

Appendix C.1

Guidance for Completing the BSE/Animal Food Establishment Audit Form

This document provides guidance on assigning ratings during an audit for each of the performance factors listed on the *Appendix C, BSE/Animal Food Establishment Audit Form*. For each performance factor, examples of actions and observations that would likely result in a “needs improvement” rating are provided.

I. Pre Inspection Assessment

1. Did the inspector prepare for the establishment inspection (e.g., review the previous inspection report, possible complaints, and/or access other available resources in preparation for the inspection)?

References:

- State's establishment files
- Applicable compliance programs referenced in the contract
- Investigations Operations Manual (IOM)

Examples of a “needs improvement” rating

- a. The inspector does not review the previous inspection report, including previously cited deficiencies and regulatory history.
- b. The inspector does not review a firm’s response letter to the previous establishment inspection in which corrective actions were promised.
- c. The inspector does not verify the days of operation for a firm that closes for a period of time during the winter.
- d. The inspector does not follow-up a consumer complaint contained in the state's establishment file.

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

References:

- Applicable compliance programs referenced in the contract
- Applicable inspection guides

Examples of a “needs improvement” rating:

- a. During an inspection of an animal foods manufacturer, the inspector does not have a calculator and current Animal Food Additive Compendium (or a copy of 21 CFR 225 and Chapter 500).
- b. The inspector does not have a camera to document violations.
- c. The inspector does not have a flashlight to examine poorly lit raw material storage areas.

II. Inspection Observations and Performance

1. Was FDA jurisdiction established?

References:

- FD&C Act – Section 704
- IOM 701 – Statutory Authority

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 Animal Food mill. S/he fails to determine that product or ingredients have not been received or shipped in interstate commerce by the manufacturer since the last inspection.

2. Were FDA credentials presented and Notice of Inspection (FDA 482) with attachments issued to the firm?

References:

- IOM 166 – Official credentials and badges
- IOM 501 – Authority to enter and inspect
- IOM 511 – Notice of inspection

Example of a “needs improvement” rating

- a. Inspector fails to present his/her credentials to the owner, operator, or agent in charge of the establishment when s/he is on site.
- b. Inspector enters the firm through the rear entrance and immediately begins his/her inspection without issuing a Notice of Inspection.
- c. Upon entering the firm, the inspector fails to issue the Notice of Inspection to the most responsible person.

3. Was a copy of the Animal Food Mill License (AFML) and drug registration verified to be active and current?

References:

- IOM 582 – Medicated Animal Foods and Type A Articles
- FD&C Act – Section 501
- 21 CFR 510 – New Animal Drugs
- 21 CFR 515 – Medicated Animal Food Mill License

Example of a “needs improvement” rating

- a. The inspector failed to verify the firm’s medicated animal food mill license was current and active.
- b. The inspector failed to verify the medicated animal food manufacturer drug registration was current and active.

4. Is the firm required to be registered under Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BT Act) and, if so, was the BT registration the verified?

References:

- 21 CFR 170.3
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Example of a “needs improvement” rating

- a. The inspector failed to verify if the animal food manufacturer was required to be registered under the BT Act.
- b. Although the firm met the registration requirements, the inspector failed to verify the status of the firm’s registration.

5. Did the inspector select appropriate product(s) during the inspection, and, if necessary, make appropriate adjustments based on what the firm was producing?

References:

- Applicable compliance program referenced in the contract

Example of a “needs improvement” rating

- a. The inspector covers only a Category I product when the firm is also producing Category II products on the day of the inspection.
- b. The inspector does not cover a small medicated premix operation in a complete feed processing plant.
- c. While inspecting an animal food manufacturing plant whose primary product is bulk medicated animal food pellets, the inspector ignores a medicated crumbles bagging operation at the site.
- d. The inspector selected and covered animal foods that contained no prohibited materials (PM) when products containing PM were being produced by the firm.

