AFRPS

Animal Feed Regulatory Program Standards

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

The collection of information has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

OMB Control No. 0910-0760
Expiration Date: February 29, 2020

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Background

In the United States, Federal and State government agencies ensure the safety of ANIMAL FEED. The Food and Drug Administration (FDA) is responsible for ensuring that all foods and feeds moving in interstate commerce, except those under the United States Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. State agencies are responsible for conducting inspections and regulatory activities that help ensure food and feed produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. State agencies primarily perform inspections under their own regulatory authority. Some State agencies conduct inspections of feed facilities under contract with the FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect ANIMAL FEED. To better facilitate a partnership among regulatory authorities, regulatory programs should be EQUIVALENT IN EFFECT.

Maximizing resources between FDA and the States supports the ongoing work of the Partnership for Food Protection (PFP) to develop an Integrated Food Safety System (IFSS). The FDA and the Association of American Feed Control Officials (AAFCO) are members of the PFP. The vision for an IFSS was developed in 2009[1]. One of the foundational principles of an 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. Prior to 2010, the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) and the Manufactured Food Regulatory Program Standards (MFRPS) were examples of such model standards. However, the VNRFRPS and MFRPS were developed for human food only and did not apply to ANIMAL FEED. As further development on the IFSS progressed, there was a recognized need to develop standards for ANIMAL FEED regulatory programs. One of the key recommendations that came from the 2010 50-State workshop ("A United Approach to Public Health") was the development of standards for ANIMAL FEED regulatory programs. 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.

The Food Safety Modernization Act (FSMA) provides further support for developing Animal Feed Regulatory Program Standards (AFRPS). FSMA was signed into law in January 2011 and calls for enhanced partnerships and integration with Federal, State, local, tribal, and territorial partners. The enhanced partnerships and integration called for by FSMA will allow FDA to rely on inspections and data collected by other agencies to support regulatory activities and further the idea of an IFSS.

In 2011, FDA and AAFCO entered into a partnership to develop the AFRPS and the AFRPS were initially launched in January 2014. These standards are designed to promote uniformity and consistency among ANIMAL FEED regulatory programs. This is consistent with the principles of the FSMA and the fundamental goal of AAFCO and FDA to provide a mechanism for developing and implementing uniform and equitable statutes, regulations, and standards to enhance the protection of the nation's ANIMAL FEED supply.

[1]Link to the current PFP vision documents available at http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/ProgramsInitiatives/PartnershipforFoodProtectionPFP/UCM408081.pdf

Introduction

The Animal Feed Regulatory Program Standards (AFRPS) establish a uniform foundation for the design and management of State PROGRAMS responsible for the regulation of ANIMAL FEED. Through implementing the AFRPS, a State PROGRAM is able to achieve and maintain programmatic improvements that help ensure the safety and integrity of the U.S. ANIMAL FEED supply. IMPLEMENTATION of the AFRPS is voluntary. A State's IMPLEMENTATION of the AFRPS helps ensure a uniform and consistent approach to ANIMAL FEED regulation among jurisdictions including the sharing of information and the coordination of resources.

The AFRPS is composed of eleven standards that serve as an objective framework to evaluate and improve components of a State PROGRAM. The standards cover the State PROGRAM'S REGULATORY FOUNDATION, training, inspection program, auditing, feed-related illnesses or death and emergency response, enforcement program, outreach activities, budget and planning, laboratory services, sampling program, and assessment and improvement of standard IMPLEMENTATION.

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 AFRPS. Program elements and corresponding conditions described as "should" are best practices but are optional and not required to fully implement a standard. To fully implement the AFRPS, the PROGRAM must implement all eleven standards. "Notes" are used throughout the AFRPS to provide clarification, alternatives, and guidance that the State PROGRAM may use to help implement the AFRPS. "Notes" do not contain requirements and thus will not be subject to a FDA verification audit.

Each standard has a self-assessment worksheet. The State 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 standards.

The standards have forms, worksheets, and templates that will help the State PROGRAM assess and meet the program elements in the standard. State PROGRAMS are not obligated to use the forms provided in the AFRPS. Other manual or automated forms, worksheets, and templates may be used as long as the pertinent data elements are present. Records and other documents specified in the standards must be maintained in good order by the State PROGRAM and must be available to verify the information for the purposes of a verification audit. These program standards are not intended to address the performance appraisal processes that a State agency may use to evaluate individual employee performance.

Definitions

Animal Feed: Used to represent the definitions for: (1) food and animal feed in the Federal Food, Drug, and Cosmetic Act (FD&C Act) sections 201(f) and 201(w), (2) for animal food in Title 21 of the Code of Federal Regulations section 507.3 (21 CFR 507.3), and (3) for animal feed in the AAFCO Official Publication (AAFCO OP), and is inclusive of feed (including raw materials and other ingredients) for food-producing animals and pets.

Contact Hour(s): One contact hour equals 60 minutes.

Cross-Sector Event(s): For purposes of this standard, a "cross-sector event" is a feed-related event that impacts human food or an event involving human food that impacts ANIMAL FEED.

Emergency(ies): An unforeseen or sudden occurrence requiring immediate action to protect against substantial risk to animal and/or public health, and that involves the safety, efficacy, and security of ANIMAL FEED supply.

Enforcement Strategies: Plans of action designed to prioritize and achieve enforcement goals and are developed by the State PROGRAM based on critical and chronic violations and violators and contain guidelines for selecting enforcement tools.

Equivalent: State law directly references the relevant FD&C Act provision or Federal regulation.

Equivalent in Effect: State law has the same regulatory effect as the relevant FD&C Act provision or Federal regulation.

Implementation: Means a State PROGRAM has a particular element, system, or program as required in the Program Elements and Documentation sections of the AFRPS; and can demonstrate the use of that particular element, system, or program.

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

Not Equivalent: (1) There is no State law EQUIVALENT to the relevant Federal law or regulation, (2) there is such a State law but it does not apply to the State's PROGRAM, or (3) the Federal and State laws address the same matter but are inconsistent and do not have the same regulatory effect.

Outreach Activity Event: An outreach activity which the State PROGRAM hosts, co-hosts, or is an invited presenter such as seminars, workshops, conferences, trainings, or meetings that relate to feed topics and that support communication and information exchange among feed industry stakeholders, academia, other regulators, or consumers.

Definitions

Program(s): An operational unit(s) in a regulatory agency that is responsible for the regulatory oversight of ANIMAL FEED.

Qualified Field Inspection Auditor: An individual who is recognized by the State's PROGRAM as having field experience and communication skills necessary to audit inspectors/investigators.

Qualified Field Inspection Trainer: An individual who is recognized by the State's PROGRAM as having field experience and communication skills necessary to train inspectors/investigators.

Regulatory Foundation: The laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of an ANIMAL FEED facility.

Regulatory Testing Laboratory(ies): A laboratory that conducts measurements and analyses on food or feed and associated physical samples, which result in qualitative or quantitative analytical findings that may be used as a basis for regulatory action.

Start Date: Date employee is hired or reassigned in or into the ANIMAL FEED PROGRAM as the beginning date for training timelines.

STANDARD 1
Regulatory Foundation

1.1 Purpose

This standard describes the elements of the REGULATORY FOUNDATION used by a State PROGRAM to regulate ANIMAL FEED.

1.2 Requirement Summary

The State PROGRAM evaluates the scope of its legal authority and regulatory provisions to perform inspections and investigations, gather evidence, collect samples, and take regulatory actions under State law to ensure the safety and security of ANIMAL FEED.

The State PROGRAM 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 Federal regulations specified in appendix 1.2.

1.3 Program Elements

1.3.1 The State PROGRAM conducts an evaluation to determine whether the State's legal authority and regulatory provisions are EQUIVALENT, EQUIVALENT IN EFFECT, or NOT EQUIVALENT to the sections of the FD&C Act and Federal regulations specified in appendix 1.2.

1.3.1.1 "EQUIVALENT" means that the State law directly references the relevant FD&C Act provision or Federal regulation. For State law found EQUIVALENT, the State PROGRAM:

1.3.1.1.1 Specifies the Federal statute or regulation that is incorporated into the State law;
1.3.1.1.2 Includes the revision date of the State statutory provision or regulation as appropriate;
1.3.1.1.3 Identifies the date the Federal statutory provision or regulation was incorporated into the State law.

Note: In conducting such an evaluation, the State PROGRAM should consult with its 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.

STANDARD 1
Regulatory Foundation

Note: "EQUIVALENT IN EFFECT" means that the State law has the same regulatory effect as the relevant FD&C Act provision or Federal regulation. A State law may have the same regulatory effect as the Federal law or regulation if either a single State law or rule has the same regulatory effect as the Federal law or regulation, or when multiple laws of that State are combined and deemed EQUIVALENT IN EFFECT to a single Federal law or regulation.

Note: "NOT EQUIVALENT" means there is no State law EQUIVALENT to the relevant Federal law or regulation, there is such a State law but it does not apply to the State's PROGRAM, or the Federal and State laws address the same matter but are inconsistent and do not have the same regulatory effect. For provisions found to be "NOT EQUIVALENT", the State PROGRAM should identify which State agency has authority and jurisdiction over said provisions, if there is one, in appendix 1.2.

Note: In addition, if the State has laws and regulations pertinent to the regulation of ANIMAL FEED for which there are no comparable Federal provisions, these laws can be listed in appendix 1.2.

1.3.2 The State PROGRAM has a documented process, which includes:

1.3.2.1 Procedures to review the statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that:

1.3.2.1.1 Apply to the regulation of ANIMAL FEED;
1.3.2.1.2 Delegate authority to the State agency;
1.3.2.1.3 Describe the State agency's administrative procedures for establishing its authority and incorporating rules by reference.

1.3.2.2 Timeframes for the review.

1.4 Outcome

The State PROGRAM has conducted an evaluation of the scope of their legal authority and has a REGULATORY FOUNDATION adequate to protect the public health by ensuring the safety and security of ANIMAL FEED.

1.5 Documentation

The State PROGRAM maintains the records listed here.

1.5.1 Appendix 1.1: Self-Assessment Worksheet
1.5.2 Appendix 1.2: REGULATORY FOUNDATION Worksheet

STANDARD 1
Regulatory Foundation

1.5.3 Documented process for reviewing appropriate statutes, regulations, rules, ordinances, and other prevailing regulatory requirements

1.5.4 The statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that: (1) apply to the regulation of ANIMAL FEED, (2) delegate authority to the State agency, and (3) describe the State agency's administrative procedures for establishing its authority and incorporating rules by reference

STANDARD 2
Training

2.1 Purpose

This standard describes the elements of training for inspectors in a State PROGRAM to ensure they will have the knowledge, skills, and abilities to competently inspect feed facilities, conduct investigations, gather evidence, collect samples, and take enforcement actions.

2.2 Requirement Summary

The State PROGRAM has a training plan that ensures all inspectors are adequately trained to perform their work.

2.3 Program Elements

2.3.1 Training Plan and Training Records

2.3.1.1 The State PROGRAM uses a written training plan that ensures all inspectors receive training required to adequately perform their work assignments. The training plan includes course curriculum for basic and advanced inspection training and continuing education.

2.3.1.2 The State PROGRAM provides, or otherwise makes available, inspection training and continuing education for all inspectors.

2.3.1.3 For inspectors that conduct limited scope inspections, as defined by the State PROGRAM, (e.g. such as only collecting samples or inspections at veterinary clinics), the State PROGRAM specifies the curriculum required by the limited scope inspectors in their documented training plan.

Note: Curriculum includes coursework and field training.

2.3.1.4 The State PROGRAM maintains records documenting the training completed by all inspectors using appendix 2.2 or a comparable form.

2.3.1.5 For inspectors with greater than five years of experience at the date of the initial self-assessment, where such documentation is not available, the State PROGRAM conducts an evaluation of the inspector's previous performance and experience to determine if the inspector has completed the required training or whether additional training is needed.

2.3.1.6 If previous coursework is completed before the inspectors START DATE and utilized to meet coursework requirements, proper supporting documents are maintained to verify successful completion of the requirement.

STANDARD 2
Training

2.3.2 Basic Feed Inspector Training

2.3.2.1 Timeframe: The State PROGRAM requires a basic inspector to successfully complete the basic coursework and field training within 24 months from the START DATE.

2.3.2.2 Coursework: The basic feed inspection training consists of coursework in the following subject areas:

2.3.2.2.1 Animal and Public Health Principles: Fundamental animal and public health protection principles that support the foundational roles of the feed inspector.

2.3.2.2.2 Basic Animal Nutrition: Basic means of digestion and nutritional requirements for various animal classes and ingredients that can cause toxicity.

2.3.2.2.3 Basic Feed Ingredients, Processing, and Technology: Typical ingredients, feedstuffs, processing methods, and technologies commonly used to manufacture ANIMAL FEED.

2.3.2.2.4 Basic National Incident Management System and Incident Command System (ICS): Introduction to the history, principals, and organizational structure of the ICS via ICS100, ICS200, IS700, and IS800.

2.3.2.2.5 Communication: Techniques and skills for effective oral and written communication and interviewing.

2.3.2.2.6 Current Statutes, Regulations, and Policies: Basic knowledge of Federal and State laws, regulations, and policies.

2.3.2.2.7 Feed Defense: Feed defense principles for the protection of feed from intentional hazard contamination.

2.3.2.2.8 Inspections, Compliance, and Enforcement: Conduct inspections applying the relevant laws and regulations to gather and document evidence to support possible regulatory actions.

2.3.2.2.9 Labeling: Basic feed labeling requirements.

2.3.2.2.10 Professionalism: Character conduct, strengths, and values directed toward providing high quality service to the regulated industry and the State PROGRAM.

2.3.2.2.11 Risk Awareness: Basic principles of BSE; medicated feeds including VFDs; and physical, chemical, and biological contaminants.

2.3.2.2.12 Safety: Appropriate personal safety and bio-security requirements when conducting field activities.

2.3.2.2.13 Sampling: Techniques and skills for collecting various types of samples using the appropriate methods for preparation, collection, and shipping.

2.3.2.3 Field training: The State PROGRAM has established basic field training to complement the basic coursework. The basic field training specifies the following:

2.3.2.3.1 Field training checklist of competencies to be mastered and verified in the field by the QUALIFIED FIELD INSPECTION TRAINER;
2.3.2.3.2 Documented procedures for JOINT FIELD TRAINING INSPECTIONS;
2.3.2.3.3 Number of JOINT FIELD TRAINING INSPECTIONS that are conducted in firms that represent the feed facilities in the State PROGRAM inventory and the type of routine or basic work that will be performed by the inspector;
2.3.2.3.4 The inspector completes basic field training prior to performing independent inspections;
2.3.2.3.5 Appendix 2.3 or a comparable form must be used to list the competencies and the minimum number of JOINT FIELD TRAINING INSPECTIONS.

2.3.3 Advanced Feed Inspector Training

2.3.3.1 Timeframe: The State PROGRAM requires each inspector who conducts advanced feed inspections to successfully complete the advanced inspector coursework and field training within 60 months from the START DATE.
2.3.3.2 Coursework: The advanced feed inspection training consists of coursework in the following subject areas:

2.3.3.2.1 Advanced Feed Ingredients, Processing, and Technology: Ingredients, feedstuffs, processing methods, and technologies that are complex or less common and explore the major elements of modern feed manufacturing and advances in feed technology.
2.3.3.2.2 Advanced Labeling: Knowledge and application of ANIMAL FEED labeling requirements (i.e. medicated feed and pet food labeling requirements).
2.3.3.2.3 Animal Sickness and Death Investigation: Principles of outbreak investigations.
2.3.3.2.4 Current Statutes, Regulations, and Policies: Federal and State laws, regulations, and policies for advanced feed inspections.
2.3.3.2.5 Epidemiology: Acquire basic knowledge of epidemiology principles and concepts and apply them to animal outbreak investigations
2.3.3.2.6 Microbiological Pathogens: Microbial hazards in feed that could lead to animal or human illnesses or death.
2.3.3.2.7 Traceback and Traceforward Investigations: Traceback and traceforward of an implicated product and steps for conducting and concluding the investigation and reporting the results.

2.3.3.3 Specialized Curriculum: Inspectors who assist in emergency response or conduct specialized inspections listed below must complete relevant specialized coursework specific to the type of specialized inspections that they will be performing in the following subject areas.

2.3.3.3.1 Advanced National Incident Management System and Incident Command Systems (ICS).

Note: Courses should be specific to the individual's responsibilities but include at a minimum ICS300 and ICS400.

2.3.3.3.2 BSE and Ruminant Feeding Ban: Complete coursework required to conduct inspections of rendering facilities and feed manufactures under the ruminant feed ban regulations, 21 CFR 589.2000 and 21 CFR 589.2001, that prohibit certain cattle materials from being included in any ANIMAL FEED.

2.3.3.3.3 Medicated Feed Good Manufacturing Practices Regulations: Complete coursework required to conduct inspections and differentiate between the regulations that apply to FDA-licensed medicated feed mills and unlicensed medicated feed mills, and the requirements under 21 CFR part 225 Current Good Manufacturing Practice for Medicated Feeds, and 21 CFR part 226 Current Good Manufacturing Practice for Type A Medicated Articles.

