Sections in This Document

1. Purpose

These work instructions provide direction and guidance on how to complete the Qualtiy Factor Checklist (QFC) for State Contract Establishment Inspection Reports (EIRs). Responses to each quality factor question listed in the procedure section of this document requires a Yes, No or an N/A response.

Each Quality Factor question listed on the QFC is in parenthsis in the bolded text following each procedure section sub-heading.

Examples of actions that would likely result in a “no” rating to the quality factor questions are provided. Any questions that are not applicable require a N/A rating on the QFC.

2. References

A. OHAFO State Contract Establishment Inspection Report Review Process Procedure

B. OHAFO State Contract Report Quality Factor Checklist

3. Procedure

3.1. Inspection information is entered

“Inspection information is entered in the eSAF system or other FDA-approved systems.”

A. Examples of a “no” rating:

1. The inspection results are not entered in the eSAF.
2. The inspection information in eSAF is incomplete.

3.2. Records are complete and accurate

“The record in eSAF or other FDA-approved systems, contains accurate and complete information. For example: legal firm name, operation status, PAC code(s), etc.”

A. Examples of a “no” rating:

1. The State inspector entered an incorrect inspection start date in eSAF.

2. The State inspector did not update the legal firm name in eSAF. The legal firm name in eSAF is different than what is reported in the narrative report and/or FDA 482, Notice of Inspection.
3. The State inspector did not update the operation status in eSAF. ESAF displays the firm is operational (OPR), however the narrative report explains the firm operates on a seasonal basis, from September to November only.
4. The State inspector completed a BSE Checklist in eSAF, however does not report inspection time in eSAF under PAC 71S011.
5. The State inspector did not update the firm point of contact in eSAF. The narrative inspection report mentions a new plant manager was employed since the last inspection, however the point of contact listed in eSAF contains the name and telephone number of the former plant manager.
6. The State inspector did not update the mailing address in eSAF. The mailing address in eSAF is different than what is reported in the narrative report.

3.3. The information is detailed

"The information contained in the narrative report holds the level of detail negotiated between the FDA division and state agency."

A. Examples of a "no" rating:

1. The narrative inspection report lacks responsibility information, as previously requested by the FDA division.
2. The narrative inspection report lacks observation relevance information, as previously requested by the FDA division.
3. The narrative inspection report is incomplete.

3.4. The report is factual, objective, and free of opinions.

"The report and record in eSAF (or other FDA-approved systems) is factual, objective, and free of opinions."

A. Examples of a "no" rating:

1. The State inspector wrote there were no regulatory observations in the eSAF Summary section, however the State inspector classified the inspection in eSAF as VAI. A copy of a three-item FDA 483, List of Observations was included in the report packet submitted to FDA.
2. The State inspector detailed his opinion in the narrative report that the products manufactured during the inspection were contaminated with listeria monocytogenes due to the manufacturing conditions observed.

3.5. Appropriate FDA forms are utilized

"Appropriate FDA forms (such as FDA 3501, FDA 2481, VFD Tool, etc.) are utilized for inspection reporting per the SOW or as directed by the FDA division."

A. Example of a "no" rating:

1. The State inspector conducted a licensed medicated feed mill inspection and the report packet for the inspection lacked the completed FDA 2481 form. The Animal Food SOW requires the use of the FDA 2481 form when performing licensed medicated feed mill inspections.

3.6. All forms are legible, correct and complete

"All FDA or equivalent state forms associated with the inspection are legible, correct, and complete. Forms are properly executed and signed."

A. Examples of a "no" rating:

1. The State inspector conducted a food inspection under FDA authority. The FDA 482, Notice of Inspection failed to include the title of the person who it was issued to.
2. The State inspector conducted a preventive control animal food (PCAF) contract inspection under FDA authority. The FDA 483, List of Observations is illegible and contains several spelling and grammatical errors.
3. An incorrect inspection end date is listed on the state deficiency letter.

3.7. The Form FDA 483 includes appropriate statement, if applicable

"If applicable and required by the SOW, the Form FDA 483 includes the following statements as a header above the 483 cites: "The observations noted in this form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements."

A. Example of a "no" rating:

1. The State inspector conducted a medical device inspection where a two-item FDA 483, List of Observations was issued. However, the FDA 483 did not include the required statement as described in the SOW as a header above the 483 citations.

3.8. Exhibits and attachments are correctly identified

"All exhibits (including labels and labeling) and/or attachments are identified per method mutually agreed upon with the FDA division."

