Manufactured Food Regulatory Program Standards

September 2010

The collection of information has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and has been assigned OMB control number 0910-0601.

To request a copy of the standards go to:

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

OMB Control No. 0910-0601
Expiration Date: 09-30-2013

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INTRODUCTION

The Manufactured Food Regulatory Program Standards (program standards) establish a uniform foundation for the design and management of State programs[1] responsible for the regulation of food plants. The elements of the program standards describe best practices of a high-quality regulatory program. Achieving conformance with them will require comprehensive self-assessment on the part of a State program and will encourage continuous improvement and innovation.

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 has corresponding self-assessment worksheets and certain standards have supplemental worksheets and forms for determining a level of conformance with such standards. The State program is not required to use the forms and worksheets contained herein; however, alternate forms should be comparable to the forms and worksheets for program standards. These program standards do not address the performance appraisal processes that a State agency may use to evaluate individual employee performance.

FDA will use the program standards as a tool to improve contracts with States. The program standards will assist both FDA and the States in fulfilling their regulatory obligations. The implementation of the program standards will be negotiated as an option for payment under the State contract. States that are awarded this option will be expected to implement the program standards to evaluate and improve their manufactured food program. FDA recognizes that full use and implementation of the program standards by those States will take several years. Such States will, however, be expected to implement improvement plans to demonstrate that they are moving toward full implementation.

The goal is to implement a risk-based food safety program by establishing a uniform basis for measuring and improving the performance of manufactured food regulatory programs in the United States. The development and implementation of these program standards will help Federal and State programs better direct their regulatory activities toward reducing foodborne illness hazards in food plants. Consequently, the safety and security of the United States food supply will improve.

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[1] Program defined as an operational unit(s) that is responsible for the regulatory oversight of food plants.

BACKGROUND

The food safety regulatory system in the United States is a tiered system that involves Federal, State, and local governments. The Food and Drug Administration (FDA) is responsible for ensuring that all foods moving in interstate commerce, except those under United States Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. State agencies conduct inspection and regulatory activities that help ensure food produced, processed, or sold within their jurisdictions is safe. Many State agencies also conduct food plant inspections under contract with the FDA. These inspections 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.[2]" In response to their findings, FDA established a committee to develop a set of quality standards for manufactured food regulatory programs. The committee was comprised of officials from FDA and from State agencies responsible for the regulation and inspection of food plants[3].

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

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

STANDARD No. 1
Regulatory Foundation

1.1 Purpose

This standard describes the elements of the regulatory foundation[4] used by a State program to regulate food plants.

1.2 Requirement Summary

The State program has the legal authority and regulatory provisions to perform inspections and investigations, gather evidence, collect samples, and take enforcement actions under Federal and State laws. If the State adopts FDA laws and regulations by reference, the terms of adoption must be clearly defined.

> NOTE: When State code does not provide for adopting FDA laws and regulations by reference, which includes subsequent amendments and editions of the Title 21 Code of Federal Regulations (CFR), a legal review by the State agency's counsel to determine if State laws and regulations are equivalent in effect to the current Federal laws and regulations listed in appendix 1 is needed. If it has not adopted the current version of the CFR, the State must provide the revision date of the CFR that was adopted for each regulation in the box under "State citation or alternate provision" of appendix 1.

1.3 Program Elements

a. The State program has the legal authority to inspect food plants, gather evidence, collect and analyze samples, and take enforcement actions for adulteration or misbranding of foods equivalent in effect to sections of the current FD&C Act specified in appendix 1.

b. The State program enforces regulatory provisions equivalent in effect to the Federal regulations specified in appendix 1. In the absence of a corresponding law or regulation, a legal review by the State agency's counsel to determine if State laws and regulations are equivalent in effect to the current Federal laws and regulations listed in appendix 1 is needed.

c. The State program uses its laws and regulations to broaden its scope of regulatory authority.

[4] Laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of a food plant or manufacturing establishment.

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 food supply.

1.5 Documentation

The State program maintains the records listed here.

- Appendix 1 Self-assessment worksheet
- The statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that: (1) apply to the operation of food plants, (2) delegate authority to the State agency, and (3) describe the process by which the State agency establishes its authority and adopts rules by reference, for example, the administrative rulemaking process

STANDARD No. 2
Training Program

2.1 Purpose

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

2.2 Requirement Summary

The State program has a training plan that ensures all inspectors receive training required to adequately perform their work assignments. The plan provides for basic and advanced food inspection training as well as continued training for professional development in the field of food processing.

The State program has written basic and advanced food inspection training programs that include course curriculums. ORA-U offers courses that the State program should consider when developing basic and advanced training curriculums.

2.3 Program Elements

The State program maintains a history of the training provided to all inspectors. Appendix 2.1 may be used to document all training provided to inspectors. Or, the training history may be recorded and retained electronically.

The State program provides, or otherwise makes available, inspection training for all inspectors. A training record similar to appendix 2.2 is maintained for all inspectors. The individual training record should have the inspector's start date.

> NOTE: <u>All</u> required basic and advanced courses must be listed on the inspector's training record. Documentation to verify that an inspector has successfully completed a course must be retained.

a. 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.

<u>Coursework</u>

The State program requires each inspector to complete coursework in the following areas within 24 months of his or her start date with the State program.

- Prevailing statutes, regulations, and ordinances
- Public health principles
- Food defense awareness training
- Communications skills

- Microbiology
- Epidemiology
- Basics of HACCP
- Basic labeling
- Control of allergens (when available)
- Sampling technique and preparation

Coursework is obtained from sources listed here.

- In-house training provided by a government agency
- Distance learning, for example, satellite downlinks or web-based training[5]
- Colleges, schools, and research centers

Field training

The State program requires that each inspector participate in a minimum of ten joint or audit inspections with a qualified trainer and receive a minimum of two acceptable evaluations from the trainer. Joint or audit inspections are conducted in firms that are representative of the food plants in the State program's establishment inventory. Each inspector will complete the minimum field training requirements within 18 months of his or her start date with the State program and prior to conducting independent inspections.

b. Advanced Food Inspection Training

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

Coursework

The State program requires each inspector who will perform specialized food inspections to complete coursework listed here.

- Applications of epidemiology & foodborne illness investigations
- Traceback investigations
- National Incident Management System (incident command system)
- Nutrition labeling
- Acidified foods
- Low acid canned foods
- Juice HACCP
- Seafood HACCP

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

Field training

The State program requires that each inspector who will conduct specialized food inspections participate in three joint inspections with a qualified trainer and receive a minimum of two acceptable evaluations from the trainer. The joint inspections are conducted in food plants representative of the specialty area. The inspector will complete the minimum field training requirements prior to performing independent inspections.

c. Continuing education

The State program requires that each inspector participate in continuing education that includes coursework and inspections. Every 36-month interval, each inspector is required to receive 36 contact hours of classroom training and participate in at least two joint or audit inspections with a qualified trainer. These joint inspections are intended to assist the inspector with applying what was learned in the classroom to what should be covered during an inspection.
[Note: The 36-month continuing education interval starts when the basic training cycle is complete -- 24 months after the employee's start date.]

One contact hour is earned for each hour of participation in the continuing education activities from sources described in Section 2.3a.

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2.4 Outcome

The State program has trained inspectors with the knowledge, skills, and abilities to competently inspect food plants.

2.5 Documentation

The State program maintains the records listed here.

- Appendix 2.1 Self-assessment worksheet
- Appendix 2.2 Individual training record
- Documents verifying successful completion of required courses
- Course description, if necessary
- Field training and evaluations
- Continuing education certificates

STANDARD No. 3
Inspection Program

3.1 Purpose

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

3.2 Requirement Summary

The State program has an inspection system. This system provides the foundation for inspecting food plants to determine compliance with the laws administered by Federal, State, and local governments. In addition, the State program has: (1) an established recall system, (2) a system to respond appropriately to consumer complaints, (3) a system to resolve industry complaints about inspections, and (4) a recordkeeping system for all elements of the inspection program.

3.3 Program Elements

a. Risk-based inspection program

The State program updates its inventory of food plants. The inventory is categorized by the degree of risk associated with the likelihood that a food safety or defense incident will occur. Inspections are prioritized, frequencies assigned, and resources allocated based on risk categories assigned to a food plant or product, the manufacturing processes, and the inspection history of the food plant. Appendix 3.2 provides factors that may be considered when defining risk categories.

b. Inspection protocol

The State program has written policies and procedures for inspecting food plants that require the inspectors to:

1. Review the previous inspection report and consumer complaints
2. Have appropriate equipment[6] and forms needed to conduct inspections
3. Establish [FDA] jurisdiction
4. Select an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the plant is producing
5. Assess employee activities critical to the safe and sanitary production and storage of food
6. Properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded
7. Recognize significant violative conditions or practices if present and record findings consistent with State program procedures

[6] Standard number 8, appendix 8.3 Inspection Equipment

8. Distinguish between significant and insignificant observations, and isolated incidents versus trends
9. Review and evaluate the appropriate records and procedures for the establishment's operation and effectively apply the information obtained from this review [during the inspection]
10. Collect adequate evidence and documentation to support inspection observations in accordance with State program procedures
11. Verify correction of deficiencies identified during the previous inspection
12. Behave professionally and demonstrate proper sanitary practices during the inspection

As appropriate for seafood and juice processors subject to HACCP regulations:

13. Use the *Fish and Fishery Products Hazards and Controls Guide* or the *Juice HACCP Hazards and Controls Guide*, when and as appropriate, to identify and evaluate the hazards associated with the product and process
14. Assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation
15. 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
16. Recognize deficiencies in the firm's monitoring and sanitation procedures through in-plant observations

17. Make appropriate introductions, and explain the purpose and scope of the inspection
18. Use suitable interviewing techniques
19. Explain findings clearly and adequately throughout the inspection
20. Alert the firm's person in charge when an immediate corrective action is necessary
21. Answer questions and provide information in an appropriate manner
22. Write findings accurately, clearly, and concisely on the State document and provide a copy to the firm's person in charge

c. Food recalls

The State program has a food recall system.