2.3.3.4 Field training: The State PROGRAM has established advanced field training to complement the advanced coursework. The advanced field training specifies the following:

2.3.3.4.1 Field training checklist of competencies to be mastered and verified in the field by the QUALIFIED FIELD INSPECTION TRAINER;

2.3.3.4.2 Documented procedures for JOINT FIELD TRAINING INSPECTIONS;

2.3.3.4.3 Number of JOINT FIELD TRAINING INSPECTIONS that are conducted in firms that represent the feed facilities in the State PROGRAM inventory and the type of advanced work that will be performed by the inspector

2.3.3.4.4 The inspector completes field training prior to performing independent inspections requiring advanced skills;

2.3.3.4.5 Appendix 2.3 or a comparable form must be used to list the competencies and the minimum number of JOINT FIELD TRAINING INSPECTIONS.

2.3.6 Continuing Education (CE): The State PROGRAM requires that each basic and advanced inspector participate in continuing education.

2.3.6.1 Each inspector is required to receive 20 CONTACT HOURS of continuing education every 36 months.

2.3.6.2 The 36 month continuing education interval starts, as defined by the State PROGRAM, when the required curriculum is complete.

Note: The inspector may accrue one CONTACT HOUR for each clock hour of participation in any of the following training sources: in-house training provided by a government agency; distance learning, for example, satellite downlinks or web-based training, or feed-related courses provided by colleges, schools, associations, and research centers.

Note: Of the accumulated 20 CONTACT HOURS of continuing education, a maximum of ten (10) CONTACT HOURS may be accrued from the following activities: attendance at professional seminars, symposiums, or technical conferences and workshops; delivery of presentations at professional conferences; providing classroom or field training to new hires; being a course instructor in feed safety; or publishing an original article in a peer-reviewed professional or trade association journal, periodical, or publication.

2.3.6.3 Documentation must accompany each activity submitted for continuing education credit.

Note: Examples of acceptable documentation may include: certificates of completion including the course dates(s) and number of hours attended or CE credits granted; transcripts from a college or university; a letter from the administrator of the continuing education program attended; a copy of the peer-reviewed article or presentation made at a professional conference; documentation to verify technical publications related to feed 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; an agenda and attendance roster; or documentation approved by the QUALIFIED FIELD INSPECTION TRAINER.

2.4 Outcome

The State PROGRAM has trained inspectors with the knowledge, skills, and abilities to competently inspect feed facilities and conduct investigations, gather evidence, collect samples, and take enforcement actions with ANIMAL FEED facilities.

STANDARD 2
Training

2.5 Documentation

The State PROGRAM maintains the records listed here.

2.5.1 Appendix 2.1: Self-Assessment Worksheet
2.5.2 Training Plan
2.5.3 Appendix 2.2: Inspector Training Record
2.5.4 Appendix 2.3: Field Training Competencies
2.5.5 Documents verifying successful completion of required courses
2.5.6 Documentation for continuing education credit

STANDARD 3
Inspection Program

3.1 Purpose

This standard describes the elements of an effective ANIMAL FEED inspection program.

3.2 Requirement Summary

The State PROGRAM administers an inspection program to determine compliance with ANIMAL FEED laws.

3.3 Program Elements

3.3.1 Risk-Based Inspection Program

3.3.1.1 The State PROGRAM has documented procedures to:

3.3.1.1.1 Define an up-to-date inventory of feed facilities whose activities fall under the State's jurisdiction and authority;
3.3.1.1.2 Maintain the inventory of feed facilities defined in 3.3.1.1.1.

3.3.1.2 The State PROGRAM has documented procedures for defining risk categories. The three minimum required factors for defining risk categories are:

3.3.1.2.1 Types of feed and feed products;
3.3.1.2.2 Types of processing;
3.3.1.2.3 Compliance history of the facility.

3.3.1.3 The State PROGRAM is required to use a minimum of the three factors in 3.3.1.2 to assign risk categories to feed facilities.

3.3.1.4 Based on risk factors assigned to a facility or product, the manufacturing processes, and the compliance history of the facility, inspections:

3.3.1.4.1 Are prioritized;
3.3.1.4.2 Have assigned frequencies;
3.3.1.4.3 Have resources allocated.

Note: The State PROGRAM should also consider optional risk factors, such as volume of feed and feed products manufactured, scope of distribution, and other factors unique to the State's industries and practices. Appendix 3.2 provides additional information about required and optional risk factors and risk categories.

STANDARD 3
Inspection Program

3.3.2 Inspection Protocol

3.3.2.1 The State PROGRAM has documented policies and procedures for inspecting ANIMAL FEED facilities that require the inspectors to:

3.3.2.1.1 Review the feed facility's previous inspection report(s) and complaint(s);
3.3.2.1.2 Present appropriate credentials and written Notice of Inspection to the feed facility's owner, operator, or agent in charge; make appropriate introductions; explain the purpose and scope of the inspection; and determine inspection authority;
3.3.2.1.3 Follow the safety protocols required by the feed facility and the State PROGRAM;
3.3.2.1.4 Follow the biosecurity protocols required by the feed facility and the State PROGRAM;
3.3.2.1.5 Use appropriate equipment and forms needed to conduct inspections;
3.3.2.1.6 Establish interstate jurisdiction for FDA inspections, if applicable;
3.3.2.1.7 Recognize the relative risk (high to low) of feed facilities based on the State PROGRAM'S risk-based inspection program and categorization assigned to a facility or product, the manufacturing processes, and the inspection history of the facility;
3.3.2.1.8 Conduct inspection activities, appropriate for the level of risk, focused on those firms, products, and processes determined to be high risk;
3.3.2.1.9 Assess employee activities critical to the safe manufacture, distribution, storage, handling, and disposition of feed;
3.3.2.1.10 Properly evaluate the likelihood that conditions, practices, processes, components, or labeling could cause the product to become adulterated or misbranded;
3.3.2.1.11 Recognize significant non-compliant conditions or practices and document findings consistent with PROGRAM procedures;
3.3.2.1.12 Distinguish between significant and insignificant observations and isolated incidents versus trends;
3.3.2.1.13 Review and evaluate the appropriate ANIMAL FEED facility records and procedures and verify that the procedures are being followed;
3.3.2.1.14 Collect adequate evidence and documentation to support inspection observations in accordance with PROGRAM procedures;
3.3.2.1.15 Verify correction of deficiencies identified during the previous inspection(s);
3.3.2.1.16 Conduct activities in a professional manner;
3.3.2.1.17 Use effective interviewing techniques;
3.3.2.1.18 Explain findings clearly and adequately throughout the inspection;

3.3.2.1.19 Alert the feed facility's owner, operator, or agent in charge when an immediate corrective action is necessary;
3.3.2.1.20 Document findings accurately, clearly, legibly, and concisely on the applicable form(s) and provide a copy to the feed facility's owner, operator, or agent in charge;
3.3.2.1.21 Answer questions and provide information as appropriate;
3.3.2.1.22 Submit inspection report, sample(s), and supporting documents to headquarters or supervisor in a timely manner.

3.3.3 Recall System

3.3.3.1 The State PROGRAM has a documented recall system. The recall system includes:

3.3.3.1.1 Written procedures for:
3.3.3.1.1.1 Receiving
3.3.3.1.1.2 Tracking
3.3.3.1.1.3 Evaluating recall notifications
3.3.3.1.1.4 Closing
3.3.3.1.1.5 Maintaining records
3.3.3.1.2 Performing recall effectiveness checks

3.3.4 Consumer Complaints

3.3.4.1 The State PROGRAM has a documented system for handling consumer complaints. The system includes procedures for:

3.3.4.1.1 Receiving
3.3.4.1.2 Tracking
3.3.4.1.3 Evaluating
3.3.4.1.4 Answering
3.3.4.1.5 Closing
3.3.4.1.6 Maintaining records

3.3.5 Complaints Resulting from State PROGRAM Inspection Activities

3.3.5.1 The State PROGRAM has a documented system to handle complaints from industry about State PROGRAM inspections. The system includes procedures for:

3.3.5.1.1 Receiving
3.3.5.1.2 Evaluating
3.3.5.1.3 Maintaining records

STANDARD 3
Inspection Program

3.4 Outcome

The State PROGRAM has an ANIMAL FEED inspection program that may prevent the occurrence of feed adulteration or misbranding by focusing inspection resources on high risk facilities, products, processes, and facilities with a poor compliance history; obtaining immediate corrective actions and long-term compliance improvement; and preventing distribution of ANIMAL FEED that may be adulterated or misbranded.

3.5 Documentation

The State PROGRAM maintains the records listed here.

3.5.1 Appendix 3.1: Self-Assessment Worksheet
3.5.2 Documented procedures for defining the State's inventory of feed facilities
3.5.3 Documented procedures for updating the State's inventory of feed facilities
3.5.4 An inventory of feed facilities
3.5.5 Documented procedures used for categorizing feed facilities based on risk, including the inspection frequency assigned to each defined risk-based category
3.5.6 Documented policies and procedures for inspecting feed facilities
3.5.7 Documented recall system, which includes written recall procedures
3.5.8 Documented procedures for consumer complaints
3.5.9 Documented procedures for industry complaints about State PROGRAM inspection activities

STANDARD 4
Auditing

4.1 Purpose

This standard describes the auditing procedures necessary to: (1) evaluate the effectiveness of inspections and sample collections, (2) recognize trends in the inspection and sampling programs, and (3) identify areas in need of corrective actions.

4.2 Requirement Summary

The State PROGRAM conducts audits to document and evaluate the effectiveness of the PROGRAM'S inspections and sample collections. Auditing has two components: (1) a field audit component, which is an on-site performance evaluation of inspection and sample collection to verify they are consistently performed according to established performance factors and (2) a desk audit component, which is a performance review of the inspection and sample collection reports to verify the content quality and that a report was processed according to established performance factors.

4.3 Program Elements

4.3.1 The State PROGRAM has written procedures for conducting four types of audits:

4.3.1.1 Field inspection audits as specified in 4.3.3;
4.3.1.2 Field inspection report audits as specified in 4.3.4;
4.3.1.3 Sample collection audits as specified in 4.3.5;
4.3.1.4 Sample collection report audits as specified in 4.3.6.

Note: In general, each type of audit is composed of multiple performance factors. The performance factors are evaluated during an audit and then used to calculate an individual's audit score. The audit score determines the audit rating, which is recorded as "acceptable" or "needs improvement". Using all of the individual audits, the State PROGRAM calculates a performance factor score for each performance factor and a cumulative score for each type of audit. The State PROGRAM uses the audit scores, performance factor scores, and calculated scores to recognize trends in the field inspection and sample collection programs. The trends are used to identify specific areas that need improvement, and to take corrective action to improve areas.

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: The State PROGRAM conducts field inspection audits using a QUALIFIED FIELD INSPECTION AUDITOR to verify that inspections are consistently performed according to the State's written procedures.

STANDARD 4
Auditing

4.3.3.1 Frequency: A minimum of two field inspection audits of each inspector is conducted every 36 months. The inspections selected for audits must reflect the inspector's assignments and responsibilities.

4.3.3.2 Performance Factors: At a minimum, performance factors described in the inspection protocol within Standard 3: Inspection Program, and as listed in appendix 4.2, or comparable form, are evaluated.

Note: For each performance factor, examples of actions and observations that would likely result in a "needs improvement" rating are provided in appendix 4.2a.

4.3.3.3 Performance Documentation:

4.3.3.3.1 Appendix 4.2, or comparable form, is used to record the rating of each performance factor, audit score, and audit rating for each field inspection audit;

4.3.3.3.2 Appendix 4.3, or comparable worksheet, is used to calculate performance factor scores and a cumulative score for the State PROGRAM.

Note: Directions for calculating performance factor scores and the cumulative score can be found in appendix 4.4.

4.3.4 Field Inspection Report Audit: The State PROGRAM conducts periodic field inspection report audits to verify that inspectional findings are obtained and reported according to the State's written procedures.

4.3.4.1 The State PROGRAM will review a random selection of field inspection reports to be audited based on the number of inspections completed during a 12 month period of performance using the table below:

Number of Inspections in 12 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 reports	5% of reports	50

4.3.4.2 Performance Factors: At a minimum, the performance factors listed in appendix 4.5, or comparable form, are evaluated.

4.3.4.3 Performance Documentation:

4.3.4.3.1 Appendix 4.5, or comparable form, is used to record the rating of each performance factor, audit score, and audit rating for each inspection report audit;

4.3.4.3.2 Appendix 4.6, or comparable worksheet, is used to calculate performance factor scores and a cumulative score for the State PROGRAM.

Note: Directions for calculating performance factor scores and the cumulative score can be found in appendix 4.4.

4.3.5 Sample Collection Audit: The State PROGRAM conducts sample collection audits using a QUALIFIED FIELD INSPECTION AUDITOR to verify that sample collections are consistently performed according to the State's written procedures.

4.3.5.1 Frequency: A minimum of two sample collection audits of each inspector is conducted every 36 months. The sample collections selected for audits must reflect the inspector's assignments and responsibilities.

4.3.5.2 Performance Factors: At a minimum, performance factors listed in the sampling protocol described within Standard 11, Sampling Program and listed in appendix 4.7 are evaluated.

Note: For each performance factor, examples of actions and observations that would likely result in a "needs improvement" rating are provided in appendix 4.7a.

4.3.5.3 Performance Documentation:

4.3.5.3.1 Appendix 4.7, or comparable form, is used to record the rating of each performance factor, audit score, and audit rating for each sample collection audit;

4.3.5.3.2 Appendix 4.8, or comparable worksheet, is used to calculate performance factor scores and a cumulative score for the State PROGRAM.

Note: Directions for calculating performance factor scores and the cumulative score can be found in appendix 4.4.

4.3.6 Sample Collection Report Audit: The State PROGRAM conducts periodic sample collection report audits to verify that sample collection documentation is consistently performed according to the State's written procedures.

4.3.6.1 The State PROGRAM will review a random selection of sample collection reports audited based on the number of samples collected during a 12 month period of performance based using the table below:

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

4.3.6.2 Performance Factors: At a minimum, the performance factors listed in appendix 4.9, or comparable form, are evaluated.

4.3.6.3 Performance Documentation:

4.3.6.3.1 Appendix 4.9, or comparable form, is used to record the rating of each performance factor, audit score, and audit rating for each sample collection report audit;

4.3.6.3.2 Appendix 4.10, or comparable worksheet, is used to calculate performance factor scores and a cumulative score for the State PROGRAM.

Note: Directions for calculating performance factor scores and the cumulative score can be found in appendix 4.4.

4.3.7 Corrective Action Plan: The State PROGRAM has a written corrective action plan using appendix 4.11, or comparable form, if any of the following occur for any type of audit.

4.3.7.1 An inspector receives an overall audit rating of “needs improvement” (audit score below 80 percent) for an individual audit.

4.3.7.2 A State PROGRAM has a performance factor score (as a result of all audits over 12 months) below 80 percent for a single performance factor.

4.3.7.3 A State PROGRAM has a cumulative score (as a result of all audits over 12 months) below 80 percent.

4.4 Outcome

The State PROGRAM’S evaluation of its inspection and sample collection activities ensures that they are adequate, complete, and that corrective actions are implemented when necessary.

STANDARD 4
Auditing

4.5 Documentation

The State PROGRAM maintains the records listed here.

4.5.1 Appendix 4.1: Self-Assessment Worksheet
4.5.2 Written procedures for conducting four types of audits
4.5.3 Appendix 4.2: Field Inspection Audit Form
4.5.4 Appendix 4.3: Field Inspection Audit Worksheet
4.5.5 Appendix 4.5: Field Inspection Report Audit Form
4.5.6 Appendix 4.6: Field Inspection Report Audit Worksheet
4.5.7 Appendix 4.7: Sample Collection Audit Form
4.5.8 Appendix 4.8: Sample Collection Audit Worksheet
4.5.9 Appendix 4.9: Sample Collection Report Audit Form
4.5.10 Appendix 4.10: Sample Collection Report Audit Worksheet
4.5.11 Appendix 4.11: Corrective Action Plan

STANDARD 5
Feed-Related Illnesses or Death and Emergency Response

5.1 Purpose

This standard describes the functions to detect, identify, and respond to alleged feed-related illnesses, deaths, and EMERGENCIES, including coordinating roles and responsibilities with other jurisdictions and communicating with appropriate parties.

5.2 Requirement Summary

The State PROGRAM has a system to conduct emergency response to feed-related illnesses, deaths, and EMERGENCIES.

5.3 Program Elements

5.3.1 The State PROGRAM has written procedures to gather information to identify incidents of feed-related illnesses, deaths, and EMERGENCIES.

5.3.2 The State PROGRAM has written procedures to communicate with the appropriate State agencies or departments that investigate animal illnesses and food-related illnesses and outbreak.

Note: These procedures facilitate sharing of information to identify potential feed-related illnesses, deaths, EMERGENCIES, and CROSS-SECTOR EVENTS.

5.3.3 For feed-related illnesses, deaths, and EMERGENCIES, the State PROGRAM has a written procedure with criteria to:

5.3.3.1 Determine the appropriate response
5.3.3.2 Initiate the response
5.3.3.3 Complete the response

5.3.4 For feed-related EMERGENCIES, the State PROGRAM manages the event using:

5.3.4.1 A formalized Incident Command System structure or
5.3.4.2 An official action plan[2] that includes:

5.3.4.2.1 Outlining containment
5.3.4.2.2 Communication
5.3.4.2.3 Control
5.3.4.2.4 Correction
5.3.4.2.5 After-action protocols

[2]An example of an official action plan can be found in the AAFCO Emergency Response Preparedness Guidance Document (AAFCO Official Publication).

