Produce Regulatory Program Standards

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

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INTRODUCTION

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

The Produce Regulatory Program Standards (PRPS) is a critical component in establishing the FDA's IFSS. The PRPS (henceforth also referred to as "program standards") establishes a uniform foundation for regulatory agencies responsible for oversight of farms, produce commodities, and activities covered under FDA's Produce Safety Rule (21 CFR Part 112). When fully implemented, the program standards define a set of best practices of a regulatory system.

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

The program standards are comprised of ten standards that establish requirements for the critical elements of a regulatory program designed to protect the public from produce and produce-related illness, injury, outbreaks and emergencies. The elements of these standards include: regulatory foundation, training, inspection programs, audit programs, produce-related event response, compliance and enforcement, industry and community outreach, program resource management, program assessment, and laboratory support.

Each standard is laid out in the following format to ensure uniformity: purpose statement (x.1), requirement summary (x.2), description of program elements (x.3), projected outcomes (x.4), and a list of required documentation (x.5). The program elements describe the best practices of a quality regulatory program. Required elements for implementation are found in the program elements (x.3) and documentation (x.5) sections for each standard. Terms in all capital letters correspond to a defined term in the definition section of the document. The term "should" is used throughout the program standards. Program elements and corresponding conditions described as "should" are best practices but are optional and not required to fully implement a standard. To be in conformance with the program standards, the regulatory program must implement all ten standards. "Notes" are used throughout the program standards to provide clarification, alternatives, and guidance that the state program may use to help implement the program standards. "Notes" do not contain requirements and thus will not be subject to an FDA assessment.

The program standards have corresponding self-assessment and supplemental worksheets designed to assist the regulatory program in achieving and sustaining conformance. The program uses the self-assessment worksheets to determine if the standard's requirements are, or remain, fully met, partially met, or not met. The self-assessments are used to develop an improvement plan for fully implementing the requirements of the program standards.

FDA will use the program standards as a tool to continuously improve produce inspection funding. It will also be used to promote the development and implementation of high-quality produce inspection regulatory programs, which includes a process for continuous improvement based upon quality management systems. The program standards will assist both FDA and the states in fulfilling their regulatory obligations. Implementation of the program standards is voluntary. States enrolled in the program standards under an FDA funding vehicle will be expected to develop and implement improvement plans to demonstrate that they are moving toward full implementation and to participate in FDA assessments to determine the level of conformance. States are encouraged to build systems that are

sustainable and implement plans that will result in the standards being maintained in conformance.

The goal of the PRPS is to implement a nationally integrated, risk-based, produce safety system focused on protecting public health. The program standards establish a uniform basis for measuring and improving the performance of prevention, intervention, and response activities of produce inspection 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 the number and severity of produce-related incidents, thus improving the safety and security of the U.S. food supply.

Paperwork Reduction Act Statement: This program standards document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

The time required to complete this voluntary information collection is estimated to average 569 minutes per reporting response and 40 minutes per recordkeeping response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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BACKGROUND

In the U.S., federal, state, and territorial government agencies ensure the safety of fresh, raw produce (as defined in 21 CFR 112). The FDA is responsible for ensuring that all foods moving in interstate commerce, except those under United States Department of Agriculture (USDA) jurisdiction, are safe, wholesome, and labeled properly. State and territorial agencies conduct inspection and regulatory activities that help ensure produce grown, harvested, packed, or held within their jurisdictions is safe. These inspections either are performed under the states' laws and authorities or the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or both.

In an effort towards mutual reliance, FDA, states, and territories should maximize their resources, particularly when their jurisdictions are overlapping. One of the foundational principles of an integrated food safety system (IFSS) is the implementation and uniform application of model standards so that federal, state, territorial, tribal and local regulatory agencies conduct inspections under the same set of standards. The Produce Regulatory Program Standards (PRPS) is the newest of several sets of national standards, each with a key role in strengthening the IFSS: Manufactured Food Regulatory Program Standards (MFRPS), Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Animal Feed Regulatory Program Standards (AFRPS), and Egg Regulatory Program Standards (ERPS). All these standards provide a consistent, underlying foundation that is critical for uniformity across state and federal agencies to ensure the credibility of all programs under an IFSS.

In 2019, FDA awarded a cooperative agreement to the National Association of State Departments of Agriculture (NASDA), with one outcome being to deliver a completed draft of recommended PRPS content; NASDA sub-awarded the management of this objective to the Association of Food and Drug Officials (AFDO). Beginning in March 2022, a committee comprised of officials from FDA, state agencies, AFDO, and NASDA began work to develop the draft standards. The result of the committee's collaborative work is the development of the first edition of the PRPS, which will strengthen state and territorial produce regulatory programs. These program standards reflect an effort in which FDA has been engaged in partnering, leveraging and empowering agencies to move towards the vision of a nationally integrated food safety system.

DEFINITIONS

CONFORMANCE: the fulfilment of a requirement, specifically a State PROGRAM is using and can demonstrate the use of a particular element, system, or program listed in the Produce Standards.

CONSUMER COMPLAINT: complaints made by the public regarding produce commodities, produce practices, labeling, and any other related activities.

CONTACT HOUR: one contact hour equals 60 minutes.

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

CURRENT EXPERIENCED STAFF: inspectors with a START DATE prior to the PROGRAM's enrollment date in the standards and as identified in the PROGRAM's training plan.

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

EQUIVALENT: state laws or regulations directly reference the relevant Federal regulation and/or statutes.

EQUIVALENT IN EFFECT: state laws or regulations achieve the same regulatory effect as the relevant Federal statutes and/or regulations.

EVALUATION: the process by which the ability of an inspector is assessed to determine if they are competent to complete independent inspections.

FDA ASSESSMENT: conducted by the FDA, means a systematic, independent, and documented process for obtaining objective evidence and evaluating it to determine the extent to which a requirement is met.

FIELD INSPECTION AUDIT: an inspection in which a state inspector is accompanied by a QUALIFIED FIELD INSPECTION AUDITOR (either the FDA or state) for the purpose of assessing the quality and performance of inspections.

FOOD RELATED INCIDENT: an unintentional or deliberate contamination, threatened or actual, of produce that may occur at any point in the produce production system (e.g., growing, harvesting, packing, and holding) and may cause a food-related illness or injury.

IMPLEMENTATION: a PROGRAM has a particular element, system, program, and documentation as required in the PRPS.

INDUSTRY COMPLAINT: complaints made by industry about inspections or inspectors.

JOINT FIELD TRAINING INSPECTION: an inspection conducted jointly by the FDA and/or state

personnel for the purposes of training.

LABORATORY: a facility that conducts measurements and analyses on produce and associated physical samples, which result in qualitative or quantitative analytical findings that may be used as a basis for regulatory action.

NO AUTHORITY: state program lacks statutory authorization for carrying out a specific area of work.

NOT EQUIVALENT: the state law and/or regulation is not EQUIVALENT or EQUIVALENT IN EFFECT and does not have the same regulatory effect.

OUTREACH ACTIVITY: an activity related to produce safety topics that the PROGRAM participates in to support education, engagement and/or communication among and between stakeholders, including regulators, industry, academia, and consumer representatives.

PRODUCE OPERATION: a person or business that conducts one or more of the following activities on produce raw agriculture commodities: growing, harvesting, packing, or holding.

PROGRAM: An operational unit(s) in a regulatory agency that is/are responsible for the regulatory oversight of produce safety.

QUALIFIED DATE: the qualified date begins when an inspector has completed all course and field elements and has been signed off to perform independent inspections. This date is used to calculate the start of the continuing education hours.

QUALIFIED FIELD INSPECTION AUDITOR: an individual who is recognized by the PROGRAM management as having field experience and communication skills necessary to audit inspectors/investigators and who has: successfully completed produce safety inspection training coursework and field training, been assigned this auditing responsibility, and meets PROGRAM requirements for auditors.

QUALIFIED FIELD INSPECTION TRAINER: an individual who is recognized by the PROGRAM management as having field experience and communication skills necessary to train inspectors/investigators and who has~~:~~ successfully completed produce safety inspection training coursework and field training, been assigned this training responsibility, and meets the PROGRAM requirements for trainers.

RECALL AUDIT CHECK: are conducted to verify that the farm's recall was successful as defined by the State's recall procedures.

REGULATORY FOUNDATION: laws, regulations, rules, ordinances, or other regulatory requirements that govern a produce operation.

ROOT CAUSE INVESTIGATION (RCI): an in-depth, multi-disciplinary, systems-based investigation of firms, products, and the environment, intending to determine how the environment may have contributed to the introduction, proliferation, and transmission of pathogens or other hazards that caused illnesses or fresh produce contamination. An RCI may also be referred to as an environmental assessment (EA).

SAMPLING PROGRAM: a program in which the state collects samples as part of their produce safety PROGRAM in one or more of the sampling types as defined in the Partnership for Food Protection's Food/Feed Testing Laboratories Best Practices Manual (current).

START DATE: date an employee is hired or reassigned in or into the State PROGRAM as the beginning date for training timelines.

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

WORKPLAN: a plan developed by the PROGRAM to identify, support, and conduct inspectional activities for an effective produce regulatory program.

STANDARD No. 1
Regulatory Foundation

1.1 Purpose

This standard describes the elements of the REGULATORY FOUNDATION used by a PROGRAM to regulate produce.

1.2 Requirement Summary

The PROGRAM evaluates the scope of its legal authority and regulatory provisions to ensure the protection of produce within its jurisdiction. The PROGRAM'S evaluation includes a determination of how the state's legal authority and regulatory provisions correspond to the sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and Code of Federal Regulations (CFR) specified in Appendix 1.2 or equivalent form.

1.3 Program Elements

1.3.1 Evaluation of Legal Authority

The PROGRAM has a written procedure to evaluate the legal authority and regulatory provisions to inspect and investigate, gather evidence, collect and analyze samples, and take regulatory actions under state law to ensure the safety of produce. The written procedure must:

1.3.1.1 Include timeframes for a REGULATORY FOUNDATION assessment.

1.3.1.2 Describe the REGULATORY FOUNDATION evaluation process, to include whenever significant changes are made to applicable federal and/or state laws and regulations.

1.3.1.3 Address the statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that:

1.3.1.3.1 Apply to the regulation of produce.

1.3.1.3.2 Delegate authority to the PROGRAM.

1.3.1.3.3 Describe the PROGRAM'S administrative procedures for rulemaking to protect public health.

1.3.1.3.4 Identify and list other federal or state agencies that have authority for any area of the REGULATORY FOUNDATION that the PROGRAM lacks.

1.3.2 REGULATORY FOUNDATION Assessment

The PROGRAM must complete Appendix 1.2 or equivalent form. The PROGRAM conducts a baseline self-assessment to determine if they are EQUIVALENT, EQUIVALENT IN EFFECT, NOT EQUIVALENT, or NO AUTHORITY to sections of the current FD&C Act and CFR Title 21 specified in Appendix 1.2. or equivalent form.

1.3.2.1 If the PROGRAM has laws and regulations pertinent to the regulation of produce, for which there are no federal provisions, these laws and regulations can also be listed in Appendix 1.2 or equivalent form.

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

Note: In conducting a self-assessment, the PROGRAM should consult with legal counsel when state law does not provide for incorporation of subsequent revisions of the FD&C Act and CFR, the revision date of the CFR is unknown, or the federal law or regulation is partially written into state law or regulation.

1.4 Outcome

The PROGRAM has conducted an assessment of the scope of their legal authority and has a REGULATORY FOUNDATION adequate to protect public health by ensuring the safety of produce within its jurisdiction. For any part of the REGULATORY FOUNDATION that the PROGRAM lacks, the PROGRAM identifies another federal or state program with that regulatory authority to protect public health.

1.5 Documentation

The PROGRAM maintains the records, or equivalent forms or worksheets, listed here.

1.5.1 Appendix 1.1 Self-Assessment Worksheet.

1.5.2 Appendix 1.2 Regulatory Foundation Worksheet.

1.5.3 PROGRAM'S written REGULATORY FOUNDATION assessment procedure.

1.5.4 The statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that: (1) apply to the regulation of produce, (2) delegate authority to the PROGRAM, (3) describe the PROGRAM's administrative procedures for rulemaking to protect public health, and (4) identify and list other federal or state agencies that have authority for any area of the REGULATORY FOUNDATION that the PROGRAM lacks.

1.5.5 If applicable, review by legal counsel.

STANDARD No. 2
Training Program

2.1 Purpose

This standard describes the essential elements of a training program for inspectors to ensure they will have the knowledge, skills, and abilities to adequately perform their work.

