

Animal Food 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: DRAFT

Table of Contents

Table of Contents	2
Background	3
Introduction.....	5
Definitions.....	8
STANDARD 1 Regulatory Foundation.....	12
STANDARD 2 Training Program	16
STANDARD 3 Inspection Program	25
STANDARD 4 Audit Program.....	32
STANDARD 5 Animal Food-Related Illnesses or Death and Emergency Response	40
STANDARD 6 Compliance and Enforcement Program	44
STANDARD 7 Outreach Activities Program.....	47
STANDARD 8 Program Planning and Resources.....	49
STANDARD 9 Assessment and Improvement.....	55
STANDARD 10 Laboratory Services	59
STANDARD 11 Sampling Program.....	63

Background

AFRPS 2020	AFRPS 2023 – Proposed Changes
<p>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:</p>	<p>In the U.S., federal, state, local, tribal, and territorial (SLTT) regulatory agencies ensure the safety of ANIMAL FOOD. The Food and Drug Administration (FDA) and state PROGRAMS are responsible for ensuring that ANIMAL FOOD moving within their jurisdiction is safe, wholesome, and/or labeled properly. These responsibilities can include conducting inspections and regulatory activities that help ensure ANIMAL FOOD manufactured, processed, packaged, held, and distributed within their jurisdictions are safe and in compliance with applicable laws and regulations. State PROGRAMS primarily perform inspections under their own regulatory authority. Some state PROGRAMS conduct inspections of ANIMAL FOOD establishments under contract with FDA. Because jurisdictions may overlap, FDA and state PROGRAMS collaborate and share resources to protect ANIMAL FOOD. To better facilitate a partnership among regulatory authorities, state PROGRAMS should achieve IMPLEMENTATION with the Animal Food Regulatory Program Standards (AFRPS).</p>
<p>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 2009¹. 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</p>	<p>The implementation of seamless partnerships between FDA and SLTTs enable programs with comparable regulatory public health systems, as trusted partners, to rely on, coordinate with, and leverage one another's work, data, and actions to meet the public health goal of a safe national food supply. The FDA and the Association of American Feed Control Officials (AAFCO) are members of the Partnership of Food Protection (PFP). The vision for an Integrated Food Safety System (IFSS) was developed in 2009¹. One of the foundational principles of an IFSS is the IMPLEMENTATION and uniform application of model standards so that federal and SLTT regulatory agencies conduct regulatory activities 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</p>

¹ Link to the current PFP vision documents available at <https://www.pfp-ifss.org/about/pfp-vision1/>.

<p>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.</p>	<p>MFRPS were developed for human food only and did not apply to ANIMAL FOOD. As further development on the IFSS progressed, there was a recognized need to develop standards for ANIMAL FOOD state 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 FOOD state PROGRAMS. Standards provide a consistent, underlying foundation that is critical for uniformity across federal and SLTT agencies to ensure the credibility of all programs under an IFSS.</p>
<p>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.</p>	<p>The Food Safety Modernization Act (FSMA) provides further support for developing AFRPS. FSMA was signed into law in January 2011 and calls for enhanced partnerships and integration with federal and SLTT agencies. The mutual reliance called for by FSMA will allow FDA to leverage capacity, inspections, and data collected by other agencies to support regulatory activities and further enhance the idea of an IFSS.</p>
<p>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.</p>	<p>In 2011, FDA and AAFCO entered into a partnership to develop the AFRPS and was initially launched in January 2014. These standards are designed to promote uniformity and consistency among ANIMAL FOOD state 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 FOOD supply.</p>

Introduction

AFRPS 2020	AFRPS 2023 – Proposed Changes
<p>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.</p>	<p>The AFRPS establishes a uniform foundation for the design and management of state PROGRAMS responsible for the regulation of ANIMAL FOOD. Through IMPLEMENTATION of 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 FOOD supply. IMPLEMENTATION of the AFRPS is voluntary. A state PROGRAM’S IMPLEMENTATION of the AFRPS helps ensure a uniform and consistent approach to ANIMAL FOOD regulation among jurisdictions including the sharing of information and the coordination of resources.</p>
<p>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.</p>	<p>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 program, inspection program, auditing program, ANIMAL FOOD-related illnesses or death and emergency response, compliance and enforcement program, outreach program, planning and resources, laboratory services, sampling program, and assessment and improvement of standard IMPLEMENTATION.</p>
<p>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</p>	<p>Each standard is laid out in the following format to ensure uniformity: Purpose (x.1), Requirement Summary (x.2), Program Elements (x.3), Outcome (x.4), and Documentation (x.5). The program elements describe the best practices of a high-quality state PROGRAM. Required program 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 sometimes in the AFRPS. Program elements and corresponding conditions described as “should” are best practices but are optional and not required to IMPLEMENT a standard. To IMPLEMENT the AFRPS, the state PROGRAM must IMPLEMENT all eleven standards. “Notes” are used sometimes to provide clarification, alternatives, and guidance that the state PROGRAM</p>

<p>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.</p>	<p>may use to help IMPLEMENT the AFRPS. “Notes” do not contain program elements and thus will not be subject to an FDA verification assessment.</p>
	<p>Each standard has appendices designed to assist the state PROGRAM in achieving and maintaining IMPLEMENTATION. State PROGRAMS are not obligated to use the appendices provided in the AFRPS. Other manual or electronic generated forms, worksheets, and templates may be used if all program elements are present.</p>
<p>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.</p>	<p>Each standard has a corresponding self-assessment worksheet (Appendix x.1). The state PROGRAM uses the self-assessment worksheets to determine if the program elements are, or remain, fully met, partially met, or not met. The self-assessment worksheets are used to develop a strategic improvement plan for to IMPLEMENTATION of standards.</p>
<p>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. (Reworded and separated into different paragraphs.)</p>	<p>The state PROGRAM maintains CURRENT AND FIT-FOR-USE documents required in the standards to verify IMPLEMENTATION for the purposes of a verification assessment. The AFRPS is not intended to address the performance appraisal processes that an agency may use to evaluate individual employee performance.</p>
	<p>FDA uses the AFRPS as a tool to promote and verify the development of a high-quality ANIMAL FOOD regulatory PROGRAM, which includes a process for continuous improvement based upon quality management systems. The AFRPS assists both FDA and the states in fulfilling their regulatory obligations. State PROGRAMS enrolled in the AFRPS under an FDA funding vehicle are expected to develop and IMPLEMENT a strategic improvement plan to demonstrate that they are moving toward IMPLEMENTATION and to participate in FDA assessments. State</p>

	PROGRAMS are encouraged to build systems that are sustainable and IMPLEMENT plans that result in the standards being maintained.
	The collection of information is approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The OMB control number is 0910-0760.

Definitions

AFRPS 2020	AFRPS 2023 – Proposed Changes
<p>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.</p>	<p>Animal Food: 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 (CFR) section 507.3 (21 CFR 507.3), and (3) for animal feed in the AAFCO Official Publication (AAFCO OP).</p>
<p>Contact Hour(s): One contact hour equals 60 minutes.</p>	<p>Contact Hour: One CONTACT HOUR equals 60 minutes.</p>
	<p>Corrective Action: Action to correct a DEVIATION from the program elements of a standard.</p>
<p>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.</p>	
	<p>Current and Fit-for-Use: “Current” indicates that documentation is signed and dated in accordance with state PROGRAM procedures that meet criteria in the most current standard. “Fit-for-use” is a quality term used to indicate that a product or service fits the customer’s defined purpose for that product or service. Documentation may be electronic or hard copy.</p>
	<p>Curriculum: A plan which includes documented specific coursework and field training for both inspection and sample collection.</p>
	<p>Deviation: Non-fulfillment of a program element.</p>

	<p>Document Control: Ensures that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.</p>
<p>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.</p>	<p>Emergency: 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 the ANIMAL FOOD supply.</p>
<p>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.</p>	<p>Enforcement Strategy: 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.</p>
<p>Equivalent: State law directly references the relevant FD&C Act provision or Federal regulation.</p>	<p>Equivalent: State law directly references the relevant FD&C Act provision or federal regulation.</p>
<p>Equivalent in Effect: State law has the same regulatory effect as the relevant FD&C Act provision or Federal regulation.</p>	<p>Equivalent in Effect: State law has the same regulatory effect as the relevant FD&C Act provision or federal regulation.</p>
<p>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.</p>	<p>Implement/Implementation: Means a state PROGRAM has a particular program element, system, or program as required in the Program Elements and Documentation sections of the AFRPS; and can demonstrate the use of that particular program element, system, or program.</p>
<p>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.</p>	<p>Joint Field Training Inspection: 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 an establishment which may either be trainer led or trainee led.</p>

	No Authority: Responsibility for enforcing a relevant FD&C Act provision or federal regulation lies with another program or agency and not the state PROGRAM. There is such a state law, but it does not apply to the state's PROGRAM.
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.	Not Equivalent: There is no state law EQUIVALENT to the relevant FD&C Act provision or federal regulation, or 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.	
	Outreach Activity: A spontaneous or planned activity where the state PROGRAM provides materials or information that relates to ANIMAL FOOD topics to industry stakeholders, academia, other regulators, or consumers. Materials or information may include but is not limited to brochures, pamphlets, printed materials, websites, or other items.
	Outreach Event: An OUTREACH EVENT which the state PROGRAM hosts, co-hosts, or is an invited presenter such as seminars, workshops, conferences, trainings, or meetings that relate to ANIMAL FOOD topics and that support communication and information exchange among industry stakeholders, academia, other regulators, or consumers.
	Preventive Action: Action to prevent the recurrence of a DEVIATION requiring a CORRECTIVE ACTION.

