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Department of  
Agriculture**

Animal and  
Plant Health  
Inspection  
Service

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# **Scrapie Program Standards Volume 1:**

# **National Scrapie Eradication Program**

Effective April 25 2019

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## Introduction

The objective of the [National Scrapie Eradication Program \(NSEP\)](#) is to achieve classical scrapie freedom by identifying and cleaning up the remaining scrapie-infected and source flocks in the United States. Eradication will improve the overall health of the national sheep flock and goat herd, relieve sheep and goat producers of scrapie-associated economic losses, and increase international marketing opportunities.

The National Scrapie Eradication Program Standards (NSEPS) contain cooperative procedures and standards adopted by the USDA Animal and Plant Health Inspection Service (APHIS) and [Consistent States](#) for eradicating classical scrapie from the United States. These standards are intended to assist State and Federal animal health personnel in implementing the NSEP consistently and equitably throughout the United States. They are designed to prevent, monitor, and eradicate classical scrapie disease from domestic sheep flocks and goat herds and maintain Consistent State status.

These standards replace the Scrapie Eradication Uniform Methods and Rules (UM&R) dated June 1, 2005. Flock plan agreements and post-exposure management and monitoring plan (PEMMP) agreements made before the effective date of these standards will remain in force, unless changed by mutual agreement between APHIS, the State, and the owner.

These standards will be reviewed periodically by representatives of the livestock industry and appropriate State and Federal agencies, and APHIS will revise them as needed. APHIS will post future revisions of the standards at the National Scrapie Eradication webpage, [here](#).<sup>1</sup> 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 [here](#)<sup>2</sup> and select “Animal Health - Sheep and Goats” and “Federal Register Publications – Notices Regarding Animal Health.”

Additional information (such as sample formats, detailed instructions on data entry and tissue collection, and calculators) is available to State and Federal animal health employees on the [APHIS-NSEP Scrapie SharePoint](#) site<sup>3</sup> This information is also available on CD for Federal and State employees who cannot access the Scrapie SharePoint site, and can be obtained by e-mailing [scrapie@aphis.usda.gov](mailto:scrapie@aphis.usda.gov).

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<sup>1</sup> <http://www.aphis.usda.gov/animal-health/scrapie>.

<sup>2</sup> <https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new>.

<sup>3</sup> <https://share.aphis.usda.gov/sites/vs-sgh/>

**Note:** as of April 25, 2019, the VS Memoranda listed in the table below are canceled and should no longer be referenced. The information and guidance in these memoranda have been updated and incorporated into these standards.

<b>Memo<sup>4</sup></b>	<b>Title</b>	<b>Location within these standards</b>
557.2	<i>Scrapie Reports</i>	<i>part X</i> (p. 96)
557.6	<i>Approval of Laboratories to Conduct Official Genotype Tests in Sheep</i>	<i>Appendix A</i> (p. 100)
557.7	<i>Identification Requirements for Captive Sheep and Goats, both Domestic and Exotic</i>	<i>part III.A.4</i> (p. 57)
557.11	<i>Animal Identification and Sampling for Scrapie Surveillance</i>	<i>part II.D</i> (p. 27), <i>part II.E</i> (p. 30), <i>part III.A</i> (p. 51), and <i>Appendix B</i> (p. 104)
557.13	<i>Requirements for Use of Electronic Implant Devices (EID) in Registered Sheep and Goats as Official Identification in the Scrapie Eradication Program</i>	<i>part III.A.3(e)</i> (p. 56)
557.14	<i>Indemnity for Third Trimester Gestation Ewes/Does and Early Lambing Ewes/Does</i>	<i>part II.J.4(a)(4)</i> (p.37 )
557.15	<i>Sheep or Goats from Consistent States Transiting or Temporarily Residing in Inconsistent States</i>	<i>part II.O</i> (p. 46)
557.17	<i>Identification of Animals and Use of RFID for Scrapie Program Regulatory Work</i>	<i>part III.A.11</i> (p. 61)
557.18	<i>Approval of Laboratories to Conduct Official Diagnostic Tests for Scrapie in Sheep and Goats</i>	<i>Appendix B</i> (p. 104)
557.19	<i>Program Approval of Diagnostic Tests for Scrapie in Sheep and Goats</i>	<i>Appendix C</i> (p. 110)
557.21	<i>Revision of Scrapie Flock Certification Program Standards for Export Monitored Flocks</i>	<i>Scrapie Program Standards Volume 2 (SFCP), part III</i>
557.22	<i>Scrapie Control Pilot Project for Flocks Affected by Nor98-like Scrapie</i>	<i>part VIII.B.1</i> (p. 90)

<sup>4</sup> VS Memos 557.12 and 557.16 are historical documents and are still active. VS Memos 557.1, 557.3, 557.4, 557.5, 557.8, 557.9, 557.10 and 557.20 were either cancelled previously or never published.

Note: This document replaces the June 2, 2005 Scrapie Eradication Uniform Methods and Rules (UMR). Any State law or regulations that incorporate the Scrapie UMR now reference this document unless the State law or regulations specifically indicate otherwise.

## List of Acronyms

<b>AIMS</b>	Animal Identification Management System
<b>APHIS</b>	Animal and Plant Health Inspection Service
<b>AVIC</b>	Area Veterinarian in Charge
<b>AZA</b>	Association of Zoos and Aquariums
<b>CFR</b>	Code of Federal Regulations
<b>CNS</b>	Central nervous system
<b>DSE</b>	Designated Scrapie Epidemiologist
<b>EID</b>	Electronic implantable device
<b>EMRS</b>	Emergency Management and Response System
<b>EPA</b>	Environmental Protection Agency
<b>FSIS</b>	Food Safety and Inspection Service
<b>GIN</b>	Group Identification Number
<b>ID</b>	Identification
<b>MIM</b>	Mobile Information Management
<b>NASS</b>	National Agricultural Statistics Service
<b>NSD</b>	National Scrapie Database
<b>NSEP</b>	National Scrapie Eradication Program
<b>NVSL</b>	National Veterinary Services Laboratories
<b>PEMMP</b>	Post-Exposure Management and Monitoring Plan
<b>PIN</b>	Premises Identification Number
<b>RSSS</b>	Regulatory Scrapie Slaughter Surveillance
<b>SAHO</b>	State animal health official
<b>SCS SCR</b>	Surveillance Collaboration Services Scrapie
<b>SFCP</b>	Scrapie Free Flock Certification Program
<b>SGHSE</b>	Sheep and Goat Health Specialist for Epidemiology
<b>SOP</b>	Standard operating procedure
<b>VMO</b>	Veterinary Medical Officer
<b>VS</b>	Veterinary Services
<b>VSLs</b>	Veterinary Services Laboratory Submissions

## Part I: Definitions

### **Accredited veterinarian**

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

### **Administrator**

The Administrator of the Animal and Plant Health Inspection Service (APHIS) or any employee of the U.S. Department of Agriculture authorized to act for the Administrator.

### **Animal**

Any sheep or goat (animals in the genus *Ovis* or *Capra* respectively).

### **APHIS**

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

### **APHIS representative**

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

### **Approved laboratory**

A laboratory approved by the Administrator in accordance with title 9, *Code of Federal Regulations* (9 CFR) 54.11 to conduct one or more scrapie tests, or genotype tests, on one or more tissues.<sup>5</sup>

### **Area Veterinarian in Charge (AVIC)**

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

### **Blackfaced sheep**

Any purebred Suffolk, Hampshire, Shropshire, or cross thereof; any nonpurebred sheep known to have Suffolk, Hampshire, or Shropshire ancestors; and any nonpurebred sheep of unknown ancestry with a black face, except for commercial hair sheep. **Note:** Nonpurebred hair sheep known to have Suffolk, Hampshire, or Shropshire ancestors are not considered commercial hair sheep; they are considered blackfaced sheep.

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<sup>5</sup> See [Appendix A: Approval of Laboratories to Conduct Official Genotype Tests for Sheep](#), and [Appendix B: Approval of Laboratories to Conduct Official Diagnostic Tests for Scrapie in Sheep and Goats](#). For a list of approved laboratories for genotype testing, go to [http://www.aphis.usda.gov/animal\\_health/animal\\_diseases/scrapie/app-labs-genotype-test.shtml](http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/app-labs-genotype-test.shtml). For a list of approved laboratories for scrapie testing, go to [http://www.aphis.usda.gov/animal\\_health/nahln/downloads/cwd\\_scrapie\\_lab\\_list.pdf](http://www.aphis.usda.gov/animal_health/nahln/downloads/cwd_scrapie_lab_list.pdf).

**Breed associations and registries**

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

**Breeding sheep or goat**

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

**Classification or reclassification investigation**

An epidemiological investigation conducted or directed by a Designated Scrapie Epidemiologist (DSE) for the purpose of designating or redesignating the status of a flock or animal. In conducting such an investigation, the DSE will evaluate the available records for flocks and individual animals and conduct or direct any testing needed to assess the status of a flock or animal. The status of an animal or flock will be determined based on the applicable definitions in this section and, when needed to make a designation under 9 CFR 79.4 (see *part VII.B* for additional guidance), official genotype test results, exposure risk, scrapie type involved, results of official scrapie testing on live or dead animals, or any combination of these.

**Commercial sheep or goat**

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

**Commingle, commingled, commingling**

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

**Consistent State**

A State that the Administrator has determined conducts an active State scrapie control program that meets the requirements of 9 CFR 79.6 or effectively enforces a State-designated plan that the Administrator determines is at least as effective in controlling scrapie as the requirements of 9 CFR 79.6. The list of Consistent States includes all 50 U.S. States: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

**Deputy Administrator**

The Deputy Administrator for APHIS Veterinary Services or any employee of the U.S. Department of Agriculture authorized to act for the Deputy Administrator.

**Designated Scrapie Epidemiologist (DSE)**

An epidemiologist who has demonstrated the knowledge and ability to perform the functions required and who has been selected by the SAHO and the AVIC. The Sheep and Goat Health Specialist for Epidemiology (SGHSE) and the APHIS National Scrapie Program Coordinator must concur in the selection and appointment of the DSE. The DSE must satisfactorily complete training designated by APHIS.

**Designation of a flock or animal**

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

**Destroyed**

Euthanized and the carcass disposed of by burial, landfill, alkaline digestion, incineration, or other means authorized by the Administrator that will prevent its use as feed or food. **Note:** (1) Euthanasia may occur at a slaughter facility if the carcass is disposed of as required. (2) 9 CFR 54.7(a)(3) provides for the movement of scrapie-positive and suspect animals for which indemnification is sought to an approved research facility.

**Direct movement to slaughter**

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

**Electronic implant**

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

**Exposed animal**

Any animal or embryo that:

- (1) Has been in a flock with a scrapie-positive female animal;
- (2) Has been in an enclosure with a scrapie-positive female animal at any location;
- (3) Resides in a noncompliant flock; or
- (4) Has resided on the premises of a flock before or while it was designated by a DSE an infected or source flock and before a flock plan was completed. An animal shall not be designated an exposed animal if it only resided on the premises before the date that infection was most likely introduced to the premises as determined by a Federal or State representative. If the probable date of infection cannot be determined based on the epidemiological investigation, a date 2 years before the birth of the oldest scrapie-positive animal born in that flock will be used. If the actual birth date is unknown, the date of birth will be estimated based on examination of the teeth and any available records. If an age estimate cannot be made, the animal will be assumed to have been 48 months of age on the date samples were collected for scrapie diagnosis. Exposed animals will be further designated as genetically resistant exposed sheep, genetically less susceptible exposed sheep, genetically susceptible exposed animals, or low-risk exposed animals. An animal will no longer be an exposed animal if it is redesignated in accordance with 9 CFR 79.4 (see [part VII.B](#) for additional guidance).

**Exposed embryo**

See exposed animal definition.

**Exposed flock**

1. Any flock that was designated by a DSE an infected or source flock that has completed a flock plan, and that retained a female genetically susceptible exposed animal;
2. Any flock under investigation that retains a female genetically susceptible exposed animal or a suspect animal, or whose owner declines to complete genotyping and live-animal and/or post-mortem scrapie testing required by the APHIS or State representative investigating the flock; or
3. Any noncompliant flock or any flock for which a PEMMP is required that is not in compliance with the conditions of the PEMMP.
4. A flock will no longer be an exposed flock if it is redesignated in accordance with 9 CFR 79.4 (see [part VII.B](#) for additional guidance).

**Female animal**

A sexually intact female sheep or goat.

**Flock or herd**

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

1. The flocks are enrolled as separate flocks in the [Scrapie Free Flock Certification Program \(SFCP\)](#); or
2. A State or APHIS representative determines, based on examination of flock records, that:
  - a. No female animals have moved between the flocks;
  - b. The flocks never commingle and are kept at least 30 feet apart at all times or are separated by a solid wall through, over, or under which fluids cannot pass and through which contact cannot occur;
  - c. The flocks have separate flock records and identification ;
  - d. The flocks have separate lambing facilities, including buildings and pastures, and a pasture or building used for lambing by one flock is not used by the other flock at any time; and
  - e. The flocks do not share equipment without cleaning and disinfection in accordance with the guidelines published in 9 CFR 54.7.<sup>6</sup>

**Flock identification (ID) number**

A nationally unique number assigned by a State, federally recognized Tribal or Federal animal health authority to a group of animals managed as a unit on one or more premises and under the same ownership. The flock ID number must begin with the State postal abbreviation or APHIS-assigned Tribal code, must have no more than nine alphanumeric characters, and must not

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<sup>6</sup> See [Appendix G](#): Scrapie Disinfection Guidelines for cleaning and disinfection guidance.

contain the characters "I", "O", or "Q" other than as part of the State postal abbreviation or another standardized format authorized by the Administrator and recorded in the National Scrapie Database. APHIS may assign Tribal codes to any federally recognized Tribe that maintains sheep or goats on Tribal lands. The flock ID number must be recorded in and linked to one or more PINs or LIDs in the National Scrapie Database. **Note:** Flock IDs may be used with an animal number unique within the flock to provide a unique official identification number for an animal, or may be used with the date and a sequence number to provide a [Group/lot identification number \(GIN\)](#) for a group of animals when group identification is permitted.

### **Flock of origin**

The flock in which an animal most recently resided in which it either was born, gave birth, or was used for breeding purposes. The determination of an animal's flock of origin may be based either on the physical presence of the animal in the flock, the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal listed on the bill of sale, or other evidence, such as registry records.

### **Flock plan**

A written flock management agreement signed by the owner of a flock, the accredited veterinarian (if one is employed by the owner), and a State or APHIS representative in which each participant agrees to undertake actions specified in the flock plan to control the spread of scrapie from, and eradicate scrapie in, an infected flock or source flock or to reduce the risk of the occurrence of scrapie in a flock that contains a high-risk or an exposed animal. As part of a flock plan, the flock owner must provide the facilities and personnel needed to carry out the requirements of the flock plan. The flock plan must include the requirements in 9 CFR 54.8(a) to (i) (see [part VIII.B](#) for additional guidance).

### **Flock under investigation**

Any flock in which an APHIS or State representative has determined a scrapie suspect animal, high-risk animal, or scrapie-positive animal resides or may have resided. A flock will no longer be a flock under investigation if it is redesignated in accordance with 9 CFR 79.4 (see [part VII.B](#) for additional guidance).

### **Found dead**

Any sheep or goat over 14 months of age meeting any of the following criteria:

1. 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;
2. The animal died off the premises while still owned by the flock owner (such as animals in transit or at a veterinary clinic); or
3. The animal was euthanized due to illness.
4. The category includes animals that are home slaughtered or euthanized for reasons other than illness if 30 animals have not been tested for scrapie since the start of a PEMMP or the animal was designated for testing.

### **Genetically less susceptible exposed sheep**

Any sheep or sheep embryo that is:

1. An exposed sheep or sheep embryo of genotype AA QR, unless the Administrator determines

- that it is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which the Administrator has determined AA QR sheep are not less susceptible; or
2. An exposed sheep or sheep embryo of genotype AV QR, unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the Administrator has determined may be affected by valine-associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to another scrapie type to which the Administrator has determined AV QR sheep are not less susceptible; or
  3. An exposed sheep or sheep embryo of a genotype that has been exposed to a scrapie type to which the Administrator has determined that genotype is less susceptible.

In this definition R or Q refers to codon 171 and A or V refers to codon 136, and Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136.

### **Genetically resistant exposed sheep**

Any exposed sheep or sheep embryo of genotype RR, unless the Administrator determines it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are not resistant.

### **Genetically susceptible animal**

Any goat or goat embryo, sheep or sheep embryo of a genotype other than RR or QR, where Q represents any genotype other than R at codon 171 or sheep or sheep embryo of undetermined genotype.

### **Genetically susceptible exposed animal**

Excluding low-risk exposed animals, any exposed animal or embryo that is also:

1. A genetically susceptible animal;
2. A sheep or sheep embryo of genotype AV QR that the Administrator determines is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the Administrator has determined may be affected by valine-associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to a scrapie type to which AV QR sheep are susceptible;
3. A sheep or sheep embryo of genotype AA QR the Administrator determines is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are susceptible; or
4. A sheep or sheep embryo of genotype RR the Administrator determines is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are susceptible.

In this definition R or Q refers to codon 171 and A or V refers to codon 136, and Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136.

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

**Genotypes of sheep**

Two locations on DNA that code for prion protein are particularly important for classical scrapie susceptibility: Codons 136 and 171. Codon 136 may code for the amino acids alanine (A) or valine (V), and rarely threonine (T). Codon 171 may code for the amino acids arginine (R), glutamine (Q), histidine (H), or lysine (K). For the purposes of these standards, H, K, or any amino acid other than R at codon 171 will be treated as equivalent to Q at codon 171 and T or any amino acid other than A at codon 136 will be treated as V. Sheep that are VV or AV at codon 136 and RR at codon 171 are very rare and have not been identified in the United States.

**QQ sheep**

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

**QR sheep**

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

**RR sheep**

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

**AA sheep**

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

**AV sheep**

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

**VV sheep**

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

**AA QQ sheep**

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

**AV QQ sheep**

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

**VV QQ sheep**

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

designating a sheep as VV QQ.

**AA QR sheep**

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

**AV QR sheep**

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

**Group/lot identification number (GIN)**

The identification number used to uniquely identify a unit of animals managed together as one group. The format of the GIN may be either as defined in 9 CFR 86.1 or the flock identification number followed by a 6-digit representation of the date on which the group or lot of animals was assembled (MM/DD/YY). If more than one group is created on the same date a sequential number will be added to the end of the GIN (example: XX1234-MMDDYY-1). A group lot comprised of animals from a single flock of origin may be subdivided after leaving the premises on which the group was formed by adding an S followed by a sequential number to the end of the GIN to create a GIN for each subgroup. If a flock identification number is used, the flock identification number, date, and sequential number will be separated by hyphens.

**High-risk animal**

The female offspring or embryo of a scrapie-positive female animal, or any suspect animal, or a female genetically susceptible exposed animal, or any exposed animal that the Administrator determines to be a potential risk. The Administrator may base the determination that an exposed animal poses a potential risk on the scrapie type; the epidemiology of the flock or flocks with which it is epidemiologically linked, including genetics of the positive sheep; the prevalence of scrapie in the flock; any history of recurrent infection; and other flock characteristics. An animal will no longer be a high-risk animal if it is redesignated in accordance with 9 CFR 79.4 (see [part VII.B](#) for additional guidance).

**Inconsistent State**

Any State other than a Consistent State.

**Infected flock**

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

**Interstate certificate of veterinary inspection (ICVI)**

An official document issued by a Federal, State, Tribal, or accredited veterinarian certifying the inspection of animals in preparation for interstate movement or other uses as described in this part and in accordance with 9 CFR 79.5.

**Interstate commerce**

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

**Limited contact**

Any contact with a male animal or brief contact with a female animal off the flock's premises, such as occurs in the show or sales ring at fairs, shows, exhibitions, markets, and sales; between ewes being inseminated, flushed, or implanted; or between rams at ram test or collection stations. Embryo transfer and artificial insemination equipment and surgical tools must be disinfected between animals from different flocks by soaking the tools in either a 2 percent available chlorine bleach solution or a 2-molar solution of sodium hydroxide for 1 hour, or another disinfectant labeled or exempted by the EPA for this use for these contacts to be considered limited. Limited contacts do not include any contact, brief, or otherwise, including contacts through a fence, or with an animal during or up to 30 days after she lambed, kidded, or aborted or when there is any visible vaginal discharge other than that associated with estrus. Limited contacts do not include any activity where uninhibited contact occurs with a female animal, such as sharing an enclosure, sharing a section of a transport vehicle, or residing in other flocks for breeding or other purposes.

**Live-animal test**

Any test for the diagnosis of scrapie in a live animal approved by the Administrator for diagnosing scrapie as specified in the approval and conducted in a laboratory approved by the Administrator.<sup>7</sup>

**Low-risk commercial flock**

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

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<sup>7</sup> See [Appendix C](#): Program Approval of Diagnostic Tests for Scrapie in Sheep and Goats. Additionally, VS Memorandum 557.12, *Approval of Lymphoid Tissue Testing for Scrapie*, and VS Memorandum 557.16, *Approval of Rectal Biopsy Derived-Lymphoid Tissue Testing for Scrapie*, document APHIS' authorization of these specific tests for scrapie.

**Low-risk exposed animal**

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

1. The positive animal that was the source of exposure was not born in the flock and did not lamb in the flock or in an enclosure where the exposed animal resided;
2. The Administrator and SAHO concur that the animal is unlikely to be infected due to factors such as, but not limited to, where the animal resided or the time period the animal resided in the flock;
3. The exposed animal is male and was not born in an infected or source flock;
4. The exposed animal is a castrated male;
5. The exposed animal is an embryo of a genetically resistant exposed sheep or a genetically less susceptible exposed sheep unless placed in a recipient that was a genetically susceptible exposed animal; or,
6. The animal was exposed to a scrapie type and/or is of a genotype that the Administrator has determined poses a low risk of scrapie transmission.

**Note:** The Administrator has determined that Nor98-like scrapie poses a low risk of scrapie transmission.

**Male animal**

A sexually intact male sheep or goat.

**Mortgage**

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

**National Scrapie Database (NSD)**

A database designated by the Administrator in which APHIS and State animal health agencies cooperatively enter data concerning scrapie outbreaks, flocks, and premises affected by scrapie, individual animal identification and premises identification data, and other data to support the Scrapie Eradication Program and the Scrapie Flock Certification Program.

**Note:** the designated database was comprised of the following applications: SCS SCR, VSLS, MIM, EMRS, and the scrapie program utility of AIMS at time of publication.

**National Scrapie Eradication Program (NSEP)**

The cooperative State-Federal-industry program administered by APHIS and Consistent States to control and eradicate scrapie. The NSEP is also referred to in these standards as the “Program”.

**National Scrapie Eradication Program Standards (NSEPS)**

Volume 1 of the Scrapie Program Standards, NSEPS is the set of cooperative procedures and standards adopted by APHIS and Consistent States for eradicating scrapie.

**National Veterinary Services Laboratories (NVSL)**

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

**Noncompliant flock**

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

**Official eartag**

An identification tag approved by APHIS that bears an official identification number for individual animals. All official eartags manufactured must bear an official eartag shield. The design, size, shape, color, and other characteristics of the official eartag will depend on the needs of the users, subject to the approval of the Administrator. The official eartag must be tamper-resistant, have a high retention rate in the animal, and be approved in accordance with 9 CFR 79.2(k) for use in sheep or goats.<sup>8</sup>

**Official genotype test**

A test to determine the genotype of a live or dead animal conducted at either the NVSL or at an approved laboratory.<sup>9</sup> The test subject must be an animal that is officially identified and the test accurately recorded on an official form supplied or approved by APHIS, with the samples collected and shipped to the laboratory using a shipping method specified by the laboratory by:

1. An accredited veterinarian;
2. A State or APHIS representative; or
3. The animal's owner or owner's agent, using a tamper-resistant sampling kit approved by APHIS for this purpose.

**Official identification device or method**

A means approved by the Administrator of applying an official identification number to an animal of a specific species or associating an official identification number with an animal or group of animals of a specific species or otherwise officially identifying an animal or group of animals; *except that*, only devices approved and distributed for use in sheep and goats in accordance with 9 CFR 79.2 (k) and methods approved for use in sheep and goats in accordance with 9 CFR 79.2(a)(2) are included.

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<sup>8</sup> Official eartags approved for use in sheep and goats may be found at <https://vsapps.aphis.usda.gov/aims/AllProductSelect.do> Select Scrapie Program Tags from the drop down and click on "Get Approved Devices."

<sup>9</sup> See [Appendix A: Approval of Laboratories to Conduct Official Genotype Tests in Sheep](#). Approved laboratories are listed at [http://www.aphis.usda.gov/animal\\_health/lab\\_info\\_services/downloads/ApprovedLabs\\_genotyping.pdf](http://www.aphis.usda.gov/animal_health/lab_info_services/downloads/ApprovedLabs_genotyping.pdf)

**Official identification number**

A nationally unique number that is permanently associated with an animal or group of animals and adheres to one of the following systems:

1. National Uniform Eartagging System (NUES) (for sheep and goats this is the State postal abbreviation followed by two alphanumeric characters and four digits);
2. Animal identification number (AIN);
3. Location-based number system;
4. Flock-based number system; or
5. Any other numbering system approved by the Administrator for the official identification of animals.