The State program has written recall procedures for:

1. Sharing information about recalls with affected government agencies
2. Promptly removing recalled food products from the market
3. Performing recall audit checks
4. Identifying and maintaining records about essential recall information

d. Consumer complaints

The State program has a system for handling consumer complaints. The system contains written procedures for receiving, tracking, evaluating, answering, closing, and maintaining records of consumer complaints.

e. Food industry inspection complaints

The State program has a system to resolve complaints from industry about inspections. The system contains written procedures for receiving, evaluating, answering, and maintaining records of industry complaints about inspections.

3.4 Outcome

The State program has an inspection program that reduces the occurrence of foodborne illness, injury, or allergic reaction by:

1. Focusing inspection resources on high risk plants, products, and processes
2. Obtaining immediate corrections and long-term improvements from manufactured food processors
3. Responding efficiently to prevent unsafe products from reaching consumers or to remove unsafe food from the human food system

3.5 Documentation

The State program maintains the records listed here.

- Appendix 3.1 Self-assessment worksheet
- An official establishment inventory of food plants
- Written procedures and rationale used for grouping establishments based on food safety risk, including the inspection frequency assigned to each defined risk-based establishment category
- Inspection policies and procedures including guidelines for performing inspections that require immediate corrective action and re-inspection
- Written procedures for food recalls, consumer complaints, and industry complaints about inspections
- Records for the three previous years including inspection reports and reports pertaining to food recalls and follow-up activities, consumer complaints, and industry complaints about inspections

STANDARD No. 4
Inspection Audit Program

4.1 Purpose

This standard describes the basic quality assurance reviews necessary to: (1) evaluate the effectiveness of the inspection program, (2) recognize trends in inspectional coverage, and (3) identify best practices used to achieve quality inspections and sample collections.

4.2 Requirement Summary

The State program conducts quality assurance reviews to assess the effectiveness of its inspections and sample collections. The data used to determine such performance is obtained from observing an inspector conducting an inspection and the inspector's written reports. This standard is not intended, however, to evaluate individual performance.

4.3 Program Elements

The State program implements a quality assurance program (QAP) that identifies elements of its inspection and sample collection processes that need improvement. The QAP has two components: (1) a field 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. Worksheets 4.2, 4.3, and 4.4 will be used to: (1) calculate an overall audit rating for each review (field inspection performance and written reports of inspections and samples collections) and (2) evaluate ratings for a single performance factor. Managers use the ratings to identify specific aspects of its inspection program that need improvement. When performance ratings fall below 80 percent, a corrective action plan (appendix 4.8 or comparable form) is required.

The State program compiles and summarizes the results of the field and desk audits annually and determines an overall performance rating, which is reported on the self-assessment worksheet (appendix 4.1). The results of the audits are evaluated every 12 months to: (1) determine the effectiveness of the food inspection program, (2) recognize trends in inspectional coverage, and (3) identify best practices used to achieve quality inspections and sample collections.

The worksheets contained in appendices 4.1-4.4 are used to record and summarize audit findings. Or, the State program may use comparable worksheets to record audit findings.

a. Field Inspection Audit

Supervisory inspector, senior inspector, or team leader conducts field inspection audits to verify that inspections are consistently performed according to the established policies and procedures. The quality of each inspection is audited using the performance factors identified on appendix 4.5 and follows the process described in FDA's Field Management Directive No. 76. An overall rating for field inspection performance is calculated using worksheet 4.2.

Frequency	The QAP requires a minimum of two field inspection audits of each inspector be conducted every 36 months. Inspections selected for audit should include high-risk food firms such as seafood facilities, juice processors, and low-acid canned food operations.
Performance Documentation	Appendices 4.5 and 4.2 (including worksheet 4.2)
Performance Factors	Inspection procedures and policies described in standard number 3 and appendix 4.5

b. Inspection Report Audit

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

Frequency	The State program determines the number of reports for review based on its inventory of food plants and the number of inspections completed in the past 12 months. At least 75 reports, including inspection reports from field inspection audit, are randomly selected across inspectors and supervisors, and geographical locations. If less than 75 inspections were conducted; all inspection reports will be reviewed. Seven percent of the inspection reports reviewed should be taken from inspections that were audited.
Performance Documentation	Appendices 4.6 and 4.3 (including worksheet 4.3)
Performance Factors	Performance factors listed on appendix 4.6, and policies and procedures established by the State program.

c. Sample Report Audit

The QAP requires periodic review of sample reports to verify that samples were properly collected, identified, and submitted according to established procedures and policies and that appropriate information was recorded. The quality of each sample report is audited using the performance factors listed in appendix 4.7. An overall sample report rating is calculated using worksheet 4.4.

Frequency	The State program determines the number of reports for review based on the number of samples collected in the past 12 months. At least 75 reports are randomly selected across inspectors and supervisors, and according to sample type, for example, microbiology, aflatoxin, or low-acid canned foods. If less than 75 samples were collected, all reports will be reviewed.
Performance Documentation	Appendices 4.7 and 4.4 (including worksheet 4.4)
Performance Factors	Performance factors listed in appendix 4.7, and policies and procedures established by the State program.

d. Corrective Action Plan

A corrective action plan is required when an overall audit rating falls below 80 percent or when an individual performance factor is rated as "needs improvement." Appendix 4.8 is used to document how the deficiency was corrected.

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.

- Written procedures that describe the quality assurance program
- Appendix 4.1 Self-assessment worksheet
- Appendix 4.2 Summary of field inspection audit findings (includes worksheet 4.2)
- Appendix 4.3 Summary of inspection report audit findings (includes worksheet 4.3)

- Appendix 4.4 Summary of sample report audit findings (includes worksheet 4.4)
- Appendix 4.5 Contract Audit - FDA Form 3610
- Appendix 4.5a Guidance for completing contract audit form
- Appendix 4.6 Inspection report audit form
- Appendix 4.7 Sample report audit form
- Appendix 4.8 Corrective action plan (includes table 4.8)

STANDARD No. 5
Food-related Illness and Outbreak Response

5.1 Purpose

This standard describes the functions and related activities necessary to investigate food-related illnesses, outbreaks, and hazards as well as coordinating roles and responsibilities with other jurisdictions and notifying the public.

5.2 Requirement Summary

The State program establishes systems to:

a. Use epidemiological information from local, State, or Federal agencies to detect incidents or outbreaks of foodborne illness or injury
b. Investigate reports of illness, injury, and suspected outbreaks
c. Correlate and analyze data
d. Rapidly notify customers and consumers
e. Share outbreak reports and surveillance summaries with other agencies
f. Disseminate current guidance to industry on food defense
g. Provide guidance for immediate notification of law enforcement agencies when intentional food contamination or terrorism is suspected or threatened
h. Collaborate as necessary with FDA and other Federal authorities under conditions of increased threat of intentional contamination

5.3 Program Elements

The State program has procedures for investigating food-related illnesses and outbreaks that include coordinating roles and responsibilities with other authorities and notifying the public. If the responsibility for food-related illness and outbreak investigations is assigned to another agency, a memorandum of understanding with this agency is needed to fulfill the requirements of this standard. Appendix 5.2 is an example of a memorandum of understanding between the department of health and the department of agriculture.

If a State program contracts for support of foodborne illness or injury investigations, it will:

a. Develop and coordinate the operation of written support service agreements between the food program and the epidemiology support program.
b. Ensure the support service contract or agreement identifies and describes the roles, duties, and responsibilities of each program for: (1) receiving reports of foodborne illness or injury, (2) performing investigational activities to identify the source of the problem, (3) reporting and recording the results of the investigations, (4) containing or mitigating the incident, and (5) preventing recurrence.