<p>Program(s): An operational unit(s) in a regulatory agency that is responsible for the regulatory oversight of ANIMAL FEED.</p>	<p>Program: An operational unit in a regulatory agency that is responsible for the regulatory oversight of ANIMAL FOOD.</p>
<p>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.</p>	<p>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.</p>
<p>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.</p>	<p>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.</p>
<p>Regulatory Foundation: The laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of an ANIMAL FEED facility.</p>	<p>Regulatory Foundation: The statutes, regulations, rules, ordinances, or other regulatory requirements that govern the operation of an ANIMAL FOOD establishment.</p>
<p>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.</p>	<p>Regulatory Testing Laboratory: A laboratory that conducts measurements and analyses on food or ANIMAL FOOD and associated physical samples, which result in qualitative or quantitative analytical findings that may be used as a basis for regulatory action.</p>
	<p>Sample Analysis Schedule: A schedule of analyses based on the sampling plan developed in cooperation with the REGULATORY TESTING LABORATORY performing routine services to ensure compatibility with REGULATORY TESTING LABORATORY capabilities and capacities.</p>
<p>Start Date: Date employee is hired or reassigned in or into the ANIMAL FEED PROGRAM as the beginning date for training timelines.</p>	<p>Start Date: Date employee is hired or reassigned in or into the ANIMAL FOOD state PROGRAM as the beginning date for training timelines.</p>

STANDARD 1
Regulatory Foundation

	AFRPS 2020		AFRPS 2023 – Proposed Changes
1.1	Purpose	1.1	Purpose
	This standard describes the elements of the REGULATORY FOUNDATION used by a State PROGRAM to regulate ANIMAL FEED.		This standard describes the program elements used by a state PROGRAM to effectively evaluate and review the REGULATORY FOUNDATION to regulate ANIMAL FOOD.
1.2	Requirement Summary	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 establishes an evaluation 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 FOOD.
	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.		This includes an evaluation of how the state’s legal authority and regulatory provisions correspond to the sections of the FD&C Act and CFR specified in Appendix 1.2.
1.3	Program Elements	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	Evaluation of Legal Authority The state PROGRAM conducts an evaluation to determine whether the state’s legal authority and regulatory provisions are EQUIVALENT, EQUIVALENT IN EFFECT, NOT EQUIVALENT, or NO AUTHORITY to the specified sections of the current FD&C Act and CFR Title 21, and completes Appendix 1.2, or an equivalent form.
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.		Note: In conducting such an evaluation, the state PROGRAM should consult with its legal counsel when state law or regulation 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.
	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	Regulatory Foundation Evaluation The state PROGRAM has a procedure that includes:
1.3.2.1	Procedures to review the statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that:	1.3.2.1	Reviewing the statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that:
1.3.2.1.1	Apply to the regulation of ANIMAL FEED.	1.3.2.1.1	Apply to the regulation of ANIMAL FOOD.
1.3.2.1.2	Delegate authority to the State agency.	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.	1.3.2.1.3	Describe the state agency's administrative procedure for establishing its authority and incorporating rules by reference.
1.3.2.2	Timeframes for the review.	1.3.2.2	Timeframe for the review.
1.4	Outcome	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.		The state PROGRAM utilizes the evaluation of its REGULATORY FOUNDATION to protect animal and public health by ensuring the safety and security of ANIMAL FOOD.
1.5	Documentation	1.5	Documentation
	The State PROGRAM maintains the records listed here.		The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:
1.5.1	Appendix 1.1: Self-Assessment Worksheet	1.5.1	Appendix 1.1: Self-Assessment Worksheet.
1.5.2	Appendix 1.2: REGULATORY FOUNDATION Worksheet	1.5.2	Appendix 1.2: Regulatory Foundation Worksheet.

1.5.3	Documented process for reviewing appropriate statutes, regulations, rules, ordinances, and other prevailing regulatory requirements	1.5.3	Procedure 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	1.5.4	The statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that: (1) apply to the regulation of ANIMAL FOOD , (2) delegate authority to the state agency, and (3) describe the state agency's administrative procedure for establishing its authority and incorporating rules by reference.

STANDARD 2
Training Program

2.1	Purpose	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.		This standard describes the program elements used by a state PROGRAM to have an effective ANIMAL FOOD training program.
2.2	Requirement Summary	2.2	Requirement Summary
	The State PROGRAM has a training plan that ensures all inspectors are adequately trained to perform their work.		The state PROGRAM establishes a training program that ensure all inspectors complete coursework, field training, and continuing education to effectively perform their assignments and responsibilities.
2.3	Program Elements	2.3	Program Elements
2.3.1	Training Plan and Training Records	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.	2.3.1.1	The state PROGRAM has a documented training plan that includes training and continuing education, as defined by the state PROGRAM, that includes:
2.3.1.2	The State PROGRAM provides, or otherwise makes available, inspection training and continuing education for all inspectors.	2.3.1.1.1	Description of each inspection type.
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.	2.3.1.1.2	CURRICULUM for each inspection type.

	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. (Renumbered to 2.3.1.3)		
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. (Reworded. 2.3.1.2; Separated into sub-elements. 2.3.1.2.1; 2.3.1.2.2)	2.3.1.2	For inspectors with greater than five years of experience at the date of the initial self-assessment or at the inspectors START DATE , where their training documentation is not available, the state PROGRAM:
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. (Reworded. 2.3.1.2.2)	2.3.1.2.1	Documents an evaluation of the inspector's performance and experience to determine if additional training is needed.
		2.3.1.2.2	Maintains proper supporting documents to verify successful completion of the requirement, if previous coursework is completed before the inspectors START DATE and utilized to meet coursework requirements.
		2.3.1.3	The state PROGRAM maintains records documenting the training completed by all inspectors on Appendix 2.2, or an equivalent form.
2.3.2	Basic ANIMAL FOOD Inspector Training	2.3.2	Basic ANIMAL FOOD 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.	2.3.2.1	Timeframe The state PROGRAM requires a basic inspector to successfully complete the basic coursework within 24 months from the START DATE.
2.3.2.2	Coursework:	2.3.2.2	Coursework

	The basic feed inspection training consists of coursework in the following subject areas:		Basic inspector training consists of basic 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.	2.3.2.2.1	Animal and Public Health Principles
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.	2.3.2.2.2	Animal Food Defense
2.3.2.2.3	Basic Feed Ingredients, Processing, and Technology: Typical ingredients, feedstuffs, processing methods, and technologies commonly used to manufacture ANIMAL FEED.	2.3.2.2.3	Basic Animal Nutrition
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.	2.3.2.2.4	Basic Ingredients, Processing, and Technology
2.3.2.2.5	Communication: Techniques and skills for effective oral and written communication and interviewing.	2.3.2.2.5	Basic National Incident Management System and Incident Command System (ICS)
2.3.2.2.6	Current Statutes, Regulations, and Policies: Basic knowledge of Federal and State laws, regulations, and policies.	2.3.2.2.6	Communication
2.3.2.2.7	Feed Defense: Feed defense principles for the protection of feed from intentional hazard contamination.	2.3.2.2.7	Current Statutes, Regulations, and Policies
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.	2.3.2.2.8	Inspections, Compliance, and Enforcement
2.3.2.2.9	Labeling: Basic feed labeling requirements.	2.3.2.2.9	Labeling
2.3.2.2.10	Professionalism: Character conduct, strengths, and values directed toward providing high quality service to the	2.3.2.2.10	Professionalism

	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.	2.3.2.2.11	Risk Awareness
2.3.2.2.12	Safety: Appropriate personal safety and bio-security requirements when conducting field activities.	2.3.2.2.12	Safety
2.3.2.2.13	Sampling: Techniques and skills for collecting various types of samples using the appropriate methods for preparation, collection, and shipping.	2.3.2.2.13	Sample Collection
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	Field Training The state PROGRAM requires 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; (Reworded. Renumbered. 2.3.2.3.4)	2.3.2.3.1	The procedure for JOINT FIELD TRAINING INSPECTIONS.
2.3.2.3.2	Documented procedures for JOINT FIELD TRAINING INSPECTIONS; (Renumbered. 2.3.2.3.1)	2.3.2.3.2	The number of JOINT FIELD TRAINING INSPECTIONS that are conducted in establishments that represent the state PROGRAM inventory and the type of basic work that will be performed by the inspector.
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; (Renumbered. 2.3.2.3.2)	2.3.2.3.3	List the competencies and the minimum number of JOINT FIELD TRAINING INSPECTIONS on Appendix 2.3, or an equivalent form.
2.3.2.3.4	The inspector completes basic field training prior to performing independent inspections ; (Renumbered. 2.3.2.3.5)	2.3.2.3.4	The QUALIFIED FIELD INSPECTION TRAINER verifies the field training checklist of competencies in the field for each inspection type .
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	2.3.2.3.5	The inspector completes the minimum basic field training requirements for the inspection type , prior to

	FIELD TRAINING INSPECTIONS. (Reworded. Renumbered. 2.3.2.3.3)		performing independent work.
2.3.3	Advanced ANIMAL FOOD Inspector Training	2.3.3	Advanced ANIMAL FOOD 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.	2.3.3.1	Timeframe The state PROGRAM requires an advanced inspector to successfully complete the advanced coursework 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	Coursework Advanced inspector training consists of advanced coursework in the following subject areas but not limited to:
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.	2.3.3.2.1	Advanced Ingredients, Processing, and Technology
		2.3.3.2.2	Advanced Inspections, Compliance and Enforcement
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	Advanced Labeling
2.3.3.2.3	Animal Sickness and Death Investigation: Principles of outbreak investigations.	2.3.3.2.4	Animal Illness and Death Investigation
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	Current Statutes, Regulations, and Policies
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	Epidemiology

