
Summary of Changes



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

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SUMMARY OF CHANGES

This summary provides a synopsis of the changes made to the 2017 Animal Feed Regulatory Program Standards (AFRPS). The primary intent of this summary document is to provide a broad overview of the changes found in the 2017 Animal Feed Regulatory Program Standards (AFRPS) rather than to identify every word or editing change. This summary document should not be relied upon as an absolute comparison that identifies each modification.

CHANGES MADE THROUGHOUT THE AFRPS

- **Definitions.**
 - The addition of a definitions section was included in the 2017 AFRPS. Defined words are found throughout the 2017 AFRPS in SMALL CAPS.
- **Numbering of sections.**
 - The new numbering layout of the 2017 AFRPS allows for quick reference and aligns with the layout used in the international standards and assessment tools and FDA manuals (such as the FDA's Investigations Operations Manual (IOM)).

Animal Feed Regulatory Program Standards

INTRODUCTION

UPDATES MADE TO THE SECTION

- Addition of explanation for “Notes.”
- Addition of clarifying statement that the State will not be assessed against “Notes.”

STANDARD ONE – REGULATORY FOUNDATION

NEWLY DEFINED TERMS

- Animal Feed
- Equivalent
- Equivalent in Effect
- Not Equivalent
- Program
- Regulatory Foundation

NEW SECTIONS AND APPENDICES

- No new sections added.
- Appendix 1.1 – Self- Assessment Worksheet
 - The 2014 Appendix 1 – Self-Assessment Worksheet was renumbered in 2017 as Appendix 1.2 and named Regulatory Foundation Worksheet.
 - The 2017 Appendix 1.1 is a self-assessment of the program elements in the Standard.

UPDATES MADE TO THE STANDARD

- **1.1 Purpose.**
 - No change
- **1.2 Requirement Summary.**
 - Amended to clarify the term “feed” is “animal feed” and specify the correct Appendix.
- **1.3 Program Elements.**
 - Amended for clarity that for provisions found to be “not equivalent” the State program should identify the State agency that has the authority and jurisdiction over the provision.
- **1.4 Outcome.**
 - Amended to clarify the term “feed” is “animal feed.”
- **1.5 Documentation.**
 - Updated to reflect Appendix 1.1 – Self-Assessment Worksheet and 1.2 – Regulatory Foundation Worksheet.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 1.2 – Regulatory Foundation Worksheet.
 - Columns for “equivalent”, “equivalent in effect” and “not equivalent” were placed in order to reflect their order in the Standard.
 - The “Partial/Full” column under the “Equivalent” heading was removed.

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STANDARD TWO

NEWLY DEFINED TERMS

- Contact Hour(s)
- Joint Field Training Inspections
- Qualified Field Inspection Trainer
- Start Date

NEW SECTIONS AND APPENDICES

- Section 2.3.1.3 under Training Plan and Training Records is new and is specific to inspectors that conduct limited scope inspections (e.g. collect samples).
- Section 2.3.1.6 under Training Plan and Training Records is new and is specific to previous coursework completed before the inspectors start date.
- Section 2.3.2.3.2 under Field Training (Basic Feed Inspector Training) is new and is specific to include documented procedures for joint field training inspections.
- Section 2.3.3.4.2 under Field Training (Advanced Feed Inspector Training) is new and is specific to include documented procedures for joint field training inspections.
- Section 2.3.6.3 under Continuing Education is new to include documentation required for each activity submitted for continuing education credit.
- Appendix 2.1 – *Self Assessment Worksheet*
 - The 2014 Appendix 2.1 Self-Assessment Worksheet/Inspector Training Record Summary was removed.
 - The 2017 Appendix 2.1 is a self-assessment of the program elements in the Standard.

UPDATES MADE TO THE STANDARD

- **2.1 Purpose.**
 - Amended to provide clarity.
- **2.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
- **2.3 Program Elements.**
 - BSE Awareness has been included into Risk Awareness. (2.3.2.2.11)
 - Prevailing Statutes, Regulations, and Policies has been updated to Current Statutes, Regulations, and Policies. (2.3.2.2.6)
 - Sources of coursework may be obtained from was removed from both the Basic and Advanced Feed Inspector Training Coursework sections.
 - Advanced Feed Inspection Training Timeframe. Amended to clarify this is for inspectors who conduct advanced feed inspections. (2.3.3.1)
 - Advanced Statutes, Regulations, and Policies has been updated to Current Statutes, Regulations, and Policies (2.3.3.2.4)

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- Continuing Education. Each inspector is required to receive 36 contact hours of continuing education was modified to 20 contact hours of continuing education.
- Continuing Education. The option to accrue four contact hours from reading technical publications related to feed was removed.
- **2.4 Outcome.**
 - Amended to provide clarity.
- **2.5 Documentation.**
 - Updated to reflect procedures and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 2.2 – Inspector Training Record and Appendix 2.3 – Field Training Competencies were updated to reflect changes within the program elements.