Whether foodborne illness support activities are performed by the State program or under a contractual agreement, it must have [or contract for] a system to:

a. Conduct illness or injury investigations and collect information using established epidemiology procedures similar to those found in the "*International Association for Food Protection Procedures to Investigate a Foodborne Illnesses, Fifth Edition"* and the *"Guidelines for Foodborne Disease Outbreak Response."*[7]
b. Provide laboratory support[8] for investigations of illness, injury, or outbreaks
c. Maintain a current list of relevant agencies and emergency contacts
d. Coordinate the traceback and trace-forward of food implicated in an illness, injury, or outbreak
e. Identify contributing factors for reports of illness, injury, or incidents implicating food
f. Maintain investigational findings
g. Distribute the final report of illness or injury implicating food to relevant agencies, e.g. the State epidemiologist and Centers for Disease Control
h. Immediately notify all relevant agencies if intentional contamination is suspected or threatened, e.g. tampering or terrorism
i. Establish criteria for releasing information to the public (includes identifying a media person and developing guidelines for coordinating media information with other jurisdictions)
j. Mitigate and contain food-related illness and injury using enforcement activities and public awareness programs
k. Provide guidance to prevent or reduce the incidence of food-related illness, injury, and intentional contamination, e.g. tampering or terrorism
l. Collaborate as necessary with FDA and other Federal authorities under conditions of increased threat or intentional contamination

5.4 Outcome

The State program has written procedures for documenting and investigating alleged food-related illnesses, injuries, and unintentional or deliberate food. Additionally, the State program must have a rapid response system and team that is capable of detecting and distinguishing between outbreaks of foodborne disease and possible intentional contamination.

5.5 Documentation

The program maintains the records listed here.

- Appendix 5.1 Self-assessment worksheet- Food-related Illness and Outbreak Response

[7] Council to Improve Foodborne Outbreak Response (CIFOR). *Guidelines for Foodborne Disease Outbreak Response*. Atlanta: Council of State and Territorial Epidemiologists, 2009.

[8] Specific requirements for laboratory support are contained in standard number 10.

- A written description of epidemiology support or an agreement that defines epidemiology support similar to appendix 5.2
- A complaint log or database
- Up-to-date emergency contact list for all relevant jurisdictions
- Procedure and contact person for releasing information to the public
- Documented timeframes for responding to complaints
- The illness, injury, or outbreak response procedures and the data collection forms
- Policies and procedures for handling incidents and threats of deliberate contamination and for collaborations with FDA and other jurisdictions under conditions of increased threat or intentional contamination
- Written agreements that identify and describe sources of supplemental laboratory capacity and expertise including laboratory support[9] to detect contaminants not normally found in food
- Investigation reports and summaries

[9] Standard number 10 describes the elements of laboratory support for a manufactured food regulatory program.

STANDARD No. 6
Compliance and Enforcement Program

6.1 Purpose

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

6.2 Requirement Summary

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

6.3 Program Elements

The State program has a compliance and enforcement program that: (1) contains written enforcement strategies, (2) tracks critical and chronic violations and violators, (3) uses a risk-based system to determine when a directed investigation, follow-up, or re-inspection is needed, (4) establishes a timeline for progressive actions, and (5) has a system to communicate verbal and written policy and guidance to managerial and non-managerial staff. Appendix 6.1 is a framework for explaining the compliance and enforcement program required by this standard. This outline is a means through which the State should describe its program. Other aspects that may be pertinent to the State's program that have not been included in the outline should be added.

The State program conducts a performance review of enforcement actions. Enforcement actions[10] are recorded on appendix 6.2 and an overall rating is calculated to determine if internal procedures for enforcement and compliance actions (which include licensing and permitting procedures) are followed. Performance ratings that fall below 80 percent indicate a need for improvement and require corrective action.

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[10] Actions in the enforcement strategy 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.

Frequency	The performance review is conducted every 12 months. Results of the review are used to identify improvements, modify procedures, and develop enforcement strategies.
Performance Documentation	Appendix 6.2 (including worksheet 6.2) or equivalent form Written description of compliance and enforcement program (refer to appendix 6.1)
Performance Factors	Performance factors listed in appendix 6.1

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 and timeframes.

6.5 Documentation

The State program maintains the records listed here.

- Written description of compliance and enforcement program (refer to appendix 6.1)
- Appendix 6.2 Performance Review of Enforcement Actions (includes worksheet 6.2)
- Applicable laws, regulations, and guidance documents referenced in standard number 1

STANDARD No. 7
Industry and Community Relations

7.1 Purpose

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

7.2 Requirement Summary

The State program participates in activities that foster communication and information exchange among the regulators, industry, academia, and consumer representatives. It also coordinates or participates in outreach activities that provide educational information on food safety and defense issues. Outreach activities are documented on Appendix 7.

7.3 Program Elements

The State program interacts with industry and consumers by sponsoring or actively participating in meetings such as task forces, advisory boards, or advisory committees. Appendix 7 is completed for each outreach activity.

Outreach efforts are tailored to a target population and may include dissemination of information using electronic sources and traditional methods such as mailings. Topics at outreach efforts may include food defense, investigation strategies, and regulatory requirements. Representatives from affected food industries, consumers, academia, and other Federal, State, and local food protection agencies are invited to these meetings.

7.4 Outcome

The State program uses outreach activities to inform varied populations about food-related issues.

7.5 Documentation

The State program maintains the records listed here.

- Appendix 7 Self-assessment worksheet for each outreach activity
- Meeting summaries, agendas, or other records documenting interaction with food industries and consumers

STANDARD No. 8
Program Resources

8.1 Purpose

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

8.2 Requirement Summary

Staff, equipment, and funding are managed to accomplish the elements detailed in these standards.

8.3 Program Elements

Staffing

a. General Administration and Management
The State program has adequate staff to provide the direction, support, and oversight needed to implement the program standards. Capability may be needed in program management and direction, general administration, clerical support, office services, and coordination with laboratories.

b. Training Program (standard number 2)
The State program has adequate staff to coordinate a training curriculum and ensure it is properly delivered and tracked.

c. Inspection Program (standard number 3)
The State program has adequate staff to inspect food plants in its establishment inventory at an adequate frequency that is based on the plant's risk classification and the necessary inspection and travel time. The risk categories and inspection frequencies found in the statement of work for the food contracts should be considered.

Appendix 8.2 is only an example of how to calculate the number of field staff needed to conduct inspections of food plants. State programs should use verifiable data to determine the required number of inspectors.

d. Inspection Audit Program (standard number 4)
The State program has adequate staff to administer and monitor its inspection quality assurance program.

e. Food-related Illness and Outbreaks and Food Defense Preparedness and Response (standard number 5)
The State program has adequate staff to prepare for and respond to emergency situations.

f. Compliance and Enforcement Program (standard number 6)
The State program has adequate staff to implement compliance and enforcement strategies.

g. Industry and Community Relations (standard number 7)
The State program has adequate staff to participate in outreach and education activities.

h. Program Assessment (standard number 9)
The State program has adequate staff to conduct self-assessments of the manufactured food regulatory program.

Equipment

a. Calibration and Repair
Equipment including thermometers is calibrated as required by the State's standard operating procedures or industry recommendation. Government-owned vehicles are maintained and repaired following manufacturer's recommendations.

b. Program administration and recordkeeping
The State program has computers, software, and equipment necessary to maintain and secure records.

c. Communication systems and equipment
The State program has equipment needed for routine and emergency communications.

d. Inspections
The State program provides inspectors with equipment needed to conduct quality inspections. Appendix 8.3 is a list of inspection equipment.

Program funding

The State program is adequately funded to cover the following expenses:

a. Salary and benefits

b. Training costs

c. Travel-related expenses

d. Equipment and supplies

e. Industry and community outreach expenses

f. Laboratory expenses

g. Legal services fees

h. Indirect costs

i. Overhead costs

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.

- Appendix 8.1 Self-assessment worksheet
- Document showing the calculations used to determine an adequate number of inspectors such as appendix 8.2
- Inventory of assigned and available inspection equipment similar to appendix 8.3
- Document containing the number and function of administrative support staff

STANDARD No. 9
Program Assessment

9.1 Purpose

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

9.2 Requirement Summary

Managers conduct periodic self-assessments of its 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 program by determining the level of conformance with 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 an improvement plan and establish timeframes for making improvements. Subsequent self-assessments are used to track progress toward meeting and maintaining conformance with the program standards.

9.3 Program Elements

In the first year of implementing the program standards, the State program conducts a baseline self-assessment to determine if they meet the elements of each standard. The State program should use the worksheets and forms contained herein; however it can use alternate forms that are equivalent.

The State program maintains the documents required by each standard and records of all self-assessments, improvement plans, and program assessment validation audits. The information contained in the documents must be current and fit-for-use.

The State program uses the results of its self-assessments to complete the Self-Assessment and Improvement Plan Report (also known as Worksheet 9). The State program should update this worksheet each year.

If the State program fails to meet all program elements and documentation requirements of a standard, it develops a written strategic 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, and (3) projected completion dates for each task.

After the State has completed their baseline self-assessment and improvement plan,

FDA conducts a program assessment validation audit (hereafter known as validation audit). The validation audit should occur within 18 months. A subsequent validation audit will be conducted at 36 months to evaluate the State's progress toward fully implementing the standards. Then, at 60 months, FDA will conduct a comprehensive program audit. As part of the program audit, the auditor reviews the records and supporting documents required by the criteria in each standard to determine if the self-assessment and improvement plan accurately reflect the State program's level of conformance with each of the standards.

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 the records listed here.