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	Microbiological Pathogens
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.	2.3.3.2.8	Traceback and Traceforward Investigations
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:	2.3.3.3	Field Training The state PROGRAM requires 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; (Reworded. Renumbered. 2.3.3.3.4)	2.3.3.3.1	The procedure for JOINT FIELD TRAINING INSPECTIONS.
2.3.3.4.2	Documented procedures for JOINT FIELD TRAINING INSPECTIONS; (Renumbered. 2.3.3.3.1)	2.3.3.3.2	The number of JOINT FIELD TRAINING INSPECTIONS that are conducted in establishments that represent the state PROGRAM inventory and the type of advanced work that will be performed by the inspector.
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 (Renumbered. 2.3.3.3.2)	2.3.3.3.3	List the competencies and the minimum number of JOINT FIELD TRAINING INSPECTIONS on Appendix 2.3, or an equivalent form.
2.3.3.4.4	The inspector completes field training prior to performing independent inspections requiring advanced skills ; (Renumbered. 2.3.3.3.5)	2.3.3.3.4	The QUALIFIED FIELD INSPECTION TRAINER verifies the field training checklist of competencies in the field for each inspection type .
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. (Reworded. Renumbered. 2.3.3.3.3)	2.3.3.3.5	The inspector completes the minimum advanced field training for the inspection type , prior to performing independent work .
2.3.6	Continuing Education (CE) : The State PROGRAM requires that each basic and advanced inspector participate in continuing education.	2.3.4	Continuing Education The state PROGRAM requires that each basic and advanced inspector participate in continuing education. The continuing education specifies the following:
2.3.6.1	Each inspector is required to receive 20 CONTACT HOURS of continuing education every 36 months.	2.3.4.1	Each inspector receives 20 CONTACT HOURS of continuing education every 36 months.
2.3.6.2	The 36 month continuing education interval starts, as	2.3.4.2	The 36-month continuing education interval starts, as

	defined by the State PROGRAM, when the required curriculum is complete.		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.	2.3.4.3	Documentation accompanies each activity submitted for continuing education.
	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	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.		The state PROGRAM utilizes the training program to ensure inspectors have the knowledge, skills, and abilities to effectively inspect ANIMAL FOOD establishments , conduct investigations, gather evidence, collect samples, and take enforcement actions.
2.5	Documentation	2.5	Documentation
	The State PROGRAM maintains the records listed here.		The state PROGRAM maintains the records, or equivalent forms or worksheets , listed here:
2.5.1	Appendix 2.1: Self-Assessment Worksheet	2.5.1	Appendix 2.1: Self-Assessment Worksheet.
2.5.2	Training Plan	2.5.2	Training Plan.
2.5.3	Appendix 2.2: Inspector Training Record	2.5.3	Appendix 2.2: Inspector Training Record.
2.5.4	Appendix 2.3: Field Training Competencies	2.5.4	Appendix 2.3: Field Training Competencies.
2.5.5	Documents verifying successful completion of required courses	2.5.5	Documents verifying successful completion of required coursework .
2.5.6	Documentation for continuing education credit	2.5.6	Documentation for continuing education.

STANDARD 3
Inspection Program

3.1	Purpose	3.1	Purpose
	This standard describes the elements of an effective ANIMAL FEED inspection program.		This standard describes the program elements used by a state PROGRAM to have an effective ANIMAL FOOD inspection program.
3.2	Requirement Summary	3.2	Requirement Summary
	The State PROGRAM administers an inspection program to determine compliance with ANIMAL FEED laws.		The state PROGRAM establishes a risk-based inspection program to determine compliance with ANIMAL FOOD laws. The includes procedures to handle recalls, consumer complaints and complaints resulting from state program inspection activities.
3.3	Program Elements	3.3	Program Elements
3.3.1	Risk-Based Inspection Program	3.3.1	Risk-Based Inspection Program
3.3.1.1	The State PROGRAM has documented procedures to:	3.3.1.1	The state PROGRAM has a procedure to define and maintain a current inventory of ANIMAL FOOD establishments whose activities fall under the state PROGRAM'S jurisdiction and authority.
3.3.1.1.1	Define an up-to-date inventory of feed facilities whose activities fall under the State's jurisdiction and authority; (Combined with 3.3.1.1)		
3.3.1.1.2	Maintain the inventory of feed facilities defined in 3.3.1.1.1. (Combined with 3.3.1.1)		
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	The state PROGRAM has a procedure for risk categorization of ANIMAL FOOD establishments using the three minimum required factors for defining risk categories:
3.3.1.2.1	Types of feed and feed products;	3.3.1.2.1	Types of ANIMAL FOOD and ANIMAL FOOD products.

3.3.1.2.2	Types of processing;	3.3.1.2.2	Types of processing.
3.3.1.2.3	Compliance history of the facility .	3.3.1.2.3	Compliance history of the establishment .
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. (Combined with 3.3.1.2)		
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:	3.3.1.3	Based on risk categorization of an ANIMAL FOOD establishment , inspections are:
3.3.1.4.1	Are prioritized;	3.3.1.3.1	Prioritized.
3.3.1.4.2	Have assigned frequencies;	3.3.1.3.2	Assigned frequencies.
3.3.1.4.3	Have resources allocated. (Reworded. 3.3.1.3.3)	3.3.1.3.3	Allocated resources.
	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.		
3.3.2	Inspection Protocol	3.3.2	Inspection Procedure The state PROGRAM has procedures for inspecting ANIMAL FOOD establishments that require the inspectors to:
3.3.2.1	The State PROGRAM has documented policies and procedures for inspecting ANIMAL FEED facilities that require the inspectors to: (Combined with 3.3.2)		
3.3.2.1.1	Review the feed facility's previous inspection report(s) and complaint(s);	3.3.2.1	Review the ANIMAL FOOD establishment's history and determine the scope of the inspection.
3.3.2.1.2	Present appropriate credentials and written Notice of Inspection to the feed facility's owner, operator, or agent	3.3.2.2	Present appropriate credentials and written Notice of Inspection to the ANIMAL FOOD establishment's owner,

	in charge; make appropriate introductions; explain the purpose and scope of the inspection; and determine inspection authority;		operator, or agent in charge; make appropriate introductions; explain the purpose and scope of the inspection; confirm inspection authority and establish FDA jurisdiction, if applicable.
3.3.2.1.3	Follow the safety protocols required by the feed facility and the State PROGRAM;	3.3.2.3	Follow the safety protocols required by the ANIMAL FOOD establishment and the state PROGRAM.
3.3.2.1.4	Follow the biosecurity protocols required by the feed facility and the State PROGRAM;	3.3.2.4	Follow the biosecurity protocols required by the ANIMAL FOOD establishment and the state PROGRAM.
3.3.2.1.5	Use appropriate equipment and forms needed to conduct inspections;	3.3.2.5	Use appropriate equipment and forms needed to conduct inspections.
3.3.2.1.6	Establish interstate jurisdiction for FDA inspections, if applicable; (Combined with 3.3.2.1.2)		
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;	3.3.2.6	Recognize the relative risk categorization of the ANIMAL FOOD establishment based on the risk-based inspection program.
3.3.2.1.8	Conduct inspection activities, appropriate for the level of risk, focused on these firms , products, and processes determined to be high risk;	3.3.2.7	Conduct comprehensive inspection activities, appropriate for the level of risk, focused on the establishment's products and processes determined to be of higher risk.
3.3.2.1.9	Assess employee activities critical to the safe manufacture, distribution, storage, handling, and disposition of feed;	3.3.2.8	Assess employee activities critical to the safe manufacturing, processing, packaging, handling, holding, and distribution of ANIMAL FOOD.
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;	3.3.2.9	Properly evaluate the potential that conditions, practices, processes, components, or labeling could cause the product to become adulterated, contaminated , or misbranded.
3.3.2.1.11	Recognize significant non-compliant conditions or practices and document findings consistent with PROGRAM procedures;	3.3.2.10	Recognize significant non-compliant conditions or practices and document findings consistent with state PROGRAM procedure.

3.3.2.1.12	Distinguish between significant and insignificant observations and isolated incidents versus trends;	3.3.2.11	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 ; (Reworded. 3.3.2.12)	3.3.2.12	Review, evaluate, and verify that the appropriate ANIMAL FOOD establishment records, plans, programs, and/or procedures are established, maintained, and/or implemented .
3.3.2.1.14	Collect adequate evidence and documentation to support inspection observations in accordance with PROGRAM procedures;	3.3.2.13	Collect adequate evidence and documentation to support inspection observations in accordance with state PROGRAM procedures.
3.3.2.1.15	Verify correction of deficiencies identified during the previous inspection(s);	3.3.2.14	Verify deficiencies identified during the previous inspections have been addressed .
3.3.2.1.16	Conduct activities in a professional manner;	3.3.2.15	Conduct activities in a professional manner.
3.3.2.1.17	Use effective interviewing techniques;	3.3.2.16	Use effective interviewing techniques.
3.3.2.1.18	Explain findings clearly and adequately throughout the inspection;	3.3.2.17	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;	3.3.2.18	Alert the ANIMAL FOOD establishment'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;	3.3.2.19	Document findings accurately, clearly, legibly, and concisely on the applicable forms and provide a copy to the ANIMAL FOOD establishment's owner, operator, or agent in charge.
3.3.2.1.21	Answer questions and provide information as appropriate;	3.3.2.20	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 .	3.3.2.21	Submit inspection report, samples where applicable , and supporting evidence and documentation within designated timeframes consistent with state PROGRAM procedure .