**Note:** Official identification numbers for sheep and goats are limited to those distributed through the Scrapie Program application in AIMS or its predecessor TAGMAN, flock ID production number tattoos, and grandfathered non-840 RFID implants.

**Official test**

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

**Officially identified**

Identified by means of an official identification device or method approved by the Administrator for use in sheep and goats in accordance with 9 CFR 79.2 (k) or 9 CFR 79.2(a)(2) respectively.

**Owner**

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

**Owner/hauler statement**

A signed written statement by the owner or hauler that includes:

1. The name, address, and phone number of the owner and, if different, the hauler;
2. The date the animals were moved;
3. The flock identification number or PIN assigned to the flock or premises of the animals;
4. If moving individually unidentified animals, the group/lot identification number and any information required to officially identify the animals;
5. The number of animals;
6. The species, breed, and class of animals. If breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead; and
7. The name and address of point of origin, if different from the owner's address, and the destination.

An existing document that includes the same information that is signed by the owner or the hauler meets this definition.

**Permit**

An official document issued in connection with the interstate movement of animals (VS Form 1-27 or a State form that contains the same information) by an APHIS representative, State representative, or an accredited veterinarian authorized to sign such permits. A new permit is required for each change in destination for an animal. A permit lists the owner's name and

address; points of origin and destination; number of animals covered; purpose of the movement; whether the animals are from an exposed flock, flock under investigation, noncompliant, infected, or source flock; whether the animal is a high-risk, exposed, scrapie-positive, or scrapie suspect animal; transportation vehicle license number or other identification number; and seal number (if a seal is used). A permit also lists all official identifications on the animals covered. Official identifications may include: The eartag number; a registered breed association's registration tattoo, brand, or number; a USDA backtag (when applied serially, only the beginning and ending numbers need to be recorded); or any other form of official identification present on the animal.

**Person**

An individual, partnership, company, corporation, or any other legal entity.

**Person number**

A unique number assigned to an accredited veterinarian, a person authorized to redistribute tags, or an APHIS or State representative recorded in the NSD for tag allocation, data entry in VSLS, and identification on documents such as test charts.

**Post-exposure management and monitoring plan (PEMMP)**

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

**Premises**

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

**Premises identification number (PIN)**

A nationally unique number assigned by a State, Tribal, and/or Federal animal health authority to a premises that is, in the judgment of the State, Tribal, and/or Federal animal health authority, a geographically distinct location from other premises. The PIN may be used with a producer's own livestock production numbering system to provide a nationally unique and herd-unique identification number for an animal. It may be used as a component of a group/lot identification number (GIN). APHIS may also maintain historical or State premises numbers and link them to the PIN in records and databases. Such secondary or historical numbers are typically the State's 2-letter postal abbreviation followed by a number assigned by the State.

**Program**

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

**Program-approved test**

A test for the diagnosis of scrapie approved by the Administrator for use in the scrapie eradication or certification program or both.<sup>10</sup>

**Restricted animal sale or restricted livestock facility**

A sale where any animals in slaughter channels are maintained separate from other animals not in slaughter channels unless they are from the same flock of origin and are sold in lots that consist entirely of animals sold for slaughter only, or a livestock facility at which all animals are in slaughter channels and where the sale or facility manager maintains a copy of, or maintains a record of, the information from the owner/hauler statement for all animals entering and leaving the sale or facility. A restricted sale may be held at a livestock facility that is not restricted.

**Scrapie**

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

**Scrapie control pilot project**

A pilot project authorized by the Administrator in writing, designed to test or improve program procedures or to facilitate research to control and eradicate scrapie. In addition to APHIS, participants may include State animal health agencies, flock owners, and other parties as necessary. (Pilot projects are often established through a memorandum of understanding between a State and APHIS; they may also be implemented nationally through amendments to these program standards or as an interim measure through changes to a flock plan or PEMMP template. Such templates must be approved by the National Scrapie Program Coordinator and the plans signed by the State Veterinarian and the AVIC.)

**Scrapie Free Flock Certification Program (SFCP)**

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

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

**Scrapie Free Flock Certification Program Standards (SFCPS)**

Volume 2 of the Scrapie Program Standards, SFCPS are the set of cooperative procedures and standards adopted by APHIS and State scrapie certification boards for reducing the incidence and controlling the spread of classical scrapie.

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<sup>10</sup> See [Appendix C](#): Program Approval of Diagnostic Tests for Scrapie in Sheep and Goats. Additionally, VS Memorandum 557.12, *Approval of Lymphoid Tissue Testing for Scrapie*, and VS Memorandum 557.16, *Approval of Rectal Biopsy-Derived Lymphoid Tissue Testing for Scrapie*, document APHIS' authorization of these specific tests for scrapie.

**Scrapie-positive animal**

An animal for which a diagnosis of scrapie has been made by the National Veterinary Services Laboratories or another laboratory authorized by the Administrator to conduct scrapie tests in accordance with this chapter, through:

- (1) Histopathological examination of central nervous system (CNS) tissues from the animal for characteristic microscopic lesions of scrapie;
- (2) The use of proteinase-resistant protein analysis methods including but not limited to immunohistochemistry, ELISA and/or western blotting on CNS and/or peripheral tissue samples from a live or a dead animal for which a given method has been approved by the Administrator for use on that tissue;
- (3) Bioassay;
- (4) Scrapie associated fibrils (SAF) detected by electron microscopy; or
- (5) Any other method or combination of methods approved by the Administrator in accordance with 9 CFR 54.10.<sup>11</sup>

**Slaughter channels**

Animals in slaughter channels include any animal that is sold, transferred, or moved either directly to or through a restricted animal sale or restricted livestock facility to an official slaughter establishment that is under Food Safety and Inspection Service (FSIS) jurisdiction per the Federal Meat Inspection Act (FMIA) or under State inspection that FSIS has recognized as at least equal to Federal inspection; to a custom exempt slaughter establishment as defined by FSIS (9 CFR 303.1) for immediate slaughter; or to an individual for immediate slaughter for personal use or to a terminal feedlot. Animals in slaughter channels before arriving at a sale and animals that cannot meet the ID and ICVI requirements for unrestricted movement prior to leaving a sale may not be sold at an unrestricted sale. This does not preclude animals sold at an unrestricted sale from being moved in slaughter channels after sale if identified as required for animals in slaughter channels. Animals in slaughter channels must be accompanied by an owner/hauler statement completed in accordance with 9 CFR 79.3(g). Animals in slaughter channels may not be held in the same enclosure with sexually intact animals from another flock of origin that are not in slaughter channels. When selling animals that do not meet the requirements to move as breeding animals, owners must note on the bill of sale that the animals are sold only for slaughter.

**Source flock**

A flock in which a State or APHIS representative has determined that at least one animal was born that was diagnosed as scrapie positive at an age of 72 months or less. The determination that an animal was born in a flock must be based either on the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records, to show that a scrapie-

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<sup>11</sup> See [Appendix C](#): Program Approval of Diagnostic Tests for Scrapie in Sheep and Goats for additional guidance.

positive animal originated from the flock combined with the absence of records indicating that the animal was purchased and added to the flock. If DNA from the animal was collected when the animal resided in the flock of birth by an accredited veterinarian and stored at an approved genotyping laboratory, or if DNA collection and storage is required for breed registration and the breed registration has appropriate safeguards in place to ensure the integrity of the banking process, the owner may request verification of the animal's identity based on DNA comparison if adequate records and identification have been maintained by the owner and the repository to show that the archived DNA is that of the animal that has been traced to the flock. A flock will no longer be a source flock after it has completed the requirements of a flock plan.

**State**

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

**State Animal Health Official (SAHO)**

An individual employed by the State as the chief animal health official of the State, often but not always the State veterinarian.

**State representative**

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

**Suspect animal**

1. A mature sheep or goat (as evidenced by eruption of the first incisor) that has been condemned by FSIS or a State inspection authority for CNS signs, or that exhibits any of the following clinical signs of scrapie and has been determined to be suspicious for scrapie by an accredited veterinarian or a State or USDA representative, based on one or more of the following signs and the severity of the signs:
  - a. Weakness of any kind including, but not limited to, stumbling, falling down, or having difficulty rising, not including those with visible traumatic injuries and no other signs of scrapie;
  - b. Behavioral abnormalities;
  - c. Significant weight loss despite retention of appetite or in an animal with adequate dentition;
  - d. Increased sensitivity to noise and sudden movement;
  - e. Tremors;
  - f. Star gazing;
  - g. Head pressing;
  - h. Bilateral gait abnormalities such as but not limited to incoordination, ataxia, high stepping gait of forelimbs, bunny-hop movement of rear legs, or swaying of back end, but not including abnormalities involving only one leg or one front and one back leg;
  - i. Repeated intense rubbing with 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;
  - j. 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; or

- k. Other signs of CNS disease. An animal will no longer be a suspect animal if it is redesignated in accordance with 9 CFR 79.4 (see *part VII.B* for additional guidance).
2. A sheep or goat that has tested positive for scrapie or for the proteinase resistant protein associated with scrapie on a live-animal screening test or any other test, unless the animal is designated a scrapie-positive animal.
3. A sheep or goat that has tested inconclusive or suggestive on an official test for scrapie.

### **Tamper-resistant sampling kit**

A device or method for collecting DNA samples from sheep or goats approved by the Administrator and that identifies both the sample and the animal at the time the sample is collected. These devices or methods must ensure that the sample, its corresponding label, and the official ID device or method applied to the animal meet the requirements of 9 CFR 79.2(k) and that the sample is from the same animal to which the official ID device or method was applied. The kit must include an APHIS-approved official form or another form, device, or method acceptable to APHIS for transmitting the information required to APHIS and the approved laboratory.

**Note:** As of the publication of these standards no tamper-resistant sampling kits had been approved. If approved kit manufacturers will be listed [here](#).<sup>12</sup>

### **Terminal feedlot**

1. A drylot approved by a State or APHIS representative or an accredited veterinarian authorized to perform this function where animals in the terminal feedlot are separated from all other animals by at least 30 feet at all times or are separated by a solid wall through, over, or under which fluids cannot pass and contact cannot occur. The lot must be cleaned of all organic material before being used to contain sheep or goats not in slaughter channels. Further, only castrated males can be maintained with female animals and animals may move only to another terminal feedlot or directly to slaughter; or
2. A drylot approved by a State or APHIS representative or an accredited veterinarian authorized to perform this function where only animals that are not pregnant based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, a certificate issued by an accredited veterinarian stating the animals are open, or the animals are under 6 months of age at time of receipt. Only castrated males may be maintained with female animals, and all animals in the terminal feedlot must be separated from all other animals such that physical contact cannot occur. Animals may move only to another terminal feedlot or directly to slaughter.
3. A pasture when approved by and maintained under the supervision of the State and in which only nonpregnant animals are permitted based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, or a certificate issued by an accredited veterinarian stating the animals are open or the animals are under 6 months of age at time of receipt. Only castrated males may be maintained with female animals. There is no direct fence-to-fence contact with another flock, and animals may move only to another terminal feedlot or directly to slaughter.
4. Records of all animals entering and leaving a terminal feedlot must be maintained for 5 years after the animal leaves the feedlot and must meet the requirements of 9 CFR 79.2, including

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<sup>12</sup> [https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/sheep-and-goat-health/national-scrapie-eradication-program/ct\\_to\\_order\\_ear\\_tags](https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/sheep-and-goat-health/national-scrapie-eradication-program/ct_to_order_ear_tags).

either a copy of the required owner/hauler statements for animals entering and leaving the facility or the information required to be on the statements. Records must be made available for inspection and copying by an APHIS or State representative on request.

**Test eligible**

An animal that meets a test protocol's age and post-exposure elapsed time requirements for the test to be meaningfully applied.

**Trace**

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

**Unofficial test**

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

**Veterinary Medical Officer (VMO)**

A veterinarian employed by the State or APHIS. **Note:** This may include accredited veterinarians when paid by APHIS or the State to perform the specified function.

## Part II: Administrative Procedures

### A. Supervision of the Cooperative State-Federal-Industry National Scrapie Eradication Program (NSEP)

Animal health officials employed by the State or the Federal government will supervise the cooperative State-Federal-industry scrapie eradication program, commonly known as the NSEP. In each State, APHIS and the animal health agency of the State will sign a memorandum of understanding (MOU) delineating the respective roles of each in NSEP implementation. Additionally, APHIS may include administration of the NSEP within a State as part of an umbrella cooperative agreement with the animal health agency of that State.

### B. Appointing DSEs

The selection and appointment of DSEs will be made jointly by the SAHO and AVIC with the concurrence of the APHIS SGHSE and the APHIS National Scrapie Program Coordinator (see VS Memorandum No. 570.9).

### C. Administrative Review of Program Activities and Progress

Administrative review of a State's scrapie program will consist of the following:

1. Ongoing review of program activities and records by VS personnel at the local, district, and national levels, including but not limited to:
  - a. Evaluation of information entered into the NSD by State or Federal animal health officials, or both, in each of the States;
  - b. Review of epidemiological and ID compliance reports submitted by the DSEs for the State to the SGHSE and National Scrapie Program Coordinator; and
  - c. Review of applications for renewal or reclassification of a State as described in [part IV](#).
2. Site visits conducted in accordance with VS Memorandum No. 515.1.

### D. Inspection of Slaughter Establishments, Livestock Markets, Dealers, and Other Concentration Points for Identification and Sampling Compliance

A key component of scrapie surveillance is the ability to trace positive animals to the correct flock of origin, which requires accurate individual animal or lot identification. The goal of scrapie surveillance is to successfully trace 100 percent of positive animals. Routine inspection of sheep and goat concentration points is essential to meeting this goal.

1. Sites to inspect are:
  - a. Slaughter establishments;
  - b. Markets;
  - c. Dealers; and
  - d. Any other concentration points handling mature sheep or goats, or both.

2. Sites may be inspected by State or Federal employees or accredited veterinarians who have been authorized by the AVIC to conduct such inspections.
3. Recommendations for frequency of inspections:
  - a. Markets.
    - 1) If handling more than 100 head per sale, at least once every quarter.
    - 2) If handling fewer than 100 head per sale, at least once every 6 months.
  - b. Public sales of sheep seed stock (purebred sales and sales specifically for breeding animals such as bred ewe or replacement ewe sales not held at markets).
    - 1) If handling more than 500 head per sale, at least 75 percent of the sales conducted during the year.
    - 2) If handling 100 to 500 head per sale, at least 50 percent of the sales conducted during the year.
    - 3) If handling 50 to 99 head per sale, at least 25 percent of the sales conducted during the year.
    - 4) Smaller sales should also be inspected if noncompliance is suspected or resources permit.
    - 5) Alternatively, seed stock sales conducted multiple times a year by the same management may be inspected on the same schedule as markets.
  - c. Dealers and other concentration points.
    - 1) If handling more than 500 head per month, at least once every quarter.
    - 2) If handling 100 to 499 head per month, at least once every 6 months.
    - 3) If handling 50 to 99 head per month, at least once every year.
    - 4) Lower volume dealers should also be inspected if noncompliance is suspected or resources permit.
  - d. Slaughter establishments.

All slaughter establishments handling mature sheep or goats that are in or have been in interstate commerce are required to be Regulatory Scrapie Slaughter Surveillance (RSSS) collections sites. At sites where the establishment or a contractor collects specimens for RSSS, ID compliance and inspection of sampling protocol should be conducted at least quarterly. At sites where samples are collected by VS or State employees, ID compliance is to be informally monitored each time collections are made. If inspectors observe problems with ID compliance, they will conduct and document a formal inspection. Slaughter establishments should be formally inspected according to the following schedule:

    - 1) If handling more than 500 mature animals per month, at least once every quarter.
    - 2) If handling 100 to 499 mature animals per month, at least once every 6 months.
    - 3) If handling 2 to 99 mature animals per month, at least once every year.
  - e. The AVIC may reduce the frequency of visits once compliance is documented, but visits should be at least once every 6 months if the facility handles more than 50 animals per month and at least once every year for all others. If a site is noncompliant, maintain the original schedule until compliance is documented for at least 6 months.

- f. New facilities and facilities under new ownership or management should be inspected as soon as practical and no later than 30 days after the VS Area Office becomes aware of the change.
4. Information to record during inspections
    - a. Markets, dealers, seed stock sales, and other concentration points.
      - 1) Record the total number of sheep and the total number of goats present at the time of inspection that require official ID in accordance with 9 CFR 79.3.
      - 2) Of the sheep requiring identification, record the number of sheep with official ID (including those tagged to flock of origin at the inspection site).
      - 3) Of the goats requiring identification, record the number of goats with official ID (including those tagged to flock of origin at the inspection site).
      - 4) Indicate whether numbers recorded in 1), 2), or 3) are actual counts or estimates.
      - 5) Document the following information for any consignment not in compliance:
        - a) Name and address of the source;
        - b) Number of animals on the load that require official identification;
        - c) When practicable, photos of ears showing absence of official ID and teeth for estimating age (if a camera is not available, the basis for age determination should be documented in writing);
        - d) Absence of other allowed ID, such as tattoos and brands; and
        - e) Presence or absence of required records as described in *part III.B.*
      - 6) Review records for compliance, and record any deficiencies.

**Note:**

- a) If sheep are from a single flock of origin, markets may tag them on arrival or pen them separately until they are identified.
  - b) Ideally, animals at the market should be identified on unloading or shortly thereafter, but must be identified before being commingled or sold.
  - c) The count of sheep or goats or both with and without official ID should only include those animals ready for sale or already sold. Animals that are not tagged when the inspection begins must be penned separately from sheep or goats from any other flock of origin and must be correctly tagged to their flock of origin prior to commingling and prior to sale. At the time the inspection begins, unidentified animals commingled with other unidentified animals from a different flock of origin should be counted as animals without official ID on the inspection report.
- b. Slaughter establishments.
    - 1) On the day of inspection, as the sheep or goats, or both, are unloaded, record the following information for each load of sheep or goats (or both) that require official ID:
      - a) Name and address of the source;
      - b) Number of animals by species on the load requiring identification;
      - c) Number of animals by species with official ID;
      - d) Indicate if counts are actual or estimates;

- e) When practicable, photos of ears showing absence of official ID and teeth for estimating age (if a camera is not available, the basis for age determination should be documented in writing);
  - f) Absence of other allowed ID, such as tattoos and brands; and
  - g) Presence or absence of required records as described in *part III.B*.
- 2) Review establishment records for compliance, and record deficiencies.

**Note:**

- a) If the animals are unloaded before the inspector arrives, the inspector will make every attempt to determine the above information for each load.
- b) Alternative methods such as having the establishment place the heads from each consignment in separate containers for later inspection may be used.

5. Inspection reporting procedures are outlined in *part X.B*.

**E. Identification and Recordkeeping Compliance**

1. Federal Responsibilities:

AVICs are responsible for initiating education or compliance actions (or both) for alleged violators of Federal regulations with business addresses in the State or States for which they have responsibility. If a noncompliant supplier's business is outside the AVIC's area of responsibility, the AVIC will provide a report detailing the alleged violations to the AVIC for the State where the alleged violator's business is located and to the SGHSE for the States involved.

- a. If fewer than 95 percent of the animals required to be officially identified (described in 9 CFR 79.3) are properly identified in any consignment at a slaughter establishment, market, or other site where sheep or goats are in or were in interstate commerce, and the animals either were not or could not be officially identified at the site to the flock of origin or, when permitted by 9 CFR 79.3, to the owner before commingling with other animals, the AVIC will ensure that the following steps are taken:
  - 1) Educate the consignor who supplied the consignment about the ID requirements in 9 CFR 79.2 and the NSEPS.
  - 2) Inform the establishment or market management that in accordance with 9 CFR 79.2(a), no one, including establishments and markets, may receive or transport unidentified animals required to be identified by 9 CFR 79.3 unless they identify the animals to their flock of origin (flock in which an animal most recently resided, in which it was born, gave birth, or was used for breeding purposes) before commingling. Under certain circumstances, animals can be identified to the owner of the current flock, even if this flock is not the flock of origin (for example, certain commercial whitefaced or hair sheep, or goats if the State has exempted them from intrastate identification requirements per 9 CFR 79.6(10)(i)). Regulations in 9 CFR 79.3 and 9 CFR 79.6 specify 18 months as the age of eruption of the second permanent incisor. Eighteen months is the maximum age at which a sheep or goat may move

- unidentified in slaughter channels.
- 3) If not contrary to State ID regulations, as an alternative to refusing an animal whose flock of origin is undeterminable, markets and dealers may enter into a compliance agreement with APHIS to identify the animal with a slaughter-only tag, listing the consignor or, in the case of dealers, the market where acquired rather than the flock of origin on the tagging record. Markets and dealers must provide a list of all such occurrences to the AVIC within 15 days, so that the AVIC can follow up with the person who sold them the animal to provide education and to initiate a compliance action if the infraction meets the criteria in *D.1.b*. A similar agreement may be made with slaughter establishments, except a slaughter-only tag would not be required. A compliance agreement template is available in the National Scrapie Reference Library on the [Scrapie SharePoint](#) site.
  - 4) Document the infraction and the education provided.
- b. On the first occurrence of any of the infractions listed in 1)–4) below, the responsible AVIC will, at a minimum, issue a warning letter. Any subsequent occurrence, or individuals or other legal entities that fall under 5), should be referred to Investigation and Enforcement Services (IES) for compliance action unless there are significant mitigating circumstances.
- 1) Any consignor that supplies a single consignment with less than 90 percent of the animals identified as required.
    - a) This does not include consignments where the unidentified animals were officially identified to the flock of origin or, when permitted by 9 CFR 79.3, to the owner, at sites permitted to officially identify animals as an agent for the owner in accordance with 9 CFR 79.2(a).
    - b) When evaluating compliance in lots of fewer than 10 animals, more than 1 animal unidentified should be used as the standard rather than 90 percent unless there is a pattern of noncompliance.
  - 2) Any slaughter establishment, market or other concentration point where fewer than 90 percent of the animals present are identified as required during any inspection.
  - 3) Any noncompliance that impedes a disease investigation.
  - 4) Any person or legal entity (dealer, market, slaughter establishment, etc.) who has tagged animals with blue “MEAT” or “SLAUGHTER ONLY” tags due to lack of flock of origin information but who has not provided records to the VS Area Office indicating the source (producer, market, dealer, or other legal entity) of each individual blue “MEAT” or “SLAUGHTER ONLY” tagged animal. Tags lost after receipt of an animal are an exception; in this case all possible sources should be recorded as provided in 9 CFR 79.3 along with the new official ID number applied.
  - 5) Any person, market, slaughter establishment, or other legal entity whose compliance level is habitually below 95 percent.
- c. If the AVIC is aware of any alleged violation of State ID regulations, the AVIC for the State where the alleged violation was identified will notify and provide a detailed report to the SAHO and to the AVIC with responsibility for the State (if different).

- d. If an AVIC or SAHO becomes aware of any State that habitually does not enforce the Consistent State requirements in 9 CFR 79.6, he or she will notify the SGHSE for the districts involved, so the alleged deficiency can be investigated and an action plan developed to address any deficiency identified. Failure by a State to address significant deficiencies will result in removal of Consistent State status.
  - e. The AVIC or SAHO must provide a compliance summary as part of the Epidemiology and Compliance Report as described in *part X* to the SGHSE using the spreadsheet provided on the [Scrapie SharePoint](#) site.
2. State Responsibilities:
- a. States must have legal authorities (laws and regulations) such that the SAHO can institute any action necessary to enforce compliance with State animal ID requirements, recordkeeping requirements, and other animal health regulations required to meet Consistent State requirements as provided in 9 CFR 79.6.
  - b. The SAHO must have the authority and take regulatory action to ensure that the following persons maintain records and officially identify animals to enable State or APHIS authorities to trace exposed, high-risk, scrapie-positive, and suspect animals to all flocks in which they have resided and to determine their final disposition:
    - 1) Persons who purchase, deal in, or sell or otherwise dispose of sheep or goats over 18 months of age as well as sexually intact sheep or goats of any age that are not in slaughter channels;
    - 2) Persons who act as commission representatives or brokers of such animals; and
    - 3) Persons who operate or conduct an auction at which sheep or goats are sold.
  - c. Action must be taken by the State if there is adequate evidence to establish that a person violated or circumvented State recordkeeping, ID, or movement requirements for sheep or goats, other State animal health regulations pertaining to scrapie, or both. At a minimum, the State will issue a warning on the first occurrence and apply penalties as provided under State law or regulation for repeat offenses. If not specifically addressed by State law or regulation, States will at a minimum apply the same action levels listed under Federal responsibilities. If the SAHO is aware of any alleged violation of Federal regulations, he or she should notify and provide a detailed report to the AVIC for the area involved.
3. Issuance of Enforcement Actions to Cooperating RSSS Sites, Markets, and Dealers:
- a. APHIS will not pursue an enforcement action for not identifying sheep or goats to their flock of origin, including issuing official warnings, to subjects of investigations who have cooperated substantially with VS. This includes:
    - 1) Persons or other legal entities who have signed a compliance agreement with APHIS and were acting in compliance with that agreement at the time the violation occurred.
    - 2) Persons or other legal entities who have not signed a compliance agreement but were acting in compliance with the requirements of a compliance agreement at the time the violation occurred—e.g., if they have received

unidentified animals that required official identification to their flock of origin but that could not be identified to their flock of origin, and they have identified them using official slaughter-only eartags to the consignor and have given VS the required information.

