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Department of
Agriculture**

**Animal and
Plant Health
Inspection
Service**

**Veterinary
Services**



Scrapie Program Standards Volume 2:

Scrapie Free Flock Certification Program (SFCP)

May 2016

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I. Introduction

The Scrapie Free Flock Certification Program (SFCP) is a voluntary program that monitors participating flocks for evidence of scrapie. Any sheep or goat flock owner or manager may apply to participate in the SFCP. For flocks that participate in the Export Category, the program provides a pathway for recognition of negligible scrapie risk as an **Export Certified flock**.

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

<http://www.aphis.usda.gov/animal-health/scrapie>

Periodic summary reports from the NSD on enrolled, **infected, and source flocks** are also available through this Web site.

This version of the SFCP standards replaces the June 2013 version. In fiscal year (FY) 2013, APHIS revised the SFCP to increase animal sampling at the flock level to find the last remaining classical scrapie cases in the United States. The Complete Monitored category was removed from the program, and participants were given the option to convert to either the Export or Select category.

Under title 9 of the *Code of Federal Regulations* (CFR) part 54 Subpart B, APHIS has the authority to develop, publish, and enforce standards for the Scrapie Free Flock Certification Program. This document outlines the current SFCP standards that the Deputy Administrator of APHIS Veterinary Services (VS) has approved as of May 2016.

These standards will be reviewed periodically and will be revised as needed by APHIS. Future revisions of the standards will be posted at http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/. Substantive changes will be made through Federal Register notice and comment. We will also provide email notification to stakeholders through GovDelivery, a free email subscription service. To subscribe to this free service go to <https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new> and select "Animal Health - Sheep and Goats" and "Federal Register Publications – Notices Regarding Animal Health."

II. List of Acronyms

| | |
|--------------|---|
| AD | Assistant Director (formerly Area Veterinarian in Charge, AVIC) |
| APHIS | Animal and Plant Health Inspection Service |
| CFR | Code of Federal Regulations |
| CNS | Central Nervous System |
| DSE | Designated Scrapie Epidemiologist |
| FSIS | Food Safety and Inspection Service |
| FUI | Flock Under Investigation |
| ID | Identification |
| NSD | National Scrapie Database |
| NSEP | National Scrapie Eradication Program |
| NVSL | National Veterinary Services Laboratories |
| OIE | World Animal Health Organization |
| PEMMP | Post Exposure Management and Monitoring Plan |
| RSSS | Regulatory Scrapie Slaughter Surveillance |
| SAHO | State Animal Health Official |
| SFCP | Scrapie Free Flock Certification Program |
| VS | Veterinary Services |
| VSLs | Veterinary Services Laboratory Submission |

III. Part I: Definitions

The following definitions cover language specific to the SFCP. General scrapie program terms are defined in title 9, *Code of Federal Regulations* (CFR), parts 54 and 79, and in the National Scrapie Program Standards Volume 1: National Scrapie Eradication Program. The current versions of each of these documents are available on the APHIS scrapie Web site at:

<http://www.aphis.usda.gov/animal-health/scrapie>

Note: To reduce the length of this document, references to sheep and goats have been combined. Therefore, in these standards “flock” refers to sheep flocks and goat herds; “lambing” refers to sheep lambing and goat kidding; “ewe” refers to ewes and does; and “ram” refers to rams and bucks.

Board

The State scrapie certification board as described in **part II.B.2** of this document and 9 CFR 54.22; or, if a State does not have a board, the AD.

Category

Classification of a flock with regard to the SFCP. Categories are listed below from highest to lowest:

- Export (Statuses: Export Monitored and Export Certified)
- Select
- Nonparticipating

Certification Date

The date on which a flock obtains Export Certified status in the Export category.

Clinical Signs of Scrapie

- Weakness of any kind, not including those with visible traumatic injuries, and no other sign of scrapie. Signs of weakness may include:
 - Stumbling;
 - Falling down;
 - Difficulty rising;
- Significant weight loss, despite retention of appetite, in an animal with adequate dentition;
- Increased sensitivity to noise and sudden movement;
- Tremors;
- Star gazing;
- Head pressing;
- Bilateral gait abnormalities, not including abnormalities involving only one leg or one front and one back leg. Signs of gait abnormalities may include:
 - Incoordination (ataxia);
 - High stepping gait of forelimbs;
 - Bunny-hop movement of rear legs;
 - Swaying of hindquarters;

- Repeated intense rubbing accompanied by bare areas or damaged wool in similar locations on both sides of the animal's body or, if on the head, both sides of the poll;
- 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 central nervous system (CNS) signs;
- Death.

Note: Not all scrapie-affected animals show all clinical signs. In addition, animals in the early stages of the disease may not show any clinical signs.

Compliance Irregularity

An instance in which a flock owner does not comply with one or more of the program requirements for the category (Export or Select) in which his or her flock is enrolled.

Cull Animal

Any **mature animal** that is slaughtered for or by the flock owner or that is sold for slaughter, feeding for slaughter, or through a livestock market other than as part of a bred ewe or breeding stock sale.

Enrollment Date

- Select category: The date the application for enrollment in the SFCP, VS Form 5-22, is subsequently approved and is received by the local VS District Office. **Note:** If a Select category flock permanently relocates to a new State, the enrollment date becomes the date the new application for enrollment in the SFCP is received in the new State.
- Export category: The date of the initial satisfactory inspection of the flock for participation in the SFCP. **Note:** If an Export category flock permanently relocates to a new State, the enrollment date becomes the date of initial inspection in the new State.

Export Certified Flock

A flock participating in the Export category that met the provisions of **part III** of these standards for at least 7 years, including testing requirements, and then applied and was approved for Export Certified status.

Export Monitored Flock

A flock participating in the Export category not yet meeting the criteria for Export Certified status.

Found Dead

Any **mature animal** meeting any of the following criteria:

- The animal was discovered on the premises after death, or reasonably should have been located after death, in a condition in which a suitable sample could be collected;
- The animal died off the premises while still owned by the enrolled flock owner (such as animals in transit or at a veterinary clinic); or
- The animal was euthanized or home slaughtered. In flocks where 30 animals have been tested, this does not include:

- Animals used in research or product harvest settings that are euthanized for product harvest, research, or management reasons; or
- Animals that are home slaughtered.

If in either case they were healthy enough to have been sold as **cull animals** and were not displaying signs of scrapie as determined and documented by the examining veterinarian, these animals may instead be examined as required for **cull animals** prior to euthanasia/home slaughter.

Note: See [Appendix 1](#) for specimen collection procedures.

Foundation Flock

All sexually intact female animals present in the flock on the date the District Office was notified the flock owner intended to pursue an alternative sampling method, documented by flock records and in a list provided to the District Office, excluding animals that were subsequently **sold** before they lambed and less than 12 months of age.

Lost to Inventory

Any **mature animal** that presumably died but was never found, or was found in a condition in which a suitable sample could not be collected due to situations beyond the control of the owner, limited to the following and provided the flock owner notifies the local VS District Office within 72 hours of the event:

- Extreme weather events:
 - The carcass was never found, or
 - The weather event prevented the carcass from being found in a timely manner that a suitable sample could not be collected;
- Predation:
 - The carcass was never found,
 - The carcass was not found in a timely manner that a suitable sample could be collected, or
 - Tissues required for testing were consumed or removed by a predator;
- Large operations:
 - The size of the pasture or geography/terrain in which the animal died prevented the carcass from being found or being found in a timely manner that a suitable sample could be collected; or
- Other event determined by the District Office to be out of the control of the flock owner (for example, a barn fire).

Note: See [Appendix 1](#) for specimen collection procedures.

Lower Status Animal

An animal or flock that is nonparticipating, is in the Select category, is in a lower status within the Export category, or has less time in status (a more recent status date) than the recipient flock.

Mass Casualty

A situation in which numerous animals die over a short period of time from the same apparent cause, such as poisoning, fire, flooding, blizzard, or infectious disease.

Mature Animal

Any sheep or goat over 18 months of age as evidenced by at least one of the following:

- Birth records; and/or
- The complete eruption of one of the first permanent incisors and/or partial or complete eruption of one of the second permanent incisors.

National Scrapie Eradication Program (NSEP)

The cooperative State-Federal-industry program to eradicate classical scrapie from the United States.

National SFCP Oversight Committee

A national committee composed of flock owners, allied industry, and State and Federal representatives who provide input to APHIS on the policies and practices of the SFCP.

National Scrapie Program Coordinator

The person appointed by APHIS to coordinate the [National Scrapie Eradication Program](#), or his or her designee.

Neutered Animal

A sterilized male or female animal.

Nonparticipating Flock

A flock that is not enrolled in the SFCP.

Official Genotype Test

APHIS will recognize the results of genotype tests as official only if the following conditions are met:

- The blood is drawn by an authorized Federal or State animal health employee or an accredited veterinarian;
- The sheep is officially identified;
- The sample is submitted with a VS Form 5-29, “Cooperative State-Federal Scrapie Control Program, Scrapie Test Record” or an electronic or State issued equivalent; and
- APHIS has approved the laboratory.

Official SFCP Identification

A unique individual identification (ID) device approved by the APHIS Administrator for this purpose meeting 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 to the [flock of origin](#).

The types of ID listed below are currently approved for the SFCP:

- Tamper-evident Flock ID ear tags approved by APHIS for use in the SFCP (includes all Flock ID plastic tags approved for the **NSEP**).
- An APHIS-assigned flock (premises) ID number and unique individual number tattooed in the ear (the flock ID number is tattooed in the right ear, and an individual animal number is tattooed in the left ear), and if the ear is unusable, the flank or tail web.
- Electronic ID implants – Implants must be placed in a location allowed by the Food Safety and Inspection Service (FSIS). Implants must be used with a visual ID device or method approved for use in the scrapie eradication program when moved off the premises, unless the animal meets both criteria listed below:
 - The animal is moved or transferred under at least one of the following conditions:
 - Moved without change of ownership;
 - Transferred as a registered animal and the implant number is recorded by the registry on the registry certificate; and/or
 - Moved to another SFCP-enrolled flock.
 - The animal 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**. The owner statement must list the owner’s name and address, the 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 goat registries that have been recorded in the APHIS NSD may be used to identify goats while the animal resides on the premises where the animal was born. When the animal is moved off the premises, or is residing on another 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.
- Since some States require all sheep and goats to be officially identified, producers may use official metal “MEAT” ear tags issued to the enrolled flock owner by APHIS to meet this requirement for lambs (including sexually intact lambs) sold at less than 12 months of age for slaughter or to a **terminal feedlot**. “MEAT” tags may also be used on culled **mature animals** as a secondary form of ID in addition to the required SFCP ID.

Program

The Scrapie Free Flock Certification Program (SFCP).

Representative of the Board

A person, designated by the **board**, to act on the **board’s** behalf in its role in the program.

Scrapie

A transmissible spongiform encephalopathy of sheep and goats characterized by a nonfebrile, insidious degeneration of the CNS. Scrapie as used in these standards excludes nonclassical scrapie.

Scrapie Free Flock Certification Program (SFCP)

A voluntary State, Federal, and industry cooperative effort established under 9 CFR 54 subpart B to meet the following objectives:

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

Scrapie Qualified Accredited Veterinarian

A Category II **accredited veterinarian** approved by the VS local district office to perform specialized scrapie program activities listed in the Scrapie Program Standards.

Select Monitored Flock

A flock participating in the program in the Select category.

SFCP Approved Goat Breed Associations and Registries

APHIS-approved organizations maintaining 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 showing 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, on request, provide APHIS with information allowing any association-registered animal to be traced to its flock of origin. A link to a list of organizations whose tattoos have been approved for use by APHIS for participation in the SFCP is located at:

https://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/approval_registry_tattoos.pdf

SFCP Standards

The National Scrapie Program Standards, Volume 2, also called the SFCP standards, are the cooperative procedures and standards adopted by APHIS and State scrapie certification **boards** to reduce the incidence and control the spread of classical scrapie.

Sold

Any animal transferred to another person or legal entity through sale, gift, barter, or other means; also, any animal moved to another premises or flock, that is not a part of the enrolled flock, without transfer of ownership.

State Animal Health Official (SAHO)

Individual employed by the State as the chief animal health official of the State, often but not always the State Veterinarian.

Status

The level of participation of a flock in a program category (from highest to lowest status).

- Export category

- Export Certified status indicates a flock that has successfully met all Export category requirements, including sampling requirements, for 7 continuous years, and then applies and is approved for Export Certified status.
- Export Monitored status indicates a flock approved to participate in the Export category.
- Select category
 - Select status indicates a flock approved to participate in the Select category, and is the only status in this category.
- Suspended
 - Suspended status indicates a flock that has been suspended pending the outcome of either a disease investigation or a noncompliance investigation.
- Nonparticipating
 - Nonparticipating status indicates a flock that is not enrolled in the SFCP.

Status Date

The status date reflects the date from which an **Export Monitored flock** has been in continuous compliance with **part III** of these program standards. When a flock becomes Export Certified, it has a certified date rather than a status date. Only **Export Monitored flocks** have status dates and accrue time in status.

Test Eligible Animal

An animal that meets a test protocol's age and post-exposure elapsed time requirements, including the following:

- Genetically susceptible sheep or goats **live animal tested** at over 14 months of age or after giving birth in the flock;
- Sheep or goats postmortem tested at over 14 months of age or after giving birth in the flock;
- A sheep or goat postmortem tested at over 12 months of age because it exhibits, or in the case of dead animals exhibited, **clinical signs of scrapie**;
- A sheep or goat postmortem tested at any age because it tested suspect, inconclusive, or positive for scrapie on a **live animal test** or was determined to be a **suspect animal** by a State or Federal veterinarian.

Additionally, animals in Export category flocks:

- Must have been born on the premises or must have lambed on the premises unless the animal is genetically susceptible and all other test eligible animals have been tested, and
- May not have been scrapie tested, with a valid result, within the previous 12 months.

Note: The ages specified above for **test eligible animals** are different from the age specified for mandatory testing of animals **found dead** (18 months). This means that animals **found dead** at more than 14 months but under 18 months that did not have clinical signs or test positive or inconclusive for scrapie may be submitted to meet the sampling minimums, but are not required to be submitted.

Years in Status

The number of complete years a flock has gained from its status date through the current date.

Definitions for the following terms can be accessed in the National Scrapie Program Standards Volume 1: National Scrapie Eradication Program, also known as the “Scrapie Eradication Uniform Methods and Rules (UM&R)” at:

http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/umr_scrapie.pdf

- Accredited Veterinarian
- Commingled/Commingling
- Designated Scrapie Epidemiologist
- Exposed Animal
- Exposed Flock
- Flock of Origin
- Flock Under Investigation
- Genetically Susceptible Exposed Animal
- High-Risk Animal
- Inconsistent State
- Infected Flock
- Limited Contact
- Live Animal Test
- Noncompliant Flock
- Official Test
- Owner Statement
- Scrapie-Positive Animal
- Source Flock
- Suspect Animal
- Terminal Feedlot

IV. Part II: Overview of the Scrapie Free Flock Certification Program

A. Overview of the Program

The Scrapie Free Flock Certification Program (SFCP) was established in 1992 through the combined efforts of APHIS, the States, and the sheep and goat industries. The SFCP is a voluntary program for sheep and goat flock owners who wish to reduce or eliminate the risk of introducing classical scrapie into their flocks.

