Reporting Instructions for FDA

Audits of contract inspections are reported as investigation operations, **operation code 13**. FDA Auditor or Division Designee must enter data in the fields listed below for the OP13 completed state contract audit assignment.

Do not attach the completed Form FDA 3610 or verification memo to this OP13 assignment.

Accomplishing Division

- **Investigation Basis** –select **Surveillance**
- **PAC** – select **03R843**
- **Reason for Investigation**

  - **Select one of the following type of audits covered**

    — Contract Audit
    — Training Audit
    — Verification Audit

  - **Select one of the following inspection types covered**

    - CGMP only (CGMP)
    - Qualified Facility (QF)
    - Qualified Facility and Acidified Foods/LACF (QF.A)
    - Limited Scope PCHF only (LSPC)
    - Limited Scope PCHF and Acidified Foods/LACF (LSPC.A)
    - Full Scope PCHF only (FSPC)
    - Full Scope PCHF and Acidified Foods/LACF (FSPC.A)
    - Seafood or Juice HACCP (HACCP)
    - Seafood/Juice HACCP and Acidified Foods or LACF (HACCP.A)

- **Findings and Recommendations**

  Do not identify the auditee's name or audit results as the audit is a personal performance evaluation. Please follow your division's procedures and/or practices.

- **Endorsement Text**

Example Text:
A copy of the Form FDA 3610 audit report or memo has been provided to the state. An electronic copy of the Form FDA 3610 or memo is also filed in the Division State Liaison's records on Division shared drive. The Form FDA 3610 (and memorandum, if applicable) and associated Coversheet were reviewed, approved, and emailed to ORAOPDataHub@fda.hhs.gov.

NOTE: The instructions above do not apply to joint inspections conducted for purposes other than auditing a contract inspection. Joint inspections conducted for purposes other than auditing, such as compliance/enforcement and training should continue to be reported as an inspection under operation code 12, and against the appropriate PAC and compliance program. Only one coversheet should be prepared per inspection with both FDA and State time recorded for joint inspection purposes.

Reporting Instructions for States in Phase II and III

Only the State inspector, not the State auditor, will report his/her time in eSAF. The number of hours will be reported as an audit not an inspection. At the time data is entered into eSAF, the State data entry user will change the *Inspection Type* field on the Add/Update Inspection Operation screen from "State" to "Audit". In Phase II, the FDA investigator will report time following the instructions in the Appendix B.2.