

<b>FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS</b>	<b>Document Number: FMD-76 (DIR-000033)</b>	<b>Revision #: 04  Revised: 06/19/2020</b>
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## 1. Purpose

The purpose of this Field Management Directive (FMD) is to delineate the required: (1) procedures for conducting audits of state contract inspections, (2) frequency of audits, (3) auditor training, and (4) records documenting audits. Specific audit procedures and forms, data reporting instructions, and audit summary report forms are included as appendices.

This FMD-76 document governs the Food and Drug Administration (FDA) Office of Regulatory Affairs' (ORA's) oversight of the state contract audit program.

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## 2. Scope

FMD-76 applies to contract inspections in these programs:

- Human Food
- Animal Food
- Egg, Medical Device, and Other State Inspection Programs

When a contract or contract program is suspended or terminated, the audit requirements within this FMD are similarly suspended or terminated.

This FMD does not address training requirements and procedures for oversight of states performing inspections of mammography facilities certified by the FDA under the *Mammography Quality Standards Act of 1992 (MQSA)*.

This FMD does not delineate the procedures for reviewing the quality of state contract inspection documents. ORA program divisions are encouraged to conduct a quality assurance review of state documents as part of their quality

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assurance program. Refer to SOP-000115 *Management of ORA State Contract Inspection Process*. Deficiencies in state inspection reports completed under contract are also beyond this FMD's scope.

### 3. Responsibility

#### **A. Associate Commissioner of Regulatory Affairs (ACRA), Assistant Commissioner for Human and Animal Food Operations, Assistant Commissioner for Medical Products and Tobacco Operations**

1. Ensures Program Directors (PDs) comply with FMD-76 requirements
2. Initiates actions to correct national deficiencies

#### **B. Program Director (PD)**

1. Ensures that the PD's respective program division complies with FMD-76 requirements
2. Reviews contract modification requests

#### **C. Program Division Director (PDD)**

1. Ensures the required numbers of audits are completed
2. Ensures documented program and performance deficiencies are corrected
3. Ensures adequate staff are assigned to accomplish Audit Program responsibilities

#### **D. FDA Auditor**

1. Conducts audits of state inspectors performing contract inspections
2. Trains and verifies state auditors' performance
3. Submits audit reports to the state liaison

#### **E. State Liaison**

1. Manages the Contract Inspection Audit Program for assigned state(s)
2. Informs program division management of contract audit performance
3. Works with management and the state agency to:
  - a. Assign audits to the FDA employees
  - b. Ensure the required numbers of audits are completed and that identified inspectors are audited

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- c. Document and ensure correction of individual and program performance deficiencies
- d. Ensure required documentation, including audit reports, is completed, maintained, and distributed, as needed

**F. Director, Office of Partnerships (OP)**

- 1. Has primary oversight of the administration of the contract inspection and associated audit program
- 2. Resolves disputes in audit classification findings
- 3. Approves audit-rate reduction requests

**G. Director, OP Division of Partnership Investments and Agreements (DPIA)**

- 1. Reviews changes to the contract proposed by the program division

**H. Project Manager (PM), OP DPIA**

- 1. Leads oversight of the contractor’s technical performance, in conjunction with the Contracting Officer Representative (COR) and the state liaison
- 2. Reviews proposals for corrective actions

**I. Contracting Officer’s Representative (COR), Office of Management (OM)**

- 1. Works with the Project Manager and others to support the contract and provide financial oversight of a specific contract
- 2. Recommends contract modifications

**J. Audit Program Manager, OP DPIA**

- 1. Conducts the national system audit
- 2. Coordinates the audit program

**K. State Auditor (Phases II and III only)**

- 1. Conducts audits of state inspectors performing contract inspections.
- 2. Trains and verifies the performance of state auditors.
- 3. Submits audit report or memorandum to the state liaison for review through the state agency.

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#### 4. Background

The original FMD established procedures for joint ORA–state inspections and independent audit inspections for the human food, medicated feed (currently animal food), and interstate travel programs. In 1977, ORA expanded the audits, maintaining the requirement for joint inspections and adding references to the diagnostic X-ray program. In 1982, ORA revised the FMD, combining the general procedures for all current programs into one document. In 1999, ORA added instructions for auditing food sanitation and medicated feed contract inspections and the procedures for auditing states performing inspections of mammography facilities certified by the FDA under the *Mammography Quality Standards Act* of 1992 (MQSA).

In June 2000, the Department of Health and Human Services, Office of Inspector General (OIG), published the results of its evaluation of the FDA’s oversight of food firm inspections conducted by states contracted to do so. The report recommended that the FDA take steps to address shortcomings in its system of oversight. In 2006, ORA revised this FMD to incorporate the OIG’s recommendations and to improve the oversight of human food, animal food, and other inspections done under contract by the states. ORA removed the procedures for auditing states performing MQSA inspections, since they are contained in the state contracts and FMD-144.

ORA updated this FMD in 2012, strengthening the processes for ensuring the audit rates are met and identifying and correcting systemic problems identified during the audits. The revision expanded the oversight of egg contract inspections and added procedures and computer-automated forms to improve reporting and tracking of completed audits.