2.2 Requirement Summary

The PROGRAM establishes and maintains a written training plan that promotes development and demonstrates that all inspectors complete coursework, field training, and continuing education to adequately perform their work.

2.3 Program Elements

2.3.1 Training Plan and Training Records

2.3.1.1 The PROGRAM uses a written training plan that ensures all inspectors receive training required to adequately perform their work. The training plan includes curriculum which provides for training as well as continuing education.

2.3.1.2 The PROGRAM maintains individual training records for active inspectors. The individual training records for all inactive inspectors must be kept for a minimum of three years after the date the inspector became inactive.

2.3.1.3 The PROGRAM maintains a training record summary documenting the training completed by inspectors to adequately perform their work using Appendix 2.2 or equivalent form.

2.3.1.4 The PROGRAM training record summary must include the inspector's START DATE.

2.3.1.5 The PROGRAM assesses all inspectors' previous performance and experience to determine if the inspectors have completed the required training or whether additional training is needed to adequately perform their work.

2.3.2 Inspection Training

2.3.2.1 The PROGRAM requires that each inspector complete an inspection training curriculum consisting of coursework and field training described here prior to performing independent inspections.

2.3.2.2 Timeframe: The inspection training curriculum shall be successfully completed within 24 months of the inspector's START DATE.

2.3.2.3 Coursework: The inspection training consists of coursework in the following subject areas.

2.3.2.3.1 Prevailing statutes, regulations, and ordinances

2.3.2.3.2 Inspections, investigations, compliance, and enforcement

2.3.2.3.3 Public health principles

2.3.2.3.4 Biosecurity

2.3.2.3.5 Basic/introductory emergency management

2.3.2.3.6 Communications skills

2.3.2.3.7 Microbiology

2.3.2.3.8 Sampling technique, if applicable

2.3.2.4 Field Training: The PROGRAM has a written field training program to complement the coursework curriculum. The PROGRAM shall have the latitude to determine the number and types of activities to meet the elements detailed below:

2.3.2.4.1 The inspector must complete the field training program prior to performing independent inspections.

2.3.2.4.2 Field training checklist of competencies to be verified in the field by the QUALIFIED FIELD INSPECTION TRAINER.

2.3.2.4.3 Written procedures for JOINT FIELD TRAINING INSPECTIONS.

2.3.2.4.4 Number of JOINT FIELD TRAINING INSPECTIONS.

2.3.2.4.5 Number of field inspection EVALUATIONS.

2.3.2.4.6 Number of additional field training activities, if they are deemed necessary by the PROGRAM.

2.3.2.4.7 The qualifications, education, and experience necessary to be identified as a QUALIFIED FIELD INSPECTION TRAINER, to include at a minimum, the training as described in 2.3.2.

2.3.3 Experienced Inspectors

For CURRENT EXPERIENCED STAFF or newly hired experienced inspection staff, a PROGRAM'S training plan shall include the following unless it is determined in their training plan that all inspection staff will be required to complete the program elements as described in 2.3.2.

2.3.3.1 For CURRENT EXPERIENCED STAFF with missing training records, in addition to a statement from the PROGRAM stating an assessment has occurred and the outcomes of the assessment will satisfy the requirement for documentation, the following apply:

2.3.3.1.1 If a record is missing for a JOINT FIELD TRAINING INSPECTION, then a statement or affidavit explaining the background or experience that justifies a waiver of JOINT FIELD TRAINING INSPECTIONS must be included in the employee training file.

2.3.3.1.2 If a record is missing for coursework as described in 2.3.2.3, then document and include in the employee training file training records that are available and create a statement of affidavit explaining the background or experience that justifies a waiver of the missing coursework.

2.3.3.2 For newly hired experienced inspection staff with missing training records, in addition to a statement from the PROGRAM stating an assessment has occurred and the outcomes of the assessment will satisfy the requirement for documentation, the following apply:

2.3.3.2.1 If a record is missing for a JOINT FIELD TRAINING INSPECTION, then a statement or affidavit explaining the background or experience that justifies a waiver of some or all of the JOINT FIELD TRAINING INSPECTIONS must be included in the employee training file. Conduct two successful EVALUATIONS within six (6) months of the inspector's QUALIFIED DATE.

2.3.3.2.2 If a record is missing for coursework as described in 2.3.2.3, then document and include in the employee training file training records that are available and create a statement or affidavit explaining the background or experience that justifies a waiver of the missing coursework.

2.3.4 Continuing Education

The PROGRAM goal of continuing education is to build upon the inspector's knowledge base and enhance their skills and ability to perform inspections and investigations.

2.3.4.1 Each inspector must accumulate 20 CONTACT HOURS of continuing education every 36 months.

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

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

2.3.4.4 The inspector qualifies for CONTACT HOURS for participation in any of the following activities or other activities related specifically to inspectional work or PRODUCE OPERATIONS:

2.3.4.4.1 Attendance at national or regional seminars/technical conferences.

2.3.4.4.2 Professional symposiums/college courses.

2.3.4.4.3 Produce or food-related training provided by government agencies (e.g., Food & Drug Administration (FDA), United States Department of Agriculture (USDA), state, local).

2.3.4.4.4 Food or produce safety related conferences and workshops.

2.3.4.4.5 Distance learning opportunities that pertain to food or produce safety.

2.3.4.4.6 Training approved by the PROGRAM.

2.3.4.5 Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of 10 CONTACT HOURS may be accrued from the following produce related activities:

2.3.4.5.1 Delivering presentations at professional conferences.

2.3.4.5.2 Providing classroom and/or field training to inspectors or being a course instructor.

2.3.4.5.3 Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

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

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

2.3.4.6.1 Certificates of completion indicating the course date(s) and number of hours attended or continuous education credits granted.

2.3.4.6.2 Transcripts from a college or university.

2.3.4.6.3 A letter from the administrator of the continuing education program attended.

2.3.4.6.4 A copy of the peer-reviewed article or presentation made at a professional conference; or documentation to verify technical publications related to produce safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

2.3.4.6.5 An agenda and attendance roster.

2.3.4.6.6 Documentation approved by the PROGRAM.

2.3.4.7 Coursework Sources

Training and continuing education coursework must be obtained from one of the sources listed here:

2.3.4.7.1 Training provided by a government agency (including in-house training).

2.3.4.7.2 Distance learning, for example, web-based training.

2.3.4.7.3 Colleges, schools, research centers, and institutes.

2.3.4.7.4 Produce or Food Safety Alliances, associations or other organizations recognized by FDA.

2.4 Outcome

The PROGRAM has trained inspectors with the knowledge, skills, and abilities to adequately perform their work.

2.5 Documentation

The PROGRAM maintains the records, or equivalent forms or worksheets, listed here.

2.5.1 Appendix 2.1 Self-Assessment Worksheet or equivalent form.

2.5.2 Appendix 2.2 Inspector Training Record or equivalent form.

2.5.3 Written Training Plan.

2.5.4 Documents verifying successful completion of required courses.

2.5.5 EVALUATION for experienced inspectors.

2.5.6 Written procedures for JOINT FIELD TRAINING INSPECTIONS.

2.5.7 Documentation for continuing education credit.

STANDARD No. 3
Inspection Program

3.1 Purpose

This standard describes the elements of an effective inspection PROGRAM.

3.2 Requirement Summary

The PROGRAM has written inspection procedures to determine compliance with federal and state produce safety laws and regulations.

3.3 Program Elements

3.3.1 Risk-Based Inspection PROGRAM

The PROGRAM has written procedures to:

3.3.1.1 Define and establish an inventory of PRODUCE OPERATIONS which are under PROGRAM jurisdiction and authority.

3.3.1.2 Maintain the inventory of PRODUCE OPERATIONS as described in 3.3.1.1.

3.3.1.3 Define and document risk categories. PROGRAMS may consider additional criteria but must use the following minimum required factors for defining risk categories:

3.3.1.3.1 Commodity.

3.3.1.3.2 Farm compliance history.

3.3.1.3.3 Farm size by average annual produce sales.

3.3.1.3.4 Agricultural water source and usage.

3.3.1.3.5 Biological soil amendments of animal origin and usage.

3.3.1.4 Prioritize inspections and assign frequencies based on defined risk categories established by the PROGRAM.

3.3.2 Inspection Procedure

The PROGRAM has a written procedure for inspecting a PRODUCE OPERATION which is under PROGRAM jurisdiction and authority that requires the inspector to:

3.3.2.1 Review the previous inspection report(s), CONSUMER COMPLAINT(S), and compliance history.

3.3.2.2 Follow the pre-inspection call procedures required by the PROGRAM.

3.3.2.3 Have appropriate equipment and forms. Equipment must be verified, operated, and maintained as defined by the PROGRAM.

3.3.2.4 Follow the biosecurity protocols required by the PRODUCE OPERATION and the PROGRAM.

3.3.2.5 Follow the safety protocols required by the PRODUCE OPERATION and the PROGRAM.

3.3.2.6 Follow the procedure for the opening meeting required by the PROGRAM.

3.3.2.7 Assess personnel practices critical to the safe and sanitary growing, harvesting, packing, and holding of produce.

3.3.2.8 Evaluate conditions, practices, components, and/or labeling that may cause the produce to be deemed adulterated or misbranded or otherwise in violation of applicable law(s).

3.3.2.9 Reference appropriate and available FDA guidance documents to evaluate commodities and/or practices as applicable.

3.3.2.10 Explain findings throughout the inspection and describe the public health significance.

3.3.2.11 Recognize significant violative conditions or practices, if present, and document findings consistent with PROGRAM procedures.

3.3.2.12 Alert the PRODUCE OPERATION when an immediate corrective action is necessary.

3.3.2.13 Review and verify that required records for the PRODUCE OPERATION are being maintained.

3.3.2.14 Recognize deficiencies in the PRODUCE OPERATION'S required monitoring activities.

3.3.2.15 Collect adequate evidence and documentation to support inspection observations in accordance with PROGRAM procedures.

3.3.2.16 Verify correction of deficiencies that were identified during previous inspection(s).

3.3.2.17 Demonstrate effective communication and interpersonal skills to effectively support the inspection process.

3.3.3 Inspection Report Procedure

3.3.3.1 The PROGRAM has a written inspection report procedure that requires inspectors to:

3.3.3.1.1 Document significant violative conditions or practices, if present.

3.3.3.1.2 Complete the inspection report(s) accurately.

3.3.3.1.3 Submit the inspection report within designated timeframes consistent with PROGRAM'S procedures.

3.3.3.2 The PROGRAM has a written procedure to:

3.3.3.2.1 Review inspection reports with inspectional findings.

3.3.3.2.2 Provide the applicable inspection report(s) to the PRODUCE OPERATION within designated timeframes consistent with PROGRAM'S procedures.

3.3.3.2.3 Follow up with corrective, compliance, and enforcement actions as warranted.

3.3.4 Recalls

The PROGRAM has a recall system with written procedures to:

3.3.4.1 Receive information about recalls.

3.3.4.2 Share information about recalls with relevant industry and partner agencies.

3.3.4.3 Track the recall and work with recalling operation to remove affected product from the market.

3.3.4.4 Perform RECALL AUDIT CHECKS, as applicable.

3.3.4.5 Maintain records.

3.3.5 Consumer Complaint

The PROGRAM has a system for handling CONSUMER COMPLAINTS. The system includes written procedures to:

3.3.5.1 Receive.

3.3.5.2 Track.

3.3.5.3 Evaluate.

3.3.5.4 Answer.

3.3.5.5 Close.

3.3.5.6 Maintain records.

3.3.6 Industry Complaint

The PROGRAM has a system for handling an INDUSTRY COMPLAINT. The system includes written procedures to:

3.3.6.1 Receive.

3.3.6.2 Track.

3.3.6.3 Evaluate.

3.3.6.4 Answer.

3.3.6.5 Close.

3.3.6.6 Maintain records.

3.3.7 Sampling Program

A PROGRAM that conducts sampling must have a documented SAMPLING PROGRAM. The SAMPLING PROGRAM must contain written procedures that:

3.3.7.1 Use the appropriate method and equipment to collect samples.

3.3.7.2 Maintain and document sample chain of custody.

3.3.7.3 Handle, package, and ship samples to ensure security and prevent compromising condition of samples.

3.3.7.4 Deliver or ship samples to the appropriate LABORATORY program within prescribed timeframes.

3.3.7.5 Follows the receiving LABORATORY procedures.

3.3.7.6 Provide instructions for documenting the sample collection which may include:

3.3.7.6.1 Date of Sample Collection

3.3.7.6.2 Product Identification Including:

3.3.7.6.2.1 Name of Product

3.3.7.6.2.2 Sample type

3.3.7.6.2.3 Unique identification references

3.3.7.6.3 Description of the product

3.3.7.6.4 Collection information including:

3.3.7.6.4.1 Method of Collection

3.3.7.6.4.2 Identification of lot sampled

3.3.7.6.4.3 Lot Size

3.3.7.6.4.4 Special Sample techniques if used to collect the sample

3.3.7.6.4.5 Location where sample was collected

3.3.7.6.4.6 Name and address of responsible party, guarantor, possessor, or distributor

3.3.7.6.4.7 Reason for sample collection

3.3.7.6.4.8 Analysis requested, if applicable

3.3.7.6.4.9 Product labels or specific labeling information that is collected or reproduced per state procedure. This information is not required for environmental samples.