- 3) Persons or other legal entities who self-reported the violation and for whom there have been no subsequent violations or who have subsequently signed a compliance agreement with APHIS and are in compliance with that agreement.
  - 4) Persons or other legal entities who did not self-report for which there have been no subsequent violations and who signed a compliance agreement with APHIS when the violation was brought to their attention and who have been and are in compliance with that agreement.
  - 5) Persons or other legal entities who have provided tissues or heads to APHIS for scrapie testing, voluntarily or in accordance with 9 CFR 71.21, where the violation would not have been discovered other than through their cooperation or compliance, and who have had no subsequent violations or have subsequently signed a compliance agreement with APHIS and are in compliance with that agreement.
- b. To ensure that these mitigating circumstances are considered:
- 1) The APHIS Investigative and Enforcement Services Animal Health and Welfare Enforcement Branch (AHWEB) will review the case to determine whether the subject meets the criteria, and if necessary, will contact the AVIC for the State in which the subject does business and request information to document whether the subject meets the criteria.
  - 2) The AHWEB will request concurrence from the AVIC who requested the investigation (the concurring AVIC) before pursuing an enforcement action. If the concurring AVIC is the AVIC for the State in which the subject does business, the concurring AVIC will verify whether the subject meets the criteria. If the concurring AVIC is not the AVIC for the State in which the subject does business, the concurring AVIC will ask the SGHSE to verify the determination after consulting with the AVIC in the State where the subject maintains his, her, or its business and the concurring AVIC.

#### **F. Requirements for Program Personnel Entering Premises**

Persons entering a premises to perform activities on behalf of the NSEP must be employees of the State or APHIS or be authorized by the State or APHIS to carry out program procedures. While on those premises, they must use established biosecurity practices to minimize the risk of physically transmitting scrapie and other diseases to the premises or other premises.

#### **G. Providing Services to Livestock Owners**

Program services such as collecting blood or tissue samples, identifying animals, and other specified activities may be rendered without charge to the livestock owner. However, owners are responsible for providing facilities and for handling their animals.

Program administrators may contract with accredited veterinarians, paraprofessionals, other State and Federal agencies, or the management of privately owned firms, as needed, to assist State and Federal animal health officials in performing program services.

## **H. Exceptions to the Deadlines for Flock Plans, Investigations, and Testing**

Program officials must follow deadlines for flock plans, investigations, and testing except when a DSE determines that there are extenuating circumstances. The extenuating circumstances must make it impossible to meet the deadline established for a particular flock. The DSE must immediately set a new deadline in consultation with the flock owner or his or her representative. The new deadline must be consistent with the principles of the NSEP. The SGHSE must approve extensions to deadlines established in 9 CFR part 54.

## **I. Depopulation of All Sexually Intact Sheep and Goats in a Flock (Whole Flock Depopulation)**

When requested by the DSE, the SGHSE will review sheep and goat flocks for whole-flock depopulation, with indemnity. A recommendation will then be made to the National Scrapie Program Coordinator, based on the prevalence and epidemiology of the infection, the relative cost of whole flock depopulation versus testing, and ongoing monitoring costs associated with a genetic-based flock plan. The National Scrapie Program Coordinator will make the final determination on offering whole-flock depopulation to the producer based on disease risk, availability of funds, and cost to the government. Examples of when a whole flock depopulation may be authorized are listed in *part VIII.B.3.b*.

## **J. Indemnity**

1. Animals eligible for Federal indemnity payments:  
Federal indemnity may be paid for an animal only after its owner has applied for indemnification and been approved (9 CFR 54.4). Federal indemnity may be paid only for the following:
  - a. Destruction of high-risk animals and male genetically susceptible exposed animals of known genotype;
  - b. Destruction of high-risk animals of unknown genotype, if:
    - 1) The animal resides in a flock that has not been designated an infected or source flock;
    - 2) The animal is the offspring of a scrapie-positive female animal;
    - 3) The animal is the offspring of an indemnified ewe too young to wean on the date the dam is destroyed, or
    - 4) The National Scrapie Program Coordinator has approved a whole-flock depopulation.
  - c. Destruction of animals requested for postmortem sampling by the DSE as part of an epidemiologic investigation;
  - d. Destruction of live scrapie-positive animals;

- e. Destruction of suspect animals destroyed at the request of an APHIS representative; and
  - f. Destruction of animals based on an epidemiological investigation when the Administrator determines that destroying these animals will contribute to eradicating scrapie.
2. Requirements of flock owners to receive indemnity:  
When these standards require a flock to be on a flock plan or PEMMP or both, the owner must sign and be in compliance with the approved flock plan and/or PEMMP before receiving indemnity, including the provision of records. The owner must also sign a request for release of all records from any breed association with which they have registered animals. No indemnity will be paid until the animals have been destroyed and the premises, including all structures, holding facilities, conveyances, and materials contaminated because of occupation or use by the depopulated animals, have been properly cleaned and disinfected in accordance with 9 CFR 54.7(e)<sup>13</sup>; *except that*, partial indemnity may be paid when the National Scrapie Program Coordinator determines that weather or other factors outside the owner's control make immediate disinfection impractical. Premises or portions of premises may be exempted from the cleaning and disinfecting requirements if a designated scrapie epidemiologist determines, based on epidemiological investigation, that cleaning and disinfection of such buildings, holding facilities, conveyances, or other materials on the premises will not significantly reduce the risk of the spread of scrapie, either because effective disinfection is not possible or because normal operations on the premises prevent transmission of scrapie.
3. Notifying owners of their eligibility for indemnity:  
If funds are available<sup>14</sup>, VS will offer indemnity in writing when VS or the State informs the owner that the owner's flock is an infected or source flock or that the flock contains an animal eligible for indemnity. If funds are not available, VS will offer indemnity as soon as funds become available. Such an offer will include a copy of the applicable indemnity calculator and which categories of animals are eligible for indemnity. Owners will also be informed of the following at the time the offer is made:
- a. Females not made available for inventory, assessment of late gestational status, and testing within 30 days of first notice will not qualify for the late gestational premium. An extension may be granted by the SGHSE or the National Scrapie Program Coordinator when severe weather or other conditions beyond the owner's control prevent a timely evaluation.
  - b. Offspring born more than 60 days after a written offer of indemnity will not be indemnified unless the SGHSE or the National Scrapie Program Coordinator determines that severe weather or other conditions beyond the control of the owner prevent the timely removal of the animals.

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<sup>13</sup> See [Appendix G](#): Scrapie Disinfection Guidelines for cleaning and disinfection guidance.

<sup>14</sup> Provision of Federal indemnity is contingent on the availability of funding.

4. Amount of indemnity payments:
  - a. Federal indemnity. Indemnity paid for sheep and goats (9 CFR 54.3 to 9 CFR 54.6) will be set as follows.
    - 1) ***Sheep and goat classes covered by price reports.*** Indemnity paid for sheep or goats will be based on available price report data that most accurately reflect the type of animal being indemnified and the time at which the animal was indemnified. To calculate indemnity, APHIS may use price information provided by the Agricultural Marketing Service (AMS) or other available price information for animals sold during the calendar month before the calendar month in which APHIS offers to pay an owner; ***except that***, if an applicable price report is not available during any period for any class, APHIS will use the price established for animals for the most recent month for which price information was available. For categories for which price reports are discontinued or have remained unavailable or contain insufficient information to determine a valid price for more than 3 months, the Administrator may establish an alternate method for calculating indemnity for the category. The following report categories will be used in calculating the indemnity that may be paid:
      - a) Slaughter lamb per pound;
      - b) Slaughter ewe per pound;
      - c) Commercial ewe lamb replacement price per pound;
      - d) Commercial yearling ewe replacement price per head;
      - e) Commercial running age (young and middle age) ewe price per head;
      - f) Aged ewe price per head;
      - g) Slaughter kids per pound;
      - h) Slaughter does/nannies per pound;
      - i) Slaughter bucks/billies per pound; and
      - j) Replacement does/nannies per pound.
    - 2) ***Other classes of sheep or goats.*** When the animals to be indemnified are goats or sheep that fall outside the classes covered elsewhere in this paragraph such as club lambs or kids, or if the animals entered the flock through purchase, the DSE may take into consideration the producer's purchase records and sales records for the preceding 12 to 24 months or, in the case of purchased animals, records showing the purchase price of the animal in determining the indemnity amount. The indemnity will not exceed the maximum indemnity calculated for a registered animal of the same species, weight, and age in accordance with this section. In cases where the owner can show that a class of animals increased in value rather than decreased in value after age 2, as may be the case with rams bred for their horns, the animals in the classes over 2 years may be counted as animals over 1 year and under 2 years of age for indemnity purposes. For purchased animals the price will be adjusted for the animal's current age if the purchase was more than 12 months before indemnity is offered. A spreadsheet is posted on the [Scrapie SharePoint](#) site to assist Federal and State representatives with calculation of indemnity for club lamb/kid flocks.

- 3) **Calculating indemnity.** For animals under 1 year of age, the owner may be indemnified for the price per pound from paragraph *a(1)(a)* or *a(1)(g)* of this section for sheep and goats respectively times the greater of 50 pounds or the actual weight of the animal as determined at a public scale, or an estimate made using a weight tape or other method acceptable to the owner and APHIS; **except that**, for females under 1 year of age not in slaughter channels when indemnity was offered and were not being fed or raised for slaughter, the indemnity will equal the per-pound price from paragraph *a(1)(c)* or *a(1)(j)* of this section for sheep and goats respectively if that price is higher. For sexually intact sheep at least 1 year of age and under 2 years of age, the indemnity will equal the greater of the price per head from paragraph *a(1)(d)* of this section, or the price per pound from paragraph *a(1)(b)* of this section times the average mature slaughter weight as reported by NASS.

For sexually intact sheep at least 2 years of age and under 6 years of age, the basic indemnity will equal the greater of the price per head from paragraph *a(1)(e)* of this section or the price per pound from paragraph *a(1)(b)* of this section times the average mature slaughter weight as reported by NASS. For sexually intact sheep at least 6 years of age and under 8 years of age, the basic indemnity will equal the greater of the price per head from paragraph *a(1)(f)* of this section or the price per pound from paragraph *a(1)(b)* of this section times the average mature slaughter weight as reported by NASS.

For sexually intact sheep 8 years of age or older and castrated animals 1 year of age or older, the basic indemnity will equal the price per pound from paragraph *a(1)(b)* of this section times the average mature slaughter weight as reported by NASS.

For goats over 1 year of age that are castrated or that were in slaughter channels at the time indemnity was offered, the owner may be indemnified for the price per pound from paragraph *a(1)(h)* or *(i)* as applicable times the actual weight determined at a public scale or a weight estimate made using a weight tape or other method acceptable to the owner and APHIS. For sexually intact goats over 1 year of age not in slaughter channels at the time indemnity is offered and were not being fed or raised for slaughter the owner may be indemnified for the price per pound from paragraph *a(1)(h)* or *(i)* as applicable or the price from *(a)(1)(j)*, whichever is more, times the actual weight determined at a public scale or a weight estimate made using a weight tape or other method acceptable to the owner and APHIS.

- 4) **Premiums in addition to basic indemnity.** A premium will be added to the basic indemnity for certain animals as described in this paragraph; **except that**, no premium will be added for animals of any age that were in slaughter channels or were being fed or raised for slaughter when indemnity was offered.
- a) **Premium for registered animals and flock sires.** A premium will be added for each registered animal, equal to \$100 for each registered animal

under 1 year of age, \$200 for each registered animal at least 1 year of age and under 4 years of age, and \$100 for each registered animal at least 4 years of age and under 10 years of age. An additional \$50 premium will be added to the basic indemnity for each flock sire. The owner must provide adequate records to qualify for these premiums. Any animal owned by the current owner for less than 12 months and not registered to the current owner at the time indemnity is first offered, but eligible to be registered in the current owner's name, will receive the registered animal premium reduced by \$50. Any animal owned by the current owner for 12 months or more and not registered to the current owner at the time indemnity is first offered does not qualify for the premium.

- b) **Premium for pregnant animals.** For animals in late pregnancy, the owner may be indemnified for three-fourths of the price of the potential offspring's value in paragraphs *a(2)*, *a(3)* or *a(4)(a)* of this section for a 50-pound lamb or kid as applicable depending on the type of offspring (i.e., registerable or not) that would be produced by that animal. A female animal will be considered to be in late pregnancy if it was exposed to a ram and has udder development associated with impending lactation. To estimate the number of offspring the animal is likely carrying, the documented weaned-offspring rate for the flock's previous year will be used to calculate the average number of fetuses being carried by each of the pregnant animals; however, if this number is unknown, the national average of lambs born per ewe from NASS will be used. The calculated weaned-offspring rate will be determined by dividing the number of offspring weaned by the total number of females exposed to a breeding male. A 1:1 ratio of male to female offspring will be assumed for calculating the average value of each lamb. Females not made available for inventory, assessment of late gestational status, and testing within 30 days of first notice will not qualify for the premium; **except that**, the SGHSE or the National Scrapie Program Coordinator may grant an extension when severe weather or other conditions beyond the owner's control prevent a timely evaluation.

Offspring born within 60 days after a written offer of indemnity will be indemnified at three-fourths of the 50-pound lamb or kid price as applicable calculated in accordance with paragraphs *a(2)*, *a(3)* or *a(4)(a)* in lieu of receiving the late gestation premium for the dam. Offspring born more than 60 days after a written offer of indemnity will not be indemnified unless the SGHSE or the National Scrapie Program Coordinator determines that severe weather or other conditions beyond the owner's control prevent the timely removal of the animals. In such cases the DSE will provide a written justification for granting an extension to the SGHSE for consideration. Offspring born after the initial inventory and before completion of the flock plan must be inventoried at the time of removal or 60 days after the indemnity offer, whichever occurs first, to document the animals eligible for indemnity.

c) ***Calculating late gestational premium***

- A spreadsheet is posted on the [Scrapie SharePoint](#) site to assist Federal and State representatives with this calculation.
- Determine which ewes are in late gestation. A “late gestation ewe” has been exposed to a ram at least 2 months before the date on which indemnity was first offered, and there is visual evidence of pregnancy. Visual evidence of third trimester pregnancy, which must be present within 30 days of when indemnity is first offered, is marked udder development, enlargement and relaxation of the vulva, and relaxation of the pelvic ligaments upon inspection.
- To calculate the average number of lambs being carried by the indemnified, pregnant ewes, use the documented annual weaned lamb rate for the flock's previous year:
  - o Number of lambs weaned/number of ewes exposed to a ram= annual weaned lamb rate.
  - o If the data needed to calculate the rate are unknown, use the current national lambing average as reported by NASS.
- To calculate the value of a pregnancy:
  - o Using the scrapie indemnity calculator current when indemnity is offered, find the value of both a male and a female lamb weighing 50 pounds for the appropriate type (registration-eligible, nonregistered, or club lamb/kid).
  - o The value of the club lamb/kid price cannot exceed the registration-eligible lamb/kid price as applicable.
  - o The value for a registration-eligible lamb is the registered price less \$50.
  - o Then, calculate the average male and female value:
    - i.  $(\text{male 50-pound lamb value} + \text{female 50-pound lamb value}) / 2 = \text{averaged male and female value.}$
    - ii. Since the gender of the lamb that would be produced is unknown, a 1:1 male-to-female ratio is assumed.
- Calculate the gestational premium as follows:
  - o  $0.75(\text{averaged male and female value})(\text{annual weaned lamb rate}) = \text{gestational premium.}$
- Add the gestational premium to the indemnity value of each ewe determined to be in late gestation. Do not add the gestational premium value to the value of other ewes.
- If a dam eligible for the gestational premium when indemnity was first offered gives birth before removal, indemnity will be calculated for the live offspring as described below, and a gestational premium will not be paid for that ewe.
  - o Using the scrapie indemnity calculator current when indemnity is offered, find the dollar value of a 50-pound lamb based on gender and type of lamb for which

indemnity is being calculated.

- o Multiply the dollar value by 75 percent (0.75).

***Premium for early maturing ewes.*** Any ewe lamb or doe kid nursing a lamb or kid or that meets the requirements for a late pregnancy animal will be considered a yearling if that results in a higher valuation.

- 5) ***Age and number of animals.*** If records and identification are inadequate to determine the actual age of animals, an APHIS or State representative will count all sexually intact animals that are apparently under 1 year of age, and those that are apparently at least 1 and under 2 years of age, based on examination of their teeth, and the indemnity for these animals will be calculated. The total number of these animals will be subtracted from the total number of sexually intact animals in the group to be indemnified, and indemnity for the remainder will be calculated based on the assumption that the remainder of the flock is 80 percent aged 2 to 6 years and 20 percent aged 6 to 8 years.
- 6) ***Animal weights.*** If the owner disagrees with the average weight estimate, he may have the animals weighed at a public scale at his own expense, provided that the animals may not come in contact with other sheep or goats during movement to the public scales. Indemnity will be paid based on the actual weight times the price per pound for the class of animal as reported in the appropriate price report.
- 7) ***Eligibility for indemnity.*** Indemnity will be paid to an owner only for animals actually in a flock at the time indemnity is first offered in writing, and for offspring born to animals in that flock within 60 days after the time indemnity is first offered in writing. Animals removed from the flock as part of an investigation or a PEMMP will be paid indemnity based on the average prices at the time an APHIS representative designates, in writing, the animals for removal. If an owner declines to remove an animal within 60 days of when indemnity is first offered, the owner will receive the lower value of when indemnity was first offered in writing or when the animal was actually removed. APHIS may withdraw an indemnity offer if an owner does not make animals available for inventory, gestational assessment, and testing within 30 days or does not remove an animal within 60 days of the written indemnity offer or by the date specified in a flock plan or PEMMP.
- 8) ***Additional information and assistance.*** Spreadsheets are posted on the [Scrapie SharePoint](#) site to assist Federal and State representatives with calculating indemnity.
- 9) ***Denial of an indemnity request.*** Indemnity will be denied in the following cases:
  - a) Animals do not meet any of the criteria listed in *J.1.*
  - b) The animal, or the animal's dam or sire, has been moved or handled by the owner in violation of the requirements of the Animal Health Protection Act or the regulations promulgated thereunder.
  - c) The animal was added to the premises while the flock was under investigation or while it was an infected or source flock, other than natural additions.

- d) The animal is a natural addition born more than 60 days after the owner was notified he or she is eligible for indemnity, unless the SGHSE or the National Scrapie Program Coordinator determines the dam could not be removed within the allowed time as a result of conditions outside the owner's control.
  - e) Animals otherwise eligible for indemnity that die before the owner signs VS Form 1-23, *Appraisal and Indemnity Claim Form*.
  - f) If the owner established or increased his flock for the purpose of collecting or increasing indemnity.
  - g) The animals are State or federally owned captive wild/exotic sheep and goats.
  - h) Lack of available funds. In this case indemnity may be provided later if funds become available.
- b. State-industry indemnity:  
State or industry indemnity, or both, may be paid in addition to Federal indemnity in accordance with State regulations, industry guidelines, or both as applicable up to the fair market value of the animal.
5. Indemnity procedures for animals destroyed:
- a. Animals for which indemnification is sought must be destroyed.
  - b. An APHIS representative must monitor the destruction of animals and disposition of their carcasses and must ensure the carcasses are disposed of in a manner that prevents their use as feed or food. State personnel may conduct or supervise these activities, including signing the valuation portion of the VS Form 1-23, *Appraisal and Indemnity Claim Form*, when authorized and monitored by APHIS. The AVIC must review and sign VS Form 1-23. Before the destruction of any animal for which indemnity will be claimed, the AVIC must submit a request for indemnity and any associated disposal or other costs and obtain approval from the SGHSE and have an accounting code assigned. The owner must complete and sign VS Form 1-23. APHIS may pay, when approved in advance in writing, the reasonable and customary costs of euthanasia, disposal, or both for indemnified animals including transport of the animal for euthanasia or of the carcass for disposal or both. The owner may provide these services if the cost is within APHIS guidelines or represents the best value bid. If the owner provides these services, the owner must present to APHIS a copy of either a receipt for expenses paid or a bill for services rendered.

**K. Interstate Certificates of Veterinary Inspection (ICVI) for Sheep and Goats in Interstate Commerce**

1. Accredited veterinarians are responsible for ensuring both Federal and State ICVI requirements are met and that the certificate is correctly filled out before signing the ICVI. As State importation requirements may vary, APHIS advises checking with the SAHO for importation requirements before signing the ICVI. APHIS requires ICVIs for sexually intact sheep and goats not in slaughter channels that cross State lines, except for sheep and goats moving in either of the following circumstances:

- a. The animals are moving without a change of ownership for grazing or other management purposes provided:
    - 1) The movement is between two premises both owned or leased by the flock owner;
    - 2) Both premises are recorded in the NSD as additional flock premises; and
    - 3) Commingling will not occur with unidentified animals born in another flock or any animal not part of the flock.
  - b. The animals have been in the same flock in which they were born and have not been maintained in the same enclosure with unidentified animals born in another flock at any time and are moving to a facility approved in accordance with 9 CFR 71.20.
2. ICVIs must include:
- a. The number of animals covered by the certificate.
  - b. The purpose for which the animals are to be moved.
  - c. The species and breed or, if breed is unknown, in the case of sheep the face color and for goats the type (milk, fiber, or meat).
  - d. Class of animal such as replacement ewe lambs, slaughter lambs or kids, cull ewes, club lambs, bred ewes, etc.
  - e. The names and addresses of the points of origin and destination, and, if different, the names and addresses of the consignor, the consignee, and the current owner.
  - f. Each animal's official individual ID numbers (*provided that*, in the case of animals identified with flock ID assigned to the flock of origin and meeting the requirements for individual animal ID, the flock ID number may be recorded instead of the individual ID numbers. For animals allowed by 9 CFR 79.3 to move with [group/lot identification](#), the group/lot number may be recorded instead of the individual ID numbers).
  - g. A statement by the issuing accredited, State, Tribal, or Federal veterinarian to the effect that on the date of issuance the animals were free of evidence of infectious or contagious disease and insofar as can be determined, exposure thereto. This statement may be made with respect to scrapie for animals exposed to scrapie if their movement is not restricted and they have been designated genetically resistant or less susceptible sheep or low-risk exposed animals.
  - h. Except as provided in 9 CFR 79.5 paragraphs (b) and (c) ("*Animal identification documents attached to certificates*" and "*Ownership brands documents attached to certificates*" respectively), all information required by this paragraph must be typed or legibly written on the certificate.
3. **Note:**
- a. In accordance with paragraphs (b), (c), and (e) of 9 CFR 79.3, scrapie-positive, suspect, and high-risk animals, sexually intact genetically susceptible exposed male animals, and some animals that originated in an infected or source flock require permits rather than certificates (see [section N](#)).
  - b. These requirements apply only to the classes of animals APHIS requires to have ICVIs.

## L. Permits

A permit (VS Form 1–27 or State equivalent) is required for movement of high-risk, suspect, scrapie-positive, and sexually intact genetically susceptible exposed male animals. (See *section N* of this part for exposed animals that require a permit to move.) Such animals moving intrastate may move under permit or under conditions specified by the SAHO that ensure that these animals are destroyed or maintained under restriction.

## M. Terminal Feedlots

### 1. Approval:

- a. Terminal feedlots may be approved by APHIS, the State, or an accredited veterinarian authorized to perform this function by APHIS or the State if:
  - 1) The facility is a drylot where animals in the terminal feedlot are separated from all other animals by at least 30 feet at all times or are separated by a solid wall through, over, or under which fluids cannot pass and contact cannot occur and which can be cleaned of all organic material. The owner agrees to remove and dispose of all organic material from the terminal feedlot before using it to contain sheep or goats not in slaughter channels and to only maintain castrated male animals with female animals, and to move the animals only to another terminal feedlot or directly to slaughter; or
  - 2) The facility is a drylot where all animals in the terminal feedlot are separated from all other animals such that physical contact cannot occur, and where the owner has agreed to all of the requirements listed below.
    - a) The only animals permitted in the terminal feedlot meet at least one of the following criteria:
      - They are not pregnant based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, or a certificate issued by an accredited veterinarian stating the animals are open; or
      - The animals are under 6 months of age at time of receipt.
    - b) Only castrated males will be maintained with female animals.
    - c) Animals will be moved only to another terminal feedlot or directly to slaughter.
    - d) All required records will be maintained.
- b. A State may approve terminal feedlots that are pastures if it has adequate resources to supervise the facility and ensures compliance with all of the requirements listed below.
  - 1) The only animals permitted in the terminal feedlot meet at least one of the following criteria:
    - a) They are nonpregnant animals based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, or a certificate issued by an accredited veterinarian stating the animals are open; or

- b) The animals are under 6 months of age at time of receipt.
  - 2) Only castrated males are maintained with female animals.
  - 3) There is no direct fence-to-fence contact with another flock.
  - 4) Animals are moved only to another terminal feedlot or directly to slaughter.
  - 5) The owner has agreed to comply with these conditions and the recordkeeping requirements.
2. Records:  
Records of all animals entering and leaving a terminal feedlot must be maintained for 5 years after the animal leaves the feedlot and must meet the requirements of 9 CFR 79.2, including either a copy of the required owner/hauler statements for animals entering and leaving the facility or the information required to be on the statements. Records must be made available for inspection and copying by an APHIS or State representative on request.