Flock owners who join the SFCP commit to monitoring their flocks for evidence of scrapie and reporting all clinically **suspect animals** to APHIS or State authorities for testing. Monitoring includes individual animal identification, accurate recordkeeping, observation and evaluation of animals for **clinical signs of scrapie** (including death), and testing a specified number of **test eligible animals** for scrapie.

Participants in the SFCP benefit by decreasing their risk of introducing classical scrapie into their flocks. Many participants also benefit from the increased marketability of sheep and goats monitored in this program.

SFCP participants choose to participate in one of two categories: The Export category (**part III**), or the Select category (**part IV**).

B. Roles and Responsibilities in the SFCP

1. National SFCP Oversight Committee

- a. APHIS facilitates a **National SFCP Oversight Committee**. The Committee's membership is based on recommendations from the following:
 - (1) Sheep and goat enrolled flock owners;
 - (2) Allied industry;
 - (3) State Animal Health Officials (SAHOs);
 - (4) **Accredited veterinarians**; and
 - (5) Sheep and goat producer organizations, breed registries, and associations.
- b. Priority for committee membership is given to flock owners enrolled in the program. The committee provides individual input to APHIS regarding policy and technical improvements in the program.
- c. The committee meets quarterly, consults with scientific and technical experts and State scrapie certification **boards**, considers suggestions for program improvement, and supports the program at national, State, and local levels.

2. State scrapie certification boards

- a. Establishment of the **board**
 - (1) A State scrapie certification **board** may be formed within each State, at the discretion of the Assistant Director (AD) and the SAHO.
 - (2) A State may have only one such **board**.
- b. Membership of the **board**

- (1) Selection of **board** members. The AD, in cooperation with the SAHO and enrolled flock owners, appoints members to the **board**.
 - (2) Members may include, but are not limited to, the following:
 - (a) AD;
 - (b) SAHO;
 - (c) Enrolled flock owners;
 - (d) **Designated scrapie epidemiologist** (DSE);
 - (e) **Accredited veterinarians**; and
 - (f) Other Federal and State personnel involved in administering the SFCP within the State.
 - c. Chair of the **board**. Once established, the board may elect a chairperson.
 - d. **Board** Meetings
 - (1) The **board** meets at least annually.
 - (2) Meetings may be in person or by other means (for example, teleconference).
 - e. Functions of the **board** include:
 - (1) Reviewing and approving program enrollment applications;
 - (2) When asked, reviewing and providing input to the AD when an enrolled flock is being considered for a reduction in status, status date, or for removal from the program;
 - (3) Educating flock owners about scrapie and the SFCP; and
 - (4) Helping APHIS identify barriers and develop strategies to meet the objectives of the **National Scrapie Eradication Program (NSEP)** and the SFCP within the State.
 - (5) **Note:** A **board** may enact more stringent requirements than those outlined in the SFCP standards to fit its State scrapie situation, if the requirements are scientifically sound and have been documented and provided to the enrolled producers prior to implementation.
 - f. Delegation of authority by the **board**. The **board** is encouraged to assign a representative or subcommittee to act on its behalf for the functions listed in 2.e, and to act as a liaison to the AD and SAHO.
3. APHIS' role in the SFCP
 - a. In cooperation with the SAHO, assign a Federal or State employee, typically the DSE, to oversee SFCP activities in the State.
 - b. Maintain a records database for use in the program.
 - c. Provide guidance and education in cooperation with State animal health agencies and **accredited veterinarians**.
 - d. As resources permit, assign personnel to conduct initial inspections for new applicants and annual inspections for participants enrolled in the Export category, and other inspections as necessary. **Note:** If APHIS does not have adequate personnel or resources available to complete an inspection within 14 months of the last inspection, the flock owner is responsible for hiring a **scrapie qualified accredited veterinarian** to complete the inspection at the flock owner's expense.
 - e. As resources permit, make a reasonable attempt to contact Export category participants to remind them to schedule an annual inspection by their due date.
 - f. As resources permit, assist owners with the collection and submission of scrapie samples, and funding the testing of diagnostic samples for scrapie. **Note:** Testing

- assistance is limited to 30 scrapie tests per flock per year; additional tests are at owner expense.
- g. When collecting and submitting specimens for scrapie testing, follow the Guidelines for Specimen Collection and Submission in the SFCP Standards (**Appendix 1**), and provide the guidelines to **accredited veterinarians** collecting such samples.
4. **Accredited veterinarians** may be employed by owners to perform the following activities:
 - (1) Examine animals or flocks for **clinical signs of scrapie**; and
 - (2) Collect and submit live animal and postmortem samples from SFCP-enrolled animals for **official tests**.
 5. Flock owners who join the SFCP agree to comply with all of the program requirements applicable to their category of participation. A summary of the requirements for each category follows in the next two tables.
 - a. Export category requirements (**part III**). Table 1 shows the requirements for the Export category.

Table 1. Export Category Requirements

| Requirement | Part. Section | Page(s) |
|--|----------------------|----------------|
| Report signs of scrapie | III.D | 22 |
| Officially identify animals with SFCP-approved identification (ID) device | III.E | 23 |
| Establish and maintain flock records | III.F | 23-24 |
| When selling or transferring animals as enrolled animals, provide buyers or recipients with written documentation of the seller's name, address, flock ID number, category, status, and status date | III.F.4.d | 24 |
| Ensure access to the flock and the flock records, including gathering and handling the animals during inspections | III.G | 24 |
| Schedule and complete an annual inspection within 11 to 13 months of the previous annual inspection | III.H | 25 |
| Ensure and document that all cull animals sold , including all mature animals slaughtered for or by the owner, are either examined for signs of scrapie by a veterinarian before slaughter or their tissues are submitted for scrapie testing | III.I | 26 |
| Report, within 30 days, any action resulting in a change in status or status date such as the acquisition of and/or commingling with nonparticipating animals, animals with a lower status and/or status date, or acquisition of nonparticipating embryos or embryos with a lower status and/or status date | III.J-III.L | 26-28 |
| Ensure proper samples are collected and submitted for scrapie testing from all scrapie suspect animals over 12 months of age and all found dead (including euthanized) animals over 18 months of age | III.P.1-2 | 32-33 |

| | | |
|--------------------------------------|--------------|-------|
| Ensure sampling requirements are met | III.P | 32-40 |
|--------------------------------------|--------------|-------|

- b. Select category requirements (**part IV**). Table 2 below shows the requirements for the Select category.

Table 2. Select Category Requirements

| Requirement | Part. Section | Page(s) |
|---|----------------------|----------------|
| Report signs of scrapie | IV.C | 48 |
| Officially identify animals | IV.D | 49 |
| Establish and maintain flock records | IV.E | 49 |
| Ensure access to flock records | IV.F | 49 |
| Ensure proper samples are collected and submitted for scrapie testing from all scrapie suspect animals | IV.G.1 | 49-50 |
| Ensure sampling requirements are met | IV.G | 49-51 |

C. Participating Flocks from **Inconsistent States**

Per 9 CFR 79.3, breeding sheep and goats from **Inconsistent States** that are not in slaughter channels must be enrolled in the Complete Monitored or equivalent category of the SFCP to move in interstate commerce. For the purposes of 9 CFR 79.3, the Export category of the revised program is considered equivalent to the Complete Monitored category. The Select category is not considered automatically equivalent.

Therefore, the following additional requirements apply to Select Monitored flocks permanently or seasonally located in a scrapie **Inconsistent State**:

1. All animals in the flock that are **found dead** or euthanized must be tested for scrapie.
2. Movement and Identification
 - a. No animal from the flock may be moved or sold outside the State unless it was born and raised in that flock, or has lived in the flock for a minimum of 12 months.
 - b. All animals from the flock must be officially identified, regardless of age, when moved or sold outside the flock (whether outside or inside the State).

These requirements do not apply to animals moving direct to slaughter or within slaughter channels, in which case the animal can only move in accordance with 9 CFR 79.3 (b) and (c).

V. Part III: Export Category

A. Objective of the Export Category

The Export category monitors and samples participating flocks for evidence of scrapie. If conditions are met, then monitoring and sampling under the Export category may lead to Export Certified status and recognition of negligible scrapie risk.

B. Application for Participation in the Export Category

Key Point

A full application package includes an SFCP application form, a flock inventory, and an initial flock inspection report.

1. An interested flock owner submits a complete program application to the local VS District Office. A complete application includes the following:
 - a. Program application form, VS Form 5-22, “Application for the Scrapie Flock Certification Program”; and
 - b. An inventory of the animals in the flock. The following information must be provided for each animal:
 - (1) The animal’s official ID (if already applied);
 - (2) Breed (or cross) and, if breed is unknown, type (sheep: Meat, dairy, or fiber *and* face color; goat: Meat, dairy, or fiber);
 - (3) Date of birth, or estimated age;
 - (4) Natural addition or acquired; and
 - (5) Sex.

Note: It is desirable, but not required, that this information be provided in a Microsoft Excel spreadsheet via e-mail to the District Office. Microsoft Excel and Microsoft Word templates are available from the District Office. The use of one of these formats will decrease the time required to conduct future flock inspections and inventories.
2. On receipt of the complete application, the VS local District Office and/or State personnel will:
 - a. Assign a State or APHIS veterinarian to schedule an inspection and inspect the flock. (Alternatively, a flock owner may use a **scrapie qualified accredited veterinarian** to inspect the flock, at the owner’s expense.) At the inspection, the inspector:
 - (1) Verifies the information provided by the flock owner;
 - (2) Verifies official SFCP ID is present on each animal over 12 months of age and is accurately listed in the inventory provided with the application (if the official ID was applied by the flock owner after the application was submitted, the official ID number must be added to the inventory for each animal during the inspection);
 - (3) Verifies that no animals in the flock exhibit signs of scrapie; and
 - (4) Completes the inspection report, VS Form 5-19A “Scrapie SFCP Flock Inspection Report”.

- b. The inspector submits the initial inspection report and inventory to the VS local district office within 30 business days of the initial inspection date for approval.
 - c. The AD/**board** reviews the program application within 30 business days of receiving the complete application package.
 - d. If the application is approved, the **enrollment date** is the date the inspection was conducted.
3. Flock owners may not apply for enrollment in both the Select and the Export categories.

C. Statuses Within the Export Category

1. The distinction between flocks with an Export Monitored and an Export Certified status is described below (listed from higher to lower status).
 - a. An **Export Certified flock** is a flock in the Export category that has at least 7 **years in status**, has met the requirements to advance to Export Certified status including the sampling requirement, and has been approved for Export Certified status.
 - b. An **Export Monitored flock** is a flock that has been approved to participate in the Export category of the program that has not yet gained Export Certified status.
2. An Export category flock gains time in status based on its status date and sampling. Once a flock is approved to participate in the Export category, it is considered an enrolled flock with a status date based on the date of the initial enrollment inspection. New flocks assembled entirely from one or more Export category flocks will have their status dates determined as described in **part III.O**.

D. Reporting Signs of Scrapie

Key Point

All animals suspected of having scrapie, whether dead or alive, must be reported.

The following must be reported to the local VS District Office (or as directed):

1. As soon as practicable and no later than 24 hours after discovery: Animals displaying signs of scrapie prior to death, including animals suspected of having another neurologic and/or chronic debilitating (prolonged wasting) illness and were either **found dead** or euthanized; and
2. As soon as practicable, but no later than 48 hours after discovery: Live animals displaying signs of scrapie, including animals suspected of having another neurologic and/or chronic debilitating (prolonged wasting) illness.

Note: When determining whether a flock owner has complied with this requirement, the AD will consider times such as holidays and weekends when it might not be possible to reach a staff member in the office. However, in the case of **found dead** or euthanized animals, the flock owner is still responsible for ensuring tissues required for testing are preserved, such as by chilling the head. (See **Appendix 1**.)

E. Animal Identification (ID) Requirements for Export Category Flocks

Key Point

All animals over 12 months of age are required to be identified with an **official SFCP identification** device.

1. Identify all animals in the flock that are 12 months of age and older with an official SFCP ID.
2. If an acquired animal is not identified with an official SFCP ID, properly identify it with an official SFCP ID before **commingling** it with the flock.
 - a. Any official ID already on an animal should not be removed.
 - b. Leased rams already identified with official ear tags approved for use in the **NSEP** that are not approved for SFCP use, such as official metal tags, do not need to be retagged.
 - c. An animal purchased from an enrolled flock must be identified with official SFCP ID from its **flock of origin** to be treated as an enrolled animal.
3. Identify all sexually intact animals less than 12 months of age with official SFCP ID prior to change of ownership or removal from the flock, unless moving direct to slaughter, to slaughter-only auctions, or to a **terminal feedlot**.

F. Recordkeeping Requirements for Export Category Flocks

Key Point

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

1. Maintain and organize required records so they can be easily located and used to reconcile the animal inventory during inspections.
2. Keep records for a minimum of 7 years after an animal dies or has otherwise been removed from the flock.
3. Maintain, for future inspections, records on all animals present in the flock at the time of the initial enrollment inspection and all animals acquired after the initial inspection including the information listed below:
 - a. Official and any secondary identification or marks.
 - b. Sex.
 - c. Species and breed (or cross) or, if breed unknown, type (sheep: Meat, dairy, or fiber *and* face color; goats: Meat, dairy, or fiber).
 - d. Date of birth or estimated month and year of birth. The actual date of birth (or at least the month and year of birth) must be recorded for animals born in the flock after the initial inspection.
 - e. **Flock of origin** (owner name, address, and flock ID number):
 - (1) List animals acquired prior to enrollment for which this information is unavailable as “unknown”; and
 - (2) Include the date of entry for those animals not born in the flock (the estimated date may be used for animals acquired before the initial inspection).

- f. Whether the **flock of origin** is an Export category flock and, if so, the flock of origin's status and status date and, if different, the animal's status and status date on the date of acquisition.
 - g. If acquired as an enrolled animal, the documentation provided by the seller as described in 4.d.
 - h. If imported, a copy of the import documentation.
 - i. For registered animals, the registry and registration number.
 - j. If known, information on genotyping including the following:
 - (1) Genotype at codons 136, 154, and 171;
 - (2) Name of the person who collected the samples for genotyping (and indicate if the collector is an **accredited veterinarian**); and
 - (3) Copy of the official lab report.
4. If an animal leaves the flock, record the information listed below.
- a. Disposition of the animal (dead, **sold**, or missing).
 - b. If the animal is dead:
 - (1) Official ID, date died/**found dead**, and diagnosis/cause of death; and
 - (2) The laboratory or collection facility to which necropsy samples were submitted by the owner or date and name of sample collector if submitted by APHIS, State personnel, or an **accredited veterinarian** and the date the samples were sent to the laboratory.
 - c. If the animal was **sold** or removed, official ID, reason removed (sold for slaughter, breeding, exhibition, etc.), date removed, and name and address of buyer.
 - d. If an animal is **sold** as an enrolled animal, the buyer must be provided in writing all the information regarding the animal that is required to be kept, including the seller's name, address, flock ID number, category, the flock's status and status date and, if different, the animal's status and status date on the date of sale.
 - e. If the animal is missing, official ID, date noted missing, and any known supporting details (for example weather events, predation, theft, etc.).
5. The flock owner will follow all recordkeeping requirements for embryos as described in **part III.M.4.d**.