- Worksheet 9 Self Assessment and Improvement Plan Report
- Completed appendices 1, 2.1 – 6.1, 7, 8.1, 10
- Documents required under Section *x*.5 of each standard
- Records and supporting documents required in the elements for each standard

STANDARD No. 10
Laboratory Support

10.1 Purpose

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

10.2 Requirement Summary

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

10.3 Program Elements

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

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

c. The State program has a contract or written agreement with its primary servicing laboratories[11].

d. The State program utilizes laboratories that have a current A2LA[12] accreditation.

e. Or, the State program utilizes laboratories that have quality assurance programs that incorporate management and technical requirements found in ISO/IEC 17025:2005.

10.4 Outcome

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

[11] Primary laboratory is a laboratory that analyzes more than 51 percent of the samples collected by the State program. State programs are not required to have written agreements with FDA laboratories.
[12] American Association for Laboratory Accreditation

10.5 Documentation

The State program maintains records listed here.

- Appendix 10 Self-assessment worksheet
- Contracts or written agreements with primary servicing laboratories
- A list of all servicing laboratories used by the State program

Appendix 1
Self-Assessment Worksheet

The State program describes how equivalency is accomplished when it lacks authority to enforce the sections of the current FD&C Act and the parts of the CFR listed in the following tables and subsequent final rules. For example, the State program may comply with standard number 1 either by identifying its equivalent State authorities or by describing how equivalency is attained through alternative procedures or agreements.

a. Federal Food, Drug, and Cosmetic Act (FD&C Act)

The State law must be equivalent in effect to the sections of the current FD&C Act. The language used does not have to be identical if the same outcome is achieved. If the provisions contained in the relevant sections of your food laws and codes are not the same as those contain the corresponding Federal citations, please identify the difference between the two.

Section	Title	State citation or alternate provision	Differences with Federal law
201	Definitions (f), (k), (m), and (ff)		
301	Prohibited acts (a), (b), (c), (d), (e), (f), (k), and (v)		
303*	Penalties		
304**	Seizure		
401	Definitions and standards for food		
402	Adulterated food		
403	Misbranded food (a)-(s)		
413	New dietary ingredients		
701	Regulations and hearings		
703***	Records of interstate shipments		
704	Factory inspection		

*Penalties may vary from Federal statute.
**Seizure authority is not required under this standard. The agency, however, should have legal authority to stop adulterated and misbranded products from moving in commerce, for example, detention, stop-sale orders, and embargoes.
***This section covers records in interstate commerce. State law should include intrastate records.

b. Code of Federal Regulations (CFR)

The State regulation must be equivalent in effect to the sections listed in the current CFR. The language used does not have to be identical if the same outcome is achieved. States may have more stringent regulations unless preempted. If a specific version of the CFR is adopted, please provide the date of the CFR.
If the provisions contained in the relevant sections of your food regulations differ from the corresponding Federal citations found in the current CFR, please report the difference between the two. Differences between the CFR adopted by the State and the current CFR should be reported.

Part	Title	State citation or alternate provision	Differences with Federal code
1	General enforcement regulations (ONLY § 1.20-1.24)		

Part	Title	State citation or alternate provision	Differences with Federal code
7	Enforcement policy (ONLY § 7.1-7.13 and § 7.40-7.59)		
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		
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	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		

Part	Title	State citation or alternate provision	Differences with Federal code
115	Shell eggs		
118	Production, Storage, And Transportation of Shell Eggs		
120	Hazard Analysis and Critical Control Point (HACCP) systems		
123	Fish and fishery products		
129	Processing and bottling of bottled drinking water		
130	Food standards: general (EXCEPT § 130.5-6 and § 130.17)		
131	Milk and cream		
133	Cheeses and related cheese products		
135	Frozen desserts		
136	Bakery products		
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		
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		
Part	**Title**	**State citation or alternate provision**	**Differences with Federal code**

176	Indirect food additives: paper and paperboard components		
177	Indirect food additives: polymers		
178	Indirect food additives: adjuvants, production aids, and sanitizers		
180	Food additives permitted in food or in contact with food on an interim basis pending additional study		
181	Prior-sanctioned food ingredients		
182	Substances generally recognized as safe		
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		

c. State law and regulations

State laws and regulations used by the program to broaden its scope of regulatory authority are listed below.

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Assessment completed by:

_____

(NAME) **(DATE)**

Appendix 2.1
Self-Assessment Worksheet

State agency: _____ Year _____

Instructions: Record the name of the employee and the completion date for each training component. Use additional sheets if needed.

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	Course work	Field work

Assessment completed by:

_____

(NAME) **(DATE)**

Appendix 2.2
Individual Training Record

State agency _____

Name of inspector _____ **Start date** _____

Basic Food Inspection Curriculum Coursework			
Please provide the course name and location for the subject areas listed here.	**Completion Date**	**Inspector's Initials**	**Supervisor's Initials**
Prevailing statutes, regulations, and ordinances			
Public health principles			
Communication skills			
Microbiology			
Epidemiology			
Basics of HACCP			
Control of allergens			
Basic food labeling			

Basic Food Inspection Curriculum Fieldwork				
Joint Inspections		**Completion Date**	**Inspector's Initials**	**Supervisor's Initials**
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
	Evaluations			
1.				
2.				

Advanced Food Inspection Curriculum Coursework			
Please provide the name and location of the course.	**Completion Date**	**Inspector's Initials**	**Supervisor's Initials**
Applications of foodborne illness investigations			
Traceback investigations			
Nutrition labeling			
Acidified food			
Conducting Acidified Food Inspections (FD202) *Note: Acidified food inspections done under FDA contract shall only be performed by state inspectors who have successfully completed the FDA course, Conducting Acidified Food Inspections (FD202).*			
Low acid canned food			
Conducting LACF Inspections (FD203) *Note: LACF food inspections done under FDA contract shall only be performed by state inspectors who have successfully completed the FDA course, Conducting LACF Inspections (FD203).*			
Juice HACCP			
Juice HACCP and Conducting Juice HACCP Inspections (FD219) *Note: Juice HACCP inspections done under FDA contract shall only be performed by state inspectors who have successfully completed the FDA course, Juice HACCP and Conducting Juice HACCP Inspections (FD219).*			
Seafood HACCP			
Conducting Seafood Inspections (FD249) *Note: Seafood HACCP inspections done under FDA contract shall only be performed by state inspectors who have successfully completed the FDA course, Seafood HACCP Inspections (FD249).*			

Advanced Food Inspection Curriculum Fieldwork				
Specialized food inspection:				
Joint Inspections		**Completion Date**	**Inspector's Initials**	**Supervisor's Initials**
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				
Evaluations				
1.				
2.				

Specialized food inspection:				
Joint Inspections		**Completion Date**	**Inspector's Initials**	**Supervisor's Initials**
Please provide the name of the food plant and identification number.				
1.				
2.				
3.				
Evaluations				
1.				
2.				

Continuing Education Coursework				
Please provide the name and location of the course.	**Completion Date**	**Contact Hours[1]**	**Inspector's Initials**	**Supervisor's Initials**

Continuing Education Fieldwork				
Joint Inspections		**Completion Date**	**Inspector's Initials**	**Supervisor's Initials**
Please provide the name of the food plant and identification number.				
1.				
2.				

[1] The inspector will earn contact hours at a rate of one contact hour for every course hour.

Appendix 3.1
Self-Assessment Worksheet

State agency: _____

Program Elements	Yes/No	If no, please explain why element is not met
Section I. Risk-based inspection system		
a. Is the establishment inventory updated? • Does inventory have both licensed and unlicensed firms? • Are addresses for the physical locations of firms listed in the inventory?		
b. Are eSAF (electronic State Access to FACTS) entries hard-copy inspection reports cross referenced to ensure the firm information is accurately entered?		
c. Are establishments grouped based on identified risk factors?		
d. Are risk categories used to prioritize inspections, assign routine inspection frequencies, and allocate resources?		
Section II. Inspection protocol		
Does the program's inspection protocol require inspectors to:		
a. Review the establishment file, consumer complaints, and other relevant documents prior to inspection?		
b. Use appropriate equipment and forms?		
c. Establish jurisdiction?		
d. Select appropriate product/process (high risk products and processes)?		
e. Assess employee practices critical to the safe production and storage of food?		
f. Properly evaluate the likelihood that conditions, practices, components, and labeling could cause the product to be adulterated or misbranded?		
g. Recognize significant violative conditions or practices, and record findings consistent with program procedures?		
h. Distinguish between significant and insignificant observations, and isolated incidents and trends?		
i. Review and evaluate the appropriate operational records and procedures and apply the information obtained from this review?		
j. Collect adequate evidence and documentation in accordance with program procedures given the nature of the inspectional findings?		

k. Verify correction of deficiencies from a previous inspection?		
l. Behave professionally and demonstrate proper sanitary practices during the inspection?		
m. Use the "Fish and Fishery Products Hazards and Controls Guide" or the "Juice HACCP Hazards and Controls Guide," to identify and evaluate the hazards associated with the product and process?		
n. Assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation?		
o. 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?		
p. Recognize deficiencies in the firm's monitoring and sanitation procedures through in-plant observations?		
q. Identify himself/herself, present credentials, and make appropriate introductions, including explaining the purpose and scope of the inspection?		
r. Use suitable interviewing techniques?		
s. Explain findings clearly and adequately throughout the inspection?		
t. Alert the firm's appropriate management when an immediate corrective action is necessary?		
u. Write findings accurately, clearly, and concisely on the State document?		
v. Answer questions and provide information in an appropriate manner?		
w. And, does the program have an adequate recordkeeping system and does this system contain prescribed records associated with inspections?		
Section III. Food recalls		
Does the recall system include:		
a. Guidance for sharing information?		
b. Procedures for prompt removal of recalled products?		
c. Procedures for recall audit checks?		
d. And, does the program have an adequate recordkeeping system and does this system contain prescribed records associated with food recalls?		
Section IV. Consumer complaints		
a. Does the program have procedures for receiving, tracking, evaluating, responding to, and closing consumer complaints?		
b. Does the program have a recordkeeping system and are records associated with consumer complaints retained?		