**N. Movement Restrictions, Release Procedures, and Criteria for Releasing Movement Restrictions on Infected or Source Flocks, Animals Required for Testing, and Exposed Animals**

The movement restrictions are summarized in Table 1.

1. Suspect animals may not be moved from the premises where identified, except under permit, to a research facility designated by APHIS, to a site for destruction, or, when appropriate, to the flock of origin for quarantine. Such animals will be placed under movement restriction until an investigation is completed. If the investigation concludes the animal is a [scrapie suspect](#), the animal will either be indemnified for diagnostic purposes and necropsied and tested for scrapie or maintained under restriction until it either recovers and is released, or dies and is necropsied and tested for scrapie (see [part VII.C](#)).
2. No sexually intact animal will be permitted to move from an infected or source flock until a flock plan agreement has been signed and the owner is in compliance; an exception is made for animals moving under permit to an APHIS-approved research or quarantine facility or for destruction at another site. The movement restrictions on the flock and criteria for release of these restrictions will be specified as part of the flock plan or PEMMP.
3. The following animals may be moved unrestricted once they have been officially individually identified and entered into the National Scrapie Database (directly in SCS SCR or through VSLS), if not restricted by the DSE and if they originate from flocks in compliance with a plan or not required to be on a plan:
  - a. Genetically resistant exposed sheep;
  - b. Genetically less susceptible exposed sheep; and
  - c. Low-risk exposed animals.
4. Genetically less susceptible exposed female sheep restricted by the DSE may move only as permitted in the flock plan or PEMMP. The DSE, with the concurrence of the

- AVIC, SAHO, and the SGHSE, may also require the removal or restriction of some or all genetically less susceptible female animals in flocks based on the epidemiology of the flock including genetics of the positive sheep, the prevalence of scrapie in the flock, any history of recurrent infection, or other characteristics that may make these sheep a potential risk. If removal with indemnity is being considered, the SGHSE must be consulted to determine if indemnity is available.
5. High-risk animals and sexually intact genetically susceptible exposed male animals must be restricted to the premises where found or moved under permit to an APHIS-approved research or quarantine facility or for destruction at another site. Such animals not indemnified may be moved under permit to slaughter. Animals old enough to test will have tissues submitted for testing when they die or are euthanized in accordance with the instructions available in the National Scrapie Reference Library on the [Scrapie SharePoint](#) site. When requested by the SGHSE, tissues from these animals are to be collected as specified for research and developmental work. If the number of animals to be euthanized is too large for available resources to sample, contact the SGHSE to establish an appropriate sampling plan. Such plans must include sampling of all animals where such testing could change the status of a flock including all purchased animals over 14 months of age or that have given birth in the flock.
  6. Scrapie-positive animals must be restricted to the premises where found or moved under permit to an APHIS-approved research or quarantine facility or for destruction at another site. Tissues from these animals are to be collected as specified by the SGHSE for research and developmental work.
  7. Animals from noncompliant flocks are considered exposed animals under 9 CFR part 79 and may be moved only as allowed for exposed animals. **Note:** This means female animals and sexually intact male animals from these flocks are restricted to movement under permit for slaughter only unless they are officially genotyped by the owner and determined to be genetically resistant or less susceptible.
  8. Animals designated for testing as part of a flock investigation must be restricted to the premises where found until the required testing is completed, unless moved under permit to slaughter or to an APHIS-approved research or quarantine facility or for destruction at another site. These animals will be submitted for testing if they are slaughtered, die, or are euthanized before completion of the required testing and are old enough for a scrapie test to be meaningfully applied. **Note:** Animals for which indemnity is provided may not be slaughtered for human or animal food.
  9. Exposed wethers of any species or genotype may move unrestricted once they have been officially individually identified and entered into the NSD.

**Table 1—Restrictions on Classical Scrapie Exposed Animals**

Positive Animals	Exposed Animals				
	Goats	QQ Sheep	AVQR Sheep	AAQR Sheep	RR Sheep
AAQQ sheep and goats	X	X	Free	Free	Free
AVQQ & VVQQ Sheep	X	X	X*	Free	Free
AVQR Sheep	X	X	X	Free	Free
AAQR Sheep	X	X	X	X	Free
RR Sheep	X	X	X	X	X

**Positive animals** = Classical scrapie positive animals found in or traced to or from the flock in which the exposed animal was exposed. If there is more than one type of positive animal, use the genotype for the positive animal listed lowest on the chart to determine which animals to remove or restrict. All positive animals are to be destroyed or permanently restricted.

\*If the DSE has determined that the flock is unlikely to be affected by valine-associated scrapie, these animals may be reclassified as genetically less susceptible sheep and be allowed to move unrestricted.

**Free** = Move unrestricted (rare exceptions to this general class are listed in [part II N.3 and 4.](#))

**X** = Destroyed or permanently restricted.

**Note:** Nor98-like scrapie exposed animals are treated as low-risk exposed animals and may move unrestricted once they are officially identified. APHIS, with the concurrence of the involved SAHO, may conduct genetics-based pilot projects for goats and release goats determined to be genetically resistant or less susceptible.

## **O. Procedures for Sheep and Goats Transiting or Temporarily Residing in Inconsistent States**

1. Sheep and goat producers whose animals reside in an Inconsistent State must comply with the requirements in 9 CFR 79.3 for Inconsistent States to move animals interstate:
  - a. Sheep and goats not in slaughter channels must be enrolled in the SFCP and be in compliance with the requirements for such flocks or an equivalent APHIS-recognized program. They may also be sheep that are officially genotyped and determined to be AA QR or AA RR, officially identified, and accompanied by an ICVI that also states the individual animal identification numbers, the flock of origin and, for any animal born after January 1, 2002, the flock of birth, if different.

- b. Animals in slaughter channels must be officially identified with an official blue eartag marked with the words “MEAT” or “SLAUGHTER ONLY” and may move only directly to slaughter or to a terminal feedlot. Animals 18 months of age and older (as evidenced by the eruption of the second incisor) in slaughter channels must also be accompanied by an ICVI that states the individual animal identification numbers and, for any animal born after January 1, 2002, the flock of birth (and the flock of origin, if different).
2. For sheep and goats temporarily residing in an Inconsistent State at the time the State becomes inconsistent:
  - a. The animals must return to their flock of origin’s State within 30 days of the State’s inconsistent designation.
  - b. If the animals are moved within the required time period, their movement from the Inconsistent State may follow the regulatory requirements for sheep and goats from Consistent States.
  - c. If the animals are not moved within the required time period, their movement from the Inconsistent State must follow the regulatory requirements for sheep or goats from Inconsistent States.
3. Sheep and goats transiting an Inconsistent State:
  - a. If the animals transit the Inconsistent State without unloading, they may move under the movement requirements applicable to their State of origin.
  - b. If the animals are unloaded in the Inconsistent State they may thereafter be moved interstate only under the requirements for animals moved from an Inconsistent State. Exception: Rest stops of less than 24 hours for food and water. Animals attending an exhibit, receiving veterinary care, or maintained in an artificial insemination collection center or other site where only limited contact will occur and where the animals will not reside on the premises of a flock may be moved interstate from the Inconsistent State back to their flock of origin if they are moved directly to and from the site in accordance with a valid certificate issued in a Consistent State under 9 CFR 79.5 and reside in the Inconsistent State for less than 30 days unless the AVIC, with the State of origin SAHO’s concurrence, approves an extension.

**P. National Scrapie Database (NSD) – Data Entry Requirements**

1. The NSD includes SCS SCR, VSLS, the scrapie investigation records in EMRS, the scrapie program tag function of AIMS, and any subsequent applications that replace or augment these. Complete information on data entry is available in the National Scrapie Reference Library on the [Scrapie SharePoint](#) site. Data must be entered as provided in the User Guides published on this site.
2. Information that must be entered by State or APHIS animal health personnel:
  - a. Accurate and complete information for each premises, flock or person that meets any of the following criteria:
    - 1) Is or has participated in the SFCP;

- 2) Is or has been designated an infected, source, exposed, or noncompliant flock or a flock under investigation, or owned or managed such a flock or the premises on which such a flock resided;
  - 3) Owns or owned an exposed, scrapie suspect, or scrapie-positive animal, or such an animal currently resides or previously resided on their premises; or
  - 4) Has been issued official ID devices or numbers.
- b. Each animal that has been designated scrapie-positive, scrapie-suspect, high-risk, or exposed or that resides in an infected or source flock, or that has been restricted, or tested or designated for test must have an individual animal record completed and maintained in SCS SCR.
  - c. Individual records, including movement records, must be completed and maintained in SCS SCR for animals in SFCP Export flocks as described in the SCS SCR User Guide.
  - d. A test record must be entered in VSLS for each animal tested for scrapie or for genetic resistance to scrapie. Test records are not entered in SCS SCR. These records will automatically be transferred to SCS SCR.
  - e. Official eartags for use on sheep and goats must be ordered and distributed to the end user through the scrapie program tag function of AIMS or as provided in the User Guides for SCS SCR.
  - f. Each animal involved in a trace out or trace back investigation must be entered in accordance with the applicable SOPs available on the [Scrapie SharePoint](#) site.

## **Q. Genotyping Administrative Procedures**

1. Authorization from the Sheep and Goat Commodity Team must be obtained before submitting genotype samples to a laboratory for testing under the APHIS contract. Send an email with the following information: Name of flock, flock identification number (flock ID), type of test requested, reason for test (provide narrative such as flock plan, trace exposed animals, missing ewe investigation, etc.), genotype of the associated positive animals, any previous official genotype tests performed on the sheep and laboratory that conducted the test, number of sheep to be tested, sample collection medium (Flinders Technology Associates (FTA) card, tissue, tissue swab, or blood tubes), flock status, 10-day/5-day turnaround requested. If requesting a 5-day turnaround, provide justification. APHIS will email back approval for the codon testing to the requestor, as well as which laboratory to send the samples. Further information on this procedure is available on the [Scrapie SharePoint](#) site.
2. The genotype of high-risk and exposed sheep the owner wants to keep will be determined at two different approved laboratories or at NVSL. Ideally, samples should be collected on two separate dates unless one of the following applies:
  - a. Radio frequency ID is used with the Mobile Information Module (MIM); or
  - b. Three or fewer animals are being sampled.In the case of infected or source flocks, the second collection should occur after the genetically susceptible animals have been removed. When separate collection cannot reasonably be done, the eartag numbers and sample labels must be read and checked for accuracy by both the owner or owner's representative and a State or APHIS

representative.

## **R. Appeals of APHIS Actions**

1. The following APHIS actions may be appealed by an owner or authorized representative of a laboratory, test manufacturer, or eartag manufacturer (9 CFR 79.4(c)(3)):
  - a. The designation of an animal as a scrapie-positive animal, high-risk animal, exposed animal, genetically susceptible exposed animal, genetically resistant exposed sheep, genetically less susceptible exposed sheep, low-risk exposed animal, or suspect animal.
  - b. The designation of a flock as an exposed flock, an infected flock, a source flock, a flock under investigation, or a noncompliant flock.
  - c. Withdrawal of assigned official ID numbers or denial of a request to issue official ID numbers.
  - d. Withdrawal of laboratory or test approval.
  - e. Withdrawal of identification device approval.
2. Appeal process
  - a. The owner must appeal, in writing, to the National Scrapie Program Coordinator within 10 days after being informed of the reasons for the proposed action:

National Scrapie Program Coordinator  
USDA, APHIS, Veterinary Services  
4700 River Road, Unit 43  
Riverdale, MD 20737
  - b. The appeal must include all of the facts and reasons on which the owner relies to show that the reasons for the proposed action are incorrect or do not support the action.
  - c. The action under appeal will remain effective pending final determination in the proceeding unless the National Scrapie Program Coordinator determines such action is not necessary to prevent the possible spread of scrapie.
  - d. The National Scrapie Program Coordinator will review the appeal and grant or deny the appeal in writing as promptly as circumstances permit, and the written decision will include the reasons for the decision. In the event that the National Scrapie Program Coordinator made the initial decision the appeal will be reviewed by the National Scrapie Program Coordinator's supervisor or his or her designee.
  - e. If an owner disputes a material fact or facts leading to the decision on an appeal, the owner may submit a written request for reconsideration specifying the material fact or facts in dispute and the basis for disputing the facts to the National Scrapie Program Coordinator or National Scrapie Program Coordinator's supervisor as appropriate within 10 days after being informed of a denied appeal.
  - f. The National Scrapie Program Coordinator or National Scrapie Program Coordinator's supervisor, as appropriate, will review any information regarding

the material fact or facts in dispute, including the owner's written argument and supporting documentation, and make a determination with respect to the material fact or facts as promptly as circumstances permit.

- g. The National Scrapie Program Coordinator's or National Scrapie Program Coordinator's supervisor decision constitutes final agency action.

## Part III: Identification Requirements

### A. Identification of Sheep and Goats in Commerce

#### 1. Identification requirements:

- a. Animals required to be identified in 9 CFR 79.3, or 9 CFR 79.6 for Consistent States, must be officially identified to the flock of birth or origin on change of ownership as required by State regulations or before entering interstate commerce. No sheep or goat required to be individually identified or group identified may be sold, disposed of, acquired, exhibited, transported, received for transportation, offered for sale or transportation, loaded, unloaded, or otherwise handled in interstate commerce or commingled with any animals that fall into these categories or be loaded or unloaded at a premises or animal concentration point (including premises that exhibit animals) where animals have been received that have been in interstate commerce or from which animals have moved in interstate commerce or leave the premises on which they currently reside if they are owned by a person who engages in the interstate commerce of animals unless each sheep or goat has been officially identified to the flock of birth or, when allowed, flock of origin. Unless prohibited by State law or regulation, this does not preclude a person from moving animals as part of a group/lot directly to another site in the same State where official eartags that have been assigned to the animal's flock of origin in the NSD will be applied to the animals, or to an approved market where the animals will be officially identified.
- b. In cases where the flock of birth cannot be determined, the animal must be officially identified to the flock of origin (flock in which an animal most recently resided for breeding). Allowed identification methods are listed in *paragraph A.3*.

**Note:** Check with the receiving State to ensure that both State and Federal requirements are met.

- c. *Sheep and goats required to be officially identified (see d. for exceptions) include:*
  - 1) All sexually intact sheep and goats not in slaughter channels;
  - 2) All sheep and goats over 18 months of age as evidenced by eruption of the second incisor;
  - 3) Animals for exhibition, including sexually intact sheep and goats of any age and wethers 18 months of age and older. There is an exclusion which would rarely apply for animals that have never been in interstate commerce, that have not resided on premises where animals have been received that have been in interstate commerce or from which animals have moved in interstate commerce and are not owned by persons who engage in the interstate commerce of animals, that are moved to exhibitions conducted at premises where animals have not been received that have been in interstate commerce or from which animals have moved in interstate commerce and where none of the animals exhibited has been in interstate commerce and where the State and the exhibit do not require the animals to be identified. **Note:** Many States and exhibitions require official identification of all sheep and goats.

- 4) All exposed and high-risk animals, including all low-risk exposed animals, genetically susceptible exposed animals, genetically less susceptible exposed sheep, and genetically resistant exposed sheep.
  - 5) All suspect and test-positive animals.
  - 6) Sheep and goats from noncompliant flocks.
- d. *Sheep and goats not required to be individually identified for interstate commerce that may move with a group/lot ID and an owner hauler statement include (Note: some States require all sheep and goats to be identified):*
- 1) Sheep and goats under 18 months of age that are in slaughter channels (**Note:** The market or seller must note on the bill of sale that the animal was sold for slaughter and must retain a copy of an owner/hauler statement from the buyer listing the slaughter establishment, restricted animal sale, restricted livestock facility, or terminal feedlot where the animal is being moved, or indicating that the animal was purchased for slaughter for personal use).
  - 2) Wethers under 18 months of age.
  - 3) Sheep and goats of any age shipped directly to a slaughter establishment or an approved market (9 CFR 71.20) that has agreed to act as an agent for the owner to apply official ID and when all the animals in a section of a truck are from the same flock of origin and are accompanied by an owner/hauler statement. (**Note:** The owner/hauler statement must contain the information needed for the establishment or market to officially identify the animals. Slaughter establishments may maintain the identity of the animals to the flock of origin by slaughtering them by flock of origin in group/lots rather than by applying eartags if the flock of origin number is correlated with the heads or samples collected for scrapie testing.)

This includes animals in slaughter channels at 18 months and older (as evidenced by the eruption of the second incisor) if the animals were kept as a group on the same premises on which they were born and have not been maintained in the same enclosure with unidentified animals from another flock at any time, including throughout the feeding, marketing, and slaughter process. Such groups must have a group/lot ID that includes the flock of origin flock ID or PIN/LID. If such a group is subdivided such subdivision must be noted by adding a hyphen, an “S”, and a sequential number starting with 1 to the end of the group/lot ID.

- 4) Sheep or goats moved for grazing or similar management reasons without a change of ownership when the animals are moved from a premises owned or leased by the owner of the animals to another premises owned or leased by the owner of the animals. The premises must be recorded in the National Scrapie Database as additional flock premises and commingling must not occur with unidentified animals born in another flock or any animal not part of the flock.
- e. *Sheep and goats not required to be officially identified:* Sheep or goats that have only resided on premises and in flocks in the same State and where the animals and premises are owned by persons who do not engage in the interstate commerce of sheep or goats and where the sheep or goats are of a class exempted from official ID by the State while in intrastate commerce.

2. Issuance of premises and flock ID numbers:
  - a. The VS Area Office or the SAHO's office will issue a PIN to each sheep or goat owner who requests one.
    - 1) The office will enter premises and flock information in the NSD and permanently assign a PIN and a flock ID number that in the case of breeding flocks can be used on official tags or as the flock ID portion of a tattoo.
    - 2) In some States, the numbers will be the same.
  - b. All 2- and 3-character alphabetical sequences not currently assigned must be reserved for use by producers who use registered tattoo prefixes.
  - c. All 2- and 3-character numeric and alphanumeric sequences not currently assigned must be reserved for producers using flock ID tattoos.
  - d. When possible, the flock ID number for flocks with registered tattoo prefixes will be the State postal abbreviation followed by the producer's registered tattoo prefix.
  - e. Alphabetical and alphanumeric sequences that contain I, O, or Q other than as part of a State postal abbreviation may not be assigned.
3. Allowed identification devices and methods and restrictions on their use:
  - a. Official identification devices approved for use in sheep and goats may be found [here](#).<sup>15</sup> Select "List ID Devices" from Public Tools, then "Scrapie Program Tags" from the drop-down menu, and click on "Get Approved Devices". APHIS adds new devices to this site on approval.
    - 1) Restricted use of colored tags: Official red, yellow, and blue metal or blue plastic eartags may only be used for the following purposes:
      - a) Official red metal eartags are only to be used for animals that have tested positive for scrapie on an official program approved test.
      - b) Official yellow metal eartags are only to be used for exposed animals permanently restricted to a premises.
      - c) Official blue eartags (metal or plastic) produced after [Insert effective date of final rule] are to be imprinted with "Slaughter Only" or "MEAT." Such eartags are only to be applied to animals in slaughter channels.
    - 2) Official eartag placement:
      - a) Recommendation for wool sheep and fiber producing goats: To aid in shearing place eartags in the animal's left ear in the middle of the ear halfway between base and tip of ear. If a one-piece tag is used place it around the lower edge of the ear. Use of metal tags in animals that may be sheared may pose a hazard; consider this when selecting the type of tag to use.
      - b) Official eartags may not be placed in any tissue other than the ear.
      - c) Animals that cannot be ear tagged because of absent or injured ears, or because the application of an eartag would obscure an official tattoo, may have the official eartag attached to a durable neck strap or collar that can only be removed by cutting the strap, collar, or eartag and which must accommodate the expected growth of the animal. When a neck strap or collar

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<sup>15</sup> <https://vsapps.aphis.usda.gov/aims/>.

is used in this manner, the neck strap or collar with eartag must be treated the same as an eartag and may not be removed or replaced other than as allowed in 9 CFR 79.2(h). If moving directly to slaughter, an APHIS approved-backtag may be applied instead within 3 inches of the poll.

- 3) Use of backtags:
  - a) The SAHO, with concurrence of the AVIC for the State involved, may allow in a compliance agreement or an approved market agreement the use of APHIS-approved backtags applied to the back for mature sexually intact male goats with horns moving direct to slaughter that are considered unsafe to eartag at a livestock facility or other site. **Note:** Animals in lots consisting only of animals from the same flock of origin may be moved through a restricted sale without individual ID for movement to slaughter as a group/lot using the flock of origin group/lot ID followed by a dash and an S and a sequential number indicating any subdivision of the original group/lot. (**Note:** The market or seller must note on the bill of sale that the animal was sold for slaughter and must retain a copy of an owner/hauler statement from the buyer listing the group lot ID and the slaughter establishment, restricted animal sale, restricted livestock facility, or terminal feedlot where the animal is being moved, or indicating that the animal was purchased for slaughter for personal use).
  - b) Animals moving direct to slaughter that cannot be ear tagged because of absent or injured ears, or because the application of an eartag would obscure an official tattoo, may be officially identified with an APHIS-approved backtag applied within 3 inches of the poll.
  - c) The SAHO and AVIC for the State involved, with concurrence of the National Scrapie Program Coordinator, may approve other uses of backtags for direct to slaughter movements on a case-by-case basis in a compliance or approved market agreement.
- b. Allowed official identification methods and restrictions on their use:
  - 1) Permanent brands and ear notches, registered with an official brand registry, are allowed for the official identification of sheep and goats allowed to move with group/lot identification by 9 CFR 79.3 as described in *III.A.3.e* when accompanied by:
    - a) A brand inspection certificate and an owner statement dated within 30 days, stating that the animals were born in and have resided throughout their lives in low-risk commercial flocks, and
    - b) A veterinarian's statement issued within 12 months of the movement indicating that the flock of origin identified in the owner statement was inspected and met the requirements of a low-risk commercial flock on the date of issuance.
  - 2) Registration tattoos, recorded in the book of record of a sheep or goat registry, may be used to officially identify sheep or goats required to be individually identified by 9 CFR 79.3, moving without a transfer of ownership or moving after a transfer of ownership if an application for transfer of registration is completed and accompanies the animal when it leaves the sale or premises of origin if:
    - b) The association registry premises or flock tattoo prefix has been linked in the

NSD to the APHIS-assigned PIN and flock ID number of the flock of birth, and documentation of such accompanies the animal; or the breed registry has been approved based on information provided to APHIS indicating that the tattoos are unique within the registry, retrievable, traceable, and that the registry rules allow for release of information to APHIS for regulatory disease purposes such as the tracing of scrapie-positive and scrapie-exposed animals and that the registry agrees to provide such information (approved registries can be found [here](#)).<sup>16</sup>The tattoo is legible; and

- c) The animal is accompanied by:
  - A copy of the registration certificate or temporary registration certificate before its expiration date, and, if not in the name of the current owner, a copy of the completed application for transfer of ownership in the name of the current owner where the sale occurred within 60 days, or
  - For animals under 60 days of age, a copy of a completed application for registration, or
  - An interstate certificate of veterinary inspection that lists the flocks of origin and birth, the registry, and the registry tattoo.
- 3) Official flock identification tattoos, a combination of the flock identification number assigned to the flock of birth or origin in the NSD and an individual number unique within the flock, may be used to officially identify sheep or goats required to be individually identified by 9 CFR 79.3 if:
  - a) The tattoo is legible.
  - b) The animals are not in slaughter channels or moving through a concentration point where a transfer of ownership may occur, such as a livestock market or buying station. This excludes sales of breeding or show stock at a livestock show, seed stock sale, or similar event when the flock ID and individual number tattoo of each animal is read and recorded with the name and address of the seller and the buyer of each animal and the record maintained for 5 years by the seller or sale management.
  - c) The animals are accompanied by an owner/hauler statement that contains the information needed to officially identify the animals to their flock of origin and, when required, their flock of birth.
  - d) The numbers are placed in different ears or in the same ear with the flock identification number above the individual number or, in the case of animals with absent or injured ears, the tail fold or in animals where the tail fold is too small, the flank.
- c. Electronic implantable identification (EID)
  - 1) Registered sheep or goats and animals from flocks listed in the NSD required to be individually identified by 9 CFR 79.3, may be identified with an EID if:
    - a) The implant is placed between the skin and the cartilage of the back side of the ear near where the ear joins the head or between the skin and the bone of the tail near the base of the tail;
    - b) The animal is tattooed with a legible “E” if the implant is at the base of the ear, or “ET” if the implant is in the tail fold;

