Manufactured Food Regulatory Program Standards

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs

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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 the 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 food firms. 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.

The 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 the 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 the 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 manufactured food firms. 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 FDA is responsible for ensuring that all foods moving in interstate commerce, except those under the United States Department of Agriculture (USDA) 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 manufactured food firm 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, the FDA established a committee to develop a set of quality standards for manufactured food regulatory programs. The committee was comprised of officials from the FDA and state agencies responsible for regulating manufactured food firms.[2] The result of the committee was the first edition of the program standards published by the 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 the FDA has been engaged in for many years of partnering, leveraging and empowering agencies to move the vision of a nationally integrated food safety system.

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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 structure or facility or parts thereof, used for or in connection with the manufacturing, processing, packaging, or holding of human food as defined by 21 CFR Part 117.3.

[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.

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 the 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 three-year continuing education period.

5. **Correction:** action to eliminate a detected non-CONFORMITY.

6. **Corrective Action(s):** action to eliminate the cause of a non-CONFORMITY and to prevent recurrence.

7. **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.

8. **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.

9. **Current Experienced Staff:** defined by the state program in their training plan.

10. **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.

11. **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.

12. **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.

13. **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 a self-assessment, the state program may need to consult with its legal counsel when a provision is determined to be equivalent in effect.

14. **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 basic and each advanced (specialized) inspection type. 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 advanced (specialized) inspection types (as applicable).

    Appendix 4.3 Field Inspection 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 4.3 – Field Inspection Audit Form, the evaluations may be counted toward the total audits for that year.

15. **Field Inspection Audit:** means an inspection in which a state inspector is accompanied by a QUALIFIED FIELD INSPECTION AUDITOR (either the 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 4.3 is used.

16. **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.

17. **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.

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

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

20. **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 manufactured food firm and may either be trainer led or trainee led.

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

22. **No Authority:** responsibility for enforcing a specific section of the federal statutes and/or regulations lies with another program or agency and not the state program. There is such a state law, but it does not apply to the state program.

23. **Not Equivalent:** means 1) there is no state law EQUIVALENT to the relevant federal law or regulation, or 2) the federal and state laws address the same matter but are inconsistent and do not have the same regulatory effect.

24. **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.

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

26. **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 2.3.5.

27. **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 canned foods, acidified foods, seafood HACCP, or juice inspections;
    - Been assigned this auditing responsibility; and
    - Completed the required audit training per the state program requirements

28. **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 canned 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.

29. **Recall Audit Checks**: are conducted by the state agency to verify that the manufactured food firm's recall was successful as defined by the state's recall procedures.

30. **Regulatory Foundation:** means laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of a manufactured food firm.

31. **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 (PFP) Food/Feed Testing Laboratories Best Practices Manual[4] . The program can be based on state defined sampling frequency and does not have to be continuous or routine.

32. **Start Date:** date an employee is hired or assigned to the manufactured food program as the beginning date for training timelines.

33. **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.

34. **Traceback**: begins at the end of the supply chain at the point of purchase or point of service (e.g., grocery stores and restaurants) and follows the food product back through the points of distribution, processing, and production to determine the source of the product and its ingredients.

35. **Traceforward**: traceforward follows the movement of a food in the opposite direction, from the source (e.g., a farm or manufacturer) forward to the retail shelf, to determine the scope of a potential recall and the impact of the contaminated product on the public health.

36. **Verification Audit Inspection:** means an inspection in which a qualified FDA or state QUALIFIED FIELD INSPECTION AUDITOR observes a state QUALIFIED FIELD INSPECTION AUDITOR performing an audit of a state inspector conducting an inspection

[4] Reference: PFP Human and Animal Food Testing Laboratories Best Practices Manual: https://www.pfp-ifss.org/ifss-resources/human-and-animal-food-testing-laboratories-best-practices-manual-december-2018/

STANDARD 1
Regulatory Foundation

1.1 Purpose

This standard describes the elements of the REGULATORY FOUNDATION used by a state program to regulate manufactured food firms.

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 manufactured food firms, 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.

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.
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

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, NOT EQUIVALENT or have NO AUTHORITY 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.

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 determining 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 Self-Assessment Worksheet (or equivalent form).
- 1.5.5 Appendix 1.2 Regulatory Foundation Worksheet (or equivalent form).
- 1.5.6 If applicable, review by legal counsel.

STANDARD 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
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.

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 10 JOINT FIELD TRAINING INSPECTIONS, field inspection audits, or evaluations with a qualified field inspection trainer, and

2.3.2.3.1.2 Of the 10, 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 inspections, 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 INSPECTIONS or FIELD INSPECTION AUDITS/EVALUATIONS are conducted in manufactured food firms

that are representative of the manufactured food 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 are 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[5]
2.3.3.1.6 Foodborne Illness Investigations[5]
2.3.3.1.7 Preventive Controls for Human Food

2.3.3.2 Field Training

The state program requires that each inspector successfully complete each of 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.
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 a 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 required coursework is intended for new employees or employees new to the food safety

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

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 food inspections course work	Document training records available. Create a statement or affidavit explaining the background or experience that justifies a waiver of the missing basic food inspection 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 food inspection training course work.

2.3.4.2 Newly Hired 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 EVALUATIONS or FIELD INSPECTION AUDITS within 6 months of the inspector's QUALIFIED DATE.
2.3.4.2.2	Basic food inspection training course work	Document training records available. Statement or affidavit explaining the background or experience that justifies a waiver of the basic food inspection 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 food inspection training course work.

