



---

---

**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:**

## Table of Contents

<b><u>Table of Contents</u></b>	<b>1</b>
<b><u>Background</u></b>	<b>4</b>
<b><u>Introduction</u></b>	<b>5</b>
<b><u>Definitions</u></b>	<b>6</b>
<b><u>Standard 1</u></b> <i>Regulatory Foundation</i>	<b>8</b>
<b><u>Standard 2</u></b> <i>Training</i>	<b>11</b>
<b><u>Standard 3</u></b> <i>Inspection Program</i>	<b>17</b>
<b><u>Standard 4</u></b> <i>Auditing</i>	<b>21</b>
<b><u>Standard 5</u></b> <i>Feed-Related Illnesses or Death and Emergency Response</i>	<b>26</b>
<b><u>Standard 6</u></b> <i>Enforcement Program</i>	<b>29</b>
<b><u>Standard 7</u></b> <i>Outreach Activities</i>	<b>31</b>
<b><u>Standard 8</u></b> <i>Planning and Resources</i>	<b>33</b>
<b><u>Standard 9</u></b> <i>Assessment and Improvement</i>	<b>36</b>
<b><u>Standard 10</u></b> <i>Laboratory Services</i>	<b>38</b>
<b><u>Standard 11</u></b> <i>Sampling Program</i>	<b>40</b>
<b><u>Appendix 1.1</u></b> <i>Self-Assessment Worksheet</i>	<b>42</b>
<b><u>Appendix 1.2</u></b> <i>REGULATORY FOUNDATION Worksheet</i>	<b>43</b>
<b><u>Appendix 2.1</u></b> <i>Self-Assessment Worksheet</i>	<b>48</b>
<b><u>Appendix 2.2</u></b> <i>Inspector Training Record</i>	<b>50</b>
<b><u>Appendix 2.3</u></b> <i>Field Training Competencies</i>	<b>55</b>
<b><u>Appendix 3.1</u></b> <i>Self-Assessment Worksheet</i>	<b>57</b>
<b><u>Appendix 3.2</u></b> <i>Risk Categorization for Feed Facilities</i>	<b>60</b>
<b><u>Appendix 4.1</u></b> <i>Self-Assessment Worksheet</i>	<b>62</b>
<b><u>Appendix 4.2</u></b> <i>Field Inspection Audit Form</i>	<b>64</b>
<b><u>Appendix 4.2a</u></b> <i>Completing the Field Inspection Audit Form</i>	<b>68</b>

## Table of Contents

<b><u>Appendix 4.3</u></b>	73
<i><u>Field Inspection Audit Worksheet</u></i>	
<b><u>Appendix 4.4</u></b>	75
<i><u>Instructions for Completing the Audit Worksheets</u></i>	
<b><u>Appendix 4.5</u></b>	76
<i><u>Field Inspection Report Audit Form</u></i>	
<b><u>Appendix 4.6</u></b>	79
<i><u>Field Inspection Report Audit Worksheet</u></i>	
<b><u>Appendix 4.7</u></b>	81
<i><u>Sample Collection Audit Form</u></i>	
<b><u>Appendix 4.7a</u></b>	83
<i><u>Completing the Sample Collection Audit Form</u></i>	
<b><u>Appendix 4.8</u></b>	85
<i><u>Sample Collection Audit Worksheet</u></i>	
<b><u>Appendix 4.9</u></b>	87
<i><u>Sample Collection Report Audit Form</u></i>	
<b><u>Appendix 4.10</u></b>	89
<i><u>Sample Collection Report Audit Worksheet</u></i>	
<b><u>Appendix 4.11</u></b>	91
<i><u>Corrective Action Plan</u></i>	
<b><u>Appendix 5.1</u></b>	92
<i><u>Self-Assessment Worksheet</u></i>	
<b><u>Appendix 5.2</u></b>	94
<i><u>Emergency Contact List</u></i>	
<b><u>Appendix 6.1</u></b>	98
<i><u>Self-Assessment Worksheet</u></i>	
<b><u>Appendix 6.2</u></b>	99
<i><u>Enforcement Tools</u></i>	
<b><u>Appendix 6.3</u></b>	99
<i><u>Factors, Descriptions, and Numerical Weights for Consideration When Selecting an Enforcement Tool</u></i>	
<b><u>Appendix 6.4</u></b>	102
<i><u>Enforcement Matrix</u></i>	
<b><u>Appendix 7.1</u></b>	104
<i><u>Self-Assessment Worksheet</u></i>	
<b><u>Appendix 7.2</u></b>	105
<i><u>Outreach Plan</u></i>	
<b><u>Appendix 7.3</u></b>	106
<i><u>OUTREACH ACTIVITY EVENT Overview and Evaluation</u></i>	
<b><u>Appendix 8.1</u></b>	107
<i><u>Self-Assessment Worksheet</u></i>	
<b><u>Appendix 8.2</u></b>	109
<i><u>Example Formula for Calculating the Number of Inspectors Required to Conduct Inspections of Feed Facilities</u></i>	
<b><u>Appendix 8.3</u></b>	111
<i><u>Example List of Equipment Used for Inspections and Sample Collections</u></i>	
<b><u>Appendix 8.4</u></b>	112
<i><u>Resources for IMPLEMENTATION of Animal Feed Regulatory Program Standards</u></i>	

## Table of Contents

---

<b><u>Appendix 9.1</u></b>	<b>113</b>
<i>Self-Assessment Worksheet</i>	
<b><u>Appendix 9.2</u></b>	<b>115</b>
<i>Assessment and Improvement Plan</i>	
<b><u>Appendix 9.3</u></b>	<b>116</b>
<i>IMPLEMENTATION Status of Animal Feed Regulatory Program Standards</i>	
<b><u>Appendix 10</u></b>	<b>117</b>
<i>Self-Assessment Worksheet</i>	
<b><u>Appendix 11</u></b>	<b>119</b>
<i>Self-Assessment Worksheet</i>	

---

## Background

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

12  
13 Maximizing resources between FDA and the States supports the ongoing work of the Partnership  
14 for Food Protection (PFP) to develop an Integrated Food Safety System (IFSS). The FDA and  
15 the Association of American Feed Control Officials (AAFCO) are members of the PFP. The  
16 vision for an IFSS was developed in 2009<sup>1</sup>. One of the foundational principles of an IFSS is the  
17 IMPLEMENTATION and uniform application of model standards so that Federal, State, territorial,  
18 tribal, and local regulatory agencies conduct inspections under the same set of standards. Prior  
19 to 2010, the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) and the  
20 Manufactured Food Regulatory Program Standards (MFRPS) were examples of such model  
21 standards. However, the VNRFRPS and MFRPS were developed for human food only and did  
22 not apply to ANIMAL FEED. As further development on the IFSS progressed, there was a  
23 recognized need to develop standards for ANIMAL FEED regulatory programs. One of the key  
24 recommendations that came from the 2010 50-State workshop (“A United Approach to Public  
25 Health”) was the development of standards for ANIMAL FEED regulatory programs. Standards  
26 provide a consistent, underlying foundation that is critical for uniformity across State and Federal  
27 agencies to ensure the credibility of all PROGRAMS under an IFSS.

28  
29 The Food Safety Modernization Act (FSMA) provides further support for developing Animal  
30 Feed Regulatory Program Standards (AFRPS). FSMA was signed into law in January 2011 and  
31 calls for enhanced partnerships and integration with Federal, State, local, tribal, and territorial  
32 partners. The enhanced partnerships and integration called for by FSMA will allow FDA to rely  
33 on inspections and data collected by other agencies to support regulatory activities and further  
34 the idea of an IFSS.

35  
36 In 2011, FDA and AAFCO entered into a partnership to develop the AFRPS and the AFRPS  
37 were initially launched in January 2014. These standards are designed to promote uniformity  
38 and consistency among ANIMAL FEED regulatory programs. This is consistent with the principles  
39 of the FSMA and the fundamental goal of AAFCO and FDA to provide a mechanism for  
40 developing and implementing uniform and equitable statutes, regulations, and standards to  
41 enhance the protection of the nation’s ANIMAL FEED supply.

---

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

## Introduction

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

49  
50 The AFRPS is composed of eleven standards that serve as an objective framework to evaluate  
51 and improve components of a State PROGRAM. The standards cover the State PROGRAM'S  
52 REGULATORY FOUNDATION, training, inspection program, auditing, feed-related illnesses or death  
53 and emergency response, enforcement program, outreach activities, budget and planning,  
54 laboratory services, sampling program, and assessment and improvement of standard  
55 IMPLEMENTATION.

56  
57 Each standard is laid out in the following format to ensure uniformity: purpose statement (x.1),  
58 requirement summary (x.2), description of program elements (x.3), projected outcomes (x.4),  
59 and a list of required documentation (x.5). The program elements describe the best practices of a  
60 quality regulatory program. Required elements for IMPLEMENTATION are found in the program  
61 elements (x.3) and documentation (x.5) sections for each standard. Terms in all capital letters  
62 correspond to a defined term in the Definition section of the document. The term "should" is  
63 used throughout the AFRPS. Program elements and corresponding conditions described as  
64 "should" are best practices but are optional and not required to fully implement a standard. To  
65 fully implement the AFRPS, the PROGRAM must implement all eleven standards. "Notes" are  
66 used throughout the AFRPS to provide clarification, alternatives, and guidance that the State  
67 PROGRAM may use to help implement the AFRPS. "Notes" do not contain requirements and thus  
68 will not be subject to a FDA verification audit.

69  
70 Each standard has a self-assessment worksheet. The State PROGRAM uses the self-assessment  
71 worksheets to determine if the standard's requirements are, or remain, fully met, partially met, or  
72 not met. The self-assessments are used to develop an improvement plan for fully implementing  
73 the requirements of the standards.

74  
75 The standards have forms, worksheets, and templates that will help the State PROGRAM assess  
76 and meet the program elements in the standard. State PROGRAMS are not obligated to use the  
77 forms provided in the AFRPS. Other manual or automated forms, worksheets, and templates  
78 may be used as long as the pertinent data elements are present. Records and other documents  
79 specified in the standards must be maintained in good order by the State PROGRAM and must be  
80 available to verify the information for the purposes of a verification audit. These program  
81 standards are not intended to address the performance appraisal processes that a State agency  
82 may use to evaluate individual employee performance.

83

## Definitions

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

89

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

91

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

94

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

98

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

102

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

105

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

108

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

112

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

116

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

121

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

126

## Definitions

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

129  
130 **Qualified Field Inspection Auditor:** An individual who is recognized by the State's PROGRAM  
131 as having field experience and communication skills necessary to audit inspectors/investigators.  
132

133 **Qualified Field Inspection Trainer:** An individual who is recognized by the State's PROGRAM  
134 as having field experience and communication skills necessary to train inspectors/investigators.  
135

136 **Regulatory Foundation:** The laws, regulations, rules, ordinances, or other regulatory  
137 requirements that govern the operation of an ANIMAL FEED facility.  
138

139 **Regulatory Testing Laboratory(ies):** A laboratory that conducts measurements and analyses on  
140 food or feed and associated physical samples, which result in qualitative or quantitative  
141 analytical findings that may be used as a basis for regulatory action.  
142

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



## **STANDARD 1**

### **Regulatory Foundation**

#### **1.1 Purpose**

146  
147 This standard describes the elements of the REGULATORY FOUNDATION used by a State PROGRAM  
148 to regulate ANIMAL FEED.

#### **1.2 Requirement Summary**

151  
152 The State PROGRAM evaluates the scope of its legal authority and regulatory provisions to  
153 perform inspections and investigations, gather evidence, collect samples, and take regulatory  
154 actions under State law to ensure the safety and security of ANIMAL FEED.

155  
156 The State PROGRAM evaluation includes a determination of how the State’s legal authority and  
157 regulatory provisions correspond to the sections of the Federal Food, Drug, and Cosmetic Act  
158 (FD&C Act) and Federal regulations specified in appendix 1.2.

#### **1.3 Program Elements**

161  
162 1.3.1 The State PROGRAM conducts an evaluation to determine whether the State’s legal  
163 authority and regulatory provisions are EQUIVALENT, EQUIVALENT IN EFFECT, or NOT  
164 EQUIVALENT to the sections of the FD&C Act and Federal regulations specified in  
165 appendix 1.2.

166  
167 1.3.1.1 “EQUIVALENT” means that the State law directly references the relevant FD&C  
168 Act provision or Federal regulation. For State law found EQUIVALENT, the State  
169 PROGRAM:

170  
171 1.3.1.1.1 Specifies the Federal statute or regulation that is incorporated into the  
172 State law;

173 1.3.1.1.2 Includes the revision date of the State statutory provision or regulation  
174 as appropriate;

175 1.3.1.1.3 Identifies the date the Federal statutory provision or regulation was  
176 incorporated into the State law.

177  
178 Note: In conducting such an evaluation, the State PROGRAM should consult with  
179 its legal counsel when State law does not provide for incorporation of  
180 subsequent revisions of the FD&C Act and CFR, the revision date of the CFR is  
181 unknown, or the Federal law or regulation is partially written into State law or  
182 regulation.

183  
184

## **STANDARD 1**

### **Regulatory Foundation**

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

191  
192 Note: “NOT EQUIVALENT” means there is no State law EQUIVALENT to the  
193 relevant Federal law or regulation, there is such a State law but it does not apply  
194 to the State’s PROGRAM, or the Federal and State laws address the same matter  
195 but are inconsistent and do not have the same regulatory effect. For provisions  
196 found to be “NOT EQUIVALENT”, the State PROGRAM should identify which State  
197 agency has authority and jurisdiction over said provisions, if there is one, in  
198 appendix 1.2.

199  
200 Note: In addition, if the State has laws and regulations pertinent to the  
201 regulation of ANIMAL FEED for which there are no comparable Federal  
202 provisions, these laws can be listed in appendix 1.2.

203  
204 1.3.2 The State PROGRAM has a documented process, which includes:

205  
206 1.3.2.1 Procedures to review the statutes, regulations, rules, ordinances, and other  
207 prevailing regulatory requirements that:

- 208  
209 1.3.2.1.1 Apply to the regulation of ANIMAL FEED;  
210 1.3.2.1.2 Delegate authority to the State agency;  
211 1.3.2.1.3 Describe the State agency’s administrative procedures for establishing  
212 its authority and incorporating rules by reference.

213  
214 1.3.2.2 Timeframes for the review.

#### 215 216 **1.4 Outcome**

217  
218 The State PROGRAM has conducted an evaluation of the scope of their legal authority and has a  
219 REGULATORY FOUNDATION adequate to protect the public health by ensuring the safety and  
220 security of ANIMAL FEED.

#### 221 222 **1.5 Documentation**

223  
224 The State PROGRAM maintains the records listed here.

- 225  
226 1.5.1 Appendix 1.1: Self-Assessment Worksheet  
227 1.5.2 Appendix 1.2: REGULATORY FOUNDATION Worksheet

**STANDARD 1**  
**Regulatory Foundation**

- 228 1.5.3 Documented process for reviewing appropriate statutes, regulations, rules, ordinances,  
229 and other prevailing regulatory requirements
- 230 1.5.4 The statutes, regulations, rules, ordinances, and other prevailing regulatory  
231 requirements that: (1) apply to the regulation of ANIMAL FEED, (2) delegate authority to  
232 the State agency, and (3) describe the State agency’s administrative procedures for  
233 establishing its authority and incorporating rules by reference

## **STANDARD 2**

### **Training**

234 **2.1 Purpose**

235  
236 This standard describes the elements of training for inspectors in a State PROGRAM to ensure they  
237 will have the knowledge, skills, and abilities to competently inspect feed facilities, conduct  
238 investigations, gather evidence, collect samples, and take enforcement actions.