3.3.7.6.4.10 Identification of the sample with the unique sample identifier.

3.4 Outcome

The PROGRAM has implemented and maintains an inspection program that reduces the occurrence of a FOOD RELATED INCIDENT.

3.5 Documentation

The PROGRAM maintains the records, or equivalent forms or worksheets, listed here.

3.5.1 Appendix 3.1 Self-Assessment Worksheet or equivalent form.

3.5.2 An inventory of PRODUCE OPERATIONS under the PROGRAM'S jurisdiction and authority.

3.5.3 Written risk categorization criteria.

3.5.4 Written procedure for inspection prioritization and frequency based upon risk categories.

3.5.5 Written inspection procedure.

3.5.6 Written inspection report procedure.

3.5.7 Written inspection reports.

3.5.8 Written procedure for release of the inspection report to the PRODUCE OPERATION.

3.5.9 Written procedure to review inspection reports with inspectional findings.

3.5.10 Written procedure for follow-up activities and subsequent documentation.

3.5.11 Written recall procedure.

3.5.12 Essential recall information.

3.5.13 Written CONSUMER COMPLAINT procedure.

3.5.14 CONSUMER COMPLAINT information.

3.5.15 Written INDUSTRY COMPLAINT procedure.

3.5.16 INDUSTRY COMPLAINT information.

3.5.17 Written SAMPLING PROGRAM and sampling procedures if sampling is conducted by the PROGRAM.

3.5.18 Sample reports and associated documentation, if conducted.

STANDARD No. 4
Inspection Audit Program

4.1 Purpose

This standard describes auditing procedures necessary for a PROGRAM to (1) evaluate the effectiveness and accuracy of the inspection PROGRAM and inspection records, and if applicable, the sample collection and sampling records and (2) identify areas in need of corrective actions.

4.2 Requirement Summary

The PROGRAM has a written auditing procedure which includes processes to conduct audits to assess the effectiveness and accuracy of its inspections and, if applicable, sample collections. The auditing procedure has two components: (1) a FIELD INSPECTION AUDIT component, which is an on-site performance evaluation of inspections and, if applicable, sample collections, and (2) a desk audit component, which is a performance review of the written reports of inspections and if applicable, sample collections.

4.3 Program Elements

4.3.1 Audit Program

The PROGRAM has written procedures for:

4.3.1.1 The qualifications, education, and experience necessary to be identified as a QUALIFIED FIELD INSPECTION AUDITOR, to include at a minimum the training as described in 2.3.

4.3.1.2 FIELD INSPECTION AUDITS as described in 4.3.3.

4.3.1.3 Inspection report audits as described in 4.3.4.

4.3.1.4 Sample report audits as described in 4.3.5, if applicable.

4.3.1.5 Corrective actions as described in 4.3.6.

4.3.2 A review of the performance factor scores and cumulative scores for each type of audit is completed at least every 12 months.

4.3.3 Field Inspection Audit

4.3.3.1 A QUALIFIED FIELD INSPECTION AUDITOR conducts FIELD INSPECTION AUDITS to verify that inspections are consistently performed according to the PROGRAM'S written procedures described in Standard 3.

4.3.3.2 Frequency: A minimum of one FIELD INSPECTION AUDIT of each inspector, after the QUALIFIED DATE, is conducted within 12 months and a minimum of once every 36 months thereafter. The inspections selected for audits must reflect the inspectors' assignments and responsibilities.

4.3.3.3 If samples are collected during the FIELD INSPECTION AUDIT, the collection of the samples shall also be audited, and the appropriate question(s) answered on Appendix 4.2, or equivalent form.

4.3.3.4 Performance is documented on Appendices 4.2 and 4.2a, or equivalent forms, that meet the program elements as described in 3.3.2.

4.3.4 Inspection Report Audit

The PROGRAM conducts annual reviews of inspection reports to verify that inspectional findings are documented according to the PROGRAM'S written procedures. The quality of each inspection report is audited using the performance factors listed in Appendix 4.3 or equivalent form. An overall inspection report rating is calculated using Appendix 4.3a, or equivalent form.

4.3.4.1 The PROGRAM will review a random selection of inspection reports based on the overall number of inspections performed in the last 12 months using the table below:

Number of Inspections in Twelve Months*	Minimum Number of Reports Required	Maximum Number of Reports Required
Less than 20 reports	All	All
20-400 reports	20	20
More than 400	5% of reports	50

*Total number of inspections conducted by the PROGRAM in the last 12 months

4.3.4.2 Performance is documented on Appendices 4.3 and 4.3a, or equivalent forms.

4.3.5 Sample Report Audit

The PROGRAM conducts annual reviews of sample reports to verify that sample information is documented according to the PROGRAM'S written procedures. The quality of each sample report is audited using the performance factors listed in Appendix 4.4 or equivalent form. An overall sample report rating is calculated using Appendix 4.4a, or equivalent form. Sample report audits do not need to be performed unless samples are collected.

4.3.5.1 The PROGRAM will review a random selection of sample reports based on the overall number of samples collected, if applicable, in the last 12 months using the table below:

Number of Samples in Twelve Months*	Minimum Number of Reports Required	Maximum Number of Reports Required
Less than 20 reports	All	All
20-400 reports	20	20
More than 400	5% of reports	50

*Total number of samples collected by the PROGRAM in the last 12 months

4.3.5.2 Performance is documented on Appendices 4.4 and 4.4a, or equivalent forms.

4.3.6 Corrective Actions

The PROGRAM shall initiate corrective actions for the FIELD INSPECTION AUDIT, inspection report audit, and if applicable, sample report audit, when one or more of the conditions below occurs:

4.3.6.1 An individual receives an overall rating of "needs improvement";

4.3.6.2 A single performance factor for the PROGRAM falls below 80%; or

4.3.6.3 An overall rating for the PROGRAM falls below 80%.

4.4 Outcome

The PROGRAM systematically evaluates and improves its inspection PROGRAM, and if applicable, its SAMPLING PROGRAM to ensure that activities and documentation are adequate, complete, and comply with their procedures and policies.

4.5 Documentation

The PROGRAM maintains the records, or equivalent forms or worksheets, listed here.

4.5.1 Appendix 4.1 Self-Assessment Worksheet or equivalent form.

4.5.2 Appendix 4.2 Field Inspection Audit Form or equivalent form.

4.5.3 Appendix 4.2a Summary of Field Inspection Audit Findings or equivalent form.

4.5.4 Appendix 4.3 Inspection Report Audit Form or equivalent form.

4.5.5 Appendix 4.3a Summary of Inspection Report Audit Findings or equivalent form.

4.5.6 Appendix 4.4 Sample Report Audit Form or equivalent form.

4.5.7 Appendix 4.4a Summary of Sample Report Audit Findings or equivalent form.

4.5.8 Written auditing procedures.

STANDARD No. 5
Foodborne Illness, Outbreak, Response

5.1 Purpose

This standard describes the functions to detect, identify, and respond to FOOD-RELATED INCIDENTS to stop, control, and prevent foodborne illness, injury, or outbreak.

5.2 Requirement Summary

The PROGRAM has a written system to conduct a response to FOOD-RELATED INCIDENTS. The PROGRAM describes surveillance, investigation activities, control measures, and post-response activities in collaboration with other agencies and jurisdictions for responding to reports of FOOD-RELATED INCIDENTS, and for generating recommendations for foodborne illness prevention.

5.3 Program Elements

5.3.1 Coordination of FOOD-RELATED INCIDENTS

The PROGRAM:

5.3.1.1 Designates, in writing, a coordinator to guide investigation and response efforts in collaboration with all agencies involved and manage events using the Incident Command System (ICS)/Incident Management Team (IMT) structure or a written response plan that includes:

5.3.1.1.1 Identifying and executing investigation objectives.

5.3.1.1.2 Managing communications.

5.3.1.1.3 Implementing control measures.

5.3.1.1.4 Conducting post-response activities.

5.3.1.2 Determines if Memorandums of Understanding or written agreements with other state regulatory agencies is needed when the responsibility for FOOD RELATED INCIDENTS and outbreak investigations is assigned to or shared with another regulatory agency within the state. If a written agreement is required, it is in effect.

5.3.1.3 Has a written procedure that includes:

5.3.1.3.1 Identifying and describing the roles, duties, and responsibilities for each activity for the requirements as described in 5.3.2-5.3.5.

5.3.1.3.2 Describing PROGRAM collaboration as necessary with FDA and other appropriate federal, state, or local authorities in multi-jurisdictional FOOD-RELATED INCIDENTS.

5.3.1.3.3 Describing communication with relevant agencies during FOOD-RELATED INCIDENTS, including defined timelines for initial notification of the incident, communication of ongoing developments, and sharing of relevant findings.

5.3.1.3.4 Providing guidance for notification of appropriate law enforcement agencies when intentional food contamination is suspected or threatened.

5.3.1.3.5 Maintaining a list of relevant agencies and emergency contacts that is reviewed and updated at least annually.

5.3.2 Surveillance

The PROGRAM:

5.3.2.1 Uses epidemiological information, CONSUMER COMPLAINTS, or other incident-related information from appropriate departments or agencies (federal, state, or local), to detect outbreaks or other FOOD-RELATED INCIDENTS.

5.3.2.2 Maintains notifications of relevant outbreaks or other FOOD-RELATED INCIDENTS that are reported to the PROGRAM in a log(s) or database(s).

5.3.3 Investigation

The PROGRAM:

5.3.3.1 Has a written procedure that includes:

5.3.3.1.1 Determining the appropriate response.

5.3.3.1.2 Initiating the response.

5.3.3.1.3 Completing the response.

5.3.3.2 Conducts an investigation using established processes similar to those found in the current versions of:

5.3.3.2.1 International Association for Food Protection's (IAFP) "Procedures to Investigate Foodborne Illnesses."

5.3.3.2.2 Council to Improve Foodborne Outbreak Response's (CIFOR) "Guidelines for Foodborne Disease Outbreak Response" Chapter 5.

5.3.3.2.3 FDA IOM Chapter 4 and Chapter 8, as appropriate.

5.3.3.2.4 RRT Best Practices Manual Volume II, Chapter 12 "Environmental Sampling and Records Collection."

5.3.3.3 Has a written procedure to coordinate the traceback and traceforward of produce suspected or implicated in an illness, injury, or outbreak or found to contain a hazard.

5.3.3.4 Has access to LABORATORY support for investigation of outbreaks or other FOOD-RELATED INCIDENTS.

Note: Specific requirements for support are described in Standard 10

5.3.3.5 Analyzes ROOT CAUSE INVESTIGATION (RCI) data, if conducted.

5.3.4 Control Measures

The PROGRAM has written procedures for:

5.3.4.1 Strategies to mitigate and contain outbreaks or other FOOD-RELATED INCIDENTS that include enforcement, public awareness activities, industry education, and outreach.

5.3.4.2 Releasing information to the public, including:

5.3.4.2.1 Identifying a point(s) of contact.

5.3.4.2.2 Developing guidelines for coordinating media information with other jurisdictions.

5.3.5 Post Response

The PROGRAM has written procedures that include:

5.3.5.1 Maintaining investigational findings and reports.

5.3.5.2 Distributing final investigation report(s), including ROOT CAUSE INVESTIGATION (RCI), if completed, to relevant agencies, as necessary.

5.3.5.3 Providing recommendations, when available, from investigation and ROOT CAUSE INVESTIGATION (RCI) reports to relevant agencies and stakeholders responsible for prevention, education, outreach, and research.

5.4 Outcome

The PROGRAM has a written system to document and investigate FOOD-RELATED INCIDENTS. The PROGRAM has established communication pathways with appropriate parties to gather and share information to stop, control, and prevent FOOD-RELATED INCIDENTS.