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:

- 2.3.5.4.1 Attendance at national or regional seminars / technical conferences.
- 2.3.5.4.2 Professional symposiums / college courses.
- 2.3.5.4.3 Food-related training provided by government agencies (e.g., USDA, state, local).
- 2.3.5.4.4 Food safety related conferences and workshops.
- 2.3.5.4.5 Distance learning opportunities that pertain to food safety.
- 2.3.5.4.6 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:

- 2.3.5.5.1 Delivering presentations at professional conferences.
- 2.3.5.5.2 Providing classroom and/or field training to newly hired inspectors, or being a course instructor in food safety.
- 2.3.5.5.3 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:

- 2.3.5.7.1 Certificates of completion indicating the course date(s) and number of hours attended or CE credits granted.
- 2.3.5.7.2 Transcripts from a college or university.
- 2.3.5.7.3 A letter from the administrator of the continuing education program attended.
- 2.3.5.7.4 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.

2.3.5.7.5 An agenda and attendance roster.

2.3.5.7.6 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.6

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 firms.

2.5 Documentation

The state program maintains the records listed here.

2.5.1 Appendix 2.1 Self-Assessment Worksheet (or equivalent form).
2.5.2 Appendix 2.2 State Training Record Summary (or equivalent form).
2.5.3 Appendix 2.3 Individual Training Record (or equivalent form).
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.

[6] FDA/ORA Office of Education Training and Development courses (classroom and online) are listed at: https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted.

STANDARD 3
Inspection Program

3.1 Purpose

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

3.2 Requirement Summary

The state program has a manufactured food inspection system. This system provides the foundation for inspecting manufactured 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 manufactured food firms 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 a 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:

3.3.1.2.1 FD&C Act, section 421(a)(1), or

3.3.1.2.2 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 manufactured food firms that requires the inspectors to:

3.3.2.1 Review the previous inspection report and consumer complaints.

3.3.2.2 Have appropriate equipment and forms (if necessary). Equipment must be verified and maintained as defined by the state's standard operating procedures or manufacturer'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 manufactured food firm 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, 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 manufactured food firm 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 Properly evaluate good manufacturing practice requirements (21 CFR 117, Subparts A, B, and F (for training records only) or equivalent state regulation).

3.3.2.15 When appropriate, verify the manufactured food firm has a written food safety plan which includes a written hazard analysis that appropriately addresses hazards, and when appropriate, addresses preventive controls (process controls, allergen controls, sanitation controls, supply-chain controls, other controls) and a recall plan.

3.3.2.16 When appropriate, review the manufactured food firm's written procedures, monitoring, verification, correction, and corrective action records for process, allergen, sanitation, supply-chain controls, and other controls which are identified in their food safety plan.

3.3.2.17 When appropriate, verify the manufactured food firm is in compliance with the modified requirements that apply to a qualified facility (attestation).

3.3.2.18 When appropriate, verify the modified requirements and time/temperature controls that apply to a facility solely engaged in the storage of unexposed packaged foods that require refrigeration for safety.

3.3.2.19 When appropriate, assess the sanitary transportation of human food requirements that apply to transportation operations.

3.3.2.20 When appropriate, review the manufactured food firm's food defense plan, including mitigation strategies, monitoring, corrective action, and verification activities.

3.3.2.21 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.

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

3.3.2.23 When appropriate, review the manufactured food 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.

3.3.2.24 Recognize deficiencies in the manufactured food firm's monitoring controls and sanitation procedures through in manufactured food firm observations.

3.3.2.25 Use suitable interviewing techniques.

3.3.2.26 Explain findings clearly and adequately throughout the inspection.

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

3.3.2.28 Answer questions and provide information in an appropriate manner.

3.3.2.29 Write findings accurately, clearly, and concisely on the state document and provide a copy to the manufactured food 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.

3.3.3.4 Follow-up with corrective action, compliance, and enforcement.

3.3.4 Food Recalls[7]

[7] Reference: PFP Best Practices for Improving FDA and State Communication During Recalls (version 2) can be found: https://www.pfp-ifss.org/ifss-resources/best-practices-for-improving-fda-and-state-communications-during-recalls-fall-2021/.

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.

3.3.4.3 Performing recall audit checks.

3.3.5 Consumer complaints

The state program has a system for handling CONSUMER COMPLAINTS that contains written procedures for:

3.3.5.1 Receiving.

3.3.5.2 Tracking.

3.3.5.3 Evaluating.

3.3.5.4 Responding.

3.3.5.5 Closing.

3.3.6 Complaints Resulting from State Program Inspection Activities

The state program has a system for handling INDUSTRY COMPLAINTS about inspections that contains written procedures for:

3.3.6.1 Receiving.

3.3.6.2 Evaluating.

3.3.6.3 Responding.

3.3.7 Sampling Procedure4

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, to 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

3.3.7.2.5 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.
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 9.3.5.2 for the following:

3.3.8.1 Inspection reports which include follow-up activities.

3.3.8.2 Essential recall information.

3.3.8.3 Consumer complaints.

3.3.8.4 Industry complaints about inspections.[8]

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.

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

3.5 Documentation

The state program maintains the records listed here.