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<sup>16</sup> [www.aphis.usda.gov/animal-health/scrapie](http://www.aphis.usda.gov/animal-health/scrapie)

- c) The tattoo is at least 0.3 inches high in the ear or, in the case of earless animals, the tail fold;
  - d) The animal is not in slaughter channels or moving through a concentration point where a transfer of ownership will occur, such as a livestock market or buying station, excluding sales of registered animals where an application for transfer of registration is completed and accompanies the animal when it leaves the sale or premises of origin;
  - e) For registered animals:
    - The electronic implant number has been recorded in the book of record of a sheep or goat registry association and on the registration certificate; and
    - The animal is accompanied by a copy of the registration certificate and, if not in the name of the current owner, a copy of the completed application for transfer of ownership in the name of the current owner where the sale occurred within 60 days, or for animals under 60 days of age, a copy of a completed application for registration.
  - f) For animals from flocks listed in the NSD (which may also be used for registered animals that originate from flocks listed in the NSD):
    - The animal is legibly tattooed with the flock identification number in the ear, or, in the case of earless animals, the tail fold; or, in animals where the tail fold is too small, the flank;
    - The animal is accompanied by an ICVI or, if an ICVI is not otherwise required, an owner/hauler statement that lists the flock of origin, the flock ID number, the electronic implant number, and, if required by 9 CFR 79.2(a)(1), the flock of birth.
  - g) The animal is accompanied by an implant reader that can read the implant in the animal and is made available for use by APHIS or State authorities to verify the implant number in the animal;
  - h) The movement is either for exhibition purposes or other movement without change in ownership, or for change in ownership that includes transfer of the registration papers, or for change in ownership that may not include transfer of registration papers but is directly to a flock listed in the NSD and the animal is tattooed as required in paragraph f) of this section and where the new owner has a reader that can read the implant in the animal;
  - i) The implant is used in accordance with other applicable laws and regulations; and
  - j) The implant complies with ISO 11784 and ISO 11785, or has been approved as a new device type as described above, and the device was approved under 9 CFR 79.2(k). The implant number must be an Animal Identification Number (840) issued to the flock of origin in the AIMS module of the NSD or applied to the animal before March 11, 2015.
- d. Animals may be identified with any other official identification method or device approved by the Administrator for particular circumstances.
  - e. Group/lot identification: Animals may be identified with a GIN when group/lot identification is allowed by 9 CFR 79.3 in lieu of individual identification and the animals are accompanied by an owner/hauler statement. Group/lot identification may be used for:

- 1) Animals in slaughter channels under 18 months of age.
  - 2) Animals in slaughter channels at 18 months and older (as evidenced by the eruption of the second incisor) if the animals were kept as a group on the same premises on which they were born and have not been maintained in the same enclosure with unidentified animals from another flock at any time, including throughout the feeding, marketing, and slaughter process.
  - 3) Animals in slaughter channels 18 months of age and older (as evidenced by the eruption of the second incisor) identified with official individual ID or, in the case of animals from flocks that are low-risk commercial flocks, identified using identification methods or devices approved for this purpose. (Note: This provision exists in 9 CFR 79.3(a) to allow these animals to move with an owner/hauler statement rather than an ICVI.).
  - 4) Animals moving for grazing or other management purposes between two premises both owned or leased by the flock owner and recorded in the NSD as additional flock premises and where commingling will not occur with unidentified animals that were born in another flock or any animal that is not part of the flock. A request to APHIS to enter additional flock premises in the NSD is required before animals are first moved to the premises. Notification is not required for each movement of animals to that premises. Neither group/lot ID nor an owner-hauler statement is required for movements of a flock or its members for flock management purposes within a contiguous premises spanning two or more States. This provision does not include the transiting or sale of animals through such a premises in circumvention of the other 9 CFR part 79 requirements.
  - 5) Animals moving to a livestock facility approved in accordance with 9 CFR 71.20; if facility management has agreed to act as an agent for the owner to apply official identification and if the animals have been in the same flock in which they were born and have not been maintained in the same enclosure with unidentified animals born in another flock at any time. The owner/hauler statement must contain the information needed to officially identify the animals to their flock of origin and, when required, their flock of birth.
- f. Only APHIS provided or approved devices for sheep and goats will be used. APHIS-provided tags will have a unique alphanumeric sequence or flock ID number and a production (animal) number unique within a flock. The flock ID number will be the Postal Service State abbreviation followed by up to 7 alphanumeric characters. States may allow producers to use a national premises (NPIN) or location identification number (LID) in place of a flock ID. All tags must have the U.S. shield. Premises/flock ID tags produced by approved tag companies will have the premises/flock ID number and a unique production number. Series of alphanumeric USDA sheep and goat eartags may be assigned to premises or flocks if they are linked to the premises or flock in the NSD. Premises/flock ID eartags may only be assigned to breeding flocks.
- g. Animals may be identified with any other official identification method or device approved by the Administrator for particular circumstances. Device manufacturers may contact the National Scrapie Program Coordinator at [scrapie@aphis.usda.gov](mailto:scrapie@aphis.usda.gov) to request approval. For additional information see 9 CFR 79.2 (k).

4. Identification requirements for captive exotic sheep and goats, and domestic sheep and goats maintained in AZA-accredited facilities:
  - a. For the purposes of 9 CFR parts 54 and 79, all captive animals of the genus *Ovis* are considered to be sheep and all captive animals of the genus *Capra* are considered to be goats. Therefore, all nontraditional livestock species and captive exotic species in the genus *Ovis* and genus *Capra* are subject to the requirements for sheep and goats in 9 CFR parts 54 and 79.<sup>17</sup>
  - b. Exceptions to identification requirements for sheep and goats housed at AZA-accredited zoological parks (zoos):
    - 1) Domestic and exotic sheep and goats housed in AZA-accredited zoos may be identified in accordance with AZA accreditation standards while on exhibit in or while in transit between AZA-accredited facilities, if the records required in 9 CFR 79.2 are properly maintained and linked to the facilities' internal identification systems.
    - 2) Sheep or goats required to be officially identified per 9 CFR 79.3 or the State moved to or from a facility not AZA-accredited must have official ID.
5. Issuance of official identification devices or numbers:
  - a. The State or APHIS official responsible for issuing official sheep and goat ear tags or official ID numbers in a State may assign serial numbers of official ear tags to accredited veterinarians, State and APHIS representatives, and persons who own or handle sheep or goats and may only assign flock ID and production numbers of official ear tags to persons who own breeding flocks. The SAHO or the Administrator may limit the assignment of official identification devices or numbers to persons for use on animals that did not originate in a breeding flock owned by them to slaughter-only devices or numbers.
  - b. The State or APHIS official responsible for issuing official sheep and goat ear tags or official ID numbers in a State may assign serial numbers of official ear tags to other responsible persons if the SAHO and the AVIC agree that such assignments will improve scrapie control and eradication within the State, and if appropriate records are maintained and submitted to the VS Area Office to permit traceback of animals to the flock of origin and flock of birth. Such serial numbers must be redistributed in AIMS or SCS SCR.
  - c. Accredited veterinarians, State and APHIS representatives, and other responsible persons assigned official identification devices or numbers must have a person record and be assigned a person number in the NSD.
  - d. Persons who handle sheep or goats who are assigned official identification devices or numbers must be assigned premises numbers in the NSD.
  - e. Persons who own breeding flocks who are assigned official identification devices or numbers must be assigned premises and flock ID numbers in the NSD.

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<sup>17</sup> Mouflon are known to be susceptible to scrapie. Other exotic sheep and goats may also be susceptible to scrapie, and could transmit the disease to domestic sheep and goats when they are maintained together. Therefore, it is important to individually identify all animals in the genus *Ovis* and genus *Capra* when they are moved or exhibited, including nontraditional sheep and goat livestock species and sheep and goat species kept at zoos.

- f. Persons assigned official identification devices or numbers for use on animals not born in a flock owned by them must provide, if requested, in a manner acceptable to APHIS, assignment data associating assigned serial sequences to the flock of origin and, when required, the flock of birth. One such method would be to enter the data into the online animal identification management system module of the NSD.
        - g. All official devices must be distributed through the scrapie program application of AIMS and, if redistributed, redistributed through the scrapie program application of AIMS or as provided in the User Guides for SCS SCR or a successor APHIS system.
6. Responsibility of the owner of the flock of origin for officially identifying animals:
  - a. The owner of the flock of origin or his or her agent is primarily responsible for and must officially identify any animal that requires official identification. This will enable sheep or goats to be identified to their flock of birth. Animals born on a premises do not have to be identified when officially identified animals from another flock of birth are added to the premises.
  - b. Producers are strongly encouraged to officially identify their animals before the animals leave their premises to prevent any error from occurring in the later identification of the animals and to ensure they will meet intra- and interstate movement requirements.
  - c. If official identification is required and has not been placed on the animal by the owner before leaving the flock of origin, the owner must ensure the animal is officially identified before it is put in the same enclosure with animals from a different flock of origin and before a change of ownership.
7. Responsibility of persons handling sheep and goats in commerce to identify animals:
  - a. Although the owner of the flock of origin is the primary person responsible for officially identifying animals, no person may handle sheep or goats at any point in interstate commerce before ensuring that all animals requiring identification have been officially identified to their flock of origin or birth.
  - b. A person must not buy, transport, receive, deliver or otherwise handle in commerce an animal required to be identified by 9 CFR or the State that has not been officially identified.
  - c. If a person transporting animals is aware of any animal in the shipment that loses its identification to its flock of origin while in interstate commerce, the person transporting the animal is required to inform the receiving party of this fact, and it is the responsibility of the person who has control or possession of the animal on unloading or delivery to identify the animal or have the animal identified before commingling it with any other animals.
  - d. A person who engages in interstate commerce of sheep and goats may not receive a sheep or goat required to be identified that has not been officially identified, or, when allowed, officially identified upon unloading, regardless of whether that animal moved interstate.
8. Restrictions on the application of official identification assigned to flocks:
  - a. No person will apply a premises or flock ID number, a brand, or an ear notch pattern to an animal not from the flock of origin to which the number or the brand or the ear

- notch pattern was assigned by a State or APHIS representative. This prohibition includes individual identification (such as USDA tags) that has been assigned to a premises or flock and registration tattoos that contain prefixes that have been assigned to a premises or flock. This procedural requirement does not prevent an owner from applying individual animal official identification assigned to his or her premises or flock to an owned animal that resides on the premises or that is part of the flock, as long as a record is maintained linking the individual animal official identification to the animal's flock of origin or birth.
- b. No person will use an official identification device or number provided for the identification of sheep and goats other than for the identification of a sheep or goat.
9. Removal or loss of official identification devices: Official identification devices are intended to provide permanent identification of livestock and to ensure the ability to find the source of animal disease outbreaks and locate exposed animals. Removal of these devices, including devices applied to imported animals in their countries of origin and recognized by the Administrator as official, is prohibited except at the time of slaughter, at any other location on the death of the animal, or as otherwise approved by the State or Tribal animal health official or an AVIC when a device needs to be replaced as allowed in 9 CFR 79.2(i).
- a. All man-made identification devices affixed to sheep or goats moved interstate must be removed at slaughter and correlated with the carcasses through final inspection by means approved by FSIS. If diagnostic samples, including whole heads, are taken, the identification devices must be packaged with the samples and must be left attached to approximately 1 inch of tissue or to the whole head to allow for identity testing. Devices collected at slaughter must be made available to APHIS and FSIS.
  - b. All official identification devices affixed to sheep or goat carcasses moved interstate for rendering must be removed at the rendering facility and made available to APHIS.
  - c. If a sheep or goat loses an official identification device, the person applying the new official identification device must record the official ID number on the old device, if known, in addition to the information required to be recorded in accordance with [B.2](#) of this part. If the person transporting animals is aware of any animal in the shipment that loses its identification to its flock of origin while in interstate commerce, the person transporting the animal is required to inform the receiving party of this fact. It is the responsibility of the person who has control or possession of the animal on unloading or delivery to identify the animal or have the animal identified before commingling with any other animals. This will be done by applying official individual animal identification to the animal and recording the means of identification and the corresponding animal identification number on the waybill or other shipping document. A record must be kept linking the identification number to the flock of origin. In the case of animals in interstate commerce, if the flock of origin cannot be determined, all possible flocks of origin will be listed on the record of official identification applied. If this cannot be done, the animal must be identified with a slaughter-only eartag and may only move in slaughter channels. In the case of sheep, the animal may move for other purposes if it is inspected by an accredited veterinarian, found free of evidence of infectious or contagious disease, and officially genotyped as AA QR or AA RR.

10. Loss of ability to apply official identification: Any person who fails to comply with *Part III, Identification Requirements*, will no longer be assigned serial numbers of USDA backtags, official sheep and goat tattoos, official eartags, or flock ID numbers for use as official identification or any official identification device.
11. Identification of scrapie suspect, scrapie-positive, scrapie-exposed, and high-risk animals including all low-risk exposed animals, genetically susceptible exposed animals, genetically less-susceptible exposed animals, and genetically resistant exposed sheep:
  - a. The identification device required is an official tamper-resistant or tamper-evident metal or plastic eartag or another official identification device approved for this use by APHIS. Other official identification may be used when eartags cannot be used due to the absence or deformation of the ears. These animals will be identified with at least two forms of official identification unless there is an existing unique unofficial flock tag or tattoo that would preclude the application of more than one official eartag. RFIDs will be used as one form of official ID when such use will facilitate the inventory or testing of these animals.
  - b. Animals that are positive on an official live-animal test will be identified with a red metal tag on each ear. Only APHIS or State representatives may acquire official red metal tags.
  - c. High-risk animals and sexually intact genetically susceptible exposed male animals not removed will be identified with both official yellow metal eartags and with a secondary official permanent identification method or device such as an RFID implant or official tattoo.
  - d. Other animals may be identified with an official eartag of any other approved color/material combination approved for the intended use (blue is restricted to slaughter only eartags).
  - e. Tag application must be done by, under the supervision of, or verified by an APHIS or State representative or an accredited veterinarian authorized by APHIS or the State to perform this function.
  - f. All identification applied to these animals will be recorded in the NSD.

**Note:** All forms of identification on suspect, positive, exposed, and high-risk animals (including low-risk exposed animals, genetically susceptible exposed animals, genetically less susceptible exposed animals, and genetically resistant exposed sheep) must be recorded on VS Form 5-20 or equivalent and forwarded to the DSE and the VS Area Office. The AVIC must ensure that an individual animal record is created for each animal in the NSD.

## **B. Records of Animals Handled**

1. General requirements:
  - a. Persons who sell, dispose of, acquire, exhibit, transport, receive for transport, offer for sale or transportation, load, unload, or otherwise handle sheep or goats in interstate commerce or commingle sheep or goats with sheep or goats in interstate commerce and required to be identified by 9 CFR 79.3 must officially identify the

- animals and maintain records linking the official identification to their premises of birth or origin if they are not already officially identified. (Persons may not sell or dispose of unidentified animals required to be identified unless arrangements have been made with the person acquiring the animals to act as his or her agent to identify the animals, including maintaining records linking the official ID to their premises of birth or origin. Persons may not purchase or acquire unidentified animals required to be identified unless they identify them and maintain the required records while acting as an agent for the person disposing of the animals.)
- b. Persons who purchase, acquire, sell, or dispose of sheep and goats, whether or not the animals are required to be identified, must maintain business records (such as yarding receipts, sale tickets, invoices, and waybills) for 5 years. These records must include the information described in *B.3*, “Records required of persons who purchase, acquire, sell, or dispose of animals.”
  - c. The original tag number or all possible flocks of origin and the new official ID number must be listed in the record of official identification applied when an animal loses an eartag while in interstate commerce.
2. Records required of persons who apply official identification to animals:  
Persons who apply official individual or group/lot identification to animals must maintain records for 5 years. The records must include the following information:
- a. The flock ID number of the flock of origin, the name and address of the person who currently owns the animals, and the name and address of the owner of the flock of origin if different;
  - b. The name and address of the owner of the flock of birth, if known, for animals born after January 1, 2002, in another flock and not already identified to flock of birth;
  - c. The date the animals were officially identified;
  - d. The number of sheep and the number of goats identified;
  - e. The breed and class of the animals. If breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead;
  - f. The official ID numbers applied to animals by species or the GIN applied in the case of a group/lot;
  - g. Whether the animals were identified with “Slaughter Only” or “MEAT” identification devices; and
  - h. Any GIN with which the animal was previously identified.
3. Records required of persons who purchase, acquire, sell, or dispose of animals:  
Persons who purchase, sell, or transfer without sale sheep or goats must maintain normal business records that include the following information:
- a. The number of animals purchased, sold, or transferred without sale;
  - b. The date of purchase, sale, or other transfer;
  - c. The name and address of the person from whom the animals were purchased or otherwise acquired, or to whom they were sold or otherwise transferred;
  - d. The species, breed, and class of animal, and if breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead;
  - e. A copy of the brand inspection certificate for animals officially identified with brands or ear notches;

- f. A copy of any certificate or owner/hauler statement required for movement of the animals purchased, sold, or otherwise transferred; and
  - g. If the flock of origin or the receiving flock is under a flock plan or PEMMP, any additional records required by the plan.
4. Keeping of records/making records available:
- Each person required to keep records under *Part III* must maintain the records for at least 5 years after the person has sold or otherwise disposed of the sheep or goat to another person. This record retention requirement may be extended for such further period as the Administrator (through the DSE) may require by written notice to the person, for purposes of any investigation or action involving the sheep or goat identified in the records. The person must make the records available for inspection and copying during ordinary business hours (8 a.m. to 5:30 p.m., Monday through Friday) by any authorized APHIS or State employee on that employee's request and presentation of his or her official credentials.

## Part IV: Shows and Sales

- A.** For practical purposes sexually intact sheep and goats of any age and wethers 18 months of age and older that are exhibited require official ID. There is an exclusion which would rarely apply for animals that have never been in interstate commerce, that do not reside on premises that engage in interstate commerce of animals, and are not owned by persons who engage in interstate commerce of animals that are moved to exhibitions conducted at premises where animals are not received that have been in interstate commerce or from which animals are moved in interstate commerce and where none of the animals exhibited has been in interstate commerce. Note: Many States and exhibitions require official identification of all sheep and goats.
- B.** Whenever practical, ewes over 12 months of age (as evidenced by eruption of the first permanent incisor) should be housed in separate enclosures from animals from different flocks. Pens used by mature female sheep and goats should be thoroughly cleaned and all organic material removed before use by an animal from another flock.
- C.** All sheep and goats from SFCP-enrolled flocks must be housed and handled to prevent direct contact with female sheep and female goats from flocks of lower status. Spacing sufficient to prevent contact or solid partitions may be used to maintain separation. Pens must be thoroughly cleaned and all organic material removed before use by an animal from an SFCP flock.
- D.** Special arrangements should be made to keep the following animals separate from sheep and goats from different flocks such that direct contact does not occur and to keep them in an area that will be properly cleaned and disinfected, if such animals are allowed at a show:
1. Sheep or goats that are within 30 days of parturition;
  2. Sheep or goats that are within 30 days postpartum or since having aborted; and
  3. Pregnant sheep and goats that have a vaginal discharge.
- E.** Should a lambing or kidding occur at the show, the placenta, placental fluids, and soiled bedding should be removed immediately and disposed of in a sanitary landfill or by another method approved by the State. The dam and her offspring should be removed from the show grounds or separated from sheep and goats from different flocks using spacing or solid partitions such that direct contact does not occur. The pen should be thoroughly cleaned and disinfected before use by another animal.

## **Part V: Consistent State Status in the National Scrapie Eradication Program**

### **A. State Status in the NSEP**

1. States are classified as Consistent or Inconsistent in the NSEP.
  - a. A Consistent State is a U.S. State, Territory, or possession the Administrator has determined conducts an active State scrapie control program that meets the requirements of 9 CFR 79.6 or effectively enforces a State-designed plan the Administrator determines is at least as effective in controlling scrapie as the requirements of 9 CFR 79.6.
  - b. Sheep and goats from Inconsistent States have more restrictive interstate movement requirements than animals from Consistent States.
2. See the definition for [Consistent State](#) for a current list of States with Consistent status.

### **B. Standards for State Programs to Qualify as Consistent**

Consistent State status is granted to qualified States by the Administrator in accordance with 9 CFR 79.6. A Consistent State meets all elements of the 10 requirements listed below.

1. The State has the authority to restrict the movement of all scrapie-infected and source flocks.
2. The State has the authority to require the reporting of all scrapie-suspect animals and the results of all scrapie tests to State or Federal authorities.
3. The State has signed a memorandum of understanding with APHIS delineating the respective role of each in implementing the NSEP.
4. The State has placed all known scrapie-infected and source flocks under the required movement restrictions.
5. The State has effectively implemented policies to:
  - a. Investigate all scrapie suspects reported within 7 days;
  - b. Designate a flock's status within 15 days of notification that the flock contains or contained a scrapie-positive animal;
  - c. Restrict the movement of newly designated scrapie-infected and source flocks within 7 days after they are designated;
  - d. Maintain movement restrictions on infected and source flocks until the flocks have completed a flock plan and the flock owner has agreed to comply with a 5-year PEMMP;
  - e. Conduct epidemiological investigations of source and infected flocks;
  - f. Conduct trace backs of scrapie-positive animals and trace outs of high-risk and exposed animals and report any out-of-State traces to the appropriate State within 45 days of receipt of notification of a scrapie-positive animal;



- [webpage](#) at least 6 months before the start of the collection period; or
- 4) Conducts annual surveillance at a level that will detect scrapie if it is present at a prevalence of 0.1 percent in the population of targeted animals originating in the State, with a 95 percent confidence.

**C. Scrapie Classification, Renewal, or Reclassification of a State or Zone**

1. Each Consistent State is evaluated annually for renewal of its Consistent State status. See *Part X.D* for the protocol for completing the renewal application, VS Form 5-24.
2. Each Consistent State undergoes a Consistent State Review at least once every 10 years, to determine if the State's laws, regulations, and enforcement mechanisms are effectively meeting the requirements of 9 CFR 79.6.
3. Reclassification
  - a. If the Administrator determines that statutory changes are needed to bring a State into full compliance with 9 CFR 79.6, the Administrator may grant up to a 2-year extension to allow the State to acquire additional authorities before removing its Consistent State Status.
  - b. If the Administrator determines that a State is Inconsistent, APHIS will publish a notice in the Federal Register announcing the State's Inconsistent status, and will remove the State from the list of Consistent States on the APHIS Web site.
  - c. An Inconsistent State may request that the Administrator review it for reclassification to Consistent State status once it has demonstrated that it meets the requirements for Consistent State Status.

## Part VI: Surveillance and Monitoring

- A. Identifying scrapie infected and source flocks is a fundamental component of the NSEP. APHIS has implemented a National Scrapie Surveillance Plan (NSSP) that provides a framework for identifying scrapie-positive animals through slaughter and non-slaughter surveillance. The NSSP is available on the Internet [here](#).<sup>18</sup>

Surveillance methods include:

1. Regulatory Scrapie Slaughter Surveillance (RSSS):  
APHIS coordinates sampling and testing of mature sheep and goats at slaughter that have a higher than average probability of being scrapie infected. See [Appendix D](#) for how sampling minimums are determined and the RSSS targeted selection criteria, and the RSSS Handbook for detailed sample collection instructions.
2. Non-slaughter surveillance:  
In addition to slaughter surveillance, VS collects sheep and goat samples for scrapie testing from a diverse set of sample streams.
  - a. On-farm scrapie surveillance. Sheep and goats over 18 months of age that are down or disabled or that die from causes other than slaughter should be sampled when it is practical to do so. Sheep and goats slaughtered at home, or at other sites that do not qualify as RSSS sites, should be sampled if they meet the RSSS sampling criteria (up to 30 per flock).
  - b. Suspect animals. Clinically suspicious sheep or goats (see [part VII.C](#)).
  - c. Mature traceable dead or disabled sheep or goats at markets and slaughter facilities that do not participate in RSSS, and other off-farm sites will be sampled and tested when practical to do so.
  - d. Live animal surveillance testing. Live-animal sampling programs may be used for at-risk populations on farms, at markets, or other locations in areas of high scrapie prevalence or in high-prevalence classes within an area or for other appropriate reasons. If testing will be done at Federal expense, the plan must be a part of a cooperative agreement or must be approved by the SGHSE.
  - e. Scrapie Free Flock Certification Program (SFCP). Sheep and goat producers participating in the SFCP must meet animal sampling requirements. Details of these requirements are available in the SFCP standards, which may be obtained on the Internet [here](#).<sup>19</sup> or from APHIS VS Sheep, Goat, Cervid and Equine Health, 4700 River Road, Unit 43, Riverdale, MD 20737–1235.
  - f. Laboratories. Diagnostic laboratories should be reminded and encouraged to forward appropriate tissues for scrapie testing from all mature sheep and goats presented for necropsy; similarly, public health laboratories should be reminded and encouraged to forward appropriate tissues from sheep and goats of any age

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<sup>18</sup> [https://www.aphis.usda.gov/animal\\_health/animal\\_diseases/scrapie/downloads/national\\_scrapie\\_surv\\_plan.pdf](https://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/national_scrapie_surv_plan.pdf)

<sup>19</sup> [http://www.aphis.usda.gov/animal\\_health/animal\\_diseases/scrapie/](http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/)

that test negative for rabies.