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STANDARD THREE

NEWLY DEFINED TERMS

- There are no new terms defined for this section.

NEW SECTIONS AND APPENDICES

- No new section added.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **3.1 Purpose.**
 - No change
- **3.2 Requirement Summary.**
 - No change
- **3.3 Program Elements.**
 - Risk-Based Inspection Program. Added the requirement of documented procedures to define an inventory of feed facilities and maintain the inventory. (3.3.1.1)
 - Risk-Based Inspection Program. Added the requirement of documented procedures for defining risk categories. (3.3.1.2)
 - Feed Recall Effectiveness Audits was renamed to Recall System. (3.3.3)
 - Recall System. Added the requirement of documented recall system. (3.3.3.1)
 - Recall System. Added the requirement of written procedures. (3.3.3.1.1)
- **3.4 Outcome.**
 - Amended to provide clarity.
- **3.5 Documentation.**
 - Updated to reflect procedures and records generated for each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Modified Appendix 3.1 – Self-Assessment Worksheet to reflect changes within the program elements.

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STANDARD FOUR

NEWLY DEFINED TERMS

- Qualified Field Inspection Auditor

NEW SECTIONS AND APPENDICES

- No new sections added.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **4.1 Purpose.**
 - No change
- **4.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
- **4.3 Program Elements.**
 - Added the requirement of written procedures for conducting four types of audits. (4.3.1)
 - The minimum number of Inspection Reports to be audited is now a scale based on the total number of inspections conducted in 12 months. (4.3.4.1)
 - The minimum number of Sample Reports to be audited is now a scale based on the total number of samples collected in 12 months. (4.3.6.1)
 - Corrective Action Plan. Added the requirement of a written corrective action plan. (4.3.7)
 - Corrective Action Plan. Added clarity that an overall audit rating of “needs improvement” is an audit score below 80 percent for an individual audit. (4.3.7.1)
- **4.4 Outcome.**
 - No change.
- **4.5 Documentation.**
 - Updated to reflect procedures and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Modified Appendix 4.1 – Self-Assessment Worksheet to reflect changes within the program elements.
- Modified Appendix 4.2 – Field Inspection Audit Form to reflect the program elements crossed referenced with Standard 3, element 3.3.2.1.2.
- Modified Appendix 4.7 – Sample Collection Audit Form to reflect the program elements crossed referenced with Standard 11, element 11.3.2.5.

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- Modified Appendix 4.7a – Completing the Sample Collection Audit Form to reflect the program elements crossed referenced with Standard 11, element 11.3.2.5.
- Modified Appendix 4.9 – Sample Collection Report Audit Form to reflect the program elements crossed referenced with Standard 11, element 11.3.3.3 and 11.3.3.9.
- Modified Appendix 4.11 – Corrective Action Plan to reflect changes within the program elements.

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STANDARD FIVE

NEWLY DEFINED TERMS

- Cross-Sector Event(s)
- Emergencies

NEW SECTIONS AND APPENDICES

- No new sections added.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **5.1 Purpose.**
 - No change
- **5.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
- **5.3 Program Elements.**
 - Added requirement of written procedures. (5.3.1)
 - Added requirement of written procedures. (5.3.3)
 - Added requirement of written procedures. (5.3.6)
 - Added requirement of written procedures. (5.3.7)
 - Added requirement of written procedures. (5.3.8)
- **5.4 Outcome.**
 - Amended to provide clarity.
- **5.5 Documentation.**
 - Updated to reflect procedures and records generated for each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 5.1- Self-Assessment Worksheet has been updated to reflect updated elements in new format.

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STANDARD SIX

NEWLY DEFINED TERMS

- Enforcement Strategies

NEW SECTIONS AND APPENDICES

- No new sections added.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **6.1 Purpose.**
 - No change.
- **6.2 Requirement Summary.**
 - No change.
- **6.3 Program Elements.**
 - Moved the definition of “enforcement strategies” to the Definitions Section. (6.3.1)
 - Added requirement of documented written description for all factors. (6.3.3)
 - Added requirement of documented relative conditions for all factors. (6.3.4)
 - Amended to provide clear requirements for an annual evaluation. (6.3.7)
- **6.4 Outcome.**
 - No Change.
- **6.5 Documentation.**
 - Updated to reflect procedures and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 6.1 – Self-Assessment Worksheet was updated to reflect the changes within the program elements.

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STANDARD SEVEN

NEWLY DEFINED TERMS

- Outreach Activity Event

NEW SECTIONS AND APPENDICES

- No new sections added.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **7.1 Purpose.**
 - No change
- **7.2 Requirement Summary.**
 - Amended to provide clarity and remove any program element requirements and place them within the Program Elements section.
- **7.3 Program Elements.**
 - Amended to clarify “feed” is “animal feed” and include “other regulators”. (7.3.1)
 - Amended the order of “objective of an outreach plan”, “target population” and “the types of outreach activities”. (7.3.2)
- **7.4 Outcome.**
 - Amended to include the “other regulators” and clarify the term “feed” is “animal feed.”
- **7.5 Documentation.**
 - No change

UPDATES TO APPENDICES AND WORKSHEETS

Modified Appendix 7.1 – Self-Assessment Worksheet was updated to reflect the changes within the program elements.