3.3.3	Recall System	3.3.3	Recall System The state PROGRAM has procedures to handle recalls that includes:
3.3.3.1	The State PROGRAM has a documented recall system. The recall system includes: (Combined with 3.3.3)		
3.3.3.1.1	Written procedures for : (Combined with 3.3.3)		
3.3.3.1.1.1	Receiving	3.3.3.1	Receiving
3.3.3.1.1.2	Tracking	3.3.3.2	Tracking
3.3.3.1.1.3	Evaluating recall notifications	3.3.3.3	Evaluating recall notifications
3.3.3.1.1.4	Closing	3.3.3.4	Closing
3.3.3.1.1.5	Maintaining records	3.3.3.5	Maintaining records
3.3.3.1.2	Performing recall effectiveness checks (Renumbered. 3.3.36)	3.3.3.6	Performing recall effectiveness checks, as applicable
3.3.4	Consumer Complaints	3.3.4	Consumer Complaints The state PROGRAM has a procedure to handle consumer complaints that includes:
3.3.4.1	The State PROGRAM has a documented system for handling consumer complaints. The system includes procedures for : (Reworded. Combined with 3.3.4)		
3.3.4.1.1	Receiving	3.3.4.1	Receiving
3.3.4.1.2	Tracking	3.3.4.2	Tracking
3.3.4.1.3	Evaluating	3.3.4.3	Evaluating
3.3.4.1.4	Answering	3.3.4.4	Answering

3.3.4.1.5	Closing	3.3.4.5	Closing
3.3.4.1.6	Maintaining records	3.3.4.6	Maintaining records
3.3.5	Complaints Resulting from State PROGRAM Inspection Activities	3.3.5	Complaints Resulting from State PROGRAM Inspection Activities The state PROGRAM has a procedure to handle industry complaints resulting from state PROGRAM inspection activities that includes:
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: (Reworded. Combined with 3.3.5)		
3.3.5.1.1	Receiving	3.3.5.1	Receiving
3.3.5.1.2	Evaluating	3.3.5.2	Evaluating
3.3.5.1.3	Maintaining records	3.3.5.3	Maintaining records
3.4	Outcome	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.		The state PROGRAM utilizes the risk-based ANIMAL FOOD inspection program to significantly minimize or prevent the occurrence of ANIMAL FOOD adulteration, contamination, and misbranding.
3.5	Documentation	3.5	Documentation
	The State PROGRAM maintains the records listed here.		The state PROGRAM maintains the records, or equivalent forms or worksheets , listed here:
3.5.1	Appendix 3.1: Self-Assessment Worksheet	3.5.1	Appendix 3.1: Self-Assessment Worksheet.

3.5.2	Documented procedures for defining the State's inventory of feed facilities (Combined with 3.5.3. Renumbered to 3.5.3)	3.5.2	An inventory of ANIMAL FOOD establishments.
3.5.3	Documented procedures for updating the State's inventory of feed facilities (Combined with 3.5.2. Renumbered to 3.5.3)	3.5.3	Procedure for defining and maintaining the state PROGRAM'S current inventory of ANIMAL FOOD establishments.
3.5.4	An inventory of feed facilities (Renumbered to 3.5.2)		
3.5.5	Documented procedures used for categorizing feed facilities based on risk, including the inspection frequency assigned to each defined risk-based category (Renumbered to 3.5.4)	3.5.4	Procedure for categorizing ANIMAL FOOD establishments 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 (Renumbered to 3.5.5)	3.5.5	Procedures for inspecting ANIMAL FOOD establishments.
3.5.7	Documented recall system, which includes written recall procedures	3.5.6	Procedures for recall system.
3.5.8	Documented procedures for consumer complaints	3.5.7	Procedure for consumer complaints.
3.5.9	Documented procedures for industry complaints about State PROGRAM inspection activities	3.5.8	Procedure for industry complaints about state PROGRAM inspection activities.

STANDARD 4
Audit Program

4.1	Purpose	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.		This standard describes the program elements used by a state PROGRAM to have an effective ANIMAL FOOD audit program.
4.2	Requirement Summary	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.		The state PROGRAM establishes an audit program to document and evaluate the effectiveness of the state PROGRAM'S inspection and sample collections. This includes two components: (1) a field audit component, which is an on-site performance evaluation of inspection and sample collection procedures and (2) a report audit component, which is a performance evaluation of the inspection and sample collection reports, to verify they are consistently performed according to established performance factors.
4.3	Program Elements	4.3	Program Elements
4.3.1	The State PROGRAM has written procedures for conducting four types of audits:	4.3.1	Audit Program The state PROGRAM has procedures for conducting four types of audits:
4.3.1.1	Field inspection audits as specified in 4.3.3;	4.3.1.1	Field inspection audits as described in 4.3.3
4.3.1.2	Field inspection report audits as specified in 4.3.4;	4.3.1.2	Field inspection report audits as described in 4.3.4
4.3.1.3	Sample collection audits as specified in 4.3.5;	4.3.1.3	Sample collection audits as described in 4.3.5
4.3.1.4	Sample collection report audits as specified in 4.3.6.	4.3.1.4	Sample collection report audits as described in 4.3.6
	Note: In general, each type of audit is composed of multiple		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.		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 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.	4.3.2	Audit Program Review The state PROGRAM conducts a review of the performance factor scores and cumulative scores for each of the four types of audits 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.	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 PROGRAM procedures.
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. (Separated into sub-elements. 4.3.3.1.1; 4.3.3.1.2)	4.3.3.1	Frequency
		4.3.3.1.1	Conduct a minimum of two field inspection audits of each inspector every 36 months.
		4.3.3.1.2	Select field inspections for audits that 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. (Reworded)	4.3.3.2	Performance Factors Evaluate performance factors listed in the inspection procedure as described in 3.3.2 and as listed in Appendix 4.2, or an equivalent form.
	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. (Appendix 4.2a is now a Job Aid.)		
4.3.3.3	Performance Documentation:	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; (Reworded)	4.3.3.3.1	Record the rating of each performance factor, audit score, and audit rating for each field inspection audit on Appendix 4.2, or an equivalent form. State PROGRAMS may use the current Appendix C found in FMD-76 in lieu of Appendix 4.2.
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. (Reworded)	4.3.3.3.2	Calculate performance factor scores and a cumulative score for the state PROGRAM on Appendix 4.3, or an equivalent worksheet.
	Note: Directions for calculating performance factor scores and the cumulative score can be found in appendix 4.4. (Appendix 4.4 is now a Job Aid. Subsequent Appendices have been renumbered to reflect the removal of 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	Field Inspection Report Audit The state PROGRAM conducts field inspection report audits to verify that inspectional findings are consistently reported according to the state PROGRAM’S 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 :	4.3.4.1	Frequency Review a random selection of field inspection reports to be audited based on the number of inspections completed in 12 months of performance using Table 1 .

				Table 1 Field Inspection Report Audit Requirements			
Number of Inspections in 12 Months		Minimum Number of Reports Required	Maximum Number of Reports Required	# of Inspections in 12 Months		Min # of Reports Required	Max # Reports Required
Less than 20 reports		All	All	Less than 20 reports		All	All
20 – 400 reports		20	20	20 – 400 reports		20	20
More than 400 reports		5% of reports	50	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. (Reworded)			4.3.4.2	Performance Factors Evaluate the performance factors listed in Appendix 4.4, or an equivalent form.		
4.3.4.3	Performance Documentation:			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; (Reworded)			4.3.4.3.1	Record the rating of each performance factor, audit score, and audit rating for each inspection report audit on Appendix 4.4, or an equivalent form.		
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. (Reworded)			4.3.4.3.2	Calculate performance factor scores and a cumulative score for the state PROGRAM on Appendix 4.5, or an equivalent worksheet.		
	Note: Directions for calculating performance factor scores and the cumulative score can be found in appendix 4.4. (Appendix 4.4 is now a Job Aid. Subsequent Appendices have been renumbered to reflect the removal of 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	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 PROGRAM'S procedures.		
4.3.5.1	Frequency: A minimum of two sample collection audits of each inspector			4.3.5.1	Frequency		

	is conducted every 36 months. The sample collections selected for audits must reflect the inspector’s assignments and responsibilities. (Separated into sub-elements. 4.3.5.1.1; 4.3.5.1.2)		
		4.3.5.1.1	Conduct a minimum of two sample collection audits of each inspector every 36 months.
		4.3.5.1.2	Select sample collections for audits that 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.	4.3.5.2	Performance Factors Evaluate the performance factors listed in the sample collection procedure as described in 11.3.2 and as listed in Appendix 4.6 , or an equivalent form .
	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. (Appendix 4.7a is now a Job Aid.)		
4.3.5.3	Performance Documentation:	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;	4.3.5.3.1	Record the rating of each performance factor, audit score, and audit rating for each sample collection audit on Appendix 4.6 , or an equivalent form .
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.	4.3.5.3.2	Calculate performance factor scores and a cumulative score for the state PROGRAM on Appendix 4.7 , or an equivalent worksheet .
	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	4.3.6	Sample Collection Report Audit The state PROGRAM conducts sample collection report audits to verify that sample collection documentation is consistently performed according to the state PROGRAM’S procedures.