239  
240 **2.2 Requirement Summary**

241  
242 The State PROGRAM has a training plan that ensures all inspectors are adequately trained to  
243 perform their work.

244  
245 **2.3 Program Elements**

246  
247 2.3.1 Training Plan and Training Records

248  
249 2.3.1.1 The State PROGRAM uses a written training plan that ensures all inspectors  
250 receive training required to adequately perform their work assignments. The  
251 training plan includes course curriculum for basic and advanced inspection  
252 training and continuing education.

253 2.3.1.2 The State PROGRAM provides, or otherwise makes available, inspection training  
254 and continuing education for all inspectors.

255 2.3.1.3 For inspectors that conduct limited scope inspections, as defined by the State  
256 PROGRAM, (e.g. such as only collecting samples or inspections at veterinary  
257 clinics), the State PROGRAM specifies the curriculum required by the limited  
258 scope inspectors in their documented training plan.

259  
260 Note: Curriculum includes coursework and field training.

261  
262 2.3.1.4 The State PROGRAM maintains records documenting the training completed by  
263 all inspectors using appendix 2.2 or a comparable form.

264 2.3.1.5 For inspectors with greater than five years of experience at the date of the initial  
265 self-assessment, where such documentation is not available, the State PROGRAM  
266 conducts an evaluation of the inspector's previous performance and experience  
267 to determine if the inspector has completed the required training or whether  
268 additional training is needed.

269 2.3.1.6 If previous coursework is completed before the inspectors START DATE and  
270 utilized to meet coursework requirements, proper supporting documents are  
271 maintained to verify successful completion of the requirement.

272  
273

## STANDARD 2 Training

### 274 2.3.2 Basic Feed Inspector Training

275

276 2.3.2.1 Timeframe: The State PROGRAM requires a basic inspector to successfully  
277 complete the basic coursework and field training within 24 months from the  
278 START DATE.

279 2.3.2.2 Coursework: The basic feed inspection training consists of coursework in the  
280 following subject areas:

281

282 2.3.2.2.1 Animal and Public Health Principles: Fundamental animal and  
283 public health protection principles that support the foundational roles  
284 of the feed inspector.

285 2.3.2.2.2 Basic Animal Nutrition: Basic means of digestion and nutritional  
286 requirements for various animal classes and ingredients that can  
287 cause toxicity.

288 2.3.2.2.3 Basic Feed Ingredients, Processing, and Technology: Typical  
289 ingredients, feedstuffs, processing methods, and technologies  
290 commonly used to manufacture ANIMAL FEED.

291 2.3.2.2.4 Basic National Incident Management System and Incident Command  
292 System (ICS): Introduction to the history, principals, and  
293 organizational structure of the ICS via ICS100, ICS200, IS700, and  
294 IS800.

295 2.3.2.2.5 Communication: Techniques and skills for effective oral and written  
296 communication and interviewing.

297 2.3.2.2.6 Current Statutes, Regulations, and Policies: Basic knowledge of  
298 Federal and State laws, regulations, and policies.

299 2.3.2.2.7 Feed Defense: Feed defense principles for the protection of feed  
300 from intentional hazard contamination.

301 2.3.2.2.8 Inspections, Compliance, and Enforcement: Conduct inspections  
302 applying the relevant laws and regulations to gather and document  
303 evidence to support possible regulatory actions.

304 2.3.2.2.9 Labeling: Basic feed labeling requirements.

305 2.3.2.2.10 Professionalism: Character conduct, strengths, and values directed  
306 toward providing high quality service to the regulated industry and  
307 the State PROGRAM.

308 2.3.2.2.11 Risk Awareness: Basic principles of BSE; medicated feeds including  
309 VFDs; and physical, chemical, and biological contaminants.

310 2.3.2.2.12 Safety: Appropriate personal safety and bio-security requirements  
311 when conducting field activities.

312 2.3.2.2.13 Sampling: Techniques and skills for collecting various types of  
313 samples using the appropriate methods for preparation, collection,  
314 and shipping.

315

## **STANDARD 2**

### **Training**

- 316 2.3.2.3 Field training: The State PROGRAM has established basic field training to  
317 complement the basic coursework. The basic field training specifies the  
318 following:  
319
- 320 2.3.2.3.1 Field training checklist of competencies to be mastered and verified in  
321 the field by the QUALIFIED FIELD INSPECTION TRAINER;
  - 322 2.3.2.3.2 Documented procedures for JOINT FIELD TRAINING INSPECTIONS;
  - 323 2.3.2.3.3 Number of JOINT FIELD TRAINING INSPECTIONS that are conducted in  
324 firms that represent the feed facilities in the State PROGRAM inventory  
325 and the type of routine or basic work that will be performed by the  
326 inspector;
  - 327 2.3.2.3.4 The inspector completes basic field training prior to performing  
328 independent inspections;
  - 329 2.3.2.3.5 Appendix 2.3 or a comparable form must be used to list the  
330 competencies and the minimum number of JOINT FIELD TRAINING  
331 INSPECTIONS.  
332
- 333 2.3.3 Advanced Feed Inspector Training  
334
- 335 2.3.3.1 Timeframe: The State PROGRAM requires each inspector who conducts advanced  
336 feed inspections to successfully complete the advanced inspector coursework  
337 and field training within 60 months from the START DATE.
  - 338 2.3.3.2 Coursework: The advanced feed inspection training consists of coursework in  
339 the following subject areas:  
340
    - 341 2.3.3.2.1 Advanced Feed Ingredients, Processing, and Technology: Ingredients,  
342 feedstuffs, processing methods, and technologies that are complex or  
343 less common and explore the major elements of modern feed  
344 manufacturing and advances in feed technology.
    - 345 2.3.3.2.2 Advanced Labeling: Knowledge and application of ANIMAL FEED  
346 labeling requirements (i.e. medicated feed and pet food labeling  
347 requirements).
    - 348 2.3.3.2.3 Animal Sickness and Death Investigation: Principles of outbreak  
349 investigations.
    - 350 2.3.3.2.4 Current Statutes, Regulations, and Policies: Federal and State laws,  
351 regulations, and policies for advanced feed inspections.
    - 352 2.3.3.2.5 Epidemiology: Acquire basic knowledge of epidemiology principles  
353 and concepts and apply them to animal outbreak investigations
    - 354 2.3.3.2.6 Microbiological Pathogens: Microbial hazards in feed that could lead  
355 to animal or human illnesses or death.
    - 356 2.3.3.2.7 Traceback and Traceforward Investigations: Traceback and  
357 traceforward of an implicated product and steps for conducting and  
358 concluding the investigation and reporting the results.

**STANDARD 2**  
**Training**

359 2.3.3.3 Specialized Curriculum: Inspectors who assist in emergency response or  
360 conduct specialized inspections listed below must complete relevant specialized  
361 coursework specific to the type of specialized inspections that they will be  
362 performing in the following subject areas.

363  
364 2.3.3.3.1 Advanced National Incident Management System and Incident  
365 Command Systems (ICS).

366  
367 Note: Courses should be specific to the individual’s responsibilities  
368 but include at a minimum ICS300 and ICS400.

369  
370 2.3.3.3.2 BSE and Ruminant Feeding Ban: Complete coursework required to  
371 conduct inspections of rendering facilities and feed manufactures  
372 under the ruminant feed ban regulations, 21 CFR 589.2000 and 21  
373 CFR 589.2001, that prohibit certain cattle materials from being  
374 included in any ANIMAL FEED.

375 2.3.3.3.3 Medicated Feed Good Manufacturing Practices Regulations: Complete  
376 coursework required to conduct inspections and differentiate between  
377 the regulations that apply to FDA-licensed medicated feed mills and  
378 unlicensed medicated feed mills, and the requirements under 21 CFR  
379 part 225 Current Good Manufacturing Practice for Medicated Feeds,  
380 and 21 CFR part 226 Current Good Manufacturing Practice for Type  
381 A Medicated Articles.

382  
383 2.3.3.4 Field training: The State PROGRAM has established advanced field training to  
384 complement the advanced coursework. The advanced field training specifies  
385 the following:

386  
387 2.3.3.4.1 Field training checklist of competencies to be mastered and verified in  
388 the field by the QUALIFIED FIELD INSPECTION TRAINER;

389 2.3.3.4.2 Documented procedures for JOINT FIELD TRAINING INSPECTIONS;

390 2.3.3.4.3 Number of JOINT FIELD TRAINING INSPECTIONS that are conducted in  
391 firms that represent the feed facilities in the State PROGRAM inventory  
392 and the type of advanced work that will be performed by the inspector

393 2.3.3.4.4 The inspector completes field training prior to performing independent  
394 inspections requiring advanced skills;

395 2.3.3.4.5 Appendix 2.3 or a comparable form must be used to list the  
396 competencies and the minimum number of JOINT FIELD TRAINING  
397 INSPECTIONS.

398

## **STANDARD 2**

### **Training**

399 2.3.6 Continuing Education (CE): The State PROGRAM requires that each basic and advanced  
400 inspector participate in continuing education.

401  
402 2.3.6.1 Each inspector is required to receive 20 CONTACT HOURS of continuing  
403 education every 36 months.

404 2.3.6.2 The 36 month continuing education interval starts, as defined by the State  
405 PROGRAM, when the required curriculum is complete.

406  
407 Note: The inspector may accrue one CONTACT HOUR for each clock hour of  
408 participation in any of the following training sources: in-house training provided  
409 by a government agency; distance learning, for example, satellite downlinks or  
410 web-based training, or feed-related courses provided by colleges, schools,  
411 associations, and research centers.

412  
413 Note: Of the accumulated 20 CONTACT HOURS of continuing education, a  
414 maximum of ten (10) CONTACT HOURS may be accrued from the following  
415 activities: attendance at professional seminars, symposiums, or technical  
416 conferences and workshops; delivery of presentations at professional  
417 conferences; providing classroom or field training to new hires; being a course  
418 instructor in feed safety; or publishing an original article in a peer-reviewed  
419 professional or trade association journal, periodical, or publication.

420  
421 2.3.6.3 Documentation must accompany each activity submitted for continuing  
422 education credit.

423  
424 Note: Examples of acceptable documentation may include: certificates of  
425 completion including the course dates(s) and number of hours attended or CE  
426 credits granted; transcripts from a college or university; a letter from the  
427 administrator of the continuing education program attended; a copy of the peer-  
428 reviewed article or presentation made at a professional conference;  
429 documentation to verify technical publications related to feed safety have been  
430 read including completion of self-assessment quizzes that accompany journal  
431 articles, written summaries of key points/findings presented in technical  
432 publications, and/or written book reports; an agenda and attendance roster; or  
433 documentation approved by the QUALIFIED FIELD INSPECTION TRAINER.

## **2.4 Outcome**

434  
435 The State PROGRAM has trained inspectors with the knowledge, skills, and abilities to  
436 competently inspect feed facilities and conduct investigations, gather evidence, collect samples,  
437 and take enforcement actions with ANIMAL FEED facilities.  
438  
439  
440  
441



## **STANDARD 2**

### **Training**

#### 442 **2.5 Documentation**

443

444 The State PROGRAM maintains the records listed here.

445

446 2.5.1 Appendix 2.1: Self-Assessment Worksheet

447 2.5.2 Training Plan

448 2.5.3 Appendix 2.2: Inspector Training Record

449 2.5.4 Appendix 2.3: Field Training Competencies

450 2.5.5 Documents verifying successful completion of required courses

451 2.5.6 Documentation for continuing education credit

## **STANDARD 3**

### **Inspection Program**

#### **3.1 Purpose**

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

#### **3.2 Requirement Summary**

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

#### **3.3 Program Elements**

##### 3.3.1 Risk-Based Inspection Program

3.3.1.1 The State PROGRAM has documented procedures to:

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

3.3.1.1.2 Maintain the inventory of feed facilities defined in 3.3.1.1.1.

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

3.3.1.2.1 Types of feed and feed products;

3.3.1.2.2 Types of processing;

3.3.1.2.3 Compliance history of the facility.

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

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

3.3.1.4.1 Are prioritized;

3.3.1.4.2 Have assigned frequencies;

3.3.1.4.3 Have resources allocated.

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

**STANDARD 3**  
**Inspection Program**

495 3.3.2 Inspection Protocol

496  
497  
498  
499  
500  
501  
502  
503  
504  
505  
506  
507  
508  
509  
510  
511  
512  
513  
514  
515  
516  
517  
518  
519  
520  
521  
522  
523  
524  
525  
526  
527  
528  
529  
530  
531  
532  
533  
534  
535  
536

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

**STANDARD 3**  
**Inspection Program**

- 537 3.3.2.1.19 Alert the feed facility's owner, operator, or agent in charge when an  
538 immediate corrective action is necessary;  
539 3.3.2.1.20 Document findings accurately, clearly, legibly, and concisely on the  
540 applicable form(s) and provide a copy to the feed facility's owner,  
541 operator, or agent in charge;  
542 3.3.2.1.21 Answer questions and provide information as appropriate;  
543 3.3.2.1.22 Submit inspection report, sample(s), and supporting documents to  
544 headquarters or supervisor in a timely manner.  
545

546 3.3.3 Recall System

547  
548 3.3.3.1 The State PROGRAM has a documented recall system. The recall system  
549 includes:

- 550  
551 3.3.3.1.1 Written procedures for:  
552 3.3.3.1.1.1 Receiving  
553 3.3.3.1.1.2 Tracking  
554 3.3.3.1.1.3 Evaluating recall notifications  
555 3.3.3.1.1.4 Closing  
556 3.3.3.1.1.5 Maintaining records  
557 3.3.3.1.2 Performing recall effectiveness checks  
558

559 3.3.4 Consumer Complaints

560  
561 3.3.4.1 The State PROGRAM has a documented system for handling consumer  
562 complaints. The system includes procedures for:

- 563  
564 3.3.4.1.1 Receiving  
565 3.3.4.1.2 Tracking  
566 3.3.4.1.3 Evaluating  
567 3.3.4.1.4 Answering  
568 3.3.4.1.5 Closing  
569 3.3.4.1.6 Maintaining records  
570

571 3.3.5 Complaints Resulting from State PROGRAM Inspection Activities

572  
573 3.3.5.1 The State PROGRAM has a documented system to handle complaints from  
574 industry about State PROGRAM inspections. The system includes procedures for:

- 575  
576 3.3.5.1.1 Receiving  
577 3.3.5.1.2 Evaluating  
578 3.3.5.1.3 Maintaining records  
579  
580

**STANDARD 3**  
**Inspection Program**

581 **3.4 Outcome**

582

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

588

589 **3.5 Documentation**

590

591 The State PROGRAM maintains the records listed here.

592

593 3.5.1 Appendix 3.1: Self-Assessment Worksheet

594 3.5.2 Documented procedures for defining the State's inventory of feed facilities

595 3.5.3 Documented procedures for updating the State's inventory of feed facilities

596 3.5.4 An inventory of feed facilities

597 3.5.5 Documented procedures used for categorizing feed facilities based on risk, including  
598 the inspection frequency assigned to each defined risk-based category