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STANDARD EIGHT

NEWLY DEFINED TERMS

- Implementation

NEW SECTIONS AND APPENDICES

- Section 8.3.3 under State program has a documented procedure for identifying and reviewing its resources to accomplish the workplan. Added Note about resources needed to train staff, support the laboratory, compliance, education and outreach should be determined by the State program.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **8.1 Purpose.**
 - No change.
- **8.2 Requirement Summary.**
 - No change.
- **8.3 Program Elements.**
 - Added requirement of documented procedure for identifying and reviewing resources to accomplish the workplan. (8.3.3)
 - Amended language throughout to provide clarification and simplify. (8.3.4)
 - Amended to provide clarity. (8.3.6.1)
 - Amended language throughout to provide clarification and simplify. (8.3.7)
 - Amended to provide clarity. (8.3.8)
- **8.4 Outcome.**
 - No change.
- **8.5 Documentation.**
 - Updated to reflect procedures and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 8.1 – Self-Assessment Worksheet was updated to reflect changes within the program elements.
- Appendix 8.3 – Example List of Equipment Used for Inspections and Sample Collections. The list was placed in alphabetical order and “vehicle” was added to the list.

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STANDARD NINE

NEWLY DEFINED TERMS

- There are no new terms defined for this section.

NEW SECTIONS AND APPENDICES

- 9.3.2.5 under the baseline evaluation section is new to include completion date for each task.
- Appendix 9.1 – Self- Assessment Worksheet
 - The 2017 Appendix 9.1 is a self-assessment of the program elements in the Standard.
 - The 2014 Appendix 9.1 – Assessment and Improvement Plan was renumbered in 2017 as Appendix 9.2

UPDATES MADE TO THE STANDARD

- **9.1 Purpose.**
 - Amended to provide clarity.
- **9.2 Requirement Summary.**
 - No change.
- **9.3 Program Elements.**
 - Amended to provide clarity that the self-assessments from each standard must be completed to conduct a baseline evaluation. (9.3.1)
 - Amended to provide clarity. (9.3.3)
 - Amended to provide clarity. (9.3.4)
 - Amended to provide clarity. (9.3.5)
 - Amended to provide clarity. (9.3.6)
- **9.4 Outcome.**
 - No change.
- **9.5 Documentation.**
 - Updated to reflect changes and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 9.2 – Assessment and Improvement Plan. Amended to remove the exception for Standard 9.
- Appendix 9.3 – Implementation Status of Animal Feed Regulatory Program Standards. Amended to include a column to record the status of “Complete/Incomplete” or “Date” for the self-assessment for each Standard.

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STANDARD TEN

NEWLY DEFINED TERMS

- Regulatory Testing Laboratory(ies)

NEW SECTIONS AND APPENDICES

- No new sections added.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **10.1 Purpose.**
 - Amended to provide clarity.
- **10.2 Requirement Summary.**
 - Amended to provide clarity.
- **10.3 Program Elements.**
 - Amended to provide clarity. (10.3.1)
 - Added the requirement for written procedures to maintain the integrity of samples sent to the regulatory testing laboratory. (10.3.4)
 - Amended “sample submission” to “sample receipt.” (10.3.4.1)
 - Amended the order of the regulatory testing laboratory requirements. (10.3.5)
- **10.4 Outcome.**
 - No change.
- **10.5 Documentation.**
 - Updated to reflect changes and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 10.1 – Self-Assessment Worksheet has been updated to reflect changes within the program elements.

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STANDARD ELEVEN

NEWLY DEFINED TERMS

- There are no new terms defined for this section.

NEW SECTIONS AND APPENDICES

- No new sections added.
- No new appendices added.

UPDATES MADE TO THE STANDARD

- **11.1 Purpose.**
 - No change.
- **11.2 Requirement Summary.**
 - No change.
- **11.3 Program Elements.**
 - Amended to add “annual.” (11.3.1)
 - Amended to provide clarity. (11.3.1.1)
 - Added the requirement of documented sampling procedures for collecting, storing, and transporting samples. (11.3.2)
 - Added the requirement of documented instructions for the Sample Collection Report. (11.3.3)
 - Amended to provide clarity. (11.3.3.2.2)
 - Amended to provide clarity. (11.3.3..9)
 - Amended to provide clarity. (11.3.3.11)
- **11.4 Outcome.**
 - Amended to add “annual.”
- **11.5 Documentation.**
 - Updated to reflect changes and records generated in each element.

UPDATES TO APPENDICES AND WORKSHEETS

- Appendix 11.1 – Self-Assessment Worksheet has been updated to reflect changes within the program elements.