	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:	4.3.6.1	Frequency Review a random selection of sample collection reports to be audited based on the number of samples collected in 12 months of performance based using Table 2. Table 2 Sample Collection Report Audit Requirements																								
	<table border="1"> <thead> <tr> <th>Number of Samples Collected in 12 Months</th> <th>Minimum Number of Reports</th> <th>Maximum Number of Reports</th> </tr> </thead> <tbody> <tr> <td>Less than 40 reports</td> <td>All</td> <td>All</td> </tr> <tr> <td>40 – 800 reports</td> <td>40</td> <td>40</td> </tr> <tr> <td>More than 800 reports</td> <td>5% of reports</td> <td>70</td> </tr> </tbody> </table>	Number of Samples Collected in 12 Months	Minimum Number of Reports	Maximum Number of Reports	Less than 40 reports	All	All	40 – 800 reports	40	40	More than 800 reports	5% of reports	70		<table border="1"> <thead> <tr> <th># of Samples Collected in 12 Months</th> <th>Min # of Reports Required</th> <th>Max # of Reports Required</th> </tr> </thead> <tbody> <tr> <td>Less than 40 reports</td> <td>All</td> <td>All</td> </tr> <tr> <td>40 – 800 reports</td> <td>40</td> <td>40</td> </tr> <tr> <td>More than 800 reports</td> <td>5% of reports</td> <td>70</td> </tr> </tbody> </table>	# of Samples Collected in 12 Months	Min # of Reports Required	Max # of Reports Required	Less than 40 reports	All	All	40 – 800 reports	40	40	More than 800 reports	5% of reports	70
Number of Samples Collected in 12 Months	Minimum Number of Reports	Maximum Number of Reports																									
Less than 40 reports	All	All																									
40 – 800 reports	40	40																									
More than 800 reports	5% of reports	70																									
# of Samples Collected in 12 Months	Min # of Reports Required	Max # 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. (Reworded)	4.3.6.2	Performance Factors Evaluate the performance factors listed in Appendix 4.8, or an equivalent form.																								
4.3.6.3	Performance Documentation:	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;	4.3.6.3.1	Record the rating of each performance factor, audit score, and audit rating for each sample collection report audit on Appendix 4.8, or an equivalent form.																								
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.	4.3.6.3.2	Calculate performance factor scores and a cumulative score for the state PROGRAM on Appendix 4.9, or an equivalent worksheet.																								
	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	4.3.7	Corrective Action Plan The state PROGRAM documents CORRECTIVE ACTIONS as described in 9.3.2 for each of the four types of audits when																								

	occur for any type of audit.		any of the following conditions are met:
4.3.7.1	An inspector receives an overall audit rating of “needs improvement” (audit score below 80 percent) for an individual audit.	4.3.7.1	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.	4.3.7.2	A state PROGRAM has a performance factor score (as a result of all audits in 12 months of performance) 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.	4.3.7.3	A state PROGRAM has a cumulative score (as a result of all audits in 12 months of performance) below 80 percent.
4.4	Outcome	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.		The state PROGRAM utilizes the audit program to evaluate its inspection and sample collection activities for effectiveness, to recognize trends, and to document CORRECTIVE ACTIONS, when necessary.
4.5	Documentation	4.5	Documentation
	The State PROGRAM maintains the records listed here.		The state PROGRAM maintains the records, or equivalent forms or worksheets , listed here:
4.5.1	Appendix 4.1: Self-Assessment Worksheet	4.5.1	Appendix 4.1: Self-Assessment Worksheet.
4.5.2	Written procedures for conducting four types of audits	4.5.2	Procedure for conducting four types of audits.
4.5.3	Appendix 4.2: Field Inspection Audit Form	4.5.3	Appendix 4.2: Field Inspection Audit Form.
4.5.4	Appendix 4.3: Field Inspection Audit Worksheet	4.5.4	Appendix 4.3: Field Inspection Audit Worksheet.
4.5.5	Appendix 4.5: Field Inspection Report Audit Form	4.5.5	Appendix 4.4: Field Inspection Report Audit Form.
4.5.6	Appendix 4.6: Field Inspection Report Audit Worksheet	4.5.6	Appendix 4.5: Field Inspection Report Audit Worksheet.
4.5.7	Appendix 4.7: Sample Collection Audit Form	4.5.7	Appendix 4.6: Sample Collection Audit Form.
4.5.8	Appendix 4.8: Sample Collection Audit Worksheet	4.5.8	Appendix 4.7: Sample Collection Audit Worksheet.

4.5.9	Appendix 4.9: Sample Collection Report Audit Form	4.5.9	Appendix 4.8: Sample Collection Report Audit Form.
4.5.10	Appendix 4.10: Sample Collection Report Audit Worksheet	4.5.10	Appendix 4.9: Sample Collection Report Audit Worksheet.
4.5.11	Appendix 4.11: Corrective Action Plan		

STANDARD 5
Animal Food-Related Illnesses or Death and Emergency Response

5.1	Purpose	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.		This standard describes the program elements used by a state PROGRAM to effectively detect, identify, and respond to ANIMAL FOOD-related illnesses or deaths and EMERGENCIES.
5.2	Requirement Summary	5.2	Requirement Summary
	The State PROGRAM has a system to conduct emergency response to feed -related illnesses, deaths, and EMERGENCIES.		The state PROGRAM establishes a system to conduct EMERGENCY response to ANIMAL FOOD-related illnesses or deaths and EMERGENCIES.
5.3	Program Elements	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.	5.3.1	Animal Food-Related Illnesses or Deaths and Emergencies Procedure
		5.3.1.1	The state PROGRAM has a procedure to gather information to identify incidents of ANIMAL FOOD-related illnesses or 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.	5.3.1.2	The state PROGRAM has a procedure to communicate with the appropriate agencies or departments that investigate ANIMAL FOOD-related illnesses or deaths and EMERGENCIES.
	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:	5.3.1.3	For ANIMAL FOOD-related illnesses or deaths and EMERGENCIES, the state PROGRAM has a procedure to:

5.3.3.1	Determine the appropriate response	5.3.1.3.1	Determine the appropriate response.
5.3.3.2	Initiate the response	5.3.1.3.2	Initiate the response.
5.3.3.3	Complete the response	5.3.1.3.3	Complete the response.
5.3.4	For feed -related EMERGENCIES, the State PROGRAM manages the event using:	5.3.2	Emergency Event Management For ANIMAL FOOD-related EMERGENCIES, the state PROGRAM manages the event using:
5.3.4.1	A formalized Incident Command System structure or	5.3.2.1	An Incident Command System, or
5.3.4.2	An official action plan ² that includes:	5.3.2.2	An official action plan. The official action plan includes:
5.3.4.2.1	Outlining containment	5.3.2.2.1	Containment
5.3.4.2.2	Communication	5.3.2.2.2	Communication
5.3.4.2.3	Control	5.3.2.2.3	Control
5.3.4.2.4	Correction	5.3.2.2.4	Correction and/or Corrective Actions
5.3.4.2.5	After-action protocols	5.3.2.2.5	After-action protocols
		5.3.3	Animal Food-Related Illnesses or Deaths and Emergencies Notification Procedures
5.3.5	The State PROGRAM maintains a list of relevant agencies and emergency contacts.	5.3.3.1	The state PROGRAM maintains a current list of relevant agencies and emergency contacts that is reviewed and updated at least every 12 months.
5.3.5.1	The list is reviewed and updated based on the State defined frequency. (Reworded and combined with 5.3.3.1)		

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

	Note: Appendix 5.2 provides a template for an emergency contact list. (Appendix 5.2 is now a Job Aid.)		
5.3.6	The State PROGRAM establishes written procedures to rapidly notify government agencies, departments, or appropriate parties of relevant findings.	5.3.3.2	The state PROGRAM has a procedure to rapidly notify government agencies, departments, and 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.	5.3.3.3	The state PROGRAM has a procedure to rapidly notify law enforcement agencies when intentional ANIMAL FOOD contamination or ANIMAL FOOD -related terrorism is suspected or threatened.
5.3.8	The State PROGRAM has a written procedure for:	5.3.3.4	The state PROGRAM has a procedure for:
5.3.8.1	Releasing information to the public;	5.3.3.4.1	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.	5.3.3.4.2	Coordinating media information with other jurisdictions to reduce the impact of ANIMAL FOOD -related illnesses or deaths and EMERGENCIES.
5.4	Outcome	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.		The state PROGRAM utilizes the EMERGENCY response system to work with government agencies, departments, and appropriate parties to gather and share information to reduce ANIMAL FOOD -related illnesses or deaths and EMERGENCIES.
5.5	Documentation	5.5	Documentation
	The State PROGRAM maintains the records listed here.		The state PROGRAM maintains the records, or equivalent forms or worksheets , listed here:
5.5.1	Appendix 5.1: Self-Assessment Worksheet	5.5.1	Appendix 5.1: Self-Assessment Worksheet.
5.5.2	Documented written procedure to gather information to	5.5.2	Procedure to gather information to identify incidents of

	identify incidents of feed -related illnesses, deaths, and EMERGENCIES		ANIMAL FOOD -related illnesses or deaths and EMERGENCIES.
5.5.3	Documented procedure to communicate with Agency/ Departments	5.5.3	Procedure to communicate with agency/departments.
5.5.4	Documented written procedures to determine the appropriate response, initiate the response, and complete the response for feed -related illnesses, deaths, and EMERGENCIES	5.5.4	Procedure to determine the appropriate response, initiate the response, and complete the response for ANIMAL FOOD -related illnesses or deaths and EMERGENCIES.
5.5.5	Documented written procedures using a formalized Incident Command System structure or an official action plan	5.5.5	Procedure using an Incident Command System or an official action plan.
5.5.6	Emergency contact list	5.5.6	Emergency contact list.
5.5.7	Documented written procedures to rapidly notify government agencies, departments, or appropriate parties of relevant findings	5.5.7	Procedure to rapidly notify government agencies, departments, and appropriate parties of relevant findings.
5.5.8	Documented written procedure to immediately notify law enforcement agencies when intentional feed contamination or feed -related terrorism is suspected or threatened	5.5.8	Procedure to rapidly notify law enforcement agencies when intentional ANIMAL FOOD contamination or ANIMAL FOOD -related terrorism is suspected or threatened.
5.5.9	Documented procedure for releasing information to the public and coordinating media information with other jurisdictions	5.5.9	Procedure for releasing information to the public and coordinating media information with other jurisdictions.