ORA had based evaluations on audit rate (as a percentage of the total number of contract inspections), but its May 2015 revision of this FMD changed to an inspector-focused evaluation. This change makes this audit program consistent with the requirements for Manufactured Food Regulatory Program Standards (MFRPS) and the Animal Feed Regulatory Program Standards (AFRPS) and ensures that each inspector performing contract work is periodically evaluated.

ORA updated this FMD in March 2019 to reflect the organizational structural changes stemming from the May 2017 implementation of Program Alignment, which transformed ORA programs and offices from being geographic-district focused to being regulated-commodity focused (i.e., specialized for specific FDA-regulated commodities). Terminology was updated to reflect changes in regulations and included an elective for the Animal Food programs to participate in the audit phases, previously reserved for Human Food programs.

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The current changes are intended, where possible, to align the state contract audit program with the other audit programs. In addition, to improve oversight, ORA added audit questions — regarding Limited Scope and Modified Preventive Controls — to the human and animal food program audit forms. ORA also added an audit option for the egg program.

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## 5. References

SOP-000115 Management of ORA State Contract Inspection Process  
Contract Statement of Work (SOW)  
ORA Records Management Program  
SOP-000321 OHAFO State Contract Inspection Report Review Process  
Procedure  
FORM-000585 OHAFO State Contract Report Quality Factor Checklist

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## 6. Procedure

### 6.1. Overview

The FDA audits contract inspectors to ensure that the quality of state-conducted inspections purchased through contracts is adequate and complies with the contract requirements. The Contract Inspection Audit Program (hereafter known as the Audit Program) is a standardized system of formal audits conducted by qualified FDA and state auditors at a minimum frequency or audit rate.

The Audit Program is implemented in three phases:

1. **Phase I:** The program division is responsible for conducting the minimum number of contract audits.
2. **Phase II:** The program division and state agency share responsibility for conducting the minimum number of contract audits to meet the audit rate.
3. **Phase III:** The state agency assumes full responsibility for conducting the minimum number of contract audits to meet the audit rate.

NOTE: Phases II and III apply only to the human food and animal food contracts. Section 6.3 provides instructions for implementing Phases II and III of the Audit Program.

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## **6.2. Auditor Qualifications**

To conduct contract audits, the FDA or state auditor must have completed the auditor training below, the training courses specified in the contract, and all training course prerequisites, as required by Office of Training Education and Development (OTED). The auditors must have experience in conducting inspections in the program area and understand the relevant FDA compliance program and regulations. Additional program qualifications for state auditors are listed in Section 6.2.1.

### **6.2.1. Contract Auditor Training Requirements**

- A. All Human Food Contract Auditors
  - 1. FD320 - FDA State Food Contract Audit Course
  - 2. Program specific training
- B. All Animal Food Contract Auditors
  - 1. VM212 - FDA Bovine Spongiform Encephalopathy (BSE)/Feed Establishment Contract Audit Course
  - 2. Program specific training

### **6.2.2. Auditor Training and Verification**

- A. The program division and state agency develop a plan to accomplish the training and verification audits for those state inspectors who have completed the training requirements in Section 6.2.1 and the SOW. If requested by the program division, the state agency provides records to verify that state auditors have completed the training requirements.
- B. The state auditor must complete one training audit and one verification audit for each type of inspection the auditor will be responsible for auditing. For example, to conduct audits for current Good Manufacturing Practices (cGMP) and Seafood Hazard Analysis Critical Control Points (HACCP) the state auditor must complete at least one training and one verification audit for cGMP and one training and one verification audit for Seafood HACCP. A state auditor must pass a cGMP audit to qualify as a specialty area auditor. An audit may cover multiple areas in one inspection depending on the scope of the inspection.
- C. The FDA auditors train and verify the performance of state auditor trainees. States with one qualified auditor may conduct the training and verification audits for new state auditor trainees. States with two qualified state auditors may conduct verification audits of state auditors following the Phase III

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audit procedures (See Section 6.3.2). The contract audits completed during the training and verification audits are counted toward the audit obligation.

- D. One auditor should train only one state auditor trainee during a contract inspection. The state supervisor or additional state inspectors are not permitted to accompany the auditor during a training or verification audit.
- E. During the training audit, the state auditor trainee observes the FDA or state auditor conducting a contract inspection audit. The auditor, not the trainee, completes *Form FDA 3610* (Appendix B) or the *Animal Food Audit Form* (Appendix C).
- F. During the verification audit, the FDA or state auditor observes the state auditor trainee conducting a contract audit. The state auditor trainee completes *Form FDA 3610* or *Animal Food Audit Form*. The original audit forms are submitted to the state liaison no later than 30 business days after the audit. The auditor follows the guidelines in Appendix D to document the state auditor trainee's performance during the verification audit. The FDA sends a copy of the memorandum to the state agency when FDA conducts the audit, and vice versa.
- G. Only the state inspector, not the state auditor, reports his/her time in the electronic State Access to Field Accomplishment and Compliance Tracking System (eSAF). The number of hours is reported as an audit, not an inspection. At the time data is entered in eSAF, the state data entry user changes the Inspection Type field on the Add/Update Inspection Operation screen from "State" to "Audit."

