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1. Purpose

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

FMD-76 is the overarching document for oversight of the state contract audit program.

2. Scope

FMD-76 addresses the oversight of contract inspections in the following program areas:

- Human Food
- Animal Food
- Egg, medical device, and other inspection programs

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

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

Those requirements are contained in the MQSA contractual agreements with the states and the FMD-144.

This FMD does not contain procedures for reviewing the quality of state contract inspection documents. Program Divisions are encouraged to conduct a quality assurance review of state documents as part of their quality assurance program. Refer to SOP-000115 Management of ORA State Contract Inspection Process. Performance deficiencies with state inspection reports completed under contract are outside the scope of this document.

3. Responsibility

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

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

B. Program Director (PD)

1. Ensures the Program Division comply with the requirements of FMD-76.
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 is assigned to meet the responsibilities of the Audit Program.

D. FDA Auditor

1. Conducts audits of state inspectors performing contract inspections.
2. Trains and verifies the performance of state auditors.

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3. Submits audit reports to the State Liaison.

E. State Liaison

In the contract Statement of Work the State Liaison’s role is referred to as **Division Technical Advisor**.

1. Manages Contract Inspection Audit Program for assigned state(s).
2. Informs PDD management of contract audit performance.
3. Works with management and state agency to:
 - a. Assign audits to FDA employees.
 - b. Ensure the required numbers of audits are completed and that identified inspectors are audited
 - c. Document and ensures correction of individual and program performance deficiencies
 - d. Ensure required documentation, including audit reports, are completed, maintained, and distributed, as needed.

F. Director, Office of Partnerships (OP)

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

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

1. Reviews changes to the contract proposed by the Program Division

H. Project Manager (PM), Office of Partnerships

1. Leads oversight of the contractor’s technical performance, in conjunction with the COR and the State Liaison
2. Reviews proposals for corrective actions.

I. Contracting Officer 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

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

K. State Auditor (Phase 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.

4. Background

The original FMD established procedures for joint inspections and independent audit inspections for the human food, medicated feed (currently animal food), and interstate travel programs. In 1977, a revision expanded the audits, maintained the requirement for joint inspections, and added references to the diagnostic x-ray program. In 1982, a revision combined the general procedures for all current programs into one document. Instructions for auditing food sanitation and medicated feed contract inspections, and the procedures for auditing states performing inspections of mammography facilities certified by FDA under the Mammography Quality Standards Act of 1992 (MQSA) were added in 1999.

In June 2000, the Department of Health and Human Services, Office of Inspector General (OIG) published the results of its evaluation of FDA’s oversight of food firm inspections conducted by states through contracts. The report recommended that FDA take steps to address shortcomings in its system of oversight. In 2006, this FMD was revised 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. The procedures for auditing states performing MQSA inspections were removed since they are contained in the state contracts and the FMD-144.

This FMD was updated in 2012 to strengthen 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.

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May 2015 revisions included a change to the audit rate from a percentage of the total number of contract inspections to an inspector focused evaluation. This change ensures that each inspector performing contract work is periodically evaluated and aligns this audit program with the audit requirements for MFRPS and AFRPS.

The document was updated in March 2019 to reflect changes in ORA structure due to Program Alignment. 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.

December 2019 changes are intended to align the state contract audit program with the other audit programs, where possible. In addition, Limited Scope and Modified Preventive Controls audit questions were added to the human and animal food program audit forms along with the inclusion of an audit option for the egg program, to improve oversight.

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

6. Procedure

6.1. Overview

FDA audits contract inspectors to ensure the quality of inspections purchased through contracts with states 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.

Implementation of the Audit Program is described here. There are three phases of auditing.

1. **Phase I:** The Program Division is responsible for conducting the minimum number of contract audits.

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

6.2. Auditor Qualifications

Contract audits are conducted by FDA and state auditors who have completed the required training courses (including appropriate pre-requisite courses) relevant to the inspection programs following Office of Training Education and Development (OTED) requirements and any additional training courses listed in the current contract. The auditors must have experience in conducting inspections in the program area and should 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 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 cGMP and seafood HACCP the state

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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 GMP 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. 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 audit procedures (See Section 6.3.2). The contract audits completed during the training and verification audits are counted towards 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. A copy of the memorandum is sent 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 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 their food (human and animal) contract inspections. This process begins in Phase II and is completed in Phase III.

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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) must be signed by the PDD and the Director of the state inspection program. The signed agreement (Appendix H) must be submitted with the state’s contract quote/proposal prior to award of the contract.