5.5 Documentation

The PROGRAM maintains the records, or equivalent forms or worksheets, listed here.

5.5.1 Appendix 5.1 Self-Assessment Worksheet.

5.5.2 Written response plan, if ICS/IMT management structure is not utilized.

5.5.3 Memorandums of understanding or written agreements, as applicable.

5.5.4 Written procedure for coordination of FOOD RELATED INCIDENTS, including communication with other agencies.

5.5.5 Written contact list.

5.5.6 Notification log of relevant outbreaks or other FOOD-RELATED INCIDENTS.

5.5.7 Written procedure for response to an outbreak or other FOOD-RELATED INCIDENTS.

5.5.8 Written procedure for traceback/traceforward coordination and activities.

5.5.9 Written strategies to mitigate and contain outbreaks or other FOOD-RELATED INCIDENTS.

5.5.10 Written procedure for releasing information to the public.

5.5.11 Written procedure to maintain and distribute reports.

5.5.12 Investigational reports, including ROOT CAUSE INVESTIGATION (RCI) reports.

5.5.13 Written procedure to provide recommendations to stakeholders.

STANDARD No. 6
Compliance and Enforcement Program

6.1 Purpose

This standard describes the elements of an effective compliance and enforcement program that includes strategies, procedures, and actions to achieve compliance with laws and regulations, and to evaluate the enforcement program.

6.2 Requirement Summary

The PROGRAM has a documented compliance and enforcement program which describes its strategies and procedures. The PROGRAM conducts an annual evaluation of the enforcement activities to identify potential improvements or modifications.

6.3 Program Elements

6.3.1 The PROGRAM has written compliance and enforcement procedures that includes:

6.3.1.1 Describing compliance and enforcement strategies, use of enforcement tool(s) and progressive enforcement action(s).

6.3.1.2 Describing the process used to determine appropriate enforcement action(s).

6.3.2 The PROGRAM has a written procedure for conducting an annual evaluation of its enforcement activities.

6.3.3 The PROGRAM conducts an annual evaluation of all enforcement activities, or uses a statistical approach to determine a representative number of enforcement activities, that includes:

6.3.3.1 Determining if enforcement actions follow procedures described in 6.3.1.

6.3.3.2 Implementing improvements or modifications related to the compliance and enforcement procedures, if any.

6.3.3.3 Documenting results from 6.3.3.1 and 6.3.3.2 on Appendix 6.2 or equivalent form.

6.4 Outcome

The PROGRAM has an effective compliance and enforcement program that has written procedures to ensure that enforcement actions are in accordance with established procedures.

6.5 Documentation

The PROGRAM maintains the records, or equivalent forms or worksheets, listed here.

6.5.1 Appendix 6.1 Self-Assessment Worksheet.

6.5.2 Appendix 6.2 Calculation of the Level of Conformance to Compliance Procedures.

6.5.3 Written compliance and enforcement procedures.

6.5.4 Written procedure for conducting an annual review of the compliance and enforcement procedures.

STANDARD No. 7
Outreach Activities

7.1 Purpose

This standard describes the elements of OUTREACH ACTIVITY developed or provided by the PROGRAM.

7.2 Requirement Summary

The PROGRAM participates in OUTREACH ACTIVITY that supports communication and information exchange among produce industry stakeholders such as regulators, academia, PRODUCE OPERATIONS, consumer representatives, and consumers.

7.3 Program Elements

7.3.1 The PROGRAM has a written procedure of the methods that will be used for communication with the produce industry stakeholders and consumers that includes:

7.3.1.1 Identifying the methods for communication such as on-farm education, electronic sources, and mailings.

7.3.1.2 Interacting with produce industry stakeholders and consumers by sponsoring or actively participating in OUTREACH ACTIVITY.

7.3.1.3 Tailoring outreach efforts to a target population. Consider target population characteristics such as:

7.3.1.3.1 Geography

7.3.1.3.2 Language and/or learning needs

7.3.1.3.3 Coverage status

7.3.1.3.4 Growing, harvesting, packing, and holding practices

7.3.1.3.5 Commodity specific considerations

7.3.1.4 Tailoring outreach topics to a target population. Topics of outreach efforts may include:

7.3.1.4.1 Regulatory requirements and guidance

7.3.1.4.2 Emerging issues

7.3.1.4.3 Regional specific considerations

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

7.4 Outcome

The PROGRAM uses OUTREACH ACTIVITY that will inform and educate produce industry stakeholders on ways that may reduce the occurrence of a FOOD RELATED INCIDENT.

7.5 Documentation

The PROGRAM maintains the records, or equivalent forms or worksheets, listed here.

7.5.1 Appendix 7.1 Self-Assessment Worksheet.

7.5.2 Appendix 7.2 Outreach Activity Event and Self-Evaluation Worksheet or equivalent documentation for each OUTREACH ACTIVITY event.

7.5.3 Written procedure for the methods used for communication with produce industry stakeholders and consumers.

7.5.4 Agendas, meeting summaries, program evaluations, or other records documenting interaction with food industry stakeholders and consumers.

STANDARD No. 8
Program Resources

8.1 Purpose

This standard describes the elements required for assessing and validating the WORKPLAN and allocating resources needed to support a PROGRAM.

8.2 Requirement Summary

The PROGRAM has procedures for evaluating and validating the WORKPLAN. The PROGRAM conducts an assessment of resource needs to fully implement the Produce Regulatory Program Standards.

8.3 Program Elements

8.3.1 The PROGRAM has a written WORKPLAN that includes:

8.3.1.1 Inspection plan

8.3.1.1.1 Number of inspections.

8.3.1.1.2 Type of inspection.

8.3.1.1.3 Risk category of the PRODUCE OPERATION.

8.3.1.1.4 Frequency of inspection.

8.3.1.2 If there is a SAMPLING PROGRAM, a sampling plan is required.

8.3.2 The WORKPLAN has a timeframe that is applicable within a 12-month period.

8.3.3 The WORKPLAN has a written evaluation procedure that includes:

8.3.3.1 A documented annual review for alignment with PROGRAM objectives and resources.

8.3.3.2 A documented review when PROGRAM objectives or resources change.

8.3.4 The PROGRAM has a written procedure for identifying and reviewing its resources to accomplish the WORKPLAN within the applicable timeframe. The resource review must include resources needed to fully support the WORKPLAN including:

8.3.4.1 Staffing.

8.3.4.2 Equipment.

8.3.4.3 Funding.

8.3.4.4 Administrative Support.

8.3.5 To validate the WORKPLAN, the PROGRAM calculates the number of staff needed to accomplish the WORKPLAN based on the PROGRAM'S data.

Note: The PROGRAM should have the necessary staff to meet the requirements of the

WORKPLAN.

8.3.6 A list of the equipment required for inspections and sample collections must be:

8.3.6.1 Established by the PROGRAM.

8.3.6.2 Maintained by the PROGRAM.

8.3.7 The PROGRAM conducts an annual review of the resources needed to fully implement the Produce Regulatory Program Standards by using Appendix 8.2 or equivalent form.

8.4 Outcome

The PROGRAM has a written WORKPLAN and assesses and allocates resources needed to support the IMPLEMENTATION of the Produce Regulatory Program Standards.

8.5 Documentation

The PROGRAM maintains the records, or equivalent forms or worksheets, listed here.

8.5.1 Appendix 8.1 Self-Assessment Worksheet.

8.5.2 Appendix 8.2 Resource Summary Report.

8.5.3 Written WORKPLAN.

8.5.4 Written procedure for evaluating the WORKPLAN.

8.5.5 Written procedure for identifying and reviewing resources to accomplish the WORKPLAN within the applicable timeframe.

8.5.6 Supportive documentation for calculating the staff needed to accomplish the WORKPLAN.

STANDARD No. 9
Program Assessment

9.1 Purpose

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

9.2 Requirement Summary

The PROGRAM conducts a baseline self-assessment and subsequent periodic self-assessments against the criteria established in each program standard. These self-assessments are designed to identify the strengths and weaknesses of the PROGRAM. The baseline self-assessment identifies areas or functions of the PROGRAM that need improvements and is used to develop a STRATEGIC IMPROVEMENT PLAN and establish timeframes for making improvements. Subsequent periodic self-assessments track progress toward achieving and maintaining CONFORMANCE with the program standards.

9.3 Program Elements

9.3.1 The PROGRAM:

9.3.1.1 Conducts a baseline self-assessment in the first year to determine if the PROGRAM meets the program elements of each standard.

9.3.1.2 Completes the self-assessment worksheets, which are the first appendices for each standard, to establish the baseline self-assessment.

9.3.1.3 Uses the results of its self-assessments to complete Appendix 9.2 Self-Assessment Summary Report, or equivalent form.

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

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

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

9.3.2.3 Projected completion dates for each task.

9.3.2.4 Personnel responsible.

9.3.2.5 Date completed for each task.

9.3.3 The PROGRAM reviews and updates the self-assessment appendices and its STRATEGIC IMPROVEMENT PLAN at least annually.

9.3.4 The PROGRAM participates in FDA ASSESSMENTS to determine IMPLEMENTATION and CONFORMANCE to the standards. The PROGRAM addresses FDA ASSESSMENT observations and establishes corrective action(s)

following the requirements listed in 9.3.5, unless already identified in the STRATEGIC IMPROVEMENT PLAN prior to the start of the FDA ASSESSMENT.

9.3.5 The PROGRAM shall demonstrate it:

9.3.5.1 Has a written DOCUMENT CONTROL procedure that ensures all guidance, procedures, documents, and forms required by the standards are CURRENT AND FIT FOR USE. All documents subject to this procedure are CURRENT AND FIT FOR USE through maintenance of a master document list or other systems that show:

9.3.5.1.1 Documents are reviewed for accuracy.

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

9.3.5.1.3 Documents are distributed to the applicable end user(s) and used at the location where the prescribed activity is performed.

9.3.5.2 Retains records or procedures required under the Documentation section of each standard for the three previous years, or per the PROGRAM'S record retention policy, whichever is longer. Records or procedures can be retained electronically or hard copy.

9.4 Outcome

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

9.5 Documentation

The PROGRAM maintains the records, or equivalent forms or worksheets, listed here.

9.5.1 Appendix 9.1 Self-Assessment Worksheet.

9.5.2 Appendix 9.2 Self-Assessment Summary Report.

9.5.3 STRATEGIC IMPROVEMENT PLAN.

9.5.4 FDA ASSESSMENT reports.

9.5.5 Written DOCUMENT CONTROL procedure.

9.5.6 Record retention policy.

STANDARD No. 10
Laboratory Support

10.1 Purpose

This standard describes the elements of utilizing LABORATORY services to support a PROGRAM.

10.2 Requirement Summary

If a PROGRAM collects samples, the PROGRAM has access to LABORATORY services needed to support regulatory functions.

10.3 Program Elements

10.3.1 LABORATORY Support

10.3.1.1 The PROGRAM shall have access to a LABORATORY that is capable of analyzing food and environmental samples.

10.3.1.2 The PROGRAM shall maintain a list of all analytical services the LABORATORY can provide the PROGRAM.

10.3.1.3 The PROGRAM shall have a written agreement with each LABORATORY. The agreement must contain, at a minimum, the components below:

10.3.1.3.1 Define the responsibilities of each party.

10.3.1.3.2 Describe the analytical services to be performed.

10.3.1.3.3 Describe how changes to planned work will be communicated by each party.

10.3.1.3.4 Describe how results are reported to the PROGRAM.

10.3.2 LABORATORY Requirements

The PROGRAM utilizes a LABORATORY which:

10.3.2.1 Is accredited by a recognized accreditation body to the International Organization for Standardization/International Electrotechnical Commission ISO/IEC 17025:2017, or current version; or

10.3.2.2 Implements and complies with the ISO/IEC 17025:2017, or current version. If the LABORATORY is not accredited to ISO/IEC 17025:2017 (or current version), then the following must be provided to the PROGRAM:

10.3.2.2.1 A copy of the written LABORATORY quality manual.

10.3.2.2.2 A written attestation that the LABORATORY meets the requirements of ISO/IEC 17025:2017 (or current version).

10.4 Outcome

The PROGRAM has access to LABORATORY services described in this standard to support regulatory

functions.

10.5 Documentation

The PROGRAM maintains the records, or equivalent forms or worksheets, listed here.