- 3.5.1 Appendix 3.1 Self-Assessment Worksheet (or equivalent form).
- 3.5.2 An inventory of manufactured food firms for which the state has regulatory oversight.
- 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 procedure for inspecting manufactured food firms.
- 3.5.6 Written inspection reports procedure.
- 3.5.7 Written inspection reports, which include follow-up activities.
- 3.5.8 Written procedure for food recalls.
- 3.5.9 Essential recall information.
- 3.5.10 Written procedure for consumer complaints.
- 3.5.11 Consumer complaints.
- 3.5.12 Written procedure for industry complaints about inspections.
- 3.5.13 Industry complaints about inspections.8
- 3.5.14 Written procedures for sampling or, in the absence of any sampling program, a statement explaining how public health is protected.
- 3.5.15 Sample collection reports.
- 3.5.16 Documentation associated with sample collection.

STANDARD 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 QAP 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 QAP that contains written procedures for:

4.3.1.1 Conducting field inspection audits as described in section 4.3.2.

4.3.1.2 Conducting inspection report audits as described in section 4.3.3.

4.3.1.3 Conducting sample report audits as described in section 4.3.4.

4.3.1.4 Initiating corrective action(s), which will be documented on the strategic improvement plan as described in section 9.3.2.

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 manufactured food firms that the inspector is trained for including specialized food inspections.

4.3.2.2 Performance is documented on Appendix 4.3 or equivalent form and Appendix 4.3a or a state audit form that meets the program elements in Standard 3, Program Element 3.3.2.

4.3.2.3 State programs may use the current Form FDA 3610 in lieu of Appendix 4.3.

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 4.4. An overall inspection report rating is calculated using Appendix 4.4a or equivalent form.

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 4.4 and 4.4a 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 4.5. An overall sample report rating is calculated using Appendix 4.5a or equivalent form.

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 4.5 and 4.5a or equivalent forms.

4.3.5 Corrective action

The state program shall initiate CORRECTIVE ACTIONS as described in 9.3.2 when the FIELD INSPECTION AUDIT, inspection report audit, or sample report audit meets one or more of the conditions below:

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%, or four or more "needs improvement" ratings are identified in a single performance factor. Note that if fewer than four audits are conducted, a performance deficiency may be considered for a single performance factor that "needs improvement".

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 (or equivalent form).
4.5.3 Appendix 4.3 Field Inspection Audit form (or equivalent form) or a state audit form that meets the program elements in Standard 3, Program Element 3.3.2.
4.5.4 Appendix 4.3a Summary of Field Inspection Audit Findings (or equivalent form).
4.5.5 Appendix 4.4 Inspection Report Audit Form (or equivalent form).
4.5.6 Appendix 4.4a Summary of Inspection Report Audit Findings (or equivalent form).
4.5.7 Appendix 4.5 Sample Report Audit Form (or equivalent form).
4.5.8 Appendix 4.5a Summary of Sample Report Audit Findings (or equivalent form).

STANDARD 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 the 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 assessment data using established procedures similar to those found in the most current versions of "International Association for Food Protection Procedures to Investigate Foodborne Illnesses" and the CIFOR "Guidelines for Foodborne Disease Outbreak Response."9

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 support10 for investigation of reports of food-related incidents.

5.3.3.5 Correlates and analyzes 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).

5.3.5 Post Response

The state program:

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

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

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 (or equivalent form).
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 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.
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.[11]

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:

[11] 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.

6.3.2.4 Require a corrective action if performance ratings fall below 80%, which will be documented on the strategic improvement plan as described in 9.3.2.

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 (or equivalent form).
6.5.2 Written Compliance and Enforcement Program.
6.5.3 Appendix 6.2 Performance Review of Enforcement Actions (or equivalent form).

STANDARD 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 food industry stakeholders and consumers. The written procedure includes how the state program will:

7.3.1 Identify the methods for communication with 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 (or equivalent form).
7.5.3 Appendix 7.2 or equivalent documentation for each outreach activity event (or equivalent form).

7.5.4 Meeting summaries, agendas, or other records documenting interaction with food industry stakeholders and consumers.

STANDARD 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 Resource Summary Report to assess staffing, funding, and equipment using Appendix 8.2 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 and documents the calculation for determining the required number of inspectors to inspect manufactured food firms in its manufactured food firm inventory at a frequency that is based on the manufactured food firm'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.

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 (or equivalent form).
8.5.2 Appendix 8.2 Resource Summary Report (or equivalent form).
8.5.3 Documentation of the calculation of number of inspectors.
8.5.4 List of equipment used for inspections and sample collections.

STANDARD 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 and FDA ASSESSMENTS are used to track progress toward meeting and maintaining CONFORMANCE with the program standards or identifying any non-CONFORMANCE when the program was previously in CONFORMANCE with the 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 9.2) or equivalent form.

9.3.2 If the state program fails to meet any of the program elements and documentation requirements of a standard, whether identified through self-assessment or FDA assessments, the program shall develop or update a written strategic improvement plan that includes the following information (as applicable):

9.3.2.1 The individual element or documentation requirement of the standard that was not met.

9.3.2.2 Improvements or corrections needed to meet the program element or documentation requirement of the standard.

9.3.2.3 The cause for any non-conformance requiring correction when the program was previously in conformance with the individual element or documentation requirement of a standard.

9.3.2.4 The corrective action taken to prevent future similar non-conformance when the program was previously in conformance with the individual element or documentation requirement of the standard that was corrected.

9.3.2.5 Projected completion dates for each task.

9.3.2.6 Personnel responsible.

9.3.2.7 Date completed for each task.

9.3.3 The state program shall review and update self-assessment appendices and its strategic improvement plan at least annually.

