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OPI: SP/FSLD

PROCEDURES FOR EVIDENTIARY SAMPLES

I. PURPOSE

This Directive establishes policy and procedures to be followed by Science Laboratories when receiving, handling, processing and disposing of samples which may be used as evidence in a court of law. These samples may include, but are not limited to, those originating from the Compliance Program Epidemiology activities, Emergency Programs, Contamination Response System, consumer complaints, Office of the Inspector General, Food and Drug Administration, and other special samples submitted by field personnel. These samples are referred to herein as Evidentiary Samples.

II. (RESERVED)

III. REASON FOR ISSUANCE

Agency personnel may be required to testify regarding samples offered as evidence in Federal court proceedings. If FSIS is requested to provide a sample and associated laboratory documentation as evidence for a trial, an Agency employee may be required to testify that the evidence is authentic. Therefore, samples that are to be introduced as evidence must have been controlled in a manner that allows FSIS to demonstrate that: (1) the sample has been identified correctly; (2) that custody has been adequately controlled and thoroughly documented during the period the sample was in laboratory possession; and (3) the sample itself has not been altered in any way by parties other than the sample preparer and the analyst (Note: The preparer and analyst may alter the sample in ways such as grinding and removing a small portion of the sample for analysis). This control ensures "sample integrity", that is, the sample has not been lost, tampered with or otherwise rendered inadmissable as evidence in a future legal proceeding.

Sample integrity is achieved by:

A. Thorough documentation of:

1. Sample transfer from collecting person to laboratory receipt;

2. Condition of sample upon receipt by the laboratory;

3. Procedures performed upon the sample while under laboratory control;

4. All persons who had access to the sample, including times of access and reasons for access.

B. Security of the sample, i.e., restricting access to it.

C. Demonstration that the sample was secured at all times and never left unattended while under laboratory control.

IV. POLICY

It is the policy of FSIS laboratories to control evidentiary samples in accordance with the Federal Rules of Evidence and judicial standards. This is to assure that:

A. Sample integrity and identity are maintained;

B. Analytical findings are reliable, accurate, and supportable; and

C. The chain of custody of the sample will withstand cross-examination in the event that the sample and/or laboratory results are introduced into evidence at a trial.

V. REFERENCES

FSIS Directives 8150.1, 8410.1, 10600.1 and 10600.2; Meat and Poultry Inspection Manual, Part 23A; MPI Bulletin 83-26.

VI. DEFINITIONS:

A. Laboratory - includes the three Field Service Laboratories (Athens, Ga.; St. Louis, Mo.; and Alameda, Ca.) and the Beltsville National Laboratories, Beltsville, Md.

B. Laboratory Director - includes the Directors of the three Field Service Laboratories and the Branch Chiefs of the Beltsville National Laboratories.

C. Responsible Supervisor - includes In-Charges and First Line Supervisors (for Chemistry, Pathology, and Microbiology) in the Field Service Laboratories, and the Section Chiefs in the Beltsville National Laboratories.

D. Responsible Analyst - is the lead analyst to whom the sample is assigned.

E. Sample Custodian-person at laboratory responsible for control of evidentiary sample.

VII. INITIAL CONTROL

A. Designating a Sample Custodian

1. Each laboratory shall assign one person and a back-up as

Sample Custodian for sample receipt and control. In addition, this person will supervise mailroom activities.

B. Identification

1. Most evidentiary samples originate from Compliance Division investigations. All Compliance Division investigatory samples shall be sealed with FSIS Form 8040-1, "OFFICIAL SEAL" (See FSIS Directive 8150.1: "Sample Collection and Integrity"). Samples originating from consumer complaints, amenability, epidemiology and emergency programs shall not be sealed unless instructed by the area office. However, a "Priority Sample Sticker," FSIS Form 8000-12, shall be placed on the outside shipping container of all samples submitted by the Compliance Program.

2. Evidentiary samples are identified by the seal on the closure of the internal container (e.g., the neck or flap of the bag containing the sample). If possible, all products (including intact cans or jars) should be individually placed in separate polyethylene bags. For jars that cannot be placed in a polyethylene bag, a seal should be placed at the juncture of the lid and glass container. For other container types, the seal should be attached so that tampering would damage the seal. Seals should tear or self destruct upon removal or tampering.

3. Unsealed samples subsequently identified as evidentiary samples are to be immediately secured. The Sample Custodian must notify the Laboratory Director, who will contact the Director, FSLD, for instructions on how to proceed.

NOTE: The Compliance Division is the only FSIS program authorized to use the "Official Seal" (FSIS Form 8040-1). If other programs initiate special seals for the same purpose, the procedures in this directive shall apply.

C. Processing.

1. After receipt and identification, the evidentiary sample shall be taken to the Sample Custodian. If a sample is received beyond the normal tour of duty, the carton shall be secured in locked storage until the next working day.

2. If the sample is received during the normal tour of duty but analysis cannot be initiated immediately, the Sample Custodian shall secure the sample in appropriate storage.

3. If, upon receipt, the seal is intact, the Sample Custodian shall:

a. Examine the enclosed form(s) to determine the analytical unit; and

b. Initiate an Evidentiary Sample Control Form (Attachment

l) and complete blocks 1 through 13. If the sample has been shipped by other than normal mail, shipping documentation will be kept with the official form.