At the end of the contract performance period, the Appendix H agreement is updated by the Program Division to include a yearend 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 OP audit mailbox ContractAudits@fda.hhs.gov no later than 30 business days after the end of the contract period of performance.

6.3.1. Phase III

Phase III occurs when the state agency assumes full responsibility of auditing their human food and animal food contract inspections. The state agency must have a quality assurance program (QAP) that requires correcting performance deficiencies found during an inspection or an audit. The QAP should 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) inspector’s performance that should be rated as “needs improvement”, as discussed in Section 6.8 of this FMD.

All state auditors are listed in 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, it stays 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 they have a minimum of two qualified auditors trained in all areas in which contract audits will be conducted.

6.3.2. FDA Verification Audits

FDA conducts two verification audits per auditor every 36 months for those states in Phase II of the audit program. For Phase III states, FDA conducts one of the two verification audits. The state program conducts the other

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verification audit. The FDA auditor evaluates the state auditor’s performance while they are auditing a state contract inspector, giving priority to new state auditors who have not previously been audited by FDA. Verification audits should be conducted in a specialized area, whenever possible.

States in Phase II & III can count new auditor verification audits toward the verification audit rate. Verification audits of specialized inspection types count towards the state auditor’s verification audit rate.

Follow the procedures in Sections 6.5.2 of this FMD for conducting and documenting a verification audit.

6.3.3. Verification Audit Failure

If the verification audit in a specialized area is overall rated “needs improvement”, the auditor is removed from performing audits in that specialty area. The auditor may continue to perform audits in the cGMP area if determined by the Division and state program. The State Liaison must notify the Audit Program Manager at ContractAudits@fda.hhs.gov within 10 business days and copy the Program Division Director if the failure will impact the contract, to determine an appropriate course of action.

The needs improvement audit performed counts towards the audit rate only, but not towards the performance rating.

In the event of a verification audit failure the inspector **would** undergo another audit.

6.4. Audit Requirements

6.4.1. Minimum Audit Requirements

The minimum audit requirements to be accomplished each contract year by 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 separate Appendix H should be completed for each state contract program in Phases II and III and for each contract type, human food or animal food. For states in the audit program, Appendix H must be submitted with the contract proposal or option year letter. At the end of the contract year, State Liaison completes Section IV Planned and Completed Audits and Section VII Yearend Evaluation of Appendix H for the contract performance period.

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For states in Phase I, the State Liaison must obtain the following information from the state agency and submit to OP:

- Contract type (human food or animal food)
- Number of inspections to be performed
- Number of inspectors performing contract inspections
- Number of audits to be performed during the contract year
- Names of inspectors and inspection types (GMP, Seafood HACCP, BSE, etc.) to be audited during the contract year.

Table 1 Audit Rate for Contract Inspection Programs

Inspection program	Minimum audit rate
Human Food ¹	2 audits per inspector every 36 months
Animal Food ²	2 audits per inspector every 36 months
Egg	One joint audit inspection or audit per performance year
Medical Device, and other inspection programs	One joint audit inspection of each inspection program per performance year

OP emails a status reminder to the State Liaison at the end of the second quarter of the contract period of performance if less than 25 percent of the required audits of a state's human food or animal food contract inspections have been completed.

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

¹ Includes low-acid canned foods and acidified foods, Preventive Controls, seafood HACCP, and juice HACCP inspections, where appropriate.

² Includes BSE only inspections and inspections at licensed and non-licensed feed mill inspections.

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the “Statement of Work” section of the contract 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, LACF, Preventive Control, medicated feed, BSE, etc.). 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.

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, they 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. OP considers the number and type of contract inspections, the number of state inspectors conducting the contract inspections, and previous individual and program performance when evaluating an audit reduction request. 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 (Appendix I). Audit reduction requests for other contract types are made by memoranda.

The Program Division must submit the request for audit reduction to OP via email to ContractAudits@fda.hhs.gov, during the first quarter of the contract period of performance. Requests may be submitted later if conditions change

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during the contract period of performance. Submit a separate form for each program if an audit reduction is being requested in both human and animal food. OP provides a response within 20 business days of receiving the request. The audit rate reduction is valid for the specified period of performance and can be canceled if conditions change.

The state and Program Division understand that the audit reduction is valid for the period of performance specified in this agreement. The audit reduction will be reevaluated if any of the following conditions occur:

1. the state changes the number of inspectors conducting contract inspections;
2. an inspector receives an overall rating of needs improvement; and/or
3. there are significant modifications to the contract (e.g. adding specialized inspections or increasing number of inspections).

