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Voluntary Scrapie Flock Certification Program Standards

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Introduction

The Scrapie Flock Certification Program (SFCP) is designed to monitor flocks and certify the scrapie status of the animals enrolled in the program. Any sheep or goat owner or manager may apply to participate in the SFCP.

The Animal and Plant Health Inspection Service (APHIS) maintains a national information database that includes information about participating flocks in the SFCP. The following information is made available to the public on flocks participating in the program: name, address, flock ID, breeds of enrolled animals, enrollment date, and status date on the APHIS Web site at:

http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/. APHIS also prepares periodic summary reports from the national database on enrolled, infected, and source flocks that are available at:

http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/monthly_scrapie_rpt.pps

This document outlines the SFCP Standards and was approved by the Deputy Administrator of APHIS, Veterinary Services (VS), on April 5, 2007.

Part I—Definitions

The following definitions cover language specific to the SFCP. General scrapie program terms are defined in the Scrapie Eradication Uniform Methods and Rules (UM&R) at: http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/umr.pdf. A copy of the definitions from the June 1, 2005, edition of the UM&R is provided in appendix 5 but may be superseded in later editions. The SFCP Standards definitions and the UM&R definitions also will be superseded by any definitions pertaining to scrapie that are subsequently published in title 9, *Code of Federal Regulations* (9 CFR), parts 54 and 79, found at: http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/9cfr-54_79.pdf.

Board

The State Scrapie Certification Board as described in part II.B.

Certified Flock

A complete monitored category flock that has been participating in the program and has met the provisions of part III for 5 years or more.

Cull Animal

Any mature animal sold for slaughter, home slaughter, feeding for slaughter or through a livestock market other than as part of a bred ewe or breeding stock sale.

Enrolled Flock

A complete monitored or export monitored category flock that has been participating in the program but has not yet met the criteria for certified status.

Enrollment Date

The date on which the State Scrapie Certification Board received a complete application including an acceptable inspection report that was subsequently approved for initial program participation.

Export Certified Flock

An export monitored category flock that has been participating in the program and has met the provisions of part III for 7 years or more.

Flock Category

Classification of a flock with regard to scrapie or the SFCP. The possible categories include:

- Complete monitored (Enrolled, Certified);
- Export monitored (Export enrolled, Export certified);
- Selective monitored (Select);
- Pending enrollment;
- Exposed;

- Flock under investigation (FUI);
- Infected; and
- Source.

Found Dead

Any sheep or goat over 14 months of age that was located after death, or reasonably should have been located after death, in a condition such that an adequate sample could have been collected.

Mature Animal

Any sheep or goat over 14 months of age as evidenced by birth records or the eruption of the first permanent incisor.

National Scrapie Oversight Committee

A national committee composed of industry, State, and Federal representatives that gives guidance to APHIS on the policies and practices of the SFCP.

Nonparticipating Flock

A flock that is not enrolled in the SFCP.

Official SFCP Identification (ID)

A unique individual ID method approved by the Administrator that meets the following criteria:

- Permanent or tamper evident;
- Secure;
- Carries unique numbers from a central repository, or a unique premises number and individual number; and
- Traceable.

The following types of ID are currently approved for the SFCP:

- Tamper-evident ear tags approved by APHIS for use in the SFCP;
- An APHIS assigned premises and unique individual number tattoo in the flank, tail web, or ear;
- Electronic ID implants – Implants must be placed in a location allowed by FSIS, and used in conjunction with a visual ID device or method approved for use in the scrapie eradication program when moved off of the premises unless the animal is (1) moved without change of ownership; (2) transferred as a registered animal when the implant number is recorded by the registry on the registry certificate; or (3) moved to another SFCP enrolled flock and in any of these cases is accompanied by an implant reader and either a copy of the registration certificate listing the implant number as the registry ID or an owner statement listing the owner's name and address, scrapie premises ID number, the radio frequency ID device number, the name and address of the owner of the flock of birth if different, and the

destination;

- Registry tattoos – Legible registry tattoos from approved registries that have been recorded in the APHIS Scrapie National Generic Database (SNGD) may be used to identify goats while the animal resides on the premises where the animal was born. When the animal is moved off of the premises, the animal must be (1) accompanied by a copy of its registration papers and either moved without change of ownership or transferred as a registered animal; or (2) identified with another ID device or method approved for use in the scrapie eradication program.

Program

The Scrapie Flock Certification Program (SFCP).

Scrapie

A nonfebrile, transmissible, insidious, degenerative disease affecting the central nervous system (CNS) of sheep and goats. Scrapie, a transmissible spongiform encephalopathy, may cause, but is not limited to causing, the following signs in affected mature animals:

- Signs of CNS disease:
 - Weakness of any kind, including stumbling, falling down, having difficulty rising, or unable to rise; or
 - Behavioral abnormalities; or
 - Increased sensitivity to noise and sudden movement; or
 - Tremors; or
 - Star gazing; or
 - Head pressing; or
 - Bilateral gait abnormalities, including incoordination, ataxia, high stepping gait of forelimbs, bunny-hop movement of rear legs, or swaying of backend, but not including abnormalities involving only one leg or one front and one back leg; or
 - Intense rubbing, abrasions, or rough, thickened, and/or hyperpigmented skin:
 - Repeated intense rubbing with bare areas in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; or
 - Abraded, rough, thickened, or hyperpigmented areas of skin in areas of wool/hair loss in similar locations on both sides of the animal's body or, if on the head, both sides of the poll.
 - Other CNS signs; or
 - Weight loss despite retention of appetite or chronic weight loss in an animal with good teeth;
 - Death.

It is important to note that not all scrapie-affected animals show all clinical signs.

Scrapie Flock Certification Program (SFCP)

A voluntary State–Federal–Industry cooperative effort established and maintained to:

- Reduce scrapie’s occurrence and spread;
- Identify flocks that have been free of evidence of scrapie over specified time periods;
- Contribute to the eventual eradication of scrapie; and
- Enhance the marketability of enrolled animals.

SFCP Approved Breed Associations and Registries

Organizations approved by APHIS that maintain the permanent records of ancestry or pedigrees (including the animal’s sire and dam), individual ID, and ownership of animals. To be approved, the registry must submit documentation to APHIS that it is an established registry and each registry tattoo issued by the registry contains a unique premises ID number assigned by the registry and a unique individual animal ID number. The registry will, upon request, provide APHIS with information that will allow any association-registered animal to be traced to its flock of origin. A list of organizations approved by APHIS for participation in the SFCP are located at: http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/free-certi.shtml.

SFCP Standards

Cooperative procedures and standards adopted by APHIS and State scrapie certification boards for reducing the incidence and controlling the spread of scrapie through certification of flocks.

Status

The classification of a flock participating in the complete monitored category or export monitored category. Enrolled status is given to flocks that are approved to participate in the complete or monitored category. After the flock has successfully met all complete monitored program requirements for 5 continuous years, the flock will be eligible for certified status and, if enrolled in the export monitored category, will be eligible for export certified status after 7 years. Flocks that transfer to the export monitored status by October 1, 2009, will be grandfathered with their current status date or, in the case of certified complete monitored flocks, 5 years of status.

Status Date

Initially, the status date is equivalent to the enrollment date and is issued as the date of initial program participation. If the flock continues to meet all program standards, the status date will not change.

For flocks that acquire animals or commingle with animals that do not meet program standards under part III, the status date will change to the date the non-enrolled animals are acquired or commingled or to the status date of the flock with the most recent status date for animals commingled or acquired from an enrolled flock.

Part II—Administrative Procedures

A. Oversight of the SFCP

The National Scrapie Oversight Committee will be appointed by APHIS from recommendations made by the following groups:

- Animal Producers;
- Allied Industry;
- State Animal Health Officials;
- Accredited Veterinarians; and
- Animal Breed Registries and Associations.

Priority for committee membership will be given to producers enrolled in the program. The committee reviews the SFCP and makes individual recommendations to the Deputy Administrator regarding policy and technical improvements in the Certification Program.

The committee will meet at least once a year, consult with scientific and technical experts, consider program improvement suggestions, and support the program at national, State, and local sheep or goats events and in the sheep- and goat-producing community.

B. State Scrapie Certification Board

A State Scrapie Certification Board may be formed within each State to:

- Administer the SFCP;
- Review program enrollment applications and status advancement;
- Review situations that may result in a reduction of certification status or dismissal from the program; and
- Educate producers regarding scrapie.

The State Scrapie Certification Board will consist of APHIS' Area Veterinarian in Charge (AVIC), enrolled animal producers, and State animal health officials in cooperating States and may include accredited veterinarians and federal VMOs.

State Certification Boards should:

- Be chaired by an enrolled producer;
- Encourage sheep and goat breeding stock producers to be enrolled in the program;
- Support the program at State and local sheep or goat events and in the sheep and goat producing community; and
- Meet at least annually.

The AVIC, in cooperation with the State animal health official and enrolled flock owners, will appoint members to the State Scrapie Certification Board. Boards may delegate their authority to subcommittees and may enact more stringent requirements to fit their State's scrapie situation.

C. Duties of Program Participants

1. APHIS will:

- a. Perform inspections, provide guidance and education in cooperation with State animal health agencies and accredited veterinarians;
- b. When resources permit, assist owners with the collection and submission of diagnostic samples; and
- c. Maintain a records data base for use in the program.

2. Producers will:

- a. Establish and maintain records;
- b. Make animals available for inspection and records available for inspection and copying by APHIS representatives or State animal health officials and State Scrapie Certification Board representatives, given reasonable prior notice;
- c. Schedule an annual inspection within 11-13 months of the preceding inspection;
- d. Authorize access to records maintained by breed associations, registries, livestock markets, and packers;
- e. Identify animals with official SFCP ID as specified by these program standards;
- f. Allow State, Federal, or State Scrapie Certification Board representatives to enter premises to carry out program procedures;
- g. Have the necessary facilities and personnel available to assist in the inspection of animals and animal records;
- h. Report the following, as soon as discovered, to the APHIS Veterinary Services (VS) Area Office or as otherwise instructed:
 - o Scrapie suspect animals including any animals exhibiting CNS or other signs consistent with scrapie so that they can be evaluated and if indicated tested by a State or Federal veterinarian;
 - o Other animals found dead at over 14 months of age so that if possible they can be sampled for scrapie testing.
- i. Ensure that tissue samples are collected and submitted for scrapie testing from all animals exhibiting clinical signs of scrapie that do not recover or are culled. In the case of export monitored category participants, tissues must be submitted from all

- animals found dead at over 14 months of age, and if a mature animal is lost to inventory, a minimum of two mature culled animals must be sampled during the next 12 month period for each mature animal lost to inventory. An extension for sampling culls may be granted if insufficient animals are culled during the period. (NOTE: APHIS will assist producers when possible in collecting the required samples, but it is the responsibility of the producer to, if necessary, hire an accredited veterinarian to collect the sample or to ship the entire head chilled to a cooperating laboratory for collection.) Samples that do not yield a valid test result because they are improperly collected or shipped will be treated as animals lost to inventory;
- j. Report acquisitions of lower status or nonparticipating animals in accordance with part III;
 - k. Provide written notice to the board when voluntarily withdrawing from the program.
3. Breed registries and associations, livestock markets, and packers will:
- a. Maintain liaison with flock owners;
 - b. Assist in providing flock owners with information on the SFCP;
 - c. Facilitate the information exchange regarding transfer of animals; and
 - d. Encourage information reporting among flock owners, State animal health agencies, and APHIS.

D. Application for Program Status

1. Entry into the program

The State Scrapie Certification Board will review enrollment applications within 60 days of receiving the application package. If an application is approved, the status date for initial flock enrollment will be the date the State Board received the completed application package.

The application package includes:

- a. A completed program application, VS Form 5-22;
- b. A list of animals in the flock including the official ID numbers, breed, and sex information as specified by the certification category applied for; and
- c. An inspection report, VS Form 5-19, by an authorized State or APHIS regulatory official or an accredited veterinarian authorized by APHIS to perform this function. The inspection report includes verification of the information provided on the application by the flock owner, verification of the official SFCP ID on each animal listed in the application, and a statement that there are no animals in the flock exhibiting signs consistent with scrapie on the date of inspection.

State or Federal animal health officials will provide each enrolling program participant

and, if available, his or her accredited veterinarian with an educational scrapie review.

Once approved to enter the program, a flock will be issued an enrollment date. This date will serve as the status date until the flock fails to meet any of the program standards.