### **6.3. Contract Audit Elective**

Full implementation of the Audit Program occurs when the state agency assumes responsibility for auditing its food (human and animal) contract inspections. This process begins in Phase II and is completed in Phase III. Phases II and III of the Audit Program are offered to the state agency as an elective under the Human Food & Animal Food Contract SOWs. If the state agency bids on this elective, an agreement (Appendix H *State Implementation Agreement and Yearend Evaluation*) must be completed and signed by the PDD and the director of the state inspection program. The state must submit this signed agreement with its contract quote/proposal prior to award of the contract.

At the end of the contract performance period, the program division updates the agreement to include a year-end evaluation and a summation of the number of audits completed. The updated agreement is emailed to the director of the state program and to the Contract Audits mailbox



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([ContractAudits@fda.hhs.gov](mailto:ContractAudits@fda.hhs.gov)) no later than 30 business days after the end of the contract performance period.

### 6.3.1. Phase III

Phase III occurs when the state agency assumes full responsibility for auditing its human food and animal food contract inspections. The state agency must have a quality assurance program (QAP) that requires correcting inspection or audit performance deficiencies. The QAP must describe the remedial training process and an internal audit of an auditor who fails to recognize: (1) deficient performance by an auditor or inspector or (2) an inspector’s performance that should be rated as “needs improvement,” as discussed in Section 6.8 of this FMD.

The state lists all state auditors who can conduct contract audits for the contract performance period when completing Appendix H, (Section V). The state agency must audit its own auditors every 36 months, considering the inspection priorities listed in the human food and animal food contract SOW and the inspections performed under contract. To meet this requirement, the state agency must have a minimum of two qualified state auditors. If during the contract year the state agency is unable to retain a qualified auditor for contracted specialized inspections or a minimum of two auditors, the state remains in Phase III for the remainder of the contract year. The state agency is moved to Phase II the following contract year and remains in Phase II until it has a minimum of two qualified auditors trained in all areas in which contract audits will be conducted.

### 6.3.2. FDA Verification Audits

For Phase II states, the FDA conducts two verification audits per auditor every 36 months. For Phase III states, the FDA conducts one of the two verification audits, and the state conducts the second. The FDA or state auditor evaluates a state auditor performing an audit of a state contract inspector. The FDA auditor prioritizes evaluation of new state auditors who have not previously been audited by the FDA. Verification audits should be conducted in a specialized area (e.g., Seafood HACCP, Juice HACCP), whenever possible.

States in Phases II and III may count new auditor verification audits toward the verification audit rate. Verification audits of specialized inspection types count toward the state auditor’s verification audit rate.

The performance and documentation of a verification audit follows the procedures in Section 6.5.2 of this FMD.

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### 6.3.3. Verification Audit Failure

If the verification auditor assigns an overall rating of “needs improvement” in a specialized area (e.g., Seafood HACCP, Juice HACCP), the auditor is considered to have failed and is removed from performing audits in that specialty area. The auditor may continue to perform audits in the cGMP area, if approved by the program division and state program. To determine an appropriate course of action, the state liaison must notify the Audit Program Manager at the Contract Audits mailbox ([ContractAudits@fda.hhs.gov](mailto:ContractAudits@fda.hhs.gov)) within 10 business days and copy the Program Division Director if the failure may impact the contract.

The “needs improvement” audit rating counts only toward the audit rate, not the performance rating.

In the event an inspector fails a verification audit, the inspector must undergo another audit.

## 6.4. Audit Requirements

### 6.4.1. Minimum Audit Requirements

The minimum audit requirements to be accomplished each contract year by the inspection program are shown in Table 1. All human food and animal food inspectors must be audited a minimum of twice in a 36-month period. The 36-month period is distinct to each inspector. All inspectors within a state program are not required to be on the same 36-month cycle.

A state must complete a separate Appendix H *State Implementation Agreement and Yearend Evaluation* form for each contract program in Phases II and III and for each contract type, human food or animal food. For states in the audit program, a state implementation agreement (Appendix H) must be submitted with the contract proposal or option year letter. At the end of the contract year, the state liaison completes Section IV (Planned and Completed Audits) and Section VII (Yearend Evaluation) for the contract performance period.

The state liaison must enter the following information in the Contract Audit Tracker for all human food and animal food contracts:

- Number of inspections to be performed
- Names of inspectors performing contract inspections
- Names of auditors performing contract audits (Phase II & III)
- Number of audits to be performed during the contract year

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**Table 1. Audit Rate for Contract Inspection Programs**

<b>Inspection Program</b>	<b>Minimum Audit Rate</b>
Human Food <sup>1</sup>	2 audits per inspector every 36 months
Animal Food <sup>2</sup>	2 audits per inspector every 36 months
Egg	One joint audit inspection or audit option audit per performance year
Medical Device, and Other State Inspection Programs	One joint audit inspection of each inspection program per performance year

By the end of the second quarter of the contract performance period, if less than 25 percent of the required audits of a state’s human food or animal food contract inspections have been completed, the Audit Program Manager emails a status reminder to the state liaison.

#### **6.4.2. Audit Selection**

The program division and the state agency managers develop an audit schedule when assigning the firms to be inspected under contract by the state agency. Firm selection should be based on the inspection priorities listed in the SOW and the contractual obligation of the contractor including the state’s implementation of the contract audit program.