599 3.5.6 Documented policies and procedures for inspecting feed facilities

600 3.5.7 Documented recall system, which includes written recall procedures

601 3.5.8 Documented procedures for consumer complaints

602 3.5.9 Documented procedures for industry complaints about State PROGRAM inspection  
603 activities

## **STANDARD 4**

### **Auditing**

#### **4.1 Purpose**

604  
605  
606 This standard describes the auditing procedures necessary to: (1) evaluate the effectiveness of  
607 inspections and sample collections, (2) recognize trends in the inspection and sampling  
608 programs, and (3) identify areas in need of corrective actions.  
609

#### **4.2 Requirement Summary**

610  
611 The State PROGRAM conducts audits to document and evaluate the effectiveness of the  
612 PROGRAM'S inspections and sample collections. Auditing has two components: (1) a field audit  
613 component, which is an on-site performance evaluation of inspection and sample collection to  
614 verify they are consistently performed according to established performance factors and (2) a  
615 desk audit component, which is a performance review of the inspection and sample collection  
616 reports to verify the content quality and that a report was processed according to established  
617 performance factors.  
618  
619

#### **4.3 Program Elements**

620  
621  
622 4.3.1 The State PROGRAM has written procedures for conducting four types of audits:  
623

- 624 4.3.1.1 Field inspection audits as specified in 4.3.3;
- 625 4.3.1.2 Field inspection report audits as specified in 4.3.4;
- 626 4.3.1.3 Sample collection audits as specified in 4.3.5;
- 627 4.3.1.4 Sample collection report audits as specified in 4.3.6.  
628

629 Note: In general, each type of audit is composed of multiple performance factors. The  
630 performance factors are evaluated during an audit and then used to calculate an  
631 individual's audit score. The audit score determines the audit rating, which is recorded  
632 as "acceptable" or "needs improvement". Using all of the individual audits, the State  
633 PROGRAM calculates a performance factor score for each performance factor and a  
634 cumulative score for each type of audit. The State PROGRAM uses the audit scores,  
635 performance factor scores, and calculated scores to recognize trends in the field  
636 inspection and sample collection programs. The trends are used to identify specific  
637 areas that need improvement, and to take corrective action to improve areas.  
638

639 4.3.2 A review of the performance factor scores and cumulative scores for each type of  
640 audit is completed at least every 12 months.  
641

642 4.3.3 Field Inspection Audit: The State PROGRAM conducts field inspection audits using a  
643 QUALIFIED FIELD INSPECTION AUDITOR to verify that inspections are consistently  
644 performed according to the State's written procedures.  
645

**STANDARD 4**  
**Auditing**

646 4.3.3.1 Frequency: A minimum of two field inspection audits of each inspector is  
647 conducted every 36 months. The inspections selected for audits must reflect  
648 the inspector’s assignments and responsibilities.

649 4.3.3.2 Performance Factors: At a minimum, performance factors described in the  
650 inspection protocol within Standard 3: Inspection Program, and as listed in  
651 appendix 4.2, or comparable form, are evaluated.  
652

653 Note: For each performance factor, examples of actions and observations that  
654 would likely result in a “needs improvement” rating are provided in appendix  
655 4.2a.  
656

657 4.3.3.3 Performance Documentation:

658  
659 4.3.3.3.1 Appendix 4.2, or comparable form, is used to record the rating of  
660 each performance factor, audit score, and audit rating for each field  
661 inspection audit;

662 4.3.3.3.2 Appendix 4.3, or comparable worksheet, is used to calculate  
663 performance factor scores and a cumulative score for the State  
664 PROGRAM.  
665

666 Note: Directions for calculating performance factor scores and the  
667 cumulative score can be found in appendix 4.4.  
668

669 4.3.4 Field Inspection Report Audit: The State PROGRAM conducts periodic field  
670 inspection report audits to verify that inspectional findings are obtained and reported  
671 according to the State’s written procedures.  
672

673 4.3.4.1 The State PROGRAM will review a random selection of field inspection reports to  
674 be audited based on the number of inspections completed during a 12 month  
675 period of performance using the table below:  
676

Number of Inspections in 12 Months	Minimum Number of Reports Required	Maximum Number of Reports Required
Less than 20 reports	All	All
20 – 400 reports	20	20
More than 400 reports	5% of reports	50

677  
678 4.3.4.2 Performance Factors: At a minimum, the performance factors listed in appendix  
679 4.5, or comparable form, are evaluated.  
680

**STANDARD 4**  
**Auditing**

- 681 4.3.4.3 Performance Documentation:  
682  
683 4.3.4.3.1 Appendix 4.5, or comparable form, is used to record the rating of each  
684 performance factor, audit score, and audit rating for each inspection  
685 report audit;  
686 4.3.4.3.2 Appendix 4.6, or comparable worksheet, is used to calculate  
687 performance factor scores and a cumulative score for the State  
688 PROGRAM.  
689  
690 Note: Directions for calculating performance factor scores and the  
691 cumulative score can be found in appendix 4.4.  
692  
693 4.3.5 Sample Collection Audit: The State PROGRAM conducts sample collection audits  
694 using a QUALIFIED FIELD INSPECTION AUDITOR to verify that sample collections are  
695 consistently performed according to the State’s written procedures.  
696  
697 4.3.5.1 Frequency: A minimum of two sample collection audits of each inspector is  
698 conducted every 36 months. The sample collections selected for audits must  
699 reflect the inspector’s assignments and responsibilities.  
700 4.3.5.2 Performance Factors: At a minimum, performance factors listed in the  
701 sampling protocol described within Standard 11, Sampling Program and  
702 listed in appendix 4.7 are evaluated.  
703  
704 Note: For each performance factor, examples of actions and observations that  
705 would likely result in a “needs improvement” rating are provided in appendix  
706 4.7a.  
707  
708 4.3.5.3 Performance Documentation:  
709  
710 4.3.5.3.1 Appendix 4.7, or comparable form, is used to record the rating of  
711 each performance factor, audit score, and audit rating for each  
712 sample collection audit;  
713 4.3.5.3.2 Appendix 4.8, or comparable worksheet, is used to calculate  
714 performance factor scores and a cumulative score for the State  
715 PROGRAM.  
716  
717 Note: Directions for calculating performance factor scores and the  
718 cumulative score can be found in appendix 4.4.  
719  
720  
721 4.3.6 Sample Collection Report Audit: The State PROGRAM conducts periodic sample  
722 collection report audits to verify that sample collection documentation is consistently  
723 performed according to the State’s written procedures.



**STANDARD 4**  
**Auditing**

724 4.3.6.1 The State PROGRAM will review a random selection of sample collection reports  
725 audited based on the number of samples collected during a 12 month period of  
726 performance based using the table below:  
727

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

728  
729 4.3.6.2 Performance Factors: At a minimum, the performance factors listed in appendix  
730 4.9, or comparable form, are evaluated.

731 4.3.6.3 Performance Documentation:

732  
733 4.3.6.3.1 Appendix 4.9, or comparable form, is used to record the rating of each  
734 performance factor, audit score, and audit rating for each sample  
735 collection report audit;

736 4.3.6.3.2 Appendix 4.10, or comparable worksheet, is used to calculate  
737 performance factor scores and a cumulative score for the State  
738 PROGRAM.

739  
740 Note: Directions for calculating performance factor scores and the  
741 cumulative score can be found in appendix 4.4.  
742

743 4.3.7 Corrective Action Plan: The State PROGRAM has a written corrective action plan using  
744 appendix 4.11, or comparable form, if any of the following occur for any type of audit.  
745

746 4.3.7.1 An inspector receives an overall audit rating of “needs improvement” (audit  
747 score below 80 percent) for an individual audit.

748 4.3.7.2 A State PROGRAM has a performance factor score (as a result of all audits over  
749 12 months) below 80 percent for a single performance factor.

750 4.3.7.3 A State PROGRAM has a cumulative score (as a result of all audits over 12  
751 months) below 80 percent.  
752

753 **4.4 Outcome**  
754

755 The State PROGRAM’s evaluation of its inspection and sample collection activities ensures that  
756 they are adequate, complete, and that corrective actions are implemented when necessary.  
757

## **STANDARD 4**

### **Auditing**

758 **4.5 Documentation**

759

760 The State PROGRAM maintains the records listed here.

761

762 4.5.1 Appendix 4.1: Self-Assessment Worksheet

763 4.5.2 Written procedures for conducting four types of audits

764 4.5.3 Appendix 4.2: Field Inspection Audit Form

765 4.5.4 Appendix 4.3: Field Inspection Audit Worksheet

766 4.5.5 Appendix 4.5: Field Inspection Report Audit Form

767 4.5.6 Appendix 4.6: Field Inspection Report Audit Worksheet

768 4.5.7 Appendix 4.7: Sample Collection Audit Form

769 4.5.8 Appendix 4.8: Sample Collection Audit Worksheet

770 4.5.9 Appendix 4.9: Sample Collection Report Audit Form

771 4.5.10 Appendix 4.10: Sample Collection Report Audit Worksheet

772 4.5.11 Appendix 4.11: Corrective Action Plan

## **STANDARD 5**

### **Feed-Related Illnesses or Death and Emergency Response**

#### **773 5.1 Purpose**

774  
775 This standard describes the functions to detect, identify, and respond to alleged feed-related  
776 illnesses, deaths, and EMERGENCIES, including coordinating roles and responsibilities with other  
777 jurisdictions and communicating with appropriate parties.

#### **779 5.2 Requirement Summary**

780  
781 The State PROGRAM has a system to conduct emergency response to feed-related illnesses,  
782 deaths, and EMERGENCIES.

#### **784 5.3 Program Elements**

785  
786 5.3.1 The State PROGRAM has written procedures to gather information to identify incidents  
787 of feed-related illnesses, deaths, and EMERGENCIES.

788  
789 5.3.2 The State PROGRAM has written procedures to communicate with the appropriate State  
790 agencies or departments that investigate animal illnesses and food-related illnesses and  
791 outbreak.

792  
793 Note: These procedures facilitate sharing of information to identify potential feed-  
794 related illnesses, deaths, EMERGENCIES, and CROSS-SECTOR EVENTS.

795  
796 5.3.3 For feed-related illnesses, deaths, and EMERGENCIES, the State PROGRAM has a written  
797 procedure with criteria to:

798  
799 5.3.3.1 Determine the appropriate response

800 5.3.3.2 Initiate the response

801 5.3.3.3 Complete the response

802  
803 5.3.4 For feed-related EMERGENCIES, the State PROGRAM manages the event using:

804  
805 5.3.4.1 A formalized Incident Command System structure or

806 5.3.4.2 An official action plan<sup>2</sup> that includes:

807  
808 5.3.4.2.1 Outlining containment

809 5.3.4.2.2 Communication

810 5.3.4.2.3 Control

811 5.3.4.2.4 Correction

812 5.3.4.2.5 After-action protocols

813

---

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

**STANDARD 5**  
**Feed-Related Illnesses or Death and Emergency Response**

814 5.3.5 The State PROGRAM maintains a list of relevant agencies and emergency contacts.

815

816 5.3.5.1 The list is reviewed and updated based on the State defined frequency.

817

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

819

820 5.3.6 The State PROGRAM establishes written procedures to rapidly notify government  
821 agencies, departments, or appropriate parties of relevant findings.

822

823 5.3.7 The State PROGRAM has a written procedure to immediately notify law enforcement  
824 agencies when intentional feed contamination or feed-related terrorism is suspected or  
825 threatened.

826

827 5.3.8 The State PROGRAM has a written procedure for:

828

829 5.3.8.1 Releasing information to the public;

830 5.3.8.2 Coordinating media information with other jurisdictions to reduce the impact of  
831 feed-related illnesses, deaths, or EMERGENCIES.

832

833 **5.4 Outcome**

834

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

839

840 **5.5 Documentation**

841

842 The State PROGRAM maintains the records listed here.

843

844 5.5.1 Appendix 5.1: Self-Assessment Worksheet

845 5.5.2 Documented written procedure to gather information to identify incidents of feed-  
846 related illnesses, deaths, and EMERGENCIES

847 5.5.3 Documented procedure to communicate with Agency/Departments

848 5.5.4 Documented written procedure to determine the appropriate response, initiate the  
849 response, and complete the response for feed-related illnesses, deaths, and  
850 EMERGENCIES

851 5.5.5 Documented written procedures using a formalized Incident Command System  
852 structure or an official action plan

853 5.5.6 Emergency contact list

854 5.5.7 Documented written procedures to rapidly notify government agencies, departments, or  
855 appropriate parties of relevant findings

**STANDARD 5**  
**Feed-Related Illnesses or Death and Emergency Response**

- 856 5.5.8 Documented written procedure to immediately notify law enforcement agencies when
- 857 intentional feed contamination or feed-related terrorism is suspected or threatened
- 858 5.5.9 Documented procedure for releasing information to the public and coordinating media
- 859 information with other jurisdictions

## **STANDARD 6**

### **Enforcement Program**

#### **6.1 Purpose**

861 This standard describes the elements of an effective enforcement program.

#### **6.2 Requirement Summary**

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

#### **6.3 Program Elements**

871 6.3.1 The State PROGRAM has an enforcement program that contains documented  
872 ENFORCEMENT STRATEGIES.

874 6.3.2 The State PROGRAM must use the following six factors listed when selecting an  
875 appropriate enforcement tool:

877 6.3.2.1 Compliance history

878 6.3.2.2 Responsiveness

879 6.3.2.3 Scope

880 6.3.2.4 Nature of the Violation

881 6.3.2.5 Impact of the Violation

882 6.3.2.6 Resources

883  
884 Note: Appendix 6.2 provides examples of common enforcement tools. When selecting  
885 enforcement tools, the State PROGRAM may consider other factors in addition to the  
886 ones listed above.

888 6.3.3 The State PROGRAM has a documented written description for all factors.

890 6.3.4 The State PROGRAM has documented relative conditions for all factors.

892 6.3.4.1 Relative conditions of each factor will be assigned a numerical weight.

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

897 6.3.5 The State PROGRAM has a documented enforcement matrix designed to incorporate the  
898 relative conditions of each factor and the application of enforcement tools.

900 Note: Appendix 6.4 is an example enforcement matrix.

901  
902  
903

**STANDARD 6**  
**Enforcement Program**

904 6.3.6 The State PROGRAM has a documented process for conducting the annual evaluation  
905 described in 6.3.7.

906  
907 6.3.7 The State PROGRAM conducts an annual evaluation of its ENFORCEMENT STRATEGIES to:

908  
909 6.3.7.1 Determine if the PROGRAM’S ENFORCEMENT STRATEGIES were successful in  
910 achieving compliance;

911 6.3.7.2 Identify potential improvements or modifications of the ENFORCEMENT  
912 STRATEGIES, if any;

913 6.3.7.3 Determine if the enforcement priorities remain the same or require modification.

914

915 **6.4 Outcome**

916

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

921

922 **6.5 Documentation**

923

924 The State PROGRAM maintains the records listed here.

925

926 6.5.1 Appendix 6.1: Self-Assessment Worksheet

927 6.5.2 Documented ENFORCEMENT STRATEGIES

928 6.5.3 Documented factors including the description, relative conditions, and associated  
929 numerical weight for each

930 6.5.4 Enforcement matrix

931 6.5.5 Documented process for conducting an evaluation of the ENFORCEMENT STRATEGIES

932 6.5.6 Documented annual evaluation of the ENFORCEMENT STRATEGIES

## **STANDARD 7**

### **Outreach Activities**

933 **7.1 Purpose**

934  
935 This standard describes the elements of outreach activities developed and provided by the State  
936 PROGRAM.