A. Examples of a "no" rating:

1. The inspection report packet contains two exhibits. They are not identified per the method mutually agreed upon with the FDA division. The agreement was to include the following information: FEI Number, Legal Firm Name, Firm Physical Address, Dates of Inspection, and Exhibit Number.
2. The FDA 482, Notice of Inspection accompanying the contract inspection report contains an adhesive label with the following information: FEI Number, Legal Firm Name, Firm Physical Address, Dates of Inspection, and Exhibit Number. FDA forms are considered "attachments" which are not to be altered after issuance per the agreement between the State agency and the FDA division.

3.9. Inspection was pre-announced, if applicable.

"If applicable, the inspection was pre-announced to firm management following the instructions set forth in the applicable SOW or as directed by the FDA division."

A. Examples of a "no" rating:

1. The State inspector conducted a targeted egg safety contract inspection without pre-announcing the inspection to farm management. As such, the egg safety inspection report (either eSAF or written narrative) does not include pre-announcement details. The Egg SOW instructs the contractor to conduct the inspection in accordance with compliance program guidance manual 7303.836, which recommends pre-announcement. The action of pre-announcing the inspection was mutually agreed upon between the State and FDA division.
2. The state inspector fails to pre-announce the contract medical device inspection.
3. The State inspector pre-announces a preventive control human food (PCHF) contract inspection at a very large food company not operating within a private residence. The action of pre-announcing human food inspections when operations occur within a private residence was instructed by the FDA division only.

3.10. Guidance Documents and Handouts were provided, if applicable

"If applicable, appropriate guidance documents and/or required handouts (per the applicable SOW or as directed by the FDA division) are provided to the firm."

A. Example of a "no" rating:

1. The State inspector conducted a preventive control animal food (PCAF) contract inspection. As such, the summary section of the inspection report (either eSAF or written narrative) does not include a statement that the

inspector provided Guidance for Industry #235: *CGMP Requirements for Food for Animals* to firm management, as directed in the Animal Food SOW.

3.11. FDA regulated activities perform by inspected facility are fully documented

"FDA regulated activities performed by the inspected facility are fully documented in the narrative report to allow for a correct determination of the firm's workload obligation status by FDA."

A. Examples of a "no" rating:

1. The State inspector claims inspection time in eSAF for covering the manufacturing process of medicated feed (M-69). The report does not include information regarding the firm's FDA license status nor does it provide enough details for the reader to ascertain whether the firm needs a medicated feed mill license. It also lacks whether the firm handles prohibited materials (BSE).
2. The State inspector conducts a contract food inspection at a candy shop. The narrative report does not contain details of the establishment's primary business status (retail or wholesale) and annual gross wholesale sales.

3.12. The narrative report established jurisdiction and interstate commerce

"The narrative report establishes clear FDA jurisdiction and interstate commerce."

A. Examples of a "no" rating:

1. The narrative report does not contain interstate commerce information for the FDA regulated product found stored in insanitary conditions. There is no documentation showing the product or its ingredients were received or shipped in interstate commerce by the warehouse.
2. The narrative report states the medicated feed with high levels of vitamin D was shipped in interstate commerce to a feed retailer. The only supporting documentation referenced in the report is an invoice showing the purchase.

3.13. The report details adherence to proper biosecurity procedures, if applicable

"If applicable, the report (for an inspection at egg laying farm, for example) details adherence to proper biosecurity procedures."

A. Examples of a "no" rating:

1. The narrative report for a licensed medicated feed mill inspection residing on the premises of an egg laying farm lacks details of the FDA biosecurity procedures adhered to by the State inspector.

2. The targeted egg safety contract inspection report includes biosecurity procedures adhered to by the State inspector, however it does not mention measures instituted for the State vehicle driven on the farm premises.

3.14. Full names and titles of firm management are detailed in the narrative report

"Full names and titles of owners, partners, and/or corporate officers and their responsibilities and authorities are detailed in the narrative report. If required, supporting documentation is included."

A. Examples of a "no" rating:

1. The narrative inspection report lacks the full name (first, middle initial and last) of the person who has the duty and power to prevent the violation observed during the contract inspection.
2. The narrative inspection report identifies the full name of the owner of the inspected facility, however does not outline what the official's responsibilities are.

3.15. The report contains contact information of top management

"The report contains the name, title, and address (i.e. mailing, e-mail) of top management official to whom FDA correspondence should be addressed."