G. Access to Records

- 1. Flock owners will make available for inspection and copying all records required to be maintained.
- 2. Flock owners will request breed associations and registries, livestock markets, and slaughter facilities to disclose records to APHIS and the State, when needed, to trace potential sources of exposure or **exposed animals**, or to verify owner records.

H. Annual Flock Inspections

Key Points

- An annual inspection is required.
- A Federal or State veterinarian or a **scrapie qualified accredited veterinarian** must inspect the flock for signs of scrapie annually.

1. An initial inspection and thereafter annual inspections are required for all Export category flocks.
2. The annual inspection must be conducted 11 to 13 months after the last inspection.
3. At the inspection, the inspector will:
 - a. Observe each animal and the flock as a whole for signs of scrapie;
 - b. Verify and record the SFCP ID of each animal present on the date of inspection (**Note:** This can be done by checking animals off the inventory list from the previous year's inspection and adding any new additions);
 - c. Examine records for completeness and accuracy and reconcile flock records with those of the previous inspection to ensure each addition and removal is documented; and
 - d. Determine whether all sampling requirements have been met to maintain current status or to qualify for Export Certified status.
4. Requirement for veterinary inspection. A Federal or State veterinarian, an **accredited veterinarian**, or a **scrapie qualified accredited veterinarian** must inspect all animals in Export category flocks at least once a year for signs of scrapie as per 3.a. However, an authorized Federal or State animal health employee who is not a veterinarian may perform the parts of the annual inspection listed in 3.b-3.d. under the direction of a State or Federal veterinarian. Therefore, to meet the requirement for veterinary inspection, the District Office may elect to do one of the following:
 - a. Have a Federal or State veterinarian or a **scrapie qualified accredited veterinarian** perform the entire inspection; or
 - b. Have a Federal or State veterinarian, an **accredited veterinarian**, or a **scrapie qualified accredited veterinarian** inspect the flock for **clinical signs of scrapie** within 3 months of an annual inspection conducted by an authorized Federal or State animal health employee who is not a veterinarian.
5. Federal and State animal health employees, **accredited veterinarians**, and **scrapie qualified accredited veterinarians**, while allowed to participate in the SFCP and to submit samples from animals in their own flocks, may not inspect their own flocks or conduct scrapie diagnostic tests on their own animals.
6. If it is necessary to change the annual inspection date, a flock may be inspected before 11 months from its first annual inspection, and then every 11 to 13 months thereafter.

I. Veterinary Inspection of Cull Animals

Key Point

All **cull animals** must be inspected for signs of scrapie within 30 days of sale or removal from the flock, and the flock owner will maintain the required documentation of the inspection for 7 years from the date the animal was removed.

1. The flock owner will ensure and document that all **cull animals** sold, including all **mature animals** slaughtered for or by the owner, are either examined by a State, Federal, or accredited veterinarian for signs of scrapie before slaughter or tissues from slaughtered animals are submitted for scrapie testing. The examination requirement can be met by any one of the following methods:
 - a. The animal is sold within 30 days after the flock's annual inspection;
 - b. The animal is slaughtered under State or Federal inspection; or
 - c. The animal is inspected by a State, Federal, or accredited veterinarian within 30 days before it is sold.
2. The flock owner will obtain a certificate of veterinary inspection or a signed statement from the State, Federal, or accredited veterinarian showing the date the **cull animals** were inspected, listing the animal's official identification numbers, and stating the animals were found free of signs of scrapie. This inspection may occur on farm or at another site such as a livestock market.
3. This document must be kept with the flock records for 7 years from the date the animal was removed from the flock.

J. Animal Acquisitions

Key Points

- All acquisitions of lesser status must be reported to the District Office within 30 days of the acquisition.
- Female animals may only be acquired from flocks of equal or greater status.
- Male animals may be acquired from any flock, with a few exceptions.

1. All acquisitions resulting in a downgrade in status or status date must be reported to the District Office within 30 days of the acquisition.
2. Information on all acquisitions must be provided to the inspector during the annual inspection process.
3. **Female animal acquisitions.** Export category flocks may acquire female animals only from flocks of greater status or from flocks of equal status with an equal or older status date without a reduction in status or status date. The specific reductions are described in **part III.R.**

4. **Male animal acquisitions.**

- a. Currently, there is little scientific evidence that male animals pose a significant risk of spreading classical scrapie. Nonetheless, male animals can be infected with scrapie and, therefore, cannot be ruled out as a risk of scrapie exposure. Acquired male animals that are positive for scrapie will affect the status date of Export category flocks, as described in **part III.R.13**. Therefore, flock owners should consider risks when selecting male animals from nonparticipating or lower status flocks.
- b. Participating flocks may acquire a male animal for breeding, without a reduction in status or status date, from any flock if the following conditions are met:
 - (1) The male animal is not a **scrapie positive**, **scrapie suspect**, or **genetically susceptible exposed animal**;
 - (2) The male animal does not show any **clinical signs of scrapie** at the time of acquisition; and
 - (3) The male animal is officially identified to its flock of birth with official SFCP ID.
 - (a) If the male animal was acquired from a **nonparticipating flock**, official SFCP ID must be applied and a record kept as per **part III.E**.
 - (b) Leased or loaned male animals residing in the flock only during the breeding season do not need to be retagged if already identified with official ID.
- c. Status date of acquired male animals.
 - (1) If the male animal is acquired from a **nonparticipating flock**, its status date is the date it entered the enrolled flock.
 - (2) If the male animal is acquired from an SFCP flock, its status date is the most recent status date of the following:
 - (a) Its **flock of origin**;
 - (b) The receiving flock;
 - (c) That of any flock while it resided there; or
 - (d) That of any female animals with which it has been **commingled**.
- d. Male animals acquired from a lower status flock and/or from a flock with less time in status than the receiving flock must be maintained:
 - (1) Separate from the female animals except during the breeding season, and
 - (2) Separate from lambs at all times.

The animals also may not be maintained in confined lambing facilities.

5. Acquired **neutered animals** are treated the same as male breeding animal acquisitions, unless they were acquired from a flock of lower status or status date; then they must be maintained separately from the breeding flock (including any lambs that may be retained or **sold** for breeding purposes).

K. Commingling

Key Point

The flock's status will be affected if any of its animals are **commingled** with female animals of lower status, other than **limited contacts**.

1. An Export category flock's status and status date will change if its female animals are either commingled with female animals with a lower status and/or status date, other than **limited contacts**, or are maintained on the premises of a lower status flock and then returned to the original flock. See **part III.N** for adding a new premises to a flock and **part III.R.12** for specific reduction.
2. Male animals and **neutered animals** from an Export category flock will be treated as acquired animals if they are returned to their flock after they have been either **commingled** with lower status female animals, other than **limited contacts**, or maintained on the premises of a lower status flock (see **part III.J.4**).

L. Imported Animals

An Export category flock may import a sheep or goat, or sheep or goat embryos/oocytes from a foreign country, without a reduction in status and/or status date if the imported animal or embryos/oocytes meet all of the following requirements:

1. If importing a sheep or goat:
 - a. The animal has been imported legally;
 - b. The animal was moved directly from the port of entry to the flock or, when required, from the post-entry quarantine to the flock;
 - c. The animal has never **commingled** with female animals of lower status and/or status date and has not been maintained on the premises of a flock with a lower status and/or status date; and
 - d. The animal originates from:
 - (1) A country that APHIS recognizes as scrapie free, or
 - (2) A flock that has reached an equivalent or higher status in a scrapie flock certification program that APHIS recognizes.
 - e. If importing an embryo/oocyte, it must have been legally imported for unrestricted use and meet the requirements in **part III.M.4.b.(1)(b)**.

M. Use of Semen, Embryos, and Sheep or Goat Milk, Colostrum, or Milk- or Colostrum-Derived Products

Key Points

- The status of semen used does not affect the status of the receiving flock, with some exceptions.
- The status of the embryo donor initially determines the status of the embryo.
- The embryo and the receiving flock will have the same status after implantation, and the status and status date will be the lower of the two statuses/status dates.
- The status of the embryo will affect the status of the receiving flock if the embryo has a lower status than the receiving flock.
- Export category flocks may only use sheep or goat milk, colostrum, or milk- or colostrum-derived products only from sheep/goats in the same flock, from flocks of greater status, or from flocks of equal status with an equal or older status date.

1. Export category flocks may not use germplasm, sheep or goat milk, colostrum, or milk- or colostrum-derived products from any animal that is designated a **scrapie-positive animal**, a scrapie suspect, a **genetically susceptible exposed animal**, or a **high-risk animal**.
2. All germplasm, sheep or goat milk, colostrum, or milk- or colostrum-derived product use resulting in a downgrade in status or status date must be reported to the District Office within 30 days of use.
3. **Semen.** Participating flocks may use semen from nonparticipating or lower status male animals with no effect on status or status date, as long as the conditions listed in *1* are met.
4. **Embryos.**
 - a. 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 (see **part III.J.4**).
 - b. Determining the status of the embryo:
 - (1) Until implantation, an embryo will have the highest status and status date achieved by the donor at or following collection. Exceptions:
 - (a) If the donor's status is downgraded as a result of the donor or donor's flock having been exposed to scrapie within 72 months before collection, the embryo will have the highest status and status date achieved by the donor following the downgrade; and
 - (b) Embryos legally imported into the United States for unrestricted use and U.S.-origin embryos meeting the requirements for import into the United States may be used without a reduction in status or status date. For foreign-origin embryos, the producer must maintain a copy of the import documentation. For U.S.-origin embryos, the producer must provide and retain a copy of VS Form 17-140, "U.S. Origin Health Certificate", documenting the applicable donor, collection, and storage requirements were met.
 - (2) 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.

- c. Determining the status of the embryo recipient's flock:
 - (1) The status and status date of the recipient flock converts to the embryo's status and status date, if lower, at the time of implantation.
 - (2) Changes in the 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, unless the donor was determined to be either a **scrapie-positive animal** or a high-risk animal, or a genetically susceptible exposed animal that was not tested for scrapie on obex and lymphoid tissue with the result "Not Detected".
 - (3) **Note:** A flock owner may request the AD/**board** review the status and status date of an embryo before implantation.
- d. Recordkeeping requirements for embryos. The following must be recorded:
 - (1) All official and other identification, the **flock of origin**, status, and status date of the embryo donor at the time of collection;
 - (2) All official and other identification, the **flock of origin**, status and, if applicable, status date of the embryo sire at the time of collection; and
 - (3) All identifying information on the embryo storage container.
- 5. **Sheep or goat milk, colostrum, or milk- or colostrum-derived products**
 - a. Export category flocks may use sheep or goat milk, colostrum, or milk or colostrum-derived products only from sheep/goats in the same flock, from flocks of greater status, or from flocks of equal status with an equal or older status date without a reduction in status or status date. This does not preclude the use of cow's milk or colostrum or products derived therefrom.
 - b. If a flock uses sheep or goat milk, colostrum, or milk- or colostrum-derived products from a flock of lesser status or of equal status with a more recent status date, its status and status date will be reduced in accordance with **part III.R.15**.

N. Relocation of an Established Flock and Addition of a New Premises to an Established Flock

The following conditions apply when permanently relocating an established flock (interstate or intrastate), temporarily relocating an established flock (interstate or intrastate), or adding a new premises to an established flock (purchased or leased):

1. The flock owner must notify the District Office by letter or email of the following within 60 days of the relocation or addition:
 - a. Flock ID;
 - b. Date relocated or date new premises was added;
 - c. Address of the new location or added premises;
 - d. If the new location or added premises was purchased, the previous owner's name and current address, or if leased, the current owner's name and address;
 - e. If, to the flock owner's knowledge, the new location or added premises housed sheep or goats in the past 5 years; and
 - f. If, to the flock owner's knowledge, the new location or added premises has ever housed a scrapie-infected or **source flock**.
 - g. **Note:** If the flock is being relocated to a new State, both District Offices must be notified by letter or email within 60 days of the relocation.

2. For permanent relocations, if moving between States or intrastate to a premises not previously inspected as part of the SFCP, a new application (VS Form 5-22) must be submitted and an inspection must be scheduled within 60 days of relocation of the flock.
3. For temporary relocations, the local VS District Office, on receipt of the notification, will determine whether the new temporary location requires an inspection within 60 days or at the next annual inspection.
4. For additional premises that were not previously inspected as part of the SFCP, an inspection must be scheduled within 60 days of the premises acquisition or start date of the lease.
5. Effect on **enrollment date**. When a flock moves to a permanent location in another State, the new **enrollment date** for the flock is the date that the flock is accepted into the program in that State.
6. Effect on status and/or status date. If all requirements for continuing in the program are met, the status date remains the same, unless the new location or premises, whether permanent or temporary, has housed either sheep or goats within the past 5 years or **infected/source flocks**. In this case, the following changes to the status date described below apply:
 - a. Relocation to a new premises (permanent or temporary) or addition of a new premises (purchased or leased) having housed sheep or goats within the past 5 years will result in a change of status and/or status date to the date of the move. This status change will take place unless all confined lambing areas (i.e., pens or barns) used by the previous flock are either cleaned and disinfected or made permanently inaccessible before the move. (Permanently inaccessible means that the area/structure has been permanently altered so that it can no longer be used for housing, grazing, or lambing.)
 - b. Relocation to a new premises (permanent or temporary) or addition of a new premises (purchased or leased) that has housed an **infected or source flock** within the past 5 years will result in a change of status and/or status date to the date of the move.
 - c. Relocation to a new premises (permanent or temporary) or addition of new premises (purchased or leased) that have housed an **infected or source flock** more than 5 years ago will result in a change of status and/or status date to the date of the move — unless all confined lambing areas (i.e., pens or barns) used by the previous flock are either cleaned and disinfected or made permanently inaccessible before the move. (Permanently inaccessible means that the area/structure has been permanently altered so that it can no longer be used for housing, grazing, or lambing.)
7. Applications or notifications received beyond 60 days will be treated as new applicants to the program.

O. Establishing a New Flock Entirely from Animals Enrolled in the SFCP

1. If a new flock is established entirely from animals already enrolled in the SFCP, the flock owner must apply as a new participant within 60 days of acquisition of the first animal and undergo an initial inspection to maintain the acquired status and status date of the purchased animals.
2. If all acquired animals constituting the new flock originate from the same SFCP flock, then the new flock will acquire the status and status date of the originating flock and the

number of **test eligible animals** collected by the originating flock on the date of acquisition.