2. Advancement to Certified Status

When a flock has obtained a status date that is over 5 years old, or in the case of export monitored category 7 years (that is, it has met all of the program standards and has not acquired or commingled with unapproved animals), it may be advanced to certified status. The State Scrapie Certification Board will review flocks for advancement from enrolled status to certified status within 60 days of the receipt of the inspection for certification report. If the inspection report is approved, the certification status date will be the date the State Board received the completed inspection package.

The inspection report will include:

- a. A list of animals in the flock, including official ID numbers, breed, date of birth, sex and for rams their individual status dates, if different from the flock, and a list of all premises from which animals were acquired following enrollment provided by the owner and verified by the inspector; and
- b. An inspection report by a State or APHIS regulatory official indicating that the flock met all standards for certification and that the inspection included a complete inventory, inspection of each animal for clinical signs, a comprehensive review of the owner's records, including a reconciliation of the animal inventory and verification of the official SFCP ID.

3. Maintenance of Status

- a. During the annual inspection, a flock's status date will be maintained if:
 - The flock has not been designated as a source or infected flock since its status date;
 - The requirements for the status currently held by a flock have been fulfilled;
 - The flock has only had acquisitions or commingling of animals approved for the current status; and
 - It is determined that any high-risk animal that may have lambed in the flock is tested at necropsy and found negative on brain and lymph node.
- b. If a flock (1) has not met the minimum requirements for the status currently held; (2) has not remained in compliance with scrapie program requirements; and/or (3) has acquired or has commingled animals in the flock that did not meet the

requirements of the current status, then the flock's status date will convert to the date when the flock was brought back into program compliance or to the status date of the acquired or commingled animals. A lesser reduction may only be made in cases where the noncompliance was corrected and did not adversely impact the program's integrity.

- c. If a flock is placed in investigation and/or exposed status, the SFCP status will be suspended until the investigation and exposed status is closed. If it is determined that a high-risk animal lambled in the flock and that animal was not tested at necropsy and found negative on brain and lymph node, the flock's status date will be reduced to the date on which the animal left the flock. If a high-risk animal is retained, the flock's status will remain in suspension until the high-risk animal is tested at necropsy and found negative. If the animal dies without a test, the flock will be removed from the program.

E. Downgrading of Status

1. Scrapie is Found

If an enrolled or certified flock has a confirmed diagnosis of scrapie or is revealed through epidemiological investigation to be a source flock, the flock will be removed from the program. The owner of the removed flock may reapply for enrollment in the program after all high risk animals are removed and the flock has completed a flock cleanup plan.

2. Female Animals are Added

If a certified or export certified flock acquires or commingles with female animals that are not from a certified flock or export certified flock respectively, the status of the certified flock or export certified flock will be lowered, and its status date will change. If an enrolled flock acquires or commingles with female animals from a nonparticipating flock or from a flock with a more recent status date, the receiving flock will continue with enrolled status, but the status date will change. After acquiring or commingling with female animals from nonparticipating flocks, the receiving flock's status date will become the date that the female animals were acquired or commingled. After acquiring or commingling with female animals from enrolled flocks with a more recent status date, the receiving flock will have its status date reduced to the most recent status date of the flocks involved. If an acquired animal was subsequently determined to be a high-risk animal which may have lambled or aborted in the flock, and that animal was not tested at necropsy and found negative on brain and lymph node, the flock's status date will be reduced to the date on which the animal left the flock.

3. Male Animals are Added

If male animals are acquired from nonparticipating flocks, there will be no effect on

status unless the male animal does not meet the requirements in part III, section A.6.a. If they do not meet these requirements, the status date of the receiving flock will be changed to the most recent status date of the flocks involved or for nonparticipating flocks to the date of acquisition or commingling. Rams acquired from lower status or non-participating flocks will maintain the status of the flock from which they were acquired and may accrue status as long as they are not later determined to be an exposed or suspect animal and the flock in which they reside has the same or higher status. See part III, section A.7, for germ plasm acquisitions.

4. Compliance Irregularities

Except for owner-reported reductions, the AVIC will notify a flock owner that his or her flock is being considered for reduction in status or removal from the program. The State Board will give the owner of the affected flock an opportunity to present his or her views to the board before it makes its final recommendation about reduction or removal. The State Scrapie Certification Board shall recommend downgrading a participating flock's status or removing it from the program if its owner or manager has not complied with the standards. The AVIC may suspend the status of the flock pending action by the board. The AVIC will decide the status of the flock after considering the board's recommendation and will notify the flock owner of the decision. If the board fails to act in situations that may compromise the integrity of the program, the AVIC shall downgrade the status.

Any flock whose owner does not arrange inspection within 14 months of the preceding inspection will have its status reduced by the number of months delinquent. Any flocks that are not inspected within 18 months of the preceding inspection will be removed from the program.

While not a comprehensive list, the following infractions will result in a status downgrade to the date the flock was brought back into program compliance:

- a. Failure to report acquisitions that would have resulted in a downgrade of status;
- b. Failure to officially identify sexually intact animals moved from the premises other than to slaughter or to a terminal feedlot at under 12 months of age;
- c. Failure to submit required samples;
- d. Failure to report animals exhibiting clinical signs or found dead at over 14 months of age;
- e. Failure to properly document dispositions and acquisitions.

If the same infraction occurs on a second occasion, the flock will be removed from the program.

5. Owner-reported reductions in flock status or status date

These status changes will be made as soon as possible following notification of the State Scrapie Board or AVIC and without review by the board, unless the owner requests that the board do a formal review at the time the acquisition or commingling is reported.

F. Suspension of Status

1. Flock is designated an exposed flock or a FUI.

If a flock is designated an exposed flock or FUI, it will retain its current status date but will be suspended from selling animals as enrolled animals until the FUI and/or exposed designation is closed. If as a result of the investigation, it is determined that a high-risk animal lambled in the flock and that animal was not tested at necropsy and found negative on brain and lymph node, the flock's status date will be reduced to the date on which the animal left the flock. If a high-risk animal is retained, the flock's status will remain in suspension until the high risk animal is tested at necropsy and found negative. If the animal dies without test, the flock will be removed from the program.

2. Flock owner has been notified of pending downgrade in status.

The AVIC may suspend the status of the flock pending the outcome of the hearing.

G. Appeal

The flock owner may appeal a decision to downgrade the status of a flock to the Administrator within 30 days after notification of the decision.

H. Withdrawal from the Program

Producers may voluntarily withdraw by written notice to the State Scrapie Board or AVIC. If producers voluntarily withdraw from the program and then request in writing to the board to be re-enrolled within 1 year, they may be re-enrolled upon completion of a satisfactory inspection without submitting a new application. They will keep the original enrollment date, but their status date will be reset to reflect the date of the inspection.

Producers who have been withdrawn for more than a year will need to go through the complete application procedure and State Board approval. They will be given a new enrollment and status date to reflect the date the board approves their application.

Part III—Program Requirements

A. Complete Monitored and Export Monitored Categories

1. Program Status

Complete monitored and export monitored category flocks gain program status based on the flock's status date. Once a flock is approved to participate in the program, that flock will be considered an enrolled flock with a status date based on the date the approved application is received by the board. An enrolled flock is one that has been approved to participate in the program under part II, section D.1. A certified flock is an enrolled flock that has participated in the program for more than 5 years and has met the necessary requirements to progress beyond enrolled status. An export certified flock is a flock that has participated in the program for more than 7 years and has met the necessary requirements to progress in the export monitored category.

2. General Provisions

The flock owner and managers who participate in the complete monitored or the export monitored category agree to:

- a. Immediately report to a State or Federal animal health official or an accredited veterinarian scrapie-suspect animals, animals suspected of other neurologic and chronic debilitating (prolonged wasting) illnesses, and animals found dead at over 14 months of age.
- b. Ensure that proper tissue samples are collected and submitted for diagnostic purposes from animals that exhibit, or in the cases of dead animals exhibited, clinical signs of scrapie. Participants in the export monitored category will submit samples from all dead animals over 14 months of age. Animals exhibiting clinical signs shall not be used for breeding or be disposed of without the prior approval of a State or APHIS representative.
- c. Officially identify all animals 1 year of age or older within a flock. Officially identify all acquired animals prior to commingling with the flock if not already identified with an SFCP approved ID device. Leased rams may be identified with any official scrapie program individual animal ID method. All sexually intact animals less than 1 year of age must be officially identified when a change of ownership occurs, with the exception of those moving direct to slaughter or to a terminal feed lot.

The following are types of program-approved ID:

- Official tamper-evident eartags;
- APHIS assigned ear tattoo or in the case of earless animals and animals that

- cannot be ear tattooed, a flank or tail fold tattoo;
- Electronic implant – When moved off the premises, the animal must be accompanied by a reader that can read the implant and an owner statement listing the implant number or a Certificate of Veterinary Inspection (CVI) or registration certificate listing the number. If moving with change of ownership, a visual official ID must also be used unless moving to another SFCP flock that uses microchips or in the case of registered animals as described for registry tattoos; or
 - Registry tattoos – When the animal is registered with an approved goat registry organization, the animal may be identified with registry tattoos or registry microchips if the following conditions are met:
 - Each tattoo contains a unique premises ID number and a unique individual animal ID number;
 - The registry has provided APHIS with a letter indicating that the registry: (a) uses the required type of tattoo; and (b) will, upon request, provide APHIS with information that will allow any association-registered animal to be traced to its flock of origin. A list of the approved organizations can be found at: http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/free-cert.shtml
 - The tattoo prefixes are recorded in the SNGD;
 - When moved off the premises, the animal is accompanied by a copy of the registration certificate or a CVI showing the tattoo or microchip number, and if there is a transfer of ownership, the transfer is recorded with the breed registry; and
 - If moved without the registration certificate or a CVI, the animal must be identified with another form of official ID.

NOTE: Users of tattoos must:

- Use two separate tattoos. A scrapie premises identification number assigned by APHIS or an approved registry tattoo prefix that has been provided to APHIS for entry into the SNGD as explained above and a legible, unique, individual animal number; and
- Apply the scrapie premises identification number in the right ear and individual animal number in the left ear, or place both numbers in each ear or on the right flank in the wool-free area.

A secondary form of ID may be maintained at the owner discretion.

- d. Maintain records in accordance with the following:

Required records must be maintained in an organized manner that can be easily located and used to reconcile the animal inventory during inspections. Records

must be kept for a minimum of 7 years after an animal dies or has otherwise been removed from the flock.

The following records must be kept on animals present in the flock at the time of initial participation:

- Official and any secondary ID number or marks;
- Sex;
- Species and breed or cross, or if breed unknown color and type;
- Disposition including, disposition or sale date; if dead, cause of death if known; and scrapie test report for animals required to be tested, or movement date and to whom (name and address);
- Date of birth or if date of birth is unknown, estimated year of birth;
- Flock of origin and date of entry if not born in flock;
- Sire and dam's official and any secondary ID if known; and
- Genotype at codon 136, 154, and 171 if known.

The following records are to be kept on acquired or natural additions to the flock subsequent to enrollment:

- Official and any secondary ID number;
 - Sex;
 - Species and breed or cross, or if breed unknown, color and type;
 - Date of birth (must have at least month and year of birth);
 - If acquired, the flock of origin (name, address, and flock ID number) and date of entry and their flock of origin's status and status date on date of acquisition;
 - Disposition, disposition or sale date; if dead, cause of death if known; and scrapie test report for animals required to be tested, or movement date and to whom (name and address);
 - For registered animals, sire and dam's official and any secondary ID numbers including registration number; and
 - Genotype at codon 136, 154, and 171 if known.
- e. Request breed associations and registries, livestock markets, and packers to disclose records to APHIS representatives or State animal health officials when requested by the State or APHIS. These records will be used to trace a source of exposure and other exposed animals.
 - f. Notify the State Scrapie Certification Board or AVIC about acquisitions that would lower the status, status date, or both, of a flock, as per part III, section A, within 30 days after the animal enters the flock.
 - g. Schedule an inspection within 11-13 months of the preceding inspection. Make

animals and records available for inspection by APHIS representatives, State animal health officials, and State Scrapie Certification Board representatives, given reasonable prior notice. The owner will provide the necessary facilities and personnel to assist in inspecting the ID of each animal and the records.