9.3.4 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.

9.3.5 The state program must:

9.3.5.1 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.

9.3.5.1.1 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:

9.3.5.1.1.1 Documents are reviewed for accuracy.

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

9.3.5.1.1.3 Documents are distributed to applicable staff, as appropriate, and used at the location where the prescribed activity is performed.

9.3.5.2 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.

9.4 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 Worksheet (or equivalent form).
9.5.2 Appendix 9.2 Self-Assessment Summary Report (or equivalent form).
9.5.3 Strategic improvement plan.
9.5.4 Document control procedure.
9.5.5 Record retention rules, policies, or procedures.
9.5.6 FDA Assessment reports.

STANDARD 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. The contract or written agreement must be documented such as a memorandum of understanding, e-mail, or any written format but must contain each 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.
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 17025:2017 (or current version) 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 17025:2017 (or current version) 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 17025:2017 (or current version) at a minimum:

10.3.3.1 A documented quality system which incorporates management and technical requirements of ISO/IEC 17025:2017 (or current version) and associated procedures, that include but are 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.
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, sample analysis including data collection, equipment calibration and maintenance, and 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 (or equivalent form).
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 17025:2017 (or current version) 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

Instructions: The state program identifies if they have a specified component then evaluates if it includes the associated components. If the state program has the main component and associated components indicate "Yes". If not, indicate "No".

State Agency: _____

Program Elements	Yes/No	If No, please explain why element is not met. May use this space for additional notes.
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 AUTHORITY assessment include a baseline self-assessment using Appendix 1.2 or equivalent form to determine if the state is EQUIVALENT, EQUIVALENT IN EFFECT, NOT EQUIVALENT, or NO AUTHORITY to sections of the FD&C Act and CFRs as specified in Appendix 1.2?		

Assessment Completed By:

Name _____ **Date:** _____

Appendix 1.2: Regulatory Foundation Worksheet

Instructions: *Determine if state laws and regulations are EQUIVALENT, EQUIVALENT IN EFFECT, or NOT EQUIVALENT to Federal statutes and regulations. Select "NO AUTHORITY" if the program has no regulatory responsibility for a statue or regulation or the authority falls under the jurisdiction of another agency.*

For those statutes and regulations for which the state program does have authority, record the state law or regulations and the date it was incorporated. The Notes section shall be used in part to detail differences between state and federal laws and regulations, and to clarify when other agencies may have regulatory jurisdiction. This self-assessment relates only to human food and public health. Any commodities within the statutes and regulations outside this scope do not need to be included on the self-assessment.

Note: the FD&C Act reference links direct you to the relevant U.S. Code section number. For a cross reference of FD&C Act and U.S. Code sections please visit the FDA's website: https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act

State Agency: _____

Federal Food, Drug & Cosmetic Act

FD&C Act/US Code	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
201/321	Definitions (f), (k), (m), and (ff)				
301/331	Prohibited acts (a), (b), (c), (d), (e), (f), (k), and (v)				
303/333*	Penalties				
304/334**	Seizure				
401/341	Definitions and standards for food				
402/342	Adulterated food				

FD&C Act/US Code	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
403/343	Misbranded food (a)-(s)				
413/350b	New dietary ingredients				
701/371	Regulations and hearings				
703/373***	Records of interstate shipments				
704/374	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

21 CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
1	General Enforcement Regulations (§ 1.20-1.24); Foreign Supplier Verification Program (Subpart L § 1.500-1.514); and Sanitary Transportation (Subpart O § 1.900-1.934)				
7	Enforcement Policy (ONLY § 7.1-7.13 and § 7.40-7.59)				

21 CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
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)				
102	Common or Usual Name for Nonstandardized Foods (EXCEPT § 102.19)				
104	Nutritional Quality guidelines for foods				
105	Foods for Special Dietary Use				

21 CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
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				
110[1]	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				

[1] 21 CFR Part 110 was modernized and codified in 21 CFR Part 117 by the current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food Rule.

21 CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
115	Shell Eggs				
117	Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food				
118	Production, Storage, And Transportation of Shell Eggs				
120	Hazard Analysis and Critical Control Point (HACCP) systems				
121	Mitigation Strategies to Protect Food from Intentional Adulteration				
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				

21 CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
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				
164	Tree Nut and Peanut Products				
165	Beverages				
166	Margarine				
168	Sweeteners and Table Syrups				

21 CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
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				
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				

21 CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
181	Prior-Sanctioned Food Ingredients				
182	Substances Generally Recognized As Safe				
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 laws and regulations used by the program to address regulatory responsibilities outside of the FDA jurisdiction are listed below.

Assessment Completed By:

Name _____ **Date:** _____

Appendix 2.1: Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluates if it includes the associated components. If the state program has the main component and associated components indicate "Yes". If not, indicate "No".

State Agency: _____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
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 their 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 manufactured food firms complete 10 JOINT FIELD TRAINING INSPECTIONS 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?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
5. Who will inspect non-high risk food warehouses complete five JOINT FIELD TRAINING INSPECTIONS, FIELD INSPECTION AUDITS, or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER?		
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 manufactured food 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 manufactured food 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?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
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 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?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
2.3.6 Coursework Sources		
Is all basic, advanced, and continuing education coursework obtained from sources listed in 2.3.6.1 – 2.3.6.4?		