3. If the acquired animals constituting the new flock originate from more than one SFCP flock, then the new flock will acquire the status and status date of the originating flock with the lowest status and most recent status date. The new flock will acquire the lowest number of **test eligible animals** of the flocks involved.

P. Sampling Requirements for Export Category Flocks

Key Points

- Any animal that tests suspect, inconclusive, or positive on a **live animal test** must be submitted for testing regardless of age.
- Any animal greater than 12 months of age that demonstrates, or demonstrated in the case of dead/euthanized animals, clinical signs associated with scrapie must be submitted for testing.
- Any animal greater than 18 months **found dead** or euthanized must be submitted for scrapie testing.
- At least one **test-eligible animal** must be tested for scrapie, with valid results, for each **year in status** held by the flock until the flock reaches Export Certified status, unless the flock is following one of the alternative sampling protocols.
- **Export Monitored flock** owners who have not had at least 1 **test eligible animal** tested for scrapie for 2 sequential years will be removed from the program, unless the flock is following one of the alternative sampling protocols.
- At least 15 **test-eligible animals** must be tested for scrapie, with valid results, to gain 6 **years in status**, unless the flock is following one of the alternative sampling protocols.
- At least 30 **test-eligible animals** must be tested for scrapie, with valid results, before a flock is eligible for Export Certified status, unless the flock elects to follow one of the alternative sampling protocols.

An Export category flock must meet all of the sampling requirements listed below to maintain its status date and to become eligible for Export Certified status.

1. **All animals exhibiting **clinical signs of scrapie** or have tested suspect, inconclusive, or positive for scrapie on a **live animal test** must be tested.**
The flock owner will ensure suitable tissue samples are collected and submitted for diagnostic purposes from the following:
 - a. Animals over 12 months of age that exhibit, or exhibited in the cases of dead animals, clinical signs consistent with scrapie, including animals suspected of having another neurologic and/or chronic debilitating (prolonged wasting) illness; and
 - b. Animals of any age that have tested suspect, inconclusive, or positive for scrapie on a **live animal test** or have been determined to be a scrapie suspect by a State, Federal, or **accredited veterinarian**.

- c. Tissues shall be submitted to an APHIS-approved laboratory or collection facility in accordance with **part V**. Additional tissues must be submitted if requested by a State or Federal animal health official.
2. **All animals found dead, including euthanized animals, must be tested.**
- a. The flock owner will ensure suitable tissue samples are submitted from all **found dead** animals (including euthanized animals) over 18 months of age to an approved laboratory or collection facility. This includes animals that resided in the flock and were still owned by the flock owner when they died off the premises of the flock (such as at veterinary clinics, while in transit, or loaned out).
 - b. This requirement is limited to five animals per occasion when a State or Federal veterinarian determines that the animals died from a **mass casualty**. In these cases, the DSE will select the five highest-risk animals for sampling.
 - c. **Exception:** Animals used in research or product harvest settings that are euthanized for product harvest or management reasons that were healthy enough to have been sold as **cull animals** as determined by the examining veterinarian may be examined as allowed for **cull animals** rather than submitted for testing if:
 - (1) The flock owner or manager notifies the District Office the flock will follow this protocol, and
 - (2) The flock owner keeps records so results of each examination can be verified at the flock's annual inspection.

Note: Animals that have any of the **clinical signs** associated with scrapie listed in the definition for **clinical signs** must be submitted for scrapie testing.
3. **Export Monitored flocks must meet an annual sampling minimum to maintain status and to remain enrolled in the program.**
- a. At least one **test-eligible animal** must be tested for scrapie, with valid results, for each **year in status** held or since the preceding annual inspection.
 - (1) The number of test-eligible animals tested for scrapie will be reviewed at each annual inspection.
 - (2) Samples to meet the annual minimum requirement can be from live animals, necropsies of **found dead** or culled animals, and samples collected at slaughter (including those collected through RSSS).
 - b. One additional animal must be tested for each animal over 18 months of age that is **lost to inventory**.
 - (1) The AD determines whether an animal qualifies as an animal **lost to inventory** when notified by the flock owner that an animal has left the flock due to circumstances beyond his or her control. (See the definition for **lost to inventory**.)
 - (2) A maximum of 30 additional animals will be tested under this requirement per year. For example, if 5 animals over 18 months of age are **lost to inventory** in a year, 5 additional animals must be sampled; if 35 animals over 18 months of age are **lost to inventory** in a year, 30 additional animals must be sampled.
 - (3) If more than 30 animals have already been tested for scrapie, a **mature animal** that was tested for scrapie with "Not Detected" results within the previous 12 months can be counted toward the **lost to inventory** sampling requirement. This does not apply to animals meeting the **found dead** definition.

- (4) If the animal **lost to inventory** had been live-animal tested with “Not Detected” results within the previous 12 months, no additional animals need to be tested.
- (5) The additional animals tested to make up for the **lost to inventory** animals will not be counted toward the sampling requirements for either advancement in status date or Export Certified status.
- (6) These additional animals must be tested before the second inspection after the loss to inventory occurs, or the flock’s status date will be reduced by 12 months.
 - (a) Samples to meet the **lost to inventory** requirement can be from live animals, necropsies of culled animals, and samples collected at slaughter (including those collected through RSSS).
 - (b) **Note:** Tests on **found dead** animals will not count toward satisfying the **lost to inventory** sampling requirement.
- (7) The additional animals cannot be sheep that are known to be genetically resistant or genetically less susceptible sheep unless both of the following conditions are met:
 - (a) All the genetically susceptible animals in the flock over 18 months of age have already been tested; and
 - (b) The animals are sampled at slaughter or necropsy (i.e., live-animal testing of genetically resistant or genetically less susceptible sheep is not counted toward meeting sampling requirements).
- c. Flocks that do not meet the annual sampling requirement:
 - (1) If not all requirements listed in 3.a-3.b are satisfied at the time of the annual inspection, the flock will have a 3-month grace period to correct the deficit. If the deficit has not been corrected by the end of the 3-month grace period, the flock’s status will be reduced by 1 year.
 - (2) If not all requirements in 3.a-3.b are satisfied for 2 sequential years, the flock will be removed from the program.
- d. Waivers from the annual sampling requirement:
 - (1) The annual sampling minimum is waived for flocks that comply with sampling Alternative 1 or sampling Alternative 2 (See 5.c-5.d).
 - (2) The annual sampling minimum is waived for genetically resistant flocks (all animals in the flock are sheep, and are either genetically resistant or genetically less susceptible [RR or QR at codon 171, respectively], and only RR rams are used for breeding).
 - (3) The annual sampling requirement is waived for genetically susceptible flocks (contains one or more genetically susceptible animals [QQ sheep or goats]) that have tested for scrapie all genetically susceptible animals that are over 14 months of age or that have ever lambed/kidded, 4 times with at least 1 valid result, or all such animals have had a valid scrapie test within the preceding 12 months.
 - (4) Note: The flock must continue to meet all other testing requirements in Part III.P.1-3.
4. **Export Monitored flocks must reach specific sampling thresholds to gain more than 5 years in status.**
 - a. **Note:** The sampling requirements listed below assume that the Export category flock has been in continuous compliance with these Standards for the same number of years being described.

- b. To gain 6 years in status, at least 15 **test-eligible animals** must be tested for scrapie, with valid results, unless following either Alternative 1 or Alternative 2 sampling protocol.
- c. **Export Monitored flocks** cannot gain more than 7 years in status (i.e., they cannot have 8 or more years in status).
 - (1) If the flock is following the standard sampling protocol, its status will revert to 7 **years in status** at each subsequent annual inspection until it has completed the sampling requirement and gained Export Certified status.
 - (2) If the flock is following either of the alternative sampling protocols, its status will revert to 7 **years in status** at each subsequent annual inspection until the sampling requirements for the alternative sampling protocol it is following have been completed and it has gained Export Certified status.
 - (3) If the flock does not meet all requirements of the Export category during this period, the flock will be downgraded for the noncompliance as described in **part III.R**.
- 5. **Export Monitored flocks** must complete a sampling protocol to be eligible for Export Certified Status.
 - a. In addition to meeting all sampling requirements in *I-4*, an **Export Monitored flock** must complete one of the three sampling protocols listed in *5.b-5.d* to be eligible for Export Certified status.
 - b. Standard Sampling Protocol:
 - (1) At least 30 **test-eligible animals** must be tested for scrapie, with valid results.
 - (2) The animals tested must represent the breeds and use category of animals present in the flock, and they must be sampled over a reasonably distributed period of time.
 - (3) Samples to meet the 30-animal requirement for Export Certified status can be from live animals, necropsies of **found dead** or culled animals, and samples collected at slaughter (including those collected through RSSS).
 - (4) When the flock has 6 **years in status**, if 15 animals have not been tested, then a sufficient number of genetically susceptible sheep or goats may be **live animal tested** to meet the 15-animal requirement. If the flock has an insufficient number to meet the 15-animal requirement, then all remaining genetically susceptible sheep and all goats over 14 months of age (except those tested during the preceding 12 months with valid results and those tested 4 times with at least 1 valid result) must be live-animal tested with negative results to meet the requirement.
 - (5) When the flock has 7 **years in status**, if 30 animals have not been tested, then a sufficient number of genetically susceptible sheep or goats over 14 months of age may be live-animal or postmortem tested to meet the 30-animal requirement. If the flock has an insufficient number to meet the 30-animal requirement, then all remaining genetically susceptible sheep and all goats over 14 months of age (except those tested during the preceding 24 months with valid results or that have been tested 4 times with at least one valid result) must be live-animal tested with negative results.
 - (a) If needed to meet the 30-animal requirement, genetically susceptible sheep and all goats under 14 months of age when the flock is otherwise eligible for

Export Certified status must either be tested when they are 14 months of age or sold before they reach 14 months of age and before they lamb.

- (b) If no additional genetically susceptible animals are in the flock, as evidenced by **official genotype test** reports, no additional animals need to be tested for the flock to be Export Certified.
- c. **Alternative 1 sampling protocol.** Testing all genetically susceptible animals **sold** and home slaughtered:
 - (1) To follow this sampling protocol, the flock owner must notify the District Office by letter or email of his or her intention to pursue Alternative 1. The flock owner must also submit a complete inventory of animals in the flock at the time of conversion, including the animals' official ID, breed or cross (if breed is unknown, then type), date of birth or estimated age, sex, and genotype if known.
 - (2) If a flock owner who is already enrolled in the SFCP elects to follow this alternative sampling protocol, the flock's status date will become the lesser of the flock's current status date or 12 months of status for each **test-eligible animal** sampled.
 - (3) If an animal is **lost to inventory** or any of the sampling requirements listed in *c.(4)(a)* are not met, the flock owner must decide between one of the two following penalties:
 - (a) The flock will no longer be able to participate in either Alternative 1 or Alternative 2 and will have to meet the standard sampling protocol to become eligible for Export Certified status; and the flock's status date will become the lesser of the flock's current status date or 12 months of status for each test-eligible animal sampled. The flock must also meet the additional sampling requirements of the standard sampling protocol to retain more than 5 years in status.
 - (b) The flock can continue to participate in Alternative 1, but its status date will be reset to the date the District Office was notified of the animal **lost to inventory** or the animal sold after 14 months of age/before giving birth without officially genotyping and **live animal testing** with valid "Not Detected" results.
 - (4) Alternative 1 sampling requirement
 - (a) Live-animal test all genetically susceptible sheep and all goats that are either over 14 months of age or have given birth in the flock before sale or disposal (including home slaughter).
 - i. All **official genotype tests** and collection of samples for **live animal tests** will be conducted at owner expense.
 - ii. All genetic susceptibility tests and tests for scrapie must be **official tests**.
 - iii. The test must have "Not Detected" results (inconclusive tests must be repeated).
 - iv. An animal may be sampled at slaughter or necropsy as an alternative; the flock owner is responsible for ensuring arrangements are made to sample the animal.
 - (5) When the flock has **7 years in status**, if 30 animals have not been tested, then a sufficient number of genetically susceptible sheep or goats may be live-animal or

postmortem tested with negative results to meet the 30-animal requirement. If the flock has an insufficient number to meet the 30-animal requirement, then all remaining genetically susceptible sheep and all goats over 14 months of age (except those tested during the preceding 24 months with valid results or that have been tested 4 times with at least 1 valid result) must be live-animal tested with negative results.

- a) If needed to meet the 30-animal requirement, genetically susceptible animals under 14 months of age when the flock is otherwise eligible for Export Certified status must either be tested when they are 14 months of age or sold before they reach 14 months of age and before they lamb.
 - b) If no additional genetically susceptible animals are in the flock, as evidenced by **official genotype test** reports, no additional animals have to be tested for the flock to be Export Certified.
- d. Alternative 2 sampling protocol. Testing the **foundation flock**.
- (1) To follow this sampling protocol, the flock owner must notify the District Office by letter or email of his or her intention to pursue Alternative 2. The notification must include a list of the official ID of each animal composing the **foundation flock**.
 - (2) If a flock owner who is already enrolled in the SFCP elects to follow this alternative sampling protocol, the flock will maintain its current status date (i.e., electing to follow Alternative 2 will not change the flock's status or status date).
 - (3) If an animal is **lost to inventory** or any of the sampling requirements listed in *d.(4)(a)-(b)* are not met, the flock owner must decide between one of the two following penalties:
 - (a) The flock will no longer be able to participate in either Alternative 1 or Alternative 2 and will have to meet the standard sampling protocol to be eligible for Export Certified status. The status date will be changed to the lesser of the current status date or 12 months of status for each animal tested. The flock must meet the additional sampling requirements of the standard sampling protocol to retain more than 5 years in status.
 - (b) The flock can continue to participate in Alternative 2, but its status date will be reset to the date the VS office was notified the animal was **lost to inventory**, died, or was sold.
 - (4) Alternative 2 sampling requirement:
 - (a) Postmortem testing, before Export Certified status is approved, of all females present when the **foundation flock** was formed, unless:
 - i. They died or were sold/gifted at less than 12 months of age and never lambed or aborted; or
 - ii. They were officially genotyped, determined to be genetically less susceptible or genetically resistant, and sold or gifted.
 - (b) Postmortem testing, before Export Certified status is approved, of all females acquired after the **foundation flock** was formed (other than females acquired from countries APHIS recognizes as scrapie free or from **Export Certified flocks**) that have or may have lambed on the premises.
 - (c) The flock will not gain **6 years in status** until at least 50 percent of the **foundation flock** has been postmortem tested with negative results or all

genetically susceptible sheep and all goats in the **foundation flock** have been live-animal or postmortem tested, with valid results (except those tested during the preceding 12 months with valid results or that have been tested 4 times with at least 1 valid result).