- h. Ensure that tissues from scrapie-suspect animals and animals over 14 months of age suspected of other neurologic and chronic debilitating (prolonged wasting) illnesses will be submitted to an official laboratory in accordance with part IV and appendix 1. Tissues other than those listed in appendix 1 and tissue from any animal found dead at over 14 months will be submitted if requested by the State Scrapie Certification Board or State or Federal animal health official. Flocks enrolled in the export monitored category will submit samples from all animals found dead at over 14 months of age or that have lambed in the flock.
- i. Owners of flocks enrolled in the export monitored category will ensure and document that all culls are either slaughtered under State or Federal inspection or inspected by an accredited veterinarian prior to sale and that tissues are submitted from any animal exhibiting a chronic wasting condition or other signs associated with scrapie or that dies at over 14 months of age. It is expected that at least 1 percent of the mature animals in the flock will exhibit such signs and be sampled each year. Export monitored flocks will test for scrapie, at least 30 animals over 14 months of age born on the premises that are representative of the flock with at least 5 in each 2-year period and an additional 2 animals for each animal over 14 months of age lost to inventory. Lost to inventory only applies to animals on operations where dead animals are not discovered due to predators, adverse weather, or similar situations. Animals known to be genetically less susceptible or resistant may not be used to meet this requirement unless all the genetically susceptible members are also tested. Testing must be completed prior to being export certified. If insufficient animals die or are culled to meet the necropsy testing requirement, it may be met through third lid, lymph node/tonsil biopsy, or other approved live animal test of all genetically susceptible animals in the flock with negative results. Once export certified, all animals over 14 months of age found dead and 2 cull animals for each animal over 14 months lost to inventory must be sampled. If less than 5 are found dead or cull animals are available for sampling in a 2-year period, live animal testing may be used.

3. Inspections

An authorized Federal or State animal health official or an accredited veterinarian authorized by APHIS must inspect enrolled flocks every 11-13 months, after the first inspection. If it is necessary to change the annual date to facilitate flock management, a flock may be inspected before 11 months and every 11-13 months thereafter. Inspectors will conduct a complete inventory and will reconcile that inventory with the producer's records.

The inspector will check each animal for official ID and scrapie signs and will examine records for:

- a. Completeness;
- b. Accuracy; and
- c. All acquisitions, departures, births, and deaths.

4. Evidence of Scrapie

Enrolled flocks identified as infected or source or designated noncompliant will be removed from the program and handled according to 9 CFR, parts 54 and 79. If an enrolled flock receives a high-risk animal and declines to make it available for necropsy testing, the flock's status will be suspended until the animal dies and is necropsied. If it is determined that a high-risk animal lambled in the flock and that animal was not tested at necropsy and found negative on brain and lymph node, the flock's status date will be reduced to the date on which the animal left the flock. SFCP flocks required to complete a Post Exposure Management and Monitoring Plan (PEMMP) in accordance with the scrapie eradication UM&R will have tissues (brain and retropharyngeal lymph nodes) submitted for diagnostic purposes from all animals 14 months of age or older that die on the farm as part of the PEMMP. The probable cause of death must be maintained in the records. These submissions will continue for 5 years. If current regulations mandate more restrictive actions, the regulations will take precedence over the recommendations of this program.

5. Alternative Option for Certifying Flocks (Piloted to determine its effectiveness before being used for export certification)

Flocks may qualify for certification by (1) maintaining a closed ewe flock other than to ewes from export certified flocks for 7 years and must remain closed once export certified to maintain certified status; (2) comply with the flock inspection and cull animal inspection requirement; (3) comply with the ID and record keeping requirements for animals entering and leaving the flock; (4) archive an official DNA sample from all rams used for breeding at an APHIS designated laboratory so that random parentage testing can be conducted to verify that the flock is closed; (5) test a minimum of 30 representative animals over 14 months of age of unknown or susceptible genotype at necropsy or slaughter, including all mature animals found dead each year, for a total of 300 prior to certification and a minimum of 30 each year thereafter. Alternatively, producers may certify flocks by officially genotyping the entire flock, identifying all genetically susceptible animals and submitting all of them for testing at slaughter or necropsy. The submission of these animals may occur over time. To use the genotyping method, the flock must have been closed to female additions from other than export certified flocks for at least 36 months and at least 30 representative susceptible animals over 14 months of age born on the premises must be tested. To retain certification status, all mature animals found dead and mature culls

must be tested each year to total 30, unless fewer animals are culled or die during the year.

6. Acquisitions

The State Scrapie Certification Board must be notified about all acquisitions during the annual inspection process and all acquisitions that would result in a downgrade in status (do not meet program standards) within 30 days of acquisition.

a. Male animal acquisitions:

Enrolled, export certified, and certified flocks may acquire breeding male animals from any flock if the male animals are:

- Officially identified to flock of birth with SFCP approved ID. Leased or loaned rams that reside in the flock only during the breeding season may be identified with ID approved for the regulatory program
- Shown on the flock inventory with the status and if applicable the status date of their flock of origin
- Not scrapie-positive or exposed animals
- Showed no clinical sign of scrapie at time of acquisition

(See II.E.3 for male animals not meeting these requirements.)

Acquired male animals will retain the status date of their flock of origin if they are not commingled with lower status females or determined to be scrapie exposed or infected animals.

Currently, there is no scientific evidence that implicates male animals as a risk for the spread of scrapie, but male animals cannot be totally ruled out as a risk of scrapie exposure. Producers should consider risk when selecting male animals from nonparticipating flocks.

b. Female animal acquisitions:

Enrolled flocks may acquire female animals from flocks with the same status date or higher. If an enrolled flock acquires female animals from an enrolled flock with a more recent status date, the status date of the receiving flock will become the most recent status date of the flocks involved. Export enrolled flocks may acquire female animals from export enrolled flocks with the same status date or higher. If an export enrolled flock acquires female animals from an export enrolled flock with a more recent status date, the status date of the receiving flock will become the most recent status date of the flocks involved. Owners of export enrolled

flocks may not acquire animals from enrolled or certified flocks after October 1, 2009, without a loss in status. Owners or managers of certified flocks may purchase female animals from certified flocks, regardless of status date, or export monitored flocks with more than 5 years of status without a change in enrollment status. Owners or managers of export certified flocks may purchase female animals from export certified flocks, regardless of status date, without a change in enrollment status. The flock owner must notify the board of acquisitions, which may change the flock's status or status date within 30 days of acquisition and must inform buyers of the lower status date.

c. Program status transfer with purchased animals:

A purchasing flock may retain the status date of acquired animals only if the animals have not been commingled with:

- Nonparticipating animals or
- Animals from a flock with a more recent status date

When establishing a new flock entirely from one or more enrolled, export enrolled, export certified, or certified flocks, the lowest flock of origin's status date from which female animals were acquired will transfer to the new flock, if the owner of the new flock notifies the State Scrapie Board and submits an application for participation in the program, VS Form 5-22, within 30 days of the animals' arrival on the farm. Likewise when moving an established flock to a new location, the owner must notify the scrapie board or the AVIC, in writing, of the new location; and if moving between States, a new application, VS Form 5-22, must be submitted within 30 days and a complete application package within 90 days. Applications or notifications received beyond 30 days will be treated as new applicants to the program.

Animals from a flock of higher status or an enrolled flock with a status date older than the flock of destination will convert to the lower flock status (i.e., from certified to enrolled) with the status date of the flock of destination.

7. Commingling

A flock's status and status date will change if:

- a. Female animals are commingled with female animals from, or are housed in the lambing or kidding facilities of animals from, a nonparticipating flock or an enrolled flock with a more recent status date, or a lower category flock other than limited contacts, and then returned to the original flock; or
- b. Male animals do not meet program standards or if a male animal is used in a nonparticipating flock that is an infected, source, or exposed flock and then

returned to the enrolled flock. Enrolled flocks are required to use the following risk-reduction strategies when rams are maintained off the enrolled premises: (NOTE: Rams in the export certified program will take on the status of the flock in which it resided if the status is lower.)

- No commingling with pregnant female animals in the nonparticipating or lower status flock or within 60 days following lambing or kidding.
- No housing or maintenance of the male animal in confined lambing or kidding facilities of the nonparticipating or lower status flock.
- The male animal will reside in the enrolled flock except when being used for breeding purposes in another flock.

Male animals enrolled in the export certification program will have their individual status lowered to that of the other flock if the male animals are commingled with female animals from or housed in the lambing or kidding facilities of animals from a flock not enrolled in the Export program or an export enrolled flock with a more recent status date, other than limited contacts, and then returned to the original flock.

8. Use of Semen and Embryos

Participating flocks may not use germ plasm from any donor found to be a scrapie-positive animal, scrapie-suspect, genetically susceptible exposed animal, or high-risk animal.

Participating flocks may use semen from lower status or nonparticipating flocks with no effect on program status or status date. Semen may not originate from a scrapie suspect, scrapie-positive, or a genetically susceptible exposed animal.

Enrolled or certified flocks may receive embryos with no effect on program status or status date if the embryos originated from:

- a. Flocks with the same or higher program status and category and status date;
- b. A foreign country free of scrapie as designated by APHIS; or
- c. A flock in a foreign country that has program standards that APHIS has recognized as equivalent to the ones in this publication, and the flock has met the requirements for export certified free status.

To have status in the SFCP, an embryo must be stored and a record kept such that the identity, status, and status date of the embryo can be determined. Therefore, the record must include the identity, status, and status date of the embryo donor and the identity

and status of the embryo sire and whether the embryo was produced by artificial insemination.

Embryo recipients must meet the program's requirements for female animal acquisitions.

An embryo will have the highest status and the greatest number of months of status achieved by the donor at or following collection, unless the donor's status is downgraded as a result of the donor or the donor's flock having been exposed to scrapie within 72 months prior to collection. In this case, the embryo will then have the highest status and the greatest number of months of status achieved by the donor following the downgrade. Changes in donor flock's status following implantation of the embryo into the recipient will have no retroactive effect on the recipient flock's status or status date. The sire of the embryo or the semen used to produce the embryo must have met program requirements for use in enrolled flocks at the time of embryo collection. In addition, the sire must not have been determined to be scrapie positive or otherwise ineligible prior to implantation.

An embryo may be given export certified status irrespective of the donor's status if (1) the donor survives for at least 18 months after collection; (2) the donor is necropsied and tissues are submitted in accordance with appendix 1 and found negative for scrapie on brain and lymphoid tissue; (3) the resulting offspring is determined by DNA testing to have been the offspring of the donor; (4) the sire of the embryo or the semen used to produce the embryo met the program requirements for use in enrolled flocks at the time of embryo collection and the sire was not later determined to be scrapie positive, or the sire met the same requirements as the donor; and (5) the recipient resides in an export certified flock. (All testing will be done at the owner's expense.)

The status and status date of the embryo will be converted to the status and status date of the recipient on the date of implantation unless the status date of the embryo is more recent.

A flock owner may request that the State Scrapie Board review the status and status date of an embryo prior to implantation.

9. Imported Animals

Imported animals from foreign countries may enter the program if they have been legally imported and have reached certified level in an equivalent export certification program recognized by APHIS or the country of origin is recognized free of scrapie by APHIS. These animals cannot at any time have commingled with female animals of a lower program status.

B. Selective Monitored Category

The selective monitored class is open to any flock and is mainly intended to help slaughter-lamb producers who wish to have an additional method of scrapie surveillance in large production flocks. Selective monitored category flocks may apply for enrolled status in the complete monitored category by making application to the State Scrapie Certification board under part II, section D1, and by meeting the requirements of the program.

1. Entry into the Selective Monitored Category of the Program

The State Scrapie Certification Board will review enrollment applications within 60 days of receiving the application package. If an application is approved, the initial flock enrollment date will be the date the State Board received the completed application package for entry into the selective monitored category of the program.

The application package includes:

- a. A completed program application;
- b. A list of male animals over 1 year of age in the flock including at least official ID numbers, breed, and sex information as specified by the certification category applied for; and
- c. An inspection report by an authorized State or APHIS regulatory official, including verification of the information provided on the application by the flock owner and verification of the official ID of each animal listed in the application.

State or Federal animal health officials will provide each enrolling program participant and his or her accredited veterinarian with an educational scrapie review.

Once approved to enter the selective monitored category of the program, a flock will be issued an enrollment date.

2. Identification

Participants must officially identify all male animals 1 year old or older.

3. Animal Records

Participants must keep the following records for all male animals 1 year and older:

- a. Official and secondary ID;
- b. Breed;
- c. Acquisition date and flock of origin; and
- d. Disposition—date and cause of death if known, or date of movement and to whom.

4. Inspections

An authorized APHIS representative or State animal health official must inspect

participating flocks every 11–13 months.