937  
938 **7.2 Requirement Summary**

939  
940 The State PROGRAM conducts or participates in outreach activities and OUTREACH ACTIVITY  
941 EVENTS to inform ANIMAL FEED industry stakeholders, academia, other regulators, or consumers  
942 about ANIMAL FEED topics.

943  
944 **7.3 Program Elements**

945  
946 7.3.1 The State PROGRAM identifies the methods that will be used for outreach activities to  
947 inform ANIMAL FEED industry stakeholders, academia, other regulators, or consumers.

948  
949 7.3.2 The State PROGRAM develops an outreach plan that supports the State PROGRAM  
950 mission and includes:

- 951  
952 7.3.2.1 Objectives of an outreach plan  
953 7.3.2.2 Target populations  
954 7.3.2.3 The types of outreach activities (including OUTREACH ACTIVITY EVENTS)

955  
956 Note: The content and design of the plan will vary depending on the State PROGRAM  
957 priorities and mission.

958  
959 7.3.3 The templates provided in appendix 7.2, or comparable form, is used to record:

- 960  
961 7.3.3.1 Objectives of an outreach plan  
962 7.3.3.2 Target populations  
963 7.3.3.3 The types of activities (including OUTREACH ACTIVITY EVENTS)

964  
965 7.3.4 The State PROGRAM documents and evaluates OUTREACH ACTIVITY EVENTS. Appendix  
966 7.3, or comparable form, is used to document and evaluate OUTREACH ACTIVITY  
967 EVENTS.

968  
969 **7.4 Outcome**

970  
971 The State PROGRAM uses outreach activities to inform ANIMAL FEED industry stakeholders,  
972 academia, other regulators or consumers about ANIMAL FEED topics.

973



**STANDARD 7**  
**Outreach Activities**

974 **7.5 Documentation**

975

976 The State PROGRAM maintains the records listed here.

977

978 7.5.1 Appendix 7.1: Self-Assessment Worksheet

979 7.5.2 Outreach plan

980 7.5.3 OUTREACH ACTIVITY EVENTS overview and evaluation

981 7.5.4 Documents to verify the OUTREACH ACTIVITY EVENTS occurred

## **STANDARD 8**

### **Planning and Resources**

#### **8.1 Purpose**

982  
983  
984 This standard describes the elements of workplanning and resource evaluation used by a State  
985 PROGRAM.  
986

#### **8.2 Requirement Summary**

987  
988  
989 A State PROGRAM is required to have a documented workplan to support its inspection and  
990 sample collection programs.  
991

992 A State PROGRAM is required to conduct an evaluation of resource needs for completing the  
993 inspection and sample collection projections identified by the workplan and additional work  
994 conducted by the PROGRAM.  
995

996 A State PROGRAM is required to conduct an evaluation of the resources needed to fully implement  
997 the Animal Feed Regulatory Program Standards (AFRPS).  
998

#### **8.3 Program Elements**

1000  
1001 8.3.1 The State PROGRAM has a documented workplan. The workplan must include:  
1002

1003 8.3.1.1 Inspection plan  
1004

1005 8.3.1.1.1 Number of inspections

1006 8.3.1.1.2 Type of inspection

1007 8.3.1.1.3 Risk category of facility or product

1008 8.3.1.1.4 Frequency  
1009

1010 8.3.1.2 Sample plan  
1011

1012 8.3.1.2.1 Number of samples

1013 8.3.1.2.2 Type of samples  
1014

1015 8.3.1.3 Timeframe that the workplan is applicable.  
1016

1017 8.3.2 The State PROGRAM has a documented procedure for evaluating the workplan that  
1018 includes:  
1019

1020 8.3.2.1 Conducting periodic and annual evaluations of the workplan;

1021 8.3.2.2 Evaluating alignment with PROGRAM objectives and resources.  
1022

1023 Note: FDA and the State PROGRAM may meet periodically and develop a coordinated  
1024 workplan.

**STANDARD 8**  
**Planning and Resources**

1025 8.3.3 The State PROGRAM has a documented procedure for identifying and reviewing its  
1026 resources to accomplish the workplan within the applicable timeframe.

1027  
1028 Note: The resource review should include staffing, equipment, and funding needed to  
1029 support the inspection and sample collection activities identified in the workplan.

1030  
1031 Note: The resources needed to train and audit field staff, to support laboratory services,  
1032 compliance, education and outreach, and to respond to feed-related illnesses, deaths, or  
1033 EMERGENCIES should be determined by the State PROGRAM. The administrative  
1034 functions needed to support all PROGRAM areas should be considered when determining  
1035 PROGRAM resources.

1036  
1037 8.3.4 To validate the workplan, the State PROGRAM develops a formula that:

1038  
1039 8.3.4.1 Calculates the number of staff needed to conduct inspections of its ANIMAL FEED  
1040 inventory;

1041 8.3.4.2 Calculates the number of staff needed to conduct sample collections;

1042 8.3.4.3 Uses numerical values that are based on the State PROGRAM'S data;

1043 8.3.4.4 Must be used by the State PROGRAM.

1044  
1045 Note: The State PROGRAM should have adequate staff to inspect the State PROGRAMS  
1046 ANIMAL FEED inventory and to conduct sample collections, which could include  
1047 ANIMAL FEED facilities and retail establishments, based on risk categorization and  
1048 inspection frequency established by the PROGRAM in its workplan.

1049  
1050 Note: Appendix 8.2 provides example formulas that can be used as a baseline for a  
1051 State PROGRAM'S workplan. The formulas in appendix 8.2 do not include methods for  
1052 estimating staff numbers needed for sample collections, compliance activities,  
1053 administrative, or other programmatic activities.

1054  
1055 8.3.5 The inspection and sample collection staff must have the equipment needed to conduct  
1056 inspections and sample collections.

1057  
1058 8.3.6 A list of the equipment required for inspections and sample collections must be:

1059  
1060 8.3.6.1 Established by the State PROGRAM

1061 8.3.6.2 Maintained by the State PROGRAM

1062  
1063 Note: Appendix 8.3 provides an example list of equipment that may be used for  
1064 inspections and sample collections.

1065

**STANDARD 8**  
**Planning and Resources**

1066 8.3.7 The State PROGRAM must conduct a review of the resources required to fully implement  
1067 the AFRPS, including each of the program elements in the individual standards. The  
1068 review recorded in appendix 8.4 must determine whether the PROGRAM has:

- 1069
- 1070 8.3.7.1 Adequate staff
- 1071 8.3.7.2 Equipment
- 1072 8.3.7.3 Funding

1073

1074 Note: Information technology may be considered as part of the State PROGRAM’S  
1075 resource needs.

1076

1077 8.3.8 A baseline resource review in 8.3.7 must be made concurrently with the baseline  
1078 evaluation required for AFRPS Standard 9 and recorded in appendix 8.4.

1079

1080 8.3.9 Subsequent resource evaluations to determine the resources necessary for the State  
1081 PROGRAM to partially meet, fully meet, or maintain full IMPLEMENTATION of each  
1082 standard’s requirements must be completed within three years of the previous  
1083 evaluation.

1084

1085 **8.4 Outcome**

1086

1087 The State PROGRAM has a documented workplan to support its inspection and sample collection  
1088 programs and assesses the resources needed to support an ANIMAL FEED regulatory program and  
1089 implement the AFRPS.

1090

1091 **8.5 Documentation**

1092

1093 The State PROGRAM maintains the records listed here.

- 1094
- 1095 8.5.1 Appendix 8.1: Self-Assessment Worksheet
- 1096 8.5.2 Workplan
- 1097 8.5.3 Documented procedure for evaluating the workplan
- 1098 8.5.4 Documented procedure for identifying and reviewing its resources to accomplish the  
1099 workplan within the applicable timeframe
- 1100 8.5.5 Formula used to calculate number of staff needed to conduct inspections and sample  
1101 collections and supporting data
- 1102 8.5.6 List of required equipment for inspection and sample collection
- 1103 8.5.7 Appendix 8.4: Resources for IMPLEMENTATION of AFRPS

**STANDARD 9**  
**Assessment and Improvement**

1104 **9.1 Purpose**

1105  
1106 This standard tracks the IMPLEMENTATION of each standard and describes the requirements for an  
1107 improvement plan.

1108  
1109 **9.2 Requirement Summary**

1110  
1111 The State PROGRAM conducts a baseline evaluation utilizing the self-assessments completed for  
1112 each standard. The results of the baseline evaluation are used to create an improvement plan that  
1113 aids the PROGRAM in meeting the requirements of each standard.

1114  
1115 The State PROGRAM regularly evaluates its status in meeting the requirements of the standards.

1116  
1117 **9.3 Program Elements**

1118  
1119 9.3.1 The State PROGRAM uses the self-assessment worksheets from each standard to  
1120 complete a baseline evaluation. The baseline evaluation is used to determine if a  
1121 standard is fully met, partially met, or not met, and identify areas or functions in the  
1122 State PROGRAM that need improving in order to fully meet the requirements of each  
1123 standard.

1124  
1125 9.3.2 Following the baseline evaluation, the State PROGRAM develops an improvement plan  
1126 for requirements of the standards that are not fully met using appendix 9.2, or  
1127 comparable form. The improvement plan includes the following:

1128  
1129 9.3.2.1 The individual element or documentation requirement for the standard that was  
1130 not fully met;

1131 9.3.2.2 Improvements needed to fully meet the program element or documentation  
1132 requirement(s) of the standard;

1133 9.3.2.3 Lists of individual tasks that will be used to address the improvement;

1134 9.3.2.4 A projected completion date for each task;

1135 9.3.2.5 Completion date for each task.

1136  
1137 9.3.3 The State PROGRAM reviews and updates its improvement plan (appendix 9.2) on an  
1138 annual basis.

1139  
1140 9.3.4 The State PROGRAM completes an evaluation of IMPLEMENTATION status at least every  
1141 three years following the baseline evaluation to determine if each standard is fully met,  
1142 partially met, or not met. This evaluation includes a review and update of the  
1143 following:

1144  
1145 9.3.4.1 Self-assessment worksheets for each standard;

1146 9.3.4.2 Required documentation for each standard;

**STANDARD 9**  
**Assessment and Improvement**

- 1147           9.3.4.3 Improvement plan (appendix 9.2);  
1148           9.3.4.4 IMPLEMENTATION status (appendix 9.3).  
1149  
1150           9.3.5 Appendix 9.3, or comparable form, is used to track IMPLEMENTATION status of all the  
1151           standards.  
1152  
1153           9.3.6 The State PROGRAM retains records required under x.5 of each standard for the three  
1154           previous years, or per the State PROGRAM’S record retention policy.  
1155  
1156           Note: If FDA provides a State PROGRAM with financial assistance to implement the AFRPS,  
1157           FDA will conduct a verification audit of the State PROGRAM’S AFRPS IMPLEMENTATION.  
1158  
1159   **9.4 Outcome**  
1160  
1161   The State PROGRAM works to meet the requirements of all standards and continues to evaluate  
1162   and improve the PROGRAM to ensure the required elements for all standards remain met.  
1163  
1164   **9.5 Documentation**  
1165  
1166   The State PROGRAM maintains the records listed here.  
1167  
1168           9.5.1 Appendix 9.1: Self-Assessment Worksheet  
1169           9.5.2 Appendix 9.2: Assessment and Improvement Plan  
1170           9.5.3 Appendix 9.3: IMPLEMENTATION Status of Animal Feed Regulatory Program Standards

## **STANDARD 10**

### **Laboratory Services**

#### **10.1 Purpose**

1171  
1172  
1173 This standard describes the elements of utilizing REGULATORY TESTING LABORATORY(IES)  
1174 services that support the State PROGRAM.  
1175

#### **10.2 Requirement Summary**

1176  
1177  
1178 The State PROGRAM has access to laboratory services that provide analytical data that support  
1179 regulatory functions.  
1180

1181 The State PROGRAM receives accurate, timely, reliable, and defensible data from the  
1182 REGULATORY TESTING LABORATORY(IES).  
1183

#### **10.3 Program Elements**

1184  
1185  
1186 10.3.1 The State PROGRAM maintains a list of analytical services provided by REGULATORY  
1187 TESTING LABORATORY(IES). These types of services include the following:  
1188

1189 10.3.1.1 Routine

1190 10.3.1.2 Non-routine  
1191

1192 10.3.2 The State PROGRAM has a documented formal agreement with the REGULATORY  
1193 TESTING LABORATORY(IES) that conduct routine analytical services, unless the  
1194 laboratory is managed within the PROGRAM.  
1195

1196 10.3.3 The State PROGRAM prepares a sample analysis schedule based on a sampling plan<sup>3</sup>  
1197 in cooperation with REGULATORY TESTING LABORATORY(IES) performing routine  
1198 services to ensure compatibility with laboratory capabilities and capacities. At a  
1199 minimum, the sample analysis schedule must include:  
1200

1201 10.3.3.1 The type(s) of ANIMAL FEED to be analyzed;

1202 10.3.3.2 Number of samples to be collected;

1203 10.3.3.3 Estimated timeframe for collection;

1204 10.3.3.4 Type(s) of analysis to be performed.  
1205

1206 10.3.4 The State PROGRAM has written procedures developed by the REGULATORY TESTING  
1207 LABORATORY(IES) to maintain the integrity of the samples sent to the laboratory for  
1208 analytical testing that includes:  
1209

1210 10.3.4.1 Sample receipt

1211 10.3.4.2 Preservation

1212 10.3.4.3 Storage

---

<sup>3</sup>A description of a sampling plan can be found in Animal Feed Regulatory Program Standard 11: Sampling Program.

**STANDARD 10**  
**Laboratory Services**

- 1213 10.3.4.4 Retention
- 1214 10.3.4.5 Disposal
- 1215 10.3.4.6 Chain of custody
- 1216 10.3.4.7 Report of analysis
- 1217 10.3.4.8 Method(s) used to communicate information between the State PROGRAM
- 1218 and REGULATORY TESTING LABORATORY(IES)

1219

1220 10.3.5 State PROGRAM utilizes REGULATORY TESTING LABORATORY(IES) that:

1221

1222 10.3.5.1 Are accredited by a recognized accreditation body to ISO/IEC  
1223 17025:2005<sup>4</sup>, or

1224 10.3.5.2 Implement and comply with the AAFCO Quality Assurance/Quality  
1225 Control guidelines, or

1226 10.3.5.3 Implement and comply with the ISO/IEC 17025:2005.

1227

1228 **10.4 Outcome**

1229

1230 The State PROGRAM utilizes valid and defensible laboratory testing data to ensure their mission in  
1231 protecting animal and public health and enforcing feed regulations.

1232

1233 **10.5 Documentation**

1234

1235 The State PROGRAM maintains the records listed here.

1236

1237 10.5.1 Appendix 10: Self-Assessment Worksheet

1238 10.5.2 A list of routine and non-routine analytical services provided by the REGULATORY  
1239 TESTING LABORATORY(IES)

1240 10.5.3 An agreement with REGULATORY TESTING LABORATORY(IES) that provide routine  
1241 analytical services unless the laboratory is managed within the PROGRAM

1242 10.5.4 A current sample analysis schedule

1243 10.5.5 Written procedures to maintain the integrity of the samples sent to the REGULATORY  
1244 TESTING LABORATORY(IES)

1245

1246

1247

1248

1249

1250

1251

1252

---

<sup>4</sup> A recognized accreditation body must be signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).