6. Did the inspector evaluate employee activities that may effect safe production and storage of animal food?

References:

- 21 CFR 225, cGMP for Medicated Animal Foods
- 21 CFR 589, Substances Prohibited from Use in Animal Food or Feed

Example of a “needs improvement” rating

- a. 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.
- b. The inspector fails to recognize the significance of an employee loading medicated feed into an uncovered feed truck in a rainstorm.
- c. The inspector fails to recognize distressed dog food being placed into a re-grinder bin containing regrinds for ruminant feed.
- d. The inspector fails to note an employee using Rumensin in a lamb feed when the formula did not call for the addition of this drug product.

7. Did the inspector evaluate conditions, practices, components, and/or labeling that may cause the product to be adulterated or misbranded?

References:

- Applicable compliance programs referenced in the contract
- GMP inspection guide for non-registered firms
- 21 CFR 500 or Current Animal Food Additive Compendium
- 21 CFR 589, Substances Prohibited from Use in Animal Food or Feed

Example of a “needs improvement” rating

- a. Inspector fails to identify feed containing an unapproved drug combination.
- b. The inspector fails to recognize when a firm’s finished medicated product labeling does not contain a drug declaration.
- c. The inspector fails to note the significance of “back hauling” prohibited materials in a bulk truck used to carry ruminant feeds.
- d. The inspector fails to recognize the addition of a drug during the production of a complete animal food and fails to review the animal food label.

8. Did the inspector recognize significant violative conditions or practices, if present, and record findings consistent with federal procedures?

References:

- Applicable compliance program referenced in the contract
- 21 CFR 225, cGMP for Medicated Animal Foods
- 21 CFR 589, Substances Prohibited from Use in Animal Food or Feed

Examples of a “needs improvement” rating

- a. The inspector fails to recognize that the firm’s clean out procedure is inadequate, because the equipment is used for products containing PM and products containing only non-prohibitive materials.
- b. The inspector fails to review the firm’s daily drug inventory records.
- c. The inspector does not document the firm’s failure to maintain records for PM through receipt, processing, and distribution of the feed materials.
- d. The inspector fails to recognize PM is used regularly as a component of an animal food ingredient.

9. Did the inspector demonstrate the ability to distinguish between significant versus insignificant observations and isolated incidents versus trends?

References:

- Applicable compliance program referenced in the contract
- 21 CFR 589, Substances Prohibited from Use in Animal Food or Feed
- 21 CFR 225, cGMP for Medicated Animal Foods

Examples of a “needs improvement” rating:

- a. The inspector observes minor deficiencies, such as dusty equipment, but overlooks areas where cross contamination of prohibited materials and ruminant feed product might occur.
- b. The inspector identifies record keeping deficiencies in two month old records. The inspector objects to these recorded deficiencies without considering corrective actions have been implemented by the firm and the deficiencies have not been repeated.
- c. During the inspection of a warehouse, the inspector observes products stored away from the wall but fails to see several pallets of pet food are adulterated with moths, bird droppings, and rodent droppings.

10. Did the inspector review and evaluate the appropriate records and procedures for this establishment’s operation and effectively apply the information obtained from this review?

References:

- Applicable compliance programs referenced in the contract

Examples of a “needs improvement” rating:

- a. During record review, the inspector detects actual mixing times routinely fail to meet or exceed master record file mixing times but does not inquire about the corrective measures the firm has taken.
- b. The inspector discovers swine feed mix containing PM but fails to check the finished label for the required cautionary statement.
- c. Mixer cleanout records are reviewed, but the inspector fails to note cleanout procedures were not done according to the firm’s SOPs.
- d. The inspector fails to confirm the required number of assays collected and performed. Furthermore, the inspector fails to report the finding on the FDA 483 and forgets to discuss it with the firm’s managers.
- e. Inspector identifies PM in protein premix for ruminant feeds but fails to notify firm management and record the finding on the FDA 483.

11. Did the inspector collect adequate evidence and documentation given the nature of the inspectional findings?

References:

- Applicable compliance programs referenced in the contract

Examples of a “needs improvement” rating:

- a. The inspector fails to collect labels from animal food to document a violation according to FDA requirements.
- b. The inspector fails to collect samples of animal food ingredients and finished animal food to document a violation according to FDA requirements.
- c. In a medicated animal food processing plant, the final product drug levels are questionable. The inspector, however, fails to collect a sample of the product for drug level analysis according to state procedures.
- d. The inspector fails to obtain receiving records that document the use of PM in dairy feed.
- e. The inspector fails to collect formulation records for super potent lots of animal food product.