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 (Yes/No)**
Prevailing statutes, regulations, and ordinances		
Public health principles		
Emergency management		
Communication skills		
Microbiology		
Epidemiology		
Basics of HACCP		
Allergen management		
Basic food labeling		
Food defense		
Sampling techniques and preparation		

Name of Inspector: _____ **Start Date:** _____

Basic Food Inspection Curriculum Fieldwork				
JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS		**Date Completed**	**EVALUATION/AUDIT Acceptable (Yes/No)**	**Documentation Available for Review (Yes/No)**
Please provide the name of the manufactured food firm and identification number.				
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

Name of Inspector: _____ **Start Date:** _____

Advanced Food Inspection Curriculum Fieldwork		
Course *Please provide the name and location of the course.*	**Completion Date**	**Course Documentation Available For Review (Yes/No)**
Acidified foods		
Low-acid canned food		
Juice HACCP		
Seafood HACCP		
Traceback investigations		
Foodborne illness investigations		
Preventive controls for human foods		

Name of Inspector: _____ **Start Date:** _____

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, seafood HACCP, or preventive controls for human foods.

Advanced Food Inspection Curriculum Fieldwork				
Specialized food inspection				
JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS		**Completion Date**	**EVALUATION/AUDIT Acceptable (Yes/No)**	**Documentation Available for Review (Yes/No)**
Please provide the name of the manufactured food firm and identification number.				
1.				
2.				
3.				
4.				
Specialized food inspection				
JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS		**Completion Date**	**EVALUATION/AUDIT Acceptable (Yes/No)**	**Documentation Available for Review (Yes/No)**
Please provide the name of the manufactured food firm and identification number.				
1.				
2.				
3.				
4.				

Name of Inspector: _____ **Start 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 (Yes/No)**	**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 (Yes/No)**	**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 (Yes/No)**	**CONTACT HOURS Earned**
Subtotal			
Total CONTACT HOURS Earned			

Appendix 3.1: Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluates if it includes the associated components. If the state program has the main component and associated components indicate "Yes". If not, indicate "No".

State Agency: _____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
3.3.1 Risk-based Inspection Program		
1. Does the state program maintain an inventory of manufactured food firms 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-RELATED 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 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 an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the manufactured food firm is producing?		
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?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
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 identified during the previous inspection?		
13. Behave professionally and demonstrate proper sanitary practices during the inspection?		
14. Properly evaluate good manufacturing practice requirements (21 CFR 117, Subparts A, B, and F (for training records only) or equivalent state regulation)?		
15. Verify manufactured food firm has a written food safety plan which includes a written HAZARD analysis that appropriately addresses HAZARDS, and when appropriate, addresses preventive controls (process controls, allergen controls, sanitation controls, supply-chain controls and other controls) and a recall plan?		
16. When appropriate, review the manufactured food firm's written procedures, monitoring, verification, correction, and corrective action records for process, allergen, sanitation controls, supply-chain controls, and other controls which are identified in their food safety plan?		
17. When appropriate, verify the manufactured food firm is in compliance with the modified requirements that apply to a qualified facility (attestation)?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
18. When appropriate, verify the modified requirements and time/temperature controls that apply to a facility solely engaged in the storage of unexposed packaged foods that require refrigeration for safety?		
19. When appropriate, assess the sanitary transportation of human food requirements that apply to transportation operations?		
20. When appropriate, review the manufactured food firm's food defense plan, including the mitigation strategies, monitoring, corrective action, and verification activities?		
21. 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?		
22. Assess the manufactured food firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation when required by regulation?		
23. When appropriate, review the manufactured food 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?		
24. Recognize deficiencies in the manufactured food firm's monitoring controls and sanitation procedures through in manufactured food firm observations?		
25. Use suitable interviewing techniques?		
26. Explain findings clearly and adequately throughout the inspection?		
27. Alert the manufactured food firm's person in charge when an immediate corrective action is necessary?		
28. Answer questions and provide information in an appropriate manner?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
29. Write findings accurately, clearly, and concisely on the state document and provide a copy to the manufactured food 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 within designated timeframes?		
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 with 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 Complaints Resulting from State Program Inspection Activities		
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. Procedures that require sample collectors to:		
a. Use the appropriate method and equipment to collect the sample?		
b. Record sample chain of custody per state procedures?		
c. Handle, package, and ship sample using procedures appropriate to prevent compromising condition of the sample and ensuring security of the sample?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
d. Deliver or ship sample to the appropriate laboratory within prescribed timeframes?		
2. 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, and lot size?		
e. Location where sample was collected?		
f. Name and address of responsible party, guarantor, processor or distributor?		
g. Sample type?		
h. Analysis requested (if applicable)?		
i. Product labeling or labeling information?		
j. Identification of the sample with a sample number assigned at the time of collection?		
3. 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 9.3.5.2 for the following:		
1. Inspection reports which include follow-up activities?		
2. Essential recall information?		
3. CONSUMER COMPLAINTS?		
4. INDUSTRY COMPLAINTS about inspections?[8]		
5. Documentation associated with sample collection?		

Assessment Completed By:

Name _____ **Date:** _____

Appendix 4.1: Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluates if it includes the associated components. If the state program has the main component and associated components indicate "Yes". If not, indicate "No".

