Sections in This Document

1. Purpose

This procedure establishes the process by which Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA) reviews state contract inspection reports. In addition, this procedure establishes the responsibilities and methodologies for developing and using the OHAFO State Contract Report Quality Factor Checklist (QFC). The QFC serves as a tool for determining the "Fit-for-Use" status of state contract work products in support of mutual reliance initiatives.

2. Scope

Divisions apply this procedure to, at a minimum, quality control contract work accompanying FMD-76 for audit inspections performed by state agencies on behalf of FDA. This procedure applies to human food, animal food, medical

device, and egg contracts, and excludes contracts conducted under the Mammography Quality Standards Act.

The stakeholders for this procedure include, but is not limited to, representatives from the Office of Human and Animal Food Operations (OHAFO), the Advisory Council for State Liaisons, Office of Partnerships (OP) and Contract Officer Representatives (COR).

State agencies that have elected to participate in Phases II and III of the audit program under the Human Food Contract are required by the statement of work (SOW) to complete the Quality Factor Checklist (FORM-000585) for audits they perform. After completion of the audit, the state will submit both FORM-000585 and FORM FDA-3610 to the FDA Program Division.

For state agencies that are in Phase I of the audit program and for Phase II audits conducted by FDA under the Human Food Contract, the State Liaisons complete the Quality Factor Checklist (FORM-000585).

Joint inspections are subject to this procedure only if a state EIR is generated and is counted towards the audit program requirement.

The use and trending of QFCs is to identify systematic problems and not for identifying individual personnel issues.

3. Responsibility

A. Division/Program management or designee: (Program Division Directors (PDD), Director, Investigation Branch (DIB); Director, Compliance Branch (DCB))

1. Ensures proper management of state contract inspections.
2. Provides the resources required to effectively manage the state contract inspection process.

B. State Liaison or designee

1. Reviews each state audit phase from Appendix H document for current contract year.
2. Ensures state provided information is properly entered into FDA-approved systems.
3. Reviews work products submitted to FDA and provides feedback to state management.
4. Is familiar with the QFC.
5. Uses the QFC as needed, or as directed.

6. Notifies Quality System Manger (QSM) when significant quality issues are observed with state contract work (for example, trending or repeated issues, public health concerns).

C. Quality System Manager (QSM): (Program Division QSM (PDQSM), Program QSM (PQSM))

1. Works with State Liaison when significant quality issues are observed with state contract work (for example, trending or repeated issues, public health concerns).
2. Ensures quality related issues are communicated to ORA management, public health risks are evaluated, and corrective and/or preventive actions are implemented.
3. Monitors, tracks, and trends state contract quality deficiencies at the local and national level.
4. Collaborates with State Liaisons to revise the QFC as needed.

4. Background

State contracts expand FDA's capacity by using trained state inspectors to perform inspectional activities as part of general industry coverage and for emergency response. FDA relies on the contract work conducted by the states to impact public health and may use the results of this work for regulatory or other appropriate action, where applicable.

The QFC is based on criteria set forth in the FDA contract statement of work (SOW) and the most current version of the Investigations Operations Manual (IOM). The QFC is designed to build uniform standards for product quality and improve the quality and oversight of inspections conducted by the states participating in the state contract inspection program.

5. References

A. Appendix H: State Implementation Agreement and Yearend Evaluation (FORM-000163)

B. Contractor Performance Assessment Reporting System (CPARS).

C. Control of Non-Conforming Processes, Services or Products (SOP-000133)

D. Electronic State Access to FACTS (eSAF)

E. FDA Human Food Contract SOW, per State

F. FDA Animal Food Contract SOW, per State

G. FDA Shell Egg Contract SOW, per State

H. FDA Medical Device SOW, per State

I. FMD-50 FDA-State Communication Field Management Directive (FMD)

J. FMD-76 State Contracts – Evaluation of Inspectional Performance (DIR-0000033)

K. FMD-86 Establishment Inspection Report Conclusions and Decisions

L. How to Launch a QFC in the Process Module Video (JA-000302)

M. Investigations Operations Manual (IOM)

N. OHAFO Audit Staff Dashboard

O. OHAFO State Contract Report Quality Factor Checklist (FORM-000585)

P. OHAFO State Programs Completing the State Contract Report Quality Factor Checklist Work Instructions (WI-000193)

Q. OHAFO Transferring Work Products to Compliance Branch Procedure

R. Quality Management Information System (QMiS)

S. Quality Factor Checklists Procedure (SOP-000235)

T. Quality Event Management (QEM) and Corrective Action/Preventive Action (CAPA) (SOP-000235)

U. Management of ORA State Contract Inspection Process Procedure (SOP-000235)

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6. Procedure

6.1. Contract Inspection Review Process

6.1.1. State Liaison Procedures

A. The State Liaison reviews the inspection report including sample reports and accompanying documentation, and corresponding eSAF information, if applicable, according to Management of ORA State Contract Inspection Process Procedure.