The types of contract inspections conducted by an inspector must be considered when scheduling an audit. The most complex inspections should be audited. The state or program division must rotate inspection types to ensure the state inspector is audited in all applicable program areas (i.e., Seafood HACCP, Juice HACCP, Low-Acid Canned Foods (LACF), Preventive Controls (PC), medicated feed, BSE). If an inspector is trained in multiple specialized inspection areas, at least one of the audits in the 36-month period should be in a specialized area. Refer to Appendix D.

A training or verification audit is counted as one audit, because a single contract audit is being performed during a training or verification audit of a state auditor.

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<sup>1</sup> Includes low-acid canned foods and acidified foods, Preventive Controls, Seafood HACCP, and Juice HACCP inspections, where appropriate.

<sup>2</sup> Includes BSE only for inspections at licensed and non-licensed feed-mill inspections.

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Program divisions may schedule joint inspections as needed for training purposes. These approved joint inspections count toward the FMD-76 audit requirement when an audit form is completed.

If a state auditor also performs inspections under the contract, the state auditor must be audited as an inspector as well.

#### **6.4.3. Audit Reduction Request**

In limited circumstances, a state agency may request a reduction in the number of audits to be conducted in a contract year. Reductions are not given when a program division or state agency fails to conduct the required audits. When evaluating such a request, OP considers the number and type of contract inspections, the number of state inspectors conducting the contract inspections, and previous individual and program performance. The OP director has final discretion in granting a reduction. If the request is not approved, OP provides an explanation and the program division and state agency has an opportunity to provide additional information.

Audit reduction requests for human and animal food are requested using the Request for Audit Reduction Form (see Appendix I). Audit reduction requests for other contract types are made by memoranda.

The program division must submit the request for audit reduction via email to Contract Audits mailbox ([ContractAudits@fda.hhs.gov](mailto:ContractAudits@fda.hhs.gov)) during the first quarter of the contract performance period. Requests may be submitted later, if conditions change during the contract performance period. Submission of a separate form for each program is required to request an audit reduction in both human and animal food. A response will be provided by OP within 20 business days of receiving the request. The audit rate reduction is valid for the specified contract performance period and can be canceled if conditions change.

The state and program division understand that the audit reduction is valid for the contract performance period specified in this agreement. If any of the following conditions occur, the audit reduction is reevaluated:

1. The state changes the number of inspectors conducting contract inspections;
2. An inspector receives an overall rating of “needs improvement”; and/or
3. The contract is significantly modified (e.g., increases in the specialized inspections or number of inspections).

The program division and state are responsible for reporting any changes to the information provided on the request form (Appendix I). The state notifies

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the program division of any changes within 10 working days. The program division is responsible for reporting the changes to OP within 10 working days.

#### **6.4.4. Posting of Audit Completion Data**

The annual summary audit completion data for each state program is posted by OP on the FDA internet site. Information includes:

- Number of contract inspections completed
- Number of audits completed
- State program overall audit performance rating (see Section 6.8.2)

### **6.5. Audit Procedures**

This section describes the references, audit requirements, performance documentation and factors, and timeframes for submitting performance documents for all contract inspection programs.

#### **6.5.1. Human and Animal Food Contract Audits**

**A. Audit Requirements** - Every inspector must be audited a minimum of twice in 36 months.

#### **B. Timeframe for Submitting Performance Documentation**

1. When the FDA conducts the audit, the FDA auditor sends a copy of the audit form to the state liaison. The state liaison sends the audit information to the state agency no later than 30 business days after the audit is completed.
2. When the state agency conducts the audit, the state agency sends the original audit form to the state liaison no later than 30 business days after the audit is completed.
3. If a contract audit is rated as “needs improvement,” the state liaison or state agency must notify the other party no later than 10 business days after the audit is completed.

##### **6.5.1.1. Human Food Contract Audits**

#### **A. References**

1. Appendix A - *Instructions for Evaluating Contract Inspections*
2. Appendix B.1 - *Instructions for Completing the Contract Audit Form* (Form FDA 3610)
3. Appendix B.2 - *Instructions for Reporting Human Food Contract Audits*

**B. Performance Documentation** - Appendix B - *Contract Audit Form* (Form FDA 3610) is used to evaluate the state inspector’s performance.

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C. **Performance Factors** - See Appendix B.

#### 6.5.1.2. **Animal Food Contract Audits**

##### A. **References**

1. Appendix A - *Instructions for Evaluating Contract Inspections*
2. Appendix C.1 - *Instructions for Completing the Animal Food Safety Inspection Audit Form*
3. Appendix C.2 - *Instructions for Reporting Animal Food Contract Audits*

B. **Performance Documentation** - Appendix C - *Animal Food Safety Inspection Audit Form*

C. **Performance Factors** - See Appendix C.

#### 6.5.2. **Human and Animal Food Verification Audits**

A. **Audit Requirement** - Each state auditor must be audited a minimum of twice in 36 months. Verification Audits for programs in Phase II are conducted by the FDA. Verification Audits for programs in Phase III are shared between the FDA and the state program.

##### B. **Timeframe for Submitting Performance Documentation**

1. The program division sends a copy of the audit memorandum to the state liaison and state agency no later than 30 business days after the audit is completed.
2. When the state agency conducts the audit, the state agency sends the memorandum for the verification audit to the state liaison no later than 30 business days after the audit is completed.
3. If a verification audit is unacceptable, the program division or the state agency should notify the other party no later than 10 business days after the audit is completed.

