agency determines that after allowances for annual leave, sick leave, holidays, training, administrative time, and other activities each State program FTE has 1200 hours available for conducting inspections.

2. Calculate the number of hours required to inspect establishments in each risk category.

Formula for high risk establishment inspection time:
1000 firms x 100% coverage = 1000 inspections + 10% reinspection = 1100 total inspections per year x 7.2 hours = 7920 hours

Formula for medium risk establishment inspection time:
2000 firms x 66.6% coverage = 1333 inspections + 10% reinspection = 1466 total inspections per year x 5.7 hours = 8356 hours

Formula for low risk establishment inspection time:
1000 firms x 50% coverage = 500 inspections + 10% reinspection = 550 inspection total inspections x 4.2 hours = 2320 hours

3. Calculate the number of FTE's required.

Formula:
7920 hours for high risk + 8356 hours for medium risk + 2320 hours for low risk = 18596 inspection hours required / 1200 inspection hours available per FTE = **<u>15.5 FTEs</u>**

[21] Includes routine surveillance, reinspections, complaint or outbreak investigations, compliance follow-up investigations, risk assessment reviews, process reviews, and other direct establishment contact time such as on-site training.

[22] Inspection times based on calculations presented in "DHHS Office of Inspector General's FDA Oversight of State Food Firm Inspections" dated June 2000.

Appendix 8.3: Inspection Equipment

State agency: _____

Assessment completed by:_____

(NAME) (DATE)

The State program should develop a list of equipment needed to conduct inspections and sample collections. Please add and remove equipment from the table. Then indicate if the equipment is assigned, available, or a "wish list" item. Also indicate in the verified column if the equipment item is to be verified and maintained. Items checked as "verified" will need to have a written verification and maintenance procedure as required in Standard 3, 3.3.2.2. "Wish list" items include equipment requested by inspectors but not available.

EQUIPMENT	ASSIGNED	AVAILABLE	WISH LIST	VERIFIED
Computer and printer				
Camera				
Credentials				
Important phone numbers (supervisor and servicing laboratory)				
Regulation and policies				
Paper, pen, masking tape, and permanent marker				
Clipboard				
Required forms (attached)				
Alcohol swabs and wipes				
Flashlight and holder				
Blacklight				
Light meter				
Thermometer				
Infrared thermometer				
Exacto knife and scissors				
Putty knife and scraper				
Sampling devices (sieves, triers, and swabs)				
Sampling equipment (sterile containers and scoops)				
Coolant (ice and freezer paks)				
Shipping containers				
Appropriate sanitizer test strips				
Official seals				
Protective clothing(lab coat, gloves, and boots)				
Eye protection				
Hair restraint				
Hearing protection				
Hard hat				
Safety shoes				
Respirator				

Appendix 9.1: Self-Assessment Summary Report

State agency: _____

Report completed by:_____
(NAME) (DATE)

Standard	Self Assessment	IMPLEMENTATION	Explain improvements needed to fully IMPLEMENT standards *(required for incomplete self-assessment and partial IMPLEMENTATION)*
1. Regulatory Foundation	**Complete** ☐ **Incomplete** ☐ **Hours used** ____	**Full** ☐ **Partial** ☐	
2. Training Program	**Complete** ☐ **Incomplete** ☐ **Hours used** ____	**Full** ☐ **Partial** ☐	
3. Inspection Program	**Complete** ☐ **Incomplete** ☐ **Hours used** ____	**Full** ☐ **Partial** ☐	
4. Inspection Audit Program	**Complete** ☐ **Incomplete** ☐ **Hours used** ____	**Full** ☐ **Partial** ☐	
5. Food-related Illness, Outbreak, and Hazards Response	**Complete** ☐ **Incomplete** ☐ **Hours used** ____	**Full** ☐ **Partial** ☐	
6. Compliance and Enforcement	**Complete** ☐ **Incomplete** ☐ **Hours used** ____	**Full** ☐ **Partial** ☐	
7. Industry and Community Relations	**Complete** ☐ **Incomplete** ☐ **Hours used** ____	**Full** ☐ **Partial** ☐	

Appendix 9.1: Self-Assessment Summary Report (continued)