The Program Division and state are responsible for reporting any changes to the information provided on the Appendix I or request memo. The state notifies the Program Division of any changes within 10 working days. The Program Division is responsible for reporting the changes to Office of Partnerships (OP) within 10 working days. A new Request for Audit Reduction form may be needed.

6.4.4. Posting of Audit Completion Data

OP posts the annual summary audit completion data for each state program on the FDA internet site. Information will include:

- 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, performance 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

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1. When FDA conducts the audit, the FDA auditor (CSO) 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 will send 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 in FACTS/eNSpect and eSAF

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

C. Performance Factors - Performance factors are found in 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 CVM Contract Audits in FACTS/eNSpect

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

C. Performance Factors - Performance factors are found in Appendix C.

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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 FDA. Verification Audits for programs in Phase III are shared between FDA and the state program.
- B. **Timeframe for Submitting Performance Documentation**
 - 1. Program Division sends a copy of the 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, it will send 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 will prepare a memorandum to document the state auditor’s performance.
- E. **Performance Factors** - Follow instructions in Appendix D.

6.5.3. Egg, Medical Device, and Other Applicable State Inspection Programs

- A. **Audit Requirement** - One joint audit inspection or audit (audit option applies to egg program only) of each inspection program every contract year.
- B. **Audit Option for Egg Program:** The decision will be made by the Program Division in consultation with the FDA auditor and state program and based on the number of trained inspectors in the program. If the state program has 2 or more trained inspectors, the annual requirement will be an audit, unless the Division determines training is needed and elects to do a Joint Audit Inspection. The Division will identify which state inspectors will be audited based on past audit history and inspector performance. Each inspector will be assigned specific roles during the audit, determined at the pre-audit meeting, and the auditor will evaluate each inspector on their performance in those roles. A separate audit memo will be created,

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one for each inspector, to document the assigned areas and the inspector’s performance in those assigned areas. The audit memo will also be used to plan future audits to ensure inspectors are audited in all aspects of an egg inspection.

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

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

C. Timeframe for Submitting Performance Documentation - FDA sends a copy of the 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 will prepare a memorandum to document the state inspector’s performance.

F. Performance Factors - Performance factors for joint audit inspections are found in 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 a quarterly basis. The State Liaison enters prior contract year audit 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:

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1. To ensure state inspectors and auditors meet the minimum audit requirements
2. To ensure verification audits are completed timely
3. To calculate an overall rating for the contract period of performance
4. To evaluate the audit ratings for a single performance factor
5. To 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. For contract audits, also record 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 applicable state inspection programs as joint audit inspections and 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 for why the audit requirement was not met no later than 30 business days after the end of the contract period of performance. The memorandum is emailed to the ContractAudits@fda.hhs.gov mailbox. The memorandum should have 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 period of performance

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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.

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. The PDD forwards it to the PD with concurrence that 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 period of performance

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:
 1. A contract audit is rated “needs improvement”
 2. A verification audit is rated needs improvement (applies to human food and animal food contracts only)
 3. A joint audit inspection of an inspector conducting an egg, medical device, or other inspections done under contract is 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

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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.
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 period of performance.

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

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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 period of performance.

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. Develops a plan to correct the deficiencies. The plan must address:
 - a. The possible causes for the individual or program performance deficiency.
 - b. The corrective actions that will improve performance.
2. Complete the Appendix J, Corrective Action Plan for Program and Individual Performance Deficiencies, 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 QMS for national trending.

5.1. 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 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 Director, Division of Partnership Investments and Agreements (DPIA) no later than 10 business days after the end of the contract period of performance.
- C. The recommendation must contain the following information:
 1. Documentation of the problem. Attach copies of pertinent state inspection reports and FDA audit reports.

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

6.9. 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 Director, OP 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.

6.10. Quality Assurance

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

6.10.1. 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

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and the Program Division’s management of the state contract inspection program

The internal audit findings are be provided to the PDD, State Liaison, and OP and addressed per QMS procedures.

6.10.2. Contract Program System Audit

The OP conducts a comprehensive review and analysis 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 OHAFO, and other designated managers.

7. Glossary/Definitions

The types of audits relevant to the oversight of contract inspections are defined here.

Audit Performance Rating is the comprehensive assessment of all audits conducted in a contract program during a single period of performance. The performance rating is calculated based on the rating of all individual performance factors as follows: $\text{Total Acceptable} / (\text{Total Acceptable} + \text{Total Needs Improvement}) * 100$. The Audit Performance Rating is expressed as a percentage. The Audit Performance Rating must be greater than or equal to 80 percent.

Contract audit is an evaluation of a contract inspection in which a qualified auditor accompanies a state inspector to document the inspector’s performance. 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 is the period of performance for a state contract. It is specific to the state contract. This may or may not coincide with the calendar year or federal fiscal year.