- (d) **Exception:** Any animal having lived for at least 7 years in the flock since the foundation flock was formed that is still alive and not displaying clinical signs associated with scrapie when the flock is eligible for Export Certified status may be exempted from postmortem testing (all genetically susceptible animals must be **live animal tested** with results “Not Detected”).
 - (e) When the flock has 7 **years in status**, if 30 animals have not been tested, then a sufficient number of genetically susceptible sheep or goats may be live-animal tested with negative results to meet the 30-animal requirement. If the flock has an insufficient number to meet the 30-animal requirement, then all remaining genetically susceptible sheep and all goats over 14 months of age (except those tested during the preceding 24 months with valid results or that have been tested 4 times with at least 1 valid result) must be live-animal tested with negative results.
 - i. This includes **foundation flock** animals exempted from necropsy that are goats or genetically susceptible sheep.
 - ii. If needed to meet the 30-animal sampling minimum, genetically susceptible sheep and all goats under 14 months of age when the flock is otherwise eligible for Export Certified status must either be tested when they are 14 months of age or sold before they reach 14 months of age and before they lamb.
 - iii. If no additional genetically susceptible animals are in the flock, as evidenced by **official genotype test** reports, no additional animals have to be tested for the flock to be Export Certified.
 - iv. Note that (e) does not modify the requirements in (a) and (b).
6. Sampling requirements for **Export Certified flocks**:
- a. All **Export Certified flocks** must continue to meet all sampling requirements listed in **part III.P.1-2**.
 - b. Additionally, two **cull animals** (maximum of 30 per year) for each animal over 18 months of age **lost to inventory** must be sampled. (Note that the number of animals to be tested for each animal over 18 months of age **lost to inventory** is higher for **Export Certified flocks** than for **Export Monitored flocks**.)
 - (1) The testing requirement must be met by the second inspection after the animal was **lost to inventory**. Flocks not meeting the requirement after the second inspection will lose their Export Certified status, will be reduced to Export Monitored status with a 6-year status date, and may not reapply for Export Certified status until the sampling requirement has been met.
 - (2) If **cull animals** 18 months of age or older are unavailable for sampling during this period, live-animal testing of genetically susceptible sheep and goats over 14 months of age not tested in the preceding 12 months may be used. Previously tested animals may only be used if there are no untested genetically susceptible sheep and goats over 14 months of age in the flock.

- (3) A **mature animal** that was tested for scrapie with “Not Detected” results within the previous 12 months can be applied to the **lost to inventory** sampling requirement if the flock had already tested 30 animals (this does not apply to animals meeting the **found dead** definition).
7. Testing requirements
 - a. All tests for scrapie or genetic susceptibility must be **official tests**. APHIS will recognize the results of genotype tests as official only if the following conditions are met:
 - (1) The blood is drawn by an authorized Federal or State animal health employee or an **accredited veterinarian**;
 - (2) The sheep is officially identified;
 - (3) The sample is submitted with a VS Form 5-29, “Cooperative State-Federal Scrapie Control Program, Scrapie Test Record,” or an electronic or State issued equivalent; and
 - (4) APHIS has approved the laboratory.
 - b. Exempting lambs born in genetically resistant flocks following the Standard and Alternative 1 sampling protocols from the genotyping requirement:
 - (1) If there are no genetically susceptible animals in the flock and all rams on the premises over 4 months of age are officially genotyped and determined to be RR from that point forward, lambs do not need to be genotyped to be considered genetically less susceptible animals.
 - (2) Note: These conditions will be confirmed at each subsequent annual inspection, and if an inspector believes at any time that one or more of the animals in the flock may be a QQ animal, the inspector will require that the animal or animals be officially genotyped.
 - c. All samples for scrapie testing must be submitted promptly. If the flock owner elects to store animal samples to facilitate shipping multiple samples in one shipment, all samples must be shipped within 30 days of collection and before the next occurring annual inspection. Samples stored beyond this time will not be counted toward the flock’s annual minimum or toward gaining Export Certified status.
 - d. To facilitate collection of samples at slaughter facilities where VS provides collection, the flock owner should contact the District Office before shipping the animal to coordinate sample collection. Information provided to the District Office should include:
 - (1) Official ID;
 - (2) Age;
 - (3) Sex;
 - (4) Breed;
 - (5) Shipping date; and
 - (6) Receiving slaughter plant information (name, address, and contact information).

Note: APHIS will make reasonable efforts to collect samples from SFCP animals at slaughter facilities where APHIS routinely collects samples. APHIS does not guarantee collection of SFCP samples at slaughter plants. If the slaughter plant does not have an agreement with APHIS to collect samples, if the owner does not make prior arrangements with APHIS to collect the sample, or if the sample must

be taken for the flock to retain status, it is the flock owner's responsibility to retrieve the head and submit it to an APHIS collection facility (see [Appendix 1](#)).

Q. Suspension of Export Category Status

1. Reasons for suspending status:
 - a. Disease investigation. If a flock has a potential scrapie exposure, it will be designated a **flock under investigation** (FUI). Its status will be suspended until the investigation of the potential exposure is completed. **Note:** The flock's status will remain suspended until one of the following conditions is met:
 - (1) All scrapie-**exposed animals** have been tested for scrapie on brain and lymph tissue;
 - (2) The owner elects to have the flock's status date reduced to the date the **exposed animals** entered the flock, all scrapie-**exposed animals** are **officially genotyped**, and all genetically susceptible animals have been tested for scrapie on brain and lymph tissue; or
 - (3) It is determined the **exposed animals** are no longer in the flock and cannot be located and tested, all animals designated for testing as part of the disease investigation have been tested, and the flock's status date is reduced to the date the **exposed animals** entered the flock.
 - b. Noncompliance investigation. If a flock is suspected of not complying with these program standards, its status will be suspended until the AD/**board** completes an investigation of the possible **compliance irregularity** and applies one of the outcomes described in 3.a.
2. Flock owner and public notification of suspended status:
 - a. The AD will notify the flock owner by letter or email that the status of the flock has been suspended pending the outcome of an investigation.
 - b. The flock's SFCP status will appear as "Suspended" on the APHIS Web site until the investigation is completed and an outcome is determined.
3. Removal of suspended status:
 - a. The suspended status of a flock will be removed once the investigation has been completed and the AD has determined which of the following investigation outcomes to apply to the flock:
 - (1) Retained status and status date;
 - (2) Retained status and status date with a warning letter;
 - (3) Reduction in status and/or status date; or
 - (4) Removal from the program.
 - b. The "Suspended" status will be replaced on the Web site with the restored status and/or status date or the reduced status and/or status date. If the flock is removed from the program, the flock will be removed from the Web site.

R. Removal of an Export Category Flock/Reduction in Status or Status Date

The following are reasons an Export category flock will either be removed from the program or have a reduction in status and/or status date. The reductions in status and/or status date described below are the minimum reductions for noncompliance. The AD/**board** may determine the situation warrants more severe action, including removal of the flock from the

program. **Note:** For **Export Certified flocks** any noncompliance will result in a reduction of status to Export Monitored, and any specified reduction in status date will be from 7 years.

1. If an Export category flock is designated an **infected or source flock**, it will be removed from the program. The flock owner may reapply for enrollment in the program after all **high-risk animals** are removed and a flock cleanup plan has been completed.
2. If an Export category flock is determined to be an **exposed flock**, that retained a known **high-risk animal** not subsequently necropsied on death or euthanasia and found negative for scrapie on obex and lymphoid tissue, it will be removed from the program. These flocks are ineligible to apply for reenrollment in the SFCP for 24 months if testable tissues were not submitted for testing.
3. If an Export category flock does not comply with a requirement for which it was previously downgraded or for which it received a warning letter within the past 5 years or does not comply with multiple requirements on more than one occasion, the flock may be removed from the program. These flocks are ineligible to apply for reenrollment in the SFCP for 24 months.
4. If the flock owner does not report and ensure satisfactory samples are submitted for testing from animals displaying signs consistent with scrapie or animals that tested positive, suspect, or inconclusive on a live animal scrapie test in accordance with **part III.P.1**, the flock will be removed from the program and cannot reapply for 24 months.
5. If the flock owner does not submit satisfactory tissue samples for testing from an animal **found dead** or euthanized at over 18 months of age in accordance with **part III.P.2**, the impact on the flock's status and status date is described below.
 - a. First offense: Reduction in status date to the date the animal died.
 - (1) If mitigating circumstances can be shown, the AD/**board** may treat the animal as "**lost to inventory**" and require the flock to meet the sampling requirement for **lost to inventory** animals. If this option is selected, the flock's status date will be reduced 12 months or, if the flock is Export Certified, its status date will be reduced to 6 years. If the animal is determined to have been lost to inventory and had also been live-animal tested with "Not Detected" results within the previous 12 months, there will be no change in the status date.
 - (2) **Exception.** If the AD, SAHO, and **National Scrapie Program Coordinator** determine that the situation leading to noncompliance was partially out of the flock owner's control, there will not be a reduction in status or status date if the following conditions are met within 12 months of the time VS is made aware of the untested **found dead**/euthanized animal:
 - (a) If the flock contains sheep and the animals have not already been officially genotyped, the flock owner will officially genotype all sheep.
 - (b) Thirty genetically susceptible animals (sheep testing QQ at codon 171 and any goats) 14 months of age or older that have not been live-animal tested within the past 12 months are live-animal or necropsy tested with valid "Not Detected" results. If there are fewer than 30 genetically susceptible animals in the flock, then all genetically susceptible animals will be tested. In cases where there are not 30 genetically susceptible animals over 14 months of age available for testing, genetically susceptible animals (including animals that have not been genotyped) that have not been bred and are under 14 months of

- age may be sold to slaughter instead of being held for testing at 14 month of age.
- (c) If there are more than 30 genetically susceptible animals in the flock that have not been live-animal tested in the previous 12 months, the DSE will select the animals for testing based on scrapie risk. In most cases this will result in testing animals between 14 and 60 months of age.
 - (d) The flock's status will be suspended, and will appear on the APHIS Web page as suspended, until the required testing is completed.
 - (e) If a flock has no genetically susceptible animals the flock's status will be suspended until 2 **cull animals** 14 months of age or older are tested at necropsy/slaughter with valid "Not Detected" results on obex and lymphoid tissue. (Note: These animals will not count toward the sampling minimum.)
 - (f) The **National Scrapie Program Coordinator** may require additional testing if deemed necessary to assess the scrapie risk in the flock.
- b. Second offense within 5 years: Mandatory reduction in status date to the date the animal was reported missing or dead. If the flock is Export Certified, it will be reduced to Export Monitored status with a status date of the date the animal died.
 - c. Third offense within 5 years: The flock will be removed from the SFCP and the owner cannot reapply for 24 months.
6. If the annual sampling requirements listed in **part III.P.3** are not satisfied at the time of the annual inspection, and the flock is not following either of the alternative sampling protocols, then:
- a. The flock will have a 3-month grace period to correct the deficit. If the deficit has not been corrected by the end of the 3-month grace period, the flock will be reduced by **1 year in status**.
 - b. If these requirements are not satisfied for 2 sequential years, the flock will be removed from the program and cannot reapply for 24 months.
7. If the flock owner does not report an acquisition, **commingling**, or use of germplasm or sheep or goat milk, colostrum, or milk- or colostrum-derived product normally resulting in a downgrade of status or status date to the District Office within 30 days of the animal's entry into the flock or use of the germplasm or sheep or goat milk, colostrum, or milk- or colostrum-derived product, then:
- a. First offense: The status date will be decreased by the number of days the germplasm, sheep or goat milk, colostrum, or milk- or colostrum-derived product or animal's status date would have reduced the flock's status date plus the number of days delinquent in reporting. If the flock is Export Certified, the status will be reduced to Export Monitored and the status date will be the status date of the **flock of origin** further reduced by the number of days delinquent.
 - b. Second offense within 5 years: The status date will be decreased by the number of days the germplasm, sheep or goat milk, colostrum, or milk- or colostrum-derived product or animal's status date would have reduced the flock's status date plus 12 months. In the case of **Export Certified flocks**, the status will be reduced to Export Monitored and the status date will be the status date of the **flock of origin** further reduced by 12 months.
 - c. Third offense within 5 years. The flock will be removed from the SFCP and the owner cannot reapply for 24 months.

8. If the flock owner does not officially identify a sexually intact animal prior to sale in accordance with **part III.E**, then:
 - a. The flock's status date will be reduced to the date the noncompliance was identified.
 - b. Flocks with a status date reduction for this reason within the previous 5 years will be removed from the program and the flock owner cannot reapply for 24 months.
9. The flock has a potential exposure to scrapie:
 - a. If a **scrapie-positive animal** was **commingled**, other than **limited contacts**, with the flock and the flock does not meet the definition of an **infected or source flock**, the flock's status date will be reduced to the date on which the positive animal left the flock, died, or the **commingling** ceased.
 - b. If a flock receives or **commingles**, other than **limited contacts**, with a **high-risk animal** not tested at necropsy and found negative on obex and lymphoid tissue, the flock's status date will be reduced to the date on which the animal left the flock, died, or the **commingling** ceased.
 - c. If the flock owner fails to make animals available for testing or to submit tissues from dead animals as part of a disease investigation, the flock will be removed from the program and the flock owner cannot reapply for 24 months.
10. The flock owner does not properly document dispositions and acquisitions of animals.
 - a. If the acquisition and disposition history is reconstructed, the following apply:
 - (1) **Export Monitored flocks**: The flock's status date will be reduced by 12 months.
 - (2) **Export Certified flocks**: The flock's status will be reduced to Export Monitored with a status date of 6 years.
 - b. If the acquisition and disposition history is not reconstructed, the status date will be reduced to the date the flock was brought into compliance. Flocks downgraded within the previous 5 years for this reason will be removed from the program and cannot reapply for 24 months.
11. The flock has not been inspected on schedule in accordance with **part III.H**:
 - a. If 14 to 18 months have passed since the flock's last inspection, the status date will be reduced by the number of months, over 13, it is overdue.
 - b. If 18 or more months have passed since its last inspection, the flock will be removed from the program and the flock owner cannot reapply for 12 months unless the **AD/board** determines unusual mitigating circumstances apply. If mitigating circumstances exist, at a minimum the status date will be reduced by the number of months, over 13, the flock inspection is overdue.
 - c. In the case of **Export Certified flocks**, the flock will be reduced to Export Monitored and the status date reduction taken from 7 years.
12. If the flock acquired or **commingled** with a lower status female animal, then:
 - a. **Export Monitored Flocks**:
 - (1) If an **Export Monitored flock** acquires or **commingles** with a female animal from a **nonparticipating flock** or **Select monitored flock**, its status date will be reduced to the date the female animal was added to or **commingled** with the flock.
 - (2) If an **Export Monitored flock** acquires or **commingles** with a female animal from an **Export Monitored flock** with a more recent status date, its status date will be reduced to the most recent status date of the flocks involved.
 - b. **Export Certified Flocks**:

- (1) If an **Export Certified flock** acquires or **commingles** with a female animal from a **nonparticipating flock** or **Select Monitored flock**, its status will be reduced to Export Monitored and its status date will be reduced to the date the female animal was added to or **commingled** with the flock.
 - (2) If an **Export Certified flock** acquires or **commingles** with a female animal from an **Export Monitored flock** with less than 7 years in status, its status will be reduced to Export Monitored and its status date will be reduced to the most recent status date of the flocks involved.
 - (3) If an **Export Certified flock** acquires or **commingles** with a female animal from an **Export Monitored flock** with **7 years in status** but has not completed the sampling requirement to qualify for Export Certified status, then:
 - (a) The flock will maintain Export Certified status if all acquired female animals are **officially genotyped** and all genetically susceptible females identified are live-animal tested at over 14 months of age for scrapie with “Not Detected” results *before* they are **commingled** with the receiving flock. The **certification date** will change to the date of acquisition or **commingling**.
 - (b) If genetically susceptible additions are **commingled** with the **Export Certified flock** before valid test results are obtained, then:
 - i. The flock’s Export Certified status will be suspended until valid test results are obtained. Export Certified status will be reinstated once all valid test results are obtained with “Not Detected” results, and the **certification date** will change to the date of acquisition or **commingling**.
 - ii. If valid test results cannot be obtained after the date of acquisition or **commingling** (e.g., multiple **live animal tests** do not yield valid test results and the flock owner elects not to euthanize the animal, or if the animal dies without samples being submitted) the flock’s status will be downgraded to Export Monitored with **6 years in status**.
 - (c) If the female animals are added to or **commingled** with the **Export Certified flock** and are either not **officially genotyped** or, if genetically susceptible, not live-animal tested, the flock’s status will be downgraded to Export Monitored with **6 years in status**.
 - (d) Sample collection and genotyping expenses will not be paid for by APHIS.
13. The flock acquired male animals that affect status and/or status date.
- a. If a male animal is acquired from a nonparticipating or lower status flock or flocks and is maintained as required by **part III.J.4.d**, then it will have no effect on status or status date unless the male animal is **scrapie-positive**, a **scrapie suspect**, a **genetically susceptible exposed animal**, or is not identified and recorded as required.
 - (1) If the acquired male is a **scrapie-positive animal**, the status date of the receiving flock will be reduced to the date on which the animal died or left the flock.
 - (2) If the acquired male is a scrapie suspect, a **genetically susceptible exposed animal**, or is not identified and recorded as required, the status date of the receiving flock will be reduced to the date of acquisition or **commingling**.
 - (3) If an acquired male animal of lower status is not maintained as required in **part III.J.4.d**, the flock’s status and status date will be reduced to the male’s status and status date.