STANDARD 6
Compliance and Enforcement Program

6.1	Purpose	6.1	Purpose
	This standard describes the elements of an effective enforcement program.		This standard describes the program elements used by a state PROGRAM to have an effective ANIMAL FOOD compliance and enforcement program.
6.2	Requirement Summary	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.		The state PROGRAM establishes a compliance and enforcement program with ENFORCEMENT STRATEGIES to achieve compliance with ANIMAL FOOD laws. This includes an annual evaluation of the ENFORCEMENT STRATEGIES to identify potential improvements or modifications.
6.3	Program Elements	6.3	Program Elements
		6.3.1	Compliance and Enforcement Program
6.3.1	The State PROGRAM has an enforcement program that contains documented ENFORCEMENT STRATEGIES. (Reworded)	6.3.1.1	The state PROGRAM has a documented compliance and enforcement program that contains ENFORCEMENT STRATEGIES.
6.3.2	The State PROGRAM must use the following six factors listed when selecting an appropriate enforcement tool: (Reworded)	6.3.1.2	The state PROGRAM selects an appropriate enforcement tool using the following six factors:
6.3.2.1	Compliance history	6.3.1.2.1	Compliance history
6.3.2.2	Responsiveness	6.3.1.2.2	Responsiveness
6.3.2.3	Scope	6.3.1.2.3	Scope
6.3.2.4	Nature of the Violation	6.3.1.2.4	Nature of the Violation
6.3.2.5	Impact of the Violation	6.3.1.2.5	Impact of the Violation

6.3.2.6	Resources	6.3.1.2.6	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. (Appendix 6.2 is now a Job Aid.)		
6.3.3	The State PROGRAM has a documented written description for all factors.	6.3.1.3	The state PROGRAM has a documented description for all factors.
6.3.4	The State PROGRAM has documented relative conditions for all factors.	6.3.1.4	The state PROGRAM has documented relative conditions with an assigned numerical weight for all factors.
6.3.4.1	Relative conditions of each factor will be assigned a numerical weight. (Combined with 6.3.4)		
	Note: Appendix 6.3 is an example of factor descriptions, relative conditions, and the associated numerical weights. (Appendix 6.3 is now a Job Aid.)		
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.	6.3.1.5	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. (Appendix 6.4 is now a Job Aid.)		
6.3.6	The State PROGRAM has a documented process for conducting the annual evaluation described in 6.3.7.	6.3.2	Performance Review The state PROGRAM has a procedure for conducting an evaluation of its ENFORCEMENT STRATEGIES at least every 12 months to:
6.3.7	The State PROGRAM conducts an annual evaluation of its ENFORCEMENT STRATEGIES to: (Combined with 6.3.2)		
6.3.7.1	Determine if the PROGRAM'S ENFORCEMENT STRATEGIES were successful in achieving compliance;	6.3.2.1	Determine if the state PROGRAM'S ENFORCEMENT STRATEGIES were successful in achieving compliance.

6.3.7.2	Identify potential improvements or modifications of the ENFORCEMENT STRATEGIES, if any;	6.3.2.2	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.	6.3.2.3	Determine if the enforcement priorities remain the same or require modification.
6.4	Outcome	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.		The state PROGRAM utilizes the compliance and enforcement program to achieve compliance with ANIMAL FOOD laws.
6.5	Documentation	6.5	Documentation
	The State PROGRAM maintains the records listed here.		The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:
6.5.1	Appendix 6.1: Self-Assessment Worksheet	6.5.1	Appendix 6.1: Self-Assessment Worksheet.
6.5.2	Documented ENFORCEMENT STRATEGIES	6.5.2	ENFORCEMENT STRATEGIES.
6.5.3	Documented factors including the description, relative conditions, and associated numerical weight for each	6.5.3	The ENFORCEMENT STRATEGIES factors including the description, relative conditions, and associated numerical weight for each.
6.5.4	Enforcement matrix	6.5.4	Enforcement matrix.
6.5.5	Documented process for conducting an evaluation of the ENFORCEMENT STRATEGIES	6.5.5	Procedure for conducting an evaluation of the ENFORCEMENT STRATEGIES.
6.5.6	Documented annual evaluation of the ENFORCEMENT STRATEGIES	6.5.6	Evaluation of the ENFORCEMENT STRATEGIES at least every 12 months.

STANDARD 7
Outreach Activities Program

7.1	Purpose	7.1	Purpose
	This standard describes the elements of outreach activities developed and provided by the State PROGRAM.		This standard describes the program elements used by a state PROGRAM to effectively conduct an ANIMAL FOOD outreach program.
7.2	Requirement Summary	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.		The state program establishes an outreach program with OUTREACH ACTIVITIES or OUTREACH EVENTS to inform ANIMAL FOOD industry stakeholders, academia, other regulators, or consumers about ANIMAL FOOD topics.
7.3	Program Elements	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.	7.3.1	Outreach Methods The state PROGRAM identifies the methods that will be used for outreach to inform ANIMAL FOOD industry stakeholders, academia, other regulators, or consumers about ANIMAL FOOD topics.
7.3.2	The State PROGRAM develops an outreach plan that supports the State PROGRAM mission and includes:	7.3.2	Outreach Plan The state PROGRAM has a documented outreach plan at least every 12 months that supports the state PROGRAM mission and that includes:
7.3.2.1	Objectives of an outreach plan	7.3.2.1	Objectives of an outreach plan.
7.3.2.2	Target populations	7.3.2.2	Target populations.
7.3.2.3	The types of outreach activities (including OUTREACH ACTIVITY EVENTS)	7.3.2.3	The types of outreach (including OUTREACH ACTIVITIES or OUTREACH 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: (Appendix 7.2 is now a Job Aid. Subsequent Appendices have been renumbered to reflect the removal of Appendix 7.2)		
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. (Reworded)	7.3.3	Outreach Events The state PROGRAM documents and evaluates OUTREACH EVENTS using Appendix 7.2, or an equivalent form.
7.4	Outcome	7.4	Outcome
	The State PROGRAM uses outreach activities to inform ANIMAL FEED industry stakeholders, academia, other regulators, or consumers about ANIMAL FEED topics.		The state PROGRAM utilizes an outreach program to inform ANIMAL FOOD industry stakeholders, academia, other regulators, or consumers about ANIMAL FOOD topics.
7.5	Documentation	7.5	Documentation
	The State PROGRAM maintains the records listed here.		The state PROGRAM maintains the records, or equivalent forms or worksheets , listed here:
7.5.1	Appendix 7.1: Self-Assessment Worksheet	7.5.1	Appendix 7.1: Self-Assessment Worksheet.
7.5.2	Outreach plan	7.5.2	Outreach plan.
7.5.3	OUTREACH ACTIVITY EVENTS overview and evaluation	7.5.3	Appendix 7.2: Outreach Event Overview and Evaluation.
7.5.4	Documents to verify the OUTREACH-ACTIVITY-EVENTS-occurred		

STANDARD 8
Program Planning and Resources

8.1	Purpose	8.1	Purpose
	This standard describes the elements of workplanning and resource evaluation used by a State PROGRAM. (Reworded)		This standard describes the program elements used by a state PROGRAM to effectively conduct the ANIMAL FOOD work planning and resource evaluation.
8.2	Requirement Summary	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 establishes a 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.		This includes an evaluation of resource needs for completing the workplan and to IMPLEMENT and maintain the AFRPS.
	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	Program Elements
8.3.1	The State PROGRAM has a documented workplan. The workplan must include:	8.3.1	Workplan The state PROGRAM has a documented workplan that includes the:
8.3.1.1	Inspection plan	8.3.1.1	Inspection plan
8.3.1.1.1	Number of inspections	8.3.1.1.1	Number of inspections
8.3.1.1.2	Type of inspection	8.3.1.1.2	Type of inspection
8.3.1.1.3	Risk category of facility or product	8.3.1.1.3	Risk category of establishment or product
8.3.1.1.4	Frequency	8.3.1.1.4	Frequency

8.3.1.2	Sample plan	8.3.1.2	Sample plan
8.3.1.2.1	Number of samples	8.3.1.2.1	Number of samples
8.3.1.2.2	Type of samples	8.3.1.2.2	Type of samples
8.3.1.3	Timeframe that the workplan is applicable.	8.3.1.3	Timeframe that the workplan is applicable.
		8.3.2	Workplan Procedure
8.3.2	The State PROGRAM has a documented procedure for evaluating the workplan that includes:	8.3.2.1	The state PROGRAM has a procedure for evaluating the workplan that includes:
8.3.2.1	Conducting periodic and annual evaluations of the workplan;	8.3.2.1.1	Conducting evaluations of the workplan at least every 12 months.
8.3.2.2	Evaluating alignment with PROGRAM objectives and resources.	8.3.2.1.2	Evaluating alignment with state PROGRAM objectives and resources.
	Note: FDA and the State PROGRAM may meet periodically and develop a coordinated workplan.		
8.3.3	The State PROGRAM has a documented procedure for identifying and reviewing its resources to accomplish the workplan within the applicable timeframe.	8.3.2.2	The state PROGRAM has a procedure for identifying and evaluating 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 resource evaluation 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.		Note: The resources needed to train and audit field staff, to support laboratory services, compliance and enforcement program , outreach program , and to respond to ANIMAL FOOD -related illnesses, deaths, or EMERGENCIES should be determined by the state PROGRAM. The administrative functions needed to support all state PROGRAM areas should be considered when determining state PROGRAM resources.

