FMD-76 Appendix B.1
Instructions for Completing the Contract Audit Form (Form FDA 3610)

This document provides instructions on assigning ratings during an audit for each of the performance factors listed on the Contract Audit Form (Form FDA 3610). For each performance factor examples of actions and observations that would likely result in a "needs improvement" rating is provided.

General Reference Documents:

Applicable Compliance Programs Referenced in the Contract
Applicable Inspection Guides
21 CFR 117
State's Establishment Files
Previous FDA report

I. Pre-Inspection Assessment

1. Did the inspector review the state's establishment file for the previous inspection report and possible complaints or access other available resources in preparation for the inspection?

Examples of a "needs improvement" rating:

a. The inspector does not review the state's previous inspection report and follow-up on previously cited deficiencies.

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

c. The inspector does not verify the firm's normal days of operation or seasonal hours.

d. The inspector does not appropriately follow-up on 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?

Examples of a "needs improvement" rating:

a. During an inspection of a cream-filled pie manufacturer, the inspector does not have a calibrated thermometer available to accurately determine if the product is time/temperature abused.

b. During an inspection of a cooked, ready-to-eat food processor, the inspector does not have a method to test the concentration of iodine sanitizer in the hand dip station.

c. The inspector does not have a flashlight available during an inspection to examine poorly lit raw material storage areas.

II. Inspection Observations and Performance

1. Was FDA jurisdiction established?

References

IOM 4.4 - Documenting Interstate Shipments
IOM 2.2 – Statutory Authority

Examples of a "needs improvement" rating:

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

b. The inspector conducts an inspection of a candy manufacturer and fails to discover that the manufacturer has not shipped in interstate commerce in the past 24 months. This manufacturer has no ingredients or packaging components shipped interstate.

2. Did the inspector select an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the firm was producing?

Examples of a "needs improvement" rating:

a. The inspector covers only a low-risk product, when the firm is also producing a high-risk product on the day of the inspection.

b. The inspector does not cover a small ready-to-eat sandwich operation in a large frozen dinner processing plant.

c. While inspecting a beverage bottling plant whose primary product is institutional-sized root beer syrup, the inspector ignores a bottled water processing operation at that site.

d. The inspector selects a product or raw ingredient to cover that isn't under FDA jurisdiction.

3. Did the inspector assess the employee practices critical to the safe production and storage of food?

Examples of a "needs improvement" rating:

a. The inspector fails to evaluate the hygienic practices of employees working in a food processing area.

b. The inspector is unaware of the need for employees processing cooked, ready-to-eat foods to first wash their hands prior to sanitizing each time they touch an unclean surface.

c. A firm has a trash bin and a reclaim bin in the same area. The inspector notes this but does not evaluate practices sufficiently enough to identify an employee placing trash in the reclaim bin that subsequently re-enters the process flow.

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

References

NLEA Inspection Guide

Examples of a "needs improvement" rating:

a. The inspector fails to recognize when a firm's finished product labeling does not contain a sulfite declaration, even though the raw material does contain a sulfite declaration.

b. The inspector fails to note the significance of "back hauling" raw eggs in a tanker used to carry pasteurized ice cream mix.

c. During an inspection of a baby food manufacturer, the inspector observes a belt moving rapidly causing glass jars to rattle and notices shards of glass on the belt. The inspector fails to relate that observation to a recent increase in complaints about glass in baby food.

d. The inspector fails to recognize the addition of an allergen during the production of a breaded product or notes it but fails to follow-up on the label review.

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

References:

IOM Chapter 5

Examples of a "needs improvement" rating:

a. The inspector fails to recognize the presence of food residues and mold growth on food contact surfaces as a violation.

b. The inspector does not recognize that employees handling cooked, ready-to-eat product with soiled hands is a deficiency.

c. The inspector fails to recognize cumulative time/temp abuse that occurred during the cooling, holding and processing of a potentially hazardous food.

d. The inspector fails to determine that the WD-40™, observed in the processing area, is being used to lubricate machine parts over food contact surfaces.

e. The inspector fails to recognize that a firm's cooler dripping condensate on finished product provides an opportunity for cross contamination.