12. Did the inspector verify that deficiencies from the previous inspection were corrected?

References:

- Applicable compliance programs referenced in the contract

Examples of a “needs improvement” rating:

- a. Although significant cleanout material handling deficiencies were identified during the previous inspection, the inspector does not determine whether these deficiencies have been corrected.
- b. The previous inspection of a firm listed inaccurate drug levels on labeling of several feed products. During the current inspection, the manager informs the inspector that the problem has been corrected and the lab results are acceptable. The inspector reviews these lab results but does not review the feed labels to verify they are correct.
- c. The inspector fails to follow up on deficiencies from the previous inspection for palletized cross-contaminated product, because the product is not being processed at the time of the inspection. And, the inspector does not review process records related to the product

to determine if the firm took appropriate corrective actions.

13. Did the inspector act in a professional manner and demonstrate proper safety practices during the inspection?

Examples of a “needs improvement” rating:

- a. The inspector does not use the boot bath when entering in the firm’s processing areas.
- b. At the conclusion of an inspection, the inspector accepts dog food as a gift from a manager at the firm.
- c. The inspector fails to wear protective safety devices that are required by the firm.

III. Oral and Written Communication

1. Did the inspector identify herself/himself and make appropriate introductions, which include explaining the purpose of the inspection?

Examples of a “needs improvement” rating:

- a. The inspector fails to explain why s/he is at the facility and the purpose of the inspection.
- b. The inspector enters through the back door and begins examining a storage area without making his/her presence known to anyone in the firm.

2. Did the inspector use suitable interviewing techniques?

Examples of a “needs improvement” rating:

- a. The inspector’s requests for information are ambiguous, consequently, the firm provided documents that were not relevant to the inspection.
- b. The inspector’s requests contain jargon unfamiliar to the firm causing confusion in their responses to inspector.
- c. The inspector fails to question the plant manager when his responses to questions about the equipment cleanout program were evasive.
- d. After receiving information from the firm’s management and production

personnel, the inspector fails to follow up on discrepancies between the two parties.

3. Did the inspector explain findings accurately, clearly, and adequately throughout the inspection?

Examples of a “needs improvement” rating:

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

4. Did the inspector notify the most responsible person at the firm 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 PM are being packaged and shipped.
- b. The inspector fails to notify the firm manager that he witnessed direct contamination of bagged animal food ingredients with used motor oil.
- c. After witnessing direct product contamination with a toxic chemical, the inspector immediately notified an employee not the most responsible person of the problem.

5. Did the inspector answer questions and provide information in an appropriate manner?

Examples of a “needs improvement” rating:

- a. The inspector revealed specific information about a pending compliance action against a competitor.
- b. The inspector gave a competitor’s formulation to the farm manager.

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

6. Did the inspector write his/her findings accurately, clearly, and concisely on the inspection report?

References:

- Applicable compliance programs referenced in the contract
- 21 CFR 589, Substances Prohibited from use in Animal Food or Feed

Examples of a “needs improvement” rating:

- a. The inspector fails to list an inspectional observation about product containing PM that failed to have the cautionary statement on label.
- b. The inspector fails to write on the inspectional observation about excreta found in animal food or animal food ingredients.
- c. An inspectional observation states, “Firm did not control hazards”, but no further explanation is provided.
- d. The inspector fails to write an inspectional observation about significant the drug discrepancies that were found in inventory records.
- e. The inspector failed to identify on the list of inspectional observations the drug products for the three assays that were not performed.

Reporting Instructions for States in Phase II and III

Only the State inspector, not the State auditor, will report his/her time in eSAF. The number of hours will be reported as an audit not an inspection. At the time data is entered into eSAF, the State data entry user will change the Inspection Type field on the Add/Update Inspection Operation screen from "State" to "Audit". In Phase II, the FDA investigator will report time following the instructions in the Appendix C.1.