10.5.1 Appendix 10.1 Self-assessment worksheet.

10.5.2 List of analytical services provided by the LABORATORY.

10.5.3 Written agreements with each LABORATORY.

10.5.4 For ISO Accredited LABORATORY: ISO/IEC 17025:2017 (or current version) Certificate and Scope of Accreditation.

10.5.5 For Non-ISO Accredited LABORATORY:

10.5.5.1 Written LABORATORY quality manual.

10.5.5.2 Attestation from LABORATORY that it meets the requirements of ISO/IEC 17025:2017(or current version).

Appendix 1.1: Self-Assessment Worksheet

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

PROGRAM _____

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
1.3.1 Written Procedure for Evaluation of Legal Authority		
Does the PROGRAM'S written procedure:		
1. Describe the REGULATORY FOUNDATION assessment process?		
2. Include timeframes for conducting a REGULATORY FOUNDATION assessment; including whenever significant changes are made to applicable federal and/or state laws and regulations?		
3. Address statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that:		
a. Apply to the regulation of produce?		
b. Delegate authority to the PROGRAM?		
c. Describe the PROGRAM'S administrative procedures for rulemaking to protect public health?		
d. Identify and list other federal or state agencies that have authority for any area of the REGULATORY FOUNDATION the PROGRAM lacks?		
1.3.2 REGULATORY FOUNDATION Assessment		
Does the PROGRAM'S REGULATORY FOUNDATION assessment include:		
1. A baseline self-assessment using Appendix 1.2 or equivalent form to determine if the PROGAM is EQUIVALENT, EQUIVALENT IN EFFECT, NOT EQUIVALENT, or NO AUTHORITY to sections of the FD&C Act and CFRs as specified in Appendix 1.2 or equivalent form?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
2. Publication date of the CFR that was adopted or served as the basis for each regulation, if the PROGRAM has not utilized the current version of a CFR provision?		

Assessment completed by:

Name _____ **Date** _____

Appendix 1.2 – Regulatory Foundation Worksheet

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

For those statutes and regulations for which the PROGRAM does have authority, record the state law or regulations and the date it was published. The Notes section shall be used in part to detail differences between federal and state laws and regulations. If regulatory responsibility for a FD&C or CFR falls under the jurisdiction of another agency or program, that particular FD&C or CFR row should be left blank- with documentation provided in the notes section of which agency or program has the jurisdiction.

To the extent that any federal statutes or regulations cited below reference FDA regulated products other than produce or human food that includes produce, such references are not intended to be within the scope of this self-assessment which relates only to produce.

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

The worksheet below is divided into two sections.

Section 1 - Core Regulatory Authorities *- Authorities that are required by a PROGRAM to conduct regulatory activities under provisions of 21 CFR 112 are listed in this section. It is essential that PROGRAMS have these authorities within their regulatory framework to participate with FDA in the implementation of the Produce Safety rule at the state level.*

Section 2 - Supplemental Regulatory Authorities *– The authorities outlined in this section, also found in 21 CFR, may be required, in addition to the Core Regulatory Authorities listed in section 1, to conduct a fully functional PROGRAM.*

Several options exist to create a fully functional PROGRAM at the state level, depending upon existing state programs and authorities. Jurisdictional responsibilities may differ for PROGRAMS if similar state authority to the FD&C Act already exists for PROGRAMS administered within the same agency or a different agency. A Memorandum of Understanding may be the appropriate mechanism to transfer specific and limited authority or responsibility to another agency to create adequate authority for conducting a fully functional PROGRAM. Some states authorize a Memorandum of Understanding, Memorandum of Agreement, or some other contractual agreement. If the authority does not exist at the state level, it will need to be created.

PROGRAM: _____

Section 1 - Core Regulatory Authorities

Federal Food, Drug & Cosmetic Act/ US Code

FD&C Act / US Code	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
201/321	Definitions (f), (k), (m)(r), and (gg)				
301/331	Prohibited acts (a), (b), (e), (f), (kk), and (vv)				
304/334*	Seizure				
402/342	Adulterated Food (a)(1), (a)(2)(B),(a)(3), (a)(4), (a)(6), (a)(7), (b), (c), and (i)				
702/372	Examinations and Investigations (a)(1)(A)				
704/374 **	Inspection				

*Although the PROGRAM may not have authority for seizure, the PROGRAM could have legal authority to stop adulterated and misbranded products from moving in commerce, for example, detention, stop-sale orders, withdrawal from distribution, and embargoes.
** This section covers records in interstate commerce. State laws should include intrastate records.

Title 21 Code of Federal Regulations: Food and Drugs

21 CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
112	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption				

Section 2 - Supplemental Regulatory Authorities

Federal Food, Drug & Cosmetic Act

FD&C Act /US Code	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
303/333***	Penalties				
403/343	Misbranded Food (a), (d), (e), (f), (l)				
701/371	Authority to promulgate regulations (a)				

*** Penalties may vary from Federal statute

Title 21 Code of Federal Regulations: Food and Drugs

21 CFR Part	Title	Equivalency Status	State Citation	Date Incorporated into State Law	Notes
1	General enforcement regulations (§ 1.20, 1.21, 1.22, 1.24), Sanitary Transport (Subpart O § 1.900-1.934)				
7	Enforcement policy (ONLY § 7.1-7.13 and § 7.40-7.59)				

73	Listing of colors exempt from certification ONLY § 73.1-§ 73.615)				
74	Listing of color additives subject to certification (ONLY § 74.101-706)				
101	Food labeling (ONLY §101.1, 101.2, 101.3, 101.4, 101.5, 101.7, 101.13, 101.14, 101.15, 101.18, 101.54-101.65, 101.91and 101.100				
102	Common or usual name for non-standardized foods (ONLY 102.5(a))				
170	Food additives EXCEPT § 170.6, § 170.15, and § 170.17)				
182	Substances generally recognized as safe				

Additional State Authorities:

Instructions: List any state authorities, laws, and/or regulations used by the PROGRAM that are pertinent to the regulation of produce but are outside the scope of 21 CFR 112.

State authority	Title	Date Incorporated	Notes

Assessment Completed By:

Name _____ **Date:** _____

Appendix 2.1: Self-Assessment Worksheet

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

PROGRAM _____

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
2.3.1. Training Plan and Training Records		
Does the PROGRAM:		
1. Have a written training plan that includes training and continuing education, to ensure all inspectors receive training required to adequately perform their work assignments?		
2. Maintain individual training records for active inspectors?		
3. Maintain individual training records for all inactive inspectors for a minimum of three years?		
4. Use Appendix 2.2 or equivalent form to document and summarize all training provided to inspectors?		
5. Include the inspector's START DATE in the training record summary?		
6. Assess all inspectors' previous performance and experience to determine if the inspectors have completed required training, or determine if additional training is needed?		
2.3.2. Inspection Training		
Does the PROGRAM require that each inspector:		
1. Complete the training curriculum prior to performing independent inspections?		
2. Complete the training curriculum within 24 months of the inspector's START DATE?		
3. Complete the coursework in the subject areas listed in 2.3.2.3.1 – 2.3.2.3.8?		
4. Complete the field training program prior to performing independent inspections that meet the elements detailed in 2.3.2.4.1 - 2.3.2.4.6?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
5. Have competencies been verified in the field by the QUALIFIED FIELD INSPECTION TRAINER?		
Does the PROGRAM have written procedures for:		
1. Competencies to be verified in the field?		
2. JOINT FIELD TRAINING INSPECTIONS?		
3. The number of JOINT FIELD INSPECTIONS to be completed by the inspector?		
4. The number of field inspection EVALUATIONS?		
5. Additional field training activities, if deemed necessary by the PROGRAM?		
6. The qualifications, education, and experience necessary to be identified as a QUALIFIED FIELD INSPECTION TRAINER?		
2.3.3 Experienced Inspectors		
For CURRENT EXPERIENCED STAFF or newly hired experienced inspection staff, does the PROGRAM'S training plan include the following unless the PROGRAM determines in their training plan that all staff will be required to complete the program elements in 2.3.2?		
For CURRENT EXPERIENCED STAFF, does the PROGRAM'S training plan include the following for those who are missing training records?		
1. A statement or affidavit from the PROGRAM stating an assessment has occurred and the outcomes of the assessment satisfy the requirements for documentation?		
2. A statement or affidavit from the PROGRAM explaining that the CURRENT EXPERIENCED STAFF'S background or experience justifies a waiver of JOINT FIELD TRAINING INSPECTIONS?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
3. A statement or affidavit from the PROGRAM explaining that the CURRENT EXPERIENCED STAFF'S background or experience justifies a waiver of coursework requirements?		
For newly hired experienced inspection staff, does the PROGRAM'S training plan include the following for those who are missing training records?		
1. A statement or affidavit from the PROGRAM stating an assessment has occurred and the outcomes of the assessment satisfy the requirements for documentation?		
2. A statement or affidavit from the PROGRAM explaining the background or experience that justifies a waiver of some or all of the JOINT FIELD TRAINING INSPECTIONS?		
3. A requirement that inspectors who are missing JOINT FIELD TRAINING INSPECTION records conduct two successful EVALUATIONS within six (6) months of the inspector's QUALIFIED DATE?		
4. A statement from the PROGRAM explaining that the newly hired experienced inspection staff's background or experience justifies a waiver of coursework requirements?		
2.3.4 Continuing Education		
1. Does each inspector conducting produce inspections accumulate 20 CONTACT HOURS of continuing education, in the manners outlined in 2.3.4.4 and 2.3.4.5, every 36 months, starting from the QUALIFIED DATE?		
2. Does the PROGRAM maintain documentation for continuing education credit as outlined in 2.3.4.6?		
3. Is all coursework obtained from sources listed in 2.3.4.7?		

Assessment completed by:

Name _____ **Date** _____

Appendix 2.2: Inspector Training Record

PROGRAM _____

Name of Inspector _____ **Start Date** _____

Note: *If an assessment of the inspector's previous performance and experience demonstrates adequate training has been completed as referenced in 2.3.1, Mark the "Coursework Name and Location of Training Column", with "Met via Evaluation".*

Subject Areas	Date Completed	Coursework Name and Location of Training	Documentation Verifying Completion (Y/N)
Prevailing statutes, regulations, and ordinances			
Inspections, compliance, and enforcement			
Public health principles			
Biosecurity			
Basic/Introductory emergency management			
Communication skills			
Microbiology			
Sampling technique, if applicable			

JOINT FIELD TRAINING INSPECTIONS

As referenced in 2.3.2.4.4, the minimum Number of JOINT FIELD TRAINING INSPECTIONS Required: ____

JOINT FIELD TRAINING INSPECTIONS		
Farm Name and Location	**Date Completed**	**Documentation Available for Review (Y/N)**

As referenced in 2.3.2.4.2, the PROGRAM should determine a Field training checklist of competencies to be verified in the field by the QUALIFIED FIELD INSPECTION TRAINER

COMPETENCIES		
Competency	**Date Observed**	**EVALUATION Acceptable (Y/N)**

As referenced in 2.3.2.4.6, additional field training activities deemed necessary.

OTHER FIELD ACTIVITIES			
Field Activity	**Date Completed**	**EVALUATION Acceptable (Y/N)**	**Documentation Available for Review (Y/N)**

As referenced in 2.3.2.4.5, the minimum Number of field inspection EVALUATIONS Required: ____

EVALUATIONS			
Farm Name and Location	**Date Completed**	**EVALUATION Acceptable (Y/N)**	**Documentation Available for Review (Y/N)**

CONTINUING EDUCATION

A total of 20 CONTACT HOURS required every 36 months. Total CONTACT HOURS is the sum of both charts below.