C. **References** - Appendix D - *Instructions for Conducting Joint Audit Inspections, Verification Audits for State Auditors, and Joint Inspections*

D. **Performance Documentation** - The FDA or state auditor prepares a memorandum documenting the state auditor's performance.

E. **Performance Factors** - Follow instructions in Appendix D.

#### 6.5.3. **Egg, Medical Device, and Other State Inspection Programs**

A. **Audit Requirement** - One joint audit inspection or audit (audit option applies to egg program only) is required of each inspection program every contract year.

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**B. Audit Option for Egg Program** - The program division makes auditing decisions, in consultation with the FDA auditor and state program, based on the number of trained inspectors in the program. If the state program has two or more trained inspectors, the annual requirement is an audit, unless the division determines training is needed and elects to do a Joint Audit Inspection. The division identifies the state inspectors to be audited, based on past audit history and inspector performance. Each inspector is assigned specific roles during the audit, determined at a pre-audit meeting. The auditor evaluates each inspector on performance in those roles. A separate audit memo is created for each inspector to document the assigned areas and the inspector's performance in those assigned areas. The audit memo is also used to plan future audits to ensure inspectors are audited in all aspects of an egg inspection.

The program division determines how many inspectors can be evaluated during an audit. This decision should consider the firm's requirements for the number of personnel allowed in their facility. One inspection report is created by the designated lead inspector. Evaluation of the inspection report is not part of this audit.

(NOTE: This process remains in place until the draft Egg Safety Regulatory Program Standards are approved by Office of Management and Budget.)

**C. Timeframe for Submitting Performance Documentation** – The FDA sends a copy of the audit memorandum to the state agency no later than 30 business days after the audit is completed. If the audit/joint audit inspection is unacceptable, the program division should notify the state agency no later than 10 business days after the audit is completed.

**D. References**

1. Refer to Relevant Contract: Statement of Work (SOW)
2. Appendix A - *Instructions for Evaluating Contract Inspections*
3. Appendix D - *Instructions for Conducting Joint Audit Inspections, Verification Audits for State Auditors, and Joint Inspections*

**E. Performance Documentation** - The FDA auditor prepares a memorandum to document the state inspector's performance.

**F. Performance Factors for Joint Audit Inspections** - See Appendix D.

**6.6. Reporting Audit Findings**

The state liaison reports the audit findings for each quarter. All audit results must be reported, even when more than the required numbers are performed.

The state liaison enters the audit results in the Contract Audit Tracker (CAT) on at least a quarterly basis. The state liaison enters prior contract year audit

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data before the program division conducts work planning with the state. This enables them to plan audits for the current contract year. The CAT is used to:

1. Ensure state inspectors and auditors meet the minimum audit requirements
2. Ensure verification audits are completed timely
3. Calculate an overall rating for the contract performance period
4. Evaluate the audit ratings for a single performance factor
5. Ensure the minimum audit requirement is being met

#### **6.6.1. Human and Animal Food Contracts**

The state liaison records the type of audit as joint inspection, contract audit, or verification audit and the inspection type. Contract audits also contain a record of the inspection individual performance factor results.

#### **6.6.2. Egg, Medical Device, and Other State Inspection Programs**

The state liaison records egg, medical device, and other state inspection programs as joint audit inspections and records the overall rating of the audit.

#### **6.7. Audit Requirement Deficiencies**

When the minimum audit requirement is not met, the PDD must provide a written explanation as to why the audit requirement was not met no later than 30 business days after the end of the contract performance period. The memorandum is emailed to the Contract Audits mailbox ([ContractAudits@fda.hhs.gov](mailto:ContractAudits@fda.hhs.gov)) and includes the following information:

1. The number of inspections awarded in the contract and the number of inspections for each type of inspection
2. The number of audits completed for each type of inspection
3. The number of audits not completed
4. Detailed reasons for not completing the required number of audits
5. Detailed recommendations for solving issues that caused the required number of audits not to be met
6. Detailed proposal for meeting the required number of audits for the next contract performance period

The OP Director reviews the memorandum and discusses the need to adjust the state agency's implementation phase with the PDD and the director of the state commodity program.

In Phase I, the PDD prepares the memorandum.



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In Phase II, the PDD and state agency work together to prepare the memorandum. The PDD also documents how to increase oversight of the program and, if necessary, implement action to assume increased responsibility for completing the audits.

In Phase III, the director of the state agency prepares the memorandum and sends it to the PDD for concurrence; the PDD forwards it to the PD. The memorandum includes the following content:

1. Support of the memorandum submitted by the state agency
2. Summary of discussions held between PDD, state liaison, and state agency to prevent program deficiencies from reoccurring
3. The proposal for increasing oversight of the audit program to ensure the required number of audits are met in the next contract performance period

## **6.8. Performance Deficiencies**

### **6.8.1. Individual Inspector Performance Deficiencies**

- A. When there is an individual performance deficiency, the program division or state agency notifies the other party no later than 10 business days after the audit is completed. The program would be credited with completing a contract inspection and receive payment.
- B. An individual performance deficiency occurs when a:
  1. Contract audit is rated as “needs improvement”;
  2. Verification audit is rated as “needs improvement” (this applies to human food and animal food contracts only); or
  3. Joint audit inspection of an inspector conducting an egg, medical device, or other inspection done under contract is rated as “unacceptable.” (Refer to Appendix D).
- C. The program division or state agency follows these steps to address individual performance deficiencies identified during audits. The state inspector or state auditor cannot return to performing inspections or audits until all these steps are completed and passed.
  1. The program division and state agency discuss the deficiencies identified during the audit.
  2. The state inspector or state auditor discontinues conducting or auditing that type of inspection, respectively, until remedial training is completed. The state may be required to absorb the cost of the training.