## STANDARD 11 Sampling Program

### 1253 **11.1 Purpose**

1254

1255 This standard describes the elements of an effective ANIMAL FEED sampling program.

1256

### 1257 **11.2 Requirement Summary**

1258

1259 The State PROGRAM has a sampling program to support an ANIMAL FEED regulatory program.

1260

### 1261 **11.3 Program Elements**

1262

1263 11.3.1 The State PROGRAM has a documented annual sampling plan for collecting  
1264 surveillance, compliance, investigational, regulatory samples, or other samples.<sup>5</sup>

1265

1266 11.3.1.1 The annual sampling plan is jointly developed and amended by the State  
1267 PROGRAM and REGULATORY TESTING LABORATORY(IES) performing  
1268 routine analytical services to allow for advanced planning and scheduling  
1269 of work.

1270 11.3.1.2 The sampling plan outlines the State PROGRAM'S:

1271

11.3.1.2.1 Sampling priorities

1272

11.3.1.2.2 Sample analysis schedule

1273

11.3.1.2.3 Availability or coordination of analytical support

1274

1275

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

1276

1277

1278 11.3.2 The State PROGRAM has documented sampling procedures for collecting, storing,  
1279 and transporting samples that includes:

1280

11.3.2.1 Following safety precautions on feed labels;

1281

11.3.2.2 Following the State PROGRAM'S safety protocol for collecting samples;

1282

11.3.2.3 Using appropriate method and equipment to collect the sample;

1283

11.3.2.4 Sealing the sample to initiate chain of custody;

1284

11.3.2.5 Maintaining and documenting sample integrity, security, and chain of  
custody;

1285

1286

11.3.2.6 Issuing receipt<sup>6</sup> for sample(s);

1287

11.3.2.7 Handling<sup>7</sup>, packaging, and shipping sample using procedures appropriate  
to prevent compromising the condition of sample;

1288

1289

11.3.2.8 Delivering or shipping sample to the appropriate laboratory within  
acceptable timeframes.

1290

1291

1292

---

<sup>5</sup>Regulatory samples may be used to support inspection observations.

<sup>6</sup>Receipt could include cost of sample and method of payment.

<sup>7</sup>Includes storing sample.

**STANDARD 11**  
**Sampling Program**

- 1293 11.3.3 The State PROGRAM has documented instructions for the Sample Collection Report
- 1294 that includes:
- 1295
- 1296 11.3.3.1 Date of the sample collection;
- 1297 11.3.3.2 Product identification including:
- 1298
- 1299 11.3.3.2.1 Name
- 1300 11.3.3.2.2 Lot numbers or any other codes referencing manufacture
- 1301 identification
- 1302
- 1303 11.3.3.3 Description of product;
- 1304 11.3.3.4 Method of collection and any special techniques used to collect sample;
- 1305 11.3.3.5 Lot sampled;
- 1306 11.3.3.6 Lot size;
- 1307 11.3.3.7 Location where sample was collected;
- 1308 11.3.3.8 Name and address of responsible party, guarantor, possessor, or
- 1309 distributor;
- 1310 11.3.3.9 Sample type (surveillance, compliance, investigational, regulatory, or other);
- 1311 11.3.3.10 Analysis requested, if applicable;
- 1312 11.3.3.11 Collection or reproduction of product labels, including customer-formula
- 1313 feed labels;
- 1314 11.3.3.12 Receiving and distribution information.
- 1315

**11.4 Outcome**

1316 The State PROGRAM has a sampling program that aligns sampling resources with State PROGRAM

1317

1318 priorities. The annual sampling plan will facilitate efficient use and coordination of resources

1319 to obtain timely information. Samples are collected, stored, transported, and documented to

1320 support regulatory actions.

1321

1322

**11.5 Documentation**

- 1323 The State PROGRAM maintains the records listed here.
- 1324
- 1325 11.5.1 Appendix 11: Self-Assessment Worksheet
  - 1326
  - 1327 11.5.2 Documented annual sampling plan
  - 1328
  - 1329 11.5.3 Documented sampling procedures
  - 1330 11.5.4 Documented sample collection report instructions

## Appendix 1.1: Self-Assessment Worksheet

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

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	The State PROGRAM conducts an evaluation to determine whether the State's legal authority and are EQUIVALENT, EQUIVALENT IN EFFECT, or NOT EQUIVALENT to the sections of the FD&C Act and Federal regulations specified in appendix 1.2.
<i>Notes:</i>		

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	If a State law or regulation is determined to be "EQUIVALENT" to a Federal law or regulation, the State PROGRAM:
<i>Check "Not Applicable" box to the left if requirement is not applicable because no State law or regulation was determined to be EQUIVALENT.</i>		
<i>Not Applicable:</i>		
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	Specifies the Federal statute or regulation that is incorporated into the State law;
<input type="checkbox"/>	<input type="checkbox"/>	Includes the revision date of the State statutory provision or regulation;
<input type="checkbox"/>	<input type="checkbox"/>	Identifies the date the Federal statutory provision was incorporated into the State law.
<i>Notes:</i>		

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	The State PROGRAM has a documented process, which includes:
<i>Yes No</i>		
<input type="checkbox"/>	<input type="checkbox"/>	Procedure for reviewing the statutes, regulations, rules, ordinances and other prevailing regulatory requirements that:
<input type="checkbox"/>	<input type="checkbox"/>	Apply to the regulation of ANIMAL FEED;
<input type="checkbox"/>	<input type="checkbox"/>	Delegate authority to the State Agency;
<input type="checkbox"/>	<input type="checkbox"/>	Describe the State agency's administrative procedures for establishing its authority and incorporating rules by reference.
<input type="checkbox"/>	<input type="checkbox"/>	Timeframes for the review.
<i>Notes:</i>		

**Assessment Completed By:**

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

## Appendix 1.2: REGULATORY FOUNDATION Worksheet

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

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

\*Penalties may vary from Federal statute.

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

**Appendix 1.2: REGULATORY FOUNDATION Worksheet (continued)**

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

**Appendix 1.2: REGULATORY FOUNDATION Worksheet (continued)**

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

**Appendix 1.2: REGULATORY FOUNDATION Worksheet (continued)**

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

**Appendix 1.2: REGULATORY FOUNDATION Worksheet (continued)**

---

**Additional State Authorities (optional):**

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

---

---

---

---

---

**Additional notes and comments:**

---

---

---

---

---

---

---

---

**Assessment Completed By:**

---

Name

---

Date



## Appendix 2.1: Self-Assessment

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

### Training

Yes No

<input type="checkbox"/>	<input type="checkbox"/>	The State PROGRAM uses a written training plan that includes:
<input type="checkbox"/>	<input type="checkbox"/>	Basic curriculum
<input type="checkbox"/>	<input type="checkbox"/>	Advanced curriculum
<input type="checkbox"/>	<input type="checkbox"/>	Continuing education
<input type="checkbox"/>	<input type="checkbox"/>	For inspectors that conduct limited scope inspections (e.g. such as only collecting samples or inspections at veterinary clinics), the State PROGRAM specifies the curriculum required by the limited scope inspectors in their documented training plan.
<input type="checkbox"/>	<input type="checkbox"/>	The State PROGRAM maintains records documenting the training completed by all inspectors using appendix 2.2 or comparable form.
<input type="checkbox"/>	<input type="checkbox"/>	For inspectors with greater than 5 years of experience that do not have documentation of previous training, the State PROGRAM conducts an evaluation of the inspector's previous performance and experience to determine if the inspector has completed the required training or whether additional training is needed. (This is only permitted at the date of the initial self-assessment and not subsequent self-assessments.)
<input type="checkbox"/>	<input type="checkbox"/>	If previous coursework is completed before the inspectors START DATE and utilized to meet coursework requirements, proper supporting documents are maintained to verify successful completion of the requirement.

### Basic Feed Inspector Training

Yes No

<input type="checkbox"/>	<input type="checkbox"/>	The State PROGRAM requires an inspector to successfully complete coursework and field training within 24 months from the START DATE.
<input type="checkbox"/>	<input type="checkbox"/>	The basic feed inspection training consists of coursework in the following subject areas:
<input type="checkbox"/>	<input type="checkbox"/>	Animal and Public Health Principles
<input type="checkbox"/>	<input type="checkbox"/>	Basic Animal Nutrition
<input type="checkbox"/>	<input type="checkbox"/>	Basic Feed Ingredients, Processing and Technology
<input type="checkbox"/>	<input type="checkbox"/>	Basic National Incident Management System and Incident Command System (ICS)
<input type="checkbox"/>	<input type="checkbox"/>	Communication
<input type="checkbox"/>	<input type="checkbox"/>	Current Statutes, Regulations, and Policies
<input type="checkbox"/>	<input type="checkbox"/>	Feed Defense
<input type="checkbox"/>	<input type="checkbox"/>	Inspections, Compliance, and Enforcement
<input type="checkbox"/>	<input type="checkbox"/>	Labeling
<input type="checkbox"/>	<input type="checkbox"/>	Professionalism
<input type="checkbox"/>	<input type="checkbox"/>	Risk Awareness
<input type="checkbox"/>	<input type="checkbox"/>	Safety
<input type="checkbox"/>	<input type="checkbox"/>	Sampling
<input type="checkbox"/>	<input type="checkbox"/>	The State PROGRAM has established basic field training to complement the basic coursework.
<input type="checkbox"/>	<input type="checkbox"/>	Field training checklist of competencies to be mastered and verified in the field by the QUALIFIED FIELD INSPECTION TRAINER;
<input type="checkbox"/>	<input type="checkbox"/>	Documented procedures for JOINT FIELD TRAINING INSPECTIONS;



## Appendix 2.2: Inspector Training Record

Inspector Name: \_\_\_\_\_ Employment START DATE: \_\_\_\_\_

### A. Basic Feed Inspector Training

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

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



**Appendix 2.2: Inspector Training Record (continued)**

**Inspector Name:** \_\_\_\_\_ **Employment START DATE:** \_\_\_\_\_

**B. Advanced Feed Inspector Training**

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

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











## Appendix 3.1: Self-Assessment Worksheet

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

Program Elements	Yes/No	Specific Reference <sup>8</sup>	Notes
<b>Section I. Risk-Based Inspection Program</b>			
The State PROGRAM has documented procedures to: <ul style="list-style-type: none"> <li>Define an up-to-date inventory of feed facilities whose activities fall under the State's jurisdiction and authority;</li> <li>Maintain the inventory of feed facilities defined in 3.3.1.1.1.</li> </ul>			
The State PROGRAM has documented procedures for defining risk categories. The three minimum required factors for defining risk categories are: <ul style="list-style-type: none"> <li>Types of feed and feed products;</li> <li>Types of processing;</li> <li>Compliance history of the facility.</li> </ul>			
The State PROGRAM is required to use a minimum of the three factors in 3.3.1.2 to assign risk categories to feed facilities.			
Based on risk factors assigned to a facility or product, the manufacturing processes, and the inspection history of the facility, inspections: <ul style="list-style-type: none"> <li>Are prioritized;</li> <li>Have assigned frequencies;</li> <li>Have resources allocated.</li> </ul>			
<b>Section II. Inspection Protocol</b>			
The State PROGRAM has documented policies and procedures for inspecting feed facilities that require inspectors to:			
1. Review the feed facility's previous inspection report(s) and complaint(s);			
2. Present appropriate credentials and written Notice of Inspection to the feed facility's owner, operator, or agent in charge; make appropriate introductions; explain the purpose and scope of the inspection; and determine inspection authority;			
3. Follow the safety protocols required by the feed facility and the State PROGRAM;			
4. Follow the biosecurity protocols required by the feed facility and the State PROGRAM;			
5. Use appropriate equipment and forms needed to conduct inspections;			
6. Establish interstate jurisdiction for FDA inspections, if applicable;			

<sup>8</sup>Cite the reference (title and date of publication, section, and page number) to demonstrate the program element has been met.

### Appendix 3.1: Self-Assessment Worksheet (continued)

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

**Appendix 3.1: Self-Assessment Worksheet (continued)**

Program Elements	Yes/No	Specific Reference	Notes
<b>Section III. Recall System</b>			
The State PROGRAM has a documented recall system.			
<ul style="list-style-type: none"> <li>• The recall system includes written procedures for:               <ul style="list-style-type: none"> <li>○ Receiving</li> <li>○ Tracking</li> <li>○ Evaluating recall notifications</li> <li>○ Closing</li> <li>○ Maintaining records</li> </ul> </li> <li>• The recall system includes performing recall effectiveness checks</li> </ul>			
<b>Section IV. Consumer Complaints</b>			
The State PROGRAM has a documented system for handling consumer complaints.			
<ul style="list-style-type: none"> <li>• The consumer complaint system includes procedures for:               <ul style="list-style-type: none"> <li>○ Receiving</li> <li>○ Tracking</li> <li>○ Evaluating</li> <li>○ Answering</li> <li>○ Closing</li> <li>○ Maintaining records</li> </ul> </li> </ul>			
<b>Section V. Complaints Resulting from State Inspection Activities</b>			
The State PROGRAM has a documented system to handle complaints from industry about State PROGRAM inspections.			
<ul style="list-style-type: none"> <li>• The industry complaint system includes procedures for:               <ul style="list-style-type: none"> <li>○ Receiving</li> <li>○ Evaluating</li> <li>○ Maintaining records</li> </ul> </li> </ul>			

**Assessment Completed By:**

\_\_\_\_\_

Name

\_\_\_\_\_

Date

## Appendix 3.2: Risk Categorization for Feed Facilities

---

### Determining Risk Factors for Feed Facilities

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

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

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

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

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

### Risk Categorization Factors for Feed Facilities

#### A. Required Factors

##### 1. Type of Processing

The following types of processing should be considered.

- Rendering
- Pelletting
- Extrusion
- Roasting
- Steam Flaking
- Refrigeration
- Mixing
- Milling
- Salvaging
- Thermal processing
- Heating

##### 2. Type of Feed

The following types of feed should be considered.

- Mixes species
- Raw pet food
- Pet food
- Medicated feed
- Customer formula feed
- Feed containing prohibited mammalian tissue
- Feed ingredients subject to adulterants such as mycotoxins, pesticides, or industrial chemicals
- Single specie feed
- Non-medicated feed

## Appendix 3.2: Risk Categorization for Feed Facilities (continued)

---

### 3. Compliance History

The following types of compliance history should be considered.

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

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

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

### B. Optional Factors

#### 1. Volume of Product Manufactured

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

#### 2. Scope of Distribution

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

## Appendix 4.1: Self-Assessment Worksheet

---

### Auditing

---

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

#### Yes No

<input type="checkbox"/>	<input type="checkbox"/>	The State program has written procedures for conducting four types of audits:
<input type="checkbox"/>	<input type="checkbox"/>	Field inspection audits
<input type="checkbox"/>	<input type="checkbox"/>	Field inspection report audits
<input type="checkbox"/>	<input type="checkbox"/>	Sample collection audits
<input type="checkbox"/>	<input type="checkbox"/>	Sample collection report audits
<input type="checkbox"/>	<input type="checkbox"/>	A review of the performance factor scores and cumulative scores for each type of audit is completed at least every 12 months.