Activities in Program Element 2.3.4 *Maximum of 20 CONTACT HOURS*			
Type of Activity *(Provide Title and Brief Description)*	**Date Completed**	**Documentation Available for Review (Y/N)**	**CONTACT HOURS Earned**
		Subtotal	
Presenting, Training, or Publishing (Program Element 2.3.4.6) *Maximum of 10 CONTACT HOURS*			
Type of Activity *(Provide Title and Brief Description)*	**Date Completed**	**Documentation Available for Review (Y/N)**	**CONTACT HOURS Earned**
		Subtotal	
		Total CONTACT HOURS Earned	

Appendix 3.1: Self-Assessment Worksheet

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

PROGRAM _____

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
3.3.1 Risk-Based Inspection PROGRAM		
Does the PROGRAM have written procedures to:		
1. Define and establish an inventory of PRODUCE OPERATIONS under the PROGRAM'S jurisdiction and authority?		
2. Maintain the inventory of PRODUCE OPERATIONS?		
3. Define and document risk categories, using at least the minimum required risk factors identified in 3.3.1.3.1 – 3.3.1.3.5?		
4. Prioritize inspections and assign frequencies based on the risk categories established?		
3.3.2 Inspection Procedure		
Does the PROGRAM have written procedures that require the inspector to:		
1. Review the previous inspection report(s), CONSUMER COMPLAINT(S), and compliance history?		
2. Follow the pre-inspection call procedures required by the PROGRAM?		
3. Have appropriate equipment and forms, and equipment verified, operated, and maintained as defined by the PROGRAM?		
4. Follow the biosecurity protocols required by the PRODUCE OPERATION and the PROGRAM?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
5. Follow the safety protocols required by the PRODUCE OPERATION and the PROGRAM?		
6. Follow the procedure for the opening meeting required by the PROGRAM?		
7. Assess personnel practices critical to the safe and sanitary growing, harvesting, packing, and holding of produce?		
8. Evaluate conditions, practices, components, and/or labeling that may cause the produce to be deemed adulterated, misbranded, or otherwise in violation of applicable law(s)?		
9. Reference appropriate and available FDA guidance documents, as applicable?		
10. Explain findings throughout the inspection and describe the public health significance?		
11. Recognize significant violative conditions or practices and document findings consistent with PROGRAM procedures?		
12. Alert the PRODUCE OPERATION when an immediate corrective action is necessary?		
13. Review and verify the required records for the PRODUCE OPERATION are maintained?		
14. Recognize deficiencies in the PRODUCE OPERATION'S required monitoring activities?		
15. Collect adequate evidence and documentation to support inspection observations in accordance with the PROGRAM procedures?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
16. Verify correction of deficiencies that were identified during previous inspection(s)?		
17. Demonstrate effective communication and interpersonal skills?		
3.3.3 Inspection Report Procedure		
Does the PROGRAM have written inspection report procedures that require inspectors to:		
1. Document significant violative conditions or practices?		
2. Complete the inspection report(s) accurately?		
3. Submit the inspection report within designated timeframes?		
Does the PROGRAM have written procedures to:		
1. Review inspection reports with inspectional findings?		
2. Provide the applicable inspection report(s) to the PRODUCE OPERATION within designated timeframes?		
3. Follow up with corrective, compliance, and enforcement actions as warranted?		
3.3.4 Recalls		
Does the PROGRAM have a recall system with written procedures to:		
1. Receive information about recalls?		
2. Share information about recalls with relevant industry and partner agencies?		
3. Track the recall and work with the recalling operation to remove affected product from the market?		
4. Perform RECALL AUDIT CHECKS as applicable?		
5. Maintain recall records?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
3.3.5 Consumer Complaint		
Does the PROGRAM have a CONSUMER COMPLAINT system with written procedures to:		
1. Receive the complaint?		
2. Track the complaint's follow-up?		
3. Evaluate the complaint?		
4. Answer the complaint?		
5. Close the complaint?		
6. Maintain a record of the complaint?		
3.3.6 Industry Complaint		
Does the PROGRAM have an INDUSTRY COMPLAINT system with written procedures to:		
1. Receive the complaint?		
2. Track the complaint's follow-up?		
3. Evaluate the complaint?		
4. Answer the complaint?		
5. Close the complaint?		
6. Maintain a record of the complaint?		
3.3.7 Sampling		
For PROGRAMS that conduct sampling, does the PROGRAM have a SAMPLING PROGRAM with written procedures that:		
1. Use the appropriate method and equipment to collect samples?		
2. Maintain and document sample chain of custody?		
3. Handle, package, and ship samples to ensure security and prevent compromising condition of samples?		
4. Deliver or ship samples to the appropriate LABORATORY program within prescribed timeframes?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
5. Follow the receiving LABORATORY procedures?		
6. Provide instructions for documenting the sample collection, if applicable, as described in 3.3.7.6.1 – 3.3.7.6.4 (and all sub-elements)?		

Assessment completed by:

Name _____ **Date** _____

Appendix 4.1 – Self-Assessment Worksheet

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

PROGRAM _____

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
4.3.1 Audit Program		
Does the PROGRAM have written procedures for:		
1. The qualifications, education, and experience necessary to be identified as a QUALIFIED FIELD INSPECTION AUDITOR?		
2. FIELD INSPECTION AUDITS as described in section 4.3.3?		
3. Inspection report audits as described in section 4.3.4?		
4. Sample report audits as described in section 4.3.5?		
5. Corrective actions as described in section 4.3.6?		
4.3.2 Score Review		
Does the PROGRAM review the performance factor scores and cumulative scores for each type of completed audit at least every 12 months?		
4.3.3 Field Inspection Audit		
Does the PROGRAM have written procedures for conducting FIELD INSPECTION AUDITS that include:		
1. A QUALIFIED FIELD INSPECTION AUDITOR conducts FIELD INSPECTION AUDITS to verify that inspections are consistently performed according to the PROGRAM'S written procedures described in Standard 3?		
2. A minimum of one FIELD INSPECTION AUDIT of each inspector is conducted within twelve months and a minimum of once every 36 months after their QUALIFIED DATE?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
3. Sample collection audits, if samples are collected during the FIELD INSPECTION AUDIT, and the appropriate question(s) answered on Appendix 4.2, or equivalent form?		
4. Documentation in Appendices 4.2 and 4.2a, or equivalent form, that demonstrate meeting the PROGRAM elements in Standard 3, section 3.3.2?		
4.3.4 Inspection Report Audits		
Does the PROGRAM have written procedures for inspection report audits that include:		
1. The PROGRAM conducts annual reviews of inspection reports to verify that inspectional findings are documented according to the PROGRAMs written procedures?		
2. The PROGRAM reviews a random selection of inspection reports based on the number of inspections performed in the last 12 months using the table in 4.3.4.1?		
3. Performance is documented using the factors listed in Appendix 4.3 and 4.3.a, or equivalent forms?		
4.3.5 Sample Report Audit		
Does the PROGRAM collect samples?		
If samples were collected, does the PROGRAM have written procedures for conducting sample report audits that include:		
1. An annual review of sample reports?		
2. Reviewing a random selection of sample reports based on the number of samples collected in the last 12 months using the table in 4.3.5.1?		
3. The quality of each sample report is audited using the performance factors listed in Appendix 4.4, or equivalent form?		
4. The overall sample report rating is calculated using Appendix 4.4a, or equivalent form?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
4.3.6 Corrective Actions		
Does the PROGRAM initiate corrective actions when:		
1. An individual receives an overall rating of "needs improvement"?		
2. A single performance factor for the PROGRAM falls below 80%?		
3. An overall rating for the PROGRAM falls below 80%?		

Assessment completed by:

Name _____ **Date** _____

Appendix 4.2: Field Inspection Audit Form

PRODUCE REGULATORY PROGRAM STANDARDS **FIELD INSPECTION AUDIT FORM**	
AUDITOR:	INSPECTOR:
FIRM/FARM NAME:	FIRM /FARM ID:
FIRM/FARM ADDRESS:	
PRODUCT(S) COVERED:	
AUDIT DATE:	
TIME IN:	TIME OUT:
TOTALS: Total # "Acceptable": Total # "Needs Improvement": Audit Score:	AUDIT RATING ☐Acceptable ☐Needs Improvement

NOTE: All questions must be answered "Acceptable" or "Needs Improvement". Every item marked "Needs Improvement" must be accompanied by an explanation of why the item was judged as needing improvement.

INSTRUCTIONS TO THE AUDITOR

All performance factors must be rated "Acceptable" or "Needs Improvement." The total number of "Acceptable" and "Needs Improvement," as well as the Audit Score and Audit Rating, must be recorded in the space above.

To calculate the Audit Score:

Audit Score = [# Acceptable Performance Factors/ (# Acceptable Performance Factors + # Needs Improvement Performance Factors)] x 100.

Audit Rating:

If the Audit Score is below 80%, the Audit Rating must be marked as "Needs Improvement."

Corrective Action(s):

If the individual receives an overall rating of "needs improvement" from the audit, the PROGRAM management must be notified by the QUALIFIED FIELD INSPECTION AUDITOR that additional training or other performance improvement measures for the inspector being audited should be initiated. All inspectors who receive an overall audit score of "needs improvement" shall receive remedial training in deficient areas as determined by the PROGRAM prior to resuming routine inspections in the field.

I. **PRE-INSPECTION ASSESSMENT**
1. Did the inspector review the previous inspection report(s), CONSUMER COMPLAINT(S), and compliance history? ☐Acceptable ☐Needs Improvement Comments *(required for Needs Improvement)*
2. Did the inspector follow the pre-inspection call procedures required by the PROGRAM? ☐Acceptable ☐Needs Improvement Comments *(required for Needs Improvement)*
3. Did the inspector have appropriate equipment and forms? ☐Acceptable ☐Needs Improvement Comments *(required for Needs Improvement)*
II. INSPECTION OBSERVATIONS AND PERFORMANCE
1. Did the inspector follow the biosecurity protocols required by the PRODUCE OPERATION and the PROGRAM? ☐Acceptable ☐Needs Improvement Comments *(required for Needs Improvement)*
2. Did the inspector follow the safety protocols required by the PRODUCE OPERATION and the PROGRAM? ☐Acceptable ☐Needs Improvement Comments *(required for Needs Improvement)*
3. Did the inspector assess personnel practices critical to the safe and sanitary growing, harvesting, packing, and holding of produce? ☐Acceptable ☐Needs Improvement Comments *(required for Needs Improvement)*

4. Did the inspector evaluate conditions, practices, components, and/or labeling that may cause the produce to be deemed adulterated or misbranded or otherwise in violation of applicable law(s)?

☐Acceptable ☐Needs Improvement

Comments *(required for Needs Improvement)*

5. Did the inspector reference appropriate and available FDA guidance documents to evaluate commodities and/or practices as applicable?

☐Acceptable ☐Needs Improvement

Comments *(required for Needs Improvement)*

6. Did the inspector review and verify that required records for the PRODUCE OPERATION are being maintained?

☐Acceptable ☐Needs Improvement

Comments *(required for Needs Improvement)*

7. Did the inspector recognize deficiencies in the PRODUCE OPERATION required monitoring activity?

☐Acceptable ☐Needs Improvement

Comments *(required for Needs Improvement)*

8. Did the inspector collect adequate evidence and documentation to support inspection observations in accordance with PROGRAM procedures?

☐Acceptable ☐Needs Improvement

Comments *(required for Needs Improvement)*

9. Did the inspector verify correction of deficiencies that were identified during previous inspection(s)?

☐Acceptable ☐Needs Improvement

Comments *(required for Needs Improvement)*

III. ORAL AND WRITTEN COMMUNICATION
1. Did the inspector demonstrate effective communication and interpersonal skills to effectively support the inspection process? ☐Acceptable ☐Needs Improvement Comments *(required for Needs Improvement)*
2. Did the inspector follow the procedure for the opening meeting required by the PROGRAM? ☐Acceptable ☐Needs Improvement Comments *(required for Needs Improvement)*
3. Did the inspector explain findings throughout the inspection and describe the public health significance? ☐Acceptable ☐Needs Improvement Comments *(required for Needs Improvement)*
4. Did the inspector alert the PRODUCE OPERATION when an immediate corrective action is necessary? ☐Acceptable ☐Needs Improvement Comments *(required for Needs Improvement)*
5. Did the inspector recognize significant violative conditions or practices, if present, and document findings consistent with PROGRAM procedures? ☐Acceptable ☐Needs Improvement Comments *(required for Needs Improvement*
IV. SAMPLE COLLECTION
Note: this section only needs to be completed if a sample is collected as a part of the audit.
1. Did the inspector follow the PROGRAM'S sampling policies and procedures to assure sample integrity, security, accountability, and chain of custody? ☐Acceptable ☐Needs Improvement ☐Not Applicable Comments *(required for Needs Improvement*

2. Did the inspector use the appropriate method and equipment to collect the sample?

☐Acceptable ☐Needs Improvement ☐Not Applicable

Comments *(required for Needs Improvement*

3. Did the inspector seal the sample and initiate chain of custody to maintain and document sample integrity and security?

☐Acceptable ☐Needs Improvement ☐Not Applicable

Comments *(required for Needs Improvement)*

ADDITIONAL COMMENTS

SIGNATURE OF AUDITOR

DATE

Appendix 4.2a: Summary of Field Inspection Audit Findings

Instructions for completing this form can be found at the end of this document.