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3. State inspectors receiving an overall rating of “needs improvement” must complete remedial training in deficient areas. The program division and state agency managers agree on the remedial training needed to allow the state inspector or state auditor to resume conducting or auditing contract inspections, respectively. The remedial training should directly address the deficiencies noted during the audit.
4. After remedial training is completed, the state agency conducts an internal audit of the state inspector or state auditor while conducting or auditing a non-contract inspection, respectively. The internal audit should evaluate the effectiveness of the remedial training.
5. The program division audits the state inspector or state auditor while conducting or auditing a contract inspection, respectively, once remedial training and the internal audit has been completed.

#### **6.8.2. Program Performance Deficiencies**

When there is a program performance deficiency, the PDD or state agency notifies the other party no later than 10 business days after the end of the contract performance period.

A program performance deficiency occurs when:

1. A single performance factor is rated as “needs improvement.” Needs Improvement for a single performance factor is defined as either:
  - a. A score of less than 80% conformance in a single performance factor,
  - or
  - b. Four or more “needs improvement” ratings in a single performance factor. If fewer than four audits are conducted, a performance deficiency may be considered for a single performance factor rated as “needs improvement” at the discretion of the program division and the state agency.

The program division determines which performance measure will be used at the beginning of the contract performance period.

2. The overall audit performance rating is below 80 percent.

#### **6.8.3. Documenting Performance Deficiencies**

The program division and state agency follow these steps to address individual or program performance deficiencies:

1. Develop a plan to correct the deficiencies. The plan must address:

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- a. The possible causes for the individual or program performance deficiency
  - b. The corrective actions that will improve performance.
2. Complete the *Corrective Action Plan for Program and Individual Performance Deficiencies* (Appendix J) form and submit to the Audit Program Manager upon completion of the corrective action.
  3. The program division records corrective actions taken by the state in the Quality Management System (QMS) for national trending.

**6.9. Process for Contract Modifications for Program and Performance Deficiencies**

- A. The OP Audit Program Manager or state liaison immediately notifies the Project Manager of any individual or program performance deficiency that may affect a contractual requirement. The Project Manager works with the Contracting Officer's Representative (COR) to make any necessary contract changes. The program division provides the Project Manager with additional notification of all follow-up actions and copies of any written correspondence to the state agency.
- B. If the program division proposes a change to the contract, the PDD emails a recommendation to change the contract to the PD and OP DPIA Director, no later than 10 business days after the end of the contract performance period.
- C. The recommendation must contain the following information:
  1. Documentation of the problem including attached copies of pertinent state inspection reports and the FDA audit reports
  2. A description of the steps taken by the state agency and the program division to correct the problem
  3. Copies of correspondence such as emails between the program division and state agency documenting efforts to address and correct the problem
  4. An assessment by the program division of the cause of the problem and suggested changes to the contract
- D. The OP DPIA Director, Project Manager, and COR review the program division's proposal to determine if the recommended action is appropriate and complies with contracting regulations and procedures. The OP DPIA Director discusses with the program division any potential action to be taken. OP requests the Office of Acquisitions and Grant Services (OAGS) send an official notification of any action to the contractor. Any actions

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pursued under this section are in accordance with the instructions provided in the SOW regarding alteration of the contract and payment for work conducted under the contract.

### **6.10. Dispute Resolution**

The program division and the state agency must make every effort to resolve disputes about audit findings and overall audit ratings. If, however, the program division and state agency are unable to resolve a dispute, both parties send a written summary of the situation and a proposed resolution to the Director, OP. All related documents, including the FDA audit reports and state inspection reports, shall be included. The OP Director reviews the reports and works with the program division and the state agency to arrive at a resolution. If the state agency fails to respond, the disposition of the contract may be affected.

### **6.11. Quality Assurance**

Quality assurance for the contract programs is a combined effort between the state program, program division, and OP. The inspection audits referenced in this FMD ensure the quality assurance of individual inspector performance in relation to meeting contract requirements.

#### **6.11.1. State Program Quality Assurance**

The program division conducts a performance audit of each state program within the first quarter of the fiscal year for the completed contract year. The internal audit evaluates program performance as described in Section 6.8.2 and the division's management of the state contract inspection program. The internal audit findings are provided to the PDD, state liaison, and OP and addressed per QMS procedures.

#### **6.11.2. Contract Program System Audit**

A comprehensive review and analysis is conducted by OP of the national performance data and evaluation of state program performance and identifies continuous improvement opportunities. The OP director provides a written report of the audit findings, accomplishments, national trends, describes systemic deficiencies, and recommends corrective actions or opportunities for improvement to the ACRA, and to the manager of OHAFO and other designated managers.