Inspectors will check:

- a. Each male animal 1 year old or older for official ID;
- b. Records of slaughter at the Food Safety and Inspection Service (FSIS) or State inspected establishments for all cull animals;
- c. The flock for signs of scrapie; and
- d. The records for completeness and accuracy.

5. Routine Monitoring for Evidence of Scrapie

These flocks will be monitored for evidence of scrapie by one of the following methods:

- a. Flocks with 1,000 female animals or fewer must submit 1 animal for scrapie diagnosis as specified in part IV and appendix 1 each year. For flocks with more than 1,000 female animals, a submission rate of 1 animal per 1,000 must be made. The animal(s) should be an animal that was culled or died at more than 2 years old.
- b. If any animal 2 years old or older is necropsied by an accredited veterinarian, tissues will be submitted for scrapie diagnosis as specified in part IV and appendix 1.

The scrapie diagnostic requirement would be waived if a flock had no death or cull losses in animals more than 2 years old during the reporting period. All submissions of tissues for scrapie diagnosis must be made by an accredited veterinarian or an APHIS representative or a State animal health official.

6. Slaughter Inspection

An accredited veterinarian, State, or Federal veterinarian will inspect all cull female animals in selective monitored flocks for clinical signs suggestive of scrapie:

- a. Before slaughter; and
- b. While the animals are still identifiable to the flock of origin.

7. Evidence of Scrapie

Any animal(s) showing clinical scrapie signs (e.g., neurologic signs) in a selective monitored flock must be reported to the AVIC or to a State animal health official. Upon death, the animal must be necropsied by an accredited veterinarian or an APHIS or State regulatory veterinarian, and its tissues must be submitted in accordance with part IV and appendix 1.

These animals shall not be used for breeding or be disposed of without the prior approval of a State or APHIS representative.

Selective monitored flocks identified as infected, source, or exposed flocks will be handled according to 9 CFR, part 79. Upon confirmation of scrapie, the flock's status will change to infected or source flock. Flocks on PEMMPs must be in compliance with the PEMMP in order to remain in the selective monitored category.

8. Acquisitions and Movements

Selective monitored flocks must not receive animals from flocks listed as infected, source, noncompliant, or exposed flocks.

Owners or managers of selective monitored flocks:

- a. Are encouraged to acquire animals from complete monitored flocks, and
- b. Must officially identify all male animals 1 year old or older and all male animals when ownership changes, except for those animals moving in slaughter channels.

9. Maintaining Status in the Selective Monitored Category

A selective monitored flock will maintain its status indefinitely, provided that the flock continues to meet the selective monitored requirements, or until it enters the complete monitored category.

Part IV—Laboratory Procedures and Test Interpretation

A. General Considerations

APHIS approved laboratories will examine all SFCP tissues when submitted per appendix 1. The approved laboratory will report diagnostic findings to APHIS. Any result other than not detected will be confirmed and reported by National Veterinary Services Laboratories (NVSL) through the AVIC to the submitter.

B. Laboratories

Scrapie testing will be conducted at NVSL or at a laboratory approved by APHIS to conduct scrapie testing. Samples from clinical suspects will be submitted directly to NVSL unless the animal was submitted to a State diagnostic laboratory for necropsy by the owner. In the latter case, the State diagnostic laboratory may conduct testing to rule out other conditions before forwarding the required samples to NVSL. Samples from suspect animals are sent to NVSL so that supplementary tests can be run if indicated.

C. Diagnostic Tests

Approved laboratories must use currently recognized procedures for examining tissues and for establishing a presumptive scrapie diagnosis. All positive and inconclusive tests conducted at approved laboratories will be confirmed and further evaluated at NVSL.

Part V—Flock Information

The National Animal Health Programs staff of VS prepares periodic reports from the national database on Enrolled, Infected, and Source flocks. The following information will be made available to the public on flocks participating in the program: name, address, flock ID, breeds of enrolled animals, enrollment date, and status date. These reports or lists are publicly available through:

1. State animal health representative;
2. AVIC;
3. National Animal Health Programs staff at (301) 734-6954; and
4. APHIS' Website: http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/

Appendix 1—Specimen Collection and Submission

When scrapie is suspected in a live or dead animal or when an animal dies at over 14 months of age¹, the owner shall contact an APHIS representative, a State animal health official, or an accredited veterinarian. If an APHIS representative or a State animal health official is unavailable, it is the responsibility of the producer to have an accredited veterinarian collect the sample or to preserve the head for sampling by skinning, refrigeration, and shipment to a diagnostic laboratory designated by the AVIC for this purpose (see **Head Removal and Whole Head Packaging Procedures section for instructions.**) The collector will include the following with each diagnostic submission:

1. Completed VS Form 10-4 (NOTE: the VS Form 10-4 is only for use by an APHIS representative, a State animal health official, or an accredited veterinarian with approval of the AVIC) or in the case of whole heads submitted by the owner, the owners, name, address, phone number, flock ID, and the animal's ID numbers, age, breed, sex and any clinical signs observed;
2. All ID devices, tattoos, and brands on the animal;
3. Age of animal based on dental examination and owner records;
4. Flock ID, species, breed, and sex of animal;
5. Brain and other tissues collected and packaged as described below; and
6. Any additional samples as requested by the AVIC or State Veterinarian, including samples requested for research.

A. Safety Precautions

It is the responsibility of the collector to take appropriate safety precautions. Measures should be taken to avoid contact with specimens. Adhere to the following safety precautions to ensure that you minimize your risk of exposure to pathogens:

1. Wear personal protective equipment (PPE) at all times;
2. Cover cuts, abrasions, and wounds with waterproof dressing if left not covered by PPE;
3. Use face and respiratory protection, which includes a well-fitted respiratory mask and face shield or goggles to protect from infective droplets or tissue particles. Wear gloves

¹Unless instructed to do so by an APHIS or State representative only producers enrolled in the export monitored category must submit all found deads.

while handling specimens and formalin;

4. Use formalin in a well ventilated area;
5. Take steps to avoid creating aerosols, splashes, and dusts;
6. Wash hands and exposed skin following collection procedures; and
7. Wash and disinfect protective clothing and instruments thoroughly after use. Use 50 ounces. [6-1/4 cups] bleach to enough water (78 ounces. or 9 3/4 cups) to give 1 gallon of solution) at room temperature (at least 18.3 °C [65 °F]) for 1 hour.

B. PPE

PPE is designed to minimize exposure to pathogens while collecting samples.

According to Occupational Safety and Health Administration, PPE is defined as “specialized clothing or equipment worn by employees for protection against health and safety hazards. PPE is designed to protect many parts of the body, i.e., eyes, head, face, hands, feet, and ears.”

PPE is selected based upon the environment, physical hazards, and ability to complete the task. PPE is a balance between protection and comfort. PPE should protect you from the physical hazards of the collection environment, while allowing you to comfortably collect specimens. Even though the environment where you are collecting specimens will differ, the following PPE must be worn at all times during collection of scrapie specimens:

1. Skin Protection:
Protect your skin from contact with fluids during specimen collection. Wear waterproof coveralls, preferably disposable, or coveralls with a waterproof apron and forearm protectors.
2. Eye and Face Protection:
Protect your eyes and face from any aerosols, splashes, or dusts that may be created while collecting specimens. Eye protection includes safety glasses, safety goggles, or a face shield.
3. Hand Protection Gloves:
 - a. Wear metal or mesh gloves. Always wear the cut resistant glove (Hantover, Koch, or Packer) on your off hand (left hand for right handed individual and right hand for left handed individual.) Find a cut resistant glove that fits against your skin and then wear a rubber glove on top of it.
 - b. Wear latex or nitrile examination gloves or thick rubber gloves that extend half way

up the forearm. Many people prefer the long thick rubber gloves for the added protection.

4. Foot Protection:

Protect your feet from injuries such as spills or splashes, impact, compression or exposure. Wear steel toed rubber boots when collecting specimens. If steel toed boots are not available, pullover rubber boots are acceptable.

5. Respiratory Protection:

Face masks/respirators are recommended if the environment includes aerosols, splashing, or flying debris as may be encountered with certain methods of brain removal or tissue handling. Though scrapie is not known to be transmissible through air nor is it known to be transmissible to man, during scrapie specimen collection other zoonotic diseases such as rabies, Q fever, or *Listeria* may be present.

C. Instructions for Veterinarians and Animal Health Technicians

1. Collector's Responsibility

It is vital that specimens submitted to NVSL or the contract laboratories are able to be traced to the source animal and farm. As the collector of the specimens, it is vital that you accurately complete the specimen collection and submission process. Failure to accurately collect and submit specimens may result in the erroneous eradication of animals, which is an irretrievable loss to farmers and producers.

When collecting specimens you are responsible for:

- a. Following the laboratory's procedure for notifying the laboratory of incoming specimens;
- b. Contacting the delivery service. Ensure that the package containing fresh tissues will be delivered overnight;
- c. Properly completing the specimen submission form, VS Form 10-4 or electronic 10-4. Be sure to indicate whether the animal was an exposed animal or an animal with no known exposure. Also indicate whether the animal was exhibiting clinical signs. If the animal exhibited clinical signs, list the signs in the Additional Data Section of the VS form 10-4;
- d. You will need to make four copies of the completed VS Form 10-4:
 - o One for your files (submitter's copy);
 - o One for the animal owner or collection site;
 - o One submitted to the VS Area Office; and
 - o One submitted with the specimen.
- e. Correctly label specimen collection containers; and
- f. Properly collect obex, tonsil, cerebellum, and retropharyngeal lymph nodes (RPLN).

For scrapie suspects, the remainder of the brain must also be collected.

2. Labeling Sample Containers

The specimen collection containers must be properly labeled. The information on the label provides detailed information to the laboratory regarding the specimens. The sample number or sample barcode on the sample container must be the same as on the completed VS Form 10-4.

Ensure that you clearly label both the top and the side of the sample container using the provided barcode sticker. If you do not have a barcode sticker, identify the sample by either typing the information or using a permanent marker. Verify that the sample number that appears on the top and side of the sample container and the completed VS Form 10-4 are identical.

The side label must include:

- a. Type of specimen;
- b. Animal ID number; and
- c. Sample ID number (the number assigned to this sample on the VS Form 10-4).

3. Preserving Specimens

You must properly preserve scrapie specimens to ensure accurate test results. Scrapie diagnosis requires the submission of fresh and fixed specimens.

Fresh specimens that are used for DNA comparison and additional testing must be kept chilled or frozen. While dry ice may be used, it is usually best to ship the chilled or frozen tissues overnight on icepacks.

Fresh specimens for routine submissions (animals that are not scrapie suspects) include:

- a. 2 RPLN (1 medial and 1 lateral);
- b. Brainstem/cord tissue (the cranial and caudal brainstem and spinal cord that remain after the obex section is removed); **NOTE: There should be about 1 inch of tissue cranial and caudal to the obex or 5 grams of tissue.**
- c. Entire cerebellum; and
- d. Animal ID device (Collect the animal ID device with the ½ inch of adjoining tissue. This will allow DNA verification if necessary.)

Fresh specimens for animals that are scrapie suspects include:

- a. 2 RPLN (1 medial and 1 lateral);
- b. 1 tonsil;
- c. Brainstem/cord tissue (the cranial and caudal brainstem and spinal cord that remain after the obex section is removed); **NOTE: There should be about 1 inch of tissue**

cranial and caudal to the obex or 5 grams of tissue.

- d. 1/2 cerebellum;
- e. The left half of the cerebrum and midbrain;
- f. Animal ID device. (Collect the animal ID device with the ½ inch of adjoining tissue. This will allow DNA verification if necessary.)

Formalin-fixed specimens - used for immunohistochemistry testing and histopathology. The specimen must be submerged in formalin (follow the guideline 10 parts formalin per 1 part specimen.) Do not allow the specimens to freeze.

Formalin-fixed specimens for routine submissions (animals that are not scrapie suspects) include:

- a. 1 medial RPLN;
- b. 1 tonsil; and
- c. Obex – pencil width slice (1 cm) that includes the apex of the V.

Formalin-fixed specimens for animals that are scrapie suspects include:

- a. 1 medial RPLN;
- b. 1 tonsil;
- c. Obex – pencil width slice (1 cm) that includes the apex of the V;
- d. 1/2 cerebellum;
- e. The right half of the cerebrum and midbrain; and
- f. Animal ID device (Collect the animal ID device with the ½ inch of adjoining tissue. This will allow DNA verification if necessary.)