- g. Animals sampled as part of a disease investigation other than natural additions in an infected or source flock.

## **B. Monitoring**

APHIS must to be able to trace all infected and exposed animals. As a part of surveillance activities, ID and recordkeeping compliance must be monitored and when deficiencies are identified compliance action must be taken as described in *Part II.E*.

## Part VII: Epidemiology

### A. Introduction

The designations QQ, QR, and RR refer to the results of an official genotype test conducted at codon 171; AA, AV, and VV refer to the results of an official genotype test conducted at codon 136. For the purposes of these standards, H, K, or any amino acid other than R at codon 171 is considered the same as Q at codon 171; likewise T or any other amino acid other than A at codon 136 is considered the same as V at codon 136.

Research indicates that QQ sheep are the most susceptible to scrapie infection, whereas QR sheep are much less susceptible and RR sheep are resistant. For scrapie testing purposes all goats are considered genetically susceptible<sup>20</sup>. Therefore, when determining the status of the flock, in most cases it is only necessary to test the QQ sheep and goats for scrapie. When the number of QQ sheep and goats in the flock is insufficient to conduct a reliable flock test either through live animal or necropsy testing or a combination thereof, or when valine-associated scrapie is suspected, the DSE may require testing of other genetically susceptible exposed female animals in the flock by IHC on necropsy samples. (**Note:** Very few flocks will have genetically susceptible exposed female animals that are not QQ sheep or goats.)

Additional guidance on NSD statuses and codes is available on the [Scrapie SharePoint](#) site.

### B. Reclassification Procedures: Redesignation of Suspect, High-Risk, and Exposed Animals and Exposed, Infected, Source, Under Investigation, and Noncompliant Flocks

A [reclassification investigation](#) may be conducted or directed by the DSE, the SGHSE, or the National Scrapie Program Coordinator to determine whether the current designated status of a flock or animal may be changed or removed as described in the following table.

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<sup>20</sup> There is evidence that genetic resistance to scrapie may exist in goats similar to sheep, with a similar level of certainty as genetic resistance in sheep when it was first piloted by APHIS for flock cleanup in sheep. APHIS may pilot the use of genetic resistance in goats to determine the designation of scrapie-exposed goats.

Who may redesignate <sup>21</sup>	Animals that may be redesignated	Conditions for redesignation	New designation
SGHSE	High-risk animal	1. A determination that the animal meets the definition of a low-risk exposed animal.	Low-risk exposed animal
DSE	High-risk animal	2. Necropsy testing is done, including official testing of obex and lymph node or tonsil, and no PrPsc is detected. 3. The animal's high-risk status is waived in accordance with 9 CFR 79.7(a)(1) for animals in an approved Scrapie Control Pilot Project.	Low-risk exposed animal
DSE (except that the SGHSE must approve any that are based on a determination of the Administrator)	High-risk animal	1. The animal meets the definition of a genetically resistant or less susceptible exposed sheep and there are no additional risk factors that would preclude redesignation; or 2. The animal's high-risk status is waived in accordance with 9 CFR 79.7(a)(1) for animals in an approved Scrapie Control Pilot Project.	Genetically resistant exposed sheep or genetically less susceptible exposed sheep
DSE	Live suspect animal that was classified suspect based on clinical signs of scrapie	1. Tested with an official live animal scrapie test with no PrPsc detected or there were insufficient follicles to conduct a valid test; and 2. The live animal no longer exhibits clinical signs, or it was	No designation

<sup>21</sup> If a DSE has not been selected or is temporarily unavailable, a SGHSE, the National Scrapie Program Coordinator, or the Associate National Scrapie Program Coordinator may perform any of the duties assigned to the DSE. If a SGHSE has not been selected or is temporarily unavailable, another SGHSE, the National Scrapie Program Coordinator, or the Associate National Scrapie Program Coordinator may perform any of the duties assigned to the SGHSE.

		determined that the signs were not caused by scrapie.	
SGHSE	Live suspect animal classified suspect based on an unofficial live animal test	<ol style="list-style-type: none"> <li>1. Tested with an official live animal scrapie test with no PrPsc detected; and</li> <li>2. The live animal did not or no longer exhibits clinical signs, or it was determined that the signs were not caused by scrapie.</li> </ol>	No designation
SGHSE	Dead suspect animal	The animal was unavailable for testing and a reclassification investigation showed the animal was not likely to have been infected.	No designation
DSE	Dead suspect animal	No PrPsc detected results from necropsy testing which included official testing of obex and lymph node or tonsil.	No designation
DSE	Exposed flock (including those that are also a noncompliant flock) or flock under investigation	<ol style="list-style-type: none"> <li>1. The flock has successfully completed a PEMMP and when required a flock plan following the exposure and all high-risk animals have been removed; or</li> <li>2. A flock reclassification investigation shows the flock is not likely to be infected and all high-risk animals have been removed.<sup>22</sup></li> </ol>	No designation
DSE	Exposed flock or flock under investigation	A flock reclassification investigation shows the flock to be infected or source.	Infected or source flock

<sup>22</sup> However, the DSE shall also designate the flock as a noncompliant flock if the owner does any of the following: Fails to make his or her records available when requested; fails to make animals available for testing within 60 days of notification, within 60 days of becoming test eligible, or as mutually agreed by the DSE and the owner; or fails to submit required postmortem samples.

DSE or SGHSE	Exposed flock or flock under investigation	A flock reclassification investigation could not be conducted because the owner did not provide the necessary records or did not make the selected animals available for testing within 60 days of becoming test eligible.	Noncompliant and exposed flock
SGHSE	Infected flock or source flock or a flock pending designation as a source or infected flock	The SGHSE for the States involved or the National Scrapie Program Coordinator may authorize a DSE to conduct a classification or reclassification investigation of a source or infected flock or a flock pending designation as a source or infected flock. If the reclassification investigation reveals, based on epidemiology or testing <sup>23</sup> in the flock, that the flock is not an infected or source flock, it may be redesignated or not designated.	No designation unless female genetically susceptible exposed animals have been retained, in which case the flock is an exposed flock.
DSE	Noncompliant flock	The flock has complied with any pending required testing or no longer meets the definition of a noncompliant flock.	Former flock designation, or new flock designation if indicated by test results.
DSE	Exposed animal, exposed flock, or infected flock	An epidemiological investigation determines the exposure was limited to a scrapie-positive male animal not born in the flock,	No designation

<sup>23</sup> The DSE will select all exposed sheep for scrapie susceptibility genotyping. All genetically susceptible exposed animals will be tested for scrapie unless a 95 percent confidence of detecting scrapie at a prevalence of 1 percent can be achieved by testing fewer animals. In this situation, the DSE will preferentially select those animals at greatest risk of being scrapie infected. If there are insufficient genetically susceptible exposed animals to provide this level of confidence with live animal testing, those animals that cannot be tested using a live animal test or that do not give a valid result will be selected for necropsy testing. If 95 percent confidence at a prevalence of 1 percent cannot be achieved in this manner, the DSE may require necropsy testing of all genetically susceptible exposed animals.

		and the owner has adequate records and animal identification to show that the scrapie-positive male animal was acquired from outside the flock.	
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More detailed instructions on conducting classification/reclassification investigations and designating and redesignating animals and flocks are provided in the following sections.

### C. Procedures for Investigating a Report of a Clinically Suspicious Animal

1. Accredited veterinarians are required to immediately report scrapie suspects to the AVIC and SAHO per 9 CFR 161.4(f).
2. APHIS and State representatives will notify each other of a report of a clinically suspicious animal.
3. If the flock does not already have an assigned premises and flock number, it will be assigned a number in the NSD. A “Flock Under Investigation (Sheep)” or “Flock Under Investigation (Goats)” program will be opened with a relevant status (reason for the investigation).
4. A VMO will contact the flock owner. The suspect animal and, when determined to be appropriate by the DSE with the concurrence of the SAHO, the flock, will be placed under a hold order or other appropriate restrictions until the animals’ status is determined.
5. The flock owner will be provided with information about scrapie.
6. A premises visit will be scheduled as soon as possible but within 7 days of initial notification. The purpose of the visit is to examine the suspect animal and conduct an investigation.
7. The owner will be advised not to remove or dispose of the suspect animal (or other animals that may display evidence of disease) and to notify the VMO immediately if its condition worsens or it dies.
8. If on examining the animal the VMO determines that clinical signs are compatible with scrapie, euthanasia and necropsy will be arranged with the owner’s consent. The animal may be purchased for diagnostic purposes if funds are available. If the DSE determines that the clinical signs and history make scrapie a likely rather than possible diagnosis and the SAHO concurs, the State will maintain movement restrictions on potentially exposed susceptible animals in the flock until the animal’s status has been determined.
9. Fresh and formalin-fixed tissues from clinical suspects should be submitted to NVSL for testing in accordance with the guidance provided on the [Scrapie SharePoint](#) site.
10. If the owner declines euthanasia of the suspect animal, the VMO will require the animal to be held on the premises for observation; *except that*, the VMO may permit the animal to be returned to and held at the flock of origin if the animal is designated a suspect animal while off the flock premises. The owner will be advised to isolate the suspect animal from other animals in an area that can be cleaned and disinfected, and to notify the VMO immediately if its condition worsens or it dies. If the animal

- dies, it must be necropsied, and tissues must be submitted for testing at NVSL. Movement restrictions will be maintained on the animal until the animal's status has been determined. If the DSE determines that the clinical signs and history make scrapie a likely rather than possible diagnosis and the SAHO concurs, movement restrictions will also be maintained on potentially exposed susceptible animals in the flock until the animal's status has been determined. Failure by the owner to make the animal and, if the animal dies, the carcass available for testing in a condition in which it can be tested will result in the flock being designated noncompliant or placed under a PEMMP.
11. Suspect sheep and goats not euthanized will be live animal tested and sheep genotyped at codons 171 and 136 with the owner's consent. (**Note:** If the owner refuses to test, the flock will be designated noncompliant.)
  12. Written instructions will be given to the owner regarding the restrictions and contact information will be provided for use if the animal's condition worsens or it dies. Prompt reporting by the owner is required to ensure that appropriate samples can be collected for diagnostic testing. The owner must be advised, in writing, that flock status will be jeopardized if he or she fails to promptly request a necropsy at the animal's death and maintain the head chilled such that diagnostic specimens can be obtained, or if he or she moves the animal without a permit.
  13. The animal will be inspected at a minimum of every 4 weeks until scrapie is confirmed or ruled out and to monitor compliance with movement restrictions. Severely affected animals will be observed more frequently.
  14. If the DSE determines the animal does not have scrapie, movement restrictions will be lifted and the investigation status will be closed in the NSD.
  15. An individual animal record and restriction will be created in the NSD; if scrapie or genetic testing is done, a test submission must be completed in VSLS. (Additional data entry and tissue collection instructions are available on the [Scrapie SharePoint](#) site.)
  16. Clinically suspect animals at slaughter facilities must be condemned in accordance with FSIS regulations and FSIS must report them to the AVIC so samples can be collected for diagnosis and the carcass can be removed from the food chain.

#### **D. Procedures for Investigating a Report of a Live Test-Positive Animal**

1. APHIS and SAHOs will be notified by the veterinarian or laboratory that conducted the test; the first notified will notify his or her counterpart.
2. If the flock does not already have an assigned premises and flock number, it will be assigned a number in the NSD. A program record, with program "Scrapie – Flock Under Investigation (sheep) or (goat) as appropriate, will be created. (See the [Scrapie SharePoint](#) site for data entry instructions.)
3. If the test was an official program-approved test, the flock will be handled as in [part VII.E](#) of this document.
4. If the test was an unofficial test, the animal will be classified as suspect in accordance with 9 CFR 79.
  - a. If the animal is exhibiting clinical signs, it should be handled as in [part VII.C](#).

- b. The animal will be live animal tested and, if it is a sheep, genotyped at codons 171 and 136 with the owner's consent. (**Note:** If the owner refuses to test, the flock will be designated noncompliant and all genetically susceptible female animals restricted to movement for slaughter only.)
- c. The suspect designation of an animal may be removed by the DSE if:
  - 1) The animal is not showing clinical signs of scrapie, it is over 18 months of age, and it is negative on an official program-approved test; or
  - 2) The animal is not showing clinical signs of scrapie and an epidemiological investigation shows the animal is not likely to be infected and an official live animal test cannot be done due to lack of sufficient tissue. (**Note:** If the unofficial test has a reasonable scientific basis, such as IHC on rectal or third eyelid biopsy, lymph node or tonsil, at a laboratory that has not been approved, the animal should not be redesignated unless prion protein scrapie (PrP<sup>sc</sup>) cannot be detected in any tissue at necropsy or unless NVSL was able to run a confirmatory test on the tissue used for the live animal test with not detected results. Restrictions should be placed on the flock pending the results of the necropsy.)
- d. After all factors are weighed, if there is significant concern that the animal may be at risk of having scrapie, the animal will either be purchased for diagnostic reasons and necropsied or held for observation.
5. An individual animal record and restriction will be created in the NSD. If the animal is necropsied or live animal tested, a test submission will be created in VSLs by the collector or Federal or State data entry personnel. (See the [Scrapie SharePoint](#) site for additional data entry and necropsy tissue collection instructions.)
6. The DSE will submit a summary report to the SGHSE of suspect animals investigated each month by the 15th of the following month or as instructed by the SGHSE as part of the Monthly Epidemiology and Compliance Report. The report will include the number of suspects investigated and the number of infected animals found.

**E. Procedures for Conducting an Epidemiological Investigation, Managing Flocks, and Reporting Results Following Receipt of NVSL Confirmation of a Scrapie-Positive Animal Either Through Necropsy Samples or a Live Animal Test**

1. Responsibilities of NVSL:
  - a. Notify the AVIC, the SGHSE for the States involved, and the National Scrapie Program Coordinator that a tissue submitted for scrapie testing was positive by an official scrapie test.
  - b. Conduct genotyping at codons 112, 136, 141, 154, and 171 for sheep and codons 146, 211, 222 for goats and report results to the AD, the SGHSE for the States involved, and the National Scrapie Program Coordinator.
  - c. Conduct identity testing for all slaughter samples submitted with eartags and for on-farm samples when the result may implicate another flock.
2. Responsibilities of the AVIC/VS Area Office:
  - a. Keep State officials informed.
  - b. Ensure that the deadlines listed in this section and in [part V.B](#) are met.

- c. Ensure that a field VMO is assigned to the investigation.
  - d. Request approval for indemnity from the SGHSE for the State involved.
  - e. Ensure that the NSD is updated with accurate flock status, restrictions, event, and animal data and that test submissions are submitted through VSLS (see *part II.N*, NSD) and that all traces are entered into EMRS.
  - f. Provide the SGHSE with a list of traces and provide updates as needed during the investigation.
  - g. Provide trace out information to other VS Area Offices as soon as possible but no later than 45 days after determination that an out-of-area trace exists. The notification should include, when known:
    - 1) Information about the positive animal or animals, including date of birth, sex, date of death, date of diagnosis, genotype at codons 171 and 136 for sheep and 146 and 222 for goats or that the genotype couldn't be determined, the flock of origin and date of entry into the flock if purchased, and whether the animal or animals was or were born on or lambled on the premises where the exposed animal resided and the date of each lambing;
    - 2) Information about the flock, including the prevalence of scrapie in the flock, the genotypes affected, the genotype of the animal being traced, the prevalence of scrapie in the birth cohort of the animal being traced, date of birth of all positive animals in the flock, and whether the DSE determined that some or all QR sheep should be removed or restricted, which ones, and why; and
    - 3) Information about the exposed animal being traced, including identifying marks or numbers, the name and address of the person to whom it was sold or otherwise disposed, date of birth, breed, sex, genotype at codons 171 and 136 for sheep and 146 and 222 for goats, the flock of origin and date of entry into the flock if purchased, date the animal left the flock, and whether the animal was a part of any distinct group that would affect its exposure risk, such as offspring of a female positive animal, twin of a positive, or maintained in a separate group.
    - 4) If additional information is obtained after the trace is initiated, it should be forwarded to the AVIC in the receiving State. Once notified, the AVIC is responsible for the steps listed in *VII.F*.
- Note:** the SGHSE must be copied on all trace out information sent to other VS Area Offices.
- h. Assign additional field VMOs if needed to investigate within-area trace outs.
  - i. Request records from breed registries.
  - j. Officially notify the owner of the flock under investigation of infected or source status designation as required by 9 CFR part 79.
  - k. If the positive animal was not born into the flock and was diagnosed as scrapie positive at an age of 72 months or less, an investigation will be initiated to determine the source flock.
    - 1) If the flock of birth is in the AVIC's area of responsibility, a pending designation status will be opened for the birth flock, and an investigation will be initiated.

- 2) If the birth flock is out of the AVIC's area of responsibility, notification must be made to the AVIC and the SGHSE for the birth flock's State as soon as possible, but within 45 days. The VS Area Office for the receiving State will notify the SAHO, and initiate data entry and the investigation of the birth flock. The receiving VS Area Office will notify the SGHSE and the VS Area Office for the sending State of the outcome of the investigation.
  - 3) Based on the epidemiological investigation (including testing in the infected flock) the DSE, with concurrence of the AVIC, SAHO, and the SGHSE and National Scrapie Program Coordinator, may decide to conduct testing in the flock of birth to determine if it is a source flock. It is appropriate to consider the following in determining whether to conduct testing in the positive animal's flock of birth to determine if it is the source flock:
    - a) The age of the animal at the time of diagnosis;
    - b) The age of the animal when it left the birth flock;
    - c) The scrapie history of other flocks in which it resided;
    - d) The duration and timing of its residence; and
    - e) The genotype of the positive animal (this factor should always be considered if the positive sheep traced back had valine at codon 136 and had been in the other flock for at least 12 months).
  - 4) If the flock meets the definition of a source flock it will be designated a source flock in the NSD.
    - l. If the positive animal is a female over 12 months of age that has not resided in the flock for its entire adult life, an investigation must be conducted to determine if it has lambed in any other flock. If such a flock is identified, that flock must be designated infected and handled as such. Notification of AVICs and the SGHSE of out-of-area potentially infected flocks will be handled the same as out-of-area potential birth flocks described above. Flocks where a positive female animal over 12 months of age resided, where there is reason to believe she may not have lambed but insufficient evidence to show that she did not lamb, should be tested as required for flocks pending designation as an infected flock.
    - m. If the flock is found not to be in compliance with the flock plan or PEMMP, including completion of all actions required by the flock plan that are under the control of the flock owner, within 60 days, the infected or source status will be reopened and a noncompliant status opened.
3. Responsibilities of the SAHO:
- a. Issue and enforce a hold order for all sexually intact sheep and goats on the premises, and when appropriate, for all sheep and goats owned by the owner of the flock or premises or both until the owner has signed and is in compliance with a flock plan. Once an owner is in compliance with a flock plan, the SAHO may modify the order to include only those sheep or goats required to be restricted or destroyed under the flock plan.
  - b. If a flock is found not to be in compliance with the flock plan or PEMMP, issue and enforce a hold order for all sheep and goats that meet the definition of high-risk animals.
  - c. Ensure the deadlines listed in this section and in *part V.B* are met.

- d. Other responsibilities as mutually agreed by the State and APHIS or as provided for in an MOU or cooperative agreement.
4. Responsibilities of the field VMO:
- a. The VMO will contact the owner and schedule a visit within 7 days of receiving the NVSL report. Before the initial visit the VMO should:
    - 1) Review the flock cleanup plans in *part VIII* and the flock plan and PEMMP templates so he or she can advise the producer of the available options. The species and genotype of the positive animal and the epidemiology of the flock will determine the flock plans that may be offered to the producer. (**Note:** In nearly all cases, a standard genetic-based flock cleanup plan will be the best option for the producer to maintain a viable business.)
    - 2) Verify that indemnity funds are available.
    - 3) Review requirements and procedures for approval of plans with the DSE.
  - b. During the initial visit, the VMO will complete items *c through f 6*). If this is not possible, the reasons for the delay must be reported to the DSE and a timeline for completing the tasks must be provided to and approved by the DSE.
  - c. Confirm the identity of the positive animal.
  - d. Inform the owner about the results of the diagnostic tests and about his or her responsibilities under the program.
  - e. Provide the owner information about scrapie and its control.
  - f. Determine if the flock is an infected or source flock. If the flock is determined to be an infected or source flock:
    - 1) Work with the State to make sure a hold order is issued for all sexually intact sheep and goats and sheep and goat embryos on the premises and, when appropriate, for all sheep and goats (including embryos) owned by the owner of the flock or premises, or both.
    - 2) Inventory all sheep and goats and sheep and goat embryos on the premises and apply two official eartags to the animals if they do not already have official ID (only one official ID may be used if the animal has another form of ID unique within the flock). The inventory will list all identification present on the animal, the sex, age, and the breed or, if breed is unknown, the color and any other identifying marks (the inventory should be documented in the NSD with an activity record and individual animal records created).
    - 3) If indemnity funds are available, provide a copy of the indemnity spreadsheet to the owner.
    - 4) Advise the producer of the available cleanup plan options.
    - 5) Confirm the status with the DSE and enter or report the information to the VS Area Office for entry into the NSD. If the status cannot be immediately determined, a Flock Under Investigation program should be opened in SCS SCR.
    - 6) Collect the additional information needed to complete the epidemiological investigation report (see epidemiological report described in *part X*).
    - 7) Prepare a flock cleanup plan and PEMMP using one of the standard templates available on the [Scrapie SharePoint](#) site, and have the DSE approve the plans. Once the DSE has approved the plans, the VMO will review them with the

- producer and have the producer sign them. If the producer has owned any registered sheep or goats, he or she must also sign a record release request for each registry.
- 8) Once the flock plan and PEMMP are signed, follow the steps outlined in *part VIII* for the plan selected and have a flock plan and PEMMP program and status entered in NSD.
  - 9) Determine whether each animal is a suspect, high-risk, scrapie positive, or low-risk exposed animal or a genetically susceptible, genetically less susceptible, or resistant exposed sheep. Sheep no longer in the flock that cannot be further designated due to insufficient information will be treated as genetically susceptible exposed animals until they are genotyped.
  - 10) Prepare an indemnity request.
  - 11) In consultation with the DSE, determine the likely date on which the premises was infected. In the case of infected flocks, it is the first date on which the infected animal could have lambed in the flock. In source flocks, it is the beginning of the lambing season 2 years before the positive animal was born. If the age of the positive cannot be determined from the records or estimated from examination of the teeth, the positive animal will be assumed to have been 48 months of age on the date samples were collected for scrapie testing.
  - 12) VS Form 5–19D, or an electronic equivalent, will be completed, and additional information, as listed in *part X*, will be collected for the epidemiological investigation report. Record all sales of animals after the date of infection including, when known, the tag numbers, brands, tattoos, and any other form of identification or identifying marks or characteristics including age, sex, breed, color, registration information, and the name and address of the person who acquired the animal. Document all steps. Provide this documentation, copies of all documents (either the completed epidemiological investigation report or the information needed to complete the epidemiological investigation report, as directed by the DSE), the signed original flock plan, the signed PEMMP, and the requests for registration records to the VS Area Office with a copy to the DSE.
- g. If the flock does not meet the definition of an infected or source flock, the Flock Under Investigation program in the database will be closed. If the flock meets the definition of a source or infected flock, the investigation program will be closed, and an infected or source program and status and a restriction will be opened in the database. All documents are to be attached to the flock record in SCS SCR.
5. Responsibilities of the DSE:
- a. Ensure that the VMO assigned to conduct an investigation understands the process.
  - b. Ensure that the deadlines listed in this section and in *part V.B* are met.
  - c. Review and approve the following:
    - 1) The status of flocks (**Note:** A flock's status must be designated within 15 days of notification that the flock contains or contained a scrapie-positive animal);
    - 2) Flock plans;
    - 3) PEMMPs;

- 4) Designation and redesignation of animals; and
  - 5) Release of exposed, infected, or source flock programs with the appropriate status.
- d. If the DSE believes that genetically less susceptible ewes should be restricted, the DSE must consult with the SAHO, the AVIC, and the SGHSE before taking action. With their concurrence, the DSE may require the restriction of some or all of the exposed QR ewes in the flock. The SGHSE must approve removal with indemnity. Following such a discussion, the DSE will prepare a memorandum giving the history of the flock, the decision, and the basis of the decision. Following review by all parties, the memorandum will be distributed to all States receiving traceout animals from the flock and will be posted on the [Scrapie SharePoint](#) site. (**Note:** If the codon 136 genotype of the positive animals cannot be determined, AVQR sheep may be removed at the discretion of the DSE with the owner's concurrence.)
  - e. Animals that meet the definition of high-risk or exposed animals and that also meet the definition of a low-risk exposed animal may be redesignated low-risk exposed animals by the DSE; or, in cases requiring a determination by the Administrator, the SGHSE will make the redesignation decision. (See definition of [low-risk exposed animal](#).)
  - f. If the DSE determines that additional testing is needed to designate the flock, the Flock Under Investigation program will remain open until testing is completed, and the flock will be tested as described in [part VII.G](#). (**Note:** The DSE may use this option only in cases where the SGHSE concurs that the scrapie exposure was minor or could not be confirmed.)
  - g. Review the NSD record to ensure that flock programs and statuses were accurately entered and released and animal designations and information were correctly entered.
  - h. Prepare or review indemnity requests for transmittal through the AVIC to the SGHSE.
  - i. Prepare or approve the epidemiological investigation report and summary for each infected, source, and exposed flock (see [part X](#)) and transmit them to the SGHSE.
6. Responsibilities of SGHSE for infected and source flocks:
    - a. Monitor States for compliance with Consistent State status requirements and take action to correct shortfalls.
    - b. Ensure that all DSEs in their area of responsibility are properly trained.
    - c. Review all epidemiological investigations for compliance with policy and maintain an electronic copy of the reports on the [Scrapie SharePoint](#) site for the national program staff.
    - d. Review and approve indemnity requests.
    - e. Identify animals to be moved to research facilities or sampled for developmental work or research.