### Field Inspection Audit

---

#### Yes No

<input type="checkbox"/>	<input type="checkbox"/>	PROGRAM conducts field inspection audits
<input type="checkbox"/>	<input type="checkbox"/>	12-month period of performance
<input type="checkbox"/>	<input type="checkbox"/>	Number of audits conducted
<input type="checkbox"/>	<input type="checkbox"/>	Number of corrective action plans required
<input type="checkbox"/>	<input type="checkbox"/>	Inspectors are audited at a minimum against the performance factors found in appendix 4.2
<input type="checkbox"/>	<input type="checkbox"/>	Audits reflect inspector's assignments and responsibilities
<input type="checkbox"/>	<input type="checkbox"/>	Two audits per inspector completed every 36 months
<input type="checkbox"/>	<input type="checkbox"/>	Audit score calculated for each individual audit
<input type="checkbox"/>	<input type="checkbox"/>	Audit rating recorded for each individual audit
<input type="checkbox"/>	<input type="checkbox"/>	Performance factor score calculated for each performance factor
<input type="checkbox"/>	<input type="checkbox"/>	Cumulative score calculated for the PROGRAM

### Field Inspection Report Audit

---

#### Yes No

<input type="checkbox"/>	<input type="checkbox"/>	PROGRAM conducts random inspection report audits
<input type="checkbox"/>	<input type="checkbox"/>	12- month period of performance:
<input type="checkbox"/>	<input type="checkbox"/>	Number of inspection reports completed:
<input type="checkbox"/>	<input type="checkbox"/>	Number of inspection reports audited:
<input type="checkbox"/>	<input type="checkbox"/>	Number of corrective action plans required:
<input type="checkbox"/>	<input type="checkbox"/>	Inspection reports were audited according to frequency chart in the standard
<input type="checkbox"/>	<input type="checkbox"/>	Inspection reports are audited at a minimum against the performance factors found in appendix 4.5
<input type="checkbox"/>	<input type="checkbox"/>	Audit score calculated for each individual audit
<input type="checkbox"/>	<input type="checkbox"/>	Audit rating recorded for each individual audit
<input type="checkbox"/>	<input type="checkbox"/>	Performance factor score calculated for each performance factor
<input type="checkbox"/>	<input type="checkbox"/>	Cumulative score calculated for the PROGRAM

**Appendix 4.1: Self-Assessment Worksheet (continued)**

---

**Sample Collection Audit**

---

Yes No

<input type="checkbox"/>	<input type="checkbox"/>	PROGRAM conducts sample collection audits
<input type="checkbox"/>	<input type="checkbox"/>	12-month period of performance:
<input type="checkbox"/>	<input type="checkbox"/>	Number of audits conducted:
<input type="checkbox"/>	<input type="checkbox"/>	Number of corrective action plans required:
<input type="checkbox"/>	<input type="checkbox"/>	Inspectors are audited at a minimum against the performance factors found in appendix 4.7
<input type="checkbox"/>	<input type="checkbox"/>	Audits reflect inspector's assignments and responsibilities
<input type="checkbox"/>	<input type="checkbox"/>	Two audits per inspector completed every 36 months
<input type="checkbox"/>	<input type="checkbox"/>	Audit score calculated for each individual audit
<input type="checkbox"/>	<input type="checkbox"/>	Audit rating recorded for each individual audit
<input type="checkbox"/>	<input type="checkbox"/>	Performance factor score calculated for each performance factor
<input type="checkbox"/>	<input type="checkbox"/>	Cumulative score calculated for the PROGRAM

**Sample Collection Report Audit**

---

Yes No

<input type="checkbox"/>	<input type="checkbox"/>	PROGRAM conducts random sample collection report audits
<input type="checkbox"/>	<input type="checkbox"/>	12-month period of performance:
<input type="checkbox"/>	<input type="checkbox"/>	Number of sample collections reports reviewed:
<input type="checkbox"/>	<input type="checkbox"/>	Number of sample collection reports audited:
<input type="checkbox"/>	<input type="checkbox"/>	Number of corrective action plans required:
<input type="checkbox"/>	<input type="checkbox"/>	Sample collection reports were audited according to frequency chart in the standard
<input type="checkbox"/>	<input type="checkbox"/>	Sample collection reports are audited at a minimum against performance factors found in appendix 4.9
<input type="checkbox"/>	<input type="checkbox"/>	Audit score calculated for each individual audit
<input type="checkbox"/>	<input type="checkbox"/>	Audit rating recorded for each individual audit
<input type="checkbox"/>	<input type="checkbox"/>	Performance factor score calculated for each performance factor
<input type="checkbox"/>	<input type="checkbox"/>	Cumulative score calculated for the PROGRAM

**Corrective Action Plan**

---

Yes No

<input type="checkbox"/>	<input type="checkbox"/>	PROGRAM develops corrective action plans using appendix 4.11 when:
<input type="checkbox"/>	<input type="checkbox"/>	An inspector has an audit score below 80 percent for an individual audit
<input type="checkbox"/>	<input type="checkbox"/>	The PROGRAM has a performance factor score below 80 percent for a single performance factor
<input type="checkbox"/>	<input type="checkbox"/>	The PROGRAM has a cumulative score below 80 percent

**Assessment Completed By:**

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date



## Appendix 4.2: Field Inspection Audit Form

<b>Field Inspection Audit</b>	
Inspector:	Auditor: Date of Audit:
Firm Name: Firm Address:	Type of Inspection: <input type="checkbox"/> BSE <input type="checkbox"/> GMP <input type="checkbox"/> Tissue Residue <input type="checkbox"/> Complaint <input type="checkbox"/> Other:
Total Number of:      Acceptable Needs Improvement  Audit Score:	Audit Rating: <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement
<p>Instructions to the Auditor:            All performance factors must be rated 'Acceptable' or 'Needs Improvement'. The total number of 'Acceptable' and 'Needs Improvement', as well as the audit score and audit rating, must be recorded in the space above.</p> <p>To calculate the audit score: <math>Audit\ Score = [\#\ Acceptable / (\#\ Acceptable + \#\ Needs\ Improvement)] \times 100</math>.</p> <p>If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement'.</p>	
<b>I. Pre-Inspection Assessment</b>	
1. Did the inspector review the feed facility's previous inspection report(s) and complaint(s)? <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement  Comments (required for Needs Improvement)	
2. Did the inspector use appropriate equipment and forms to conduct the inspection? <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement  Comments (required for Needs Improvement)	
<b>II. Inspection Observations and Performance</b>	
1. Did the inspector present appropriate credentials and written Notice of Inspection to the feed facility's owner, operator, or agent in charge? Make appropriate introductions, explain the purpose and scope of the inspection, and determine inspection authority? <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement  Comments (required for Needs Improvement)	
2. Did the inspector follow safety protocols required by the feed facility and the state program? <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement  Comments (required for Needs Improvement)	

## Appendix 4.2: Field Inspection Audit Form (continued)

<p>3. Did the inspector follow the bio-security protocols required by the feed facility and the state program?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>4. Did the inspector establish interstate jurisdiction for FDA inspections, if applicable?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>5. Did the inspector recognize relative risk (high to low) of the feed facility based on the state program's risk-based inspection program and categorization assigned to a facility or a product, the manufacturing processes, and the inspection history of the facility?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>6. Did the inspector conduct inspection activities focused on the feed facility's products and processes determined to be high risk?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>7. Did the inspector assess feed facility employee activities critical to the safe manufacture, distribution, storage, handling, and disposition of feed?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>8. Did the inspector properly evaluate the likelihood that conditions, practices, processes, components, or labeling could cause the product to become adulterated or misbranded?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>9. Did the inspector recognize significant non-compliant conditions or practices and document findings consistent with program procedures?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>10. Did the inspector distinguish between significant and insignificant observations and isolated incidents versus trends?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>

## Appendix 4.2: Field Inspection Audit Form (continued)

<p>11. Did the inspector review and evaluate the appropriate feed facility records and procedures and verify that the procedures are being followed?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>12. Did the inspector collect adequate evidence and documentation to support inspection observations in accordance with program procedures?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>13. Did the inspector verify correction of deficiencies identified during the previous inspection(s)?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>14. Did the inspector conduct activities in a professional manner?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p><b>III. Oral and Written Communications</b></p>
<p>1. Did the inspector use effective interviewing techniques?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>2. Did the inspector explain findings clearly and adequately throughout the inspection?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>3. Did the inspector alert the feed facility's owner, operator, or agent in charge when an immediate corrective action was necessary?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>
<p>4. Did the inspector document findings accurately, clearly, legibly, and concisely on the applicable form(s) and provide a copy to the feed facility's owner, operator, or agent in charge?</p> <p><input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>

**Appendix 4.2: Field Inspection Audit Form (continued)**

---

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

Acceptable

Needs Improvement

Comments (required for Needs Improvement)

**IV. General Comments**

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

---

Name of Auditor

---

Signature of Auditor

---

Date

## Appendix 4.2a: Completing the Field Inspection Audit Form

---

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

### **Pre-Inspection Assessment**

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

##### Examples of a “needs improvement” rating

- a. The inspector does not review the previous inspection report and complaints.
- b. The inspector does not review a firm’s response letter to the previous establishment inspection in which corrective actions were promised.

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

##### Examples of a “needs improvement” rating

- a. The inspector does not have a copy or have electronic access to the pertinent laws and regulations.
- b. During a medicated feed mill inspection, the inspector does not have a current copy of Title 21 of the *Code of Federal Regulations* Parts 225 and 558 (or a current Feed Additive Compendium) or access on line.
- c. The inspector does not have a calculator.
- d. The inspector does not have a camera to document violations.
- e. The inspector does not have a flashlight to examine poorly lit raw material storage areas.
- f. The inspector uses outdated, improper, or inappropriate forms for the type of inspection conducted.

### **Inspection Observations and Performance**

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

##### Example of a “needs improvement” rating

- a. Inspector fails to present credentials to the owner, operator, or agent in charge of the establishment.
- b. Inspector fails to make appropriate introductions, explain the purpose and scope of the inspection, and determine inspection authority.
- c. Inspector enters the firm through the rear entrance and immediately begins the inspection without issuing a Notice of Inspection.
- d. Upon entering the firm, the inspector fails to issue the Notice of Inspection to the appropriate person.
- e. Inspector uses only a business card as identification.

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

##### Example of a “needs improvement” rating

- a. The inspector does not ask if any particular safety protocols are mandated at the facility.
- b. The inspector does not follow the State PROGRAM’S safety protocol or use personal protective equipment appropriately.
- c. The inspector does not follow the safety protocols mandated by a particular facility.

## Appendix 4.2a: Completing the Field Inspection Audit Form (continued)

---

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

#### Example of a “needs improvement” rating

- a. The inspector does not inquire if any particular bio-security protocols are mandated at the facility.
- b. The inspector does not follow the State PROGRAM’S bio-security protocol.
- c. The inspector does not follow the bio-security protocols mandated by the feed facility.

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

#### Examples of a “needs improvement” rating

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

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

#### Examples of a “needs improvement” rating

- a. The inspector does not recognize the relative risk of the facility because the inspector is not knowledgeable with the manufacturing process involved at this facility and does not inquire with facility personnel.
- b. The inspector organizes inspection activities focused on low risk items and ignores high risk products and processes.

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

#### Examples of a “needs improvement” rating

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

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

#### Examples of a “needs improvement” rating

- a. The inspector conducts the inspection without input from employees responsible for critical activities.
- b. The inspector does not review employee training records when required.
- c. The inspector observes a trash bin and a reclaim bin in the same area, but he fails to evaluate practices sufficiently to identify an employee placing trash in the reclaim bin, which subsequently re-enters the process flow.
- d. The inspector fails to recognize distressed dog food being placed into a re-grinder bin containing regrinds for ruminant feed.
- e. The inspector fails to note an employee using medication in a feed when the formula does not call for the addition of this medication.

## Appendix 4.2a: Completing the Field Inspection Audit Form (continued)

---

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

#### Examples of a “needs improvement” rating

- a. The inspector does not observe critical activities during the inspection and does not discuss procedures in place to prevent distribution when an error has occurred.
- b. The inspector does not review labeling protocols and verify a system was in place to assure proper labeling.
- c. The inspector does not recognize possible adulterants (pesticides) that are stored above bagged feeds.
- d. The inspector does not investigate a pallet of stacked bags that lack labeling and identification.
- e. The inspector fails to investigate feed containing an unapproved drug combination.

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

#### Examples of a “needs improvement” rating

- a. The inspector concentrates on one item and does not recognize other significant non-compliant conditions.
- b. The inspector notices non-compliant products but fails to adequately address them at the time of the inspection or at the end of the inspection.
- c. Inspector fails to identify a feed containing an unapproved drug combination.
- d. The inspector fails to note the significance of “back hauling” prohibited materials in a bulk truck used to transport cattle feed.

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

#### Examples of a “needs improvement” rating

- a. The inspector keeps reviewing documents until he finds an insignificant violation.
- b. The inspector does not emphasize the severity or outcome of significant observations and the need for immediate action.
- c. The inspector does not discuss patterns or trends that were observed.
- d. The inspector does not recognize significant pest infestations.
- e. The inspector identifies and objects to record keeping deficiencies without considering that corrective action plans have been implemented by the firm and the deficiency has not reoccurred.

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

#### Examples of a “needs improvement” rating

- a. The inspector asks for the invoices for customer formula feeds for labeling information and does not realize that the facility’s procedures use the facility’s mix ticket as the label.
- b. The inspector notices drugs are being added to the mixer before any other ingredient when the facility’s SOP for addition of medications states that medications will be added at five minutes into the mix time.
- c. The inspector fails to question alarm notifications and the resulting required procedures.
- d. The inspector encounters out of limit drug assays and does not look for follow up actions.
- e. The inspector reviews mixer cleanout records but fails to note cleanouts were not done according to the facility’s SOP.

## **Appendix 4.2a: Completing the Field Inspection Audit Form (continued)**

---

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

#### Examples of a “needs improvement” rating

- a. The inspector reviews the drug inventory and notes that the drug inventory is not accurate but does not collect documents to support the finding.
- b. The inspector notices dead rodents around the mixer hand add area and does not provide supporting evidence such as photographs, detailed narrative, or affidavits.
- c. The inspector mentions that proper caution statements are missing from medicated feed labels yet does not provide copies of the labeling involved.
- d. The inspector simply notes that “housekeeping needs improved” and does not provide documentation to support the observation.

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

#### Examples of a “needs improvement” rating

- a. The previous inspection of the facility listed inaccurate drug levels on labeling of several feeds. During the current inspection, the manager informs the inspector that the problem has been corrected. The inspector simply notes in the report the management’s statement and does not verify that the labels have been changed.
- b. The previous inspection noted improper cleanout procedures for all handling equipment. The inspector verifies that the mixer is being adequately cleaned out but does not verify proper procedures are being used for other handling equipment.
- c. The previous inspection noted that production records were not being checked at the end of the day. The inspector notes there are initials on some of the records, but the inspector does not further inquire about their procedures.

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

#### Examples of a “needs improvement” rating

- a. The inspector does not dress appropriately for the inspection. Upon arrival, clothes were torn and dirty.
- b. The inspector fails to wear protective safety equipment that is required by the firm or the State.
- c. The firm asks the inspector to use the boot bath before entering the production area, but the inspector ignores the firm’s request and enters the production area.
- d. The inspector is rude and demanding

## **Oral and Written Communications**

### **1. Did the inspector use effective interviewing techniques?**

#### Examples of a “needs improvement” rating

- a. The inspector’s requests for information are ambiguous; consequently, the firm provides documents that are not relevant to the inspection.
- b. The inspector’s requests contain jargon unfamiliar to the firm causing confusion in the facility personnel responses to inspector.
- c. The inspector is confrontational.
- d. The inspector asks pointed and directed questions in order to solicit a desired response.
- e. The inspector is not a good listener and kept interrupting the facility personnel in their responses.