STANDARD 5
Feed-Related Illnesses or Death and Emergency Response

5.3.5 The State PROGRAM maintains a list of relevant agencies and emergency contacts.

5.3.5.1 The list is reviewed and updated based on the State defined frequency.

Note: Appendix 5.2 provides a template for an emergency contact list.

5.3.6 The State PROGRAM establishes written procedures to rapidly notify government agencies, departments, or appropriate parties of relevant findings.

5.3.7 The State PROGRAM has a written procedure to immediately notify law enforcement agencies when intentional feed contamination or feed-related terrorism is suspected or threatened.

5.3.8 The State PROGRAM has a written procedure for:

5.3.8.1 Releasing information to the public;
5.3.8.2 Coordinating media information with other jurisdictions to reduce the impact of feed-related illnesses, deaths, or EMERGENCIES.

5.4 Outcome

The State PROGRAM has written procedures for documenting and investigating feed-related illnesses, deaths, and EMERGENCIES within the PROGRAM'S authority. The State PROGRAM has established communication pathways with government agencies, departments, or appropriate parties to gather and share information to reduce feed-related illnesses, deaths, or EMERGENCIES.

5.5 Documentation

The State PROGRAM maintains the records listed here.

5.5.1 Appendix 5.1: Self-Assessment Worksheet
5.5.2 Documented written procedure to gather information to identify incidents of feed-related illnesses, deaths, and EMERGENCIES
5.5.3 Documented procedure to communicate with Agency/Departments
5.5.4 Documented written procedure to determine the appropriate response, initiate the response, and complete the response for feed-related illnesses, deaths, and EMERGENCIES
5.5.5 Documented written procedures using a formalized Incident Command System structure or an official action plan
5.5.6 Emergency contact list
5.5.7 Documented written procedures to rapidly notify government agencies, departments, or appropriate parties of relevant findings

STANDARD 5
Feed-Related Illnesses or Death and Emergency Response

5.5.8 Documented written procedure to immediately notify law enforcement agencies when intentional feed contamination or feed-related terrorism is suspected or threatened

5.5.9 Documented procedure for releasing information to the public and coordinating media information with other jurisdictions

STANDARD 6
Enforcement Program

6.1 Purpose

This standard describes the elements of an effective enforcement program.

6.2 Requirement Summary

The State PROGRAM has documented ENFORCEMENT STRATEGIES. An annual evaluation of the ENFORCEMENT STRATEGIES is conducted to identify potential improvements or modifications.

6.3 Program Elements

6.3.1 The State PROGRAM has an enforcement program that contains documented ENFORCEMENT STRATEGIES.

6.3.2 The State PROGRAM must use the following six factors listed when selecting an appropriate enforcement tool:

6.3.2.1 Compliance history
6.3.2.2 Responsiveness
6.3.2.3 Scope
6.3.2.4 Nature of the Violation
6.3.2.5 Impact of the Violation
6.3.2.6 Resources

Note: Appendix 6.2 provides examples of common enforcement tools. When selecting enforcement tools, the State PROGRAM may consider other factors in addition to the ones listed above.

6.3.3 The State PROGRAM has a documented written description for all factors.

6.3.4 The State PROGRAM has documented relative conditions for all factors.

6.3.4.1 Relative conditions of each factor will be assigned a numerical weight.

Note: Appendix 6.3 is an example of factor descriptions, relative conditions, and the associated numerical weights.

6.3.5 The State PROGRAM has a documented enforcement matrix designed to incorporate the relative conditions of each factor and the application of enforcement tools.

Note: Appendix 6.4 is an example enforcement matrix.

6.3.6 The State PROGRAM has a documented process for conducting the annual evaluation described in 6.3.7.

6.3.7 The State PROGRAM conducts an annual evaluation of its ENFORCEMENT STRATEGIES to:

6.3.7.1 Determine if the PROGRAM'S ENFORCEMENT STRATEGIES were successful in achieving compliance;
6.3.7.2 Identify potential improvements or modifications of the ENFORCEMENT STRATEGIES, if any;
6.3.7.3 Determine if the enforcement priorities remain the same or require modification.

6.4 Outcome

The State PROGRAM has an effective enforcement program with documented ENFORCEMENT STRATEGIES that identify a means to appropriately select and apply enforcement tools. An annual evaluation of the enforcement program is conducted to identify potential improvements or modifications.

6.5 Documentation

The State PROGRAM maintains the records listed here.

6.5.1 Appendix 6.1: Self-Assessment Worksheet
6.5.2 Documented ENFORCEMENT STRATEGIES
6.5.3 Documented factors including the description, relative conditions, and associated numerical weight for each
6.5.4 Enforcement matrix
6.5.5 Documented process for conducting an evaluation of the ENFORCEMENT STRATEGIES
6.5.6 Documented annual evaluation of the ENFORCEMENT STRATEGIES

STANDARD 7
Outreach Activities

7.1 Purpose

This standard describes the elements of outreach activities developed and provided by the State PROGRAM.

7.2 Requirement Summary

The State PROGRAM conducts or participates in outreach activities and OUTREACH ACTIVITY EVENTS to inform ANIMAL FEED industry stakeholders, academia, other regulators, or consumers about ANIMAL FEED topics.

7.3 Program Elements

7.3.1 The State PROGRAM identifies the methods that will be used for outreach activities to inform ANIMAL FEED industry stakeholders, academia, other regulators, or consumers.

7.3.2 The State PROGRAM develops an outreach plan that supports the State PROGRAM mission and includes:

7.3.2.1 Objectives of an outreach plan
7.3.2.2 Target populations
7.3.2.3 The types of outreach activities (including OUTREACH ACTIVITY EVENTS)

Note: The content and design of the plan will vary depending on the State PROGRAM priorities and mission.

7.3.3 The templates provided in appendix 7.2, or comparable form, is used to record:

7.3.3.1 Objectives of an outreach plan
7.3.3.2 Target populations
7.3.3.3 The types of activities (including OUTREACH ACTIVITY EVENTS)

7.3.4 The State PROGRAM documents and evaluates OUTREACH ACTIVITY EVENTS. Appendix 7.3, or comparable form, is used to document and evaluate OUTREACH ACTIVITY EVENTS.

7.4 Outcome

The State PROGRAM uses outreach activities to inform ANIMAL FEED industry stakeholders, academia, other regulators or consumers about ANIMAL FEED topics.

STANDARD 7
Outreach Activities

7.5 Documentation

The State PROGRAM maintains the records listed here.

7.5.1 Appendix 7.1: Self-Assessment Worksheet
7.5.2 Outreach plan
7.5.3 OUTREACH ACTIVITY EVENTS overview and evaluation
7.5.4 Documents to verify the OUTREACH ACTIVITY EVENTS occurred

STANDARD 8
Planning and Resources

8.1 Purpose

This standard describes the elements of workplanning and resource evaluation used by a State PROGRAM.

8.2 Requirement Summary

A State PROGRAM is required to have a documented workplan to support its inspection and sample collection programs.

A State PROGRAM is required to conduct an evaluation of resource needs for completing the inspection and sample collection projections identified by the workplan and additional work conducted by the PROGRAM.

A State PROGRAM is required to conduct an evaluation of the resources needed to fully implement the Animal Feed Regulatory Program Standards (AFRPS).

8.3 Program Elements

8.3.1 The State PROGRAM has a documented workplan. The workplan must include:

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 facility or product
8.3.1.1.4 Frequency

8.3.1.2 Sample plan

8.3.1.2.1 Number of samples
8.3.1.2.2 Type of samples

8.3.1.3 Timeframe that the workplan is applicable.

8.3.2 The State PROGRAM has a documented procedure for evaluating the workplan that includes:

8.3.2.1 Conducting periodic and annual evaluations of the workplan;
8.3.2.2 Evaluating alignment with PROGRAM objectives and resources.

Note: FDA and the State PROGRAM may meet periodically and develop a coordinated workplan.

STANDARD 8
Planning and Resources

8.3.3 The State PROGRAM has a documented procedure for identifying and reviewing its resources to accomplish the workplan within the applicable timeframe.

Note: The resource review should include staffing, equipment, and funding needed to support the inspection and sample collection activities identified in the workplan.

Note: The resources needed to train and audit field staff, to support laboratory services, compliance, education and outreach, and to respond to feed-related illnesses, deaths, or EMERGENCIES should be determined by the State PROGRAM. The administrative functions needed to support all PROGRAM areas should be considered when determining PROGRAM resources.

8.3.4 To validate the workplan, the State PROGRAM develops a formula that:

8.3.4.1 Calculates the number of staff needed to conduct inspections of its ANIMAL FEED inventory;
8.3.4.2 Calculates the number of staff needed to conduct sample collections;
8.3.4.3 Uses numerical values that are based on the State PROGRAM'S data;
8.3.4.4 Must be used by the State PROGRAM.

Note: The State PROGRAM should have adequate staff to inspect the State PROGRAMS ANIMAL FEED inventory and to conduct sample collections, which could include ANIMAL FEED facilities and retail establishments, based on risk categorization and inspection frequency established by the PROGRAM in its workplan.

Note: Appendix 8.2 provides example formulas that can be used as a baseline for a State PROGRAM'S workplan. The formulas in appendix 8.2 <u>do not include methods for estimating staff numbers needed for sample collections, compliance activities, administrative, or other programmatic activities.</u>

8.3.5 The inspection and sample collection staff must have the equipment needed to conduct inspections and sample collections.

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

8.3.6.1 Established by the State PROGRAM
8.3.6.2 Maintained by the State PROGRAM

Note: Appendix 8.3 provides an example list of equipment that may be used for inspections and sample collections.

STANDARD 8
Planning and Resources

8.3.7 The State PROGRAM must conduct a review of the resources required to fully implement the AFRPS, including each of the program elements in the individual standards. The review recorded in appendix 8.4 must determine whether the PROGRAM has:

8.3.7.1 Adequate staff
8.3.7.2 Equipment
8.3.7.3 Funding

Note: Information technology may be considered as part of the State PROGRAM'S resource needs.

8.3.8 A baseline resource review in 8.3.7 must be made concurrently with the baseline evaluation required for AFRPS Standard 9 and recorded in appendix 8.4.

8.3.9 Subsequent resource evaluations to determine the resources necessary for the State PROGRAM to partially meet, fully meet, or maintain full IMPLEMENTATION of each standard's requirements must be completed within three years of the previous evaluation.

8.4 Outcome

The State PROGRAM has a documented workplan to support its inspection and sample collection programs and assesses the resources needed to support an ANIMAL FEED regulatory program and implement the AFRPS.

8.5 Documentation

The State PROGRAM maintains the records listed here.

8.5.1 Appendix 8.1: Self-Assessment Worksheet
8.5.2 Workplan
8.5.3 Documented procedure for evaluating the workplan
8.5.4 Documented procedure for identifying and reviewing its resources to accomplish the workplan within the applicable timeframe
8.5.5 Formula used to calculate number of staff needed to conduct inspections and sample collections and supporting data
8.5.6 List of required equipment for inspection and sample collection
8.5.7 Appendix 8.4: Resources for IMPLEMENTATION of AFRPS

STANDARD 9
Assessment and Improvement

9.1 Purpose

This standard tracks the IMPLEMENTATION of each standard and describes the requirements for an improvement plan.

9.2 Requirement Summary

The State PROGRAM conducts a baseline evaluation utilizing the self-assessments completed for each standard. The results of the baseline evaluation are used to create an improvement plan that aids the PROGRAM in meeting the requirements of each standard.

The State PROGRAM regularly evaluates its status in meeting the requirements of the standards.

9.3 Program Elements

9.3.1 The State PROGRAM uses the self-assessment worksheets from each standard to complete a baseline evaluation. The baseline evaluation is used to determine if a standard is fully met, partially met, or not met, and identify areas or functions in the State PROGRAM that need improving in order to fully meet the requirements of each standard.

9.3.2 Following the baseline evaluation, the State PROGRAM develops an improvement plan for requirements of the standards that are not fully met using appendix 9.2, or comparable form. The improvement plan includes the following:

9.3.2.1 The individual element or documentation requirement for the standard that was not fully met;
9.3.2.2 Improvements needed to fully meet the program element or documentation requirement(s) of the standard;
9.3.2.3 Lists of individual tasks that will be used to address the improvement;
9.3.2.4 A projected completion date for each task;
9.3.2.5 Completion date for each task.

9.3.3 The State PROGRAM reviews and updates its improvement plan (appendix 9.2) on an annual basis.

9.3.4 The State PROGRAM completes an evaluation of IMPLEMENTATION status at least every three years following the baseline evaluation to determine if each standard is fully met, partially met, or not met. This evaluation includes a review and update of the following:

9.3.4.1 Self-assessment worksheets for each standard;
9.3.4.2 Required documentation for each standard;

9.3.4.3 Improvement plan (appendix 9.2);
9.3.4.4 IMPLEMENTATION status (appendix 9.3).

9.3.5 Appendix 9.3, or comparable form, is used to track IMPLEMENTATION status of all the standards.

9.3.6 The State PROGRAM retains records required under x.5 of each standard for the three previous years, or per the State PROGRAM'S record retention policy.

Note: If FDA provides a State PROGRAM with financial assistance to implement the AFRPS, FDA will conduct a verification audit of the State PROGRAM'S AFRPS IMPLEMENTATION.

9.4 Outcome

The State PROGRAM works to meet the requirements of all standards and continues to evaluate and improve the PROGRAM to ensure the required elements for all standards remain met.

9.5 Documentation

The State PROGRAM maintains the records listed here.

9.5.1 Appendix 9.1: Self-Assessment Worksheet
9.5.2 Appendix 9.2: Assessment and Improvement Plan
9.5.3 Appendix 9.3: IMPLEMENTATION Status of Animal Feed Regulatory Program Standards

STANDARD 10
Laboratory Services

10.1 Purpose

This standard describes the elements of utilizing REGULATORY TESTING LABORATORY(IES) services that support the State PROGRAM.

10.2 Requirement Summary

The State PROGRAM has access to laboratory services that provide analytical data that support regulatory functions.

The State PROGRAM receives accurate, timely, reliable, and defensible data from the REGULATORY TESTING LABORATORY(IES).

10.3 Program Elements

10.3.1 The State PROGRAM maintains a list of analytical services provided by REGULATORY TESTING LABORATORY(IES). These types of services include the following:

10.3.1.1 Routine
10.3.1.2 Non-routine

10.3.2 The State PROGRAM has a documented formal agreement with the REGULATORY TESTING LABORATORY(IES) that conduct routine analytical services, unless the laboratory is managed within the PROGRAM.

10.3.3 The State PROGRAM prepares a sample analysis schedule based on a sampling plan[3] in cooperation with REGULATORY TESTING LABORATORY(IES) performing routine services to ensure compatibility with laboratory capabilities and capacities. At a minimum, the sample analysis schedule must include:

10.3.3.1 The type(s) of ANIMAL FEED to be analyzed;
10.3.3.2 Number of samples to be collected;
10.3.3.3 Estimated timeframe for collection;
10.3.3.4 Type(s) of analysis to be performed.

10.3.4 The State PROGRAM has written procedures developed by the REGULATORY TESTING LABORATORY(IES) to maintain the integrity of the samples sent to the laboratory for analytical testing that includes:

10.3.4.1 Sample receipt
10.3.4.2 Preservation
10.3.4.3 Storage

[3]A description of a sampling plan can be found in Animal Feed Regulatory Program Standard 11: Sampling Program.

10.3.4.4 Retention
10.3.4.5 Disposal
10.3.4.6 Chain of custody
10.3.4.7 Report of analysis
10.3.4.8 Method(s) used to communicate information between the State PROGRAM and REGULATORY TESTING LABORATORY(IES)

10.3.5 State PROGRAM utilizes REGULATORY TESTING LABORATORY(IES) that:

10.3.5.1 Are accredited by a recognized accreditation body to ISO/IEC 17025:2005[4], or
10.3.5.2 Implement and comply with the AAFCO Quality Assurance/Quality Control guidelines, or
10.3.5.3 Implement and comply with the ISO/IEC 17025:2005.

10.4 Outcome

The State PROGRAM utilizes valid and defensible laboratory testing data to ensure their mission in protecting animal and public health and enforcing feed regulations.

10.5 Documentation

The State PROGRAM maintains the records listed here.

10.5.1 Appendix 10: Self-Assessment Worksheet
10.5.2 A list of routine and non-routine analytical services provided by the REGULATORY TESTING LABORATORY(IES)
10.5.3 An agreement with REGULATORY TESTING LABORATORY(IES) that provide routine analytical services unless the laboratory is managed within the PROGRAM
10.5.4 A current sample analysis schedule
10.5.5 Written procedures to maintain the integrity of the samples sent to the REGULATORY TESTING LABORATORY(IES)

[4] A recognized accreditation body must be signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

STANDARD 11
Sampling Program

11.1 Purpose

This standard describes the elements of an effective ANIMAL FEED sampling program.

11.2 Requirement Summary

The State PROGRAM has a sampling program to support an ANIMAL FEED regulatory program.

11.3 Program Elements

11.3.1 The State PROGRAM has a documented annual sampling plan for collecting surveillance, compliance, investigational, regulatory samples, or other samples.[5]

11.3.1.1 The annual sampling plan is jointly developed and amended by the State PROGRAM and REGULATORY TESTING LABORATORY(IES) performing routine analytical services to allow for advanced planning and scheduling of work.