State Agency: _____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
4.3.1 Quality Assurance		
The state program has a written Quality Assurance Program (QAP) that contains written procedures for:		
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. Initiating CORRECTIVE ACTION, which will be documented on the STRATEGIC IMPROVEMENT PLAN as described in section 9.3.2?		
4.3.2 FIELD INSPECTION AUDIT		
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 manufactured food firms that the inspector is trained for including specialized food inspections?		
4. Complete Appendix 4.3 or equivalent form be used to document FIELD INSPECTION AUDITS?		
5. Complete Appendix 4.3a or equivalent form document overall rating calculations of FIELD INSPECTION AUDITS?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
4.3.3 Inspection Report Audit		
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?		
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 4.4 or equivalent form to document inspection report audits?		
5. Complete Appendix 4.4a or equivalent form to document overall rating calculations of inspection report audits?		
4.3.4 Sample Report Audit		
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 4.5 or equivalent form to document sample report audits?		
4. Complete Appendix 4.5a or equivalent form to document overall rating calculations of sample report audits?		
4.3.5 CORRECTIVE ACTION		
Does the state program initiate CORRECTIVE ACTIONS as described in 9.3.2 when the FIELD INSPECTION AUDIT, inspection report audit, or sample report audit meets one or more of the conditions below:		
1. An individual receives a rating of "needs improvement"?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
2. A single performance factor for the program falls below 80%, or four or more "needs improvement" ratings are identified in a single performance factor. Note that if fewer than four audits are conducted, a performance deficiency may be considered for a single performance factor that "needs improvement"?		
3. An overall rating for the program falls below 80%?		

Assessment Completed By:

Name _____ **Date:** _____

Appendix 4.2: Instructions for Performance Ratings of Audit Findings

The three performance rating of audit findings summary appendices (4.3a, 4.4a and 4.5a) allow the state program to recognize trends and identify specific areas in their audit program that may need improvement.

These summary appendices are used to calculate an overall rating during the performance period and identify areas for improvement. The state program shall initiate CORRECTIVE ACTIONS as described in 9.3.2 when one or more of the conditions below are met: (a) an individual receives an overall rating of "needs improvement"; (b) a single performance factor for the program falls below 80%; or (c) an overall rating for the program falls below 80%.

INSTRUCTIONS:

(1) For each audit, record the manufactured food firm identification number, inspection date, auditor's initials, and date of audit.

(2) For each audit (vertical column), record the rating for each performance factor (A = acceptable; NI = needs improvement). Record the individual audit score on the row indicated.

(3) Count the number of "A" and "NI" for each performance factor (horizontal) and record the total number of "A" and "NI" ratings. Calculate the performance factor score using the formula below:

A_t = horizontal total of acceptable ratings.
NI_t = horizontal total of needs improvement ratings.
Performance Factor Score = $[A_t/(A_t + Ni_t)] \times 100$

(4) Sum the Total Number of "A" and "NI" ratings for all audits.

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

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

(5) Calculate the cumulative score for all audits. Record the cumulative score in the space provided at the top of the worksheet.

Cumulative Score = $[\sum A_t / (\sum A_t + \sum NI_t)] \times 100$

(6) Identify and make notes about trends and single performance factors rated as "NI" in multiple audits.

Appendix 4.3: Field Inspection Audit Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
FIELD INSPECTION AUDIT

AUDITOR	STATE INSPECTOR
FIRM Name	FEI NUMBER
FIRM ADDRESS	
PRODUCT(S) COVERED	
AUDIT DATE TIME IN/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' Facilities, section IV. Inspectional Observations and Performance for Limited Scope PC and Modified Audits, section V. Inspection Observations and Performance for Transportation Operations Subject to the Sanitary Transportation of Human and Animal Food Rule, and section VI. Inspection Observations and Performance for Food Defense Plan Reviews*. If the manufactured food firm is not subject to Seafood or Juice HACCP regulations or preventive controls regulations (including modified scope requirements), sanitary transportation regulations, and intentional adulteration regulations, leave the scoring for these questions blank and check "not applicable."

If four or more evaluated items are marked as "needs improvement," the state program manager must be notified by the QUALIFIED FIELD INSPECTION AUDITOR that additional training or other performance improvement measures for the 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 state and FDA Division prior to resuming contract inspection duties.

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? 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 the FDA/state 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 and/or the FDA 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 and/or FDA 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 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 manufactured food firms not subject to HACCP regulations.

1. Did the inspector use the "Fish and Fishery Products Hazards and Controls Guide" or the "Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance", as appropriate, to identify and evaluate the HAZARDS associated with the product and process?

Acceptable Needs Improvement Not Applicable

Comments *(required for Needs Improvement)*

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

Acceptable Needs Improvement Not Applicable

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 Not Applicable

Comments *(required for Needs Improvement)*

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

Acceptable Needs Improvement Not Applicable

Comments *(required for Needs Improvement)*

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?

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 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 or Form FDA 483 left with the firm?

Acceptable Needs Improvement

Comments *(required for Needs Improvement)*

IV. INSPECTION OBSERVATIONS AND PERFORMANCE FOR LIMITED SCOPE PC AND MODIFIED AUDITS

Note to Auditor: Question 2 only applies to limited scope PC inspections. Question 3 only applies to manufactured food firms that have submitted a qualified facility attestation. Question 4 only applies to facilities solely engaged in the storage of unexposed packaged food. If these questions do not apply, select Not Applicable.

1. Did the inspector properly evaluate the current good manufacturing practice requirements (21CFR 117 Subparts A, B, and F, or equivalent state regulation)? This question applies to all audits performed including food, seafood, and juice. It cannot be left blank.