B. The State Liaison verifies inspection conclusions and proposes classification.

1. Actions for State Contract inspections with classifications of State Action Indicated (SAI) or Official Action Indicated (OAI):

a. The State Liaison determines further course of action following FMD-86 guidance and OHAFO Transferring Work Products to Compliance Branch (CB) Procedure.

2. Actions for state contracts with classification of Voluntary Action Indicated (VAI) or No Action Indicated (NAI):
    a. Follow Management of ORA State Contract Inspection Process Procedure.

C. Timeframes for review of work products.
    b. Non-violative inspections: NAI or VAI
        i. The review is performed at a frequency not to exceed 30 business days from receipt of the contract inspection report.
    c. Violative inspections: OAI or RTS
        i. The review is performed within 10 business days of receipt of contract inspection report.

V. Endorsing contract inspection (determination of fit-for-use)
1. When work product is fit-for-use, the State Liaison accepts the inspection in eSAF and follows Management of ORA State Contract Inspection Process Procedure.
2. When work product is not fit-for-use and/or incomplete, the State Liaison returns the report in eSAF to State management and requests revisions.
    a. When revised work product is fit-for-use, follow Management of ORA State Contract Inspection Process Procedure.

6.2. Quality Factor Checklist (QFC)

A. The OHAFO State Contract Report Quality Factor Checklist is a process form in the Quality Management Information Systems database (QMiS).
1. A tutorial on how to launch a QFC in QMiS can be found in How to Launch a QFC in the Process Module Video.

B. The State Liaison uses the OHAFO State Contract Report Quality Factor Checklist as a quality tool when reviewing state contract inspection reports accompanying FMD-76 audit inspections.
1. This includes contract inspections conducted by state employees during FMD-76 audits where the auditor is either a qualified FDA or state auditor.

6.2.1. Quality Control, State Review, and Training

A. Quality Control (QC)
1. The State Liaison completes the OHAFO State Contract Report Quality Factor Checklist as defined in the Section 2: Scope.
    a. This is conducted during the review of all contract inspection reports created for FMD 76 audit inspections for quality control purposes.
    b. When a deficiency is observed in the work product:

1) The deficiency is documented on the OHAFO State Contract Report Quality Factor Checklist by checking "No" and a note is entered in the comment box.
   a) See the OHAFO State Programs Completing the State Contract Report Quality Factor Checklist Work Instructions for examples of actions that require a "No" response.
2) Return the work product back to the state and request revisions from state management.
   a) State actions taken to correct the issue are documented on the OHAFO State Contract Report Quality Factor Checklist.
3) To allow for trending of data, **do not change** a "No" answer on the OHAFO State Contract Report Quality Factor Checklist to "Yes" when a correction is made to the work product.

B. State Review

1. States may use the OHAFO State Contract Report Quality Factor Checklist as a tool for determining if the work product is "fit-for-use" (meaning it contains acceptable reporting criteria) prior to submission to FDA.

C. Training

1. QFCs may be used as part of a training program (e.g. for new state employees performing contract work, for new state reviewers and State Liaisons reviewing contract work or for retraining).

6.2.2. Program Level Evaluation Procedures

A. The State Liaison communicates observed inspectional performance deficiencies to state management.

1. Inspectional performance deficiencies include systemic QFC deficiencies as described in 6.2.3 below.

B. The State Liaison evaluates cumulative inspectional performance deficiencies on an annual basis for each State contract.

1. This evaluation may be reported to Office of Management (OM) Contract Officer Representatives (COR) as part of the contractor performance evaluation required under the contract via the Contractor Performance Assessment Reporting System (CPARS).
2. OM COR provides fiscal oversight of ORA's state contract inspection program.

