

Appendix B.2

Instructions for Reporting Human Food Contract Audits in FACTS and eSAF

Reporting Instructions for FDA

Audits of contract inspections are reported as investigation operations, **operation code 13**. The PAC for Human Food contract audits is **03R843**.

1. Select **Investigation Operation**
2. Select **Stand Alone Investigation**
3. At the **Maintain Investigations** screen, data must be entered in the fields listed here.
 - **Accomplishing District**
 - **Start Date**
 - **Investigation Basis** –select **Surveillance**
 - **PAC** – select **03R843**
 - **Reason for Investigation** – enter the applicable descriptions listed here:

For general Human Food sanitation inspections:

Human Food Sanitation Contract
Audit Human Food Sanitation
Training Audit Human Food
Sanitation Verification Audit

For LACF or acidified Human Food inspections:

LACF Contract Audit
LACF Training Audit
LACF Verification Audit

For seafood HACCP inspections:

Seafood HACCP Contract Audit
Seafood HACCP Training Audit
Seafood HACCP Verification Audit

For juice HACCP inspections:

Juice HACCP Contract Audit
Juice HACCP Training Audit
Juice HACCP Verification Audit

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.