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## **7. Glossary/Definitions**

Terms relevant to audits and oversight of contract inspections are:

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Audit Performance Rating - This is the comprehensive assessment of all audits conducted in a contract program during a single contract performance period. The Audit Performance Rating is presented as a percentage based on the rating of all individual performance factors: Total rated as “Acceptable” divided by (the Total “Acceptable” plus the Total “Needs Improvement”) multiplied by 100.

$$\frac{\text{Total rated as "Acceptable"}}{(\text{Total rated "Acceptable"} + \text{Total rated "Needs Improvement"})} \times 100\%$$

The Audit Performance Rating must be greater than or equal to 80 percent.

Contract Audit - This is an evaluation of a contract inspection in which a qualified auditor accompanies a state inspector to document the inspector’s performance. The FDA investigators or state personnel are qualified to conduct a contract audit after all the requirements for the specific inspection program listed in Sections 6.2 have been successfully completed.

Contract Year - This is the contract performance period for a state contract, otherwise known as the period of performance. It is specific to the state contract. This may or may not coincide with the calendar year or federal fiscal year.

FDA Auditor – Program employee who has completed the required auditor and program training and with appropriate program experience.

Joint Audit Inspection - This is an audit conducted by an FDA investigator accompanying a state inspector and observing the latter’s performance. A joint audit inspection may be used to assess the quality of contract inspections for egg, medical device, and other industries that are not covered by an FDA audit course. Appendix D provides guidelines for conducting and reporting joint audit inspections.

Joint Inspection - This an inspection conducted jointly by the program division and state inspectors for training. Joint inspections may be counted toward the required number of audits when used to train state inspectors. Training may be necessary when a new contract is negotiated, new industries are added to an existing contract, or remedial training is needed. If authorized in the contract, the state agency may count the joint inspection as a contract inspection. Appendix D provides additional guidelines for conducting and reporting joint inspections.

Overall Audit Rating - This is the comprehensive assessment for an individual audit (see Appendices B and C). If three or fewer items are marked “needs improvement,” the overall rating is “acceptable.” If four or more items are marked “needs improvement,” the overall rating is “needs improvement.”

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Specialized Inspection - This refers to contract inspections that cover a specialized area. Specialized inspection areas include Seafood HACCP, Juice HACCP, LACF/AF, BSE, Licensed and Non-licensed Medicated Feed, and Preventive Controls. They are identified as electives in the contract. A state program can elect to perform these inspections under the contract, if it has inspection staff with the required training and experience to perform the inspections.

Training Audit - This is an audit in which a state auditor trainee accompanies an FDA or state auditor and the state inspector during a contract inspection. Its purpose is to teach the trainee how to conduct an audit by observing an audit of a state inspector. The state auditor trainee must also meet the auditor qualifications in Sections 6.2, 6.3, and relevant for the specific commodity.

## 8. Records

Contract Audit Forms

Contract Audit Tracker database

State Implementation Agreement and Yearend Evaluation Request for Audit Reduction Forms

Corrective Action Plan for Program and Performance Factors Program Audit Record

Contract Program System Audit

Annual State Contract Inspection Audit Summary

Supporting Documents

## 9. Supporting Documents

Users are responsible for ensuring they use the most up-to-date version of the referenced documents.

<b>Appendix</b>	<b>Internal Document #</b>	<b>Document Title</b>
Appendix A	JA-000024	<a href="#">Instructions for Evaluating Contract Inspections</a>
Appendix B	FORM-000161 FORM FDA 3610	<a href="#">Human Food Contract Audit Form</a>
Appendix B.1	JA-000025	<a href="#">Instructions for Completing the Contract Audit Form</a>

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<b>Appendix</b>	<b>Internal Document #</b>	<b>Document Title</b>
Appendix B.2	JA-000026	<a href="#">Instructions for Reporting Human Food Contract Audits</a>
Appendix C	FORM-000162	<a href="#">Animal Food Safety Inspection Audit Form</a>
Appendix C.1	JA-000027	<a href="#">Instructions for Completing the Animal Food Safety Inspection Audit Form</a>
Appendix C.2	JA-000028	<a href="#">Instructions for Reporting Animal Food Contract Audits</a>
Appendix D	JA-000029	<a href="#">Instructions for Conducting Joint Audit Inspections, Verification Audits for State Auditors, and Joint Inspections</a>
Appendix H	FORM-000163	<a href="#">State Implementation Agreement and Yearend Evaluation</a>
Appendix I	FORM-000164	<a href="#">Request for Audit Reduction Form and Instructions</a>
Appendix J	FORM-000165	<a href="#">Corrective Action Plan for Program and Performance Factors</a>

## 10. Document History

<b>Revision #</b>	<b>Status* (D, I, R)</b>	<b>Date</b>	<b>Author Name and Title</b>	<b>Approving Official Name and Title</b>
1.0	R	1/10/14	Beverly Kent, OP OIG Working Group	Barbara Cassens, Acting Director OP
2.0	R	4/30/15	Cathy Hosman, OP FMD 76 Working Group	Barbara Cassens, Acting Director OP
03	R	03/05/2019	Cathy Hosman, OP ACSL	Barbara Cassens, Director OP
04	R	See QMiS	SCIPI Working Group	Barbara Cassens, Director, OP