## Appendix 4.2a: Completing the Field Inspection Audit Form (continued)

---

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

#### Examples of a “needs improvement” rating

- a. The inspector does not discuss a significant deficiency observed in the shelled corn storage or conveyor system before proceeding to the hammer mill area although the general manager was present at the time.
- b. At the conclusion of the inspection, the inspector’s discussion of the deficiencies is vague; therefore, management is unclear of the significance of the observations and that corrective action should be taken by the firm.
- c. At the conclusion of the inspection, the inspector does not discuss a significant deficiency observed during the inspection.

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

#### Examples of a “needs improvement” rating

- a. The inspector fails to advise the firm manager that ruminant feed products containing prohibited material are being packaged and shipped.
- b. The inspector fails to notify the firm manager that he witnessed direct contamination of bagged feed ingredients with used motor oil.
- c. After witnessing direct product contamination with a toxic chemical, the inspector immediately notifies an employee who was not the most responsible person in the feed facility.

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

#### Examples of a “needs improvement” rating

- a. The inspector fails to list significant inspectional observations.
- b. An inspectional observation states, “Firm did not control hazards,” but no further explanation is provided.
- c. The report is illegible or contains several spelling and grammatical errors.
- d. Inspector does not leave a summary of inspectional observations with the firm’s owner, operator, or agent in charge.

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

#### Examples of a “needs improvement” rating

- a. The inspector reveals specific information about a pending compliance action against a competitor.
- b. The inspector provides a competitor’s formulation to the facility manager.
- c. The inspector falsely answers a policy question that leads the firm to take an inappropriate corrective action.

**Appendix 4.3: Field Inspection Audit Worksheet**

<b>State Program:</b> _____ <b>Performance Period:</b> _____ <b>Cumulative Score (5):</b> _____	<b>Reviewed By:</b> _____ <b>Date:</b> _____
---	---

Auditor Initials and Date of Audit (1)																	A <sub>t</sub> (3)	NI <sub>t</sub> (3)	Performance Factor Score (3)
Initials																			
Date																			
Performance Factors (2)	Performance Ratings																		
I.1																			
I.2																			
II.1																			
II.2																			
II.3																			
II.4																			
II.5																			
II.6																			
II.7																			
II.8																			
II.9																			
II.10																			
II.11																			
II.12																			
II.13																			
II.14																			
III.1																			
III.2																			
III.3																			
III.4																			
III.5																			
Audit Score (2)																			
<b>Subtotal - Enter the sum of the totals from all continuation sheets.</b>																			
<b>Total (4) - Enter the final sums (subtotal + sums of (3) on this form).</b>																			

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

**Appendix 4.3: Field Inspection Audit Worksheet (continuation sheet)**

State Program: _____																		Reviewed By: _____		
<b>Auditor Initials and Date of Audit (1)</b>																		<b>A<sub>t</sub></b> <b>(3)</b>	<b>NI<sub>t</sub></b> <b>(3)</b>	<b>Performance</b> <b>Factor Score</b> <b>(3)</b>
Initials																				
Date																				
<b>Performance</b> <b>Factors (2)</b>	<b>Performance Ratings</b>																			
I.1																				
I.2																				
II.1																				
II.2																				
II.3																				
II.4																				
II.5																				
II.6																				
II.7																				
II.8																				
II.9																				
II.10																				
II.11																				
II.12																				
II.13																				
II.14																				
III.1																				
III.2																				
III.3																				
III.4																				
III.5																				
<b>Audit Score</b> <b>(2)</b>																				
<b>Subtotal - Enter the sum of the totals from all continuation sheets.</b>																				
<b>Total (4) - Enter the final sums (subtotal + sums of (3) on this form).</b>																				
<p>(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.</p>																				

## Appendix 4.4: Instructions for Completing Audit Worksheets

---

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

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

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

1. For each audit, record the auditor's initials and date of audit.
2. For each audit, record the rating for each performance factor (A = Acceptable; NI = Needs Improvement) as well as the audit score.
3. Count the number of A and NI for each performance factor (row), and record the total number of acceptable and needs improvements ratings, as well as calculate the performance factor score.

$A_t$  = Total Number of Acceptable Ratings

$NI_t$  = Total Number of Needs Improvement Ratings

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

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

$\sum A_t$  = Sum of Total Number of Acceptable Ratings

$\sum NI_t$  = Sum of Total Number of Needs Improvement Ratings

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

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

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

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

## Appendix 4.5: Field Inspection Report Audit Form

<b>Field Inspection Report Audit</b>	
Auditor:	Date of Audit: Date of Inspection:
Firm Name: Firm Address:	Type of Inspection: <input type="checkbox"/> BSE <input type="checkbox"/> GMP <input type="checkbox"/> Tissue Residue <input type="checkbox"/> Complaint <input type="checkbox"/> Other:
Total Number of:      Acceptable Needs Improvement	Audit Rating: <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement
Audit Score:	
<p>Instructions to the Auditor:            All performance factors must be rated 'Acceptable' or 'Needs Improvement'. The total number of 'Acceptable' and 'Needs Improvement', as well as the audit score and audit rating, must be recorded in the space above.</p> <p>To calculate the audit score: <i>Audit Score = [# Acceptable / (# Acceptable + # Needs Improvement)] x 100.</i></p> <p>If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement'.</p>	
<b>I. Organization of the Report</b>	
<p>1. Format of the inspection report followed the State program's current policies and procedures.  <input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>	
<p>2. Required fields on inspection report or related report forms are completed.  <input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>	
<p>3. Written observations were clear and concise.  <input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>	
<p>4. Submitted report within timeframes.  <input type="checkbox"/> Acceptable                      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>	

**Appendix 4.5: Field Inspection Report Audit Form (continued)**

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

**Appendix 4.5: Field Inspection Report Audit Form (continued)**

---

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

---

Name of Auditor

---

Signature of Auditor

---

Date

**Appendix 4.6: Field Inspection Report Audit Worksheet**

<b>State Program:</b> _____															<b>Reviewed By:</b> _____				
<b>Performance Period:</b> _____															<b>Date:</b> _____				
<b>Cumulative Score (5):</b> _____																			
Auditor Initials and Date of Audit (1)															A <sub>t</sub> (3)	NI <sub>t</sub> (3)	Performance Factor Score (3)		
Initials																			
Date																			
Performance Factors (2)	Performance Ratings																		
I.1																			
I.2																			
I.3																			
I.4																			
II.1																			
II.2																			
II.3																			
II.4																			
II.5																			
II.6																			
III.1																			
III.2																			
Audit Score (2)																			
<b>Subtotal - Enter the sum of the totals from all continuation sheets.</b>																			
<b>Total (4) - Enter the final sums (subtotal + sums of (3) on this form).</b>																			
(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.																			



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

State Program: _____															Reviewed By: _____					
Auditor Initials and Date of Audit (1)															A <sub>t</sub> (3)	NI <sub>t</sub> (3)	Performance Factor Score (3)			
Initials																				
Date																				
Performance Factors (2)	Performance Ratings																			
I.1																				
I.2																				
I.3																				
I.4																				
II.1																				
II.2																				
II.3																				
II.4																				
II.5																				
II.6																				
III.1																				
III.2																				
Audit Score (2)																				
<b>Subtotal - Enter the sum of the totals from all continuation sheets.</b>																				
<b>Total (4) - Enter the final sums (subtotal + sums of (3) on this form).</b>																				
(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.																				

## Appendix 4.7: Sample Collection Audit Form

<b>Sample Collection Audit</b>	
Inspector:	Auditor: Date of Audit:
Firm Name: Firm Address:	Type of Sample Collection: <input type="checkbox"/> Surveillance <input type="checkbox"/> Compliance <input type="checkbox"/> Investigational <input type="checkbox"/> Regulatory <input type="checkbox"/> Other:
Total Number of:      Acceptable Needs Improvement  Audit Score:	Audit Rating: <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement
<p>Instructions to the Auditor:            All performance factors must be rated 'Acceptable' or 'Needs Improvement'. The total number of 'Acceptable' and 'Needs Improvement', as well as the audit score and audit rating, must be recorded in the space above.</p> <p>To calculate the audit score: <i>Audit Score = [# Acceptable / (# Acceptable + # Needs Improvement)] x 100.</i></p> <p>If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement'.</p>	
<b>I. Sample Collection Observations and Performance</b>	
<p>1. Did the inspector follow safety precautions on the feed label?  <input type="checkbox"/> Acceptable      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>	
<p>2. Did the inspector follow the State program's safety protocol for collecting samples?  <input type="checkbox"/> Acceptable      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>	
<p>3. Did the inspector use the appropriate method and equipment to collect the sample?  <input type="checkbox"/> Acceptable      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>	
<p>4. Did the inspector seal the sample to initiate chain of custody?  <input type="checkbox"/> Acceptable      <input type="checkbox"/> Needs Improvement</p> <p>Comments (required for Needs Improvement)</p>	

**Appendix 4.7: Sample Collection Audit Form (continued)**

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

\_\_\_\_\_  
Name of Auditor

\_\_\_\_\_  
Signature of Auditor

\_\_\_\_\_  
Date

## Appendix 4.7a: Completing the Sample Collection Audit Form

---

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

### **Sample Collection Observations and Performance**

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

Examples of a “needs improvement” rating

- a. The inspector does not review all labeling that accompanies the feed prior to sampling.
- b. The inspector does not have a label available prior to sampling.
- c. The inspector does not review the whole container or back of label.
- d. The inspector is not knowledgeable about the nature and use of the product they are sampling.

#### **2. Did the inspector follow the State program’s safety protocol for collecting samples?**

Examples of a “needs improvement” rating

- a. The inspector does not have a copy or have electronic access to the State PROGRAM’S safety protocol.
- b. Inspector does not have proper personal protective equipment that may be needed.
- c. The inspector takes bulk samples out of a bulk vehicle and does not use appropriate fall protection equipment.

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

Example of a “needs improvement” rating

- a. Inspector simply hand grabs three or four handfuls out of the top of one bag.
- b. Inspector collects a sample of a Type A medicated article and then collects a complete feed for a different species without cleaning sampling equipment in between samples to prevent cross-contamination.
- c. Inspector pours half of his collected sample into the firm’s container because the firm requested they have a portion of his sample.
- d. Inspector collects ten probes from ten fifty pound bags but does not seal the probe holes or left the product in an unsalable condition.
- e. The inspector does not have a copy or have electronic access to the State PROGRAM’S sampling procedures.
- f. The inspector collects ten probes for a lot of feed. Eight of the sample cores are white in color and two are green. The inspector does not note this on the sample collection form or investigate it further.
- g. A sample is to be tested for microbial activity, but the inspector does not follow proper aseptic protocols.
- h. Inspector calls ahead to the facility and requests they have samples collected by the facility’s personnel and ready for pickup.

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

Example of a “needs improvement” rating

- a. The inspector collects three samples in the facility but does not document and seal the open samples until returning to his car.
- b. The inspector seals the container in such a manner whereby it can be opened without breaking the official custody seal.

## Appendix 4.7a: Completing the Sample Collection Audit Form (continued)

---

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

#### Example of a “needs improvement” rating

- a. The inspector does not complete the required information (e.g. lot identification number, date of collection, or guarantees) on the sample collection report.
- b. The inspector collects a sample of feed and seals the sample with the wrong official custody seal.
- c. High fat samples are placed in containers where the fat may leach into the container (e.g. paper bags).
- d. The label on a sampled feed says to store in a cool dry place, but during a period of high temperature, the collected sample is left in a car trunk for several days prior to shipment to the laboratory.

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

#### Examples of a “needs improvement” rating

- a. The inspector collects a sample and does not issue a receipt describing the sample to the owner, operator, or agent in charge.
- b. The inspector tells the owner he would mail him the receipt later in the week.

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

#### Examples of a “needs improvement” rating

- a. The feed samples are packaged along with other substances (e.g. pesticides or fertilizers) that might contaminate the sample during shipment.
- b. The samples are not packaged to prevent breakage, spillage, crushing, or other detrimental actions that may be encountered in shipping the samples.

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

#### Examples of a “needs improvement” rating

- a. The samples are not shipped or delivered according to the State PROGRAM’S protocols.
- b. A feed sample containing urea is shipped to the fertilizer laboratory instead of the feed laboratory.
- c. A sample of corn, intended to be tested for aflatoxin contamination, is delivered to the State’s seed testing laboratory instead of the proper feed laboratory.

**Appendix 4.8: Sample Collection Audit Worksheet**

State Program: _____															Reviewed By: _____				
Performance Period: _____															Date: _____				
Cumulative Score (5): _____																			
Auditor Initials and Date of Audit (1)															A <sub>t</sub> (3)	NI <sub>t</sub> (3)	Performance Factor Score (3)		
Initials																			
Date																			
Performance Factors (2)	Performance Ratings																		
I.1																			
I.2																			
I.3																			
I.4																			
I.5																			
I.6																			
I.7																			
I.8																			
Audit Score (2)																			
<b>Subtotal - Enter the sum of the totals from all continuation sheets.</b>																			
<b>Total (4) - Enter the final sums (subtotal + sums of (3) on this form).</b>																			
(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.																			

**Appendix 4.8: Sample Collection Audit Worksheet (continuation sheet)**

State Program: _____															Reviewed By: _____					
Auditor Initials and Date of Audit (1)															A <sub>t</sub> (3)	NI <sub>t</sub> (3)	Performance Factor Score (3)			
Initials																				
Date																				
Performance Factors (2)	Performance Ratings																			
I.1																				
I.2																				
I.3																				
I.4																				
I.5																				
I.6																				
I.7																				
I.8																				
Audit Score (2)																				
<b>Subtotal - Enter the sum of the totals from all continuation sheets.</b>																				
<b>Total (4) - Enter the final sums (subtotal + sums of (3) on this form).</b>																				
(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.																				

## Appendix 4.9: Sample Collection Report Audit Form

<b>Sample Collection Report Audit</b>	
Auditor:	Date of Audit: Date of Sample Collection:
Firm Name: Firm Address:	Type of Sample Collection: <input type="checkbox"/> Surveillance <input type="checkbox"/> Compliance <input type="checkbox"/> Investigational <input type="checkbox"/> Regulatory <input type="checkbox"/> Other:
Number of:      Acceptable Needs Improvement  Audit Score:	Audit Rating: <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement
<p>Instructions to the Auditor:            All performance factors must be rated 'Acceptable' or 'Needs Improvement'. The total number of 'Acceptable' and 'Needs Improvement', as well as the audit score and audit rating, must be recorded in the space above.</p> <p>To calculate the audit score: <math>Audit\ Score = \left[ \frac{\# Acceptable}{\# Acceptable + \# Needs\ Improvement} \right] \times 100</math>.</p> <p>If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement'.</p>	
<b>I. Organization of the Report</b>	
1. Date of sample collection was recorded. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement  Comments (required for Needs Improvement)	
2. Product identification including name and lot code or any other referencing manufacture information was recorded. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement  Comments (required for Needs Improvement)	
3. Description of product was recorded. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement  Comments (required for Needs Improvement)	
4. Collection information including method of collection, lot sampled, lot size, and any special techniques used to collect sample was recorded. <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement  Comments (required for Needs Improvement)	





**Appendix 4.10: Sample Collection Report Audit Worksheet**

State Program: _____															Reviewed By: _____				
Performance Period: _____															Date: _____				
Cumulative Score (5): _____																			
Auditor Initials and Date of Audit (1)															A <sub>t</sub> (3)	NI <sub>t</sub> (3)	Performance Factor Score (3)		
Initials																			
Date																			
Performance Factors (2)	Performance Ratings																		
I.1																			
I.2																			
I.3																			
I.4																			
I.5																			
I.6																			
I.7																			
I.8																			
I.9																			
I.10																			
Audit Score (2)																			
<b>Subtotal - Enter the sum of the totals from all continuation sheets.</b>																			
<b>Total (4) - Enter the final sums (subtotal + sums of (3) on this form).</b>																			
(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.																			