C. The State Liaison records corrective actions taken by the state in QMiS for national quality trending.

1. If the state has identified issues on the QFC and has handled the issues, no action is needed to record the QFC findings.

2. If the State Liaison reviews the state EIR and the QFC has not identified the deficiencies, then State Liaison addresses the deficiencies with the state and logs the issue in a complaint in QMiS for trending.

6.2.3. Sampling and Data analysis

A. The QSM collects the OHAFO State Contract Report Quality Factor Checklists and tracks and trends the responses from all QFCs to ensure that there are no systemic issues in the process.

B. When a systemic issue is found, the QSM:

1. Reviews the trend with the division management,
2. Opens a non-conformance according to the Control of Non-Conforming Processes, Services or Products procedure, and
3. If applicable, a corrective action according to Quality Event Management (QEM) and Corrective Action/Preventive Action (CAPA) procedure.

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7. Glossary/Definitions

A. Acronyms

4. COR: Contract Officer Representatives
5. CPARS: Contractor Performance Assessment Reporting System
6. DCB: Director, Compliance Branch
7. DD: District Director
8. DIB: Director, Investigations Branch
9. eSAF: Electronic State Access to FACTS
10. FDA: Food and Drug Administration
11. FMD: Field Management Directive
12. IOM: Investigations Operations Manual
13. NAI: No Action Indicated
14. OHAFO: Office of Human and Animal Food Operations
15. OM: Office of Management
16. OP: Office of Partnerships
17. ORA: Office of Regulatory Affairs
18. PDD: Program Division Director
19. QC: Quality Control

20. QFC: Quality Factor Checklist
21. QMS: Quality Management System
22. QMiS: Quality Management Information System
23. QSM: Quality System Manager
24. SAI: State Action Indicated
25. SOP: Standard Operating Procedure
26. SOW: Statement of Work
27. VAI: Voluntary Action Indicated

B. Definitions

1. Endorsement: evaluation of the inspection finding to determine the classification and recommend an action.
2. Fit-for-Use: quality term used to indicate that a product or service fits the customer's defined purpose for that product or service.
3. Sampling interval: time period during which completed QFC forms are chosen to be checked for trends or nonconformities.
4. Stakeholders: group includes, but is not limited to, representatives from the Office of Human and Animal Food Operations (OHAFO), the Advisory Council for State Liaisons, and Contract Officer Representatives
5. Work Product: all data supplied by a state conducting FDA contract inspections, including but not limited to: inspection report, sample report, and analytical packets and data entered into eSAF (or other FDA-approved systems)

8. Records

A. QFC and quality records are kept electronically in QMiS.

B. State EIR records are filed per division/district process.

9. Supporting Documents

A. OHAFO State Contract Report Quality Factor Checklist in QMiS.

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
00	I	07/02/2019	Kathleen Close HAFW2 State Liaison	Joann Givens, OHAFO-W Program Director, Vinetta Howard-King, OHAFO-E Program Director
01	R	09/09/2020	Kumudini Carter, OHAFO-W Program Quality System Manager	Scott MacIntire, Acting OHAFO-W Program Director, Vinetta Howard-King, OHAFO-E Program Director
02	R	See Header Above	Kumudini Carter, OHAFO-W Program Quality System Manager	Scott MacIntire, Acting OHAFO-W Program Director, Vinetta Howard-King, OHAFO-E Program Director

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

11. Change History

Revision #	Change
00	New Procedure
01	• Section 2: Scope: Added scope definition on States compliant with MFRPS and AFRPS implementation. • Section 3: Responsibilities o Added OHAFO Audit Staff responsibilities. o Added State Liaison responsibilities on MFPRS and AFRPS implementation status. • Section 6.2.2.C: Added bullets 1 and 2 on recording of QFC findings.
02	• Redefined scope and removed MFRPS and AFRPS implementation. • Section 5 References: Added sop numbers to each reference and replaced QFC training video with new reference. • Section 3: Responsibilities • Removed OHAFO Audit responsibilities • Removed State Liaison responsibilities on MFPRS and AFRPS implementation status. • Added State Liaison responsibilities to review State audit phase • Section 6.2.A.1: Sentence reworded and added new reference. • Section 6.2.B.1: Sentence reworded. • Section 6.2.1.A.1: Added Section 2 reference. • Section 6.2.3.B.1: Added “division”.

12. Attachments

List of Attachments

Attachment A - Process Map