11.3.1.2 The sampling plan outlines the State PROGRAM'S:

11.3.1.2.1 Sampling priorities
11.3.1.2.2 Sample analysis schedule
11.3.1.2.3 Availability or coordination of analytical support

Note: The sampling plan may include estimates of analytical costs.

11.3.2 The State PROGRAM has documented sampling procedures for collecting, storing, and transporting samples that includes:

11.3.2.1 Following safety precautions on feed labels;
11.3.2.2 Following the State PROGRAM'S safety protocol for collecting samples;
11.3.2.3 Using appropriate method and equipment to collect the sample;
11.3.2.4 Sealing the sample to initiate chain of custody;
11.3.2.5 Maintaining and documenting sample integrity, security, and chain of custody;
11.3.2.6 Issuing receipt[6] for sample(s);
11.3.2.7 Handling[7], packaging, and shipping sample using procedures appropriate to prevent compromising the condition of sample;
11.3.2.8 Delivering or shipping sample to the appropriate laboratory within acceptable timeframes.

[5]Regulatory samples may be used to support inspection observations.
[6]Receipt could include cost of sample and method of payment.
[7]Includes storing sample.

11.3.3 The State PROGRAM has documented instructions for the Sample Collection Report that includes:

11.3.3.1 Date of the sample collection;
11.3.3.2 Product identification including:

11.3.3.2.1 Name
11.3.3.2.2 Lot numbers or any other codes referencing manufacture identification

11.3.3.3 Description of product;
11.3.3.4 Method of collection and any special techniques used to collect sample;
11.3.3.5 Lot sampled;
11.3.3.6 Lot size;
11.3.3.7 Location where sample was collected;
11.3.3.8 Name and address of responsible party, guarantor, possessor, or distributor;
11.3.3.9 Sample type (surveillance, compliance, investigational, regulatory, or other);
11.3.3.10 Analysis requested, if applicable;
11.3.3.11 Collection or reproduction of product labels, including customer-formula feed labels;
11.3.3.12 Receiving and distribution information.

11.4 Outcome

The State PROGRAM has a sampling program that aligns sampling resources with State PROGRAM priorities. The annual sampling plan will facilitate efficient use and coordination of resources to obtain timely information. Samples are collected, stored, transported, and documented to support regulatory actions.

11.5 Documentation

The State PROGRAM maintains the records listed here.

11.5.1 Appendix 11: Self-Assessment Worksheet
11.5.2 Documented annual sampling plan
11.5.3 Documented sampling procedures
11.5.4 Documented sample collection report instructions

Appendix 1.1: Self-Assessment Worksheet

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

Yes	No	
		The State PROGRAM conducts as evaluation to determine whether the State's legal authority and are EQUIVALENT, EQUIVALENT IN EFFECT, or NOT EQUIVALENT to the sections of the FD&C Act and Federal regulations specified in appendix 1.2.

Notes:

Yes	No	
		If a State law or regulation is determined to be "EQUIVALENT" to a Federal law or regulation, the State PROGRAM:

Not Applicable: ☐ *Check "Not Applicable" box to the left if requirement is not applicable because no State law or regulation was determined to be EQUIVALENT.*

Yes	*No*	
		Specifies the Federal statute or regulation that is incorporated into the State law;
		Includes the revision date of the State statutory provision or regulation;
		Identifies the date the Federal statutory provision was incorporated into the State law.

Notes:

Yes	No	
		The State PROGRAM has a documented process, which includes:

Yes	*No*	
		Procedure for reviewing the statutes, regulations, rules, ordinances and other prevailing regulatory requirements that:
		Apply to the regulation of ANIMAL FEED;
		Delegate authority to the State Agency;
		Describe the State agency's administrative procedures for establishing its authority and incorporating rules by reference.
		Timeframes for the review.

Notes:

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. If there is no State law or regulation that is EQUIVALENT or EQUIVALENT IN EFFECT, mark the NOT EQUIVALENT column; otherwise list the State law or regulation citation in the State citation column and complete the columns for either EQUIVALENT or EQUIVALENT IN EFFECT as appropriate. The Notes section should be used in part to detail differences between State and Federal laws and regulations. If regulatory responsibility for State laws relating to provisions in a particular row of this worksheet fall under the jurisdiction of another State agency, the State PROGRAM should mark "NOT EQUIVALENT" and it is recommended that the State PROGRAM identify the agency who has authority and jurisdiction in the Notes column.

		State Citation	EQUIVALENT		EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Review Date		
Federal Food, Drug & Cosmetic Act							
201	Definitions (f), (g), (k), (m), (s), (v) and (w)						
301	Prohibited acts (a), (b), (c), (d), (e), (f), and (k)						
303*	Penalties						
304**	Seizure						
401	Definitions and standards for food						
402	Adulterated food (a)-(c)						
403	Misbranded food (a)-(n)						
404	Emergency permit control						
406	Tolerances for poisonous ingredients in food						
408	Tolerances and exemptions for pesticide chemical residues						

*Penalties may vary from Federal statute.
**Although the State PROGRAM may not have authority for seizure, the State PROGRAM could have other legal authority to stop violative products from moving in commerce, for example, detention, stop-sale orders, withdrawal from distribution, and embargoes.

		State Citation	EQUIVALENT		EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Review Date		
409	Food additives						
501	Adulterated drugs and devices (ONLY: 501(a)(2)(B) and 501(a)(6))						
504	Veterinary feed directive drugs						
512	New animal drugs (ONLY: 512(a)(2))						
701	Regulations and hearings						
704	Factory inspection						
Title 21 Code of Federal Regulations: Food and Drugs (2016)							
1	General enforcement regulations (ONLY §§ 1.20-1.23, Subpart L (§§1.500-1.514), Subpart M (§§1.600-1.695), and Subpart O (§§1.900-1.934))						
7	Enforcement policy (ONLY §§ 7.1-7.13 and §§ 7.40-7.59)						
70	Color additives (ONLY §§ 70.20-70.25)						
73	Listing of colors exempt from certification (ONLY §§ 73.1-73.615)						
74	Listing of color additives subject to certification (ONLY §§ 74.101-74.706)						

Appendix 1.2: REGULATORY FOUNDATION Worksheet (continued)

		State Citation	EQUIVALENT		EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Review Date		
81	General specifications and general restrictions for provisional color additives for use in foods, drugs, and cosmetics						
82	Listing of certified provisionally listed colors and specifications (ONLY §§ 82.3-82.706)						
225	Current good manufacturing practice for medicated feeds						
226	Current good manufacturing practice for Type A medicated articles						
500.23	Thermally processed low-acid foods packaged in hermitically sealed containers (refers to regulations in 21 CFR 113 and 21 CFR 507)						
500.24	Emergency permit control (refers to regulations in 21 CFR 108 - ONLY §§ 108.25- 108.35)						
500.29	Gentian violet for use in animal feed						
500.45	Use of polychlorinated biphenyls (PCB's) in the production, handling, and storage of animal feed						
500.50	Propylene glycol in or on cat food						
500.80 - 500.92	Regulation of carcinogenic compounds used in food-producing animals						
501	Animal food labeling						

Appendix 1.2: REGULATORY FOUNDATION Worksheet (continued)

		State Citation	EQUIVALENT		EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
			Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Review Date		
502	Common or usual name for nonstandardized animal foods						
507	Current good manufacturing practice, hazard analysis, and risk-based preventive controls for food for animals						
509	Unavoidable contaminants in animal food and food-packaging material						
510	New animal drugs (ONLY Subpart D - Records and Reports)						
558	New animal drugs for use in animal feeds						
570	Food additives (EXCEPT § 570.6, § 570.15, and §570.17)						
573	Food additives permitted in feed and drinking water of animals						
579	Irradiation in the production, processing, and handling of animal feed and pet food						
582	Substances generally recognized as safe						
584	Food substances affirmed as generally recognized as safe in feed and drinking water of animals						
589	Substances prohibited from use in animal food or feed						

Additional State Authorities (optional):

Instructions: List any State Authorities used by the State PROGRAM that are pertinent to the regulation of ANIMAL FEED but do not have a comparable Federal statute or regulation (examples: tolerance for mycotoxins, fluorine, or noxious weeds in feed).

Additional notes and comments:

Assessment Completed By:

Name

Date

Appendix 2.1: Self-Assessment

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

Training

Yes	No	
		The State PROGRAM uses a written training plan that includes:
		Basic curriculum
		Advanced curriculum
		Continuing education
		For inspectors that conduct limited scope inspections (e.g. such as only collecting samples or inspections at veterinary clinics), the State PROGRAM specifies the curriculum required by the limited scope inspectors in their documented training plan.
		The State PROGRAM maintains records documenting the training completed by all inspectors using appendix 2.2 or comparable form.
		For inspectors with greater than 5 years of experience that do not have documentation of previous training, the State PROGRAM conducts an evaluation of the inspector's previous performance and experience to determine if the inspector has completed the required training or whether additional training is needed. (This is only permitted at the date of the initial self-assessment and not subsequent self-assessments.)
		If previous coursework is completed before the inspectors START DATE and utilized to meet coursework requirements, proper supporting documents are maintained to verify successful completion of the requirement.

Basic Feed Inspector Training

Yes	No	
		The State PROGRAM requires an inspector to successfully complete coursework and field training within 24 months from the START DATE.
		The basic feed inspection training consists of coursework in the following subject areas:
		Animal and Public Health Principles
		Basic Animal Nutrition
		Basic Feed Ingredients, Processing and Technology
		Basic National Incident Management System and Incident Command System (ICS)
		Communication
		Current Statutes, Regulations, and Policies
		Feed Defense
		Inspections, Compliance, and Enforcement
		Labeling
		Professionalism
		Risk Awareness
		Safety
		Sampling
		The State PROGRAM has established basic field training to complement the basic coursework.
		Field training checklist of competencies to be mastered and verified in the field by the QUALIFIED FIELD INSPECTION TRAINER;
		Documented procedures for JOINT FIELD TRAINING INSPECTIONS;

Appendix 2.1: Self-Assessment (continued)

Yes	No	
		Number of JOINT FIELD TRAINING INSPECTIONS that are conducted in firms that represent the feed facilities in the State PROGRAM inventory and the type of routine or basic work that will be performed by the inspector;
		The inspector completes basic field training prior to performing independent inspections;
		Appendix 2.3 or comparable form must be used to list the competencies and record the JOINT FIELD TRAINING INSPECTIONS.

Advanced Feed Inspector Training

Yes	No	
		The State PROGRAM requires an inspector to successfully complete coursework and field training within 60 months from the START DATE.
		The advanced feed inspection training consists of coursework in the following subject areas:
		Advanced Feed Ingredients, Processing, and Technology
		Advanced Labeling
		Animal Sickness and Death Investigation
		Current Statutes, Regulations, and Policies
		Epidemiology
		Microbiological Pathogens
		Traceback and Traceforward Investigations
		Specialized Curriculum: Inspectors who assist in emergency response or conduct specialized inspections listed below must complete relevant specialized coursework specific to the type of specialized inspections that they will be performing in the following subject areas.
		Advanced National Management Systems and Incident Command Systems
		BSE and Ruminant Feeding Ban
		Medicated Feed Good Manufacturing Practices Regulations
		The State PROGRAM has established advanced field training to complement the advanced coursework.
		Field training checklist of competencies to be mastered and verified in the field by the QUALIFIED FIELD INSPECTION TRAINER;
		Documented procedures for JOINT FIELD TRAINING INSPECTIONS;
		Number of JOINT FIELD TRAINING INSPECTIONS that are conducted in firms that represent the feed facilities in the State PROGRAM inventory and the type of advanced work that will be performed by the inspector;
		The inspector completes advanced field training prior to performing independent inspections;
		Appendix 2.3 or comparable form must be used to list the competencies and record JOINT FIELD TRAINING INSPECTIONS.

Continuing Education

Yes	No	
		The State PROGRAM requires that each basic and advanced inspector participate in continuing education.
		Each inspector is required to receive 20 CONTACT HOURS of continuing education every 36 months.
		The 36 month continuing education interval starts, as defined by the State PROGRAM, when the training curriculum is complete.

Assessment Completed By:

Name _____ Date _____

Appendix 2.2: Inspector Training Record

Inspector Name: _____ **Employment START DATE:** _____

A. Basic Feed Inspector Training

Instructions: If the inspector has greater than five years of experience and an evaluation of the inspector's previous performance and experience shows adequate training has been completed, mark the Name and Location of Training Column, with "Met via Evaluation."

Subject Areas	Name and Location of Training	Completion Date	Inspector Initials	Supervisor Initials	Documentation Verifying Completion (Y/N)
Animal and Public Health Principles					
Basic Animal Nutrition					
Basic Feed Ingredients, Processing, and Technology					
Basic National Incident Management System and Incident Command System					
Communication					
Current Statues, Regulations, and Policies					
Feed Defense					
Inspections, Compliance, and Enforcement					
Labeling					
Professionalism					
Risk Awareness					
Safety					
Sampling					

Appendix 2.2: Inspector Training Record (continued)

Inspector Name: _____ **Employment START DATE:** _____

Instructions: Record the name of the firm where the joint training inspection took place as well as the competencies covered.

Basic Field Training (Name and Location of Firm)	Competencies Covered	Completion Date	Inspectors Initials	Supervisor Initials	Mastered (Y/N)

Appendix 2.2: Inspector Training Record (continued)

Inspector Name: _____ **Employment START DATE:** _____

B. Advanced Feed Inspector Training

Instructions: If the inspector has greater than five years of experience and an evaluation of the inspector's previous performance and experience has found that no additional training for a subject area is needed, mark the Name and Location of Training Column, with "Met via Evaluation."

Subject Areas	Name and Location of Training	Completion Date	Inspector Initials	Supervisor Initials	Documentation Verifying Completion (Y/N)
Advanced Feed Ingredients, Processing, and Technology					
Advanced Labeling					
Animal Sickness and Death Investigation					
Current Statues, Regulations, and Policies					
Epidemiology					
Microbiological Pathogens					
Traceback and Traceforward Investigations					
Specialized Advanced					
Advanced National Incident Management System and Incident Command Systems					
BSE and Ruminant Feeding Ban					
Medicated Feed Good Manufacturing Practices Regulations					

Appendix 2.2: Inspector Training Record (continued)

Inspector Name: _____ **Employment START DATE:** _____

Instructions: Record the name of the firm where the joint training inspection took place as well as the competencies covered.

Advanced Field Training (Name and Location of Firm)	Competencies Covered	Completion Date	Inspectors Initials	Supervisor Initials	Mastered (Y/N)

Appendix 2.2: Inspector Training Record (continued)

Inspector Name: _____ **Employment START DATE:** _____

Instructions: Record the continuing education activity as well as the name and location of the activity.

C. Continuing Education

Type of Activity	Name and Location of Activity	Completion Date	Inspectors Initials	Supervisor Initials	CONTACT HOURS Earned

Appendix 2.3: Field Training Competencies

A. Basic Field Competencies

Instructions: List the competencies to be covered in the State PROGRAM'S basic field training and provide a short description.

Competency	Description

Minimum Number of JOINT FIELD TRAINING INSPECTIONS Required: _____

Appendix 2.3: Field Training Competencies (continued)

B. Advanced Field Competencies

Instructions: List the competencies to be covered in the State PROGRAM'S advanced field training and provide a short description.

Competency	Description

Minimum Number of JOINT FIELD TRAINING INSPECTIONS Required: _____

Appendix 3.1: Self-Assessment Worksheet

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

Program Elements	Yes/No	Specific Reference[8]	Notes
Section I. Risk-Based Inspection Program			
The State PROGRAM has documented procedures to:			
• Define an up-to-date inventory of feed facilities whose activities fall under the State's jurisdiction and authority;			
• Maintain the inventory of feed facilities defined in 3.3.1.1.1.			
The State PROGRAM has documented procedures for defining risk categories. The three minimum required factors for defining risk categories are:			
• Types of feed and feed products;			
• Types of processing;			
• Compliance history of the facility.			
The State PROGRAM is required to use a minimum of the three factors in 3.3.1.2 to assign risk categories to feed facilities.			
Based on risk factors assigned to a facility or product, the manufacturing processes, and the inspection history of the facility, inspections:			
• Are prioritized;			
• Have assigned frequencies;			
• Have resources allocated.			
Section II. Inspection Protocol			
The State PROGRAM has documented policies and procedures for inspecting feed facilities that require inspectors to:			
1. Review the feed facility's previous inspection report(s) and complaint(s);			
2. Present appropriate credentials and written Notice of Inspection to the feed facility's owner, operator, or agent in charge; make appropriate introductions; explain the purpose and scope of the inspection; and determine inspection authority;			
3. Follow the safety protocols required by the feed facility and the State PROGRAM;			
4. Follow the biosecurity protocols required by the feed facility and the State PROGRAM;			
5. Use appropriate equipment and forms needed to conduct inspections;			
6. Establish interstate jurisdiction for FDA inspections, if applicable;			

[8]Cite the reference (title and date of publication, section, and page number) to demonstrate the program element has been met.

