SMG 8076

FDA Staff Manual Guides, Volume IV – Agency Program Directives

FDA – State Relations

Contract Management

FDA State Contract Audit Program

Effective Date: 11/07/2024

1. Purpose.

The purpose of this Staff Manual Guide (SMG) 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 document governs the Food and Drug Administration (FDA) oversight of the FDA Contract Audit Program, state contractor adherence to audit requirements and is the successor directive to FMD-76 (previously managed by ORA). The current revision is primarily unchanged from FMD-76 Revision 5, with minor updates to align organizational names, and address any pending quality actions.

2. Definitions.

Terms relevant to audits and oversight of contract inspections are:

36-Month Period – For the purposes of FDA internal tracking and to align operational & contract activities, the 36-month period is defined as 3 contract budget-periods of

performance. New personnel after the contract period has started will have 3 contract budget periods (years) to complete 2 audits. The year they start counts as one. It is a best practice for new inspectors to be audited on their first contract inspection.

Animal Food Contract Audit - Animal food inspection audits are contract audits of state contract inspectors conducting the most complex inspection type based on inspector's training and experience to perform the inspections. The most complex comprehensive inspection types should be prioritized for audits. Comprehensive inspections cover everything in the facility subject to FDA jurisdiction to determine the facility's compliance status.

Audit Performance Rating - This is the comprehensive assessment of all audits conducted in a contract program during a single year aligning with the 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.

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

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 annual contract performance period for a state contract, otherwise known as the period of performance for the purposes of this SMG. 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 inspectorate 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.

Inspectorate division - The divisional component managing the respective state contract for the respective OHFI or OAFI inspectorate office.

Overall Audit Rating - This is the comprehensive assessment for an individual audit (see Appendices B and C).

Specialized Inspection - This refers to contract inspections that cover a specialized area. Specialized inspection areas in human foods include (see respective Contract Statement of Work for current list): Seafood HACCP, Juice HACCP, LACF/AF, 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.

State Auditor – State program employee who has completed the required auditor and program training, with appropriate program experience, and has passed the required training and verification audits for the program areas they are performing audits for the FDA on and are listed on the current year's approved Appendix H. See section 4.1 for further details.

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 4.2, 4.3, and relevant for the specific commodity.

Verification Audit – These serve as a formal verification by the FDA (and state, when permitted) of the State Auditor's ability to perform satisfactorily auditing contract audits of contract inspectors performing FDA contract work for their respective inspectorate division. See section 4 and Appendix D for further details.

3. Background.

This document was formerly known as Field Management Directive 76 (FMD-76) and this SMG is considered the most recent version of FMD-76.

The original FMD established procedures for joint FDA–state inspections and independent audit inspections for the human food, medicated feed (currently animal food), and interstate travel programs. In 1982, FDA revised the FMD, combining the

general procedures for all current programs into one document. In 1999, FDA added instructions for auditing food sanitation and medicated feed contract inspections.

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, FDA 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.

FDA 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.

FDA 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.

FDA updated this FMD in March 2019 to reflect the organizational structural changes stemming from the May 2017 implementation of Program Alignment, which transformed FDA 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.

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

Revision 5 changes were necessary to incorporate the revised human food audit form (FDA Form 3610H) to incorporate new questions, develop an electronic form, and to automate the audit form routing process. The form was revised to have questions that are specific to each individual human food inspection type and to include new questions that cover Full Scope Preventive Control inspections.

Current changes are necessary to incorporate the FMD-76 directive into the SMG format with FDA organizational changes and minor revisions based on identified quality concerns and subsequent clarification.

4. Policy.

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 field 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 inspectorate division is responsible for conducting the minimum number of contract audits.
2. Phase II: The inspectorate 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 4.2 provides instructions for implementing Phases II and III of the Audit Program.

4.1. 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 4.1.1.

4.1.1. Contract Auditor Training Requirements

A. All Human Food Contract Auditors
   1. FD320W100 - State Food Contract Audit Course
   2. Program specific training

B. All Animal Food Contract Auditors
   1. VM212W100 - State BSE/Feed Establishment Contract Audits course
   2. Program specific training

4.1.2. Auditor Training and Verification

A. The inspectorate 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 4.1.1 and the statement of work (SOW). If requested by the inspectorate 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 Practice (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 audit procedures (Section 4.3). 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 3610H (Appendix B) or the Form FDA 3610A (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 3610H or Form FDA 3610A (not the verification auditor).

G. 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.

H. 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."

4.2. 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 and 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 inspectorate division director 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. The state liaison will email a copy of the initial Appendix H to contractaudits@fda.hhs.gov and copy the contracting officer's representative (COR) prior to the award of the contract to the state. For contract modifications affecting the contract audit elective, the Appendix H will be updated and emailed to contractaudits@fda.hhs.gov and copy the COR.

At the end of the contract performance period, the inspectorate 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, the COR, and to the Contract Audits mailbox (ContractAudits@fda.hhs.gov) no later than 30 business days after the end of the contract performance period.

4.2.1. Phase II

Phase II occurs when the contracting agency assumes partial responsibility for auditing its human food and animal food contract inspections. 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 6.4 of this SMG.