Section V. Food industry inspection complaints		
a. Does the program have procedures for receiving, evaluating, responding to, and recording food industry complaints about inspections?		
b. Does the program have a recordkeeping system and are records associated with food industry inspection complaints retained?		

Assessment completed by:

(NAME) **(DATE)**

Appendix 3.2
Risk Classification Criteria for Food Plants

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

Standard number 3 focuses on one segment of the total food safety system – inspection of food plants. A key requirement of this standard is that the State program uses a science-based and risk-based method for classifying food plants into at least three risk categories with a baseline inspection frequency specified for each category. Although this standard does not prescribe a classification scheme or inspection frequency, frequencies could be established through: (1) risk-based assessment of foodborne hazards, (2) ranking the public health impacts of specific hazards, (3) measurement and valuation of the benefits of reducing risk, (4) evaluation of the effectiveness and cost of risk reduction intervention options, and (5) integration of these analyses to allocate resources.

When categorizing establishments by risk, State programs may consider several factors including: (1) the type of food and ingredients, (2) processing requirements, (3) volume of product manufactured or distributed, (4) intended consumer, and (5) compliance history of the food plant. The factors may be assigned numerical values that are tabulated to rank the food plants and prioritize inspections.

Foods with microbial hazards, especially those that require stringent temperature controls, are usually deemed high risk. Other foods such as unpasteurized juices may be classified as high risk based on epidemiologic implication in foodborne disease outbreaks. In addition to microbial hazards, chemical hazards should also be evaluated.

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

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

Risk Classification Criteria for Food Plants

Many classification schemes prioritize products intended for use by highly-susceptible populations[1] because these populations are more likely to experience foodborne illnesses compared to the general population.

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

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

The risk classification criteria listed on the next page are intended solely to assist State programs with establishing their own classification system. Risk categories and inspection frequencies can also be found in the statement of work for the food contract.

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

Risk Classification Criteria for Food Plants

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

Appendix 4.1
Self-Assessment Worksheet

State agency: _____

The results of the field inspection and desk audits are summarized below. Performance ratings that fall below 80 percent indicate a need for improvement and require corrective action. Worksheets 4.2 – 4.4 can be used to identify the specific aspects of the inspection program that need improvement.

Overall Audit Rating **(based on five-year average)**	
Circle one:	*Performance rating criteria:*
Acceptable	All performance rating averages ≥ 80 percent.
Needs improvement	One or more performance rating averages < 80 percent.

	Audits		
	Field inspection	**Inspection report**	**Sample report**
Year _____	_____	_____	_____
Year _____	_____	_____	_____
Year _____	_____	_____	_____
Year _____	_____	_____	_____
Year _____	_____	_____	_____
Five-year average			

Assessment completed by:

_____

(NAME) **(DATE)**

Appendix 4.2
Summary of Field Inspection Audit Findings

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

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

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

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

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

(4) Calculate the overall rating for the field inspection audits.
Record the rating in the space provided in the box located at the top of worksheet 4.2.

FORMULA:

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

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

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

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

Worksheet 4.2 Performance rating for the field inspection audits

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

Performance rating (4): _____

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

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

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

Worksheet 4.2
Continuation sheet

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

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

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

Appendix 4.3
Summary of Inspection Report Audit Findings

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

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

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

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

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

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

FORMULA:

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

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

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

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

Worksheet 4.3 Performance rating for the inspection report audits

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

Performance rating (4): _____

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

Performance factors (5)	Firm identification number and date of inspection (1)																				A_t (3)	NI_t (3)
	Performance ratings (2)																					
I.1																						
I.2																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
II.7																						
II.8																						
II.9																						
II.10																						
II.11																						
II.12																						
III.1																						
III.2																						
III.3																						
III.4																						
IV.1																						
IV.2																						
IV.3																						
IV.4																						
IV.5																						
IV.6																						
V.1																						
V.2																						
V.3																						
V.4																						
V.5																						
V.6																						
V.7																						
V.8																						
Subtotal	*Enter the sum of the totals from all continuation sheets.*																					
Total	*Enter the final sums (subtotal + sums of (3) on this form).*																					

Worksheet 4.3
Continuation sheet

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																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
II.7																						
II.8																						
II.9																						
II.10																						
II.11																						
II.12																						
III.1																						
III.2																						
III.3																						
III.4																						
IV.1																						
IV.2																						
IV.3																						
IV.4																						
IV.5																						
IV.6																						
V.1																						
V.2																						
V.3																						
V.4																						
V.5																						
V.6																						
V.7																						
V.8																						
Total	*Enter the sums of (3).*																					

Worksheet 4.3

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

Appendix 4.4
Summary of Sample Report Audit Findings

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

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

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

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

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

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

FORMULA:

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

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

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

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

Worksheet 4.4 Performance rating for the sample report audits

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

Performance rating (4): _____

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

Performance factors (5)	Sample report identification number and date of sample collection (1)																				A_t (3)	NI_t (3)
	Performance ratings (2)																					
I.1																						
I.2																						
I.3																						
I.4																						
I.5																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
II.7																						
III.1																						
III.2																						
III.3																						
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.

Worksheet 4.4
Continuation sheet

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																						
I.5																						
II.1																						
II.2																						
II.3																						
II.4																						
II.5																						
II.6																						
II.7																						
III.1																						
III.2																						
III.3																						
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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CONTRACT AUDIT

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

I. PREINSPECTION ASSESSMENT

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

II.	INSPECTION OBSERVATIONS AND PERFORMANCE

1. WAS FDA JURISDICTION ESTABLISHED?

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE *(Continued)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. A. INSPECTION OBSERVATIONS AND PERFORMANCE FOR 'HACCP-REGULATED' FACILITIES

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

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

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 AN IMMEDIATE CORRECTIVE ACTION WAS NECESSARY?

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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 I*I.A. Inspection Observations and Performance for 'HACCP-Regulated' firms*. **If the establishment is not subject to Seafood or Juice HACCP regulations, leave the scoring for these four questions blank.**

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

ADDITIONAL COMMENTS

SIGNATURE OF FDA AUDITOR	DATE

Appendix 4.5a
Guidance for Completing the Contract Audit Form (FDA Form 3610)

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

I. Pre Inspection Assessment

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

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

Examples of a "needs improvement" rating:

a. The inspector does not review the State's previous inspection report and follow-up on previously cited deficiencies.

b. The inspector does not review a firm's response letter that promised corrective actions after the last inspection, which was conducted by the State.

c. The inspector does not verify the firm's normal days of operation or seasonal hours.

d. The inspector does not follow-up on a consumer complaint contained in the State's establishment file.

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

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

Examples of a "needs improvement" rating:

a. During an inspection of a cream-filled pie manufacturer, the inspector does not have a calibrated thermometer to check the temperature of the pie.

b. During an inspection of a cooked, ready-to-eat food processor, the inspector does not have a method to test the concentration of iodine sanitizer in the hand dip station.

c. During the inspection, the inspector does not have a flashlight to examine poorly lit raw material storage areas.

II. Inspection Observations and Performance

1. Was FDA jurisdiction established?

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

Examples of a "needs improvement" rating:

a. The inspector fails to confirm interstate movement of a product or ingredients.

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

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

References:
- FDA compliance programs referenced in the contract

Examples of a "needs improvement" rating:

a. The inspector covers only a low-risk product while the firm is producing a high-risk product on the day of the inspection.

b. The inspector does not cover a small ready-to-eat sandwich operation in a large frozen dinner processing plant.

c. While inspecting a beverage bottling plant whose primary product is institutional-sized root beer syrup, the inspector ignores a bottled water processing operation at that site.

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

Examples of a "needs improvement" rating:

a. The inspector fails to evaluate the hygienic practices of employees working in a food processing area.

b. The inspector is unaware of the need for employees who are processing cooked, ready-to-eat foods to wash and sanitize their hands every time they touch an unclean surface.

c. The inspector notices that the firm has a trash bin and a reclaim bin in the same area. He/she does not, however, recognize the potential hazard. Consequently, the inspector misses an employee placing trash in the reclaim bin that contains product reintroduced into the manufacturing process.

