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Document History

1. Purpose

This procedure describes how the laboratory receives, distributes, stores and disposes of samples.

2. Scope

This procedure applies to samples received by the laboratory.

3. Responsibilities

A. Laboratory Director or designated personnel is responsible for the overall control of samples in the Laboratory.

B. Sample Custodian and assigned back-up personnel are responsible for following the policies and procedures as outline in this procedure.

C. Compliance Officers of the Compliance Branch for the home district is responsible for authorizing disposition of samples. In the case of non-FDA samples, the requesting or collecting organization authorizes disposition.

4. Background

None

5. References

ISO/IEC 17025. *General requirements for the competence of testing and calibration laboratories* (5.8 Handling of Test and Calibration Items). Geneva, Switzerland: The International Organization for Standardization and the International Electrotechnical Commission.

6. Procedure

This procedure addresses the topics of sample receipt and processing, sample rejections, sample storage, sample transfers and analyst custody, sample shipping, and sample disposal.

6.1 Sample Receipt and Processing

A. FDA Samples:

- Samples for the analyzing laboratory are received in a designated area (i.e. sample processing room).

- Agency samples delivered to the laboratory must have an associated Collection Report (C/R) in the Field Accomplishments and Compliance Tracking System (FACTS). FACTS assigns sequentially an unique identification number which initiates sample tracking. Sample identification is described in the Investigations Operations Manual (IOM).

B. Other (Non-FDA) Samples:

For non-agency samples (e.g. State or USDA) delivered to the laboratory, unique identification and a corresponding Collection Report is generated in FACTS. The laboratory initiates sample tracking through FACTS in order to assign the unique identification number for the sample. Refer to the appropriate sections in the FACTS Manual to generate a C/R or to initiate sample tracking.

C. Samples Submitted for Storage Only:

Samples from non-FDA agencies for storage purposes only do not need to be entered into FACTS, but each laboratory records the same information (if provided), for sample storage and sample inventory purposes. The unique identifier would be the requesting or collecting agency's identification.

D. Sample Receipt and Processing:

1. Upon receipt of the sample, the following will be done:

   a. The person who is authorized to receive the sample verifies that packages received are consistent with the description on the C/R.

   b. He or she observes and records the condition of the sample and compares it with the electronic C/R for the following items: collector, analyzing organization, number of units, collection date, sample identification number, matrix and product identification, requested analyses, and storage conditions.

   c. If a collection report and its samples are received and found to be

incomplete, notify a supervisor or analyst.

d. Modifications or instructions are annotated in FACTS.

e. The sample identification (ID) number on the sample container is crossed referenced to the C/R.

f. If the sample ID does not match the request form sample ID, the sample is held pending clarification from the requestor. If clarification cannot be satisfactorily obtained, the samples are stored temporarily or returned.

g. If the sample is rejected, the reason for rejection is documented in FACTS or per local instructions. The sample may be returned to the collector.

2. Other information will also be checked and or verified such as:

- if applicable, presence of seal and seal integrity (NOTE: Seals are not needed on all samples);
- seal quotation, including date and signature or initials are to be consistent with electronic C/R;
- analysis requested (If an analysis is not performed by the receiving lab, the supervisor is contacted or local instructions are followed to forward to the designated analyzing laboratory.);
- storage conditions in accordance with shipping (If not, the supervisor is contacted for clarification.); and
- any records or documentation received with the sample are to accompany the sample and are included with the administrative package that accompanies the lab reporting of results.

3. Sample condition and acceptability is checked and documented. The following criteria are for determining the acceptance and rejection of samples:

a. If the physical condition of the sample container (e.g. visible damage, leakage, seals intact) is unacceptable, the sample is

classified as a Class V. The collector is notified electronically.

b. If the sample is leaking, contain the leak and notify the local Industrial Hygienist or Supervisor in accordance with the laboratory's local procedure.

c. If the loss of sample because of incomplete or improper sealing (e.g. leakage of liquids from bottles, loss of particulate material from containers and improper sealing of bags) is unacceptable, the sample is classified as a Class V. The collector is notified verbally or electronically by a Supervisor, analyst or Sample Custodian.

d. Acceptable samples are logged into FACTS. The following information at a minimum will be annotated: date received (FACTS field defaults to date entered), condition of container, shipping information, seal quotes, where (city and state), storage location, and any comments in the special handling instruction field.

e. For samples received that are perishable or an urgent priority, the applicable section Supervisor or assigned analyst is notified.