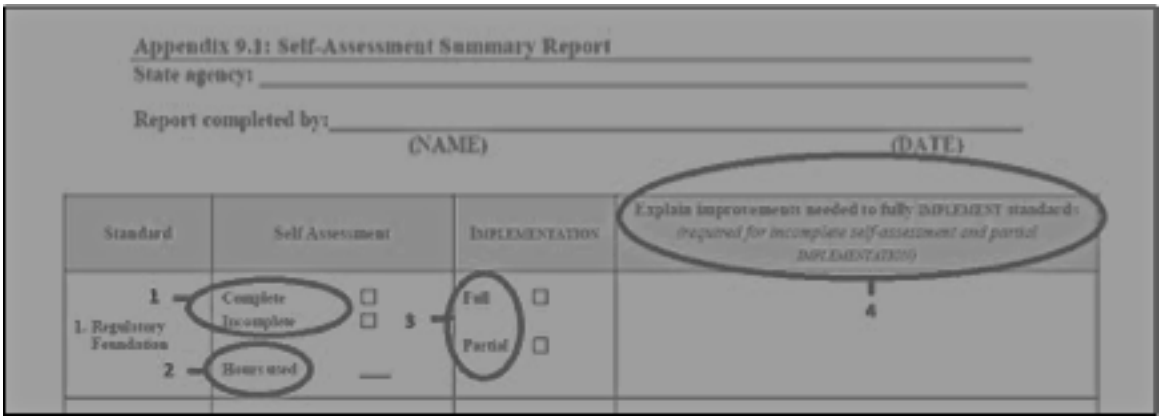
State agency: _____

Report completed by:_____
(NAME) (DATE)

Standard	Self-Assessment	IMPLEMENTATION	Explain improvements needed to fully IMPLEMENT standards *(required for incomplete self-assessment and partial IMPLEMENTATION)*
8. Program Resources	**Complete** ☐ **Incomplete** ☐ **Hours used** ____	**Full** ☐ **Partial** ☐	
9. Program Assessment	**Complete** ☐ **Incomplete** ☐ **Hours used** ____	**Full** ☐ **Partial** ☐	
10. Laboratory Support	**Complete** ☐ **Incomplete** ☐ **Hours used** ____	**Full** ☐ **Partial** ☐	

Standard 9: Appendix 9.1 Self-Assessment Summary Report Instructions

Appendix 9.1 is the Self-Assessment Summary Report. This summary report shows the implementation status of each standard and a brief description of needed improvements. Appendix 9.1 can be used to develop the STRATEGIC IMPROVEMENT PLAN (SIP). Standards that are "Incomplete" or "Partial" implementation must be addressed in the SIP.



Instructions: Complete Appendix 9.1 for each Standard. Each row has four sections that must be completed. The sections are described below:

1. ***Self-Assessment – Complete versus Incomplete*** Section:

• Check **"Complete"** if you have conducted the appropriate self-assessment worksheets or equivalent forms in each respective standard. *Otherwise*, check "**Incomplete**."

2. ***Self-Assessment – Hours Used*** Section*:*

• FDA must provide a cost estimate to the Office of Management Bureau (OMB) on the MFRPS burden of work (approximate hours per year) to develop and maintain MFRPS paperwork in accordance with the Paperwork Reduction Act (PRA)[i]. Programs shall include all hours used to develop, implement and conform to the MFRPS each year whether the hours were funded through Cooperative Agreement funds or State funds. *Programs should include time associated with the following types of activities:*

- *Completing Standards Assessments*
- *Standard 2 Training Coordination*
- *Staff Auditing/Evaluation*
- *Standard Operating Procedure Development/Revision*
- *Review/Update of Operational Manuals*
- *Equipment Verification/Calibration*
- *Outreach Activities*
- *Strategic Improvement Plan Development/Monitoring*
- *Resource Allocation/Budgeting*
- *Laboratory Coordination/Maintenance of Methods, Analysis Lists, Etc.*

- *Meeting with DSI/Participation in MFRPA Meetings*
- *MFRPA Workgroup Activities, Projects, or Surveys*
- *Tracking/Trend Analysis*
- *MFRPS Standards Coordinator Activities*
- *Subject Matter Expert Activities Associated with the Standards*

Time associated with conducting inspections, enforcement actions, foodborne illness outbreak investigations and complaint investigations should not be included in the calculation of hours.