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

References:

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

Examples of a "needs improvement" rating:

a. The inspector fails to recognize when a firm's finished product labeling does not contain a sulfite declaration, even though the raw material does contain a sulfite declaration.

b. The inspector fails to note the significance of "back hauling" raw eggs in a tanker used to carry pasteurized ice cream mix.

c. During an inspection of a baby food manufacturer, the inspector notices a rapid moving belt is causing glass jars to rattle and shards of glass are on the belt. The inspector fails to relate that observation to a recent increase in complaints about glass in baby food.

d. The inspector fails to recognize the addition of an allergen during the production of a breaded product and fails to follow-up on the label review.

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

Examples of a "needs improvement" rating:

a. The inspector fails to recognize that the food residues and mold growth on food contact surfaces are violations.

b. The inspector does not recognize that employees handling cooked, ready-to-eat product with soiled hands is a deficiency.

c. The inspector doesn't notice that machine parts over food contact surfaces are lubricated with automobile oil.

d. The inspector fails to recognize that condensate dripping from a freezer onto finished product may cause cross contamination.

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

References:

- FDA compliance programs referenced in the contract

Examples of a "needs improvement" rating:

a. The inspector notes minor deficiencies such as chewing gum and nail polish while failing to note places where cross contamination of cooked and raw product might occur.

b. The inspector identifies record keeping deficiencies in records that are two months old. The inspector objects to these deficiencies without appropriately considering that the firm's weekly management review of the records has identified the deficiencies, which have not been repeated within the last seven weeks.

c. During an inspection of a ready-to-eat salad processor, the inspector focuses primarily on filthy, non-food contact surfaces.

d. During the inspection of a warehouse, the inspector focuses on products stored against the wall but doesn't notice several pallets of rice infested with moths.

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

Examples of a "needs improvement" rating:

a. During a review of the processing records, the inspector fails to detect that cooking times are outside the scheduled process.

b. The inspector fails to detect possible evidence of record falsification such as inconsistencies among different types of records, unrealistic and repetitive data, and inconsistencies in signatures.

c. Can teardown records are reviewed, but the inspector didn't realize teardown measurements were not done at appropriate intervals.

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

Examples of a "needs improvement" rating:

a. The inspector fails to adequately document findings according to State requirements when violations are found in the firm.

b. The inspector fails to follow State requirements when collecting samples of processed food necessary to document violative conditions.

c. In an acidified food processing plant, the pH of the final product is questionable. The inspector does not, however, collect a sample of the product for pH determination.

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

Examples of a "needs improvement" rating:

a. Although significant time-temperature abuse of coconut cream pies was identified during the previous inspection, the inspector does not determine if the deficiencies were corrected.

b. In the previous inspection, the inspector reported that a private well was not equipped with a sanitary seal. During the current inspection, the manager tells the inspector that the well was repaired, and the lab results were acceptable. The inspector reviews the microbiological lab results, but does not go to the well to verify that the sanitary seal was installed.

c. The inspector fails to follow up on deficiencies from the previous inspection for cooked, ready-to-eat product because that product was not being made at the time of the inspection. Nor does the inspector review process records for the product to determine if the firm took appropriate corrective actions.

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

Examples of a "needs improvement" rating:

a. The inspector does not use the boot bath when entering in the firm's processing areas.

b. The inspector fails to sanitize his/her thermometer prior to probing product.

c. The inspector fails to wear protective clothing when entering an aseptic processing area.

d. The inspector wears dangling earrings, bracelets, and necklaces in the food processing areas of a baby food manufacturer.

II. A. Inspection Observation and Performance for 'HACCP-Required' Facilities

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

References:

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

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

Examples of a "needs improvement" rating:

a. In a tuna processing plant, the inspector fails to identify histamine as a hazard inherent to the incoming raw material and fails to question its absence in the firm's HACCP plan. (Failure to identify a hazard reasonably likely to occur.)

b. A firm is producing fresh, raw, refrigerated fish in Cryovac packaging. The inspector is not aware that C. botulinum is a significant hazard.

c. An inspector incorrectly identifies aquaculture drugs as a significant hazard for a secondary processor of a product that it receives from the primary processor. (Identification of a hazard not reasonably likely to occur.)

d. The inspector fails to recognize that a batter tank in a breaded shrimp processing operation is a possible CCP. (Failure to recognize an appropriate CCP.)

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

Examples of a "needs improvement" rating:

a. The inspector insisted the firm perform medical check-ups for crabmeat pickers.

b. The inspector cannot determine which of the eight areas of sanitation are relevant to the firm's operations.

c. The inspector fails to inquire about the firms SSOPs and monitoring practices.

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

Examples of a "needs improvement" rating:

a. The inspection reveals that the firm is processing a product that requires a HAACP plan. The inspector cites the firm's failure to have a HAACP plan, but the inspector does not determine if the necessary controls were put into place without a HACCP plan.

b. Although the inspector is told that the firm uses well water, not potable water, as its source for ice, the inspector does not verify that the firm has the water tested for coliforms to ensure its safety.

c. The inspector does not ask the plant manager for records of pest control after learning that the service is contracted to a private company.

d. The inspector does not accompany the firm's sanitarian on a routine pre-operation inspection that would have given him an indicated that the sanitation and/or sanitation monitoring may be inadequate.

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

Examples of a "needs improvement" rating:

a. The inspector fails to recognize that cumulative times and temperatures for cooling, holding, and picking of cooked crabs were substantially above such times and temperatures specified in the firm's HACCP plan.

b. The inspector fails to recognize that a firm's finished product labeling does not contain a sulfite declaration even though an ingredient contains a sulfite declaration.

c. The inspector fails to recognize that the presence of food residues and mold growth on processing equipment immediately prior to processing is evidence of unsanitary conditions.

d. The inspector does not recognize that food-contact surfaces are being sanitized with a product that is not approved for use on food contact surfaces.

III. Oral and Written Communication

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

Examples of a "needs improvement" rating:

a. The inspector fails to explain why he/she is at the firm.

b. The inspector enters through the back door and begins examining a storage area without notifying anyone at the firm.

2. Did the inspector use suitable interviewing techniques?

Examples of a "needs improvement" rating:

a. The inspector requests for information are vague; consequently, the firm provides documents that are unrelated to the inspection.

b. The firm manager is unable to respond to a request for information, because the inspector spoke in unfamiliar and confusing jargon.

c. When the plant manager's responses are evasive, the inspector does not ask follow-up questions to obtain the necessary information. Consequently, the answers to the questions are incomplete.

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

Examples of a "needs improvement" rating:

a. The inspector does not discuss a significant observation at the close-out meeting.

b. The inspector does not discuss with the general manager a significant deficiency observed in the processing area before going to the packing area of the cannery.

c. The inspector is vague during his discussion with the managers at the end of the inspection. Therefore, the managers are unaware of the significance of the observations and that corrective actions are needed.

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

Examples of a "needs improvement" rating:

a. The inspector fails to alert the appropriate manager that food containing undeclared FD&C Yellow #5 is being packaged, and, if shipped, could result in a health hazard.

b. The inspector didn't notify the plant manager when he saw blood dripping from boxes of boneless beef onto raw carrots.

c. The inspector documented condensate dripping from bins of ready-to-eat salad not packaged.

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

Examples of a "needs improvement" rating:

a. The inspector discusses specific information about a pending compliance action against a competitor with an employee on the processing line.

b. The inspector gives a competitor's product formula to a friendly plant manager.

c. The inspector fabricates an answer to a policy question that could lead the firm to take an inappropriate corrective action.

d. The inspector dictates an inappropriate corrective action for a deficiency.

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

References:

- FDA compliance programs referenced in the contract

Examples of a "needs improvement" rating:

a. The inspector fails to write that the firm has a significant process deviation on the list of findings.

b. The inspector fails to write on the list of findings that he/she observed excreta pellets in bags of rice.

c. The list of findings shows that the "Firm did not control hazards" with no further explanation.