Acceptable Needs Improvement

Comments *(required for Needs Improvement)*

2. Did the inspector conduct a broad-based assessment of the preventive controls program where necessary? Applies only to limited scope PC. If this question does not apply, select Not Applicable.

   Acceptable Needs Improvement Not Applicable

   Comments *(required for Needs Improvement)*

3. Did the inspector verify whether the facility has attested and if so confirm whether the provisions in the attestation were understood? Applies only to qualified facilities. If this question does not apply, select Not Applicable.

   Acceptable Needs Improvement Not Applicable

   Comments *(required for Needs Improvement)*

4. Did the inspector properly evaluate the implementation of time/temperature controls? Only answer if the facility is a warehouse solely engaged in the storage of unexposed packaged food that requires refrigeration for safety. If this question does not apply, select Not Applicable.

   Acceptable Needs Improvement Not Applicable

   Comments *(required for Needs Improvement)*

V. INSPECTION OBSERVATIONS AND PERFORMANCE FOR TRANSPORTATION OPERATIONS SUBJECT TO THE SANITARY TRANSPORTATION OF HUMAN AND ANIMAL FOOD RULE

1. Did the inspector conduct an assessment of the sanitary transportation practices applicable to transportation operations?

   Acceptable Needs Improvement Not Applicable

   Comments *(required for Needs Improvement)*

VI. INSPECTION OBSERVATIONS AND PERFORMANCE FOR FOOD DEFENSE PLAN REVIEWS
1. Did the inspector conduct an assessment of the food defense plan, including review of mitigation strategies, monitoring, corrective actions, and verification activities? Acceptable Needs Improvement Not Applicable Comments *(required for Needs Improvement)*
ADDITIONAL COMMENTS

SIGNATURE OF AUDITOR	DATE

Appendix 4.3a: Summary of Field Inspection Audit Findings

State Agency: _____ Performance Period: _____

Reviewed By: _____ Date: _____ Performance Rating: _____

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																					
IV. 1																					
IV.2																					
IV.3																					
IV.4																					
V.1																					
VI.1																					
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.

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																						
IV.1																						
IV.2																						
IV.3																						
IV.4																						
V.1																						
VI.1																						
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 4.4: 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 ☐ Preventive Controls ☐ 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 80%, 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 forms were 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 report writing and documentation procedures.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

5. The inspector identified violations based on state and/or federal regulations.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

6. The inspector reviewed past inspection findings and acted 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. The inspector obtained and documented 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 4.4a: Summary of Inspection Report Audit Findings

State Agency: _____ Performance Period: _____

Reviewed By: _____ Date: _____ Performance Rating: _____

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.

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 4.5: 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 80%, the audit rating must be marked as "Needs Improvement."

I. SAMPLE OBSERVATIONS AND PERFORMANCE

1. Method of collection and equipment was appropriate.

   ☐ 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 was recorded.

☐ 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 was recorded.

☐ 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 was 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 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 4.5a: Summary of Sample Report Audit Findings

State Agency: _____ Performance Period: _____

Reviewed By: _____ Date: _____ Performance Rating: _____

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.

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 5.1: Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluates if it includes the associated components. If the state program has the main component and associated components indicate "Yes". If not, indicate "No".

State Agency: _____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
5.3.1 Coordination with Other Authorities		
Does the state program:		
1. Have a Memorandum of Understanding 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 5.3.2 – 5.3.5?		
3. Have a written procedure that describes agency collaboration as necessary with the FDA and other appropriate local, state, and federal authorities 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 describes how all relevant agencies are notified in case of FOOD-RELATED INCIDENTS?		
6. Have a 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) of relevant agencies and emergency contacts that is updated at least yearly?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
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(s) or database(s)?		
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 in accordance with written procedures?		
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 that led to food contamination or adulteration causing illness, injury, or outbreak?		
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 procedure with criteria for releasing prevention guidance and information to the public?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
5.3.5 Post Response		
Does the state program:		
1. Maintain program investigation and ENVIRONMENTAL ASSESSMENT findings and reports?		
2. Distribute final program investigation report(s), including an ENVIRONMENTAL ASSESSMENT if completed to relevant agencies responsible for reporting contributing factors and antecedents to CDC?		
3. Distribute 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

Instructions: The state program identifies if they have a specified component then evaluates if it includes the associated components. If the state program has the main component and associated components indicate "Yes". If not, indicate "No".

State Agency: _____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
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?		
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, which will be documented on the STRATEGIC IMPROVEMENT PLAN, if performance ratings fall below 80%?		

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 for comments or 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:** _____

Food firm identification number (1)	Enforcement action recommended (1)	Compliance procedures followed? (2)		Use this space for comments or to explain improvements needed to follow compliance procedures
Total	Enter the sums of (2).	At =	NIt =	

Appendix 6.2a: Instructions for 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 manufactured 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

Instructions: The state program identifies if they have a specified component then evaluates if it includes the associated components. If the state program has the main component and associated components indicate "Yes". If not, indicate "No".

State Agency: _____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
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 which may include dissemination of information using electronic sources and traditional methods such as mailings?		
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.		

Assessment Completed By:

Name _____ **Date:** _____

Appendix 7.2: Outreach Activity Event and Self-Evaluation Worksheet

State Agency: _____

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

Instructions: The state program identifies if they have a specified component then evaluates if it includes the associated components. If the state program has the main component and associated components indicate "Yes". If not, indicate "No".