8.3.4	To validate the workplan , the State PROGRAM develops a formula that: (Reworded. Combined with 8.3.4.1, 8.3.4.2, 8.3.4.3, and 8.3.4.4)	8.3.2.3	The state PROGRAM develops a formula and calculates the number of staff needed to accomplish the state PROGRAM'S ANIMAL FOOD workplan based on staff assignments, responsibilities, and work hours.
8.3.4.1	Calculates the number of staff needed to conduct inspections of its ANIMAL FEED inventory ; (Reworded. Combined with 8.3.4.)		
8.3.4.2	Calculates the number of staff needed to conduct sample collections ; (Reworded. Combined with 8.3.4.)		
8.3.4.3	Uses numerical values that are based on the State PROGRAM'S data ; (Reworded. Combined with 8.3.4.)		
8.3.4.4	Must be used by the State PROGRAM. (Reworded. Combined with 8.3.4.)		
	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: The state PROGRAM should have adequate staff to inspect the state PROGRAM'S ANIMAL FOOD inventory and to conduct sample collections established in its workplan.
	Note: Appendix 8.2 provides example formulas that can be used as a baseline for a State workplan. The formulas in appendix 8.2 do not include methods for estimating staff numbers needed for sample collections, compliance activities, administrative, or other programmatic activities. (Appendix 8.2 is now a Job Aid. Subsequent Appendices have been renumbered to reflect the removal of Appendix 8.2.)		
8.3.5	The inspection and sample collection staff must have the equipment needed to conduct inspections and sample collections.	8.3.3	Equipment The state PROGRAM establishes and maintains a list of the equipment required for inspections and sample

			collections.
8.3.6	A list of the equipment required for inspections and sample collections must be: (Reworded. Combined with 8.3.6.1 and 8.3.6.2)		
8.3.6.1	Established by the State PROGRAM (Reworded. Combined with 8.3.6)		
8.3.6.2	Maintained by the State PROGRAM (Reworded. Combined with 8.3.6)		
	Note: Appendix 8.3 provides an example list of equipment that may be used for inspections and sample collections. (Appendix 8.3 is now a Job Aid. Subsequent Appendices have been renumbered to reflect the removal of Appendix 8.3.)		
		8.3.4	Resource Review
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: (Appendix 8.4 is renumbered to Appendix 8.2. Renumbered to 8.3.4.3)	8.3.4.1	The state PROGRAM conducts a baseline evaluation of the resources required to IMPLEMENT the AFRPS, including the program elements and the documentation requirements in the standards to determine whether the state PROGRAM has:
8.3.7.1	Adequate staff	8.3.4.1.1	Adequate staff
8.3.7.2	Equipment	8.3.4.1.2	Equipment
8.3.7.3	Funding	8.3.4.1.3	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. (Reworded. Renumbered to 8.3.4.1. Appendix 8.4 is		

	renumbered to Appendix 8.2. Renumbered to 8.3.4.3)		
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 standard's requirements must be completed within three years of the previous evaluation.	8.3.4.2	The state PROGRAM completes subsequent resource evaluations to determine the resources necessary for the state PROGRAM to partially meet, fully meet, or maintain IMPLEMENTATION of the program elements and documentation requirements within three years of the previous evaluation.
		8.3.4.3	The state PROGRAM records the evaluation on Appendix 8.2, or an equivalent form.
8.4	Outcome	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.		The state PROGRAM utilizes the workplan to support its inspection and sample collection programs. The state PROGRAM evaluates the resources needed to support both the state PROGRAM and the IMPLEMENTATION and maintenance of the AFRPS.
8.5	Documentation	8.5	Documentation
	The State PROGRAM maintains the records listed here.		The state PROGRAM maintains the records, or equivalent forms or worksheets, listed here:
8.5.1	Appendix 8.1: Self-Assessment Worksheet	8.5.1	Appendix 8.1: Self-Assessment Worksheet.
8.5.2	Workplan	8.5.2	Workplan.
8.5.3	Documented procedure for evaluating the workplan	8.5.3	Procedure for evaluating the workplan.
8.5.4	Documented procedure for identifying and reviewing its resources to accomplish the workplan within the applicable timeframe	8.5.4	Procedure for identifying and evaluating 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	8.5.5	Formula used to calculate the number of staff needed to accomplish the state PROGRAM'S ANIMAL FOOD workplan based on the state PROGRAM staff assignments, responsibilities, and work hours.

8.5.6	List of required equipment for inspection and sample collection	8.5.6	List of required equipment for inspection and sample collection.
8.5.7	Appendix 8.4 : Resources for IMPLEMENTATION of AFRPS	8.5.7	Appendix 8.2: Resources for Implementation of Animal Food Regulatory Program Standards .

STANDARD 9
Assessment and Improvement

9.1	Purpose	9.1	Purpose
	This standard tracks the IMPLEMENTATION of each standard and describes the requirements for an improvement plan.		This standard describes the program elements used by a state PROGRAM to effectively evaluate and demonstrate IMPLEMENTATION with each of the program standards.
9.2	Requirement Summary	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 establishes a baseline evaluation utilizing the self-assessment worksheets completed for each standard. This includes using the results to create a strategic improvement plan that aids the state PROGRAM in IMPLEMENTING the program elements of each standard.
	The State PROGRAM regularly evaluates its status in meeting the requirements of the standards.		
9.3	Program Elements	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. (Reworded. Separated into 9.3.1 and 9.3.2.)	9.3.1	State Program Baseline Evaluation The state PROGRAM conducts a baseline evaluation using the self-assessment worksheets from each standard to determine if a standard is fully met, partially met, or not met.
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: (Appendix 9.2 is now a Job Aid. Subsequent Appendices have been renumbered to reflect the removal of Appendix 9.2.)	9.3.2	Strategic Improvement Plan The state PROGRAM develops a strategic improvement plan to IMPLEMENT the program elements or documentation requirements of each standard. The strategic improvement plan includes the following, as applicable:
9.3.2.1	The individual element or documentation requirement for	9.3.2.1	The program element or documentation requirement of

	the standard that was not fully met;		the standard that was not met.
9.3.2.2	Improvements needed to fully meet the program element or documentation requirement(s) of the standard;	9.3.2.2	Improvements or CORRECTIVE ACTIONS needed to IMPLEMENT the program element or documentation requirement of the standard.
		9.3.2.3	The cause for any DEVIATIONS requiring CORRECTIVE ACTIONS when the state PROGRAM was previously in IMPLEMENTATION with the program element or documentation requirement of a standard.
		9.3.2.4	The PREVENTIVE ACTION taken to prevent future similar DEVIATIONS when the state PROGRAM was previously in IMPLEMENTATION with the program element or documentation requirement of the standard that was corrected.
9.3.2.3	Lists of individual tasks that will be used to address the improvement; (Reworded. Combined with 9.3.2.4. Renumbered to 9.3.2.5)	9.3.2.5	Projected completion date for each improvement or CORRECTIVE ACTION.
9.3.2.4	A projected completion date for each task; (Renumbered to 9.3.2.5)	9.3.2.6	Personnel responsible.
9.3.2.5	Completion date for each task. (Reworded. Renumbered to 9.3.2.7)	9.3.2.7	Date completed.
9.3.3	The State PROGRAM reviews and updates its improvement plan (appendix 9.2) on an annual basis.	9.3.3	Strategic Improvement Plan Review The state PROGRAM reviews and updates at least every 12 months the following:
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:	9.3.3.1	The self-assessment worksheets.
9.3.4.1	Self-assessment worksheets for each standard;	9.3.3.2	The strategic improvement plan.

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). (Implementation status has been added to each Appendix x.1: Self-Assessment Worksheet)		
9.3.5	Appendix 9.3, or comparable form, is used to track IMPLEMENTATION status of all the standards. (Appendix 9.3 is now a Job Aid.)		
		9.3.4	Document Control Procedure
		9.3.4.1	The state PROGRAM has a procedure for DOCUMENT CONTROL that ensures all guidance and procedures required by the standards are CURRENT AND FIT-FOR-USE.
		9.3.4.2	The state PROGRAM maintains a master document list of all documents subject to this procedure to demonstrate they are CURRENT AND FIT-FOR-USE.
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. (Renumbered to 9.3.5)	9.3.5	Record Retention 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	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.		The state PROGRAM utilizes the strategic improvement plan to achieve and maintain IMPLEMENTATION of the program elements and documentation requirements for all standards.

9.5	Documentation	9.5	Documentation
	The State PROGRAM maintains the records listed here.		The state PROGRAM maintains the records, or equivalent forms or worksheets , listed here:
9.5.1	Appendix 9.1: Self-Assessment Worksheet	9.5.1	Appendix 9.1: Self-Assessment Worksheet.
9.5.2	Appendix 9.2: Assessment and Improvement Plan	9.5.2	Strategic Improvement Plan.
9.5.3	Appendix 9.3: IMPLEMENTATION Status of Animal Feed Regulatory Program Standards	9.5.3	Procedure for Document Control.
		9.5.4	Master Document List.