Appendix 4.6

Manufactured Food Regulatory Program Standards Inspection Report Audit Form	
Auditor	Date of audit
Firm identification number	Date of inspection

I. Introduction

1. FORMAT OF THE INSPECTION REPORT FOLLOWED THE STATE PROGRAM'S CURRENT PROCEDURES AND POLICIES.
   ☐ Acceptable ☐ Needs improvement

   COMMENTS *(required for needs improvement)*

2. REQUIRED FIELDS ON INSPECTION REPORT OR RELATED REPORT FORMS ARE COMPLETED.
   ☐ Acceptable ☐ Needs improvement

   COMMENTS *(required for needs improvement)*

II. Evidence Development

1. IDENTIFIED FIRM MANAGERS AND KEY PERSONNEL AND DESCRIBED THEIR RESPONSIBILITIES.
   ☐ Acceptable ☐ Needs improvement

   COMMENTS *(required for needs improvement)*

2. VERIFIED LEGAL STATUS OF FIRM AND CORPORATE OFFICERS.
   ☐ Acceptable ☐ Needs improvement

   COMMENTS *(required for needs improvement)*

3. DOCUMENTED INDIVIDUAL RESPONSIBILITY.
   ☐ Acceptable ☐ Needs improvement

   COMMENTS *(required for needs improvement)*

4. REVIEWED QUALITY ASSURANCE PROGRAM AND FIRM'S PROCEDURES FOR IDENTIFYING RISK AND MAINTAINING CONTROLS.
   ☐ Acceptable ☐ Needs improvement

   COMMENTS *(required for needs improvement)*

5. IDENTIFIED VIOLATIONS.
   ☐ Acceptable ☐ Needs improvement

   COMMENTS *(required for needs improvement)*

Page 2

6. DOCUMENTED SIGNIFICANT FINDINGS.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

7. DOCUMENTED POSSIBLE CAUSES OF CONTAMINATION.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

8. COLLECTED SUFFICIENT SAMPLES.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

9. COLLECTED EXHIBITS, PHOTOGRAPHS, OR PHOTOCOPIES TO DOCUMENT FINDINGS.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

10. DESCRIBED FIRM'S SYSTEM FOR PRODUCT AND LOT CODING.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

11. REPORTED PRODUCT DISTRIBUTION.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

12. REVIEWED RECORDS OF COMPLAINTS RECEIVED BY FIRM.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

III. Discussions With Management

1. DISCUSSED FINDINGS AND VIOLATIONS.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

Page 3

2. REPORTED RESPONSES OR REPLIES FROM THE FIRM.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

3. RECORDED ANY WARNINGS OF POSSIBLE FURTHER ACTIONS (REINSPECTION, EMBARGO, REVOCATION OF LICENSE, OR LEGAL CONSEQUENCES OF VIOLATIVE CONDITIONS) GIVEN TO THE FIRM.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

4. RECORDED ANY REFUSALS ENCOUNTERED DURING THE INSPECTION.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

IV. Organization of the Report

1. REFERENCED EXHIBITS IN THE REPORT.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

2. WRITTEN OBSERVATIONS WERE CLEAR AND CONCISE.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

3. OBSERVATIONS WERE FACT BASED AND SUPPORTED BY LAWS AND REGULATIONS.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

4. EMPHASIZED SIGNIFICANT OBSERVATIONS.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

5. OBSERVATIONS WERE REPETITIOUS.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

Page 4

6. SUBMITTED REPORT WITHIN TIMEFRAMES.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

V. Supervisory Review

1. STATED THE REASON FOR THE INSPECTION, A BRIEF HISTORY OF THE FIRM, AND FOLLOW-UP TO THE PREVIOUS INSPECTION, IF NECESSARY.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

2. A SUMMARY OF FINDINGS AND DISPOSITION OF INSPECTION WERE RECORDED IN THE REPORT.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

3. REINSPECTION SCHEDULE AND RECOMMENDATION FOR COMPLIANCE FOLLOW UP WERE GENERATED AND RECORDED.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

4. CLASSIFICATION AND FOLLOW-UP WERE CONSISTENT WITH THE LAW, CURRENT POLICIES, AND INSPECTIONAL FINDINGS.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

5. SUPERVISORY REVIEW AND ACTION WERE DONE WITHIN ADMINISTRATIVE TIMEFRAMES.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

6. VERIFIED AND DESCRIBED CORRECTIVE ACTIONS FROM PREVIOUS INSPECTION FINDINGS.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

Page 5
7. DATES IN REPORT, COVERSHEET, AND CODING OR OTHER ADMINISTRATIVE DATA WERE RECORDED ACCURATELY. ☐ Acceptable ☐ Needs improvement COMMENTS *(required for needs improvement)*
8. DISTRIBUTION OF REPORT WAS RECORDED ACCURATELY ON THE COVERSHEET. ☐ Acceptable ☐ Needs improvement COMMENTS *(required for needs improvement)*

Appendix 4.7

Manufactured Food Regulatory Program Standards Sample Report Audit Form	
Auditor	Date of audit
Sample identification number	Date of collection

I. Introduction

1. REASON FOR SAMPLE COLLECTION WAS RECORDED.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

2. SAMPLE SIZE WAS DESCRIBED.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

3. LOT AND PRODUCT CODING WERE RECORDED ON SAMPLE REPORT.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

4. MANUFACTURER, SHIPPER, DEALER, AND THE RESPONSIBLE FIRM WERE RECORDED.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

5. REQUIRED FIELDS ON THE SAMPLE REPORT (SR) OR RELATED REPORT FORMS ARE COMPLETED.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

II. Evidence Development

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

☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

2. METHOD OF COLLECTION, INCLUDING SAMPLE SIZE, WAS APPROPRIATE FOR THE LABORATORY ANALYSES.

☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

3. SAMPLE, LABELS, AND LABELING, BEAR IDENTIFICATION MARKS AND WERE ACCURATELY REPORTED ON THE SR.

☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

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4. PRODUCT LABEL AND LABELING WERE SUBMITTED WITH SR.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

5. RECEIPT FOR SAMPLE WAS OBTAINED.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

6. AFFIDAVITS WERE CLEAR, LEGIBLE, AND COMPLETE.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

7. SR WAS SUBMITTED WITHIN TIMEFRAMES.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

III. Sample Integrity

1. SAMPLE WAS HANDLED, PACKAGED, AND SHIPPED TO PREVENT COMPROMISING THE CONDITION OR INTEGRITY OF THE SAMPLE.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

2. SAMPLE WAS DELIVERED OR SHIPPED TO THE APPROPRIATE LABORATORY WITHIN ACCEPTABLE TIMEFRAMES.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

3. SAMPLE DELIVERY (DATE AND CUSTODIAN) WAS RECORDED ON SR.
☐ Acceptable ☐ Needs improvement

COMMENTS *(required for needs improvement)*

Appendix 4.8
Corrective Action Plan

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

State agency: _____

Completed by: _____
(NAME) (DATE)

Type of audit: **FIELD INSPECTION** **INSPECTION REPORT** **SAMPLE REPORT**
(circle one)

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

Appendix 5.1
Self-Assessment Worksheet
Food-related Illness and Outbreak Response

State agency: _____

Program Elements	Yes/ No	If no, please explain why element is not met
The State program uses epidemiological information from agencies at all government levels.		
1. Is the State program responsible for epidemiological investigations identified? **If no, attach agreement with lead agency.**		
2. Is there a system to coordinate agreements between the food and epidemiology programs and that clearly identifies the roles, duties, and responsibilities of each program?		
The State program has an established system to investigate reports of illness, injury, and suspected outbreaks.		
1. Are complaints alleging food-related illness, injury, or terrorism maintained in a log or database?		
2. Does the State program initiate a response to reports of illness or injury within established timeframes?		
3. Does the State program use established epidemiology procedures to conduct illness or injury investigations and collect information?		
4. Are the factors that caused the illness, injury, or incidents reported?		
The State program notifies the public.		
1. Is a procedure in place that outlines criteria for releasing information to the public?		
2. Does the State program provide food safety education to the public and regulated industry?		
3. Are enforcement tools utilized to reduce and contain illness and injury?		

Program Elements	Yes/ No	If no, please explain why element is not met
Outbreak reports and surveillance summaries are distributed to the appropriate agencies.		
1. Does the State program maintain a current list of communication links with the appropriate agencies?		
2. Is a coordinator designated to guide investigative efforts of all agencies involved?		
3. Are investigations coordinated with the appropriate agencies?		
4. Is a procedure in place to conduct tracebacks of food implicated in an illness, injury, or outbreak, including coordination with the appropriate agencies?		
5. Are final reports of the State program's findings of foodborne illness and injury investigations maintained and shared with the appropriate agencies?		
The State program provides guidance for immediate notification of appropriate law enforcement agencies when intentional food contamination or terrorism is suspected or threatened.		
1. Does the State program have written procedures for reporting threats of intentional food contamination or terrorism?		
2. Has the State program identified a coordinator to lead investigations of suspected or threatened intentional food contamination and terrorism?		
3. Has the State program identified the appropriate agencies to be contacted and the name and phone number of designated contact persons in such agencies?		
4. Does the State program collaborate as necessary with FDA and other jurisdictions when conditions of increased threat of intentional contamination occur?		

Assessment completed by:

(NAME) **(DATE)**

Appendix 5.2
Memorandum of understanding between the department of health and the department of agriculture concerning the investigation of foodborne illnesses associated with food service establishments and food plants

I. GENERAL

This Memorandum of Understanding (MOU) replaces the MOU dated _____, and effective on _____, between the Department of Health (Health) and the Department of Agriculture (Agriculture).

The purpose of this MOU is to clarify the respective responsibilities of Agriculture and Health in the surveillance for, and investigation of, foodborne illnesses, and in furtherance of such purpose, to broaden cooperative efforts between the two agencies.

Responsible Agencies

Agriculture and Health are the responsible agencies for the implementation of this MOU. Under the authority of Sections _____ of the Public Health Law and pursuant to the power granted to the State Commissioner of Health by Agriculture Law to certify and approve service food establishment permit and inspection programs of local health agencies, the State Commissioner of Health, by execution of this instrument, binds all city and county health departments and State district health offices (local health units) to its terms and conditions.