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.

4.3. 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 6.1.1.3 of this SMG.

4.4. 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 inspectorate 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) within 10 business days and copy the COR. If the failure may impact the contract, the state liaison will also copy the inspectorate division director.

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

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

4.5. Audit Requirements

4.5.1. 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. The state liaison will email a copy of the initial Appendix H to contractaudits@fda.hhs.gov and copy the COR prior to the award of the contract to the state.

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 and emails a copy to contractaudits@fda.hhs.gov and copy the COR within 30 days.

Table 1. Audit Rate for Contract Inspection Programs

Inspection Program	**Minimum Audit Rate**
Human Food	2 “acceptable” audits per role (inspector and auditor) every 36 months
Animal Food	2 “acceptable” audits per role (inspector and auditor) 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 third quarter of the fiscal year, the Audit Program Manager emails a status update and reminder to verify audit program status with each Inspectorate division.

4.5.2. Contract Audit Tracker

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

4.5.3. Audit Selection

The inspectorate 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 inspectorate 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)). 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.

Inspectorate divisions may schedule joint inspections as needed for training purposes. These approved joint inspections count toward the contract 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 (see Table 1).

4.5.4. 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 an inspectorate division or state agency fails to conduct the required audits. When evaluating such a request, ODP considers the number and type of contract inspections, the number of state inspectors conducting the contract inspections, and previous individual and program performance. The ODP director has final discretion in granting a

reduction. If the request is not approved, ODP provides an explanation and the inspectorate division and state agency have 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 inspectorate division must submit the request for audit reduction via email to Contract Audits mailbox (ContractAudits@fda.hhs.gov) and copy the COR. 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 ODP 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 inspectorate 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/auditor 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 inspectorate division and state are responsible for reporting any changes to the information provided on the request form (Appendix I). The state notifies the inspectorate division of any changes within 10 working days. The inspectorate division is responsible for reporting the changes to ODP within 10 working days.

4.5.5. Posting of Audit Completion Data

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

- Number of contract inspections completed
- Number of audits completed
- State program overall audit performance rating (see Section 6.4.2)

5. Responsibilities.

A. Associate Commissioner for Inspections and Investigations (ACII)

1. Ensures the inspectorate office directors comply with the contract audit program requirements.

2. Initiates actions to correct national deficiencies.

B. **State Agency Program Director (PD)**

1. Ensures that the PD's respective state agency program complies with the FDA Contract Audit Program requirements.
2. Identify contract modifications necessary for state Audit Elective activities.

C. **OII OHFI Office Directors | OII OAFI Office Director**

1. Ensures the required audits are completed for the respective inspectorates.
2. Implement necessary processes to ensure consistent application of this SMG across the nation.
3. Provide direction and allocation of resources to inspectorate divisions, as necessary, to comply with this SMG.

D. **OII OHFI Division Director | OII OAFI Division Director**

1. Ensures the required audits for the respective inspectorate division are completed and in compliance with this SMG.
2. Ensures program and performance deficiencies are identified, corrected, and documented in QMiS.
3. Ensures adequate staff are assigned to accomplish FDA Contract Audit Program responsibilities.

E. **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.

F. **State Liaison**

1. Manages the Contract Inspection Audit Program for assigned state(s).
2. Informs inspectorate 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.
    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.

G. **Director, Office of Domestic Partnerships (ODP)**

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.

H. **Director, ODP Division of Domestic Partnership Investments (DDPI)**

1. Reviews changes to the contract proposed by the inspectorate division.

I. **Contracting Officer's Representative (COR), ODP DDPI**

1. Supports the contract and provide financial oversight of a specific contract.
2. Recommends contract modifications.
3. Leads oversight of the contractor's technical performance with the state liaison.
4. Reviews proposals for corrective actions.

J. **Audit Program Manager, ODP DDPI**

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.

6. Procedures.

6.1. Audit Procedures

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

6.1.1. Human and Animal Food Contract Audits

A. Audit Requirements

Every inspector must be audited a minimum of twice in 36 months for each role they serve.

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 (see also Section 6.4).

6.1.1.1. Human Food Contract Audits

A. **References**

1. Appendix A - Instructions for Evaluating Contract Inspections
2. Appendix B.2 - Instructions for Reporting Human Food Contract Audits

B. Performance Documentation

1. Appendix B - Human Food Field Inspection Audit Form (Form FDA 3610H) is used to evaluate the state inspector’s performance.

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

6.1.1.2. 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.

6.1.1.3. 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 have one (1) of the two (2) required audits conducted by FDA.

B. Timeframe for Submitting Performance Documentation

1. The inspectorate 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 inspectorate division or the state agency should notify the other party no later than 10 business days after the audit is completed (see also Section 6.8).

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 follows Appendix D to document the state auditor's performance.

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

6.1.2. 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.

B. Audit Option for Egg Program

The inspectorate 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 inspectorate division determines training is needed and elects to do a joint audit inspection. The inspectorate 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 inspectorate 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. The designated lead inspector creates one inspection report. Evaluation of the inspection report is not part of this audit.