State Agency: _____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
8.3.1 Program Assessment		
Does the state program complete the Resource Summary Report to assess staffing, funding, and equipment using Appendix 8.2 or equivalent form?		
8.3.2 Staffing		
Does the state program:		
1. Conduct a calculation for determining the required number of inspectors to inspect manufactured food firms in its manufactured food firm inventory at a frequency that is based on the manufactured food firm's risk classification and the necessary inspection and travel time?		
2. Document the calculation for determining the required number of inspectors to inspect manufactured food firms in its manufactured food firm inventory?		
8.3.3 Equipment		
Does the state program establish and maintain a list of equipment required for inspections and sampling?		

Assessment Completed By:

Name _____ **Date:** _____

Appendix 8.2: Resource Summary Report

State Agency: _____

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, and Hazard Response				
6	Compliance and Enforcement				
7	Industry and Community Relations				
8	Program Resources				
9	Program Assessment				
10	Laboratory Support				

Assessment Completed By:

Name _____ **Date:** _____

Appendix 8.2a: Resource Summary Report Instructions

The Appendix 8.2 Resource Summary Report 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 8.2 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, Outbreaks, and Hazards 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. The state program has resources to ensures that all guidance, procedures, documents, and forms required by the standards are CURRENT AND FIT-FOR-USE.

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

Appendix 9.1: Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluates if it includes the associated components. If the state program has the main component and associated components indicate "Yes". If not, indicate "No".

State Agency: _____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
9.3.1 Does the state program conduct a baseline self-assessment:		
1. Within the first year?		
2. Using the self-assessment worksheets associated with each standard?		
3. Using the results of its self-assessments to complete Appendix 9.2 (or equivalent form)?		
9.3.2 If the state program fails to meet any of the program elements or documentation requirements, whether identified through a self-assessment or FDA ASSESSMENTS, did the state program develop a STRATEGIC IMPROVEMENT PLAN?		
Does the STRATEGIC IMPROVEMENT PLAN include:		
1. The individual element or documentation requirement that was not met?		
2. Improvements or CORRECTIONS needed to meet the program element or documentation requirement of the standard?		
3. The cause for any non-CONFORMANCE requiring CORRECTION when the program was previously in CONFORMANCE with the individual element or documentation requirement of a standard?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
4. The CORRECTIVE ACTION taken to prevent future similar non-CONFORMANCE when the program was previously in CONFORMANCE with the individual element or documentation requirement of the standard that was corrected?		
5. Projected completion dates for each task?		
6. Personnel responsible?		
7. Date completed for each task?		
9.3.3 Does the state program review and update the self-assessment appendices and STRATEGIC IMPROVEMENT PLAN at least annually?		
9.3.4 Does the state program:		
1. Participate in FDA ASSESSMENTS to determine IMPLEMENTATION and CONFORMANCE to the standards?		
2. Address FDA ASSESSMENT observations and establish CORRECTIVE ACTION?		
9.3.5 Does the state program:		
1. Have a written DOCUMENT CONTROL procedure?		
a. Is the state program able to demonstrate that all documents are CURRENT AND FIT-FOR-USE through maintenance of a master document list or other system?		
b. Does the master document list or other system show:		
i. Documents are reviewed for accuracy?		
ii. Documents are approved for release by authorized personnel and signed/dated with an approval or revision date?		

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
iii. Documents are distributed to applicable staff, as appropriate, and used at the location where the prescribed activity is performed?		
2. Retain records or procedures required under each standard for the three previous years, or per the state program's record retention policy, whichever is longer?		

Assessment Completed By:

Name _____ **Date:** _____

Appendix 9.2: Self-Assessment Summary Report

State Agency: _____

Standard	Self-Assessment	IMPLEMENTATION	Explain improvements needed to fully IMPLEMENT standards *(required for incomplete self-assessment and partial IMPLEMENTATION)*
Regulatory Foundation	Complete ☐ Incomplete ☐ Hours used	Full ☐ Partial ☐	
Training Program	Complete ☐ Incomplete ☐ Hours used	Full ☐ Partial ☐	
Inspection Program	Complete ☐ Incomplete ☐ Hours used	Full ☐ Partial ☐	
Inspection Audit Program	Complete ☐ Incomplete ☐ Hours used	Full ☐ Partial ☐	
Food-related Illness, Outbreak, and Hazard Response	Complete ☐ Incomplete ☐ Hours used	Full ☐ Partial ☐	
Compliance and Enforcement	Complete ☐ Incomplete ☐ Hours used	Full ☐ Partial ☐	
Outreach Activities	Complete ☐ Incomplete ☐ Hours used	Full ☐ Partial ☐	
Program Resources	Complete ☐ Incomplete ☐ Hours used	Full ☐ Partial ☐	

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

Assessment Completed By:

Name _____ **Date:** _____

Appendix 10.1: Self-Assessment Worksheet

Instructions: The state program identifies if they have a specified component then evaluates if it includes the associated components. If the state program has the main component and associated components indicate "Yes". If not, indicate "No".

State Agency: _____

Program Elements	Yes/No	If no, please explain why element is not met. May use this space for additional notes.
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: a. Define the responsibilities of each party; b. Describe the types of testing services to be performed; and c. 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 17025:2017 (or current version) standards to analyze food and environmental samples?		

10.3.3 Non-ISO Accredited Laboratories		
If not using laboratories holding accreditation to ISO/IEC 17025:2017 (or current version) 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:		
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:** _____