- b. A male animal acquired from a lower status enrolled flock will maintain the status and status date of the flock from which it was acquired. The status date for a male animal from a **nonparticipating flock** will be the date on which it was acquired. The animal may then continue to accrue status as long as it is not later determined to be a **scrapie-positive animal**, a **scrapie suspect**, or a **genetically susceptible exposed animal**, and the flock in which it resides has the same or higher status and status date.
 - c. An acquired male animal with a higher status or earlier status date at the time of acquisition will have the status and status date of the acquiring flock.
14. **Neutered animal** acquisitions affect status and status date the same as male animal acquisitions.
- An exception to this is** any **neutered animal** that is from either a lower status flock or a flock with less time in status than the receiving flock and is **commingled** with the breeding flock at any time, including **commingling** with any lambs from the breeding flock that may be retained or **sold** for breeding purposes. In this case, the status date of the receiving flock will be reduced to that of the **neutered animal**.
15. If the flock uses sheep or goat milk, colostrum, or a milk- or colostrum-derived product from a flock with a lower status, then:
- a. **Export Monitored Flocks:**
 - (1) If an **Export Monitored flock** uses sheep or goat milk, colostrum, or a milk- or colostrum-derived product from a **nonparticipating flock** or **Select Monitored flock**, its status date will be reduced to the date the sheep or goat milk, colostrum, or milk- or colostrum-derived product was used.
 - (2) If an **Export Monitored flock** uses sheep or goat milk, colostrum, or a milk- or colostrum-derived product from an **Export Monitored flock** with a more recent status date, its status date will be reduced to the most recent status date of the flocks involved.
 - b. **Export Certified Flocks:**
 - (1) If an **Export Certified flock** uses sheep or goat milk, colostrum, or a milk- or colostrum-derived product from a **nonparticipating flock** or **Select Monitored flock**, its status will be reduced to Export Monitored and its status date will be reduced to the date the sheep or goat milk, colostrum, or milk- or colostrum-derived product was used.
 - (2) If an **Export Certified flock** uses sheep or goat milk, colostrum, or a milk- or colostrum-derived product from an **Export Monitored flock**, its status will be reduced to Export Monitored and its status date will be reduced to the most recent status date of the flocks involved or **6 years in status**, whichever is less. Alternatively, the receiving flock may request its status be suspended until the originating flock reaches Export Certified Status.
16. **Lost to inventory** and **found dead** animals live-animal tested within the previous 12 months:
- a. **Lost to inventory:** If the animal had been tested in the previous 12 months, no change in status and no additional animals need to be tested (and if the flock is following the Alternative 1 sampling protocol it does not have to switch to the Standard sampling protocol).
 - b. **Found dead:** APHIS will determine if the animal reasonably could have been sampled when found. If so, the animal will be treated as any other **found dead**. If not,

- the animal is considered **lost to inventory** and will be treated the same as other **lost to inventory** animals.
17. Any other noncompliance that is not immediately corrected by the flock owner. The status date will be reduced by at least 6 months and **Export Certified flocks** will additionally be downgraded, at a minimum, to Export Monitored with **6½ years in status**.
 18. **Note:** A flock owner may appeal an AD/**board** decision for removal or reduction in status and/or status date to the **National Scrapie Program Coordinator**; appeals must be made by letter or email within 30 days of receiving the decision.

S. Advancement to Export Certified Status

1. An **Export Monitored flock** is eligible to advance to Export Certified status when all of the following have been met:
 - a. The flock has obtained a status date of at least 7 years.
 - b. The flock has met the sampling requirement for Export Certified status; and
 - c. An inspector has validated the animals sampled are representative of the flock.
2. Procedure
 - a. At the annual inspection performed when a flock has gained at least **7 years in status** and has met the sampling requirements, the inspector will verify all the conditions in *1* have been met, and will inform the flock owner a recommendation for Export Certified status will be submitted for review. The inspector will then submit the annual SFCP inspection report, VS Form 5-19B, with a recommendation to advance the flock's status to Export Certified, to the District Office for review.

Note: This inspection can occur up to 30 days before the flock obtains a status date of 7 years. The AD may elect not to require an additional inspection for Export Certified status if the testing requirements are met after the flock obtains a 7-year status date and before the next inspection is due.
 - b. The AD/**board** will review the flock for advancement to Export Certified status; if it is determined that all requirements for Export Certified status have been met, the AD/**board** will then forward the inspection report and recommendation to the **National Scrapie Program Coordinator**. The coordinator will review the recommendation for advancement and, if all requirements have been met, will certify the flock Export Certified. Full review of the recommendation for advancement will be completed and the flock owner will be notified of the decision within 60 days of the annual inspection.
 - c. The date of the annual inspection or the date the sampling requirement was met, whichever is later, is the Export Certified date.
 - d. The status date that appears on APHIS' public Web page will be the date the flock advanced to Export Certified status.

T. Withdrawal of Export Category Flocks from the Program

1. Flock owners may voluntarily withdraw from the program by providing notice, preferably by letter or email, to the District Office. If the request is not made in writing, the District Office will send a written acknowledgement of the request as documentation.

2. If a flock owner voluntarily withdraws from the program and within 12 months requests by letter or email to the District Office to be reenrolled, the flock may be reenrolled on completion of a satisfactory inspection without submitting a new application. The flock will keep the original **enrollment date**, and the status date will be the date of the reenrollment inspection.
3. If a flock has been withdrawn for longer than 12 months, the flock owner must complete the full application procedure. The flock will have both a new **enrollment date** and a new status date.

VI. Part IV: Select Category

A. Objective of the Select Category

The Select category monitors participating flocks for evidence of scrapie by testing samples from mature sheep and goats, thereby leading to the identification and cleanup of **infected flocks**.

B. Application for Participation in the Select Category

1. An interested flock owner submits a completed program application, VS Form 5-22, to the local VS District Office.
2. On receipt of the application, the District Office schedules an orientation on the SFCP with the flock owner. The orientation can be done in person or by phone. In-person orientations are encouraged but not required. If requested by the owner, and as resources permit, a State or APHIS regulatory official may inspect the flock for evidence of scrapie at the orientation.
3. The AD/**board** reviews the program application within 30 business days of receipt.
4. If the application is approved, the **enrollment date** is the date the application was received by the District Office.
5. New **Select Monitored flocks** are listed on the APHIS Web site as “Pending” until the District Office receives the first negative result from a valid scrapie test.
6. The flock will be listed on the APHIS Web site as “Pending” until the District Office receives the first negative test result.
7. A flock cannot be simultaneously enrolled in the Select and the Export categories.

C. Reporting Signs of Scrapie

The following must be reported to the District Office (or as directed):

1. As soon as practical and no later than 24 hours after discovery: Animals displaying signs of scrapie prior to death, including animals suspected of having another neurologic and/or chronic debilitating (prolonged wasting) illness and were either **found dead** or euthanized.
2. As soon as practical and no later than 48 hours after discovery: Live animals displaying signs of scrapie, including animals suspected of having another neurologic and/or chronic debilitating (prolonged wasting) illness.

Note: The AD will consider holidays and weekends, when it may not be possible to reach a staff member in the office, when determining whether a flock owner is in compliance with this requirement. However, in the case of **found dead** or euthanized animals the owner is still responsible for ensuring tissues required for testing are preserved, such as by chilling the head.

D. Recordkeeping Requirements for Select Category Flocks

1. The flock owner will organize the required records so they can be easily located and used to trace animals if needed.
2. The flock owner will keep records for a minimum of 5 years after an animal dies or has otherwise been removed from the flock.
3. The flock owner will keep the records listed below for sexually intact animals:
 - a. If the animal was acquired:
 - (1) The **flock of origin** (owner name, address, and flock ID number, if known) and, if different, the person from whom the sheep or goats were obtained;
 - (2) Number of animals;
 - (3) Breed or cross, if known;
 - (4) Date acquired; and
 - (5) Official ID number (in the case of a group of animals identified with Flock ID where it is impractical to list individual numbers, it is acceptable to record the Flock ID number instead of the individual numbers).
 - b. If the animal leaves the flock (**sold** or removed):
 - (1) Official ID number (in the case of a group of animals identified with Flock ID where it is impractical to list individual numbers, it is acceptable to record the Flock ID and number of animals);
 - (2) Date removed; and
 - (3) Name and address of buyer.
4. While not required, it is recommended participants record the sex of animals acquired.

E. Animal Identification (ID) Requirements for Select Category Flocks

1. The flock owner will officially identify all animals 18 months of age and older prior to change of ownership.
2. The flock owner will officially identify all sexually intact animals less than 18 months of age prior to change of ownership unless moving direct to slaughter, to slaughter-only auctions or buying stations, or to a **terminal feedlot**.
3. If acquired animals are not officially identified, the flock owner will properly identify them with an official ID and maintain records linking the new ID to the animal's **flock of origin** before **commingling** with the flock.

F. Access to Records

Flock owners will request breed associations and registries, livestock markets, and slaughter facilities to disclose records to APHIS or the State when needed to trace potential sources of exposure and **exposed animals**.

G. Sampling Requirements for Select Category Flocks

1. **All animals exhibiting clinical signs of scrapie or that have tested suspect, inconclusive, or positive for scrapie on a live animal test must be tested.** The flock

- owner will ensure suitable tissue samples are collected and submitted for diagnostic purposes from the following:
- a. Animals over 12 months of age exhibiting, or exhibited in the cases of dead animals, clinical signs consistent with scrapie, including animals suspected of having another neurologic and/or chronic debilitating (prolonged wasting) illness; and
 - b. Animals of any age having tested suspect, inconclusive, or positive for scrapie on a live-animal test or determined to be a scrapie suspect by a State, Federal, or **accredited veterinarian**.
 - c. Tissues will be submitted to an APHIS-approved laboratory in accordance with **part V**. Additional tissues must be submitted if requested by a State or Federal animal health official.
2. Additional sampling requirement to maintain Select Status:
- a. Number of samples:
 - (1) **Select Monitored flocks with more than 100 mature animals** must submit suitable tissues for scrapie testing from at least 1 **test-eligible animal** every year.
 - (2) **Select Monitored flocks with 26 to 100 mature animals** must submit suitable tissues for scrapie testing from at least 1 **test-eligible animal** every 2 years.
 - (3) **Select Monitored flocks with 25 or fewer mature animals** must submit suitable tissues for scrapie testing from at least 1 **test-eligible animal** every 3 years.
 - b. Waivers from the additional sampling requirement:
 - (1) The additional sampling requirement is waived for genetically resistant flocks (all animals in the flock are sheep, and are either genetically resistant or genetically less susceptible [RR or QR at codon 171, respectively], and only RR rams are used for breeding).
 - (2) The additional sampling requirement is waived for genetically susceptible flocks (contains one or more genetically susceptible animals [QQ sheep or goats]) that has tested for scrapie all genetically susceptible animals that are over 14 months of age or that have ever lambed/kidded, 4 times with at least 1 valid result, or in which all such animals have had a valid scrapie test within the preceding 12 months.
 - (3) The additional sampling requirement is waived for any flock for which 10 or more animals have been tested through regulatory scrapie slaughter surveillance (RSSS) during the collection period.
 - (4) Note: The flock must continue to meet all other testing requirements in Part IV.G.1.
3. Testing requirements
- a. All genetic susceptibility tests and scrapie tests must be **official tests**.
 - b. All tests for scrapie testing must be submitted promptly. If the flock owner elects to store animal samples to facilitate shipping multiple samples in one shipment, all samples must be shipped within 30 days of collection. Samples stored beyond this time will not be counted toward the flock's sampling requirement.
 - c. To facilitate collection of samples at slaughter facilities where VS provides collection, the flock owner should contact the District Office before shipping the animal to coordinate sample collection. Information provided to the District Office should include:
 - (1) Official ID;

- (2) Age;
 - (3) Sex;
 - (4) Breed;
 - (5) Shipping date; and
 - (6) Receiving slaughter plant information (name, address, and contact information).
- Note:** APHIS will make reasonable efforts to collect samples from SFCP animals at slaughter facilities where APHIS routinely collects samples. APHIS does not guarantee collection of SFCP samples at slaughter plants. If the slaughter plant does not have an agreement with APHIS to collect samples, if the owner does not make prior arrangements with APHIS to collect the sample, or if the sample must be taken for the flock to retain status, it is the flock owner's responsibility to retrieve the head and submit it to an APHIS collection facility (see [Appendix 1](#)).