Appendix 3.1: Self-Assessment Worksheet (continued)

Program Elements	Yes/No	Specific Reference	Notes
7. Recognize the relative risk (high to low) of feed facilities based on the State PROGRAM'S risk-based inspection program and categorization assigned to a facility or product, the manufacturing processes, and the inspection history of the facility;			
8. Conduct inspection activities focused on those firms, products, and processes determined to be high risk;			
9. Assess employee activities critical to the safe manufacture, distribution, storage, handling, and disposition of feed;			
10. Properly evaluate the likelihood that conditions, practices, processes, components, or labeling could cause the product to become adulterated or misbranded;			
11. Recognize significant non-compliant conditions or practices and document findings consistent with PROGRAM procedures;			
12. Distinguish between significant and insignificant observations and isolated incidents versus trends;			
13. Review and evaluate the appropriate feed facility records and procedures and verify that the procedures are being followed;			
14. Collect adequate evidence and documentation to support inspection observations in accordance with PROGRAM procedures;			
15. Verify correction of deficiencies identified during the previous inspection(s);			
16. Conduct activities in a professional manner;			
17. Use effective interviewing techniques;			
18. Explain findings clearly and adequately throughout the inspection;			
19. Alert the feed facility's owner, operator, or agent in charge when an immediate corrective action is necessary;			
20. Document findings accurately, clearly, legibly, and concisely on the applicable form(s) and provide a copy to the firm's owner, operator, or agent in charge;			
21. Answer questions and provide information as appropriate;			
22. Submit inspection report, sample(s), and supporting documents to headquarters or supervisor in a timely manner.			

Program Elements	Yes/No	Specific Reference	Notes
Section III. Recall System			
The State PROGRAM has a documented recall system.			
• The recall system includes written procedures for:			
o Receiving			
o Tracking			
o Evaluating recall notifications			
o Closing			
o Maintaining records			
• The recall system includes performing recall effectiveness checks			
Section IV. Consumer Complaints			
The State PROGRAM has a documented system for handling consumer complaints.			
• The consumer complaint system includes procedures for:			
o Receiving			
o Tracking			
o Evaluating			
o Answering			
o Closing			
o Maintaining records			
Section V. Complaints Resulting from State Inspection Activities			
The State PROGRAM has a documented system to handle complaints from industry about State PROGRAM inspections.			
• The industry complaint system includes procedures for:			
o Receiving			
o Evaluating			
o Maintaining records			

Assessment Completed By:

Name

Date

Appendix 3.2: Risk Categorization for Feed Facilities

Determining Risk Factors for Feed Facilities
Standard 3 requires a State PROGRAM to categorize feed facilities based on risk and to allocate resources and establish inspection frequencies based upon that categorization. State PROGRAMS should document their categorization and inspection frequencies. Differences between State PROGRAMS will exist for many reasons including variable resources, legislative mandates, localized industries and practices, and competing priorities.

A key requirement of this standard is that the State PROGRAM uses a risk-based method for categorizing feed facilities with a baseline inspection frequency specified for each category.

State PROGRAMS must categorize feed facilities based on at least the following three factors: (1) types of feed and feed products, (2) type of processing, and (3) compliance history of the feed facility.

The State PROGRAM should consider optional risk factors such as volume of product manufactured, scope of distribution, or other factors unique to the State's industries and practices.

The risk associated with each factor may be scored with numerical values that are tabulated to rank the feed facilities and prioritize inspections.

Risk Categorization Factors for Feed Facilities

A. Required Factors

1. **Type of Processing**
   The following types of processing should be considered.
   - Rendering
   - Pelleting
   - Extrusion
   - Roasting
   - Steam Flaking
   - Refrigeration
   - Mixing
   - Milling
   - Salvaging
   - Thermal processing
   - Heating

2. **Type of Feed**
   The following types of feed should be considered.
   - Mixes species
   - Raw pet food
   - Pet food
   - Medicated feed
   - Customer formula feed
   - Feed containing prohibited mammalian tissue
   - Feed ingredients subject to adulterants such as mycotoxins, pesticides, or industrial chemicals
   - Single specie feed
   - Non-medicated feed

3. Compliance History

The following types of compliance history should be considered.

- Poor history
- No history
- Inconsistent history
- Good history

The following is an example of a risk associated with a required factor.

Risk	Score	Compliance History
High	3	Feed facility with poor history of compliance or no compliance history with feed laws and regulations
Medium	2	Feed facility with an inconsistent history of compliance
Low	1	Feed facility is routinely in compliance with feed laws and regulations

B. Optional Factors

1. Volume of Product Manufactured

- Greater than 500 tons/day
- 50 to 500 tons/day
- Less than 50 tons/day

2. Scope of Distribution

- Global
- National
- Interstate
- Regional
- Intrastate
- County
- Local

Appendix 4.1: Self-Assessment Worksheet

Auditing

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

Yes	No	
		The State program has written procedures for conducting four types of audits:
		Field inspection audits
		Field inspection report audits
		Sample collection audits
		Sample collection report audits
		A review of the performance factor scores and cumulative scores for each type of audit is completed
		at least every 12 months.

Field Inspection Audit

Yes	No	
		PROGRAM conducts field inspection audits
		12-month period of performance
		Number of audits conducted
		Number of corrective action plans required
		Inspectors are audited at a minimum against the performance factors found in appendix 4.2
		Audits reflect inspector's assignments and responsibilities
		Two audits per inspector completed every 36 months
		Audit score calculated for each individual audit
		Audit rating recorded for each individual audit
		Performance factor score calculated for each performance factor
		Cumulative score calculated for the PROGRAM

Field Inspection Report Audit

Yes	No	
		PROGRAM conducts random inspection report audits
		12- month period of performance:
		Number of inspection reports completed:
		Number of inspection reports audited:
		Number of corrective action plans required:
		Inspection reports were audited according to frequency chart in the standard
		Inspection reports are audited at a minimum against the performance factors found in appendix 4.5
		Audit score calculated for each individual audit
		Audit rating recorded for each individual audit
		Performance factor score calculated for each performance factor
		Cumulative score calculated for the PROGRAM

Appendix 4.1: Self-Assessment Worksheet (continued)

Sample Collection Audit

Yes	No	
		PROGRAM conducts sample collection audits
		12-month period of performance:
		Number of audits conducted:
		Number of corrective action plans required:
		Inspectors are audited at a minimum against the performance factors found in appendix 4.7
		Audits reflect inspector's assignments and responsibilities
		Two audits per inspector completed every 36 months
		Audit score calculated for each individual audit
		Audit rating recorded for each individual audit
		Performance factor score calculated for each performance factor
		Cumulative score calculated for the PROGRAM

Sample Collection Report Audit

Yes	No	
		PROGRAM conducts random sample collection report audits
		12-month period of performance:
		Number of sample collections reports reviewed:
		Number of sample collection reports audited:
		Number of corrective action plans required:
		Sample collection reports were audited according to frequency chart in the standard
		Sample collection reports are audited at a minimum against performance factors found in appendix 4.9
		Audit score calculated for each individual audit
		Audit rating recorded for each individual audit
		Performance factor score calculated for each performance factor
		Cumulative score calculated for the PROGRAM

Corrective Action Plan

Yes	No	
		PROGRAM develops corrective action plans using appendix 4.11 when:
		An inspector has an audit score below 80 percent for an individual audit
		The PROGRAM has a performance factor score below 80 percent for a single performance factor
		The PROGRAM has a cumulative score below 80 percent

Assessment Completed By:

Name _____ Date _____

Appendix 4.2: Field Inspection Audit Form

Field Inspection Audit	
Inspector:	Auditor: Date of Audit:
Firm Name: Firm Address:	Type of Inspection: ☐ BSE ☐ GMP ☐ Tissue Residue ☐ Complaint ☐ Other:
Total Number of: Acceptable Needs Improvement Audit Score:	Audit Rating: ☐ Acceptable ☐ Needs Improvement

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

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

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

I. Pre-Inspection Assessment

1. Did the inspector review the feed facility's previous inspection report(s) and complaint(s)?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Did the inspector use appropriate equipment and forms to conduct the inspection?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

II. Inspection Observations and Performance

1. Did the inspector present appropriate credentials and written Notice of Inspection to the feed facility's owner, operator, or agent in charge? Make appropriate introductions, explain the purpose and scope of the inspection, and determine inspection authority?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Did the inspector follow safety protocols required by the feed facility and the state program?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

3. Did the inspector follow the bio-security protocols required by the feed facility and the state program?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

4. Did the inspector establish interstate jurisdiction for FDA inspections, if applicable?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

5. Did the inspector recognize relative risk (high to low) of the feed facility based on the state program's risk-based inspection program and categorization assigned to a facility or a product, the manufacturing processes, and the inspection history of the facility?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

6. Did the inspector conduct inspection activities focused on the feed facility's products and processes determined to be high risk?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

7. Did the inspector assess feed facility employee activities critical to the safe manufacture, distribution, storage, handling, and disposition of feed?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

8. Did the inspector properly evaluate the likelihood that conditions, practices, processes, components, or labeling could cause the product to become adulterated or misbranded?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

9. Did the inspector recognize significant non-compliant conditions or practices and document findings consistent with program procedures?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

10. Did the inspector distinguish between significant and insignificant observations and isolated incidents versus trends?
    ☐ Acceptable ☐ Needs Improvement

    Comments (required for Needs Improvement)

11. Did the inspector review and evaluate the appropriate feed facility records and procedures and verify that the procedures are being followed?
    ☐ Acceptable ☐ Needs Improvement

    Comments (required for Needs Improvement)

12. 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)

13. Did the inspector verify correction of deficiencies identified during the previous inspection(s)?
    ☐ Acceptable ☐ Needs Improvement

    Comments (required for Needs Improvement)

14. Did the inspector conduct activities in a professional manner?
    ☐ Acceptable ☐ Needs Improvement

    Comments (required for Needs Improvement)

III. Oral and Written Communications

1. Did the inspector use effective interviewing techniques?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Did the inspector explain findings clearly and adequately throughout the inspection?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

3. Did the inspector alert the feed facility's owner, operator, or agent in charge when an immediate corrective action was necessary?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

4. Did the inspector document findings accurately, clearly, legibly, and concisely on the applicable form(s) and provide a copy to the feed facility's owner, operator, or agent in charge?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

5. Did the inspector answer questions and provide information as appropriate?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

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

Name of Auditor	Signature of Auditor	Date

Appendix 4.2a: Completing the Field Inspection Audit Form

For each performance factor, examples of actions and observations that would likely result in a "needs improvement" rating are provided.

Pre-Inspection Assessment

1. Did the inspector review the previous feed facility's inspection report(s) and complaint(s)?

Examples of a "needs improvement" rating

a. The inspector does not review the previous inspection report and complaints.

b. The inspector does not review a firm's response letter to the previous establishment inspection in which corrective actions were promised.

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

Examples of a "needs improvement" rating

a. The inspector does not have a copy or have electronic access to the pertinent laws and regulations.

b. During a medicated feed mill inspection, the inspector does not have a current copy of Title 21 of the *Code of Federal Regulations* Parts 225 and 558 (or a current Feed Additive Compendium) or access on line.

c. The inspector does not have a calculator.

d. The inspector does not have a camera to document violations.

e. The inspector does not have a flashlight to examine poorly lit raw material storage areas.

f. The inspector uses outdated, improper, or inappropriate forms for the type of inspection conducted.

Inspection Observations and Performance

1. Did the inspector present appropriate credentials and written Notice of Inspection to the feed facility's owner, operator, or agent in charge? Make appropriate introductions, explain the purpose and scope of the inspection, and determine inspection authority?

Example of a "needs improvement" rating

a. Inspector fails to present credentials to the owner, operator, or agent in charge of the establishment.

b. Inspector fails to make appropriate introductions, explain the purpose and scope of the inspection, and determine inspection authority.

c. Inspector enters the firm through the rear entrance and immediately begins the inspection without issuing a Notice of Inspection.

d. Upon entering the firm, the inspector fails to issue the Notice of Inspection to the appropriate person.

e. Inspector uses only a business card as identification.

2. **Did the inspector follow safety protocols required by the feed facility and the State program?**

Example of a "needs improvement" rating

a. The inspector does not ask if any particular safety protocols are mandated at the facility.

b. The inspector does not follow the State PROGRAM'S safety protocol or use personal protective equipment appropriately.

c. The inspector does not follow the safety protocols mandated by a particular facility.

3. Did the inspector follow the bio-security protocols required by the feed facility and the State program?

Example of a "needs improvement" rating

a. The inspector does not inquire if any particular bio-security protocols are mandated at the facility.

b. The inspector does not follow the State PROGRAM'S bio-security protocol.

c. The inspector does not follow the bio-security protocols mandated by the feed facility.

4. Did the inspector establish interstate jurisdiction for FDA inspections, if applicable?

Examples of a "needs improvement" rating

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

b. The inspector conducts an inspection of a licensed feed mill. The inspector fails to determine that product or ingredients have been received or shipped in interstate commerce by the manufacturer since the last inspection.

5. Did the inspector recognize relative risk (high to low) of the feed facility based on the State program's risk-based inspection program and categorization assigned to a facility or a product, the manufacturing processes, and the inspection history of the facility?

Examples of a "needs improvement" rating

a. The inspector does not recognize the relative risk of the facility because the inspector is not knowledgeable with the manufacturing process involved at this facility and does not inquire with facility personnel.

b. The inspector organizes inspection activities focused on low risk items and ignores high risk products and processes.

6. Did the inspector conduct inspection activities focused on the feed facility's products and processes determined to be high risk?

Examples of a "needs improvement" rating

a. The inspector does not prioritize high risk inspection activities.

b. The inspector concentrates inspection activities on low risk items and not high risk products and processes.

7. Did the inspector assess feed facility employee activities critical to the safe manufacture, distribution, storage, handling, and disposition of feed?

Examples of a "needs improvement" rating

a. The inspector conducts the inspection without input from employees responsible for critical activities.

b. The inspector does not review employee training records when required.

c. The inspector observes a trash bin and a reclaim bin in the same area, but he fails to evaluate practices sufficiently to identify an employee placing trash in the reclaim bin, which subsequently re-enters the process flow.

d. The inspector fails to recognize distressed dog food being placed into a re-grinder bin containing regrinds for ruminant feed.

e. The inspector fails to note an employee using medication in a feed when the formula does not call for the addition of this medication.

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

Examples of a "needs improvement" rating

a. The inspector does not observe critical activities during the inspection and does not discuss procedures in place to prevent distribution when an error has occurred.

b. The inspector does not review labeling protocols and verify a system was in place to assure proper labeling.

c. The inspector does not recognize possible adulterants (pesticides) that are stored above bagged feeds.

d. The inspector does not investigate a pallet of stacked bags that lack labeling and identification.

e. The inspector fails to investigate feed containing an unapproved drug combination.

9. Did the inspector recognize significant non-compliant conditions or practices and document findings consistent with program procedures?

Examples of a "needs improvement" rating

a. The inspector concentrates on one item and does not recognize other significant non-compliant conditions.

b. The inspector notices non-compliant products but fails to adequately address them at the time of the inspection or at the end of the inspection.

c. Inspector fails to identify a feed containing an unapproved drug combination.

d. The inspector fails to note the significance of "back hauling" prohibited materials in a bulk truck used to transport cattle feed.

10. Did the inspector distinguish between significant and insignificant observations and isolated incidents versus trends?

Examples of a "needs improvement" rating

a. The inspector keeps reviewing documents until he finds an insignificant violation.

b. The inspector does not emphasize the severity or outcome of significant observations and the need for immediate action.

c. The inspector does not discuss patterns or trends that were observed.

d. The inspector does not recognize significant pest infestations.

e. The inspector identifies and objects to record keeping deficiencies without considering that corrective action plans have been implemented by the firm and the deficiency has not reoccurred.

11. Did the inspector review and evaluate the appropriate feed facility records and procedures and verify the procedures are being followed?

Examples of a "needs improvement" rating

a. The inspector asks for the invoices for customer formula feeds for labeling information and does not realize that the facility's procedures use the facility's mix ticket as the label.

b. The inspector notices drugs are being added to the mixer before any other ingredient when the facility's SOP for addition of medications states that medications will be added at five minutes into the mix time.

c. The inspector fails to question alarm notifications and the resulting required procedures.

d. The inspector encounters out of limit drug assays and does not look for follow up actions.

e. The inspector reviews mixer cleanout records but fails to note cleanouts were not done according to the facility's SOP.

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

Examples of a "needs improvement" rating

a. The inspector reviews the drug inventory and notes that the drug inventory is not accurate but does not collect documents to support the finding.

b. The inspector notices dead rodents around the mixer hand add area and does not provide supporting evidence such as photographs, detailed narrative, or affidavits.

c. The inspector mentions that proper caution statements are missing from medicated feed labels yet does not provide copies of the labeling involved.

d. The inspector simply notes that "housekeeping needs improved" and does not provide documentation to support the observation.

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

Examples of a "needs improvement" rating

a. The previous inspection of the facility listed inaccurate drug levels on labeling of several feeds. During the current inspection, the manager informs the inspector that the problem has been corrected. The inspector simply notes in the report the management's statement and does not verify that the labels have been changed.

b. The previous inspection noted improper cleanout procedures for all handling equipment. The inspector verifies that the mixer is being adequately cleaned out but does not verify proper procedures are being used for other handling equipment.

c. The previous inspection noted that production records were not being checked at the end of the day. The inspector notes there are initials on some of the records, but the inspector does not further inquire about their procedures.

14. Did the inspector conduct activities in a professional manner?

Examples of a "needs improvement" rating

a. The inspector does not dress appropriately for the inspection. Upon arrival, clothes were torn and dirty.

b. The inspector fails to wear protective safety equipment that is required by the firm or the State.

c. The firm asks the inspector to use the boot bath before entering the production area, but the inspector ignores the firm's request and enters the production area.

d. The inspector is rude and demanding

Oral and Written Communications

1. Did the inspector use effective interviewing techniques?

Examples of a "needs improvement" rating

a. The inspector's requests for information are ambiguous; consequently, the firm provides documents that are not relevant to the inspection.

b. The inspector's requests contain jargon unfamiliar to the firm causing confusion in the facility personnel responses to inspector.

c. The inspector is confrontational.

d. The inspector asks pointed and directed questions in order to solicit a desired response.

e. The inspector is not a good listener and kept interrupting the facility personnel in their responses.