FDA Auditor is a CSO from the Program who has completed the required auditor training and is assigned to complete an audit of a state contract inspector.

Joint audit inspection is an audit conducted by an FDA investigator accompanying a state inspector and observing his/her performance. A joint

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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 is an inspection conducted jointly by Program Division and state inspectors for training. Joint inspections may be counted towards 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 is the comprehensive assessment for an individual audit (see Appendices B and C). If three or less 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.”

Specialized Inspection 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 offered as electives in the contract. A state program can elect to perform these inspections under the contract if they have inspection staff who have the required training and experience to perform the inspections.

Training audit 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 state auditor 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 in the commodity.

8. Records

Contract Audit Forms

Contract Audit Tracker database

State Implementation Agreement and Yearend Evaluation Request for Audit Reduction Forms

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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 (Appendices)

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

Appendix	Internal Document #	Document Title
Appendix A	JA-000024	Instructions for Evaluating Contract Inspections
Appendix B	FORM-000161 (Form FDA 3610)	Human Food Contract Audit Form
Appendix B.1	JA-000025	Instructions for Completing the Contract Audit Form
Appendix B.2	JA-000026	Instructions for Reporting Human Food Contract Audits in FACTS and eSAF
Appendix C	FORM-000162	Animal Food Safety Inspection Audit Form
Appendix C.1	JA-000027	Instructions for Completing the Animal Food Safety Inspection Audit Form Audit Form
Appendix C.2	JA-000028	Instructions for Reporting CVM Contract Audits in FACTS
Appendix D	JA-000029	Instructions for Conducting Joint Audit Inspections, Verification Audits for State Auditors, and Joint Inspections
Appendix H	FORM-000163	State Implementation Agreement and Yearend Evaluation
Appendix I	FORM-000164	Request for Audit Reduction Form and Instructions
Appendix J	FORM-000165	Corrective Action Plan for Program and Performance Factors

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Appendix	Internal Document #	Document Title
Appendix A	JA-000024	Instructions for Evaluating Contract Inspections
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Appendix B.1	JA-000025	Instructions for Completing the Contract Audit Form
Appendix B.2	JA-000026	Instructions for Reporting Human Food Contract Audits in FACTS and eSAF
Appendix C	FORM-000162	Animal Food Safety Inspection Audit Form
Appendix C.1	JA-000027	Instructions for Completing the Animal Food Safety Inspection Audit Form Audit Form
Appendix C.2	JA-000028	Instructions for Reporting CVM Contract Audits in FACTS
Appendix D	JA-000029	Instructions for Conducting Joint Audit Inspections, Verification Audits for State Auditors, and Joint Inspections
Appendix H	FORM-000163	State Implementation Agreement and Yearend Evaluation

10. Document History

Version #	Status* (D, I, R, C)	Date	Author Name and Title	Approving Official Name and Title
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		SCIPI Working Group	Barbara Cassens, Director, OP

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

11. Change History

Version	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.

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Version	Change
03	<p>Document migrated to updated SOP/FMD template. Section 5 procedures moved to Section 6 in new template.</p> <p>Change “Feed” to “Animal Food”.</p> <p>Change communication requirements from within 20 business days to 30 business days to be consistent with the SOWs.</p> <p>Update 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.</p> <p>Scope – added statement to suspend/terminate audit requirements for programs that have been suspended/terminated.</p> <p>Responsibilities – Change State Contract Liaison/Monitor role to State Liaison role as the Contract Technical Advisor, Add description of COR role. Add Program Manager role.</p> <p>6.3 - section moved from end of procedures.</p> <p>6.3.3 – content separated from 6.3.2 under new header</p> <p>6.3.4 – section added.</p> <p>6.4.1 – Minimum audit rates clarified frequency requirements. Required frequency unchanged.</p> <p>6.4.2 Add description of requirements for complex inspection types.</p> <p>6.4.4 - Clarify what data will be posted to the internet.</p> <p>6.5 - Added Animal Food program ability to elect audit phases. Separated inspection audit and verification audit requirements.</p> <p>6.6 – audit data to be tracked by Contract Audit Tracker (CAT). Removal of Appendices and Workbook E, F, & G. Replaced by CAT.</p> <p>6.8.2 - Clarify the performance factors to be examined by the program division audit</p> <p>6.8.3 – Add tracking of state corrective actions by ORA QMS.</p> <p>Internal document number changed from FMD.076 to DIR-000033. Internal document numbers applied to FMD appendices.</p>
04	

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12. Attachments

See Section 9 for links to document appendices.

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