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

Examples of a "needs improvement" rating:

a. The inspector notes minor deficiencies such as chewing gum and nail polish while failing to note areas where cross contamination of cooked and raw product might occur.

b. The inspector identifies record keeping deficiencies in records that are two months old. The inspector objects to these deficiencies without appropriately considering that the firm's weekly management review of the records has identified the deficiencies and that they have not been repeated within the last seven weeks.

c. During an inspection of a ready-to-eat salad processor, the inspector places extensive emphasis on soiled non-food contact surfaces.

d. During an inspection of a ready-to-eat trail mix manufacturer, the inspector observing the processing area notes only that an employee was wearing earrings, and another was chewing gum. However, the inspector fails to observe employees touching soiled surfaces and then touching the product without washing and sanitizing their hands.

e. During the inspection of a warehouse, the inspector places extensive emphasis on storing products away from the wall while not noticing that several pallets of rice are covered with moths and bird droppings.

7. 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?

Examples of a "needs improvement" rating:

a. During record review, the inspector fails to detect that cooking times routinely do not meet or exceed scheduled process and no corrective actions are documented.

b. The inspector fails to detect possible evidence of record falsification such as inconsistencies among different types of records, unrealistically repetitive data, and inconsistencies in signatures or handwriting.

c. Can teardown records are reviewed, but the inspector fails to note that teardown measurements were not done at appropriate intervals.

8. Did the inspector collect adequate evidence and documentation in accordance with state procedures given the nature of the inspectional findings?

Examples of a "needs improvement" rating:

a. The inspector fails to adequately document findings in accordance with state requirements when encountering a violative firm.

b. The inspector fails to collect samples of processed food in accordance with state requirements when necessary to document non-compliance with a state law.

c. In an acidified food processing plant, the final product pH comes into question. The inspector does not collect a sample of the product as required by state procedures for pH analysis.

9. Did the inspector verify correction of deficiencies identified during the previous state inspection?

Examples of a "needs improvement" rating:

a. Although significant time-temperature abuse of coconut cream pies was identified during the previous inspection, the inspector does not determine whether these deficiencies have been corrected.

b. The previous inspection of a firm listed a well that was not equipped with a sanitary seal. The manager informs the inspector during the current inspection that the well has been repaired and the lab results are acceptable. The inspector reviews these microbiological lab results but does not go to the well to observe the sanitary seal or ask for repair receipts.

c. The inspector fails to follow up on deficiencies from the previous inspection for cooked, ready-to-eat product because that product is not being made at the time of the inspection. The inspector does not review process records related to the product to determine if the firm took appropriate corrective actions.

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

Examples of a "needs improvement" rating:

a. The inspector fails to wash and sanitize their hands before touching the product or product contact surfaces during the inspection.

b. The inspector does not use the boot bath when entering in the firm's processing areas.

c. The inspector fails to sanitize their thermometer prior to probing product.

d. The inspector fails to wear protective clothing when entering an aseptic processing area.

e. The inspector wears jewelry, which may jeopardize open product, into a firm's manufacturing or processing areas.

IIA. Inspection Observation and Performance for 'HACCP-Required' Facilities

[Note: These four questions may be left blank if the firm is not required by regulations to have a HACCP plan.]

References

Applicable Compliance Programs referenced in the contract
Code of Federal Regulations Parts 110, 123, 1240, 117
Fish and Fishery Products Hazards & Controls Guide (Guide)
HACCP Regulation for Fish & Fishery Products – Questions and Answers
Guidance for Industry: Seafood HACCP and the FDA Food Safety Modernization Act
Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition
Juice HACCP and the FDA Food Safety Modernization Act
Code of Federal Regulations, Part 120

1. Did the inspector use the "Fish and Fishery Products Hazards and Controls Guide" and the "Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance", as appropriate, to identify and evaluate the hazards associated with the product and process?