## F. Procedures for Investigating and Monitoring a Flock that Received a High-Risk Animal

(See flowchart in Figure 1.)

1. The receiving VS Area Office will create a premises and flock record in the NSD if the flock has not already been entered. A “Flock Under Investigation (Sheep)” or “Flock Under Investigation (Goats)” Program must be opened with a relevant status (reason for the investigation). Trace forward investigations must be linked to the index case epidemiological case number using Activities. Any out-of-state traces and the outcome of the trace investigation will be entered in EMRS or other system determined by APHIS.
2. APHIS and SAHOs will notify their State or Federal counterpart.
3. The flock owner will be contacted by a State or Federal VMO.
  - a. The high-risk animals, any other animals required for testing as part of the investigation, and, when the SAHO determines the circumstances warrant it, the flock will be restricted by an authorized representative of the State. Animals may be released if all required testing has been completed and the results indicate the animals are not high-risk or scrapie-positive animals and that the flock is unlikely to be infected as determined by the DSE or SGHSE (see Table in VII.B for who can re-designate animals).
  - b. The VMO will give the owner information about scrapie. He or she will schedule a premises visit to examine the animal or animals and conduct an inventory and investigation as soon as possible but within 7 days of notification to the VS Area Office.
  - c. The owner will be advised to report immediately if the animal dies or is in danger of dying.
4. If the high-risk animal or animals traced to the flock can be positively identified and are present in the flock, they will be officially identified and:
  - a. High-risk sheep:
    - 1) Genotyped at codon 171 if exposure is not linked to an AV or VV positive sheep;
    - 2) Genotyped at both codon 171 and codon 136 if exposure is linked to an AV or VV positive sheep (see *part II.P* for genotyping procedures); or
    - 3) When the owner requests it, ewes may be indemnified and tested for scrapie at necropsy without genotyping to minimize the risk of exposing the flock to scrapie if there is a risk the exposed ewe will lamb before genotyping and disposal can be completed.
  - b. High-risk goats should be indemnified and tested at necropsy.
  - c. High-risk animals due to lamb should be isolated in an area that can be readily cleaned and disinfected until genotyping and necropsy and scrapie testing of ewes determined to be genetically susceptible animals is completed. Failure to isolate

such animals may be grounds for denial of indemnity for any animals later designated high-risk as a result.

5. Animals that meet the definition of genetically resistant exposed sheep, genetically less-susceptible exposed sheep, genetically susceptible exposed animals, or low-risk exposed sheep will be designated as such and may move only as allowed in *part II.N* of this document.
6. The presence of an exposed male animal or exposed wether in a flock will not affect the status of the flock. A PEMMP is not required for these flocks if the only exposed animals they received were male. Once this is verified, the investigation program is closed with the appropriate status. If the animal is a sexually intact genetically susceptible exposed male animal, it will be restricted to movement by permit only for destruction or research or, when requested by the owner, indemnified and destroyed. If retained, sexually intact genetically susceptible exposed male animals must be entered as restricted animals in CSC SCR and must be accounted for until they die and are tested.
7. The Flock Under Investigation program can be closed and no PEMMP is required if:
  - a. All female exposed animals traced to the flock can be positively identified and are present in the flock; and
  - b. All exposed female sheep that cannot be redesignated as genetically resistant exposed sheep or genetically less susceptible exposed sheep, all female offspring of a scrapie-positive female animal, and all high-risk goats are tested by IHC at necropsy and found negative on brain and lymphoid tissue.
8. A PEMMP is required for flocks that received high-risk female animals that could not be tested (missing or not identifiable) or that retain high-risk animals.
9. The Flock Under Investigation program will be closed, an exposed flock program will be opened, and a retained susceptible animal PEMMP will be done if a high-risk animal is retained.
  - a. The PEMMP will require:
    - 1) Permanent restriction of the high-risk animals.
    - 2) The immediate testing of all the genetically susceptible exposed female animals over 14 months of age, or when they reach 14 months of age, using a live animal test for scrapie. When the animal subsequently dies or is culled, it must be tested using brain and lymph node.
    - 3) All animals live animal tested must be identified with two official identification devices or methods before being tested. All retained high-risk animals must be identified with an official tattoo, RFID implant, or other official permanent identification to decrease the risk of their identity being lost over time.
    - 4) Animals that have an invalid test result such as insufficient follicles will be retested using a live animal test or necropsied and tested.
    - 5) Any animals that die at over 14 months of age or that have lambed will be

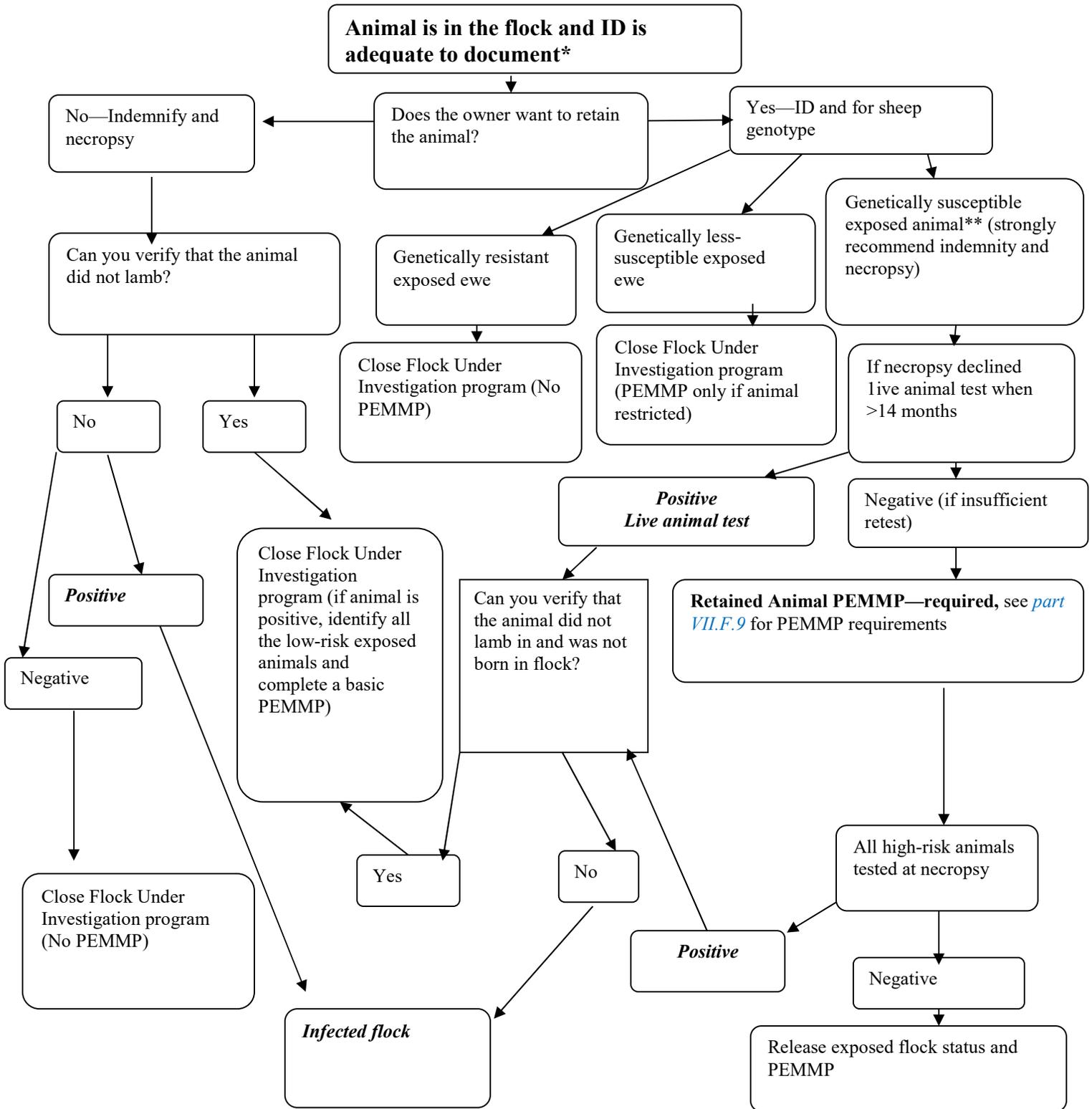
- necropsied and tested.
- 6) A negative live animal test before sale of any genetically susceptible female animal born in the same or subsequent lambing season that the high-risk animal lambled unless sent direct to slaughter. The test must be conducted after the animal is over 14 months of age.
  - 7) High-risk ewes will only be bred to rams that are RR at codon 171.
- b. These flocks will remain an exposed flock until the PEMMP is completed.
  - c. The PEMMP will remain in force until all high-risk animals have been tested for scrapie on brain and lymph node.
  - d. PEMMP formats are available on the [Scrapie SharePoint](#) site.
  - e. Failure to test as required will result in the flock being designated noncompliant with all genetically susceptible female animals restricted to movement to slaughter under permit only.
10. If high-risk female<sup>24</sup> animals that may have lambled in the flock (“may have lambled” refers to any ewe/doe old enough to lamb, unless it can be documented that she did not lamb) are no longer available (sold, died, cannot be positively identified, etc.):
- a. Their progeny and any birth cohorts of their progeny remaining in the flock, and when appropriate, subsequent lambing cohorts, will be genotyped if they are sheep. In cases where there are insufficient lambing cohorts to test, the SGHSE may approve testing of ewes or does present during the lambing seasons in which the missing ewes or does lambled. In cases where the high-risk animal is believed to be present but could be one of several animals, the SGHSE may approve genotype testing of these sheep, or if goats live animal testing or necropsy.
  - b. All goats and the QQ sheep in these groups, and, when appropriate, other susceptible animals over 14 months of age, will be tested by a live animal test or by necropsy testing of obex and lymph node. Additionally, all animals that are live animal tested must be identified with two official identification devices or methods to decrease the risk of their identity being lost over time. After reviewing the results of the initial test, the DSE will determine whether additional testing is required and the type of PEMMP that will be used. The decision will be based on the number and percent of valid tests, the infection rate and genotype distribution in the source flock, the genotype of the positive sheep, if known, and the number of high-risk animals missing. The flock will remain in Flock Under Investigation program status until all animals required for testing have been tested (see Figure 1). Once testing is completed, the Flock Under Investigation program will be closed.
- Note:** Necropsy testing with indemnity must be approved by the SGHSE; see *14* for approval criteria.
- c. All animals required for testing will be restricted until testing is completed.

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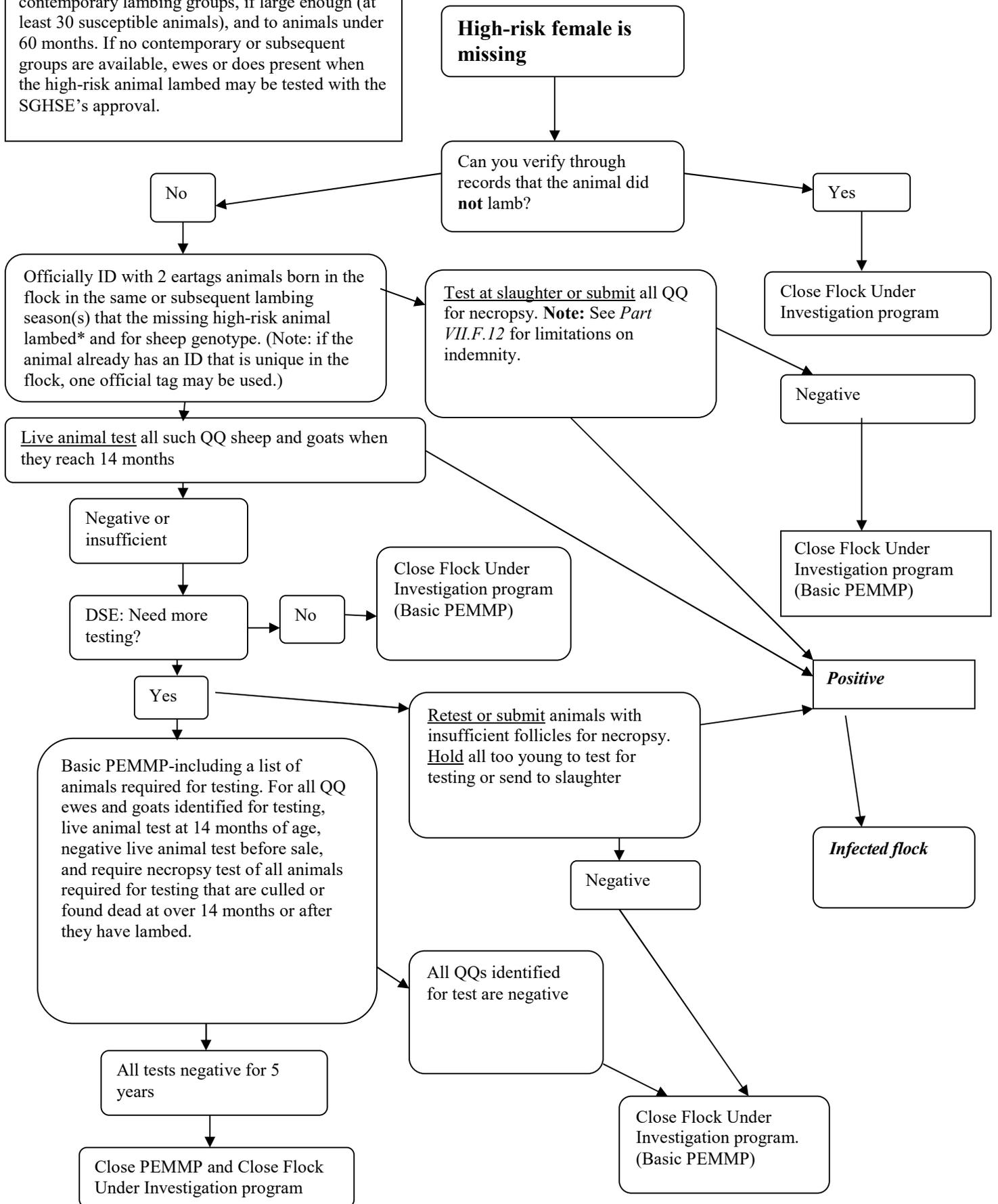
<sup>24</sup> If based on an epidemiological investigation the risk is determined to be very low, and with the concurrence of the SGHSE, AD, and the SAHO, the DSE may determine that a flock with a missing high-risk ewe does not require further flock testing.

\* If ID is not adequate, use animal missing flowchart.  
 \*\* Apply official yellow metal tag

**Figure 1—Trace High-Risk Female Animals**



\*These sheep/goats may be limited to contemporary lambing groups, if large enough (at least 30 susceptible animals), and to animals under 60 months. If no contemporary or subsequent groups are available, ewes or does present when the high-risk animal lambed may be tested with the SGHSE's approval.



11. If testing is done, a test submission will be created in VSLS. Individual records will be made in the NSD for each tested, genotyped, exposed, and high-risk animal. The exposed and high-risk animals and any other animals required for testing must be restricted until the testing is completed and the flock and individual animal statuses are determined. All animals determined to be high-risk or exposed must be maintained on the premises unless redesignated or moved in accordance with 9 CFR part 79.
12. The following animals, which are required to be tested for scrapie, may be indemnified and tested at necropsy when funds are available and with the concurrence of the owner and the SGHSE:
  - a. Sheep with insufficient follicles to test (**Note:** in the case of high-value sheep, two attempts should be made to collect biopsies.).
  - b. Sheep designated for testing in cases in which the sheep are under 1 year of age (too young to test by live animal test) and the owner does not want to retain the sheep until they are old enough to test. Tissues collected on these animals must include Peyer's patches in addition to the standard tissue set.
  - c. Sheep when it is cost effective due to their low value.
  - d. All genetically susceptible female animals in a highly exposed flock when recommended by the DSE and approved by the AVIC, the SGHSE or National Scrapie Program Coordinator, and the SAHO;
  - e. Any suspect animal; and
  - f. Goats.

**Note:** Indemnity is not available for animals subsequently required to be tested because the owner elected to retain a genetically susceptible exposed animal.

13. Owners of flocks under investigation or exposed flocks who do not make animals available for testing or do not comply with a PEMMP will have their flocks designated as noncompliant flocks.
14. The DSE must provide a monthly report to the SGHSE detailing the status of, and final disposition of, all high-risk animals traced to the State as part of the monthly Epidemiology and Compliance Report. The SGHSE will make these reports available to the national program scrapie staff through the [Scrapie SharePoint](#) site.

**Note:** All NSD flock program and status information should be entered within 1 week and individual animal information within 3 weeks of the DSE's designation.

#### **G. Testing a Flock Pending Designation as a Source or Infected Flock to Determine Whether the Flock is Infected**

1. Flocks are typically designated as source or infected flocks based on meeting the applicable definitions. In cases where the DSE, with the concurrence of the SGHSE for the States involved and the National Scrapie Program Coordinator, determines there is significant doubt as to whether a flock that is pending designation as a source

- or infected flock is currently infected, the flock may be tested to determine whether the flock should be designated as a source or infected flock. Such flocks not designated source or infected flocks will be placed on PEMMPs.
2. When the potential exposure to a flock was the result of a purchased positive female animal possibly lambing in the flock, genetically susceptible animals born after the positive animal might have lambed and female animals present during the lambing seasons in which the positive female animal resided on the premises will be tested first. Such female animals must be tested at least 18 months after the last possible lambing of the infected animal and at over 14 months of age.
  3. To detect disease at 1 percent prevalence with 95 percent confidence by IHC of the third eyelid or rectal mucosa or by necropsy, it is necessary to test, at a minimum, specific numbers of genetically susceptible animals depending on overall flock size. Table 2 provides the number of animals to test for various flock sizes. Sheep that are not of the QQ genotype may be tested only by necropsy. The number of valid diagnostic samples required is the same as the number of necropsies required when necropsy is used instead of live animal testing. Due to a 10 percent average non-testable rate when conducting the live-animal test, 10 percent more animals have been added to each sample size. Use rectal biopsy unless multiple samples did not yield a valid result.

**Table 2—Determining the Number of Animals to Test**

<b>Number of goats* and QQ sheep greater than 14 months in the flock</b>	<b>Number of valid results required**</b>	<b>Estimated number of animals to sample using rectal biopsy to achieve the required number of valid results</b>
<215	All***	All
215-300	217	237
301-400	239	263
401-500	256	282
501-1,000	293	322

\* Goats may be tested by necropsy or rectal biopsy; if rectal biopsy is used, all goats should be tested due to lower apparent sensitivity of the test in goats.

\*\*If needed to achieve the required number of valid tests, retest using a live test, test additional animals not previously tested, or necropsy animals that have invalid live animal test results.

\*\*\* Sensitivity = 87 percent for sheep and specificity = 100 percent are assumed for sheep. The confidence level in small flocks (fewer than 300) will be less than 95 percent.

## Part VIII: Flock Cleanup Plans and PEMMPs

### A. Movement Restrictions on Animals in Flocks on a Flock Plan or PEMMP

*See part II.N of these standards and the standard APHIS flock plan formats.*

### B. Requirements for Flock Plans and Post Exposure Management and Monitoring Plans (PEMMPs)

1. The VMO will prepare a flock plan and PEMMP using the standard plan formats posted on the [Scrapie SharePoint](#) site. The species and genotype of the positive animal and the epidemiology of the flock will determine the types of flock plan the VMO may offer the producer. The PEMMP selected will be determined based on whether the owner retains any high-risk animals. If no high-risk animals are retained, use a basic PEMMP. If genetically susceptible exposed female animals are retained, use a retained susceptible animal Flock Plan and PEMMP. If a flock does not retain genetically susceptible exposed female animals but does retain other animals required for testing or genetically susceptible exposed male animals, use a basic PEMMP with an attachment listing all animals required for testing and the type of tests required. The attachment should also list when the test is required and contain a separate list of the genetically susceptible exposed restricted male animals. The list must include the official ID, age, sex, and breed or face color. For flocks with animals exposed only to Nor98-like scrapie, a flock plan is not required and the PEMMP will be limited to officially identifying all sexually intact animals before change of ownership or movement off the premises, reporting of suspect animals, and submission of mature animals found dead.
2. When a flock plan requires an animal to be destroyed, the SGHSE must approve the indemnity and determine if the animal is needed for research or developmental projects.
3. Types of flock plans: Genetics-based flock plans and whole flock depopulation flock plans:
  - a. **Genetics-Based Flock Plans – General guidelines.** (See step-by-step instructions in 3.b for standard genetic plan.)
    - 1) A genetic plan is preferred for most flocks. When using a genetics-based flock cleanup plan, in most cases owners can retain or sell RR sheep, QR rams, and most QR ewes without restriction. Indemnity, if available, will be provided for animals removed as part of a flock plan.
    - 2) Genetics-based plans require removing all of the following animals:
      - a) All genetically susceptible exposed female animals<sup>25</sup>;

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<sup>25</sup> There is evidence that genetic resistance to scrapie may exist in goats similar to sheep, with a similar level of certainty as genetic resistance in sheep when it was first piloted by APHIS for flock cleanup in sheep. APHIS may pilot the use of genetic resistance in goats to determine the designation of scrapie-exposed goats as part of a herd cleanup plan.

- b) All test positive and suspect animals; and
  - c) All female offspring of positive female animals (regardless of genotype, unless the genotype proves it could not be the offspring of the positive animal).
- 3) Owners should be advised that exposed QQ rams and bucks are unlikely to transmit scrapie and exposed QR sheep are unlikely to either contract or transmit scrapie. However, retaining QQ rams for breeding will increase the risk of scrapie recurrence by increasing the genetic susceptibility of their offspring to any residual environmental contamination.
  - 4) APHIS encourages removing exposed QQ rams and bucks and strongly encourages removing AVQQ and VVQQ rams, due to their increased susceptibility, but does not require it. These animals may be removed at the owner's request. Exposed QQ rams and buck goats not removed may only move for destruction on a permit.
  - 5) Animals not designated genetically susceptible exposed animals may also be removed when requested by the SGHSE and when agreed to by the owner to provide animals or tissues for study.
  - 6) Any animals removed may qualify for indemnity. These animals must be euthanized or moved to a quarantine facility for research. Slaughter may not be used to dispose of indemnified animals and the carcass may not be used for human or animal food.
  - 7) Confirmed genetically resistant and genetically less susceptible exposed sheep and low-risk exposed animals may be retained or sold without restriction after they have been officially identified as described in 10, and entered in the NSD.
  - 8) Flocks whose owners complete a flock plan where all genetically susceptible exposed female animals are removed will not be considered exposed flocks.
  - 9) In unusual cases where producers need to keep genetically susceptible exposed ewes, a genetics-based flock plan that includes live animal testing and genetic selection will be used.
  - 10) Exposed animals will be identified with an official tamper-evident/resistant eartag, and if a suitable secondary ID is not already in place another official identification device will be added to prevent loss of identity while the flock plan is being completed.
    - a) The eartag number and the genotype will be recorded in the NSD.
    - b) High-risk animals and sexually intact genetically susceptible exposed male animals that are not removed will also be identified with electronic implants, official tattoos, or another form of permanent official ID and a yellow metal restricted animal tag to ensure that the animal can be accounted for until submitted for necropsy testing.
  - 11) Flocks where all genetically susceptible exposed female animals are not removed will be designated as exposed flocks. Accordingly, until the PEMMP is completed, these flocks will have movement restrictions placed on these animals and all other genetically susceptible female animals (and in some cases less susceptible female animals) residing in the flock, including such animals born or brought into the flock. During the annual PEMMP inspection

these animals must be accounted for and live animal tested for scrapie and the genotype of the rams verified by reconciliation of their official ID and the test charts. Flocks not in compliance with the requirements of a retained susceptible animal PEMMP will be placed in infected flock program with the appropriate status until all high-risk animals have been removed and tested.