3. ***Implementation - Full** versus **Partial*** Section:
• Check "**Full**" if the state program has all of the required elements listed in the Program Elements and

Documentation sections of that Standard.
• Check "**Partia**l" if the state program is missing any of the requirements of that Standard.

Note: The state program must update Appendix 9.1 based upon the results of the Audit Staff Audit Report. The state program must document corrective actions necessary to achieve "**Full**" IMPLEMENTATION on the SIP.

4. ***Explain Improvements Needed to Fully Implement Standard*** Section:
This section is used to describe program elements that need to be developed or modified to achieve "**Full**" IMPLEMENTATION. Brief descriptions may include:

• No documented process for annual review of REGULATORY FOUNDATION
• Continuing education credits are not captured
• No documented sampling protocol
• Inspection Report Audits are not included in the Quality Assurance Program
• The Compliance and Enforcement Program is not applied throughout the state
• Memorandum of Understanding for foodborne illness and outbreak response is in draft form or unsigned

Appendix 9.1 and other Self-Assessments are used to develop the STRATEGIC IMPROVEMENT PLAN (SIP). Each task on the SIP must include details for what individual element or documentation was not met, what improvements are needed, projected completion dates, the responsible personnel, and the completion date. Appendix 9.1 and the SIP must be updated at least annually.

State programs should work closely with their FDA Office of Partnerships, Standards Implementation Staff (SIS) specialist to ensure accurate completion of MFRPS documents. Programs receiving Cooperative Agreement funds must participate in periodic ASSESSMENTS conducted by the FDA Office of Operations, Audit Staff (AS). The AS are responsible for verifying the accuracy of the self-assessments, and determine IMPLEMENTATION and CONFORMANCE.

Appendix 10.1: Self-Assessment Worksheet

State agency: _____

Program Elements	Yes/No	If no, please explain why element is not met
10.3.1 Laboratory Support		
Does the State program:		
1. Have access to a laboratory that is capable of analyzing a variety of samples including food, environmental, and clinical samples?		
2. Maintains a list of services for routine and non-routine analyses such as biological HAZARD determinations?		
3. Have a contract or written agreement with each PRIMARY SERVICING LABORATORY unless under the same administrative agency? The contract or written agreement can be a memorandum of understanding, e-mail, or any written format but must contain the components below: 1) Define the responsibilities of each party; 2) Describe the types of testing services to be performed; and 3) Describe how exceptions to planned work will be communicated.		
4. Have documentation of the services provided, if services are provided from a non- PRIMARY SERVICING LABORATORY?		
10.3.2 ISO Accredited Laboratories		
Does the state program:		
Use laboratories that have a current accreditation to the ISO/IEC 17025:2005 or ISO/IEC 17025:2017 standards to analyze food and environmental samples?		
10.3.3 Non-ISO Accredited Laboratories		
If not using laboratories holding accreditation to ISO/IEC 17025:2005 or ISO/IEC 17025:2017 for the analysis of food and environmental samples, is the program using laboratories that have in place a quality system which incorporates the following management and technical requirements at a minimum:		

Program Elements	Yes/No	If no, please explain why element is not met
1. A quality system that is documented and includes items 10.3.3.1.1 through 10.3.3.1.6.		
2. A procedure that defines the activities necessary to take corrective action when non-conforming work occurs		
3. A document control procedure that assures documents issued to personnel are current, suitable, and reviewed and approved by authorized personnel prior to release.		
4. A documented record keeping process that assures that records of original observations and data collection are maintained and sufficient to establish traceability of test results to sample handling and storage, to sample analysis including data collection, to equipment calibration and maintenance, and to the review of test results prior to release		
5. A documented process to assure that reference materials and reference cultures used are fit for purpose, are not outdated, and are traceable to a lot number or other unique identifier.		
6. A documented process to assure that the laboratory participates in relevant and available proficiency testing activities.		

Assessment completed by:_____

(NAME) **(DATE)**