Examples of a "needs improvement" rating:

a. In a tuna processing plant, the inspector fails to identify histamine as a hazard inherent to the incoming raw material and fails to question its absence in the firm's HACCP plan. (Failure to identify a hazard reasonably likely to occur.)

b. A firm is producing fresh, raw, refrigerated fish in cryovac packaging. The inspector is not aware that *C. botulinum* is a significant hazard.

c. An inspector incorrectly identifies aquaculture drugs as a significant hazard for a secondary processor of a product that it receives from the primary processor. (Identification of a hazard not reasonably likely to occur.)

d. The inspector fails to recognize that a batter tank is a likely CCP in a breaded shrimp processing operation. (Failure to recognize an appropriate CCP.)

e. The inspector fails to inquire about the firm's 7-log reduction.

2. Did the inspector assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation?

Examples of a "needs improvement" rating:

a. The inspector insists on the need for the firm to perform medical check-ups for crabmeat pickers.

b. The inspector is unaware of which of the eight areas of sanitation are relevant to the firm's operations.

c. The inspector fails to inquire about the firms SSOPs and monitoring practices.

3. Did the inspector review firm's HACCP plan (or necessary process controls in the absence of a HACCP plan) and applicable monitoring, verification, and corrective action records, including those related to sanitation?

Examples of a "needs improvement" rating:

a. After conducting a brief walk through a crabmeat processor, the inspector relies on a review of the firm's records as the only means of evaluating whether the firm is implementing its HACCP plan. The inspector does not return to the crab picking room to observe whether the picking/packing critical limits are being met, whether the firm has the equipment to properly monitor the critical limits as specified in the plan, and whether the critical limits are, in fact, being monitored.

b. The inspection reveals that the firm does not have a HACCP plan for a product for which one is needed. The inspector cites the lack of the HACCP plan but fails to observe the firm's processing operations to determine whether the necessary controls are in place, despite the absence of a plan.

c. Although the inspector is told that the firm uses well water as its source for ice which comes into direct contact with the fish, the inspector does not verify that the firm has the water tested for coliforms to ensure its safety.

d. The plant manager tells the inspector that pest control services are contracted out to another firm for biweekly monitoring/treatment, but the inspector does not ask to see documentation for such service.

e. The inspector fails to accompany the firm's sanitarian on the regular pre-operation inspection when there would be indications that sanitation and/or sanitation monitoring may be inadequate.

4. Did the inspector recognize deficiencies in the firm's monitoring and sanitation procedures through in-plant observations?

Examples of a "needs improvement" rating:

a. The inspector fails to recognize cumulative time/temperature abuse during cooling, holding and picking of cooked crabs substantially in excess of that allowed under the firm's HACCP plan.

b. The inspector fails to recognize that a firm's finished product labeling does not contain a sulfite declaration even though the raw material does contain a sulfite declaration.

c. The inspector fails to recognize that the presence of product residues and mold growth on processing equipment immediately prior to processing is evidence of the firm's failure to adequately monitor that area of sanitation.

d. The inspector does not recognize that food-contact surfaces are being sanitized with a product that is not approved for that use.

III. Oral and Written Communication

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

Examples of a "needs improvement" rating:

a. The inspector fails to explain the reason and purpose of the visit to the facility and what products will be covered during 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 is non-specific in his/her requests for information, causing the firm to provide unnecessary paperwork that is irrelevant to the inspection.

b. The inspector's requests contain jargon that is unfamiliar to the firm causing confusion in their efforts to meet his/her requests.

c. During the inspector's interview of the plant manager concerning the firm's sanitation program, the plant manager's responses are evasive. The inspector does not ask follow-up questions to obtain the necessary information, leaving the questions only partially answered.

d. While obtaining information from the firm's management and process personnel, the inspector fails to follow up on discrepancies between statements made by the two parties.