NOTE: Place all formalin fixed specimens, the obex, tonsil and RPLN, from a single animal, in the same formalin collection container. Each fresh tissue must be placed in a separate bag. Ensure the sample container correctly lists all specimens included.

4. Collection Procedures

The collection of the obex, tonsils and RPLN can be completed using several methods. However these collection procedures describe the preferred collection methods to prevent inadvertent damage to the tissues during collection. Other methods may be used. Contact an experienced professional for more information regarding alternative collection methods.

The following equipment will help to ensure proper specimen collection:

- a. Sharp boning knives;
- b. Disposable scalpel blades, disposable scalpels, or a large scalpel blade is acceptable;

- c. Rat-tooth forceps;
- d. Meat cutting bone saw, hack saw, or electric saw when brain removal is required;
- e. Disposable cutting surfaces such as cardboard, plastic or styrofoam;
- f. Small hand nippers can be used on the hyoid bones or you may cut through at the joint using a knife;
- g. Sharp stainless steel scissor; and
- h. European brain spoon, grapefruit knife, or other brainstem scoop.

5. Obex Collection Procedures

There are two methods for collection the obex. Use the following guidelines to determine when to use each method for the collection. Collection of the obex via the foramen magnum is the preferred method for routine surveillance collections. Whole brains should be collected from scrapie suspects.

- a. Collect the obex via the foramen magnum when:
 - The carcass is reasonably fresh.
- b. Collect the obex via a complete brain removal procedure when:
 - The animal is a scrapie suspect;
 - The brain stem is too autolyzed; and
 - Removal by the spoon method is unsuccessful.

6. Obex via the Foramen Magnum

- a. Tools
 - Aggressively toothed forceps (rat tooth);
 - European brain spoon, grapefruit knife, or other brainstem scoop; and
 - Curved blunt scissors.
- b. Procedures
 - Place the head upside down in front of you so that you are looking directly at the foramen magnum;
 - With forceps and scissors remove the collar of dense dura mater that surrounds the foramen magnum and spinal cord;
 - Then gently grasp the end of the protruding spinal cord with forceps and move the spinal cord laterally to expose the caudal cranial nerves;
 - Cut the cranial nerves with scissors taking care to prevent damage to the brainstem. This is best accomplished with curved blunt scissors directing the tip

- of the scissors laterally. Repeat this procedure on the other side of the brainstem;
- Once the cranial nerves have been severed, the caudal brainstem will be easier to manipulate within the foramen magnum;
- With light pressure, use forceps to move the spinal cord to the ventral part of the foramen magnum;
- Insert the spoon into the dorsal aspect of the foramen magnum between the brainstem and the dorsal bony calvarium;
- Sever the cerebellum by advancing the spoon cranially 2 to 3 inches until you feel the leading edge of the spoon hit bone;
- Remove the spoon;
- With the forceps, lift the spinal cord dorsally and re-insert the spoon into the ventral aspect of the foramen magnum between the brainstem and the ventral bony calvarium. Sever the brain stem by advancing the handle of the spoon until the leading edge of the spoon touches bone;
- Pull the spoon toward you with gentle traction on the spinal cord with the rat-toothed forceps;
- If the brainstem is not readily removed by this method, stop. Re-examine the brainstem and sever any remaining cranial nerves or connections to the dura. Use caution, excessive caudal traction on the spinal cord may result in a mutilated non-diagnostic sample;
- After cutting any remaining cranial nerves and repeating the spoon technique to completely sever any residual attachments of the caudal brainstem from the mid brain, the brainstem should easily be extracted by caudal movement of the spoon cradling the brainstem and caudal pressure on the spinal cord with forceps; and
- The sample extracted with this method is usually 3 to 4 centimeters long with the obex in the center. Trim out the central 1/3 containing the obex and place in formalin. Place the caudle piece (spinal cord) and cranial piece (cranial brainstem) into a plastic bag for chilling or freezing.

7. Via Complete Brain Removal – Required for Clinical Suspects

a. Tools

- Meat cutting bone saw, hack saw, or electric necropsy saw;
- Wood chisel or large wide-tipped screwdriver;
- Toothed forceps (rat tooth);
- European brain spoon, grapefruit knife, or other brainstem scoop;
- Curved blunt scissors; and
- Scalpel.

Several methods may be used for collection of the obex via complete brain removal.

b. Procedures

- Skin the head;
- Using a bone saw, remove the top and back of the skull. This requires three cuts:
 - The first cut is directed from the medial aspect of the occipital condyle, dorsally to the top of the skull and then cranially to a transverse line 1 cm caudal to the lateral canthus of the eye;
 - Repeat this cut on the other side starting at the medial aspect of the other occipital condyle;
 - The final cut is a transverse cut connecting the cranial aspects of the two longitudinal cuts approximately 1 cm caudal to the lateral canthi of the eyes.
- Pry off the skullcap by inserting a wood chisel or a wide-tipped large screwdriver at the level of the transverse cut and hinge the skullcap caudally;
- If the top of the calvarium is not readily removed, review the procedure and verify that cuts are through the bone. If the cuts are placed too far laterally or cranially, the sinuses will be entered and additional sawing will be necessary to free up the top and back of the calvarium;

NOTE: If the sides or front of the cerebrum have been inadvertently damaged during the previous steps of the procedure, the samples will not be compromised.

- Open the dense, fibrous dura mater covering the sides and top of the brain with scissors and forceps by making a midline longitudinal cut from the cranial aspect of the cerebrum to the spinal cord. Ensure that you completely incise the extra tough section of the dura mater known as the tentorium cerebelli, that lies between the cerebrum and cerebellum;
- Once the entire brain is exposed, direct the nose dorsally, resting the occipital condyles on a flat surface, such as a table or floor, and sever the cranial nerves starting with the olfactory nerves and proceed caudally cutting the cranial nerves and allow gravity to assist removal of the brain from the cranial vault;
- For scrapie diagnosis, separate the brainstem from the fore brain by a transverse cut between the cerebrum and cerebellum;

NOTE: If a complete differential diagnosis is necessary or if rabies must be ruled out, please contact the public health or diagnostic laboratory that will be involved for direction on sample collection and submission.

- Remove the cerebellum from the brainstem at the level of the peduncles. At this stage, the brainstem derived from the whole brain and the brainstem derived with the spoon method should be similar;
- Remove obex by placing a pencil such that it just covers the apex of the V and slicing on either side to give an 8-10 mm cross section;

- Place the obex into formalin;
- Place the remaining brainstem tissues including the spinal cord and brain stem into a plastic bag;
- Then divide the cerebrum, midbrain, and cerebellum longitudinally into left and right halves. Put the right half in formalin. Put the left cerebellum in its own bag and label genotyping and the left midbrain and cerebrum in another bag and seal;
- Place all the fresh tissue sample bags except the cerebellum into another bag and seal.

8. Tonsil Collection Procedures

There are various successful approaches to collecting the tonsils. The tonsillar crypts on the dorso-lateral aspect of the oropharynx are useful landmarks. Keep in mind that the actual tonsillar lymphoid tissue is located deep to the superficial mucosal crypts in the submucosa. The tonsillar lymphoid tissue is readily palpable and visible when adequately exposed. Ensure that you have collected the deep tonsillar lymphoid tissue. The most common scrapie submission error is the collection and submission of the mucosal crypts instead of the tonsillar lymphoid tissue.

a. Tools

- Sharp boning knife;
- Scalpel;
- Sharp stainless steel scissors; and
- Rat-toothed forceps.

b. Procedures

- Place the head upside down on the table;
- Remove the skin from the ventral surface of the mandible;
- Grab the pharynx with your noncutting hand and pull it toward you (stretching out the pharynx), place the knife on the mandibular symphysis and cut caudally with the blade touching the ventral aspect of the mandible. As you cut caudally, follow the angle of the mandible dorsally as you approach the rami of the mandible. The hyoid bones that you encounter will need to be cut with poultry shears or disarticulated at a joint with the knife;
- The oropharynx (cranial) and nasopharynx (caudal) will now be exposed. Grab the ventrolateral aspect of the oropharynx with rat tooth forceps and observe the tonsillar crypts opening into the dorso-lateral aspect of the oropharynx. Begin a dissection plane between the pharynx and the lateral pharyngeal muscles. As the dissection is extended dorsally, a bulge of lymphoid tissue will be seen protruding from the lateral pharyngeal wall. Use the tonsillar crypt as a landmark. The lymphoid tissue is always connected to the tonsillar crypt. Be sure to collect the

lymphoid tissue in addition to the crypt;

- Once the bulge of tonsillar lymphoid tissue is identified, remove it with scissors or a scalpel and forceps. The tonsil with associated lymphoid tissue will contain medial crypts and laterally there is a readily palpable, well circumscribed mass of lymphoid tissue that will feel like a small, round, sometimes relatively flat lymph node;
- Alternatively, the tongue can be loosened cranially and laterally at the mandibular symphysis and retracted caudally until the crypts are visible and a similar dissection as described above may be used to locate the tonsils. The crypt is the landmark for the tonsillar lymphoid tissue subjacent (deep or submucosal) to the crypt; and
- Place one tonsil into a jar of formalin and the other in a resealable bag and then into the bag with the other fresh tissues from that animal.

9. Retropharyngeal Lymph Node (RPLN) Collection Procedures

The medial retropharyngeal nodes are medial to the stylohyoid bones on the dorsolateral surface of the pharyngeal muscles and dorsal to the carotid artery. They are medial and deep and rarely removed by normal processing procedures. The lateral retropharyngeal nodes are found on either side of median line midway between the larynx and the foramen magnum. They are generally smaller than the medial nodes and sometimes remain with the neck.

a. Tools

- Sharp boning knife;
- Scalpel;
- Sharp stainless steel scissors; and
- Rat-toothed forceps.

b. Procedures

- The medial retropharyngeal nodes are caudal to the nasopharynx. Place your index finger and thumb in the nasopharynx and the thumb caudally on the caudal pharyngeal muscles to feel the nasopharynx. The opposite node will be about 1 centimeter medial to the first;
- Dissect both medial retropharyngeal nodes from the surrounding pharyngeal muscles with rat-toothed forceps and scissor, scalpel, or knife;
- Place one medial RPLN into a jar of formalin; and
- Place two RPLN (one medial and one lateral) into a plastic bag for chilling or freezing.

D. Alternate Collection Procedure that may be Used by Owners if Desired.

1. Head Removal and Whole Head Packaging Procedures

Tools

- a. Sharp boning knife; and
- b. Two heavy duty plastic bags.

If the carcass is intact, remove the head from the carcass. This is done at the atlanto-occipital joint, which is where the skull meets the first cervical vertebrae.

2. Procedures

- a. Position the animal in dorsal recumbency (lying on its back).
- b. Remove the head, at the hinge joint where the skull meets the first cervical vertebrae (just behind the ears) using the following steps:
 - To locate the “hinge” area where the skull meets the first cervical vertebrae, grasp the nose and move the head up and down to locate the joint.
 - Insert the knife into the neck between the first cervical vertebrae and the throat then cut outward (ventrally) with blade directed away from you through the throat tissue and skin. (Cutting down through the skin readily dulls the blade.)
 - Cut down (dorsally) to the membrane that covers the spinal cord; cut through the membrane exposing the spinal cord. Then cut the spinal cord as far from the head (caudally) as possible so that it is kept as long as practical.
 - Cut the lateral ligaments connecting the skull to the vertebra in a ventral to dorsal direction on both sides. This is usually best accomplished with the tip of the knife directed between the skull and vertebra.
 - Once the lateral ligaments have been severed, cut through the remaining tissue to remove the head from the carcass.
 - Now move the head with a portion of the spinal cord protruding from the foramen magnum to a comfortable height for sample collection or to package the whole head.
 - Ideally, specimens should be collected from the head onsite by a veterinarian or animal health technician; however, sometimes it may be necessary to ship the entire head to the laboratory. When this is the case, skin the head leaving the ears with ID in place, place the head in a large heavy-duty plastic bag. If you are presented with a skinned head such as at slaughter plants, place the animal's ID in a separate bag with the bagged head inside the second bag.
 - Double bag the head.
 - Secure each bag in a manner that will prevent leakage such as by tying a knot in

- the bag or using twist ties, string, or cord.
- Chill the head prior to placing in the cool box and refrigerate the head until and during shipment to the laboratory in the cool box.

