

## **SMG 8076 FDA State Contract Audit Program Appendix D Instructions for Conducting Joint Audit Inspections, Verification Audits for State Auditors, and Joint Inspections**

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This appendix provides instructions on conducting joint audit inspections (JAI), verification audits for state auditors, and joint inspections (JI).

### **1. Joint Audit Inspections and Verification Audits for State Auditors**

Joint audit inspections are used: (1) to assess the quality of contract inspections for those inspection programs including egg, and medical device and (2) to assess the performance of state auditors conducting audits of human food and animal food contract inspections.

The qualified auditor follows Appendix A Instructions for Evaluating Contract Inspections for guidance on the roles and responsibilities of an auditor and an auditee. The JAI is done by an FDA investigator observing a state inspector conducting an inspection of a firm in one of the program areas mentioned in (1) above.

The verification audit is done by a qualified FDA or state auditor observing a state qualified auditor performing an audit of a state inspector conducting a human food or animal food contract inspection.

#### Performance Factors

The qualified auditor discusses the performance factors with the state inspector or state auditor prior the start of the evaluation. The state inspector or state auditor's performance is evaluated based on their application of the performance factors listed here.

Understands the program objective and regulatory authorities.

- a. Has necessary knowledge (training), skills, and abilities to conduct the inspection.
- b. Covers critical areas during the inspection.
- c. Selects an appropriate product for inspection.
- d. Recognizes significant violative conditions or practices.
- e. Notifies firm's management when an immediate corrective action is required.
- f. Explains inspection findings accurately and clearly to firm managers.

#### Performance Documentation

Use a memorandum to document the state inspector or state auditor's performance.

Detail any deficiencies in performance in the memorandum with specific information sufficient to document the performance deficiency. Overall needs improvement is defined as one or more of the above performance factors being rated as needs improvement. If an overall needs improvement is documented,

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a copy of the memoranda is sent to the Office of Partnerships Audit Program Manager at [ContractAudits@fda.hhs.gov](mailto:ContractAudits@fda.hhs.gov).

### For joint audit inspections

The FDA auditor prepares the memorandum for supervisory review. The inspectorate division sends a copy of the memorandum to the state agency no later than 30 business days after the audit is completed. If the joint audit inspection is unacceptable, the inspectorate division notifies the state agency no later than 10 business days after the audit is completed.

### For verification audits for state auditors

The FDA or state auditor prepares the memorandum for supervisory review.

FDA sends a copy of the memorandum to the state agency no later than 30 business days after the audit is completed.

When the state agency conducts the audit, the state agency sends the original memorandum to the inspectorate division no later than 30 business days after the audit is completed.

If a verification audit is unacceptable, the inspectorate division or the state notifies the other party no later than 10 business days after the audit is completed.

### Data Reporting

Joint audit inspections are reported as investigation operations, **operation code 13**. Report investigation time against the PAC for the appropriate compliance program, for example, PAC 03S836, an egg inspection assignment, may be used to report time for an egg contract inspection audit. Prepare only one coversheet per inspection with both FDA and state inspection time recorded.

## **2. Joint Inspections**

A joint inspection is an inspection conducted jointly by FDA and state personnel for the purposes of training or enforcement. A joint inspection may be used to provide training to a state inspector during an inspection of a firm contracted to the state. This joint inspection may be counted against the required number of audits. 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.

### Data Reporting

The FDA investigator reports joint inspections using the assignment created in eNSpect using **operation code 12**. Report the inspection against the PAC for the appropriate compliance program. Do not use any other audit PAC.