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

Examples of a "needs improvement" rating:

a. The inspector does not conduct a discussion of the observations at the conclusion of the inspection.

b. The inspector does not discuss a significant deficiency observed in the bean storage/conveyor system before he/she proceeds to the soak tank room in a cannery although the general manager is present at the time.

c. The inspector's discussion of the deficiencies at the conclusion of the inspection is 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 alert the firm's appropriate management when an immediate corrective action was necessary?

Examples of a "needs improvement" rating

a. The inspector fails to advise appropriate management that products containing undeclared FD&C Yellow #5 are being packaged, and that shipment of the product could result in a health hazard.

b. The inspector fails to advise appropriate management of his/her findings after witnessing direct contamination of raw carrots with blood dripping from boxes of boneless beef.

c. After witnessing direct product contamination with a toxic chemical, the inspector immediately notifies an employee performing production area cleanup 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 reveals specific information about a pending compliance action against a competitor.

b. The inspector provides information to a firm about a competitor's exclusive process.

c. The inspector makes up an answer to a policy question, which may lead the firm to take an inappropriate corrective action.

d. The inspector dictates an inappropriate corrective action for a deficiency.

6. Did the inspector write his/her findings accurately, clearly, and concisely on the state form/document left with the firm?

Examples of a "needs improvement" rating:

a. The inspector fails to write on the list of findings that the firm has a significant process deviation.

b. The inspector fails to write on the list of findings that he/she observed fresh rodent pellets in bags of rice.

c. The list of findings shows that the "Firm did not control hazards" with no further explanation.

IV. INSPECTION OBSERVATIONS AND PERFORMANCE FOR PC LIMITED SCOPE AND MODIFIED SCOPE AUDITS

1. Did the inspector properly evaluate the Good Manufacturing Requirements (117 Subparts A, B, and F or equivalent state regulation)?

This question applies to all audits performed including food, seafood, and juice. It cannot be left blank.

Examples of a "needs improvement" rating:

a. The inspector does not observe employees to verify food safety and hygiene training were satisfactory after observing GMP deficiencies related to employee duties.

b. The inspector does not recognize practices that could contribute to allergen cross-contact issues.

c. The inspector does not identify human food by-products for use as animal food is held in insanitary conditions.

d. Inspector does not cover the requirements for employee training records.

2. Did the inspector conduct a broad-based assessment of the Preventive Controls program where necessary?

Applies to limited scope PC or if they are a qualified facility that attested under 21 CFR 117.201(a)(2)(i).

If this question does not apply, select Not Applicable.

Examples of "needs improvement" rating:

a. The inspector does not identify that ready-to-eat product was exposed to environmental pathogens prior to packaging.

b. The inspector does not determine if controls were in place for undeclared allergens due to incorrect label and/or allergen cross-contact.

c. The inspector does not evaluate the process controls necessary for the safety of a food product (i.e. refrigeration, formulation, pH, metal inclusion, etc.)

3. Did the inspector evaluate if the facility was in compliance with their attestation?

Only applies when a firm self-attests under 21 CFR 117.201(a)(2)(i) or (ii).

The inspector needs to verify what the firm attested under and what provision they attested under and determine if they are in compliance with their attestation. The inspector also needs to know the inspection approach depending on the provision.

If this question does not apply, select Not Applicable.

Examples of "needs improvement" rating:

a. The inspector does not confirm the facility is in compliance with non-Federal food safety laws by reviewing state compliance history or documents such as a license, inspection report, certificate or permit by an appropriate agency.

b. The inspector does not determine if the facility implemented Preventive Controls to address hazards and were monitoring the performance of controls.

4. Did the inspector properly evaluate the implementation of time/temperature controls?

Only answer if the facility is a warehouse solely engaged in the storage of unexposed packaged food that requires refrigeration for safety.

If this question does not apply, select Not Applicable.

Examples of “needs improvement” rating:

a. The inspector does not verify the firm took corrective actions when there was a loss of time/temperature controls that would impact food safety.

b. The inspector does not check for calibration of applicable temperature recording devices.

c. The inspector does not confirm whether the firm keeps either affirmative or exception records to document time/temperature controls.