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

Examples of a "needs improvement" rating

a. The inspector does not discuss a significant deficiency observed in the shelled corn storage or conveyor system before proceeding to the hammer mill area although the general manager was present at the time.

b. At the conclusion of the inspection, the inspector's discussion of the deficiencies is vague; therefore, management is unclear of the significance of the observations and that corrective action should be taken by the firm.

c. At the conclusion of the inspection, the inspector does not discuss a significant deficiency observed during the inspection.

3. Did the inspector alert the feed facility's owner, operator, or agent in charge when an immediate corrective action was necessary?

Examples of a "needs improvement" rating

a. The inspector fails to advise the firm manager that ruminant feed products containing prohibited material are being packaged and shipped.

b. The inspector fails to notify the firm manager that he witnessed direct contamination of bagged feed ingredients with used motor oil.

c. After witnessing direct product contamination with a toxic chemical, the inspector immediately notifies an employee who was not the most responsible person in the feed facility.

4. Did the inspector document findings accurately, clearly, legibly, and concisely on the applicable form(s) and provide a copy to the feed facility's owner, operator, or agent in charge?

Examples of a "needs improvement" rating

a. The inspector fails to list significant inspectional observations.

b. An inspectional observation states, "Firm did not control hazards," but no further explanation is provided.

c. The report is illegible or contains several spelling and grammatical errors.

d. Inspector does not leave a summary of inspectional observations with the firm's owner, operator, or agent in charge.

5. Did the inspector answer questions and provide information as appropriate?

Examples of a "needs improvement" rating

a. The inspector reveals specific information about a pending compliance action against a competitor.

b. The inspector provides a competitor's formulation to the facility manager.

c. The inspector falsely answers a policy question that leads the firm to take an inappropriate corrective action.

Appendix 4.3: Field Inspection Audit Worksheet

State Program: _____ **Reviewed By:** _____

Performance Period: _____ **Date:** _____

Cumulative Score (5): _____

Auditor Initials and Date of Audit (1)																			A_t (3)	NI_t (3)	Performance Factor Score (3)
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
II.1																					
II.2																					
II.3																					
II.4																					
II.5																					
II.6																					
II.7																					
II.8																					
II.9																					
II.10																					
II.11																					
II.12																					
II.13																					
II.14																					
III.1																					
III.2																					
III.3																					
III.4																					
III.5																					
Audit Score (2)																					
Subtotal - ***Enter the sum of the totals from all continuation sheets.***																					
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.

Appendix 4.3: Field Inspection Audit Worksheet (continuation sheet)

State Program: _____ **Reviewed By:** _____

Auditor Initials and Date of Audit (1)																			A_t (3)	NI_t (3)	Performance Factor Score (3)
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
II.1																					
II.2																					
II.3																					
II.4																					
II.5																					
II.6																					
II.7																					
II.8																					
II.9																					
II.10																					
II.11																					
II.12																					
II.13																					
II.14																					
III.1																					
III.2																					
III.3																					
III.4																					
III.5																					
Audit Score (2)																					
Subtotal - ***Enter the sum of the totals from all continuation sheets.***																					
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.

Appendix 4.4: Instructions for Completing Audit Worksheets

The four audit worksheets allow the State PROGRAM to recognize trends and identify specific areas in the inspection and sample collection programs that may need improvement.

Worksheets found in appendices 4.3, 4.6, 4.8, and 4.10 are used to calculate performance factor scores and a cumulative score for a twelve month performance period. A performance factor score or cumulative score below eighty percent indicates the need for improvement and requires corrective action.

Instructions: The numbers listed in parentheses on each of the worksheets correspond to the numbered instructions below (e.g. Auditor Initials and Date of Audit (1) on the worksheet is number 1. below).

1. For each audit, record the auditor's initials and date of audit.

2. For each audit, record the rating for each performance factor (A = Acceptable; NI = Needs Improvement) as well as the audit score.

3. Count the number of A and NI for each performance factor (row), and record the total number of acceptable and needs improvements ratings, as well as calculate the performance factor score.

   A_t = Total Number of Acceptable Ratings
   NI_t = Total Number of Needs Improvement Ratings

   Performance Factor Score = $[A_t / (A_t + NI_t)] \times 100$

4. Sum the Total Number of Acceptable and Total Number of Needs Improvement ratings for all audits.

   $\sum A_t$ = Sum of Total Number of Acceptable Ratings
   $\sum NI_t$ = Sum of Total Number 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 in the box located 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 Needs Improvement in multiple audits.

Appendix 4.5: Field Inspection Report Audit Form

Field Inspection Report Audit	
Auditor:	Date of Audit: Date of Inspection:
Firm Name: Firm Address:	Type of Inspection: ☐ BSE ☐ GMP ☐ Tissue Residue ☐ Complaint ☐ Other:
Total Number of: Acceptable Needs Improvement Audit Score:	Audit Rating: ☐ Acceptable ☐ Needs Improvement

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

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

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

I.	Organization of the Report

1. Format of the inspection report followed the State program's current policies and procedures.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Required fields on inspection report or related report forms are completed.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

3. Written observations were clear and concise.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

4. Submitted report within timeframes.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

Appendix 4.5: Field Inspection Report Audit Form (continued)

II.	Record of Findings
1. Recorded name and title of facility managers and key personnel. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)	
2. Recorded name and title of personnel interviewed during the inspection. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)	
3. Recorded findings not in compliance with laws and regulations. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)	
4. Recorded significant findings (if any). ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)	
5. Recorded the collection of all samples, exhibits, photographs, or photocopies to support findings. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)	
6. Recorded any refusals encountered during the inspection. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)	
III.	**Communication with Facility Personnel**
1. Provided a summary of findings. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)	
2. Recorded responses, replies, or corrective action commitments. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)	

Appendix 4.5: Field Inspection Report Audit Form (continued)

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

Name of Auditor	Signature of Auditor	Date

Appendix 4.6: Field Inspection Report Audit Worksheet

State Program: _____ **Reviewed By:** _____

Performance Period: _____ **Date:** _____

Cumulative Score (5): _____

Auditor Initials and Date of Audit (1)																			A_t (3)	NI_t (3)	Performance Factor Score (3)
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
II.1																					
II.2																					
II.3																					
II.4																					
II.5																					
II.6																					
III.1																					
III.2																					
Audit Score (2)																					
Subtotal - ***Enter the sum of the totals from all continuation sheets.***																					
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.

Appendix 4.6: Field Inspection Report Audit Worksheet (continuation sheet)

State Program: _____ **Reviewed By:** _____

Auditor Initials and Date of Audit (1)																			A_t (3)	NI_t (3)	Performance Factor Score (3)
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
II.1																					
II.2																					
II.3																					
II.4																					
II.5																					
II.6																					
III.1																					
III.2																					
Audit Score (2)																					
Subtotal - ***Enter the sum of the totals from all continuation sheets.***																					
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.

Appendix 4.7: Sample Collection Audit Form

Sample Collection Audit	
Inspector:	Auditor: Date of Audit:
Firm Name: Firm Address:	Type of Sample Collection: ☐ Surveillance ☐ Compliance ☐ Investigational ☐ Regulatory ☐ Other:
Total Number of: Acceptable Needs Improvement Audit Score:	Audit Rating: ☐ Acceptable ☐ Needs Improvement

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

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

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

I.	Sample Collection Observations and Performance

1. Did the inspector follow safety precautions on the feed label?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Did the inspector follow the State program's safety protocol for collecting samples?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

3. Did the inspector use the appropriate method and equipment to collect the sample?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

4. Did the inspector seal the sample to initiate chain of custody?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

Appendix 4.7: Sample Collection Audit Form (continued)

5. Did the inspector maintain and document sample integrity, security, and chain of custody? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
6. Did the inspector issue a receipt for sample(s)? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
7. Were the samples handled, packaged, and shipped using procedures appropriate to prevent compromising the condition of the sample? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
8. Was the sample delivered or shipped to the appropriate laboratory within acceptable timeframes? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
II. General Comments
Enter any general comments or recommendations as a result of this audit.

Name of Auditor	Signature of Auditor	Date

Appendix 4.7a: Completing the Sample Collection Audit Form

For each performance factor, examples of actions and observations that would likely result in a "needs improvement" rating are provided.

Sample Collection Observations and Performance

1. Did the inspector follow safety precautions on the feed label?

Examples of a "needs improvement" rating

a. The inspector does not review all labeling that accompanies the feed prior to sampling.

b. The inspector does not have a label available prior to sampling.

c. The inspector does not review the whole container or back of label.

d. The inspector is not knowledgeable about the nature and use of the product they are sampling.

2. Did the inspector follow the State program's safety protocol for collecting samples?

Examples of a "needs improvement" rating

a. The inspector does not have a copy or have electronic access to the State PROGRAM'S safety protocol.

b. Inspector does not have proper personal protective equipment that may be needed.

c. The inspector takes bulk samples out of a bulk vehicle and does not use appropriate fall protection equipment.

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

Example of a "needs improvement" rating

a. Inspector simply hand grabs three or four handfuls out of the top of one bag.

b. Inspector collects a sample of a Type A medicated article and then collects a complete feed for a different species without cleaning sampling equipment in between samples to prevent cross-contamination.

c. Inspector pours half of his collected sample into the firm's container because the firm requested they have a portion of his sample.

d. Inspector collects ten probes from ten fifty pound bags but does not seal the probe holes or left the product in an unsalable condition.

e. The inspector does not have a copy or have electronic access to the State PROGRAM'S sampling procedures.

f. The inspector collects ten probes for a lot of feed. Eight of the sample cores are white in color and two are green. The inspector does not note this on the sample collection form or investigate it further.

g. A sample is to be tested for microbial activity, but the inspector does not follow proper aseptic protocols.

h. Inspector calls ahead to the facility and requests they have samples collected by the facility's personnel and ready for pickup.

4. Did the inspector seal the sample to initiate chain of custody?

Example of a "needs improvement" rating

a. The inspector collects three samples in the facility but does not document and seal the open samples until returning to his car.

b. The inspector seals the container in such a manner whereby it can be opened without breaking the official custody seal.

5. Did the inspector maintain and document sample integrity, security, and chain of custody?

Example of a "needs improvement" rating

a. The inspector does not complete the required information (e.g. lot identification number, date of collection, or guarantees) on the sample collection report.

b. The inspector collects a sample of feed and seals the sample with the wrong official custody seal.

c. High fat samples are placed in containers where the fat may leach into the container (e.g. paper bags).

d. The label on a sampled feed says to store in a cool dry place, but during a period of high temperature, the collected sample is left in a car trunk for several days prior to shipment to the laboratory.

6. Did the inspector issue a receipt for sample(s)?

Examples of a "needs improvement" rating

a. The inspector collects a sample and does not issue a receipt describing the sample to the owner, operator, or agent in charge.

b. The inspector tells the owner he would mail him the receipt later in the week.

7. Were the samples handled, packaged, and shipped using procedures appropriate to prevent compromising the condition of the sample?

Examples of a "needs improvement" rating

a. The feed samples are packaged along with other substances (e.g. pesticides or fertilizers) that might contaminate the sample during shipment.

b. The samples are not packaged to prevent breakage, spillage, crushing, or other detrimental actions that may be encountered in shipping the samples.

8. Was the sample delivered or shipped to the appropriate laboratory within acceptable timeframes?

Examples of a "needs improvement" rating

a. The samples are not shipped or delivered according to the State PROGRAM'S protocols.

b. A feed sample containing urea is shipped to the fertilizer laboratory instead of the feed laboratory.

c. A sample of corn, intended to be tested for aflatoxin contamination, is delivered to the State's seed testing laboratory instead of the proper feed laboratory.

Appendix 4.8: Sample Collection Audit Worksheet

State Program: _____ **Reviewed By:** _____

Performance Period: _____ **Date:** _____

Cumulative Score (5): _____

Auditor Initials and Date of Audit (1)																			A_t (3)	NI_t (3)	**Performance Factor Score (3)**
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
I.5																					
I.6																					
I.7																					
I.8																					
Audit Score (2)																					
Subtotal - *Enter the sum of the totals from all continuation sheets.*																					
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.

Appendix 4.8: Sample Collection Audit Worksheet (continuation sheet)

State Program: _____ **Reviewed By:** _____

Auditor Initials and Date of Audit (1)																			**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
I.5																					
I.6																					
I.7																					
I.8																					
Audit Score (2)																					
Subtotal - *Enter the sum of the totals from all continuation sheets.*																					
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.

Appendix 4.9: Sample Collection Report Audit Form

Sample Collection Report Audit	
Auditor:	Date of Audit: Date of Sample Collection:
Firm Name: Firm Address:	Type of Sample Collection: ☐ Surveillance ☐ Compliance ☐ Investigational ☐ Regulatory ☐ Other:
Number of: Acceptable Needs Improvement Audit Score:	Audit Rating: ☐ Acceptable ☐ Needs Improvement

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

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

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

I.	Organization of the Report

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

   Comments (required for Needs Improvement)

2. Product identification including name and lot code or any other referencing manufacture information was recorded.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

3. Description of product was recorded.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

4. Collection information including method of collection, lot sampled, lot size, and any special techniques used to collect 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, guarantor, possessor, or distributor were recorded.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

7. Sample type (surveillance, compliance, investigational, regulatory, or other) was recorded.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

8. Analysis requested was recorded, if applicable.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

9. Product labels, including customer-formula feed labels, are collected or reproduced.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

10. Receiving and distribution information was recorded.
    ☐ Acceptable ☐ Needs Improvement

    Comments (required for Needs Improvement)

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

Name of Auditor	Signature of Auditor	Date

Appendix 4.10: Sample Collection Report Audit Worksheet

State Program: _____ **Reviewed By:** _____

Performance Period: _____ **Date:** _____

Cumulative Score (5): _____

Auditor Initials and Date of Audit (1)																			A_t (3)	NI_t (3)	**Performance Factor Score (3)**
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
I.5																					
I.6																					
I.7																					
I.8																					
I.9																					
I.10																					
Audit Score (2)																					
Subtotal - *Enter the sum of the totals from all continuation sheets.*																					
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.

Appendix 4.10: Sample Collection Report Audit Worksheet (continuation sheet)

State Program: _____ **Reviewed By:** _____

Auditor Initials and Date of Audit (1)																			**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
I.5																					
I.6																					
I.7																					
I.8																					
I.9																					
I.10																					
Audit Score (2)																					
Subtotal - *Enter the sum of the totals from all continuation sheets.*																					
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.

Appendix 4.11: Corrective Action Plan

Type of Audit: ☐ Field Inspection Audit ☐ Sample Collection Audit
☐ Field Inspection Report Audit ☐ Sample Collection Report Audit

Instructions: The corrective action for each deficiency, whether an individual or cumulative factor below 80 percent reported during an audit will be described in the table below. The corrective action plan should be maintained with the originating audit documents.

Performance Factor (record number from audit form)	**Description of Deficiency**	**Corrective Action(s)**	**Verification that Corrective Action Implemented**

Completed By:

Name

Date

Appendix 5.1: Self-Assessment Worksheet

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

Yes	No	
		The State PROGRAM has written procedures to gather information to identify incidents of feed-related illnesses, deaths, and EMERGENCIES.

Notes:

Yes	No	
		The State PROGRAM has written procedures to communicate with the appropriate State agencies or departments that investigate animal illnesses and food-related illnesses and outbreak.

Notes:

Yes	No	
		For feed-related illnesses, deaths, and EMERGENCIES, the State PROGRAM has a written procedure with criteria to:

Yes	*No*	
		Determine the appropriate response
		Initiate the response
		Complete the response

Notes:

Yes	No	
		For feed-related EMERGENCIES, the State PROGRAM manages the event using:

Yes	*No*	
		A formalized Incident Command System structure or
		An official action plan that includes:
		Outlining containment
		Communication
		Control
		Correction
		After-action protocols

Notes:

Yes	No	
		The State PROGRAM maintains a list of relevant agencies and emergency contacts.

Notes:

Yes	No	
		The State PROGRAM establishes written procedures to rapidly notify government agencies, departments, or appropriate parties of relevant findings.

Notes:

Yes	No	
		The State PROGRAM has a written procedure to immediately notify law enforcement agencies when intentional feed contamination or feed-related terrorism is suspected or threatened.

Notes:

Yes	No	
		The State PROGRAM has a written procedure for:

Yes	*No*	
		Releasing information to the public;
		Coordinating media information with other jurisdictions to reduce the impact of feed-related illnesses, deaths, or EMERGENCIES.

Notes:

Assessment Completed By:

Name _____ Date _____

Appendix 5.2: Emergency Contact List

This template may be used to develop an emergency contact list. The content, design, and frequency of update are determined by the State PROGRAM.