To pack the cool box: Put cool packs in the bottom, insert large plastic bag, insert absorbent material, insert double bagged heads, and seal bag, place cool packs on top of bag and close cooler top, Insert submission form between cooler top and exterior box. Ship overnight. Use at least four chill packs per box and an additional chill pack for each additional head if more than two heads are shipped in the same cool box.

Appendix 2—Scrapie Disinfection Guidelines

None of the following suggested disinfection and inactivation procedures will guarantee total and complete elimination and inactivation of the infectious agent; however, based on current information on the efficiency under laboratory conditions of the disinfection methods listed, it is likely that they will reduce the amount of infectivity in the environment. Until more specific information becomes available, good sanitary practices are recommended following each lambing. The following methods below should be applied to lambing areas where infected or exposed animals have lambed.

A. Pastures

1. If practical, till soil under or do not use area to graze susceptible animals.
2. If this is not practical, do not use the pasture until the animal waste has decomposed and the weather has had an opportunity to dilute any infectivity.

B. Drylots

Remove the manure and bedding and when practical, the top 1 to 2 inches of soil to reduce contamination. Bury, till under, or compost the removed material in areas not accessed by domestic or wild ruminants until it can be buried or tilled under.

C. Earth Surfaces Inside Structures or Used for Confined Lambing Pens

Remove the organic material and when practical, the top 1 to 2 inches of soil to reduce contamination. Bury, till under, or compost the removed material in areas not accessed by domestic or wild ruminants until it can be buried or tilled under.

D. Nonearth Surfaces

(These include cement, wood, metal, tools, equipment, instruments, feed, hay, bedding, and other materials.)

1. Remove all organic material. Bury, incinerate, or compost the removed material in areas not accessed by domestic or wild ruminants and then till under, bury or incinerate.
2. When practical for other items bury or incinerate by high-temperature incineration methods.
3. Clean and wash surfaces and remaining items using hot water and detergent. Allow all surfaces, tools, and equipment to dry completely before disinfecting and sanitizing using the following suggested methods:

- a. Autoclave instruments, small tools, and other items at 136 °C (277 °F) for 1 hour. This method is more effective when preceded by the treatment described in b or c, below.
- b. To clean dry surfaces, apply a 2 percent available chlorine solution (equivalent to about 20,000 p/m; available chlorine: 50 ounces. [6-1/4 cups] bleach to enough water (78 ounces. or 9 3/4 cups) to give 1 gallon of solution) at room temperature (at least 18.3 °C [65 °F]) for 1 hour.
- c. For environmental purposes, use this disinfection method when the preceding methods are not available: Expose dry surfaces by applying 1-molar solution of sodium hydroxide (approximately 4-percent solution [5 ounces sodium hydroxide dissolved in 1 gallon water]) at room temperature (at least 18.3 °C [65 °F]) for at least 1 hour. Synonyms for sodium hydroxide are caustic soda, soda lye, and sodium hydrate.

Appendix 3—SFCP Exhibition and Transportation Guidelines

Official ID is required for any sexually intact animal to be exhibited, and a certificate of veterinary inspection is required for animals moving across State lines. State animal health authorities and show officials should be contacted to determine if there are additional requirements for a particular State or show.

All sheep and goats from SFCP enrolled flocks must be housed and handled to prevent direct contact with female sheep and female goats from other flocks of lower status. Spacing sufficient to prevent contact or solid partitions should be used while in transit and at the exhibition to maintain separation. Pens must be thoroughly cleaned and all organic material removed before use by an animal from an SFCP flock.

If sheep or goats that are postpartum, have aborted, or are pregnant and have a vaginal discharge are allowed at a show or are transported in the same vehicle, special arrangements must be made to prevent any contact with SFCP enrolled animals. Spacing sufficient to prevent contact or solid partitions must be used to maintain separation. Pens used by such animals must be thoroughly cleaned and all organic material removed and disinfected before use by an animal from an SFCP flock. If contact occurs between a postpartum animal and a female animal enrolled in the SFCP that is returned to the enrolled flock, the flock will take on the status date, if lower, of the postpartum animal. If contact occurs with a male animal enrolled in the SFCP, the male animal's status date will change to the status date, if lower of the postpartum animal, but the flock status will be unchanged.

Appendix 4—Transmission and Genetics of Scrapie

Sheep and goats are typically infected with scrapie as young lambs or kids through contact with the infected placenta or birth fluids from infected ewes or with contaminated lambing areas but not necessarily mother to offspring. Age seems to provide some protection; however, a few animals may become infected as adults. Rams get scrapie, but infected rams are not known to transmit scrapie.

The agent can enter the body by ingestion, ocular exposure, or contact with abraded skin or mucus membranes. The incubation period is typically 2-to-5 years. Animals infected at or near birth typically die by 72 months of age. Likewise, animals infected after weaning typically die at more than 72 months; however, this does not always hold true for valine associated scrapie discussed below, particularly in VVQQ sheep. Scrapie is always fatal—no treatment or vaccine is available.

Due to their genetic make-up, some sheep are more susceptible to scrapie and some are more resistant to the disease. The genes that control susceptibility/resistance can be identified by blood test known as genotyping or DNA testing.

A. General Information about Genotyping

1. The animal's genotype never changes, so it can be tested at any age.
2. Under most circumstances, one test during the animal's life is adequate to determine its genotype (susceptibility/resistance to scrapie.) In the case of exposed sheep, USDA currently requires two tests to minimize any chance of error in sampling, labeling, or testing.
3. The genotype test measures only an animal's susceptibility/resistance to scrapie, not whether it has scrapie. The third eyelid biopsy test can be used to detect scrapie infection in some animals.

B. Basic Facts about Sheep Genetics and how Genotyping is used to Determine Scrapie Resistance/Susceptibility

1. Out of the many sheep genes scientists have identified, one pair affects scrapie susceptibility as well as the disease's incubation time. That gene is the prion protein gene (PRNP).
2. Each sheep has two copies of the PRNP gene; one derived from each parent.
3. In uninfected sheep, the PRNP gene produces the normal cellular prion protein molecule

known as PrPc. In scrapie infected sheep, the abnormal prion protein, PrPsc or prions, is found. Prions are closely associated with scrapie infectivity and may be the causative agent.

4. Genes are made up of codons. Each codon instructs the body's cells to put a specific amino acid at a particular location when building a protein molecule.
5. Since PrPc is composed of 256 amino acids, these locations are numbered from 1 to 256.
6. Two codons, 136 and 171, are particularly important to scrapie susceptibility in the United States.
7. Codon 171 can give instructions to insert the amino acid Histidine (H), Glutamine (Q), Lysine (K), or Arginine (R) at a position 171 of PrPc. The letter in parentheses is the single letter biochemical abbreviation for each amino acid. For regulatory purposes, H, Q, and K are treated the same and will be represented as Q throughout the remainder of this discussion. At codon 171, R is very important because it produces the greatest scrapie resistance.
8. Codon 136 can give instructions for either Alanine (A) or Valine (V) to be the amino acid at 136 of PrPc. The presence of V at 136 makes AV QR sheep susceptible to the valine associated scrapie strain. The valine associated strain is relatively uncommon in the U.S. and only appears to infect sheep that have V at codon 136.
9. As previously stated, sheep have two copies of the PRNP gene, one from each parent that can produce one of four possible combinations of amino acids at codons 136 and 171 as shown below in Table 1.

**Table 1 –
Amino Acid Combinations Indicating Susceptibility/Resistance**

	Location	
	Codon 136	Codon 171
	A	R
Amino	A	Q*
Acid	V	Q*
	V	R**

* Q = Q, H, or K at codon 171

** This combination is very rare and has not been identified in the United States.

10. Producers need to be familiar with the six common genotypes and their corresponding amino acid combinations to understand genotyping for scrapie resistance. Based on what is now known, the following genotypes at codons 136 and 171 (shown below in Table 2) are used to determine the scrapie susceptibility of sheep by USDA.

**Table 2 –
Common Genotype Susceptibility/Resistance Combinations**

1. AA RR – Sheep that are resistant.
2. AA QR – Sheep that are rarely susceptible.
3. AV QR – Sheep that are susceptible to some scrapie strains*.
4. AA QQ – Sheep that are highly susceptible.
5. AV QQ – Sheep that are highly susceptible.
6. VV QQ – Sheep that are highly susceptible.

*These strains are believed to occur with low frequency in the United States.

At this time, no resistant genotypes have been conclusively identified in goats. There is some preliminary literature suggesting that lysine (K) at codon 222 may be resistant; however, K at codon 222 is uncommon in U.S. goats tested to date. All goats, therefore, should be assumed to be susceptible.

11. Official genotype tests -
APHIS will only recognize the results of genotype tests as official if:
- a. The blood is drawn by an accredited veterinarian or a State or Federal animal health official;
 - b. The sheep is officially identified;
 - c. The sample is submitted with a VS Form 5-29 or State equivalent; and
 - d. The laboratory has been approved by APHIS.

Appendix 5—Scrapie Eradication UM&R Definitions

Any definitions pertaining to scrapie published in 9 CFR parts 54 and 79 and the current UM&R published after the date of these Standards.

Accredited Veterinarian

A veterinarian approved by the Administrator of USDA–APHIS to perform functions required by cooperative State-Federal animal disease control and eradication programs.

Administrator

The Administrator of APHIS or any employee of USDA to whom the Administrator has delegated authority to act in his or her place.

Animal

Any sheep or goat.

APHIS

The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

APHIS Representative

An individual employed by APHIS in animal health activities who is authorized by the Administrator to perform specific functions and duties.

Approved Laboratory

A diagnostic laboratory approved by the Administrator to conduct, on one or more tissues, approved tests for scrapie or genetic susceptibility to scrapie.

Approved Test

A test for the diagnosis of scrapie approved by the Administrator of APHIS for use in the scrapie eradication or certification program.

Area Veterinarian in Charge (AVIC)

The veterinary official of APHIS assigned by the Administrator to supervise and perform the official animal health work of APHIS in the State concerned.

Blackface Sheep

Any purebred Suffolk, Hampshire, Shropshire, or cross thereof; any nonpurebred sheep known to have Suffolk, Hampshire, or Shropshire ancestors; and any nonpurebred sheep of unknown ancestry with a black face except for hair sheep. Note that hair sheep known to have Suffolk, Hampshire, or Shropshire ancestors are considered blackface sheep.

Breed Associations and Registries

Organizations that maintain the permanent records of ancestry or pedigrees (including the animal's sire and dam), individual identification, and ownership of animals.

Breeding Sheep and Goats

Any sexually intact sheep or goat that is not moving directly to slaughter, through slaughter channels to slaughter, or to a feedlot to enhance its condition for movement to slaughter.

Certificate

An official document issued in accordance with 9 CFR 79.5 by an APHIS representative, State representative, or accredited veterinarian at the point of origin of an interstate movement of animals.

Commercial Sheep or Goat

Any animal from a flock from which animals are moved only either directly to slaughter or through slaughter channels to slaughter, or any animal raised only for meat or fiber production and not registered with a sheep or goat registry or used for exhibition.

Commingled, Commingling

Animals grouped together having physical contact with each other, including contact through a fence with a confined lambing area or lambing animals, but not limited contact (as defined below.) Commingling includes sharing the same section in a transportation unit where physical contact can occur. In cases of shared fence lines, the Designated Scrapie Epidemiologist (DSE) will determine whether commingling has occurred through the fence based on relevant factors such as the type, integrity, and location of the fence, the proximity of lambing, and the stocking density.

Consistent State

A State, listed in 9 CFR 79.1, that the Administrator has determined conducts an effective State scrapie control program and is in compliance with 9 CFR 79.6.

Deputy Administrator

The Deputy Administrator for USDA–APHIS–VS or any other official to whom the Administrator has delegated authority to act for the Deputy Administrator.

Designation of a Flock or Animal

The official determination by the DSE that an animal or flock has a particular disease status or classification.

Designated Scrapie Epidemiologist (DSE)

A State or Federal veterinarian designated by APHIS to make decisions about the use and interpretation of diagnostic tests and field investigation data and the management of scrapie-affected flocks.

Destroyed

- Euthanized by means other than slaughter and the carcass disposed of by means authorized by the Administrator;
- In the case of exposed or high-risk animals not known to be infected, either euthanized or disposed of by slaughter; or
- Moved to a quarantined research facility if the Administrator has approved the movement.

Direct Movement to Slaughter

Animals that are transported to a facility for slaughter without unloading en route, other than for food and water, and that are not commingled with any other animals during transport or at such food and water stops.