H. Suspension of Select Category Status

1. Reasons for suspending status:
 - a. Disease investigation: If a flock has a potential scrapie exposure, it will be designated a **flock under investigation** and its status will be suspended while the potential exposure is investigated.
 - b. Not meeting sampling requirements: A Select category flock not meeting its sampling requirement will be suspended until the sampling requirement has been met.
 - c. **Compliance irregularity** investigation: If a flock is suspected of not complying with these program requirements, its status will be suspended while the AD/**board** investigates the possible **compliance irregularity**.
 - d. The flock is within an **Inconsistent State** and is not adhering to additional requirements for flocks in the Select category from **Inconsistent States**.
2. Flock owner and public notification of suspended status:
 - a. The AD/**board** will notify the flock owner by letter or email the status of the flock has been suspended pending the outcome of an investigation.
 - b. The flock's SFCP status will appear as "Pending" on the APHIS Web site until the investigation is completed and an outcome is determined by the AD/**board**. If the flock is removed from the program, the flock will also be removed from the Web site.
3. Removal of suspended status. The suspended status of a flock will be removed if:
 - a. The sampling requirements are met;
 - b. The **compliance irregularity** has been corrected; or
 - c. The investigation is complete and the AD/**board** has determined which of the following investigation outcomes to apply to the flock:
 - (1) Reinstated Select status;
 - (2) Reinstated Select status with a warning letter; or
 - (3) Removal from program.

I. Removal of Select Category Flocks from the Program

1. If a Select Category flock is determined to be an **infected or source flock**, it will be removed from the program. The flock owner may reapply for enrollment in the program

after all **high-risk animals** are removed and the flock has completed a flock cleanup plan.

2. If a Select category flock is determined to be a **noncompliant flock**, it will be removed from the program. The flock owner may reapply for enrollment in the program after the flock's noncompliant status has been removed by the AD.
3. If a Select category flock owner does not comply with a requirement for which it was previously suspended or for which it received a warning within the past 5 years, or is not in compliance with multiple requirements on more than one occasion, the flock may be removed from the program. These flocks are ineligible to apply for reenrollment in the SFCP for 24 months.

J. Withdrawal of Select Category Flocks from the Program

1. Flock owners may voluntarily withdraw from the program by providing notice, preferably by letter or email, to the District Office. If the request is not made in writing, the District Office will send a written acknowledgement of the request as documentation.
2. If a flock owner voluntarily withdraws from the program and within 12 months requests by letter or email to the District Office to be reenrolled, the flock may be reenrolled through written notification to the District Office without submitting a new application. The flock will keep the original **enrollment date**.
3. If a flock has been withdrawn for more than 12 months, the flock owner must complete the full application procedure, and the flock will have a new **enrollment date**.

K. Transferring to the Export Category

Because **Select Monitored flocks** do not have to meet the same requirements as Export flocks, if the owner of a **Select Monitored flock** decides to join the Export category, he or she must apply as a new Export flock. The period during which the flock participated in the program as a **Select Monitored flock** will not be credited toward its status date as a newly enrolled **Export Monitored flock**. The flock's initial status date will be the date on which it had a satisfactory inspection for enrollment as an **Export Monitored flock**, not the date it was approved to enroll as a **Select Monitored flock**.

L. Additional Requirement for Select Monitored Flocks from Inconsistent States

The following additional requirements apply to Select Monitored flocks permanently or seasonally located in a scrapie Inconsistent State:

1. All animals in the flock that are **found dead** or euthanized must be tested for scrapie.
2. Movement and identification:
 - a. No animal from the flock may be moved or sold outside of the State unless it was born and raised in that flock, or has lived in the flock for a minimum of 12 months.
 - b. All animals from the flock must be officially identified, regardless of age, when moved or sold outside the flock (whether outside or inside the State).

These requirements do not apply to animals moving direct to slaughter or within slaughter channels, in which case the animal can only move in accordance with 9 CFR 79.3 (b) and (c).

VII. Part V: Laboratory Procedures and Test Interpretation

A. General Considerations

APHIS-approved laboratories will examine SFCP tissues submitted per **Appendix 1** in accordance with the guidance provided by the National Veterinary Services Laboratories (NVSL). The approved laboratory will report diagnostic findings to APHIS. NVSL will confirm any result other than “Not Detected”. NVSL will then report the results, through the AD, to the submitter.

B. Laboratories

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

A list of laboratories approved by APHIS to conduct scrapie testing can be found at:

http://www.aphis.usda.gov/animal_health/nahln/downloads/cwd_scrapie_lab_list.pdf

C. Diagnostic Tests

APHIS-approved laboratories must use currently recognized procedures to examine tissues and establish a presumptive scrapie diagnosis. All presumptive positive, suspect, and inconclusive tests conducted at APHIS-approved laboratories will be confirmed and further evaluated at NVSL.

VIII. Part VI: Flock Information

The VS **National Scrapie Eradication Program (NSEP)** staff prepares periodic reports from the national scrapie database (NSD) on enrolled flocks. The following information about flocks participating in the program will be provided to the public: Owner and flock name, address, flock ID, breeds of enrolled animals, **enrollment date**, status, and status date. These reports or lists are publicly available at:

<http://www.aphis.usda.gov/animal-health/scrapie>

If you do not have Internet access, you may request a copy from your local VS District Office. A list of VS District Offices is publicly available at:

https://www.aphis.usda.gov/animal_health/downloads/sprs_contact/field_office_contact_info.pdf

Appendix 1: Specimen Collection and Submission

If an APHIS representative or a State animal health employee is unavailable to collect samples required for scrapie testing, the flock owner is responsible for either having an **accredited veterinarian** collect and submit the samples or for preserving and shipping the head to a diagnostic laboratory or collection facility designated by the Assistant Director (AD) for this purpose. See “Head Removal and Whole Head Packaging Procedures” in this appendix for instructions.

The collector will include the following items with each diagnostic submission:

1. A completed VS Form 10-4, “Specimen Submission”, or Veterinary Services Laboratory Submission (VSLS)-generated packing slip, or in the case of whole heads submitted by the owner, the owner’s name, address, phone number, flock ID, and the animal’s ID numbers, age, breed, sex and any clinical signs observed. **Note:** The VS Form 10-4 is only for use by an APHIS representative, a State animal health employee, or an **accredited veterinarian** with approval of the AD.
2. All ID devices (with a piece of tissue the size of a U.S. quarter attached), 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 in this appendix.
6. Any additional samples as requested by the AD or State Animal Health Official (SAHO), including samples requested for research.

Safety Precautions

If you are the collector, you are responsible for taking appropriate safety precautions. You must take measures to avoid contact with specimens and adhere to the following safety precautions to ensure 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 uncovered by PPE.
3. Use face and respiratory protection, including a well-fitted respiratory mask and face shield or goggles, to protect from infective droplets or tissue particles. Wear gloves 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.
7. Wash and disinfect protective clothing and instruments thoroughly after use. Use 50 ounces (6¼ cups) bleach to 78 ounces water (9¾ cups) to make 1 gallon of solution at room temperature (at least 65 °F) for 1 hour.

Personal Protective Equipment

Personal protective equipment (PPE) minimizes exposure to pathogens while collecting samples. The Occupational Safety and Health Administration (OSHA) defines PPE 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 on the environment, the physical hazards, and the ability to complete the task. PPE balances 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 specimens are collected differently, the following PPE must be worn at all times during scrapie specimen collections:

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.

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.

Hand Protection: Gloves

1. Wear metal or mesh gloves. Always wear the cut-resistant glove (Hantover, Koch, or Packer) on your off hand (left hand for a right-handed person and right hand for a left-handed person). Find a cut-resistant glove that fits against your skin and wear a rubber glove over it.
2. Wear latex or nitrile examination gloves or thick rubber gloves that extend halfway up the forearm. Many people prefer long, thick rubber gloves for added protection.

Foot Protection

Protect your feet from injuries that could result from spills, splashes, impact, compression, or exposure. Wear steel-toed rubber boots when collecting specimens. If steel-toed boots are unavailable, then pullover rubber boots are acceptable.

Respiratory Protection

Face masks and respirators are recommended if the environment includes aerosols, splashing, or flying debris that may be encountered when using certain methods to remove and handle brain and tissue. Though scrapie is not known to be transmissible through air and to humans, other

zoonotic diseases such as rabies, Q fever, or Listeria may be present and could be transmitted during scrapie sample collection.

Instructions for Veterinarians and Animal Health Technicians

Collector's Responsibilities

Specimens submitted to NVSL or contract laboratories must be traceable to the source animal and farm. To ensure this, the collector must accurately complete the specimen collection and submission process. Failure to accurately collect and submit specimens may result in the erroneous destruction of animals.

When collecting specimens, you must ensure that each of the actions listed below is completed:

1. Follow the laboratory's procedure for notifying the laboratory of incoming specimens.
2. Contact the delivery service. Ensure the package containing fresh tissues will be delivered overnight.
3. Properly complete the specimen submission form in the VSLS Scrapie-on-farm application. If you do not have access to VSLS, complete the 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 exhibited **clinical signs of scrapie**. If so, list the signs in "Additional Data" on VS Form 10-4.
4. Make four copies of the VSLS generated packing slip or completed VS Form 10-4.
 - a. Maintain one in the collector's files (submitter's copy).
 - b. Provide one to the animal owner or collection site.
 - c. Submit one to the District Office.
 - d. Submit one with the specimen.
5. Correctly label all specimen collection containers.
6. Properly collect obex, tonsil, cerebellum, and retropharyngeal lymph nodes (RLN). For scrapie suspects, the remainder of the brain must also be collected.

Sample Quality

1. Tissues with no autolysis (deterioration) should be collected and submitted to an APHIS approved laboratory.
2. Samples with mild or moderate autolysis may be collected only if they meet the criteria listed below and may only be submitted to NVSL:
 - a. Brain samples with mild or moderate autolysis may be collected if the obex can be identified.
 - b. Lymph nodes with mild or moderate autolysis should be collected as long as the capsule (outer membrane) is still intact.

Labeling Sample Containers

1. The specimen collection containers must be properly labeled. 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 or VSLS-generated packing slip.
2. Both the top and the side of the sample container must be clearly labeled using the provided bar code sticker. If a bar code sticker is unavailable, the sample may be

identified by either typing the information or writing it with a permanent marker. Verify the sample numbers appearing on the top and side of the sample container and the completed VS Form 10-4 or VSLS-generated packing slip are identical.

3. The side label must include the following information:
 - a. Type of specimen;
 - b. Animal ID number; and
 - c. Sample ID number (the number assigned to this sample on VS Form 10-4).

Samples and Sample Packaging

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

Fresh tissue specimen. *Fresh tissue specimens must be kept chilled or frozen.* Dry ice may be used, though shipping the chilled or frozen tissues overnight on ice packs is usually best.

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

Use the following three tables as a guide for the proper tissue specimens that must be collected for an animal, based on its situation. **Note:** Ensure the sample container correctly lists all included specimens.

Table 3. Tissue specimens for non-exposed animals without clinical signs (routine submission).

| Formalin: Single container for each animal | Fresh: None required for these animals |
|--|--|
| 1 Retropharyngeal Lymph Node (RLN) | |
| Entire brainstem (including obex) | |
| Cerebellum (Collect a minimum of 2 g, removed via the foramen magnum when possible) | |
| Animal ID device(s). (Collect all animal ID devices with a quarter-sized piece of tissue attached to each device and the skin containing any official tattoo or brand. This will allow DNA verification if necessary.) | |

Table 4. Tissue specimens for exposed animals or animals with less specific signs*.

| Formalin: Single container for each animal | Fresh: Ice packs or frozen |
|--|---|
| Obex – 1-2 cm of brainstem that includes the apex of the V at the obex. | Remainder of brainstem in its own labeled resealable bag** |
| One tonsil | One tonsil in its own labeled resealable bag** |
| One RLN | One RLN in its own labeled resealable bag** |
| Animal ID device(s). (Collect all animal ID devices with a quarter-sized piece of tissue attached to each device and the skin containing any official tattoo or brand. This will allow DNA verification if necessary.) | Cerebellum (in its own resealable bag labeled with the animal's official identification and "Genotype testing") |

* Animals with "less specific signs" include those that are nonambulatory, ante-mortem condemned, died before slaughter, unthrifty, or exhibit wool/hair loss suggestive of rubbing, biting at the legs or side, lip smacking, or intense rubbing without bare areas.

** Place the three resealable bags with tonsil, RLN, and brainstem into a larger labeled resealable bag (i.e., keep cerebellum separate from other fresh tissue).

Table 5. Tissue specimens for suspect animals* and test positive animals.

| Formalin: Single container for each animal | Fresh: Ice packs or frozen |
|--|--|
| One tonsil | One tonsil in its own labeled resealable bag** |
| One RNL | One RLN in its own labeled resealable bag** |
| Right half of the brain (cerebrum, midbrain, cerebellum) | Left half of the brain (cerebrum, midbrain, remaining brainstem) in its own labeled resealable bag** |
| Obex – 1-2 cm of brainstem that includes the apex of the V at the obex. | Left half of the cerebellum (in its own resealable bag labeled with the animal's official identification and "Genotype testing") |
| Animal ID device(s). (Collect all animal ID devices with a quarter-sized piece of tissue attached to each device and the skin containing | |

| | |
|---|--|
| any official tattoo or brand. This will allow DNA verification if necessary.) | |
|---|--|

***Suspect animals** are highly suspicious for scrapie because they exhibit CNS signs, have a chronic wasting condition, and/or intense repeat rubbing or abrasions with bare areas. Complete brain removal is required for all clinical suspects. Suspect and test-positive animals should be submitted on a separate VS Form 10-4 or VSLs-generated packing slip and shipped separately to allow NVSL to prioritize testing these cases. **Note:** If rabies testing is required, submit the entire brain to the rabies laboratory unless arrangements have been made in advance with the rabies lab to collect and place the obex in formalin. After rabies testing is completed, proceed with scrapie sampling on rabies-negative brains.

**Place the three resealable bags with tonsil, RLN, and left brain into a larger labeled resealable bag (i.e., keep cerebellum separate from other fresh tissue).

Collection Procedures

The collection of the obex, tonsils, and RLN may be completed using several methods. The following describes the preferred 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.

Equipment

The equipment listed below will help to ensure proper specimen collection.

1. Sharp boning knives.
2. Disposable scalpel blades, disposable scalpels, or a large scalpel blade is acceptable.
3. Aggressively toothed forceps (rat tooth).
4. Meat-cutting bone saw, hacksaw, or electric saw when brain removal is required.
5. Disposable cutting surfaces such as cardboard, plastic, or Styrofoam.
6. Small hand nippers may be used on the hyoid bones, or you may cut through at the joint using a knife.
7. Sharp stainless steel scissors.
8. European brain spoon, grapefruit knife, or other brainstem scoop.

Obex Collection Procedures

General Guidelines: Two methods are available to collect the obex: via the foramen magnum and whole brain collection.

1. Via the foramen magnum.
 - a. Collection of the obex via the foramen magnum is the preferred method for routine surveillance collections (i.e., the animal is *not* a scrapie suspect).
 - b. Collect the obex via the foramen magnum when the carcass is reasonably fresh.
2. Whole brain collection. This procedure should be used in the following circumstances:
 - a. The animal is a scrapie suspect;
 - b. The brain is too autolyzed; and/or
 - c. Removal by the spoon method is unsuccessful.

Obex collection via the foramen magnum:*Tools*

1. Aggressively toothed forceps (rat tooth).
2. European brain spoon, grapefruit knife, or other brainstem scoop.
3. Curved blunt scissors.