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

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## 11. Change History

Revision #	Change
1.0	Previous versions of this document exist and are archived, however version numbering was not included. This is the first version in the new format.
2.0	Removed responsibility for Program Divisions to develop individual procedures for implementing this FMD. Added recommendation in 5.3.2 for feed auditors to have the VM213 BSE Inspection Training. 5.4.1 - Revised audit rate to include minimum of two audits per inspector every 36 months. 5.4.2 - Added clarification that audits should be conducted on the most complex program. 5.8.3 – Added requirement for submission of corrective action plans to OP. 5.11 – Added requirement to initiate a corrective action in QMS for national performance deficiency trends.
03	Document migrated to updated SOP/FMD template. Section 5 procedures moved to Section 6 in new template. Changed “Feed” to “Animal Food”. Changed communication requirements from within 20 business days to 30 business days to be consistent with the SOWs. Updated FMD to correlate with changes realized by Program Alignment. District becomes Program Division. DD becomes PDD. RFDD becomes PD. Separated state liaison role from generic District reference. Scope – added statement to suspend/terminate audit requirements for programs that have been suspended/terminated. Responsibilities – Change State Contract Liaison/Monitor role to state liaison role as the Contract Technical Advisor, added description of COR role, added Program Manager role. 6.3 - Section moved from end of procedure. 6.3.3 – Content separated from 6.3.2 under new header 6.3.4 – Section added. 6.4.1 – Minimum audit rates- clarified frequency requirements. Required frequency unchanged. 6.4.2 Added description of requirements for complex inspection types. 6.4.4 - Clarified what data will be posted to the internet. 6.5 - Added Animal Food program ability to elect audit phases. Separated inspection audit and verification audit requirements. 6.6 – Added audit data to be tracked by Contract Audit Tracker (CAT). Removal of Appendices and Workbook E, F, & G. Replaced by CAT. 6.8.2- Clarified the performance factors to be examined by the program division audit 6.8.3– Added tracking of state corrective actions by ORA QMS. Internal document number changed from FMD.076 to DIR-000033. Internal document numbers applied to FMD appendices.
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Revision #	Change
04	<p>Scope - Removed tissue residue from list of program areas.</p> <p>Responsibilities - Removed District Director role since all state liaisons are now aligned with HAF program divisions. Added Project Manager role to reflect change in OP DPIA role in the contract separate from the COR role now held by OM. Changed title of Program Manager, DPIA to Audit Program Manager to differentiate from Project Manager role.</p> <p>Background – Added summary of changes from May 2015 revision of FMD to present.</p> <p>References – Added reference to SOP-000115 Management of ORA State Contract Inspection Process.</p> <p>6.2 – Removed list of specialized training courses.</p> <p>6.3 – Added clarification of who signs the Appendix H and align sequence to contract SOW.</p> <p>6.3.2 &amp; 6.3.3 – Clarified requirements.</p> <p>6.4 – Added Preventative Controls program areas</p> <p>6.5.2 – Clarified requirements.</p> <p>6.5.3 – Added egg audit option.</p> <p>6.8.1C – Added statement to clarify requirements “State inspector or state auditor cannot return to performing inspections or audits until all of these steps are completed and passed.”</p> <p>6.8.2 – Changed definition of “Needs improvement” for a single performance factor. Added “OR a score of less than 80% conformance in a single performance factor” and provided the program division to determine which is appropriate. Changed overall audit performance rating from 90% to 80% to align with the audit program in the regulatory program standards.</p> <p>6.9 – Revised to include COR role now with OM.</p> <p>Appendix B FDA-3610 form-added questions covering audits of Limited Scope and Modified Preventive Controls inspections.</p> <p>Appendix B1 Guidance for Completing the Contract Audit Form-added examples of “Needs Improvement” for new section.</p> <p>Appendix C Animal Food Safety Inspection Audit Form</p> <ol style="list-style-type: none"> <li>Renamed to “Animal Food Safety Inspection Audit Form”.</li> <li>Added new section covering AFRPS inspections.</li> <li>Revised wording of some questions to reflect changes in regulation.</li> </ol> <p>Appendix C.1 Guidance for Completing the Animal Food Safety Inspection Audit Form-updated questions to agree with audit form.</p> <p>Appendix D Guidance for Conducting Joint Audit Inspections, Verification Audits for State Auditors, and Joint Inspections.</p> <ol style="list-style-type: none"> <li>Removed tissue residue audits since they are no longer contracted work.</li> <li>Added description of findings that would warrant a “Needs Improvement” rating.</li> </ol> <p>Appendix H State Implementation Agreement and Yearend Evaluation</p> <ol style="list-style-type: none"> <li>Planned Resources-clarified the state personnel who could become qualified auditors.</li> <li>Section I. Contact Information-updated FDA and state contact information to agree with contract SOW.</li> <li>Section IV. &amp; V. Planned and Completed Audits-minor changes to form information requested.</li> </ol> <p>Appendix I Request for Audit Reduction-updated to reflect changes to audit requirement from percentage of total contract inspections to inspector audit of 2 audits in 36 months</p> <p>All - Edited for syntax, spelling, punctuation, grammar, adherence to the ORA STYLE GUIDE and to the principles of Plain Language (K. Lee Herring, OCPM, DC, SCB) 2/24/2020</p>

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## 12. Attachments

See Section 9 for links to document appendices.