Agency	Contact Name	Phone Number	Email
Intra-Agency			
Supervisor		(w)	
		(c)	
Laboratory		(w)	
		(c)	
Office of General Counsel		(w)	
		(c)	
Office of the Director or Administration		(w)	
		(c)	
Office of Legislative Affairs		(w)	
		(c)	
Office of Public Information		(w)	
		(c)	
Federal Government			
Department of Homeland Security		(w)	
		(c)	
Food and Drug Administration		(w)	
		(c)	
Department of Health and Human Services		(w)	
		(c)	
Center for Disease Control and Prevention		(w)	
		(c)	
Environmental Protection Agency		(w)	
		(c)	
U.S. Department of Agriculture		(w)	
		(c)	
Energy Department		(w)	
		(c)	
Department of Defense		(w)	
		(c)	
National Security Administration		(w)	
		(c)	

Appendix 5.2: Emergency Contact List (continued)

Agency	Contact Name	Phone Number	Email
Federal Bureau of Investigation		(w)	
		(c)	
Trade Commission		(w)	
		(c)	
Health Department		(w)	
		(c)	
Customs Service		(w)	
		(c)	
Justice Department		(w)	
		(c)	
Veterinary Medical Diagnostic Lab		(w)	
		(c)	
State/Provincial/Local Government Offices			
Department of Conservation, Natural Resources, or Environmental Protection Agency		(w)	
		(c)	
Department of Agriculture, Plant Board, or Forestry		(w)	
		(c)	
Board of Pharmacy		(w)	
		(c)	
State Chemist		(w)	
		(c)	
Department of Public Safety		(w)	
		(c)	
Department of Public Health Human Services, Social Services		(w)	
		(c)	
State Veterinarian, Animal Health, Livestock Commission		(w)	
		(c)	
Attorney General		(w)	
		(c)	
Department of Commerce		(w)	
		(c)	
Department of Wildlife and Fisheries		(w)	
		(c)	

Appendix 5.2: Emergency Contact List (continued)

Agency	Contact Name	Phone Number	Email
Department of Marine Resources		(w)	
		(c)	
Department of Professional Regulation/Inspection		(w)	
		(c)	
Veterinary Medical Diagnostic Laboratory		(w)	
		(c)	
Land Grant University/Extension Service		(w)	
		(c)	
Police, Sheriff, Constable		(w)	
		(c)	
Fire Department		(w)	
		(c)	
Hospital (local or regional)		(w)	
		(c)	
Utilities: Gas, Electric, Water, Sewage		(w)	
		(c)	
Industry Organizations			
Producer Associations (ex: cattle feeders, pork producers, poultry producers)		(w)	
		(c)	
National Grain and Feed Associations		(w)	
		(c)	
American Feed Industry Association		(w)	
		(c)	
Pet Food Institute		(w)	
		(c)	
Feed Advisory Committee (Board) Members		(w)	
		(c)	
Equipment Suppliers Association		(w)	
		(c)	
Additional Assistance			
Forensics Laboratory		(w)	
		(c)	

Appendix 5.2: Emergency Contact List (continued)

Agency	Contact Name	Phone Number	Email
Poison Control Center		(w)	
		(c)	
Toxicology		(w)	
		(c)	
Pathology		(w)	
		(c)	
Universities/University "Centers"		(w)	
		(c)	
Federal, State, and Local Emergency Management Agencies		(w)	
		(c)	

Completed By:

Name

Date

Appendix 6.1: Self-Assessment Worksheet

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

Yes	No	
		The State PROGRAM has an enforcement program that contains documented ENFORCEMENT STRATEGIES.

Notes:

Yes	No	
		The State PROGRAM must use the following six factors listed when selecting an appropriate enforcement tool.

Mark "Yes" or "No" in the columns below whether each factor was used for selecting enforcement tools and has a written description, documented relative condition(s), and a numerical weight assigned for each relative condition.

Factor	*Factor Used*	*Factor Description*	*Relative Conditions*	*Numerical Weight*
Compliance history				
Responsiveness				
Scope				
Nature of Violation				
Impact of Violation				
Resources				

Notes:

Yes	No	
		The State PROGRAM has documented enforcement matrix.

Notes:

Yes	No	
		The State PROGRAM has documented process for conducting an annual evaluation of ENFORCEMENT STRATEGIES.

Notes:

Yes	No	
		The State PROGRAM conducts an annual evaluation of its ENFORCEMENT STRATEGIES to:

Yes	*No*	
		Determine if the PROGRAM'S ENFORCEMENT STRATEGIES were successful in achieving Compliance;
		Identify potential improvements or modifications of the ENFORCEMENT STRATEGIES, if any;
		Determine if the enforcement priorities remain the same or require modification.

Notes:

Assessment Completed By:

Name _____ Date _____

Appendix 6.2: Enforcement Tools

This appendix is a list of common enforcement tools that may be used by State PROGRAMS. An explanation of each tool has been provided.

Advisory or informational letter – can be used as a form for both compliance assistance and education and would usually apply to non-repetitive violations of no risk to health, safety, or the environment. Administrative violations involving licensing, product registration, and payment of fees are examples.

Warning letters with or without a required response – usually used to clearly outline the violation and require corrective action(s). The letter might or might not request a written response upon correction. This tool would be appropriate for violations that have or could present risk to health, safety, or the environment. Further, it could be appropriate for repetitive administrative violations.

Withdrawal from distribution orders – used when health, safety, or the environment would be put at risk from distribution of a feed. It might also be used when other tools have failed to achieve compliance for serious administrative violations or gross labeling violations.

Informal hearings or meetings – used to provide an opportunity to bring together parties to discuss and understand the nature of a violation. It may lead to an agreed order or consent decree. Use of this tool would be appropriate for many violations including those that may be chronic; threats to health, safety or the environment; civil penalties, license denials, revocation, or other serious administrative actions. This tool may be used in conjunction with others to facilitate compliance.

Mediation – meeting of all parties that produces a consent decree or compliance agreement.

Civil penalty – monetary penalty assessed for a violation. Civil penalty fines are based on a numeric point matrix determined by the severity of the violation and the repeat nature of the offense. A notice shall be given and an opportunity for an administrative (formal) hearing must be provided. This tool should be used in addition to other tools to prevent chronic violations or to address illegal acts when other tools are not available. Where appropriate, an informational letter, warning letter, informal hearing or meeting, or administrative hearing should precede the use of civil penalties.

Cancellation, probation, or conditional status – actions that can be taken against a license, permit, or registration due to repeat violations, including reporting of distributions, payment of fees, or chronic analytical deficiencies.

Administrative hearing – opportunity for an administrative (formal) hearing is provided to the regulated establishment prior to the issuance of a civil penalty, license denial, or license revocation. An administrative hearing may result in a consent decree with the regulated establishment. This tool should be used in chronic violations or when threats to health or safety exist.

Condemnation and confiscation – may be applied to any lot of non-compliant feed and may involve a court in the local area. A feed found violative by the court may be subject to condemnation and disposition after first allowing the claimant or manufacturer an opportunity to seek release of the feed or request opportunity to reprocess or re-label the feed for compliance. This tool would be appropriate for use when a practice or product presents a risk to health, safety, or the environment. It may also be applicable in other cases such as chronic violations.

Injunction – may be used to restrain a firm from any or all violations. The tool would be used in case of a serious threat of immediate or irreparable harm. Use may also be appropriate to restrain a firm from operation in wanton violation of a chronic nature involving administrative aspects of the law.

Criminal prosecution – may be pursued against a firm or person that impedes, obstructs, hinders, or otherwise prevents or attempts to prevent enforcement of commercial feed regulation. This tool can be used for any violation, but other tools may be appropriate.

Appendix 6.3: Factors, Descriptions, and Numerical Weights for Consideration When Selecting an Enforcement Tool

The following six factors must be used by the State PROGRAM to develop an enforcement matrix: compliance history, responsiveness, scope, nature of the violation, impact of the violation, and resources.

Below are example descriptions of these six factors, including numerical weights[9] and assigned relative conditions. The descriptors, numerical weights, and relative conditions listed below are examples. The State PROGRAM may consider these examples when developing the descriptors, numerical weight, and relative conditions that will be utilized by the State PROGRAM for the six factors that must be included in an enforcement matrix. The State PROGRAM may consider additional factors.

The sum of the numerical values for all of the factors can be used to help select the appropriate enforcement tool from an enforcement matrix (see appendix 6.4 for an example).

Factor 1 – Compliance History
The compliance history of the firm or individual can be indicative of their commitment to assuring they are operating in compliance. Compliance history can include inspections, sample analysis, label reviews, and previous enforcement actions. It should include consideration of whether corrections were promised and completed, whether corrections were made promptly, and whether the same or similar problems occur repeatedly. The following relative weights can be used in assessing the firm's compliance history:

(0) firm has extensive history and is always found in compliance
(1) no history on file for this firm
(2) firm's history shows only minor violations, always corrected
(3) firm's history shows instances of significant violations or repeated minor violations
(4) firm's history shows instances of significant violations and promised corrections are rarely made

Factor 2 – Responsiveness
The responsiveness of the firm or individual can also be used to help assess their commitment to assuring they are operating in compliance and the level of enforcement action needed to encourage commitment. Does the firm promise correction and follow through? Are they aware of laws, regulations, and requirements for their operation? Do they have quality assurance or training programs? Do they accept responsibility for problems that are uncovered? Are corrections made promptly? Do they make corrections while an inspector is there but do not maintain the correction? When appropriate, do they examine similar systems and/or products to make overall correction? The following relative weights can be used in assessing the responsiveness of the firm:

(0) accept responsibility for assuring compliance; aware of the requirements or have quality assurance or training programs; corrections are promised and made promptly; when appropriate, extend corrections to similar products or systems
(1) accept responsibility for assuring compliance; aware of the requirements; corrections promised but not made in a timely manner or corrections are not sustained
(2) do not accept responsibility for assuring compliance; not aware of the requirements; no promise of correction; no correction

Factor 3 – Scope
Scope of the firm's business as well as the scope of the violation can be an important factor in choosing an appropriate enforcement action. Is the distribution of violative products limited to local distribution, multiple counties, Statewide, multiple States, nationwide, or worldwide? What is the quantity of violative product involved? How many animals are affected? Are the violative products intended for a limited or unique population, or are they for a broader population? Does the violation involve a single product or multiple products? Is the violation specific to a single lot? Is the violation a process violation? Is this an industry practice? The following relative weights can be used in assessing the scope of the violation:

[9]Source of the factors, descriptions, and numerical weights is the AAFCO Enforcement Guidelines-Factor Application section of the AAFCO.

(1) very limited distribution, quantity, or limited purchaser; violation is limited to a single lot
(2) distribution is limited to Statewide or bordering States; violation is limited to one or two products; quantity of product distributed is relatively small or the number of animals effected is relatively small; non critical process violation
(3) distribution is unlimited and may involve large quantities of product or affect a large number of animals; violation involves critical processes or multiple products

Factor 4 – Nature of the Violation

The nature of the violation has an impact on the type of enforcement action and may influence whether the action focuses on the product, process, or individual. Consider whether the violations are minor or significant; whether they are sporadic or continuous; whether they involve only record keeping or control issues or they include product defects or contaminations; whether they are the result of human error; whether they were the result of lack of knowledge and understanding of the firm or individual's responsibility or the legal requirements; or whether the violations were done knowingly or deliberately. When determining whether the violation is significant or not as significant, or whether it would be a major or minor violation, available and current science and policy should be considered. The following relative weights can be used in assessing the nature of the violation:

(1) minor labeling violations or minor sporadic record keeping violations
(2) violations are not minor but they are isolated incidents, the result of human error, or the result of lack of knowledge about requirements
(4) significant GMP or labeling violations; contaminations; fraud
(8) deliberate, knowing violations that result in hazard to public health

Factor 5 – Impact of the Violation

Selecting the most appropriate enforcement tool is strongly tied to the impact the violation has on the user of the product (economic impact or fraud), the safety of the animal, and human health safety. The State PROGRAM should consider whether the violations affect food producing or non-food producing animals. Are the violations economic or fraudulent in nature? Do the violations compromise animal safety? Do the violations pose a risk to human health safety? Is there a particular population at risk such as children, immuno-compromised, or the elderly? The following relative weights can be used in assessing the impact of the violation:

(1) minor economic or fraud violations
(4) animal safety concerns
(8) human health safety concern but limited population
(10) human health safety concern with a risk to all populations

Factor 6 - Resources

Consider what resources the State PROGRAM has to devote to the violative findings. Has the State PROGRAM established overall compliance goals and objectives? Are the State PROGRAM'S enforcement efforts prioritized? Are the resources devoted in part to special initiatives? Has the State PROGRAM established communication networks to determine if the violations have been encountered elsewhere? Are there other agencies that may be able to pursue action consistent with the State PROGRAM'S compliance goals? The following relative weights can be used in assessing the impact of the violation:

(1) no resources are available
(2) limited resources are available
(3) ample resources are available

Appendix 6.4: Enforcement Matrix

Instructions: This is an example that can be used to develop the State PROGRAM'S enforcement matrix. The enforcement matrix should be designed to incorporate the relative conditions of each factor (with a minimum of the six factors listed in Standard 6: Enforcement Program) identified by the State PROGRAM. The enforcement matrix can be used to aid the State PROGRAM in determining which enforcement tool to apply. The content, design, and frequency of update are determined by the State PROGRAM.

Directions for Use of the Enforcement Matrix:

1. Determine the violation categories. The Example Enforcement Matrix on page 103 provides five examples of major violation categories: labeling, GMPs, sample results, contaminations, and administrative.

2. For each violation category, identify the enforcement tools that are appropriate for the violation category and the factor value range from minor to major. Examples of enforcement tools for each violation category from minor violations (factor value range 4 to 8) to major violations (factor value range 20 to 29) are provided in the Example Enforcement Matrix.

3. Calculate the sum of the numerical values assigned to each factor. See below for an example calculation:

Factor	Relative Condition Noted	Numerical Value
1. Compliance History	Firm's history shows only minor violations, always corrected (2)	2
2. Responsiveness	Accept responsibility for assurance compliance (0)	0
3. Scope	Distribution is limited to Statewide and/or border states (2)	2
4. Nature of the Violation	Minor labeling violations (1)	1
5. Impact of the Violation	Minor economic or fraud violations (1)	1
6. Resources	Limited resources are available (2)	2
	Sum of Numerical Values for Each Factor =	8

4. Locate the "Factor Value Range" that corresponds with the calculated sum of the numerical value for all factors. The matrix can be modified to different amounts of factor value ranges and values within each factor range. Using the example calculation in item 3, the sum of the numerical values is 8. The available enforcement tools for factor value range from 4 to 8 are "no action" and "information letter." The State could choose between these two enforcement tools for the violations reported.

5. Choose the appropriate enforcement tool for the violation category based on the factor value range.

Example Enforcement Matrix[10]

Violation Category	Factor Value Range			
	4 to 8	**9 to 12**	**13 to 19**	**20 to 29**
Labeling	No Action Information Letter	Warning Letter Stop Sale Informal Hearing/Mediation	Condemnation/Seizure Informal Hearing/Meeting Injunction Refer to Other Agency Civil Penalty	Prosecution Formal Hearing Injunction Refer to Other Agency Civil Penalty
GMPs	No Action Information Letter	Warning Letter Stop Sale Informal Hearing/Mediation	Condemnation/Seizure Informal Hearing/Meeting Injunction Refer to Other Agency Civil Penalty	Prosecution Formal Hearing Injunction Refer to Other Agency Civil Penalty
Sample Results	No Action Information Letter	Warning Letter Stop Sale Informal Hearing/Mediation	Condemnation/Seizure Informal Hearing/Meeting Injunction Refer to Other Agency Civil Penalty	Prosecution Formal Hearing Injunction Refer to Other Agency Civil Penalty
Contaminations	No Action Information Letter	Warning Letter Stop Sale Informal Hearing/Mediation	Condemnation/Seizure Informal Hearing/Meeting Injunction Refer to Other Agency Civil Penalty	Prosecution Formal Hearing Injunction Refer to Other Agency Civil Penalty
Administrative	No Action Information Letter	Warning Letter Stop Sale Informal Hearing/Mediation	Condemnation/Seizure Informal Hearing/Meeting Injunction Refer to Other Agency Civil Penalty	Prosecution Formal Hearing Injunction Refer to Other Agency Civil Penalty

[10]The example enforcement matrix was derived from the Example Violation Chart found in the AAFCO Enforcement Guidelines-Factor Application section of the AAFCO Official Publication.

Appendix 7.1: Self-Assessment Worksheet

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

Yes	No	
		The State PROGRAM has identified methods used for outreach activities to inform ANIMAL FEED industry stakeholders, academia, other regulators, or consumers.

Notes:

Yes	No	
		The State PROGRAM has an outreach plan:

Yes	*No*	*The outreach plan includes:*
		Objectives of an outreach plan
		Target populations
		Types of outreach activities (including OUTREACH ACTIVITY EVENTS)

Notes:

Yes	No	
		The State PROGRAM documents outreach activities:

Yes	*No*	*Documentation includes:*
		Objectives of an outreach plan
		Target populations
		Types of outreach activities (including OUTREACH ACTIVITY EVENTS)

Notes:

Yes	No	
		The State PROGRAM documents and evaluates OUTREACH ACTIVITY EVENTS.

Notes:

Assessment Completed By:

Name _____ Date _____

Appendix 7.2: Outreach Plan

Either of the templates below can be used to develop an outreach plan. The content, design, and frequency of update should be determined by the State PROGRAM.

A. Outreach Plan in Chart Format

Effective Dates: _____

Objective	Target Population	Type of Outreach Activity	Delivery Method

Completed By:

_____ _____
Name Date

B. Outreach Plan in Paragraph Format

Effective Dates:_____

Outreach Objective 1:

List and provide details of outreach activities that will be used to help support this objective, including the audience that will be reached and the method of delivery.