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

State Program: _____															Reviewed By: _____					
Auditor Initials and Date of Audit (1)															A <sub>t</sub> (3)	NI <sub>t</sub> (3)	Performance Factor Score (3)			
Initials																				
Date																				
Performance Factors (2)	Performance Ratings																			
I.1																				
I.2																				
I.3																				
I.4																				
I.5																				
I.6																				
I.7																				
I.8																				
I.9																				
I.10																				
Audit Score (2)																				
<b>Subtotal - Enter the sum of the totals from all continuation sheets.</b>																				
<b>Total (4) - Enter the final sums (subtotal + sums of (3) on this form).</b>																				
(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.																				

**Appendix 4.11: Corrective Action Plan**

---

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

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

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

**Completed By:**

\_\_\_\_\_

Name

\_\_\_\_\_

Date

## Appendix 5.1: Self-Assessment Worksheet

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

**Yes No**

--	--

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

*Notes:*

**Yes No**

--	--

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

*Notes:*

**Yes No**

--	--

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

*Yes No*


- Determine the appropriate response
- Initiate the response
- Complete the response

*Notes:*

**Yes No**

--	--

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

*Yes No*


- A formalized Incident Command System structure or
- An official action plan that includes:
  - Outlining containment
  - Communication
  - Control
  - Correction
  - After-action protocols

*Notes:*

**Yes No**

--	--

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

*Notes:*

**Appendix 5.1: Self-Assessment Worksheet (continued)**

---

Yes No

--	--

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

*Notes:*

Yes No


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

*Notes:*

Yes No

--	--

The State PROGRAM has a written procedure for:

*Yes No*


Releasing information to the public;

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

*Notes:*

**Assessment Completed By:**

---

Name

---

Date

## Appendix 5.2: Emergency Contact List

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

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

**Appendix 5.2: Emergency Contact List (continued)**

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



**Appendix 5.2: Emergency Contact List (continued)**

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

**Appendix 5.2: Emergency Contact List (continued)**

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

**Completed By:**

\_\_\_\_\_

Name

\_\_\_\_\_

Date

## Appendix 6.1: Self-Assessment Worksheet

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

**Yes No**

--	--

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

*Notes:*

**Yes No**

--	--

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

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

<i>Factor</i>	<i>Factor Used</i>	<i>Factor Description</i>	<i>Relative Conditions</i>	<i>Numerical Weight</i>
<i>Compliance history</i>				
<i>Responsiveness</i>				
<i>Scope</i>				
<i>Nature of Violation</i>				
<i>Impact of Violation</i>				
<i>Resources</i>				

*Notes:*

**Yes No**

--	--

The State PROGRAM has documented enforcement matrix.

*Notes:*

**Yes No**

--	--

The State PROGRAM has documented process for conducting an annual evaluation of ENFORCEMENT STRATEGIES.

*Notes:*

**Yes No**

--	--

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

*Yes No*


Determine if the PROGRAM'S ENFORCEMENT STRATEGIES were successful in achieving Compliance;

Identify potential improvements or modifications of the ENFORCEMENT STRATEGIES, if any;

Determine if the enforcement priorities remain the same or require modification.

*Notes:*

**Assessment Completed By:**

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

## Appendix 6.2: Enforcement Tools

---

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

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

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

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

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

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

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

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

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

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

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

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

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

---

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

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

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

### **Factor 1 – Compliance History**

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

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

### **Factor 2 – Responsiveness**

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

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

### **Factor 3 – Scope**

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

---

<sup>9</sup>Source of the factors, descriptions, and numerical weights is the AAFCO Enforcement Guidelines-Factor Application section of the AAFCO.

## **Appendix 6.3: Factors, Descriptions, and Numerical Weights for Consideration When Selecting an Enforcement Tool (continued)**

---

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

### **Factor 4 – Nature of the Violation**

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

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

### **Factor 5 – Impact of the Violation**

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

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

### **Factor 6 - Resources**

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

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

## Appendix 6.4: Enforcement Matrix

---

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

### Directions for Use of the Enforcement Matrix:

1. Determine the violation categories. The Example Enforcement Matrix on page 103 provides five examples of major violation categories: labeling, GMPs, sample results, contaminations, and administrative.
2. For each violation category, identify the enforcement tools that are appropriate for the violation category and the factor value range from minor to major. Examples of enforcement tools for each violation category from minor violations (factor value range 4 to 8) to major violations (factor value range 20 to 29) are provided in the Example Enforcement Matrix.
3. Calculate the sum of the numerical values assigned to each factor. See below for an example calculation:

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

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

**Appendix 6.4: Enforcement Matrix (continued)**

**Example Enforcement Matrix<sup>10</sup>**

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

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



## Appendix 7.1: Self-Assessment Worksheet

---

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

**Yes No**

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

The State PROGRAM has identified methods used for outreach activities to inform ANIMAL FEED industry stakeholders, academia, other regulators, or consumers.

*Notes:*

--------------

**Yes No**

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

The State PROGRAM has an outreach plan:

*Yes No The outreach plan includes:*

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

Objectives of an outreach plan

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

Target populations

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

Types of outreach activities (including OUTREACH ACTIVITY EVENTS)

*Notes:*

--------------

**Yes No**

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

The State PROGRAM documents outreach activities:

*Yes No Documentation includes:*

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

Objectives of an outreach plan

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

Target populations

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

Types of outreach activities (including OUTREACH ACTIVITY EVENTS)

*Notes:*

--------------

**Yes No**

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

The State PROGRAM documents and evaluates OUTREACH ACTIVITY EVENTS.

*Notes:*

--------------

**Assessment Completed By:**

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

## Appendix 7.2: Outreach Plan

---

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

### A. Outreach Plan in Chart Format

Effective Dates: \_\_\_\_\_

Objective	Target Population	Type of Outreach Activity	Delivery Method

### Completed By:

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

### B. Outreach Plan in Paragraph Format

Effective Dates: \_\_\_\_\_

#### Outreach Objective 1:

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

#### Outreach Objective 2:

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

#### Outreach Objective 3:

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

### Completed By:

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

**Appendix 7.3: OUTREACH ACTIVITY EVENT Overview and Evaluation**

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

**Section I. Overview of OUTREACH ACTIVITY EVENT**

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

- Meeting                       Workshop                       Task Force/Committee  
 Extension Event                       Other: \_\_\_\_\_

B. Date of **OUTREACH ACTIVITY EVENT**: \_\_\_\_\_

C. Subject or name of **OUTREACH ACTIVITY EVENT**: \_\_\_\_\_

D. Objective of **OUTREACH ACTIVITY EVENT**: \_\_\_\_\_

E. Target population for **OUTREACH ACTIVITY EVENT**: \_\_\_\_\_

**Section II. Evaluation of OUTREACH ACTIVITY EVENT**

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

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

**Completed By:**

\_\_\_\_\_

Name

\_\_\_\_\_

Date

## Appendix 8.1: Self-Assessment Worksheet

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

**Yes No**

--	--

The State PROGRAM has a documented workplan.

*Yes No Workplan Details:*


Inspection plan

Sample plan

Timeframe that the workplan is applicable

*Notes:*

**Yes No**

--	--

The State PROGRAM has a documented procedure for evaluating the workplan.

*Yes No Procedure Details How:*


PROGRAM conducts periodic and annual evaluations of the workplan;

PROGRAM evaluates alignment with PROGRAM objectives and resources.

*Notes:*

**Yes No**

--	--

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

*Notes:*

**Yes No**

--	--

To validate the workplan, the State PROGRAM must develop a formula that:

*Yes No*


Calculates the number of staff needed to conduct inspections of its ANIMAL FEED inventory;

Calculates the number of staff needed to conduct sample collections;

Uses numerical values that are based on the State PROGRAM'S data;

Must be used by the State PROGRAM.

*Notes:*

**Yes No**

--	--

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

*Notes:*

**Appendix 8.1: Self-Assessment Worksheet (continued)**

---

**Yes No**

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

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

*Yes No*

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

Established by the State PROGRAM

Maintained by the State PROGRAM

*Notes:*

--------------

**Yes No**

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

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

*Yes No*

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

Adequate staff

Equipment

Funding

*Notes:*

--------------

**Yes No**

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

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

Date Completed:

*Notes:*

--------------

**Yes No**

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

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

*Notes:*

--------------

**Assessment Completed By:**

\_\_\_\_\_

Name

\_\_\_\_\_

Date

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

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

Calculating the Number of Inspectors:

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

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

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

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

- For High Risk Feed Facilities:*

$$[(\#HR \times \%HRF) + (\#HR \times \%HRRF)] \times HRaIT = hHRI \text{ per year}$$

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

- For Medium Risk Feed Facilities:*

$$[(\#MR \times \%MRF) + (\#MR \times \%MRRF)] \times MRaIT = hMRI \text{ per year}$$

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

- For Low Risk Feed Facilities:*

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

---

$$[(\#LR \times \%LRF) + (\#LR \times \%LRRF)] \times LRaIT = hLRI \text{ per year}$$

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

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

$$(hHRI \text{ per year} + hMRI \text{ per year} + hLRI \text{ per year}) / AIT = \text{Number of Inspectors Needed}$$

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

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

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



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

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

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

## Appendix 9.1: Self-Assessment Worksheet

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

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

	<i>Yes</i>	<i>No</i>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Determine if a standard is fully met, partially met, or not met,
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Identify areas or functions that need improving in order to fully meet the requirements of each standard.

*Notes:*

**Yes    No**  
  The State PROGRAM develops an improvement plan for requirements of the standards that are not fully met that includes:  
 Not Applicable: *Check "Not Applicable" box to left if requirement is not applicable because all requirements of the standard are fully met*

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

*Notes:*

**Yes    No**  
  The State PROGRAM reviews and updates its improvement plan (appendix 9.2) annually.  
 Date Completed: \_\_\_\_\_

*Notes:*

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

	<i>Yes</i>	<i>No</i>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Self-assessment worksheets for each standard;
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Required documentation for each standard;
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Improvement plan (appendix 9.2);
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	IMPLEMENTATION status (appendix 9.3).

*Notes:*

## Appendix 9.1: Self-Assessment Worksheet (continued)

---

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

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

*Notes:*

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

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

Date Completed: \_\_\_\_\_

*Notes:*

**Assessment Completed By:**

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

## Appendix 9.2: Assessment and Improvement Plan

---

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

Standard Number and Title: \_\_\_\_\_

Date Self-Assessment Worksheet Completed: \_\_\_\_\_

Subject Matter Expert(s): \_\_\_\_\_

IMPLEMENTATION Status

Fully Met       Partially Met       Not Met

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

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

**Assessment Completed By:**

\_\_\_\_\_

Name

\_\_\_\_\_

Date

### Appendix 9.3: IMPLEMENTATION Status of Animal Feed Regulatory Program Standards

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

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

**Evaluation Completed By:**

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

## Appendix 10: Self-Assessment Worksheet

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

**Yes No**

--	--

The State PROGRAM has a list of routine and non-routine analytical services.

*Notes:*

--

**Yes No**

--	--

The State PROGRAM has documented formal agreement with REGULATORY TESTING LABORATORY(IES) managed outside the PROGRAM that conduct routine analytical services.

*Notes:*

--

**Yes No**

--	--

The State PROGRAM prepares a sample analysis schedule based on a sampling plan in cooperation with REGULATORY TESTING LABORATORY(IES) performing routine services to ensure compatibility with laboratory capabilities and capacities.

*Notes:*

--

**Yes No**

--	--

The State PROGRAM has a sample analysis schedule with each REGULATORY TESTING LABORATORY(IES) performing routine services.

*Yes No The sample analysis schedule includes:*

		Type(s) of ANIMAL FEED to be analyzed;
		Number of samples to be collected;
		Estimated timeframe for collection;
		Type(s) of analysis to be performed.

*Notes:*

--

**Yes No**

--	--

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

*Yes No*

		Sample receipt
		Preservation
		Storage
		Retention
		Disposal
		Chain of custody
		Report of analysis
		Method(s) used to communicate information between the State PROGRAM and REGULATORY TESTING LABORATORY(IES)

**Appendix 10: Self-Assessment Worksheet (continued)**

---

*Notes:*

--

**Yes    No**

--	--

The State PROGRAM utilizes REGULATORY TESTING LABORATORY(IES) that are accredited by a recognized accreditation body to ISO/IEC 17025:2005, or implement and comply with the AAFCO Quality Assurance/Quality Control guidelines, or implement and comply with the ISO/IEC 17025:2005.

*Notes:*

--

**Assessment Completed By:**

---

Name

---

Date

## Appendix 11: Self-Assessment Worksheet

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

Program Elements	Yes/No	Specific Reference <sup>11</sup>	Notes
<b>Section I. Sampling Plan</b>			
a. The State PROGRAM has a documented annual sampling plan.			
b. The sampling plan is jointly developed and amended by the State PROGRAM and REGULATORY TESTING LABORATORY(IES) performing routine services.			
c. The sampling plan outlines the State PROGRAM'S: <ul style="list-style-type: none"> <li>• Sampling priorities</li> <li>• Sample analysis schedule</li> <li>• Availability or coordination of analytical support</li> </ul>			
<b>Section II. Sampling Procedure for Collecting, Storing and Transporting Samples</b>			
<i>The State PROGRAM'S has a documented sampling procedure for collecting, storing, and transporting samples that includes:</i>			
a. Following safety precautions on feed labels;			
b. Following the State PROGRAM'S safety protocol for collecting samples;			
c. Using appropriate method and equipment to collect the sample;			
d. Sealing sample to initiate chain of custody;			
e. Maintaining and documenting sample integrity, security, and chain of custody;			
f. Issuing receipt for sample;			
g. Handling, packaging, and shipping sample using procedures appropriate to prevent compromising condition of sample;			
h. Delivering or shipping sample to the appropriate laboratory within acceptable timeframes.			
<b>Section III. Instructions for Sample Collection Report</b>			
<i>The State PROGRAM provides instructions for the sample collection report, including:</i>			
a. Date of the sample collection;			
b. Product identification including: <ul style="list-style-type: none"> <li>• Name</li> <li>• Lot numbers or other codes referencing manufacture identification</li> </ul>			
c. Description of product;			
d. Method of collection and any special techniques used to collect sample;			
e. Lot sampled;			

<sup>11</sup>Reference the document (include section and page number) in which the program element is found.



**Appendix 11: Self-Assessment Worksheet (continued)**

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

**Assessment Completed By:**

\_\_\_\_\_

Name

\_\_\_\_\_

Date