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 inspectorate 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 or state auditor follows Appendix D to document the state auditor's performance.

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

6.2. 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 ensures the audit results in the Contract Audit Tracker (CAT) Tool are representative and accurate at least on a quarterly basis. The state liaison confirms prior contract year audit data before the inspectorate 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.

6.2.1. 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.

6.2.2. 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.

6.3. Audit Requirement Deficiencies

When the minimum audit requirement is not met, the inspectorate division director 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), copy the COR, and it 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 ODP Director reviews the memorandum and discusses the need to adjust the state agency's implementation phase with the inspectorate division director and the director of the state commodity program.

In Phase I, the inspectorate division director prepares the memorandum.

In Phase II, the inspectorate division director and state agency work together to prepare the memorandum. The inspectorate division director 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 inspectorate division director for concurrence; the inspectorate division director forwards it to the respective Inspectorate Office Director. The memorandum includes the following content:

1. Support of the memorandum submitted by the state agency.
2. Summary of discussions held between inspectorate division director, 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.

6.4. Performance Deficiencies

6.4.1. Individual Inspector Performance Deficiencies

A. When there is an individual performance deficiency, the inspectorate division or state agency notifies the other party no later than 10 business days after the audit is completed. The state 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” by receiving an overall score of less than 80%.
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 inspectorate 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 inspectorate 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 inspectorate 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 inspectorate 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.

6.4.2. Program Performance Deficiencies

When there is a program performance deficiency, the inspectorate division director or state or territorial 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 the overall audit performance rating is below 80 percent “acceptable” when averaged across the contract performance period.

6.4.3. Documenting Performance Deficiencies

The inspectorate 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:
    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:
    a. Route to the COR for review prior to implementation of the corrective action(s).
    b. Submit to the Audit Program Manager upon completion of the corrective action.
3. The inspectorate division records corrective actions taken by the state in the Quality Management System (QMS) for national trending.

6.5. Process for Contract Modifications for Program and Performance Deficiencies

A. The ODP Audit Program Manager or state liaison immediately notifies the COR of any individual or program performance deficiency that may affect a contractual requirement. The CORs makes any necessary contract changes. The inspectorate division provides the COR with additional notification of all follow-up actions and copies of any written correspondence to the state agency.

B. If the inspectorate division proposes a change to the contract, the In inspectorate division director emails a recommendation to change the contract to the respective inspectorate office director and ODP DDPI director, no later than 10 business days after the decision to propose a change to the contract is identified.

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 inspectorate division to correct the problem.
3. Copies of correspondence such as emails between the inspectorate division and state agency documenting efforts to address and correct the problem.
4. An assessment by the inspectorate division of the cause of the problem and suggested changes to the contract.

D. The ODP DDPI Director, and COR review the inspectorate division's proposal to determine if the recommended action is appropriate and complies with contracting regulations and procedures. The ODP DDPI Director discusses with the inspectorate 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 in accordance with the instructions provided in the SOW regarding alteration of the contract and payment for work conducted under the contract.

6.6. Dispute Resolution

The inspectorate division and the state agency must make every effort to resolve disputes about audit findings and overall audit ratings. If, however, the inspectorate 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, ODP. All related documents, including the FDA audit reports and state inspection reports, shall be included. The ODP Director reviews the reports and works with the inspectorate 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.

7. Quality Assurance.

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

7.1. State Program Quality Assurance

The inspectorate 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 6.4.2 and the inspectorate division's management of the state contract inspection program. The internal audit findings are be provided to the inspectorate division director, state liaison, and ODP and addressed per QMS procedures.

7.2. Contract Program System Audit

A comprehensive review and analysis are conducted by ODP of the national performance data and evaluation of state program performance and identifies continuous improvement opportunities. The ODP 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 ACII, and other designated managers.

8. Supporting Documents.

Users are responsible for ensuring they use the most up-to-date version of the referenced documents. Please see the Contracts webpage on FDA.gov to access the current revision of the appendices listed below.

Appendix	Document Title
Appendix A	Instructions for Evaluating Contract Inspections
Appendix B	Human Food Field Inspection Audit Form
Appendix B.2	Instructions for Reporting Human Food Audits
Appendix C	Animal Food Safety Inspection Audit Form
Appendix C.1	Instructions for Completing the Animal Food Safety Inspection Audit Form
Appendix C.2	Instructions for Reporting Animal Food Contract Audits
Appendix D	Instructions for Conducting Joint Audit Inspections, Verification Audits for State Auditors, and Joint Inspections
Appendix H	State Implementation Agreement and Yearend Evaluation
Appendix H.1	Completion Guide for Appendix H
Appendix I	Request for Audit Reduction Form and Instructions
Appendix J	Corrective Action Plan for Program and Performance Factors

9. Effective Date.

The effective date of this guide is November 7, 2024.

10. Document History - SMG 8076, “FDA State Contract Audit Program”

This document replaces previous versions of this document identified as Field Management Directive 76 (FMD-76).

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	10/31/2024	N/A	OIFSSP ODP DDPI	Erik Mettler, HFP OIFSSP