A. Examples of a "no" rating:

1. The narrative inspection report does not contain the full name (first, middle initial and last) of the top management official located at the inspected facility.
2. The narrative inspection report does not contain the title of the top management official located at the inspected facility.
3. The narrative inspection report does not contain the mailing address of the top management official located at the inspected facility.
4. The narrative inspection report does not contain the e-mail address of the top management official located at the inspected facility.

3.16. Registration information is detailed

"Applicable registration(s) are detailed in the report, including current status."

A. Examples of a "no" rating:

1. The preventive control animal food (PCAF) contract inspection report does not identify if the inspected facility is registered with FDA as a food facility.
2. The targeted egg safety contract inspection report does not identify if the egg producer is registered with FDA as a shell egg producer.

3.17. Detailed description of manufacturing process and routes of contamination

"When microbiologically oriented inspections are conducted (e.g. environmental sampling inspections), a more detailed description of the manufacturing process and possible routes of contamination are detailed in the narrative report."

A. Example of a "no" rating:

1. The State inspector collected environmental samples for listeria monocytogenes analysis during a human food contract inspection. The State laboratory reported confirmatory positive results for three environmental samples collected from food contact utensils. The narrative report does not contain complete manufacturing process details that include the facility's usage of food contact utensils.

3.18. Follow up actions on previous objectionable conditions conducted

"If applicable, follow-up on previous objectionable conditions noted on FDA 483 (or equivalent state form) or state actions are explained in the report. Explanation includes what measures the firm took to correct the condition(s)."

A. Examples of a "no" rating:

1. The previous inspection of the facility identified inaccurate drug levels on labeling of several feeds. The report for the current contract inspection does not indicate these same labeling deficiencies and it fails to include corrective action measures taken by the firm.
2. The previous inspection of the facility was conducted by the State but not under FDA contract. During that State inspection FDA regulated products were embargoed. The report for the current contract inspection does not explain the reason for the embargo.

3.19. Evidence supports objectionable conditions

"The report and FDA 483 (or equivalent form) detail the conditions found with sufficient narrative and evidence to enable an FDA assessment of the significance of any objectionable conditions or practices."

A. Examples of a "no" rating:

1. The inspectional observation states, "Firm did not control hazards," but no further explanation is provided.
2. The State inspector notes that the drug inventory is not accurate. The report does not include evidence (such as documents) to support the finding.

3.20. The report contains firms response and corrections promised

"The inspection report contains an appropriate level of detail to ascertain management's response and/or corrections taken or promised."

A. Example of a “no” rating:

1. The narrative inspection report does not contain management’s response or corrective actions taken or promised.

3.21. Regulatory refusals are identified, if applicable

“Regulatory refusals are clearly stated in the report (name of person who made refusal and if available, the reason why the refusal was given).”

A. Examples of a “no” rating:

1. The report does not mention the name of the person who made the refusal.
2. The report does not explain the reason why the refusal was given.

3.22. Consumer Complaints and Recalls are reported, if applicable

“The report contains a summary of follow-up to open FDA consumer complaints and/or corrective actions taken due to an FDA recall, if required per the applicable SOW or directed by the FDA division.”

A. Examples of a “no” rating:

1. The narrative report mentions the State inspector reviewed five FDA consumer complaints with the firm, however it does not provide a summary of actions the firm took to investigate the complaint.
2. The State inspector conducted an FDA contract inspection to follow-up to a recent FDA recall. The narrative report does not explain corrective actions taken by the firm to prevent future re-occurrence

3.23. Samples collected support regulatory action, if applicable

“If applicable, samples collected during contract inspection (including state regulatory samples) provide an appropriate level of detail to support FDA regulatory actions.”

A. Example of a “no” rating:

1. The State inspector collected environmental samples during an FDA contract inspection, however the narrative report does not identify FDA regulated products manufactured and stored at the time sampling occurred.

3.24. eLEXNET entry for samples collected, if applicable

“For samples collected under the contract, information is entered in eLEXNET, and/or any other approved system for reporting results.”

A. Example of a “no” rating:

1. The report does not identify the State laboratory entered analysis information into eLEXNET for physical samples collected during a contract inspection.

3.25. Other

A. Use for other reporting elements not provided above, as needed.

---

4. Records

A. State Program Quality Assurance Internal Audit Checklist

---

5. Document History

Revision #	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
00	I	07/01/2019	Kathleen Close HAFW2 State Liaison	Joann Givens, OHAFO-W Program Director Vinetta Howard-King, OHAFO-E Program Director

* - D: Draft, I: Initial, R: Revision, C: Cancel

6. Change History

Revision	Change
00	Initial Release

7. Attachments

List of Attachments

None