Electronic Implant

Any radio-frequency identification implant device approved for use in the scrapie program by the Administrator.

Exposed Animal

Any animal that has been in a flock or in an enclosure off the premises of the flock with a scrapie-positive female animal or that has resided on the premises of a flock before or while it was designated an infected or source flock and before a flock plan was completed unless the scrapie-positive animal was not born on the premises, the date on which it was first introduced to the premises is known, and the animal resided in the flock only before the scrapie-positive animal was introduced to the premises. Exposed animals will be designated as either genetically resistant exposed sheep, genetically less susceptible exposed sheep, genetically susceptible exposed animals, or low-risk exposed animals.

Exposed Embryo

Any embryo that was collected from an exposed, suspect, or scrapie-positive animal.

Exposed Flock

Any flock that was designated an infected or source flock that has completed a flock plan and that retained a high-risk animal. Any flock under investigation that retains a genetically susceptible exposed animal or a suspect animal. Any flock under investigation whose owner declines to complete the required genotyping and live-animal or necropsy scrapie testing. Any flock that is not in compliance with a postexposure management and monitoring plan (PEMMP). A flock that has completed a PEMMP following the exposure will no longer be an exposed flock.

Female Animal

A sexually intact female sheep or goat.

Flock or Herd

All animals maintained on a single premises and all animals under common ownership or supervision on two or more premises with animal interchange between the premises. Changes in ownership of part or all of a flock do not change the identity of the flock or the regulatory requirements applicable to the flock. Animals maintained temporarily on a premises for activities such as shows and sales or while in marketing channels are not a flock. More than one flock may be maintained on a single premises if:

- The flocks are enrolled as separate flocks in the Scrapie Flock Certification Program (SFCP); or
- A State or APHIS representative determines, based on examination of flock records, that:
 - No female animals have moved between the flocks;
 - The flocks never commingle and are kept at least 30 feet apart at all times or are separated by a solid wall through, over, or under which fluids cannot pass and through which contact cannot occur;
 - The flocks have separate flock records and identification;
 - The flocks have separate lambing facilities, including buildings and pastures, and a pasture or building used for lambing by one flock is not used by the other flock at any time; and
 - The flocks do not share equipment without cleaning and disinfection in accordance with the guidelines published in 9 CFR 54.7.

Flock ID

See premises identification number.

Flock of Origin

For male animals, the flock of birth. For female animals, the flock in which an animal most recently resided in which it either was born, gave birth, or resided during lambing. The determination that an animal originated in a flock must be based either on the physical presence of the animal in the flock, the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records.

Flock Plan

A written flock management agreement signed by the owner of a flock, the accredited veterinarian (if one is employed by the owner), and a State or APHIS representative in which each participant agrees to undertake actions specified in the flock plan to control the spread of scrapie from, and eradicate scrapie in, an infected flock or source flock or to reduce the risk of the occurrence of scrapie in a flock that contains a high-risk or an exposed animal. As part of a

flock plan, the flock owner must provide the facilities and personnel needed to carry out the requirements of the flock plan. The flock plan must include the requirements in 9 CFR 54.8.

Flock Under Investigation (FUI)

Any flock in which a scrapie suspect animal was born or lambed. Any flock containing a female high-risk or suspect animal or that once contained such an animal that may have lambed in the flock and from which obex and lymphoid tissues either were not submitted for official testing or were not found negative. A flock that has completed the required genotyping and live-animal or necropsy scrapie testing, that is in compliance with a PEMMP if one is required, or that has been designated an infected, source, or exposed flock will no longer be a flock under investigation.

Genetically Less Susceptible Exposed Sheep

- Any exposed AA QR sheep or embryo unless it is epidemiologically linked to a scrapie-positive RR or AA QR sheep. (The definitions for these acronyms are given under the definition of “Genotypes of Sheep.”)
- Any exposed AV QR sheep or embryo unless it is epidemiologically linked to a scrapie-positive RR, QR, AV QQ, or VV QQ sheep.

Genetically Resistant Exposed Sheep

Any exposed RR sheep or embryo unless it is epidemiologically linked to a scrapie positive RR sheep.

Genetically Susceptible Animal

- A goat or goat embryo;
- A QQ sheep or embryo;
- A sheep or embryo of undeterminable genotype; or
- A genetically susceptible exposed animal.

Genetically Susceptible Exposed Animal

Any exposed animal or embryo other than a low-risk exposed animal that is one of the following:

- A goat or goat embryo;
- A QQ sheep or sheep embryo;
- A sheep or sheep embryo of undeterminable genotype;
- An AV QR sheep or sheep embryo that is epidemiologically linked to a scrapie-positive RR, QR, AV QQ, or VV QQ sheep*;
- An AA QR sheep or sheep embryo that is epidemiologically linked to a scrapie-positive RR or AA QR sheep; or
- An RR sheep or sheep embryo that is epidemiologically linked to a scrapie positive RR sheep.

***Note:** AV QR sheep or sheep embryo epidemiologically linked to a positive animal for which the 136 codon type either cannot be determined or is unavailable at time of depopulation may also be removed.

Genotypes of Sheep

Two locations on DNA that code for prion protein are particularly important for scrapie susceptibility: codons 136 and 171. Codon 136 may code for either of the amino acids alanine (A) or valine (V). Codon 171 may code for the amino acids arginine (R), glutamine (Q), histidine (H), or lysine (K). For the purposes of these UM&R, H, K, or any amino acid other than R at codon 171 will be treated as equivalent to Q at codon 171.

RR Sheep

Any sheep that has tested RR at codon 171 on an official genotype test. APHIS may require confirmatory testing before designating a sheep as RR.

QR Sheep

Any sheep that has tested QR, KR, or HR at codon 171 on an official genotype test. APHIS may require confirmatory testing before designating a sheep as QR.

QQ Sheep

Any sheep that has tested QQ, QK, QH, HK, KK, or HH at codon 171 on an official genotype test. APHIS may require confirmatory testing before designating a sheep as QQ.

AV Sheep

Any sheep that has tested AV at codon 136 on an official genotype test. APHIS may require confirmatory testing before designating a sheep as AV.

VV Sheep

Any sheep that has tested VV at codon 136 on an official genotype test. APHIS may require confirmatory testing before designating a sheep as VV.

AA Sheep

Any sheep that has tested AA at codon 136 on an official genotype test. APHIS may require confirmatory testing before designating a sheep as AA.

AA QR Sheep

Any sheep that has tested QR, KR, or HR at codon 171 and AA at codon 136 on an official genotype test. APHIS may require confirmatory testing before designating a sheep as AA QR.

AV QR Sheep

Any sheep that has tested QR, KR, or HR at codon 171 and AV at codon 136 on an official genotype test. APHIS may require confirmatory testing before designating a sheep as AV QR.

AA QQ Sheep

Any sheep that has tested QQ, QK, QH, HK, KK, or HH at codon 171 and AA at codon 136 on an official genotype test. APHIS may require confirmatory testing before designating a sheep as AA QQ.

AV QQ Sheep

Any sheep that has tested QQ, QK, QH, HK, KK, or HH at codon 171 and AV at codon 136 on an official genotype test. APHIS may require confirmatory testing before designating a sheep as AV QQ.

VV QQ Sheep

Any sheep that has tested QQ, QK, QH, HK, KK, or HH at codon 171 and VV at codon 136 on an official genotype test. APHIS may require confirmatory testing before designating a sheep as VV QQ.

High-Risk Animal

Any female genetically susceptible exposed animal. The female offspring of a scrapie-positive female animal or any female genetically less susceptible exposed animal that the DSE (with the concurrence of the AVIC, State Veterinarian, Regional Scrapie Epidemiologist, and National Scrapie Program Coordinator) determines to be a potential risk based on the epidemiology of the flock, including genetics of the positive sheep, the prevalence of scrapie in the flock, any history of recurrent infection, or other characteristics.

Inconsistent State

Any State other than a Consistent State.

Infected Flock

Any flock in which a State or APHIS representative has determined that a scrapie-positive female animal has resided unless an epidemiological investigation conducted by a State or APHIS representative shows that the animal did not lamb or abort in the flock. A flock will no longer be considered an infected flock after it has completed the requirements of a flock plan.

Interstate Commerce

Trade, traffic, transportation, or other commerce between a place in a State and any place outside of that State or between points within a State but through any place outside that State.

Limited Contact

Any contact with a male animal or brief contact with a female animal off the flock's premises, such as occurs in the show or sales ring at fairs, shows, exhibitions, markets, and sales; between ewes being inseminated, flushed, or implanted; or between rams at ram test or collection stations. Embryo transfer and artificial insemination equipment and surgical tools must be disinfected between animals from different flocks by soaking the tools in a 2 percent available

chlorine bleach solution or a 2 molar solution of sodium hydroxide for 1 hour or another disinfectant approved by the Administrator for this use for these contacts to be considered limited contacts. Limited contacts do not include any contact, brief, or otherwise, including contacts through a fence, with an animal during or up to 30 days after she lambed, kidded, or aborted or when there is any visible vaginal discharge other than that associated with estrus. Limited contacts do not include any activity where uninhibited contact occurs with a female animal, such as sharing an enclosure, sharing a section of a transport vehicle, or residing in other flocks for breeding or other purposes, except as allowed by the SFCP standards.

Live-Animal Screening Test

Any test for the diagnosis of scrapie in a live animal that is approved by the Administrator as usually reliable but not definitive for diagnosing scrapie and that is conducted in a laboratory approved by the Administrator.²

Low-Risk Commercial Flock

A flock composed of commercial whitefaced, whitefaced cross, or commercial hair sheep or commercial goats that were born in, and have resided throughout their lives in, flocks with no known risk factors for scrapie, including any exposure to female blackfaced sheep other than whiteface crosses born on the premises; that have never contained a scrapie-positive female, suspect female, or high-risk animal; and that have never been an infected, exposed, or source flock or a flock under investigation. The animals are identified with a legible permanent brand or ear notch pattern registered with an official brand registry or with an official premises identification eartag. The term “brand” includes official brand registry brands on eartags in those States whose brand law or regulation recognizes brands placed on eartags as official brands. Low-risk commercial flocks may exist only in a State where in the previous 10 years no low-risk commercial flock has been designated a source or infected flock.

Low-Risk Commercial Goat

A low-risk goat (see definition of low-risk goat) from a herd in which animals are moved to slaughter only directly or through slaughter channels or any animal raised only for meat or fiber production and not registered with a sheep or goat registry or used for exhibition.

Low-Risk Exposed Animal

² The names and addresses of laboratories approved by the Administrator to conduct live-animal screening tests will be published in the notices section of the *Federal Register*. A list of approved laboratories is also available upon request from the APHIS, VS, National Animal Health Programs Staff, 4700 River Road, Unit 43, Riverdale, MD 20737-1235. State, Federal, and university laboratories will be approved by the Administrator when he or she determines that the laboratory (a) employs personnel trained by the National Veterinary Services Laboratories (NVSL) assigned to supervise the testing, (b) follows standard test protocols, (c) meets check test proficiency requirements, and (d) will report all test results to State and Federal animal health officials. Before the Administrator may withdraw approval of any laboratory for failure to meet any of these conditions, the Administrator must give written notice of the proposed withdrawal to the director of the laboratory and must give the director an opportunity to respond. If there are conflicts as to any material fact, a hearing will be held to resolve the conflicts.

Any exposed animal to which the DSE has determined one or more of the following applies:

- The positive animal was not born in the flock and did not lamb in the flock or in an enclosure where the exposed animal resided;
- The exposed animal most likely resided in the infected or source flock only before scrapie was introduced to the premises. This determination will be based on the flock history. If there is no information on which to base such a determination, the date 5 years prior to the earliest known exposure will be used. NOTE: If the precise date of scrapie introduction is known, such as when the positive animal is a purchased animal, an animal that transited the premises prior to that date is not an exposed animal;
- With the concurrence of a Regional or National Scrapie Epidemiologist and the State Veterinarian that the exposed animal's exposure was low risk. That is, the animal was maintained on the premises in a location or during a time period when infection was highly unlikely to have occurred and was not exposed to the lambing or kidding of an infected animal or to lambing or kidding in an infected or source flock or to the lambing or kidding area in such flocks before it had been cleaned or disinfected;
- The animal is male and was not born in an infected or source flock; or
- The animal is a wether.