Outreach Objective 2:

List and provide details of outreach activities that will be used to help support this objective, including the audience that will be reached and the method of delivery.

Outreach Objective 3:

List and provide details of outreach activities that will be used to help support this objective, including the audience that will be reached and the method of delivery.

Completed By:

_____ _____
Name Date

Appendix 7.3: OUTREACH ACTIVITY EVENT Overview and Evaluation

Instructions: Attach documents such as agendas, meeting summaries, and program evaluations to this form.

Section I. Overview of OUTREACH ACTIVITY EVENT

A. Type of **OUTREACH ACTIVITY EVENT** (select all that apply)

☐ Meeting ☐ Workshop ☐ Task Force/Committee

☐ Extension Event ☐ Other: _____

B. Date of **OUTREACH ACTIVITY EVENT**: _____

C. Subject or name of **OUTREACH ACTIVITY EVENT**: _____

D. Objective of **OUTREACH ACTIVITY EVENT**: _____

E. Target population for **OUTREACH ACTIVITY EVENT**: _____

Section II. Evaluation of OUTREACH ACTIVITY EVENT

Program Elements	Yes/No	If no, please explain
A. The purpose and objectives were clearly defined		
B. The context of the training activity was consistent with the objectives		
C. An evaluation was completed by attendees		
D. State PROGRAM reviewed and discussed comments from attendees		

Describe what went well, what could be done better, and what more could be done to improve the **OUTREACH ACTIVITY EVENT**.

Completed By:

_____ _____

Name Date

Appendix 8.1: Self-Assessment Worksheet

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

Yes	No	
		The State PROGRAM has a documented workplan.

Yes	*No*	*Workplan Details:*
		Inspection plan
		Sample plan
		Timeframe that the workplan is applicable

Notes:

Yes	No	
		The State PROGRAM has a documented procedure for evaluating the workplan.

Yes	*No*	*Procedure Details How:*
		PROGRAM conducts periodic and annual evaluations of the workplan;
		PROGRAM evaluates alignment with PROGRAM objectives and resources.

Notes:

Yes	No	
		The State PROGRAM has a documented procedure for identifying and reviewing its resources to accomplish the workplan within the applicable timeframe.

Notes:

Yes	No	
		To validate the workplan, the State PROGRAM must develop a formula that:

Yes	*No*	
		Calculates the number of staff needed to conduct inspections of its ANIMAL FEED inventory;
		Calculates the number of staff needed to conduct sample collections;
		Uses numerical values that are based on the State PROGRAM'S data;
		Must be used by the State PROGRAM.

Notes:

Yes	No	
		The inspection and sample collection staff must have the equipment needed to conduct inspections and sample collections.

Notes:

Yes	No	
		A list of the equipment required for inspections and sample collections must be:

Yes	*No*	
		Established by the State PROGRAM
		Maintained by the State PROGRAM

Notes:

Yes	No	
		The State PROGRAM must conduct a review of the resources required to fully implement the AFRPS, including each of the program elements in the individual standards. The review recorded in appendix 8.4 must determine whether the PROGRAM has:

Yes	*No*	
		Adequate staff
		Equipment
		Funding

Notes:

Yes	No	
		A baseline resource review must be made concurrently with the baseline evaluation required for AFRPS Standard 9 and recorded in appendix 8.4. Date Completed:

Notes:

Yes	No	
		Subsequent resource evaluations to determine the resources necessary for the State PROGRAM to partially meet, fully meet, or maintain full IMPLEMENTATION of each standard's requirements must be completed within three years of the previous evaluation.

Notes:

Assessment Completed By:

Name _____ Date _____

Appendix 8.2: Example Formula for Calculating the Number of Inspectors Required to Conduct Inspections of Feed Facilities

This appendix is an example of how to calculate the number of field staff required to conduct inspections of feed facilities. A State PROGRAM may use this example to develop a formula that is suitable for the PROGRAM'S needs and based on data that can be verified by the PROGRAM. This formula is specific to calculating the number of inspectors needed to conduct inspections of the establishment inventory according to the workplan and is not applicable to staff needs for other PROGRAM areas including sample collection, response, laboratory services, or administration.

Calculating the Number of Inspectors:

1. The following data must be collected. Records must be maintained to verify the data used in the calculations.

   - Risk categorization of feed facilities (example categorization: high risk, medium risk, and low risk)
   - Number of feed facilities in each risk category
   - Percent of facilities to be inspected each year in each risk category (in percent)
   - Percent of facilities to be re-inspected each year in each risk category (in percent)
   - Average inspection time, including travel time, of feed facilities in each risk category (in hours)
   - ***Note**: The following formulas do not account for sample collections. For State PROGRAMS that utilize inspectors to collect samples, the State PROGRAM should consider adding additional time to the average inspection time, if appropriate, to account for sample collection.*

2. Calculate the available annual inspection time, in hours, per inspector (AIT)

   The State PROGRAM should determine the average number of hours an inspector has available to conduct inspections each year after accounting for annual leave, sick leave, holidays, training, and other State PROGRAM activities.

3. Calculate the number of hours required to inspect feed facilities in each risk category

   The example below utilizes three risk categories: high risk, medium risk, and low risk.

   - *For High Risk Feed Facilities:*

   [(#HR x %HRF) + (#HR x %HRRF)] x HRaIT = hHRI per year

Key	Description
#HR	Number of High Risk Facilities
%HRF	Percent of High Risk Facilities to be Inspected per Year (%)
%HRRF	Percent of High Risk Facilities to be Re-Inspected per Year (%)
HRaIT	High Risk Facility Average Inspection Time (h)
hHRI per year	Total Hours of High Risk Inspections per Year

   - *For Medium Risk Feed Facilities:*

   [(#MR x %MRF) + (#MR x %MRRF)] x MRaIT = hMRI per year

Key	Description
#MR	Number of Medium Risk Facilities
%MRF	Percent of Medium Risk Facilities to be Inspected per Year (%)
%MRRF	Percent of Medium Risk Facilities to be Re-Inspected per Year (%)
MRaIT	Medium Risk Facility Average Inspection Time (h)
hMRI per year	Total Hours of Medium Risk Inspections per Year (h)

   - *For Low Risk Feed Facilities:*

[(#LR x %LRF) + (#LR x %LRRF)] x LRaIT = hLRI per year

Key	Description
#LR	Number of Low Risk Facilities
%LRF	Percent of Low Risk Facilities to be Inspected per Year (%)
%LRRF	Percent of Low Risk Facilities to be Re-Inspected per Year (%)
LRaIT	Low Risk Facility Average Inspection Time (h)
hLRI per year	Total Hours of Low Risk Inspections per year (h)

4. Using the data calculated in 2 and 3, calculate the number of inspectors required to ensure coverage of PROGRAM'S establishment inventory.

   (hHRI per year + hMRI per year + hLRI per year) / AIT = **Number of Inspectors Needed**

Appendix 8.3: Example List of Equipment Used for Inspections and Sample Collections

Standard 8 requires a State PROGRAM to develop a list of equipment needed to conduct inspections and sample collections. The list provided below is an example equipment list for inspections and sample collections. A State PROGRAM may add and remove equipment from the table in developing the PROGRAM'S list of equipment. After the State PROGRAM finalizes its list, the State PROGRAM can use the chart below to record whether the equipment is assigned, available to inspectors, or not available.

Equipment	Assigned	Available	Not Available
Alcohol swabs and wipes			
Blacklight			
Calculator			
Camera			
Cell phone			
Clipboard			
Computer and printer			
Coolant (ice and freezer packs)			
Credentials			
Dust mask			
Eye protection			
Flashlight and holder			
Hard hat			
Hearing protection			
Knife and scissors			
Light meter			
Official seals			
Paper, pen, masking tape, and marker			
Protective clothing (lab coat, gloves, and shoe covers)			
Putty knife and scraper			
Regulations, policies, and designated reference material			
Required forms			
Respirator			
Safety shoes			
Sampling devices (sieves, triers, scoops, or probes)			
Sampling equipment (sterile containers, bags, or swabs)			
Shipping containers			
Test weights			
Thermometer			
Vehicle			

Appendix 8.4: Resources for IMPLEMENTATION of Animal Feed Regulatory Program Standards

This table provides an overview of a State PROGRAM'S evaluation of the resources needed to implement the Animal Feed Regulatory Program Standards. Based on the evaluation, indicate for each standard whether the State PROGRAM has the resources needed for funding, staffing, and equipment by inserting 'Yes' or 'No' in the corresponding block. If 'No', please explain. Resources not related to funding, staffing, and equipment needed for IMPLEMENTATION should be in the "Other Resources Needed" column.

Standard		Funding	Staffing	Equipment	Other resources needed
1	REGULATORY FOUNDATION				
2	Training				
3	Inspection Program				
4	Auditing				
5	Feed-Related Illnesses or Death and Emergency Response				
6	Compliance and Enforcement				
7	Outreach Activities				
8	Planning and Resources				
9	Assessment and Improvement				
10	Laboratory Services				
11	Sampling Program				

Appendix 9.1: Self-Assessment Worksheet

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

Yes	No	
		The State PROGRAM uses the self-assessment worksheets from each standard to complete a baseline evaluation to:

Yes	*No*	
		Determine if a standard is fully met, partially met, or not met,
		Identify areas or functions that need improving in order to fully meet the requirements of each standard.

Notes:

Yes	No	
		The State PROGRAM develops an improvement plan for requirements of the standards that are not fully met that includes:

Not Applicable: *Check "Not Applicable" box to left if requirement is not applicable because all requirements of the standard are fully met*

Yes	*No*	
		Individual element or documentation requirement for the standard that was not fully met;
		Improvements needed to fully meet the program element or documentation requirement(s) of the standard;
		List of individual tasks that will be used to address the improvement;
		Projected completion date for each task;
		Completion date for each task.

Notes:

Yes	No	
		The State PROGRAM reviews and updates its improvement plan (appendix 9.2) annually.

Date Completed: _____

Notes:

Yes	No	
		The State PROGRAM completes an evaluation of IMPLEMENTATION status at least every three years following the baseline evaluation that includes reviewing and updating:

Date Completed: _____

Yes	*No*	
		Self-assessment worksheets for each standard;
		Required documentation for each standard;
		Improvement plan (appendix 9.2);
		IMPLEMENTATION status (appendix 9.3).

Notes:

Yes	No	
		Appendix 9.3, or comparable form, is used to track IMPLEMENTATION status of all the standards. *Notes:*

Yes	No	
		The State PROGRAM retains records under x.5 of each standard for the three previous years, or per the State PROGRAM'S record retention policy. Date Completed: _____ *Notes:*

Assessment Completed By:

Name _____ Date _____

Appendix 9.2: Assessment and Improvement Plan

Instructions: This appendix, or a comparable form, is completed for each standard.

Standard Number and Title: _____

Date Self-Assessment Worksheet Completed: _____

Subject Matter Expert(s): _____

IMPLEMENTATION Status

☐ Fully Met ☐ Partially Met ☐ Not Met

Instructions: For elements of the standard that are not fully met, the information listed below is completed.

Element(s) of Standard Not Fully Met	Improvement(s) Needed to Meet Element	Task(s) to Complete Identified Improvement	Projected Completion Date for Task	Date Task Completed

Assessment Completed By:

_____ _____

Name Date

Appendix 9.3: IMPLEMENTATION Status of Animal Feed Regulatory Program Standards

This table provides an overview of a State PROGRAM'S evaluation of its IMPLEMENTATION of the Animal Feed Regulatory Program Standards. The self-assessment worksheets and appendix 9.2: Assessment and Improvement Plan should be used to complete this appendix.

Standard	Self-Assessment	IMPLEMENTATION Status
1. REGULATORY FOUNDATION	Complete ☐ Date: Incomplete ☐	☐ Fully Met ☐ Partially Met ☐ Not Met
2. Training	Complete ☐ Date: Incomplete ☐	☐ Fully Met ☐ Partially Met ☐ Not Met
3. Inspection Program	Complete ☐ Date: Incomplete ☐	☐ Fully Met ☐ Partially Met ☐ Not Met
4. Auditing	Complete ☐ Date: Incomplete ☐	☐ Fully Met ☐ Partially Met ☐ Not Met
5. Feed-Related Illnesses or Death and Emergency Response	Complete ☐ Date: Incomplete ☐	☐ Fully Met ☐ Partially Met ☐ Not Met
6. Enforcement Program	Complete ☐ Date: Incomplete ☐	☐ Fully Met ☐ Partially Met ☐ Not Met
7. Outreach Activities	Complete ☐ Date: Incomplete ☐	☐ Fully Met ☐ Partially Met ☐ Not Met
8. Planning and Resources	Complete ☐ Date: Incomplete ☐	☐ Fully Met ☐ Partially Met ☐ Not Met
9. Assessment and Improvement	Complete ☐ Date: Incomplete ☐	☐ Fully Met ☐ Partially Met ☐ Not Met
10. Laboratory Services	Complete ☐ Date: Incomplete ☐	☐ Fully Met ☐ Partially Met ☐ Not Met
11. Sampling Program	Complete ☐ Date: Incomplete ☐	☐ Fully Met ☐ Partially Met ☐ Not Met

Evaluation Completed By:

Name _____ Date _____

Appendix 10: Self-Assessment Worksheet

Instructions: The State PROGRAM identifies if they have a specified documented procedure then evaluate the procedure to determine if it includes the associated components. If the State PROGRAM has the procedure and associated components check 'Yes', if not, check 'No'.

Yes	No	
		The State PROGRAM has a list of routine and non-routine analytical services.

Notes:

Yes	No	
		The State PROGRAM has documented formal agreement with REGULATORY TESTING LABORATORY(IES) managed outside the PROGRAM that conduct routine analytical services.

Notes:

Yes	No	
		The State PROGRAM prepares a sample analysis schedule based on a sampling plan in cooperation with REGULATORY TESTING LABORATORY(IES) performing routine services to ensure compatibility with laboratory capabilities and capacities.

Notes:

Yes	No	
		The State PROGRAM has a sample analysis schedule with each REGULATORY TESTING LABORATORY(IES) performing routine services.

Yes	*No*	*The sample analysis schedule includes:*
		Type(s) of ANIMAL FEED to be analyzed;
		Number of samples to be collected;
		Estimated timeframe for collection;
		Type(s) of analysis to be performed.

Notes:

Yes	No	
		The State PROGRAM has written procedures developed by the REGULATORY TESTING LABORATORY(IES) to maintain the integrity of the samples sent to the laboratory for analytical testing that includes:

Yes	*No*	
		Sample receipt
		Preservation
		Storage
		Retention
		Disposal
		Chain of custody
		Report of analysis
		Method(s) used to communicate information between the State PROGRAM and REGULATORY TESTING LABORATORY(IES)

Notes:

Yes	No	
		The State PROGRAM utilizes REGULATORY TESTING LABORATORY(IES) that are accredited by a recognized accreditation body to ISO/IEC 17025:2005, or implement and comply with the AAFCO Quality Assurance/Quality Control guidelines, or implement and comply with the ISO/IEC 17025:2005.

Notes:

Assessment Completed By:

Name

Date

Appendix 11: Self-Assessment Worksheet

Instructions: The State PROGRAM identifies if they have a specified documented procedure then evaluate the procedure to determine if it includes the associated components. If the State PROGRAM has the procedure and associated components check 'Yes', if not, check 'No'.

Program Elements	Yes/No	Specific Reference[11]	Notes
Section I. Sampling Plan			
a. The State PROGRAM has a documented annual sampling plan.			
b. The sampling plan is jointly developed and amended by the State PROGRAM and REGULATORY TESTING LABORATORY(IES) performing routine services.			
c. The sampling plan outlines the State PROGRAM'S: • Sampling priorities			
• Sample analysis schedule			
• Availability or coordination of analytical support			
Section II. Sampling Procedure for Collecting, Storing and Transporting Samples			
The State PROGRAM'S has a documented sampling procedure for collecting, storing, and transporting samples that includes:			
a. Following safety precautions on feed labels;			
b. Following the State PROGRAM'S safety protocol for collecting samples;			
c. Using appropriate method and equipment to collect the sample;			
d. Sealing sample to initiate chain of custody;			
e. Maintaining and documenting sample integrity, security, and chain of custody;			
f. Issuing receipt for sample;			
g. Handling, packaging, and shipping sample using procedures appropriate to prevent compromising condition of sample;			
h. Delivering or shipping sample to the appropriate laboratory within acceptable timeframes.			
Section III. Instructions for Sample Collection Report			
The State PROGRAM provides instructions for the sample collection report, including:			
a. Date of the sample collection;			
b. Product identification including: • Name • Lot numbers or other codes referencing manufacture identification			
c. Description of product;			
d. Method of collection and any special techniques used to collect sample;			
e. Lot sampled;			

[11]Reference the document (include section and page number) in which the program element is found.

Appendix 11: Self-Assessment Worksheet (continued)

Program Elements	Yes/No	Specific Reference	Notes
Instructions for Sampling Collection Report (continued)			
f. Lot size;			
g. Location where sample was collected;			
h. Name and address of responsible party, guarantor, possessor, or distributor;			
i. Sample type (surveillance, compliance, investigational, regulatory, or other);			
j. Analysis requested, if applicable;			
k. Collection or reproduction of product labels, including customer-formula feed labels;			
l. Receiving and distribution information.			

Assessment Completed By:

Name _____ Date _____