PROGRAM: _____ **Reviewed By:** _____

Performance Period: _____ **Date:** _____

Cumulative Score (5): _____

Inspector Initials and Date of Audit (1)																					
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																		**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
I.1																					
I.2																					
II.1																					
II.2																					
II.3																					
II.4																					
II.5																					
II.6																					
II.7																					
II.8																					
II.9																					
III.1																					
III.2																					
III.3																					
III.4																					
III.5																					
IV.1																					
IV.2																					
IV.3																					
Audit Score (2)																					
Subtotal (4) - Enter the sum of the totals from any continuation worksheets.																					
Total (4) - Enter the final sums (subtotal + sums of (3) on this form).																					

(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits. Use additional sheets if needed.

INSTRUCTIONS:

1. For each audit, record the Inspector's initials and Date of Audit

2. For each audit (vertical column) record the rating for each performance factor (A = acceptable; NI = needs improvement). Record the individual audit score at the bottom of the column.

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

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

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

   $\sum A_t$ = vertical sum of acceptable ratings.
   $\sum NI_t$ = vertical sum of needs improvement ratings.
   NOTE: $\sum$ *is the statistical symbol for the sum of all numbers.*

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

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

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

Appendix 4.3: Inspection Report Audit Form

PRODUCE REGULATORY PROGRAM STANDARDS
INSPECTION REPORT AUDIT FORM

AUDITOR:	DATE OF AUDIT:
FIRM/FARM NAME:	DATE OF INSPECTION:
FIRM/FARM ADDRESS:	Type of Inspection:
TOTALS: Total # "Acceptable": Total # "Needs Improvement": Audit Score:	AUDIT RATING ☐Acceptable ☐Needs Improvement

NOTE: All questions must be answered "acceptable" or "needs improvement". Every item marked "needs improvement" must be accompanied by an explanation of why the item was judged as needing improvement.

INSTRUCTIONS TO THE AUDITOR
All performance factors must be rated "Acceptable" or "Needs Improvement." The total number of "Acceptable" and "Needs Improvement," as well as the Audit Score and Audit Rating, must be recorded in the space above.

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

Audit Rating:
If the Audit Score is below 80%, the Audit Rating must be marked as "Needs Improvement."

I. ORGANIZATION AND RECORDS OF FINDINGS

1. The inspector submitted the report within designated timeframes.

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

2. The PROGRAM submitted the report within designated timeframes to the PRODUCE OPERATION.

☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

3. All required fields on inspection report or related forms were completed.
☐ Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

4. Written observations were clear and concise.
☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

5. The inspector followed all current and applicable report writing and documentation procedures.
☐ Acceptable ☐ Needs improvement
Comments *(required for Needs Improvement)*

6. The inspector identified violations based on federal and/or state regulations.
☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

7. The inspector reviewed past inspection findings and acted on repeated or unresolved violations.
☐ Acceptable ☐ Needs improvement
Comments *(required for Needs Improvement)*

8. The inspector recorded significant findings.
☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

9. The inspector recorded the collection of adequate evidence and documentation to support inspection observations. (e.g., samples, exhibits, photographs, or photocopies)
☐ Acceptable ☐ Needs improvement
Comments *(required for Needs Improvement)*

10. The inspector obtained and documented on-site corrective action at the time of inspection as appropriate to the type of violation.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

11. The inspector documented follow-up compliance activities per the PROGRAM policy.

☐ Acceptable ☐ Needs improvement

Comments *(required for Needs Improvement)*

GENERAL COMMENTS

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

SIGNATURE OF AUDITOR

DATE

Appendix 4.3a: Summary of Inspection Report Audit Findings

Instructions for completing this form can be found at the end of this document.

PROGRAM: _____ **Reviewed By:** _____

Performance Period: _____ **Date:** _____

Cumulative Score (5): _____

Inspector Initials and Date of Audit (1)																					
Firm/Farm ID																					
Inspection Date																					
Performance Factors (2)	**Performance Ratings**																		**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
I.1																					
I.2																					
I.3																					
I.4																					
I.5																					
I.6																					
I.7																					
I.8																					
I.9																					
I.10																					
I.11																					
Audit Score (2)																					
Subtotal (4) - Enter the sum of the totals from any continuation worksheets.																					
Total (4) - Enter the final sums (subtotal + sums of (3) on this form).																					

(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits. Use additional sheets if needed.

INSTRUCTIONS:

1. For each audit, record the Inspector's initials and Date of Audit

2. For each audit (vertical column) record the rating for each performance factor (A = acceptable; NI = needs improvement). Record the individual audit score at the bottom of the column.

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

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

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

   $\sum A_t$ = vertical sum of acceptable ratings.
   $\sum NI_t$ = vertical sum of needs improvement ratings.
   NOTE: $\sum$ *is the statistical symbol for the sum of all numbers.*

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

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

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

Appendix 4.4: Sample Report Audit Form

PRODUCE REGULATORY PROGRAM STANDARDS
SAMPLE REPORT AUDIT FORM

AUDITOR:	DATE OF AUDIT: DATE OF INSPECTION:
FIRM/FARM NAME:	FIRM /FARM ID:
DATE OF COLLECTION:	SAMPLE ID #:
TOTALS: Total # "Acceptable": Total # "Needs Improvement": Audit Score:	AUDIT RATING: ☐Acceptable ☐Needs Improvement

NOTE: All questions must be answered "Acceptable" or "Needs Improvement". Every item marked "Needs Improvement" must be accompanied by an explanation of why the item was judged as needing improvement.

INSTRUCTIONS TO THE AUDITOR
All performance factors must be rated "Acceptable" or "Needs Improvement." The total number of "Acceptable" and "Needs Improvement," as well as the Audit Score and Audit Rating, must be recorded in the space above
To calculate the Audit Score:

Audit Score = [# Acceptable Performance Factors/ (# Acceptable Performance Factors + # Needs Improvement Performance Factors)] x 100.

Audit Rating:
If the Audit Score is below 80%, the Audit Rating must be marked as "Needs Improvement.".

I. SAMPLE OBSERVATIONS AND PERFORMANCE

1. Method of collection and equipment was appropriate.
☐Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

2. Record sample chain of custody per state procedure.
☐Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

3. Sample was handled, packaged, and shipped to prevent compromising the condition or integrity of the sample.
☐Acceptable ☐ Needs Improvement
Comments *(required for Needs Improvement)*

4. Sample was submitted within prescribed timeframes.
☐Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

II. SAMPLE COLLECTION

1. Date of sample collection was recorded.
☐Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

2. Product identification name, sample type, and unique identification reference information
☐Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

3. Brief description of sample (soil, soil amendment, water, environmental, crop, etc.) including sample size was recorded.
☐Acceptable ☐ Needs Improvement
Comments *(required for Needs Improvement)*

4. Collection information (e.g., soil, soil amendment, water, environmental, crop, etc.), method of collection (i.e., how the sample was collected), identification of lot sampled, lot size, and any special techniques used to collect the sample was recorded.
☐Acceptable ☐ Needs Improvement
Comments *(required for Needs Improvement)*

5. Location where sample was collected was recorded.
☐Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

6. Name and address of responsible party, produce operation, or packing shed if different from produce operation were recorded. For environmental samples the physical location of the collection site.
☐Acceptable ☐ Needs Improvement
Comments *(required for Needs Improvement)*

7. Reason for sample collection (surveillance, compliance, investigational, or regulatory) was recorded.
☐Acceptable ☐ Needs Improvement
Comments *(required for Needs Improvement)*

8. The type of analysis requested was recorded, if applicable.
☐Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

9. Product labels or specific labeling information is collected or reproduced if required by state procedures.
☐Acceptable ☐ Needs Improvement
Comments *(required for Needs Improvement)*

10. The identification of the sample with the unique sample identifier.
☐Acceptable ☐ Needs Improvement

Comments *(required for Needs Improvement)*

GENERAL COMMENTS

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

SIGNATURE OF AUDITOR

DATE

Appendix 4.4a: Summary of Sample Report Audit Findings

Instructions for completing this form can be found at the end of this document.

PROGRAM: _____ **Reviewed By:** _____

Performance Period: _____ **Date:** _____

Cumulative Score (5): _____

Unique Sample Identifier and Date of Sample Collection (1)																					
Sample ID																					
Collection Date																					
Performance Factors (2)	**Performance Ratings**																		**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
I.1																					
I.2																					
I.3																					
I.4																					
II.1																					
II.2																					
II.4																					
II.5																					
II.6																					
II.7																					
II.8																					
II.9																					
II.10																					
Audit Score (2)																					
Subtotal (4) - Enter the sum of the totals from any continuation worksheets.																					
Total (4) - Enter the final sums (subtotal + sums of (3) on this form).																					

(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits. Use additional sheets if needed.

INSTRUCTIONS:

1. For each audit, record the Inspector's initials and Date of Audit

2. For each audit (vertical column) record the rating for each performance factor (A = acceptable; NI = needs improvement). Record the individual audit score at the bottom of the column.

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

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

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

   $\sum A_t$ = vertical sum of acceptable ratings.
   $\sum NI_t$ = vertical sum of needs improvement ratings.
   NOTE: $\sum$ *is the statistical symbol for the sum of all numbers.*

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

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

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

Appendix 5.1: Self-Assessment Worksheet

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

PROGRAM _____

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
5.3.1 Coordination of FOOD-RELATED INCIDENTS		
Does the PROGRAM:		
1. Have a coordinator, designated in writing, to guide investigation and response efforts?		
2. Manage events using the Incident Command System (ICS)/Incident Management Team (IMT)?		
a. Have a written response plan with the following components, if ICS/IMT is not utilized?		
i. Identify and execute investigation objectives?		
ii. Manage communications?		
iii. Implement control measures?		
iv. Conduct post-response activities?		
3. Have a memorandum of understanding or other written agreement with other state agencies, if necessary?		
4. Have a written procedure that identifies and describes the roles, duties, and responsibilities for each activity described in 5.3.2-5.3.5?		
5. Have a written procedure that describes PROGRAM collaboration as necessary with FDA and other appropriate federal, state, and local authorities in multi-jurisdictional FOOD-RELATED INCIDENTS?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
6. Have a written procedure that describes communication with relevant agencies during FOOD-RELATED INCIDENTS as described in 5.3.1.3.3?		
7. Have a written procedure that provides guidance for notification of appropriate law enforcement agencies when intentional food contamination is suspected or threatened?		
8. Have a written procedure that describes the maintenance of a list of relevant agencies and emergency contacts that is reviewed and updated at least yearly?		
5.3.2 Surveillance		
Does the PROGRAM:		
1. Use epidemiological information, CONSUMER COMPLAINTS, or other incident-related information from appropriate departments or agencies to detect outbreaks or other FOOD-RELATED INCIDENTS?		
2. Maintain notifications of relevant outbreaks or other FOOD-RELATED INCIDENTS that are reported to the PROGRAM in a log or database?		
5.3.3 Investigation		
Does the PROGRAM:		
1. Have a written procedure with criteria to:		
a. Determine the appropriate response?		
b. Initiate the response?		
c. Complete the response?		
2. Conduct investigations using established processes similar to those found in the documents listed in 5.3.3.2.1 – 5.3.3.2.4?		
3. Have a written procedure to coordinate the traceback and traceforward of suspected or implicated produce?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
4. Have access to LABORATORY support for investigation of outbreaks or other FOOD-RELATED INCIDENTS?		
5. Analyze ROOT CAUSE INVESTIGATION (RCI) data, if it is conducted?		
5.3.4 Control Measures		
Does the PROGRAM:		
1. Have written strategies as described in 5.3.4.1 to mitigate and contain outbreaks or other FOOD-RELATED INCIDENTS?		
2. Have written procedures to release information to the public, with the following components?		
a. Identify a point(s) of contact responsible for releasing information to the public?		
b. Have written procedures to develop guidelines for coordinating media information with other jurisdictions?		
5.3.5 Post Response		
Does the PROGRAM have written procedures to:		
1. Maintain investigational findings and reports?		
2. Distribute final investigation report(s), including ROOT CAUSE INVESTIGATION (RCI), if completed, to relevant agencies, as necessary?		
3. Provide recommendations, when available, from investigation and ROOT CAUSE INVESTIGATION (RCI) reports to relevant agencies and stakeholders responsible for prevention, education, outreach, and research?		

Assessment completed by:

Name _____ **Date** _____

Appendix 6.1: Self Assessment Worksheet

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

PROGRAM _____

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
6.3.1 Compliance and Enforcement Procedures		
Does the PROGRAM have written procedures that:		
1. Describe compliance and enforcement strategies?		
2. Describe use of enforcement tool(s)?		
3. Describe progressive enforcement action(s)?		
4. Describe the process used to determine appropriate enforcement action(s)?		
6.3.2 Annual Evaluation Procedures		
1. Does the PROGRAM have a written procedure for conducting an annual evaluation of its enforcement activities?		
6.3.3 Annual Evaluation		
Does the PROGRAM:		
1. Conduct an annual evaluation of all enforcement actions, or a representative sample of those actions?		
2. Determine if enforcement actions follow procedures described in 6.3.1?		
3. Implement improvements or modifications related to compliance and enforcement procedures, if any?		
4. Document the results of the evaluation on Appendix 6.2 or equivalent form?		