4. If, upon receipt, the seal(s) is not intact or tampering is obvious, the Sample Custodian shall alert the Laboratory Director, who will then notify the organization that submitted the sample. The sample will be secured, as specified in Section IX, pending instructions to proceed.

D. Routing.

1. After completing the required documentation, the Sample Custodian shall personally submit the sample to the Responsible Supervisor (RS), who signs and dates the Evidentiary Sample Control Form.

2. If the sample requires microbiological analysis, the Sample Custodian shall deliver the sample to the RS in microbiology. If the RS for microbiology suspects a public health hazard, he/she must immediately notify the Meatborne Hazard Control Center and other appropriate personnel if warranted.

VIII. SUPERVISORY CONTROL

A. Sample Receipt.

The Responsible Supervisor shall accept the Evidentiary Sample and associated documents from the Sample Custodian and sign and date the control form. The Sample Custodian retains the carbon copy of the control form for the laboratory file on that evidentiary sample. The RS will then assign the sample to an analyst.

B. Analysis

The Analyst:

1. Accepts the sample and signs and dates the control form. The Evidentiary Sample Control Form and associated control documents (e.g., Registered or Certified Mail receipts and seals) must accompany the sample until the analysis is completed. After initial entry into the Laboratory Sample Flow System (LSFS), the official form is returned to the responsible analyst to accompany the sample through processing.

2. Breaks the seal (if the seal is intact). He/she then initials and dates the broken seal but does not remove it. He/she examines the sample to determine if it is in condition suitable for analysis.

3. Removes only the required quantity of sample necessary to perform the analysis and retains the sample in the internal container with its broken seal.

4. Places the unused sample portion in a bag together with the original bag or container and seals it with a sealing bar. It is then placed

in a second bag and sealed with a sealing bar. Prior to sealing, the analyst will write the form number and sign and date the area where the sealing bar will be applied. If the sample is contained in something other than a bag (e.g., canned product), follow the same procedures outlined above, except retain the sample's commercial label and container identification (e.g., a can lid with the serial number). This information shall be placed in a third bag and sealed as above. The reserve is returned for secure storage to the Sample Custodian who signs and dates the control form.

5. Supervises sample preparation personally if sample preparation is required by someone other than the responsible analyst.

6. Completes the analysis. The analyst then discusses the analytical findings, interpretation, and recording of results with his/her supervisor. If the analysis requires more than one working day, the sample shall be returned to the Sample Custodian for secured storage. This transaction must be documented.

C. Final Processing

Upon completion of the sample and related documentation, the analyst will:

1. Convey the remaining portion of the sample to the Sample Custodian for control and secure storage.

2. Review and complete data entry on the laboratory form(s) and forward to LSFS for results entry.

3. Prepare a contents list for each sample file. The list is verified by the Sample Custodian.

4. Forward all documentation to the RS. The documentation should include the original Evidentiary Sample Control Form, supporting reports, official forms(s), other documentation, and the internal seal(s).

IX. STORAGE

A. Samples

1. The RS will ensure that sensitive samples are stored in a secured area. Access should be limited to the Sample Custodian and back-up.

2. The Sample Custodian will maintain sample security.

3. Persons receiving the sample from the Sample Custodian will sign out and in for the sample on the control form.

B. Sample Files

Keep in secure storage. Access to the sample file shall be authorized only by

the RS.

X. RETESTING AND TRANSFERRING

A. Retesting in Receiving Laboratory

All control procedures provided for initial analysis, final processing and storage in Sections VIII B, VIII C, and IX must be followed if a decision to retest is made subsequent to conveyance of sample custody after completion by the initial analyst.

B. Transfer to Other Government Laboratory

The surrendering laboratory will:

1. Create a record of the transfer for its files, including photo-copies of all transferred documents.

2. Transship the sample and all original documents to the new location. The receiving organization shall return to the originating laboratory a signed receipt which is placed in the file containing copies of the transferred records.

XI. REMOVAL

A. Authorization

Division directors must provide written authorization to the Laboratory Director for removal of a sample.

B. Transshipping

The person receiving the sample (including employees of the U.S. Postal Service and other common carriers) must present proper identification and sign for the sample prior to release. The Sample Custodian will control this process.

C. Opposing Litigant Party

1. A sample or associated documentation shall not be surrendered to the opposing party without a court order, which will be relayed through channels to the Laboratory Director. If issued, the terms of the court order will be followed. If the litigant is allowed access to the sample or documentation at the laboratory by terms of a court order, an appropriate staff member will accompany him/her during direct access.

2. A sample or documentation also may be surrendered upon written request from the Office of General Counsel.

XII. DISPOSAL OF EVIDENTIARY SAMPLES

A. Authorization

Disposal of evidentiary samples requires written direction from a Division Director, who shall issue disposal orders upon written authorization by a responsible official of the originating organization. The Compliance Program lists of their samples to be discarded also constitute disposal authorization.

B. Disposal Conditions

1. Generally, samples are not destroyed until litigation is completed (including appeals in case of re-trial).

2. The Laboratory Director will enter the written authorization in the sample file and give the file to the Sample Custodian, along with sample disposal instructions.

3. The Sample Custodian will update the last line of the Evidentiary Sample Control Form upon disposal. The form will then be placed in the sample file. The sample file will be retained in accordance with FSIS records retention schedules.

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Attachment

FSIS Form 10625-1 (10/85) Evidentiary Sample Control Form
(REFERENCE PAPER COPY OF THIS DIRECTIVE)