Procedure

1. Place the head upside down in front of you so you are looking directly at the foramen magnum.
2. With forceps and scissors, remove the collar of dense dura mater surrounding the foramen magnum and spinal cord.
3. Then gently grasp the end of the protruding spinal cord with forceps and move the spinal cord laterally to expose the caudal cranial nerves.
4. 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.
5. Once the cranial nerves have been severed, the caudal brainstem will be easier to manipulate within the foramen magnum.
6. With light pressure, use forceps to move the spinal cord to the ventral part of the foramen magnum.
7. Insert the spoon into the dorsal aspect of the foramen magnum between the brainstem and the dorsal bony calvarium.
8. Sever the cerebellum by advancing the spoon cranially 2 to 3 inches until you feel the leading edge of the spoon hit bone.
9. Remove the spoon.
10. With the forceps, lift the spinal cord dorsally and reinsert 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.
11. Pull the spoon toward you with gentle traction on the spinal cord with the rat-toothed forceps.
12. If the brainstem is not readily removed by this method, stop. Reexamine the brainstem and sever any remaining cranial nerves or connections to the dura. Use caution, as excessive caudal traction on the spinal cord may result in a mutilated, non-diagnostic sample.
13. 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.
14. The sample extracted with this method is usually 3 to 4 centimeters long with the obex in the center. Trim out the central one-third containing the obex and place in formalin. Place the caudal piece (spinal cord) and cranial piece (cranial brainstem) into a plastic bag for chilling or freezing.

Obex collection by complete brain collection (required for clinical suspects):

Tools

1. Meat-cutting bone saw, hacksaw, or electric necropsy saw.
2. Wood chisel or large wide-tipped screwdriver.
3. Aggressively toothed forceps (rat tooth).
4. European brain spoon, grapefruit knife, or other brainstem scoop.
5. Curved blunt scissors.
6. Scalpel.

Procedure

1. Skin the head.
2. Use a bone saw to remove the top and back of the skull. This requires three cuts:
 - a. 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.
 - b. Repeat this cut on the other side starting at the medial aspect of the other occipital condyle.
 - c. 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.
3. Pry off the skullcap by inserting a wood chisel or a large wide-tipped screwdriver at the level of the transverse cut and hinge the skullcap caudally.
4. 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 has been inadvertently damaged during the previous steps of the procedure, the samples will not be compromised.*
5. 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, which lies between the cerebrum and cerebellum.
6. 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.
7. For scrapie diagnosis, separate the brainstem from the forebrain 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.*
8. 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.
9. 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.
10. Place the obex into formalin.

11. Place the remaining brainstem tissues, including the spinal cord and brain stem, into a plastic bag.
12. 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.
13. Place each of the remaining fresh tissue samples into their own sample bags and seal.

Tonsil Collection Procedures

Various successful approaches are available to collect 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.

Tools

1. Sharp boning knife.
2. Scalpel.
3. Sharp stainless steel scissors.
4. Aggressively toothed forceps (rat tooth).

Procedure

1. Place the head upside down on the table.
2. Remove the skin from the ventral surface of the mandible.
3. 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 you encounter will need to be cut with poultry shears or disarticulated at a joint with the knife.
4. 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.
5. 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; laterally it will have a readily palpable, well circumscribed mass of lymphoid tissue that will feel like a small, round, sometimes relatively flat lymph node.
6. 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 in 5. may be used to locate the tonsils. The crypt is the landmark for the tonsillar lymphoid tissue subjacent (deep or submucosal) to the crypt.

7. Place one tonsil into a jar of formalin; place the other in a resealable bag, and then into the bag with the other fresh tissues from that animal.

Retropharyngeal Lymph Node (RLN) 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, deep, and rarely removed by normal processing procedures. The lateral retropharyngeal nodes are found on either side of the median line midway between the larynx and the foramen magnum. They are generally smaller than the medial nodes and sometimes remain with the neck.

Tools:

1. Sharp boning knife.
2. Scalpel.
3. Sharp stainless steel scissors.
4. Aggressively toothed forceps (rat tooth).
5. Flock owners: Have your veterinarian contact your inspector or the District Office for collection kits and shipping containers.

Procedure:

1. 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.
2. Dissect both medial retropharyngeal nodes from the surrounding pharyngeal muscles with rat-toothed forceps and scissor, scalpel, or knife.
3. Place one medial RLN into a jar of formalin.
4. Place two RLN (one medial and one lateral) into a plastic bag for chilling or freezing.

Alternative Collection Procedure

Owners may use the following alternative procedures for head removal and whole-head packaging:

Tools:

1. Sharp boning knife.
2. Two heavy-duty plastic bags and ties.
3. If shipping the head, shipping container with cooler, large heavy-duty plastic bag, absorbent material, and four frozen cool packs. Contact your inspector or the local District Office for shipping containers. A list of District Offices can be found at:

https://www.aphis.usda.gov/animal_health/downloads/sprs_contact/field_office_contact_info.pdf

Procedure:

1. 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. Position the animal in dorsal recumbency (lying on its back).
3. Remove the head at the hinge joint where the skull meets the first cervical vertebrae (just behind the ears) following the steps listed below:
 - a. Locate the “hinge” area where the skull meets the first cervical vertebrae by grasping the nose and moving the head up and down to locate the joint.
 - b. Insert the knife into the neck between the first cervical vertebrae and the throat, then cut outward (ventrally), with the blade directed away from you, through the throat tissue and skin. (Cutting down through the skin readily dulls the blade.)
 - c. 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.
 - d. 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.
 - e. Once the lateral ligaments have been severed, cut through the remaining tissue to remove the head from the carcass.
 - f. 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.
 - g. Ideally, specimens would 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 with about a quarter sized piece of ear tissue attached to each ear tag in a separate bag with the bagged head inside the second bag.)
 - h. Double bag the head.
 - i. Secure each bag in a manner preventing leakage such as by tying a knot in the bag or using twist ties, string, or cord.

- ii. Chill the head prior to placing in the cool box and refrigerate the head in the cool box until and during shipment to the laboratory.
4. Pack the cool box. 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.
 - a. Put cool packs in the bottom.
 - b. Insert large plastic bag.
 - c. Insert absorbent material.
 - d. Insert double bagged head(s).
 - e. Seal large plastic bag.
 - f. Place cool packs on top of large plastic bag.
 - g. Close cooler top.
 - h. Insert submission form between cooler top and exterior box.
5. Ship the cooler overnight to the laboratory or the collection facility. Inform the facility of the shipment's delivery date.

Following is the shipping address, phone number and email address for the primary VS collection facility, Remington Locker:

| Shipping Address | Phone and Email |
|--|---|
| Veterinary Services Remington Facility 18795 S 580 W Remington, IN 47977 (Or as directed by your VS contact) | Phone: (317) 347-3100 Fax: (219) 261-2357 Remington.Locker@aphis.usda.gov |

Appendix 2: Scrapie Disinfection Guidelines

The following suggested procedures do not guarantee complete disinfection and inactivation of the infectious agent. Nonetheless, current information regarding the efficiency of following these disinfection procedures under laboratory conditions suggests these procedures will reduce infectivity in the environment. Until more specific information is 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.

Pastures

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

Drylots

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

Earth Surfaces Inside Structures or Used for Confined Lambing Pens

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

Non-earth 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 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 [1 part solution to 1.5 parts water¹]), at room

¹ Assumes a 5.25 percent bleach solution.

- temperature (at least 65 °F), for at least 1 hour. **Note:** Bleach is caustic and can be hazardous if swallowed, gets in the eyes, is breathed in, or is left on the skin. Further, care must be taken to prevent contamination of water from runoff and to comply with any environmental regulations for use of this product. Read the material safety data sheet prior to use and use appropriate personal protective equipment or hire trained personnel to do the work.
- c. To clean dry surfaces, apply 1-molar solution of sodium hydroxide¹ (approximately 4-percent solution [5 ounces sodium hydroxide dissolved in 1 gallon water]) at room temperature (at least 65 °F) for at least 1 hour. Synonyms for sodium hydroxide are caustic soda, soda lye, and sodium hydrate. **Note:** Sodium hydroxide is caustic and can be hazardous if swallowed, gets in the eyes, is breathed in, or is left on the skin. Further, care must be taken to prevent contamination of water from runoff and to comply with any environmental regulations for use of this product. Read the material safety data sheet prior to use and use appropriate personal protective equipment or hire trained personnel to do the work.

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 must be contacted to determine whether additional requirements apply 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. During transit and at the exhibition, use sufficient spacing or solid partitions to prevent contact. 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. Sufficient spacing or solid partitions preventing contact 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 returned to the enrolled flock, the flock will take on the status date, if lower, of the postpartum animal. If contact occurs between a postpartum animal and a male animal enrolled in the SFCP, the male animal's status date will change to the status date of the postpartum animal, and the flock status will be unchanged.

Appendix 4: Transmission and Genetics of Scrapie

Transmission

Sheep and goats are typically infected with scrapie as young lambs or kids through contact with an infected placenta or birth fluids from infected female animals 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 it.

The agent can enter the body through the following routes:

- Ingestion;
- Ocular exposure;
- Contact with abraded skin or mucus membranes; and
- Veterinary medical procedures, including blood transfusions, invasive surgery with contaminated instruments, and injections.

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, particularly in VVQQ sheep.

Scrapie is always fatal. No treatment or vaccine is available.

Genetics

In sheep, an individual animal's genetic makeup influences its susceptibility to scrapie. Some sheep are susceptible to scrapie while others are resistant. The genes controlling susceptibility and resistance can be identified through genotyping, also called DNA testing. Genotyping of live animals is typically done using a blood sample; genotyping animals after death can also be done using other tissues, including skin and brain samples.

No resistant genotypes have been conclusively identified in goats. All goats, therefore, should be assumed susceptible. *The remainder of this section applies only to sheep.*

General information about genotyping sheep

1. The animal's genotype never changes, so it can be tested at any age.
 - a. Under most circumstances, one test during an animal's life is adequate to determine its genotype (susceptibility or resistance to scrapie).
 - b. **Note:** In the case of exposed sheep, USDA currently requires two tests to minimize the chance of error.
2. The genotype test only measures a sheep's susceptibility or resistance to scrapie, not whether it has scrapie. An approved live-animal test can be used to detect scrapie infection in some animals.

Basic facts about sheep genetics and how genotyping is used to determine scrapie resistance or susceptibility in sheep

1. Of the many sheep genes scientists have identified, one affects both scrapie susceptibility and the disease's incubation time. That gene is the prion protein gene (PRNP).
2. Every sheep has two copies of the PRNP gene; one is derived from each parent.
3. The PRNP gene produces the normal cellular prion protein, PrP^C. The function of this protein is still under investigation, and may play a role in cell repair and cell communication.
4. In scrapie-infected animals, an abnormal form of the prion protein, known as PrP^{sc} or simply prion, is also found. Prions are closely associated with scrapie infectivity, and may be the causative agent.
5. 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. PrP^C is composed of 256 amino acids; these locations are numbered from 1 to 256.
6. Two codons, 171 and 136, are particularly important to susceptibility to classical scrapie in the United States.
7. Codon 171 directs which amino acid to insert at position 171 on PrP^C. Based on current scientific understanding there are 4 possible amino acids that can be inserted at codon 171: histidine (H), glutamine (Q), lysine (K), or arginine (R) (the letter in parentheses is the single letter biochemical abbreviation for each amino acid).
 - a. Arginine (R) conveys the greatest resistance to classical scrapie.
 - b. Glutamine (Q) conveys the greatest susceptibility to classical scrapie. *The level of susceptibility conveyed by histidine and lysine are not fully understood at this time; therefore, for regulatory purposes APHIS regards Q, H, and K as equally susceptible. For the remainder of this discussion, then, Q represents Q, H, and K.*
8. Codon 136 directs which amino acid to insert at position 136 on PrP^C. Based on current scientific understanding there are three possible amino acids that can be inserted at position 136: alanine (A), valine (V), and threonine (T).
 - a. Valine (V) conveys susceptibility to the valine-associated classical scrapie strain. The valine-associated strain is relatively uncommon in the United States and only appears to infect sheep that have V at codon 136.
 - b. Threonine is extremely rare and has not been found in the United States. If it were identified in the United States, for regulatory purposes APHIS would regard it as equally susceptible to V.
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 in Table 6.

Table 6: Amino Acid Combinations at Codons 136 and 171 in Sheep

| <i>Amino Acid</i> | <i>Location</i> | |
|-------------------|------------------|------------------|
| | <i>Codon 136</i> | <i>Codon 171</i> |
| | A | R |
| | A | Q* |
| | 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. Table 7 lists the six genotypes found in the United States and their relative susceptibility or resistance to classical scrapie.

Table 7: Six Common Sheep Genotypes at Codon 136 and Codon 171 and Their Relative Susceptibility / Resistance to Classical Scrapie

| | | |
|-----------|--------------|---|
| 1. | AA RR | Sheep that are resistant to classical scrapie* |
| 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 |

*The resistance to classical scrapie in AA RR is not absolute; a very small number of cases have been found in Europe. However, no classical scrapie cases have been found in AA RR sheep in the United States.
 **These strains are believed to occur with low frequency in the United States.

11. **Official genotype tests:** APHIS will recognize the results of genotype tests as official only if the following conditions are met:
 - a. The blood is drawn by an authorized Federal or State animal health employee or an **accredited veterinarian**;
 - b. The sheep is officially identified;
 - c. The sample is submitted with a VS Form 5-29, “Cooperative State-Federal Scrapie Control Program, Scrapie Test Record” or an electronic or State issued equivalent; and
 - d. APHIS has approved the laboratory.

Appendix 5: Goat Registry Tattoos Approved for Use in the Scrapie Free Flock Certification Program (SFCP)

Background

The Scrapie Free Flock Certification Program (SFCP) standards allow an approved registry's tattoos to be used by SFCP participants to identify registered goats enrolled in the program. This document describes the criteria for approving a breed registry's tattoos for this purpose and provides a list of breed registries that have had their tattoos approved.

Criteria/Protocol for Approval of Registry Tattoos

Registry tattoos may be used as official identification for goats enrolled in the SFCP if the registry has provided the Animal and Plant Health Inspection Service (APHIS) with a letter indicating that:

- A. Each registry tattoo contains a unique premises identification number assigned by the registry and a unique individual animal identification number;
- B. The unique tattoo is linked to records that will allow any association-registered goat to be traced to its flock of origin and birth; and
- C. The registry will, on request, provide APHIS with information that will allow any association-registered goat to be traced to its flock of origin.

Registries seeking to become approved should send a letter on registry letterhead and signed by an authorized officer of the registry to:

Dr. Diane L. Sutton
Sheep & Goat Health Team Leader
Sheep, Goat, Cervid & Equine Health Center
Surveillance, Preparedness and Response Services
USDA, APHIS, VS
4700 River Rd., Unit 43
Riverdale, MD 20737

A link to a list of organizations whose tattoos have been approved for use by APHIS for participation in the SFCP is located at:

https://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/approval_registry_tattoos.pdf