Low-Risk Goat

A goat that is not a scrapie-positive, suspect, high-risk, or exposed animal; that has not been commingled with sheep other than sheep from low-risk commercial flocks; and that is from:

- A State in which scrapie has not been identified in a goat during the previous 10 years;
- A State in which scrapie has been identified in a goat during the previous 10 years, but the scrapie-positive goat was not born in the State, resided in the State for less than 72 months, and did not kid while in the State; or
- A State in which scrapie has been identified in a goat during the previous 10 years and the scrapie-positive goat was commingled with sheep and the flock records allowed a complete epidemiological investigation to be completed and all resulting infected, source, and exposed goat herds had completed flock plans and were in compliance with post-exposure monitoring and management plans.

Male Animal

A sexually intact male sheep or goat.

Mortgage

Any mortgage, lien, or other security or beneficial interest held by any person other than the one claiming indemnity.

National Veterinary Services Laboratories (NVSL)

The USDA–APHIS–National Veterinary Services Laboratories and their cooperating and contract laboratories.

Noncompliant Flock

- Any source or infected flock whose owner declines to enter into a flock plan or PEMMP agreement within 60 days of being so designated or whose owner is not in compliance with either agreement;
- Any exposed flock or flock under investigation whose owner fails to make animals available for testing within 60 days of notification, or as mutually agreed, or whose owner fails to submit required postmortem samples as directed in the PEMMP;
- Any flock whose owner has misrepresented, or who employs a person who has misrepresented, the scrapie status of an animal or any other information on a certificate, permit, owner statement, or other official document within the last 5 years; or
- Any flock whose owner or manager has moved, or who employs a person who has moved, an animal in violation of 9 CFR, part 79, within the last 5 years.

Official Eartag

An identification eartag approved by APHIS as being sufficiently tamper resistant for the intended use and providing unique identification for each animal. An official eartag may conform to the alphanumeric National Uniform Ear-Tagging System or another system approved by APHIS, or it may bear an APHIS-approved premises identification number that either contains a unique identification number or is used in conjunction with the producer's livestock production numbering system to provide a unique identification number.

Official Genotype Test

Any test to determine the genotype of a live or dead animal conducted at either an approved laboratory (see definition) or at NVSL when the animal is officially identified and the samples are collected and shipped to the laboratory by either an accredited veterinarian or a State or APHIS representative. APHIS may require confirmatory testing before designating an exposed sheep genetically resistant or less susceptible.

Official Identification

Identification approved by APHIS for use in the scrapie eradication program.

Official Test

Any test for the diagnosis of scrapie in a live or dead animal that is approved by the Administrator of APHIS for that use and conducted either at an approved laboratory or at NVSL.

Owner

A person, partnership, company, corporation, or any other legal entity that has legal or rightful title to animals, whether or not they are subject to a mortgage.

Owner Statement

A written statement by the owner that includes the owner's name, signature, address, and telephone number, the date the animals left the flock of origin, the identification number assigned to the premises, the number of animals, the premises portion of the premises identification if premises identification is used, and a statement that the animals were either born or were used for breeding purposes on the premises to which the premises identification is assigned. (NOTE: Statements for animals not identified to their flock of origin that are moved in interstate commerce to a market or slaughter facility where they will be identified must include the name and address of the market or slaughter facility to which they are being shipped.)

Permit

An official document issued in connection with the interstate movement of animals (VS form 1–27 or a State form that contains the same information) by an APHIS representative, State representative, or an accredited veterinarian authorized to sign such permits. A new permit is required for each change in destination for an animal. A permit lists the owner's name and address; points of origin and destination; number of animals covered; purpose of the movement; whether the animals are from an exposed flock, flock under investigation, noncompliant, infected, or source flock; whether the animal is a high-risk, exposed, scrapie-positive, or scrapie suspect animal; transportation vehicle license number or other identification number; and seal number (if a seal is used). A permit also lists all official identifications on the animals covered. Official identifications may include the eartag number; a registered breed association's registration tattoo, brand, or number; a USDA backtag (when applied serially, only the beginning and ending numbers need to be recorded), or any other form of official identification present on the animal.

Person Number

A unique number assigned to an accredited veterinarian or an APHIS or State representative that is recorded in the Scrapie National Generic Database (SNGD) and used to allocate tags and to identify that person on documents such as test charts.

Postexposure Management and Monitoring Plan (PEMMP)

A written agreement signed by the owner of a flock, any accredited veterinarian employed by the owner, and a State or APHIS representative in which each participant agrees to undertake actions specified in the agreement to reduce the risk of the occurrence of scrapie and to monitor for the occurrence of scrapie in the flock for at least 5 years after the last high-risk or scrapie-positive animal is removed from the flock or after the last exposure of the flock to a scrapie-positive animal unless the monitoring time is otherwise specified by a State or APHIS representative. As part of a PEMMP, the flock owner must provide the facilities and personnel needed to carry out the required elements listed in the plan. The plan must include the requirements in 9 CFR 54.8.

Premises

The ground, area, buildings, and equipment occupied by, or used for, one or more flocks of animals.

Premises Identification

An APHIS-approved eartag or tattoo bearing the premises identification number, which is either the national premises identification number or the Postal Service State abbreviation followed by a unique alphanumeric number or name assigned by a State or Federal animal health official to the premises on which the sheep or goats originated that, in the judgment of the State animal health official or AVIC, is epidemiologically distinct from other premises; or a permanent brand or ear notch pattern registered with an official brand registry. Premises identification may be used when official individual animal identification is required if the premises identification method either includes a unique animal number or is used in conjunction with the producer's livestock production numbering system to provide a unique identification number and when, if brands or ear notches are used, the animals are accompanied by an official brand inspection certificate. Paint brands may be used on animals moving directly to slaughter and animals moving for grazing or other management purposes without change in ownership.

Premises Identification Number

A unique number used on official eartags and tattoos to identify the premises of origin of an animal and that is recorded in the SNGD. The first two digits are the Postal Service abbreviation for States followed by an alphanumeric number that does not include I, O, or Q or is the national premises identification number.

Premises Number

A unique number identifying a premises in the SNGD.

Program

The cooperative State-Federal-Industry program administered by APHIS and Consistent States to control and eradicate scrapie.

Scrapie

A nonfebrile, transmissible, insidious degenerative disease affecting the central nervous system (CNS) of sheep and goats.

Scrapie Control Pilot Project

A pilot project authorized by the Administrator in writing, designed to test or improve program procedures or to facilitate research to control and eradicate scrapie. In addition to APHIS, participants may include State animal health agencies, flock owners, and other parties as necessary. (Pilot projects are established through a memorandum of understanding between a State and APHIS.)

Scrapie Eradication Program

The cooperative State-Federal-Industry program administered by APHIS and Consistent States to control and eradicate scrapie.

Scrapie Eradication Uniform Methods and Rules (UM&R)

Cooperative procedures and standards adopted by APHIS and Consistent States for controlling and eradicating scrapie.

Scrapie Flock Certification Program (SFCP)

A voluntary State-Federal-Industry cooperative effort established and maintained to reduce the occurrence and spread of scrapie, to identify flocks that have been free of evidence of scrapie over specified time periods, and to contribute to the eventual eradication of scrapie (formerly known as the “Voluntary Scrapie Flock Certification Program”.)

Scrapie Flock Certification Program Standards

Cooperative procedures and standards adopted by APHIS and State scrapie certification boards for reducing the incidence, and controlling the spread, of scrapie through certification of enrolled flocks.

Scrapie-Positive Animal

An animal for which an approved test for scrapie has been conducted with positive results by NVSL or another laboratory authorized by the Administrator to conduct scrapie tests in accordance with 9 CFR, part 54, through any of the following methods:

- Histopathologic examination of CNS tissues from the animal for characteristic microscopic lesions of scrapie;
- Protease-resistant protein analysis methods including, but not limited to, immunohistochemistry (IHC) and/or Western blotting on CNS and/or peripheral tissue samples from a live or a dead animal. The method must have been approved by the Administrator for use on that tissue;
- Bioassay;
- Scrapie-associated fibrils detected by electron microscopy; or
- Any other test method approved by the Administrator in accordance with 9 CFR 54.10.

Separate Contemporary Lambing Groups

To be a separate contemporary lambing group, the group must be maintained separately to prevent the animals from coming into physical contact with other lambs, kids, ewes, does, or birth fluids or placenta from other ewes or does. This separate maintenance must preclude contact through a fence during lambing and for 60 days following the date the last lamb or kid was born in a lambing season and must preclude using the same lambing facility as other ewes or does unless the lambing facility was cleaned and disinfected under supervision of an APHIS representative, State Veterinarian’s representative, or an accredited veterinarian between lambings in accordance with the guidelines published in the SFCP standards and the Scrapie Eradication UM&R. The flock owner must maintain adequate records to document which

animals were maintained in each contemporary lambing group and to document when cleaning and disinfection was performed and who supervised it.

Slaughter Channels

Animals in slaughter channels include any animal sold, transferred, or moved:

- Directly to a slaughter facility;
- To an individual for custom slaughter;
- For feeding expressly to improve the animal's condition for movement to slaughter; or
- Through a sale or market expressly for one of these purposes.

Markets or sale operators must notify buyers when lots of animals in slaughter channels are being sold. Sexually intact mature female animals, as evidenced by eruption of the first incisor that are maintained in the same enclosure with breeding animals from another flock are not in slaughter channels. Animals offered for unrestricted sale are not in slaughter channels. When selling animals that may move only in slaughter channels, the owner must indicate on the bill-of-sale that the animals being sold are for slaughter only.

Source Flock

A flock in which a State or APHIS representative has determined that at least one animal was born that was diagnosed as scrapie positive at an age of 72 months or less or in which a scrapie-positive animal has resided throughout its life. The determination that an animal was born in a flock must be based either on the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records, to show that a scrapie-positive animal originated from the flock combined with the absence of records indicating that the animal was purchased and added to the flock. If DNA from the animal was collected when the animal resided in the flock of birth by an accredited veterinarian and stored at an approved genotyping laboratory, or if DNA collection and storage is required for breed registration and the breed registration has appropriate safeguards in place to ensure the integrity of the banking process, the owner may request verification of the animal's identity based on DNA comparison if adequate records and identification have been maintained by the owner and the repository to show that the archived DNA is that of the animal that has been traced to the flock. A flock will no longer be a source flock after it has completed the requirements of a flock plan.

State

Each of the 50 States, the District of Columbia, the Northern Mariana Islands, Puerto Rico, and all territories or possessions of the United States.

State Representative

An individual employed in animal health activities by a State or a political subdivision of a State who is authorized by the State or political subdivision to perform the function involved.

State Veterinarian

The veterinary official of a State authorized by the State to supervise and perform the official animal health work of that State.

Suspect Animal

An animal will be designated a suspect animal in accordance with 9 CFR 79.4 if it is:

- A sheep or goat that exhibits any of the following clinical signs of scrapie and has been determined to be suspicious for scrapie by an accredited veterinarian or a State or APHIS representative: weight loss despite retention of appetite; behavioral abnormalities; pruritus (itching); wool pulling; biting at legs or side; lip smacking; motor abnormalities such as incoordination, high stepping gait of forelimbs, bunny-hop movement of rear legs, or swaying of back end; increased sensitivity to noise and sudden movement; tremor, star gazing, head pressing, recumbency, or other signs of neurological disease; or chronic wasting;
- A sheep or goat that has tested positive for scrapie or for the protease-resistant protein associated with scrapie on an unofficial test or a screening test; or
- A sheep or goat whose official scrapie test yielded inconclusive or suggestive results (i.e., the NVSL report reads inconclusive or suggestive rather than not detected.)

Terminal Feedlot

- A dry lot approved by a State or APHIS representative or an accredited veterinarian authorized to perform this function where animals are separated from all other animals by at least 30 feet at all times or are separated by a solid wall through, over, or under which fluids cannot pass and contact cannot occur and from which animals are moved only to a terminal feedlot or directly to slaughter (this means other sheep could be on the same premises if they meet this requirement); or
- A pasture when approved by, and maintained under, the supervision of the State and in which only nonpregnant animals are permitted, where there is no direct fence-to-fence contact with another flock, and from which animals are moved only to another terminal feedlot or directly to slaughter.

Trace

All actions required to identify the flock of origin or destination of an animal.

Unofficial Test

Any test for the diagnosis of scrapie or for the detection of the protease-resistant protein associated with scrapie in a live or dead animal that either has not been approved by the Administrator or that was not conducted at an approved diagnostic laboratory.

Veterinary Medical Officer (VMO)

A veterinarian employed by, or acting at the direction of, the State or APHIS.