

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

33-04

6-14-04

**COMPLIANCE AND INVESTIGATIONS DIVISION (CID) PROTOCOL FOR OFF-SITE
COLLECTION OF BRAIN SAMPLES FOR BOVINE SPONGIFORM
ENCEPHALOPATHY (BSE) TESTING**

I. PURPOSE

This notice issues the protocol for CID inquiries related to the sample collection of brain samples for BSE testing of bovine animals that were "U.S. Condemned" on ante-mortem inspection at federally-inspected establishments and moved from the federally-inspected establishment to an off-site sample collection location (See FSIS 28-04 and 29-04). The sample collection locations are typically rendering operations, 3D/4D operations, landfills, collection sites, pet food manufacturers, and other non-federally inspected establishments or locations. The Animal and Plant Health Inspection (APHIS) Area Veterinarian-in-Charge (AVIC), APHIS technician or APHIS contractor will collect the brain sample. The purpose of the protocol is to verify that ante-mortem condemned cattle arrive at the locations and the Animal and Plant Health Inspection Service (APHIS) is aware of the cattle's arrival.

II. VERIFICATION OF REGISTRATION

Program Investigators (PIs) are to inquire if the subject firm has completed FSIS Form 5020-1, Registration of Meat and Poultry Program Handlers, in compliance with 9 CFR 320.5, and as further described in FSIS Notice 27-04 dated May 17, 2004. If the subject firm is not registered, the PI should give a copy of the form to management. The name of the management official that was presented the form and the date are to be recorded in the PI Daily Activity Report (DAR).

III. NOTIFICATION

The appropriate CID Regional Manager (RM) will be notified by the District Office of establishments that have an agreement with APHIS for the off-site sample collection of brains. The CID RM will notify the appropriate District Manager if condemned carcass does not arrive at the off-site sampling location.

DISTRIBUTION: Inspection Offices;
T/A Inspectors; Plant Mgt; TRA;
ABB; TSC; Import Offices

NOTICE EXPIRES: 7-01-05

OPI: OPPED

IV. PROCEDURES FOR RECORDING OFF-SITE SAMPLE COLLECTION LOCATIONS INTO THE PLANNED COMPLIANCE PROGRAM (PCP)

PIs are to record all off-site sample collection locations they visit as status code “B” in the Planned Compliance Program (PCP). They are to assign the sample collection location a primary business code “14” if no other type of business is conducted at the location. If the location conducts any other type of business, the PIs are to assign the appropriate business code as found under Appendix B in the Compliance Officer Manual and assign business code “14” as the secondary code. PIs are to complete the remaining inquiry and PCP documentation in the following manner:

A. Meeting with APHIS AVIC, Technician, or Contractor:

1. Conduct an entrance conference with the APHIS AVIC, technician, or contractor assigned to collect brain samples from FSIS ante-mortem condemned animals received from federally inspected establishment. Identify yourself, explain the purpose of your visit, and answer questions as they relate to the sampling initiative,
2. Review and discuss the procedures conducted when condemned cattle are delivered, and how APHIS is notified that the condemned cattle have arrived.

Seek answers to such questions as:

- a. How does the firm prepare the condemned cattle for sampling?
- b. How many hours per day and days per week are the sample collectors at the location, and are there times when a carcass would have to be held at the location because there was no sample collector available?
3. Discuss sampling procedures conducted by the APHIS AVIC, technician, or contractor.

B. Meeting with Off-Site Sample Collection Point Plant Management:

1. Conduct an entrance conference with management and identify yourself. Explain the purpose of your visit and answer questions.
2. Discuss the certification that the firm has from APHIS for receiving ante-mortem condemned cattle from federally inspected establishments and collecting samples.
3. Discuss the agreement that the firm has with the federally inspected establishments for receiving FSIS ante-mortem condemned cattle and collecting samples.
4. Discuss procedures that the firm conducts when receiving condemned cattle, preparing cattle for sampling, disposition of cattle after being sampled.
5. Document the registration status of the firm.

C. Facility Observations:

1. Observe and record the area set aside for collection of brain samples and carcass disposition area.
2. Conduct a physical observation of cooler for storing brain samples (*if available*).

D. Examine or Observe Handling of Condemned Cattle, Storage, and Shipping Practices:

1. Observe U.S. condemned cattle received from federally inspected establishments that will be sampled for BSE.
2. Observe the proper disposal of the condemned carcass and parts after it has been sampled.

E. Records Review:

Review all records for completeness and accuracy (i.e., receiving records, ownership and trace-back records, laboratory forms, fed-ex air bills, sample results, APHIS records, etc.). During initial reviews, it will be important to capture all salient documentation in the PCP for future use.

F. Exit Meeting with the APHIS AVIC, Technician, or Contractor and Off-Site Sample Collection Point Management:

1. Conduct exit conferences with the APHIS AVIC, technician, or contractor and the off-site sample collection point management. The PI should decide whether to do this jointly or independently based on his or her observations and sound reason.
2. Ask questions to clarify observations.
3. Discuss findings.
4. Provide the APHIS technician or contractor and collection point management the opportunity to ask questions.
5. Advise them that a PI may conduct follow-up visits.

If the PIs have concerns about the sample collection activities he or she is to note this in the PCP and contact the RM if necessary.

Philip S. Derfler /s/

Assistant Administrator
Office of Policy, Program, and Employee Development