4. Samples received not meeting the above criteria are considered for rejection. The Quality Management System Manager, laboratory management and Supervisors are the authorizing officials to determine whether samples are rejected. For samples that have been compromised (i.e. damaged, contaminated, or integrity questioned) the requestor is notified verbally or electronically with the nature of rejection and consulted on the course of action to take with his or her Supervisor. Further instructions are given by the Supervisor in conjunction with the client in order to process the sample. All communications are documented.

6.2 Sample Storage and Sample Transfer

A. Sample Storage

1. Samples awaiting analyses are placed in the designated storage locations by the Sample Custodian in accordance with instructions received with the sample or from the Laboratory Supervisor.

2. Samples are stored frozen, refrigerated or at room temperature. Controlled drug substances are stored in a separate locked area (i.e. safe).

3. The sample storage areas are organized to prevent contamination or

cross contamination and are monitored. Each laboratory is to have a local procedure for monitoring the storage of samples.

B. Sample Transfers Within the Laboratory

1. Sample transfers between the Sample Custodian and analysts document the chain of custody. Samples received from the Sample Custodian are recorded in FACTS and documented on the worksheet.

2. Samples transferred between analysts are documented on the analytical worksheet and described in Section 2, ORA-LAB.5.10 and local instructions.

3. Reserve portions of all samples are returned to the Sample Custodian unless documented on the analytical worksheet and in FACTS.

C. Sample Transfers Outside of the Laboratory

1. Samples or portions of samples transferred outside the laboratory are entered and accomplished in FACTS.

2. The following information is documented and shows: (1) what was provided and how much, (2) how it was prepared for delivery, (3) how it was identified and sealed, (4) a brief explanation as to why the sample was sent, (5) to whom the sample was sent, and (6) the date of shipment. This is documented on the analyst worksheet and in FACTS.

3. Samples are shipped according to work instructions to ensure sample integrity and condition. Samples are shipped in accordance with Federal regulations.

D. Sample Storage During Analysis

1. Samples are kept under lock and key while in the analyst's possession.

2. If lockable storage is not obtainable or practical, the sample is returned to the Sample Custodian.

E. Sample Reserve Portions

1. Sample reserves are returned to the Sample Custodian upon completion of the analysis and documented on the worksheet and in FACTS.

2. The Sample Custodian will store the reserve in the designated storage area and under proper storage conditions.

6.3 Sample Disposition

A. Sample Disposition

1. Authorization to dispose samples comes from the Compliance Officer, the Laboratory Director, or designated laboratory personnel through the FACTS-Sample Disposition Notice (SDN). Under certain circumstance in accordance with the laboratory procedure, the analyst may dispose of a sample. In FACTS this is an *in-house disposition* of the sample reserve.

2. If the *in-house disposition* is used, a local procedure or FMD 151 for disposition of BSE samples specifies under what circumstances and conditions the analyst may destroy the reserve. Examples where reserve samples may be destroyed by the analyst are: no reserve sample remains because the entire sample was consumed during analysis, the reserve is an import product with no action indicated (NAI) classification or perishable samples with NAI classification where the Supervisor has concurred with immediate destruction.

3. The analyst documents the in-house destruction of the reserve sample on the Analyst Worksheet and in the FACTS.

4. Disposition of the sample is completed following receipt of the disposition authorization in FACTS or by memorandum in a timely manner. Date of disposal is documented in FACTS.

5. Samples are disposed in accordance with Federal, State and local regulations.

7. Definitions

FACTS - The Field Accomplishments and Compliance Tracking System (FACTS) is FDA's national operational database used to manage field work assignments, and record work results from assignment through compliance action. It's design provides an electronic history of: (1) sample receipt and possession, including future shipment; (2) storage by the Sample Custodian or other person in the laboratory; and (3) authorization for disposition and actual destruction or other approved disposal.

Sample accountability – This is a continuous record documenting that the sample's integrity has been preserved and demonstrates continuity of handling.

8. Records

The following records document sample accountability:

Collection Report
Official Seal (FD-415al)
Analyst Worksheet (FD-431 series)

9. Supporting Documents

FACTS Users Manual chapters or work instructions for:

- initiate sample tracking,
- sample transfers to analysts, and
- sample disposition.

Sample storage area work instructions

Field Management Directive (FMD) 151

10. Attachments

None

Document History					
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