For purposes of this agreement, Health and Agriculture will be responsible for its implementation.

Jurisdiction

This MOU applies to the entire State and includes all city and county health departments.

Effective Date

This agreement will be effective _____.

Legal Authority

The _____ provides requisite authority for Agriculture and Health to enter into this MOU. Section _____ of the Public Health Law and Section _____ of the Agriculture Law also authorize this MOU.

II. RESPONSIBILITIES AND IMPLEMENTATION

Determination of Responsibility

When a food-related illness from a manufactured food product regulated by Agriculture, Health, and local health departments is reported, Health will be responsible for conducting the epidemiologic investigation. Agriculture will be responsible for investigating the food preparation areas and

conducting an investigation at the food plant. Agriculture will send a copy of these reports to Health. Agriculture will also coordinate any resulting actions to remove the contaminated food from distribution. Laboratory support for investigations will be coordinated by each agency under separate existing agreements.

Implementation

Agriculture will inform its field representatives of their areas of responsibility. Health will define areas of responsibility among its local health units. Responsibilities of other State and Federal agencies also will be specified.

Health, Agriculture, and local health units will provide or sponsor joint training sessions in the interpretation and application of principles, regulations, standards, and techniques of common concern or interest.

III. MECHANISMS FOR INFORMATION EXCHANGE

Health, Agriculture, and each local health unit shall maintain rosters of regional and local Health officials and Agriculture food program supervisors and make such rosters available to each other.

If Agriculture becomes aware of actual or suspected cases of foodborne illness, it shall report such cases by telephone--without delay--to the local health unit having jurisdiction for that locality. Health and Agriculture will jointly investigate and complete final reports involving illnesses that occur at, or due to, establishments regulated by Agriculture. These reports will be forwarded to Agriculture and to Health.

Whenever one agency learns of an FDA Class I or similar recall of food or food products, it shall immediately notify the other agency of such recall. Throughout the recall process, both agencies at all levels will make a maximum effort to keep the other agency informed and cooperate in every way possible to expedite the removal of hazardous food from the marketplace.

IV. MECHANISMS FOR EMBARGO/SEIZURE OF FOOD SOURCES IMPLICATED IN EPIDEMIOLOGIC INVESTIGATIONS

Epidemiologic Investigation

Health will investigate foodborne disease outbreaks. These investigations are conducted by county, city health departments, and/or State health departments following procedures outlined in the "Environmental Health Manual." Health will notify Agriculture of all on-going investigations where a contaminated food source is the suspected cause of a disease outbreak. Agriculture will provide assistance in the investigation and may play the lead role in tracing contaminated foods back to their source by visiting retailers, wholesalers, and producers to review and obtain records that document the

chain of distribution for the products. Health will analyze the findings of the epidemiologic and source investigations and make a determination as to the likelihood of an association between the illness outbreak and its cause being one or more sources. When warranted, based on the evaluation of the investigation data and analysis, the Commissioner of Health will certify to the Commissioner of

Agriculture that food from the source(s) constitute(s) a danger to the health of the people of the State and that such source(s) is/are unapproved source(s) for food service establishments in the State.

Embargo, Seizure, Recall, and Public Notification

After receiving certification from the Commissioner of Health, the Commissioner of Agriculture shall direct the seizure quarantine and/or destruction of the food in question pursuant to the provisions of Section ____ of the Agriculture Law, following his or her determination that said food is adulterated within the meaning of Section ____ of the Agriculture Law and, as such, that the manufacture, processing, possession, sale, offering, or exposure for sale of such food would violate Section _____ of the Agriculture Law. Where they deem it appropriate, the Commissioners of Health and Agriculture shall direct that a recall of such adulterated food be implemented and that the public be notified of such recall. Health shall assist in cases involving such seizures, quarantines, destructions, and recalls by assuring the removal of any remaining contaminated food from food service establishments and food plants and by making available witnesses for any administrative proceedings and/or litigation associated with such actions.

Nothing herein contained shall be construed to restrict the power of the Commissioner of Health to take Summary Action under Public Health Law Section ___ to require the discontinuance of conditions or activities constituting a danger to public health when such action is deemed appropriate under the circumstances.

V. REVIEW OF AGREEMENT

This agreement between the two departments shall be submitted annually to the Governor's Office and the Division of the Budget for their review of effectiveness and to solicit their recommendations to both Agriculture and Health as to changes of policies and procedures with respect to this agreement.

For the Department of Agriculture	**For the Department of Health**
Signature_____	Signature _____
Title _____	Title _____
Date _____	Date _____

Appendix 6.1
Self-Assessment Worksheet

State agency: _____

The State program will explain its compliance and enforcement program. Laws, regulations, and manuals should be cited. If applicable, include web links to electronic versions.

Your written response should include:

a. Forms that are required for enforcement actions, such as Notice of Embargo, Notice and Directive to Cease and Desist, Agreement for Disposition of Product,

b. Examples of enforcement strategy(ies) and describe how they are uniformly applied,

c. A description of the system used to track critical and chronic violations and violators,

d. A description of the risk-based process used to determine when a directed investigation, follow-up, or a re-inspection is needed,

e. A description of the timeline for progressive compliance actions including but not limited to license revocation, embargoes, warning letters, and injunctions, and

f. A description of how non-supervisory and supervisory staffs receive verbal and written policy and guidance that impact their compliance decisions.

Assessment completed by:

_____

(NAME) **(DATE)**

Appendix 6.2
Performance Review of Enforcement Actions

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

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

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

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

(3) Record the A_t and NI_t .
A_t = vertical sum of acceptable ratings.
NI_t = vertical sum of needs improvement ratings.

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

FORMULA:

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

Worksheet 6.2
Calculation of the level of conformance to compliance procedures

State agency: _____

Rating for conformance to compliance procedures (4):

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

Assessment conducted by:

_____

(NAME) **(DATE)**

Worksheet 6.2
Continuation sheet

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

Appendix 7
Self-Assessment Worksheet

State agency: _____

This worksheet is completed by the State program to document outreach activities. 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 (circle one):

seminar workshop training course other: _____

b. Subject or name of outreach activity: _____

c. Date of outreach activity: _____

Section II. Evaluation of Outreach Activity

Program Elements	Yes/No	If no, please explain.
a. The purpose and objectives were clearly defined		
b. The context of the training activity 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 the Section III of the form.		

Section III. Critique of Outreach Activity

Discuss what went well, what could be done better, and what more could be done to improve the outreach activity.

Assessment completed by:

_____

(NAME) **(DATE)**

Appendix 8.1
Self-Assessment Worksheet

State agency: _____

Completed by: _____
(NAME) (DATE)

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

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

Appendix 8.2
Calculation for determining a required number of inspectors

This appendix is an example of how to calculate the number of field staff required to conduct inspections[1] of food plants. The data in the following table will vary significantly based on local or regional conditions. The State program may use the risk categories and inspection frequencies found in the statement of work for the food contract as a basis for determining the required number of inspectors.

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

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

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

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

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

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

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

3. Calculate the number of FTE's required.

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

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

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

Appendix 8.3
Inspection Equipment

State agency: _____

Completed by: _____
(NAME) **(DATE)**

The State program should develop a list of equipment needed to conduct inspections and sample collections. Please add and remove equipment from the table. Then, indicate whether the equipment is assigned or available to inspectors. Equipment requested by inspectors but not available should be marked "wish list."

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

Worksheet 9
Self Assessment and Improvement Plan Report

State agency: _____

Report completed by: _____
(NAME) (DATE)

Standard		Self Assessment	Implementation	Explain improvements needed to fully implement standard *(required for incomplete self assessment or partial implementation)*
1	Regulatory Foundation	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
2	Training Program	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
3	Inspection Program	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
4	Inspection Audit Program	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
5	Food-related Illness …Outbreaks… Food Defense…	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	

Worksheet 9 – cont'd.

State agency: _____

Report completed by: _____
(NAME) (DATE)

Standard		Self Assessment	Implementation	Explain improvements needed to fully implement standards *(required for incomplete self assessment and partial implementation)*
6	Compliance and Enforcement	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
7	Industry and Community Relations	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
8	Program Resources	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
9	Program Assessment	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	
10	Laboratory Support	Complete ☐ Incomplete ☐ Hours used ____	Full ☐ Partial ☐	

Appendix 10
Self-Assessment Worksheet

State agency: _____

Program Elements	Yes/No	If no, please explain why element is not met
Does the State program have:		
a. A current list of servicing laboratories		
b. A list of analytical capabilities for each servicing laboratory		
c. A servicing laboratory to analyze samples that may contain biological hazards.		
d. Contracts or written agreements with servicing laboratories.		
e. Verification of the servicing laboratory's accreditation or certification		
The servicing laboratory's QAP contains the requirements listed here:		
a. Calibration, verification, and maintenance of equipment		
b. Documentation of analytical results		
c. Recordkeeping (worksheets, sample records)		
d. Sample accountability		
e. Sample integrity and chain of custody		
f. Qualifications of analysts (training included)		
g. Audit procedures		

Assessment completed by:

_____

(NAME) **(DATE)**