OPI: SCI/FSLD

PROCEDURES FOR EMERGENCY RESPONSE SAMPLES

I. PURPOSE

This directive establishes procedures to be followed by Science Laboratories when processing Emergency Response Samples. Such samples may include, but are not limited to, samples originating from Emergency Programs Staff, Epidemiology Branch (consumer complaints), Compliance Division, Office of the Inspector General, Food and Drug Administration, special samples submitted by FSIS field personnel, and samples of high priority submitted by other organizations.

II. (RESERVED)

III. (RESERVED)

IV. REFERENCES

FSIS Directives 8080.1, 8150.1, 8410.1, 10,130.1, 10,600.1, 10,600.2, 10,620.1;
MPI Manual, Part 23A; Science, Microbiology Division, Policy for Response to Microbiological Incident.

V. FORMS AND ABBREVIATIONS

The following will appear as abbreviated in this directive.

AOAC Association of Official Analytical Chemists
QA Quality Assurance
QC Quality Control
FSLD Field Service Laboratories Division

VI. POLICY

A. It is the policy of FSIS laboratories to expedite handling and processing of all samples received for response to an emergency situation. Samples identified as high priority, emergency response shall be processed in a manner that provides for:

1. Maintenance of sample integrity and identity;
2. Rapid and accurate coordination of information;
3. Rapid identification of the potential problem;
4. Accurate, rapid analysis of the sample;
5. Rapid reporting of analytical results;
6. Maintenance of reserve sample for reanalysis or evidence.

B. These objectives can be accomplished by:

1. Identifying and resolving associated problems (e.g.,

analytical, QA/QC, resource or handling).

2. Coordinating and communicating information rapidly and accurately.

3. Transferring the sample to qualified staff with the equipment and supplies necessary to complete the analysis.

4. Rapidly and accurately analyzing the sample.

5. Ensuring that results are properly reported.

VII. DEFINITIONS

A. Laboratory. This includes three Field Service Laboratories (Athens, GA.; St. Louis, MO; and Alameda, CA).

B. Laboratory Director. This includes the Directors of the three Field Service Laboratories.

C. Responsible Supervisor. This includes the In-Charges and First Line Supervisors in the Field Service Laboratories.

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

VIII. RESPONSIBILITIES

A. Emergency Programs Staff And Science Program Headquarters.

1. Coordination. The Emergency Programs Staff will coordinate all responses to emergency situations. When initial information is obtained, they will determine the general problem, background information, potential impact, and what analyses should be considered. They will then meet with the Science technical staffs to determine disciplines involved, information requirements and the number of samples necessary to resolve the problem. They will provide situation summary fact sheets, updates, and case close outs directly to the affected laboratory(ies) and Headquarters staff.

2. Laboratory Designation and Sample Shipment. The Director, FSLD, in consultation with the Laboratory Director(s), will determine which laboratory(ies) will respond. Using this information, the Emergency Programs Staff will arrange sample shipment to the designated Laboratory(ies).

3. Communicating and Reporting Situation Information. Emergency Programs Staff, Compliance Division, Epidemiology Branch, or the FSIS Information Staff will coordinate, communicate and report situation information outside the Science Program.

B. Laboratory.

1. Notification of Agency Staff. If alerted to an emergency response situation by other than Science Program staff, Laboratory

Directors should notify the Director, FSLD, who will notify the Office of the Deputy Administrator, Science, and other appropriate staffs.

2. Requesting Information From the Site .

a. If routine information is required, the Responsible Supervisor or Responsible Analyst should request it from the Director, FSLD, or contact the site (establishment) directly after notifying the Regional Office .

b. If non-routine information or guidance is required from the site, request it from Emergency Programs Staff through the Director, FSLD.

3. Information From/To Non-Agency Staff. If conditions warrant, the Responsible Supervisor may contact field level staff at the Environmental Protection Agency, Food and Drug Administration, and other appropriate Federal or non-Federal organizations for technological assistance. Situation information should not be released (as part of these queries) unless authorized by the Office of the Deputy Administrator, Science, Emergency Programs staff, or a designated spokesperson.

4. Assessment of Staff Equipment and Supply Requirements. responsible supervisor will estimate the staff, equipment, and supplies necessary to perform the analyses. If staff, equipment or supplies are from another organization, request them through established channels.

5. Maintenance of a Log. The laboratory will maintain a bound log(s) to record key conversations associated with each incident. Each record will identify the parties involved, their titles, organizations, phone numbers, conversation summaries, and the dates and times of the occurrences.

6. Identification of the Sample As Emergency Response. Upon receipt of an Emergency Response Sample, follow appropriate Laboratory procedures for identification and control.

7. Initial Communication with Agency Staff.

a. Upon sample receipt, the Laboratory Director should immediately notify the Director, FSLD, who will alert other appropriate staffs.

b. The Laboratory Director will ensure that the Responsible Supervisor or Responsible Analyst obtains information on the nature of the situation to be evaluated, available methods, and health risks associated with the emergency response situation from appropriate Agency staff.

8. Methodology. If available, always use official methods. If an approved method does not exist, adapt an existing method or develop an alternative method with the technical guidance of the

appropriate headquarters staff (e.g., Chemistry Division).

9. Validity Profile Acceptance Criteria.

a. For chemical analyses, develop and implement a QA/QC plan as follows:

(1). If using an official (AOAC or FSIS validated) method, apply existing QA requirements.

(2). If using an unofficial quantitative chemical method, develop a validity profile in accordance with FSIS Directive 10,130.1.

b. For microbiology analyses, use QA/QC guidelines contained in the appropriate "Laboratory Communication(s)".

c. For pathology analyses, develop an appropriate validity profile using applicable controls.

d. If the urgency of the situation precludes this work, the validity profile acceptance criteria for each discipline may be modified with the concurrence of the appropriate Science Division Director.

10. Reporting Analytical Findings.

a. Prior to reporting the analytical findings, the Responsible Supervisor and Responsible Analyst will:

(1). Verify the receipt of forms and reports; and,

(2). Review the analytical findings.

Questionable results will be evaluated by the appropriate Science Division Director prior to official reporting.

b. Findings will be reported expeditiously to the Responsible Supervisor. Other program offices will obtain results through the Director, FSLD. The laboratory will follow special reporting instructions annotated on the FSIS Sample Control form as well as telecopy the results to FSLD.

c. For each Microbiology, Chemistry, and Pathology Section, detailed analytical records (including QA/QC analyses) as well as facsimiles of appropriate log book entries will be secured in locked file cabinet(s). These records will be maintained for at least 3 years, prior to storage in the Agency's archives.

D.L. Houston

Administrator