Assessment completed by:

Name _____ **Date** _____

Appendix 6.2 – Evaluation of Conformance of Compliance/Enforcement Procedures

PROGRAM _____

1 Identification Number	2 Record the enforcement action(s) taken	3 Procedures Followed?	4 If no, explain	5 Improvements/ Modifications

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

Instructions for Evaluation of Compliance/Enforcement Procedures

Appendix 6.2, or equivalent form, must be used to evaluate the PROGRAM'S conformance to its compliance and enforcement procedures, as required in 6.3.1. All enforcement actions taken in the previous 12 months must be reviewed as part of the evaluation; or a statistical approach must be used to determine a representative number of enforcement actions taken. Supporting documents should be referenced and maintained by the PROGRAM.

The following instructions correspond to the columns numbered in Appendix 6.2

1. *Record the identification number (e.g., PRODUCE OPERATION identification number, case number, etc.).*
2. *Record the enforcement action(s) taken, as described in the PROGRAM'S compliance and enforcement procedures.*
3. *For each enforcement action taken, record if compliance and enforcement procedures were followed (Yes/No).*
4. *For enforcement actions identified as "No" in (3), explain the reason for the nonconformance.*
5. *Record identified improvements or modifications related to compliance and enforcement procedures based on the results of this evaluation, if any.*

Appendix 7.1: Self-Assessment Worksheet

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

PROGRAM _____

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
7.3 Outreach Methods		
Does the PROGRAM have a written procedure that includes how the PROGRAM will:		
1. Identify the methods for communication?		
2. Interact with produce industry stakeholders and consumers by sponsoring or actively participating in OUTREACH ACTIVITY?		
3. Tailor outreach efforts to a target population?		
4. Tailor outreach topics to a target population?		
5. Document and evaluate OUTREACH ACTIVITY using Appendix 7.2 or equivalent form? Include documents such as agendas, meeting summaries, and program evaluations.		

Assessment completed by:

Name _____ **Date** _____

Appendix 7.2 – Outreach Activity and Self-Evaluation Worksheet

PROGRAM: _____

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

Section I: Overview of OUTREACH ACTIVITY

a. Type of OUTREACH ACTIVITY (check one):

☐ On-Farm ☐ Workshop ☐ Training course

☐ Other _____

b. Subject or Name: _____

c. Date: _____

d. Objective(s): _____

e. Target Population: _____

f. Host Organization: _____

Section II. Self-Evaluation of OUTREACH ACTIVITY

Program Elements	Yes/No	If no, please explain.
a. The purpose and objective(s) were clearly defined		
b. The content of the OUTREACH ACTIVITY was consistent with the objectives		
c. The activity was sufficiently tailored to the identified target population		
d. An evaluation was completed or feedback was otherwise received from the attendees		

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. Address comments from attendees, if available**.**

Assessment Completed By:

Name _____ **Date:** _____

Appendix 8.1: Self-Assessment Worksheet

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

PROGRAM _____

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
8.3.1 Workplan		
Does the PROGAM have a written workplan?		
Does the written workplan include:		
1. Inspection plan		
a. Number of inspections?		
b. Type of inspection?		
c. Risk category of PRODUCE OPERATION?		
d. Frequency?		
2. If there is a SAMPLING PROGRAM, does the PROGRAM have a sampling plan?		
8.3.2 Workplan Timeframe		
Does the WORKPLAN have a timeframe that is applicable within a 12-month period?		
8.3.3 Workplan Evaluation		
Does the PROGRAM have a written procedure for evaluating the WORKPLAN?		
Does the written procedure include:		
1. A documented annual review for alignment with PROGRAM objectives and resources?		
2. A documented review when PROGRAM objectives or resources change?		
8.3.4 Workplan Resources		
Does the PROGRAM have a written procedure for identifying and reviewing its resources to accomplish the WORKPLAN within the applicable timeframe?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
Does this include:		
1. Staffing?		
2. Equipment?		
3. Funding?		
4. Administrative Support?		
8.3.5 PROGRAM Staff Calculation		
Does the PROGRAM calculate the number of staff needed to accomplish the PROGRAM WORKPLAN based on the PROGRAM'S data?		
8.3.6 Inspection and Sampling Equipment		
Is a list of the equipment required for inspections and sample collections:		
1. Established by the PROGRAM?		
2. Maintained by the PROGRAM?		
8.3.7 Annual Resource Review		
Does the PROGRAM conduct an annual review of the resources needed to fully implement the PRPS by using Appendix 8.2 or equivalent form?		

Assessment completed by:

Name _____ **Date** _____

Appendix 8.2: Resource Summary Report

PROGRAM _____

Does the PROGRAM have sufficient staffing, equipment, funding, administrative support and other resources necessary to meet the PRPS? Answer yes or no in each block. If "no", please explain. Resources not related to staffing, equipment, funding, and administrative support should be in the "Other Resources Needed" column. Use additional pages as needed.

Standard		Staffing	Equipment	Funding	Administrative Support	Other Resources Needed
1	Regulatory Foundation					
2	Training Program					
3	Inspection Program					
4	Inspection Audit Program					
5	Foodborne Illness, Outbreak, Response					
6	Compliance and Enforcement					
7	Outreach Activities					
8	Program Resources					
9	Program Assessment					
10	Laboratory Support					

Assessment completed by:

Name _____ **Date** _____

Appendix 9.1: Self Assessment Worksheet

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

PROGRAM _____

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
9.3.1 Does the PROGRAM conduct a baseline self-assessment:		
1. Within the first year to determine if the PROGRAM meets the elements of each standard?		
2. Using the self-assessment worksheets associated with each standard?		
3. Using the results of its self-assessments to complete Appendix 9.2, or equivalent form?		
9.3.2 If the PROGRAM fails to meet any of the program elements or documentation requirements, whether identified through a self-assessment or FDA ASSESSMENTS, did the PROGRAM develop a STRATEGIC IMPROVEMENT PLAN?		
Does the STRATGIC IMPROVEMENT PLAN include:		
1. The individual element or documentation requirement that was not met?		
2. Improvements or corrections needed to meet the program element or documentation requirement of the standard?		
3. Projected completion dates for each task?		
4. Personnel responsible?		
5. Date completed for each task?		
9.3.3 Does the PROGRAM review and update the self-assessment appendices and STRATEGIC IMPROVEMENT PLAN at least annually?		

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
9.3.4 Does the PROGRAM:		
1. Participate in FDA ASSESSMENTS to determine IMPLEMENTATION and COFORMANCE to the standards?		
2. Address FDA ASSESSMENT observations and establish corrective actions, unless already identified in the STRATEGIC IMPROVEMENT PLAN prior to the start of the FDA ASSESSMENT?		
9.3.5 Does the PROGRAM:		
1. Have a written DOCUMENT CONTROL procedure?		
a. Is the PROGRAM able to demonstrate that all documents are CURRENT AND FIT-FOR-USE through maintaining a master document list or other system?		
b. Does the master document list or other system show:		
i) Documents are reviewed for accuracy?		
ii) Documents are approved for release by authorized personnel and signed/dated with an approval or revision date?		
iii) Documents are distributed to the applicable end user(s) and used at the location where the prescribed activity is performed.		
2. Retain records or procedures required under each standard for the three previous years, or per the PROGRAM'S record retention policy, whichever is longer?		

Assessment completed by:

Name _____ **Date** _____

Appendix 9.2: Self-Assessment Summary Report

PROGRAM _____

This summary report shows the IMPLEMENTATION status of each standard and a brief description of needed improvements. Appendix 9.2 can be used to develop the STRATEGIC IMPROVEMENT PLAN. Standards that are "Incomplete" or "Partial" IMPLEMENTATION must be addressed in the STRATEGIC IMPROVEMENT PLAN.

Instructions for completing the summary report can be found below the form.

Standard	**Self-Assessment**	**IMPLEMENTATION**	**Explain improvements needed for full IMPLEMENTATION** *(required for incomplete self-assessment and partial IMPLEMENTATION)*
1. Regulatory Foundation	Not Started ☐ Complete ☐ Incomplete ☐	Not Started ☐ Full ☐ Partial ☐	
2. Training Program	Not Started ☐ Complete ☐ Incomplete ☐	Not Started ☐ Full ☐ Partial ☐	
3. Inspection Program	Not Started ☐ Complete ☐ Incomplete ☐	Not Started ☐ Full ☐ Partial ☐	
4. Inspection Audit Program	Not Started ☐ Complete ☐ Incomplete ☐	Not Started ☐ Full ☐ Partial ☐	
5. Foodborne Illness, Outbreak, Response	Not Started ☐ Complete ☐ Incomplete ☐	Not Started ☐ Full ☐ Partial ☐	
6. Compliance and Enforcement	Not Started ☐ Complete ☐ Incomplete ☐	Not Started ☐ Full ☐ Partial ☐	

Standard	Self-Assessment	IMPLEMENTATION	**Explain improvements needed for full IMPLEMENTATION** *(required for incomplete self-assessment and partial IMPLEMENTATION)*
7. Outreach Activities	Not Started ☐ Complete ☐ Incomplete ☐	Not Started ☐ Full ☐ Partial ☐	
8. Program Resources	Not Started ☐ Complete ☐ Incomplete ☐	Not Started ☐ Full ☐ Partial ☐	
9. Program Assessment	Not Started ☐ Complete ☐ Incomplete ☐	Not Started ☐ Full ☐ Partial ☐	
10. Laboratory Support	Not Started ☐ Complete ☐ Incomplete ☐	Not Started ☐ Full ☐ Partial ☐	

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

INSTRUCTIONS

Complete Appendix 9.2 and mark each standard, as applicable. Each row has three sections that must be completed. The numbers on the screenshot above correspond to each set of instructions for each section of the appendix below:

Self-Assessment

Not Started – select "Not Started" if you have not initiated work to conduct the appropriate self-assessment worksheets or equivalent forms in each respective standard.

Complete - select "Complete" if you have conducted the appropriate self-assessment worksheets or equivalent forms in each respective standard.

Incomplete - select "Incomplete" if you have started but not completed the appropriate self-assessment worksheets or equivalent forms in each respective standard.

IMPLEMENTATION – Not Started versus Partial versus Full

Check "Not Started" if the PROGRAM has not started IMPLEMENTATION of that standard.

Check "Partial" if the PROGRAM is missing any of the requirements of that standard.

Check "Full" if the PROGRAM has all the required elements listed in the program elements and documentation sections of that standard.

Explain Improvements Needed to Fully Implement Standard

This section is required to be completed when a PROGRAM has an incomplete self-assessment and/or partial IMPLEMENTATION. In this section, describe program elements that need to be developed or modified to achieve "Full" IMPLEMENTATION. For example:

- *No documented process for annual review of regulatory foundation*
- *Continuing education credits are not captured*
- *No documented sampling protocol*
- *Inspection Report Audits are not included in the Quality Assurance Program*
- *The compliance and enforcement program is not applied throughout the state*
- *MOU for food-related illness and outbreak response is in draft form or unsigned*

Appendix 10.1: Self-Assessment Worksheet

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

PROGRAM _____

Program Elements	Yes/No	If No, please explain why the element is not met. Use this space for additional notes.
10.3.1 LABORATORY Support		
Does the PROGRAM:		
1. Have access to a LABORATORY that is capable of analyzing food and environmental samples?		
2. Maintain a list of all analytical services the LABORATORY can provide the PROGRAM?		
3. Have a written agreement with each LABORATORY that includes the components specified in 10.3.1.3.1-10.3.1.3.4?		
10.3.2 LABORATORY Requirements		
1. Does the PROGRAM use a LABORATORY that is accredited by a recognized accreditation body to the ISO/IEC 17025:2017 (or current version)?		
2. If No to Question 1, does the PROGRAM use a LABORATORY that implements and complies with the ISO/IEC 17025:2017 (or current version)?		
2a. If Yes to Question 2, has the LABORATORY provided the PROGRAM a copy of the written LABORATORY quality manual?		
2b. If Yes to Question 2, has the LABORATORY provided the PROGRAM a written attestation that the LABORATORY meets the requirements of ISO/IEC 17025:2017 (or current version)?		

Assessment completed by:

Name _____ **Date** _____