STANDARD 10
Laboratory Services

10.1	Purpose	10.1	Purpose
	This standard describes the elements of utilizing REGULATORY TESTING LABORATORY(IES) services that support the State PROGRAM.		This standard describes the program elements used by a state PROGRAM to effectively utilize REGULATORY TESTING LABORATORY services.
10.2	Requirement Summary	10.2	Requirement Summary
	The State PROGRAM has access to laboratory services that provide analytical data that support regulatory functions.		The state PROGRAM establishes access to REGULATORY TESTING LABORATORY services that provide accurate, timely, reliable, and defensible analytical data.
	The State PROGRAM receives accurate, timely, reliable, and defensible data from the REGULATORY TESTING LABORATORY(IES).		
10.3	Program Elements	10.3	Program Elements
		10.3.1	Laboratory Support
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	The state PROGRAM maintains a list of analytical services the REGULATORY TESTING LABORATORY provides for the state PROGRAM.
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.	10.3.1.2	The state PROGRAM has a documented formal agreement with the REGULATORY TESTING LABORATORY that conducts routine analytical services unless under the same administrative agency.
10.3.3	The State PROGRAM prepares a sample analysis schedule based on a sampling plan³ 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; 10.3.3.1-10.3.3.4 have been moved to Standard 11.)		
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:	10.3.2	Laboratory Sample Integrity Procedure The state PROGRAM has procedures developed by the REGULATORY TESTING LABORATORY to maintain the integrity of the samples sent to the REGULATORY TESTING LABORATORY for analytical testing that includes:
10.3.4.1	Sample receipt	10.3.2.1	Sample receipt
10.3.4.2	Preservation	10.3.2.2	Preservation
10.3.4.3	Storage	10.3.2.3	Storage
10.3.4.4	Retention	10.3.2.4	Retention
10.3.4.5	Disposal	10.3.2.5	Disposal
10.3.4.6	Chain of custody	10.3.2.6	Chain of custody
10.3.4.7	Report of analysis	10.3.2.7	Report of analysis
10.3.4.8	Method (s) used to communicate information between the State PROGRAM and REGULATORY TESTING LABORATORY (IES)	10.3.2.8	Methods to communicate information between the state PROGRAM and REGULATORY TESTING LABORATORY.
10.3.5	State PROGRAM utilizes REGULATORY TESTING LABORATORY (IES) that:	10.3.3	Laboratory Quality Assurance Program The state PROGRAM utilizes REGULATORY TESTING LABORATORIES that:

10.3.5.1	Are accredited by a recognized accreditation body to ISO/IEC 17025:2005 ⁴ or ISO/IEC 17025:2017, or	10.3.3.1	Are accredited by a recognized accreditation body to ISO/IEC 17025:2017 ³ , or current version , or
10.3.5.2	Implement and comply with the AAFCO Quality Assurance/Quality Control guidelines, or	10.3.3.2	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 or ISO/IEC 17025:2017.	10.3.3.2	Implement and comply with the ISO/IEC 17025:2017, or current version .
	Note: ISO/IEC 17025:2005 will be invalid after November 30, 2020 per ILAC. Future versions of the ISO/IEC 17025 standard shall be evaluated and incorporated into Standard 10, as applicable.		
10.4	Outcome	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 .		The state PROGRAM utilizes the valid and defensible REGULATORY TESTING LABORATORY data to protect animal and public health and to enforce ANIMAL FOOD laws .
10.5	Documentation	10.5	Documentation
	The State PROGRAM maintains the records listed here.		The state PROGRAM maintains the records, or equivalent forms or worksheets , listed here:
10.5.1	Appendix 10.1: Self-Assessment Worksheet	10.5.1	Appendix 10.1: Self-Assessment Worksheet.
10.5.2	A list of routine and non-routine analytical services provided by the REGULATORY TESTING LABORATORY (IES)	10.5.2	A list of all analytical services provided by the REGULATORY TESTING LABORATORY for the state PROGRAM .
10.5.3	An agreement with REGULATORY TESTING LABORATORY (IES) that provide routine analytical services unless the laboratory is managed within the PROGRAM	10.5.3	A formal agreement with REGULATORY TESTING LABORATORY IES that provide routine analytical services unless the laboratory is under the same administrative agency .

³ A recognized accreditation body must be signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

10.5.4	A current sample analysis schedule (10.5.4 has been moved to Standard 11.)		
		10.5.4	Procedure to maintain the integrity of the samples sent to the REGULATORY TESTING LABORATORY.
10.5.5	Written procedures to maintain the integrity of the samples sent to the REGULATORY TESTING LABORATORY(IES)	10.5.5	ISO Accredited Laboratory: ISO/IEC 17025:2017, or current version, Certificate and Scope of Accreditation, or documentation for non-ISO REGULATORY TESTING LABORATORIES.

STANDARD 11
Sampling Program

11.1	Purpose	11.1	Purpose
	This standard describes the elements of an effective ANIMAL FEED sampling program.		This standard describes the program elements used by a state PROGRAM to have an effective ANIMAL FOOD sampling program.
11.2	Requirement Summary	11.2	Requirement Summary
	The State PROGRAM has a sampling program to support an ANIMAL FEED regulatory program.		The state PROGRAM establishes a sampling program to determine compliance with ANIMAL FOOD laws. This includes a sampling plan, sample collection procedures and procedures for completing the sample collection report.
11.3	Program Elements	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.	11.3.1	Sampling Plan The state PROGRAM has a documented sampling plan, at least every 12 months , for collecting surveillance, compliance, investigational, regulatory samples, or other samples ⁴ .
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. (Reworded.)	11.3.1.1	The state PROGRAM and REGULATORY TESTING LABORATORY jointly develops and amends the sampling plan, at least every 12 months , for 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	The sampling plan includes the:
11.3.1.2.1	Sampling priorities (Renumbered to 11.3.1.2.2)	11.3.1.2.1	Availability or coordination of analytical support.
11.3.1.2.2	Sample analysis schedule (Renumbered to 11.3.1.2.3)	11.3.1.2.2	Sample priorities.

⁴ Regulatory samples may be used to support inspection observations.

11.3.1.2.3	Availability or coordination of analytical support (Renumbered to 11.3.1.2.1)	11.3.1.2.3	SAMPLE ANALYSIS SCHEDULE. The SAMPLE ANALYSIS SCHEDULE includes the:
		11.3.1.2.3.1	Types of ANIMAL FOOD to be analyzed.
		11.3.1.2.3.2	Number of samples to be collected.
		11.3.1.2.3.3	Estimated timeframe for collection.
		11.3.1.2.3.4	Types of analyses to be performed.
	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	Sample Collection Procedure The state PROGRAM has procedures for collecting, storing, and transporting samples that includes:
11.3.2.1	Following safety precautions on feed labels;	11.3.2.1	Following safety precautions on ANIMAL FOOD labels.
11.3.2.2	Following the State PROGRAM'S safety protocol for collecting samples;	11.3.2.2	Following the state PROGRAM'S safety protocols for collecting samples.
11.3.2.3	Using appropriate method and equipment to collect the sample;	11.3.2.3	Using appropriate method, sample collection procedures, and equipment to collect the sample.
11.3.2.4	Sealing the sample to initiate chain of custody;	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;	11.3.2.5	Maintaining and documenting sample integrity, security, and chain of custody.
11.3.2.6	Issuing receipt for sample(s);	11.3.2.6	Issuing receipt for the sample ⁵ .

⁵ Receipt could include cost of sample and method of payment.

11.3.2.7	Handling, packaging, and shipping sample using procedures appropriate to prevent compromising the condition of sample;	11.3.2.7	Handling ⁶ , packaging, and shipping samples to prevent compromising the condition of the sample.
11.3.2.8	Delivering or shipping sample to the appropriate laboratory within acceptable timeframes.	11.3.2.8	Delivering or shipping samples to the appropriate REGULATORY TESTING LABORATORY within designated timeframes.
11.3.3	The State PROGRAM has documented instructions for the Sample Collection Report that includes:	11.3.3	Sample Collection Report The state PROGRAM has a procedure for completing the sample collection report that includes the :
		11.3.3.1	Identification of sample collector.
11.3.3.1	Date of the sample collection;	11.3.3.2	Date of the sample collection.
11.3.3.2	Product identification including:	11.3.3.3	Product identification. The product identification includes the:
11.3.3.2.1	Name	11.3.3.3.1	Name.
11.3.3.2.2	Lot numbers or any other codes referencing manufacture identification	11.3.3.3.2	Lot numbers or any other codes referencing manufacture identification.
11.3.3	Description of product;	11.3.3.4	Description of product.
11.3.3.4	Method of collection and any special techniques used to collect sample;	11.3.3.5	Method of collection and any special techniques used to collect sample.
11.3.3.5	Lot sampled;	11.3.3.6	Lot sampled.
11.3.3.6	Lot size;	11.3.3.7	Lot size.
11.3.3.7	Location where sample was collected;	11.3.3.8	Location where sample was collected.

⁶ Includes storing sample.

11.3.3.8	Name and address of responsible party, guarantor, possessor, or distributor;	11.3.3.9	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	Sample type (example : surveillance, compliance, investigational, regulatory, or other).
11.3.3.10	Analysis requested, if applicable;	11.3.3.11	Analysis requested, if applicable.
11.3.3.11	Collection or reproduction of product labels, including customer-formula feed labels;	11.3.3.12	Collection or reproduction of product label, including customer-formula label.
11.3.3.12	Receiving and distribution information.	11.3.3.13	Receiving and distribution information.
11.4	Outcome	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.		The state PROGRAM utilizes the sampling program to align sampling resources to collect, store, transport, and document samples to achieve compliance with ANIMAL FOOD laws.
11.5	Documentation	11.5	Documentation
	The State PROGRAM maintains the records listed here.		The state PROGRAM maintains the records, or equivalent forms or worksheets , listed here:
11.5.1	Appendix 11.1: Self-Assessment Worksheet	11.5.1	Appendix 11.1: Self-Assessment Worksheet.
11.5.2	Documented annual sampling plan	11.5.2	Sampling plan.
11.5.3	Documented sampling procedures	11.5.3	Sample collection procedure.
11.5.4	Documented sample collection report instructions	11.5.4	Procedure for completing the sample collection report.