**Note:** Flocks that retain test positive, suspect animals, or genetically susceptible exposed female animals that do not have a “not detected” result on a live animal test will remain infected or source flocks until these animals are removed.

12) *Steps for completing a standard genetic based flock plan for source and infected flocks that retain only QR, HR, KR, and RR ewes and male sheep and male goats:*

- a) Complete the flock plan and PEMMP agreements labeled “For Source and Infected Flocks that Retain Only QR, HR, and RR Ewes and Male Sheep and Male Goats” posted on the [Scrapie SharePoint](#) site. Have the completed form reviewed by the DSE and then have the owner sign both forms.
- b) Request authorization to submit blood for genotyping. (See instructions in [part II.O](#) and on the [Scrapie SharePoint](#) site.)
- c) Bleed all sexually intact sheep for genotyping and send blood to the authorized APHIS contract genotyping laboratory. Request codon 171 testing on all sheep unless instructed otherwise. Do not genotype goats. All genotype submissions must be entered in VSLs.
- d) Designate all animals in the flock as suspects, genetically susceptible exposed animals, genetically less susceptible exposed animals, genetically resistant exposed sheep, high-risk animals (high-risk includes female genetically susceptible exposed animals, female offspring of positive female animals, and suspect animals), or low-risk exposed animals. Some animals will have multiple designations.
- e) Have the DSE review and approve the designations.
- f) Provide an estimate of indemnity and disposal costs through the AVIC to the SGHSE for the State involved in the format provided.
- g) Work with the DSE and AVIC to develop a necropsy (see necropsy instructions on the [Scrapie SharePoint](#) site) and disposal plan.
- h) Complete an indemnity request that includes the following:
  - All suspect and high-risk animals;
  - When agreed to by the owner, male genetically susceptible animals; and
  - Any other animals required to be removed by the flock plan.
 Have the AVIC review and approve the request and forward it to the SGHSE and copy [Scrapie@USDA.gov](mailto:Scrapie@USDA.gov), along with a preliminary epidemiological investigation report as described in [part X](#) providing whatever information is known as of the request date.
- i) Complete an indemnity form (VS Form 1–23) that includes:
  - All suspect and high-risk animals;

- Male genetically susceptible exposed animals, when agreed to by the owner; and
- Any other animals required to be removed by the flock plan.

The owner must complete the form and he or she, or a legal representative, must sign it before depopulating the animals. Animals moved for destruction must move on a VS Form 1-27 or State equivalent.

Depopulate and necropsy indemnified animals. In most cases, all animals over 14 months of age should be sampled for scrapie testing as described in the necropsy protocol posted on the [Scrapie SharePoint](#) site. When a large number of animals is involved and it is not practical to sample them all, with concurrence of the SGHSE an appropriate statistical sample may be taken. In addition, all test positive and suspect animals of any age, any high-risk QR or RR animals, female offspring of positive female animals, and any animals that may implicate another flock that are destroyed at over 14 months of age as evidenced by eruption of the first incisor must be sampled. The AVIC must review and approve VS Form 1-23, and must forward a copy to the SGHSE and copy [Scrapie@USDA.gov](mailto:Scrapie@USDA.gov).

- j) Request authorization to submit blood from the remaining sexually intact sheep at another contract laboratory to confirm the result at codon 171 and, when indicated, codon 136. **Note:** If female genetically susceptible exposed animals are retained, the retained susceptible animal Flock Plan and PEMMP must be used (which has additional requirements). High-risk animals and sexually intact genetically susceptible exposed male animals not removed are identified with EIDs, or another form of permanent official ID such as an official tattoo, and a yellow restricted animal metal tag. In most cases, this should be done at the same time the second bleeding is done.
- k) Owners should be encouraged to include the use of RR rams as part of the PEMMP. As long as funds are available APHIS will provide genotyping for sire rams when this provision is a part of a PEMMP. PEMMPs for flocks where infection has recurred in animals born on the premises after a previous flock plan was completed will include the requirement to use only RR rams unless the breed of sheep involved makes this impractical.
  - l) Observe and document cleaning and disinfection of premises.
  - m) If the owner has signed the PEMMP and the previous steps have been completed, release infected or source flock program with an appropriate status.
- b. *Whole-Flock Depopulation Flock Plan:* Whole-flock depopulation (removal of all sexually intact animals) may be used when recommended by the DSE and with the concurrence of the owner, AVIC, SAHO, and the SGHSE or National Scrapie Program Coordinator. Such concurrence will be based on the availability of funds

and whether a particular depopulation will enhance scrapie eradication. The DSE should recommend whole-flock depopulation for further consideration for:

- 1) Flocks for which the cost of depopulation is less than the cost of conducting another type of flock plan and PEMMP;
  - 2) Any flock in which an RR sheep is determined to be infected with classical scrapie;
  - 3) Goat herds;
  - 4) Flocks where infection has recurred in animals born on the premises after a flock plan was completed and where the owner agrees not to restock with sheep or goats on the premises for at least 5 years; and
  - 5) When requested by the owner, when the owner agrees not to restock with sheep or goats on the premises for at least 5 years.
4. The DSE must review and approve the flock plan and the PEMMP.
- a. The PEMMP may include enrollment in the SFCP with the subsequent requirements for exposed flocks. The flock plan, the PEMMP and, when it is a part of the PEMMP, the SFCP application, must be signed by the flock owner and a State representative and/or an APHIS official (this depends on the delegation of duties within the State).
  - b. A flock plan program and status will be entered in the NSD. Being in a flock plan program means that a flock plan and PEMMP have been signed and the owner is in compliance with the plans.
  - c. All high-risk, exposed, suspect animals, and all animals under a plan will also be entered in the NSD animal inventory, including the genotype of all exposed sheep and any other testing.
  - d. If the infected animal was not born in and did not lamb in the flock, cleaning and disinfection can be waived.
5. Before releasing the flock's plan and infected or source programs<sup>26</sup> in SCS SCR, a VMO must verify completion of the flock plan requirements through an inspection, inventory, and records review, and the PEMMP must be signed. In general the PEMMP should be signed at the same time as the flock plan so that the owner knows what he or she is agreeing to up front. On verification, some or all of the movement restrictions may be removed and the flock's plan and infected or source programs in SCS SCR will be closed. Any remaining movement restrictions must be documented in the PEMMP and in SCS SCR. Restrictions are removed from animals in SCS SCR that are not high-risk animals, animals required for test, or genetically susceptible exposed intact male animals. Restrictions will remain on any high-risk animals and any retained sexually intact genetically susceptible male animals throughout their lives and on animals required for test until testing is completed. A PEMMP program and status will be entered.
6. Actions required during a PEMMP inspection.
- a. Animal inspection and inventory
    - 1) Inspection.

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<sup>26</sup> Programs in SCS SCR are equivalent to the former Animal Health and Surveillance Management statuses.

- a) Inspect all animals currently in the flock for signs of scrapie.
  - b) Confirm with the owner that all animals exhibiting signs of scrapie or found dead at over 14 months of age were reported in a timely manner to the State or VS Area Office (if any such animals were not reported, notify the DSE immediately).
- 2) Inventory.
- a) Perform a head count of the mature and immature animals present in the flock or herd, and reconcile the count with the numbers from the previous year. If the head counts do not reconcile with the records of animals disposed of and acquired, or there is any other reason the inspector believes that the flock records are not being accurately maintained or that dead animals are not being recorded, or animals that require official ID are not officially identified, the inspector will do an individual animal inventory and ensure that the animals that require official ID are identified. If the inventory indicates noncompliance notify the DSE immediately. The inspector will attach the complete inventory to the inspection report noting any discrepancies with the flock or tagging records, animals identified during the inspection, and any evidence that found dead animals were not sampled.
  - b) If the flock is on a PEMMP that allowed the owner to retain high risk animals, confirm the status of each retained high-risk animal. If any are missing or cannot be accounted for (e.g., died, sold, or missing without scrapie testing), notify the DSE immediately.
- b. Records review (see VS Form 5-19C, *Scrapie PEMMP Inspection Report*, for the information to be reviewed).
  - c. Confirm that the producer has additional identification devices available for additions to the flock or herd. If none are available, assist the producer with obtaining them to ensure additions are properly identified.
  - d. Complete VS Form 5-19C, *Scrapie PEMMP Inspection Report*, or equivalent State form, have the owner sign the form, and turn in the signed form to the DSE within 30 days of the inspection.

## Part IX: Diagnostic Laboratory Approval Procedures and Test Interpretation

Laboratories and diagnostic tests will be approved in accordance with 9 CFR 54.11 and applicable appendices of these standards.<sup>27</sup>

NVSL will do confirmatory testing on all tissues with suspect (presumptive positive) or repeat (inconclusive) results generated by other laboratories on regulatory and surveillance samples.

## Part X: Reports

Reports will be made in accordance with the following:

### A. Epidemiological Investigation Report

1. Purpose of the Report: The VMO or DSE prepares the epidemiological report and the DSE uses it to determine which animals are designated high-risk or exposed, which animals will be redesignated, and which other flocks may be exposed, infected, or source flocks.
2. Data Source: The information required for the epidemiological report may be gathered using VS Forms 5-19D, 5-20, and 5-18, or the equivalent information may be submitted in Microsoft Word or Excel.
3. Protocol: The report will include the information listed below.
  - a. *Information about the owners:*
    - 1) Name; and
    - 2) Address (mailing and physical address, including county, and, where applicable township, section, and/or GPS coordinates).
  - b. *Information about the positive animals, including:*
    - 1) Date and place of birth or approximate age if date of birth is unknown;
    - 2) Sex, species, and breed or cross (if breed or cross is unknown, for sheep the face color and for goats the use ([dairy, meat or fiber]));
    - 3) Official identification, any other identification, and any distinguishing marks or features;
    - 4) Date of death;
    - 5) Genotype at codons 112, 136, 141, 154, and 171;
    - 6) All flocks in which the animal has resided, the dates during which the animal resided on each premises, and whether the animal lambed or may have lambed on any of the premises and the date of each lambing; and

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<sup>27</sup> See [Appendix A](#): Approval of Laboratories to Conduct Official Genotype Tests in Sheep, [Appendix B](#): Approval of Laboratories to Conduct Official Diagnostic Tests for Scrapie in Sheep and Goats, and [Appendix C](#): Program Approval of Diagnostic Tests for Scrapie in Sheep and Goats.

- 7) Results of all scrapie tests conducted and the information listed above for any additional positive animals.
- c. *Information about the flock, including:*
- 1) Address (mailing and physical address, including county, and, where applicable township, section, and/or GPS coordinates);
  - 2) An inventory of sheep and goats owned at the time of the first visit and any animals added before completion of the flock plan (inventory will include all identification numbers and marks; sex; breed; flock of origin if different; date of acquisition; date of birth or approximate age; genotype; if done, live animal test results; the designation of each animal; whether the animal will be indemnified, otherwise disposed of, or retained; any restrictions on animals not to be indemnified; and whether the animal was a part of any distinct group that would affect its exposure risk, such as offspring of a female positive animal, twin of a positive, and maintained in a separate group);
  - 3) An inventory of animals that have left the premises since the date of introduction of infection to the premises as determined by the DSE, or a date 2 years before the birth of the oldest scrapie-positive animal born in the flock will be used. If the actual birth date is unknown, the date of birth will be estimated based on examination of the teeth and any available records. If an age estimate cannot be made, the animal will be assumed to have been 4 years of age on the date samples were collected for scrapie diagnosis. The inventory will include all information required in 2) and the date the animal left the premises; the name and address of the person who acquired the animal or a statement that the animal died on the premises and any other information that would allow the animal to be traced; and whether the animal is an exposed or high-risk animal.;
  - 4) Movements of animals into the flock, including the date acquired; name and address of the previous owner; all ID numbers and marks; sex, breed, and flock of origin if different; date of acquisition; date of birth or approximate age; genotype and live animal test results if available; and whether the flock of origin has any record of scrapie infection or exposure;
  - 5) The animals required to be removed and the test results at necropsy will be added to the report when available;
  - 6) Whether any QR animals will be required to be removed or restricted specifying which ones and why;
  - 7) The management and health history of the flock; and
  - 8) A copy of the proposed flock plan and PEMMP.
- d. The epidemiological report will be provided to the DSE for review. The DSE will determine the status of the flock and review and approve the designation of the animals in the flock.
- e. The DSE will send interim summary reports to the SGHSE, including the request for indemnity and a monthly update provided by the 15th of the following month, until the complete report is provided.
- f. A summary of the epidemiological report, a copy of the full epidemiological report, and a copy of the completed VS Form 1-23 will be provided to the SGHSE by the DSE within 14 days of completing the flock plan (see the [Scrapie](#)

[SharePoint](#) site for the summary report format). The SGHSE will make these reports available to the NSEP staff through the [Scrapie SharePoint](#) site.

## **B. Monthly Epidemiology and Compliance Report**

1. Purpose: The monthly epidemiology and compliance report provides a summary of epidemiological and compliance information.
2. Data source: VS and State reports and the NSD.
3. Protocol: The DSE will use the epidemiology and compliance report template available on the [Scrapie SharePoint](#) site. The report will be electronically submitted monthly or quarterly, within 30 days of the end of the month or quarter, as instructed by the SGHSE based on the level of activity in the State. The SGHSE will then electronically submit the report to the National Scrapie Program Coordinator. The report must summarize the following information for the current fiscal year to date:
  - a. Sheep investigations;
  - b. Goat investigations;
  - c. Infected and source flock data;
  - d. Positive animals data;
  - e. Out of State traces; and
  - f. ID compliance at slaughter establishments, markets, and other sheep and goat concentration points.

## **C. End-of-Year Epidemiology and Compliance Report**

1. Purpose: The end-of-year epidemiology and compliance report accompanies the annual VS Form 5-24 (see *section D*). It provides summary epidemiological and compliance information.
2. Data source: VS and State reports and the NSD.
3. Protocol: The DSE will use the epidemiology and compliance report template available on the [Scrapie SharePoint](#) site. The report must summarize the following information for the fiscal year covered in the accompanying VS Form 5-24:
  - a. Sheep investigations;
  - b. Goat investigations;
  - c. Infected and source flock data;
  - d. Positive animals data;
  - e. Out of State traces; and
  - f. ID compliance at slaughter establishments, markets, and other sheep and goat concentration points.

**D. VS Form 5-24, Application for Scrapie Classification, Classification Renewal, or Reclassification of a State**

1. Purpose: VS Form 5-24 is the application for annual classification, classification renewal, or reclassification of a State for national scrapie status recognition as a Consistent State.
2. Data source: VS and State reports and the NSD.
3. Protocol:
  - a. *VS Area Office.* The VS Area Office must file a completed VS Form 5-24 application and a complete epidemiology and compliance summary for the fiscal year using the spreadsheet template provided on the [Scrapie SharePoint](#) site or equivalent for each State annually. Any State not meeting surveillance or identification compliance minimums must also submit an action plan and timeline for correcting the deficiency. The completed VS Form 5-24 and report must be submitted to the SGHSE by January 15 for the preceding fiscal year. The application must be signed by both the SAHO and AVIC. (Refer to the [Scrapie SharePoint](#) site for instructions.)
  - b. *National.* The SGHSE will review the VS Form 5-24 applications, the epidemiology and compliance spreadsheet, and when required an action plan from the States in his or her area of responsibility for completeness to determine if the State or States meet the requirements in both 9 CFR 79.6 and these standards, and forward them with a recommendation for approval, provisional approval, or disapproval to the National Scrapie Program Coordinator within 30 days of receipt. The National Scrapie Program Coordinator will approve, provisionally approve, or disapprove all VS Form 5-24 applications based on the recommendations of the SGHSE and the submitted application package within 30 days of receipt. The National Scrapie Program Coordinator will inform the SAHO of any proposed change in status by letter with copies to the District Director, SGHSE, and AVIC. In cases where a change in status is proposed, the National Scrapie Program Coordinator will provide a copy of the application and proposed action to the Scrapie Committee of the United States Animal Health Association for information and comment. APHIS will publish notice of changes and provide opportunity for public comment through the *Federal Register*.

## Appendix A: Approval of Laboratories to Conduct Official Genotype Tests

### A. Background

Genotype testing for susceptibility to scrapie is a key element of the NSEP. Resources to conduct large-scale genotype testing to fulfill the needs of this program are not available at NVSL. The regulations at 9 CFR 54.11 provide guidelines for approving laboratories to conduct official genotype testing for program purposes. This appendix describes the requirements for laboratories requesting such approval and the procedures for APHIS units to follow when responding to such requests.

### B. Laboratory Responsibilities

1. All initial requests for a laboratory approval should be made in writing to the NVSL Director. A laboratory may request approval to conduct one or more types of genotype tests on one or more types of tissue.
2. Application package: Once an initial request for approval is submitted to the NVSL Director, NVSL will send a copy of this appendix to the laboratory. A laboratory must send the NVSL Director an application package electronically in pdf format (or other format acceptable to NVSL) containing the information listed below.
  - a. Name and address of the laboratory;
  - b. Name of the legally responsible official and, if different, the director of the laboratory;
  - c. A description of the laboratory facilities and equipment that will be used in performing genotype tests;
  - d. A list of the types of samples that will be tested;
  - e. The SOP for each test to be used, including methods, materials, equipment, and other relevant information;
  - f. A list of the names of individuals performing specific tests and a detailed statement of each individual's qualifications;
  - g. A detailed description of the procedures used to satisfy the recordkeeping requirements of the NSEP. (**Note:** To satisfy these requirements, the approved laboratory must retain records of all tests performed and all DNA samples for 5 years.);
  - h. A description of the specific procedures used for reporting test results. (**Note:** The results must be reported to the person submitting the sample, as well as to persons designated by NVSL, within 2 working days of completing the test.);
  - i. The laboratory quality assurance manual; and
  - j. A statement authorizing APHIS to inspect the laboratory, without prior notice, during normal business hours. The inspection may include, but is not limited to, reviewing and copying records, observing tests, and interviewing personnel.

### C. NVSL and National Scrapie Program Coordinator Responsibilities

1. On receiving a request for laboratory approval, the NVSL Director will inform the National Scrapie Program Coordinator, the District Director, and the AVIC.
2. The NVSL Director will provide the requesting laboratory a copy of this appendix and discuss the requirements for laboratory approval with the laboratory director or other appropriate individuals.
3. On receiving an application package (see *B.2*), authorized NVSL personnel will review the package to ensure satisfactory completion. If the application package is determined to be deficient, it will be returned to the laboratory with a statement giving the reasons for denying approval, and inviting the laboratory to remedy the deficiencies and resubmit the package.
4. After receiving a satisfactory application package (see *B.2*), authorized NVSL personnel will schedule and conduct a site visit. An authorized NVSL employee will inform the District Director and the AVIC of the site visit. During the site visit, authorized NVSL personnel will again review the requirements for laboratory approval, review the test procedures the laboratory intends to use, and confirm the information in the application package is correct.
5. If the application process is satisfactory, the National Scrapie Program Coordinator (or designee) will notify the director of the laboratory requesting approval that the laboratory will be approved to conduct the specific tests listed in the package, provided the laboratory:
  - a. Satisfactorily completes laboratory proficiency testing; and
  - b. Demonstrates the ability to electronically receive a submission and transmit a sample set of results in the prescribed format as specified by APHIS, and to enter data and results into the VSLS system from hard copy forms.
    - 1) APHIS contract laboratories may be required to demonstrate receipt of electronic test charts, entry of results in the appropriate fields of the submission files, and transmittal of the resulting file to VSLS. APHIS contract laboratories would also need to receive and process Web submissions and hard copy forms and transmit the results to or enter the results in VSLS.
    - 2) Approved laboratories that are not contract laboratories will have the option of entering the results through a Web page rather than using electronic messaging.

**Note:** Nearly all Federal and State funded program specimens will be submitted in VSLS. Privately funded official program-approved testing specimens will, for the most part, continue to be submitted using hard copies of VS Form 5-29. This will require the genotyping laboratory to enter all the information supplied on the submitted VS 5-29 into VSLS. This reporting system is not used for unofficial privately funded testing.

6. If the laboratory proficiency testing is unsatisfactory, the NVSL Director will indicate the deficiencies in writing and send this information to the laboratory director requesting approval and to the National Scrapie Program Coordinator. The laboratory must submit a report detailing the cause of the error and the steps implemented to prevent a recurrence to reapply for approval. Those steps must be incorporated into the relevant documents that make up the application package. A corrected application package in pdf format (or other format acceptable to NVSL), must be submitted electronically to the NVSL Director, and a copy forwarded to the National Scrapie Program Coordinator. If the report and the corrected package are satisfactory, the laboratory may repeat the proficiency testing.

#### **D. Changes to Laboratory Approval**

1. A laboratory must notify NVSL of any changes in the information contained in the application package (see *B.2*). Amendments to the package must be submitted to NVSL electronically in pdf format (or other format acceptable to NVSL)).
2. The amendments will be reviewed for approval as in *section B* of this appendix.
3. NVSL may elect to forgo conducting a new site visit or requiring additional proficiency testing.

#### **E. Maintaining Laboratory Approval**

1. Laboratory proficiency tests. To maintain approval, laboratories are required annually to demonstrate satisfactory completion of proficiency tests (or as deemed necessary by NVSL). Proficiency test results will be forwarded to the National Scrapie Program Coordinator by NVSL.
2. Annual inspections. To maintain approval, laboratories will undergo inspections by NVSL or a designee annually or as deemed necessary by NVSL. Among other items, the inspector will review:
  - a. Records;
  - b. Maintaining of archival samples;
  - c. Compliance with standard operating procedures; and
  - d. Compliance with 9 CFR and this appendix.

#### **F. Removal of Laboratory Approval**

1. The NVSL Director may withdraw or suspend approval of a laboratory for any of the reasons listed below.
  - a. Failure to meet any of the conditions stated in this appendix (9 CFR 54.11).
  - b. One or more criteria for approval or for maintaining approval are no longer being met.
  - c. Submission by the approved laboratory of a request for withdrawing approval.

- d. Unsatisfactory performance on required proficiency tests or on regular samples submitted for testing.
  - e. Unsatisfactory conditions or procedures at the laboratory.
  - f. Failure to accurately input test data and report results electronically as required.
2. The NVSL Director will give written notice of a suspension or a proposed withdrawal to the director of the laboratory and will give the director an opportunity to respond. Any conflicts concerning the reasons for withdrawal will be resolved by holding a hearing.

## **G. List of Approved Laboratories**

The National Scrapie Program Coordinator will maintain a list of laboratories approved to conduct official genotype tests for scrapie. The list is publicly available [here](#).<sup>28</sup>

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<sup>28</sup> [https://www.aphis.usda.gov/animal\\_health/nahln/downloads/scrapie\\_lab\\_list.pdf](https://www.aphis.usda.gov/animal_health/nahln/downloads/scrapie_lab_list.pdf).

## **Appendix B: Approval of Laboratories to Conduct Official Program-Approved Diagnostic Tests for Scrapie in Sheep and Goats**

### **A. Purpose**

Following are the procedures for approval of laboratories to conduct diagnostic tests for scrapie in accordance with 9 CFR 54.11.

### **B. Definitions**

1. Official test:

A program-approved test for the diagnosis of scrapie conducted at a laboratory approved by VS to conduct the test, NVSL, or another laboratory to which NVSL has referred a case for confirmatory testing.

2. Program-approved test:

A test kit or test method for the diagnosis of scrapie in a live or dead animal approved for use in the NSEP or the SFCP or both in accordance with 9 CFR 54.10, or that was approved by APHIS for the diagnosis of scrapie before September 20, 2001.

3. Confirmatory test:

A test for the diagnosis of scrapie in a live or dead animal; conducted by NVSL or a laboratory to which NVSL has referred a case for such testing. Confirmatory testing may include any of the following methods, used alone or in combination: immunohistochemistry (IHC); Western Blot; histopathology; enzyme immunoassay/enzyme-linked immunosorbent assay (EIA/ELISA) test, if different from the EIA/ELISA test originally performed on the sample and the results are in agreement; or animal inoculation studies (i.e., bioassay). The results of a confirmatory test may be used to designate an animal in accordance with 9 CFR 79.4.

### **C. General**

1. Only State, Federal, and university laboratories (as required in 9 CFR 54.11) that are also members of the National Animal Health Laboratory Network (NAHLN) will be approved to conduct official scrapie diagnostic testing.
2. Only program-approved tests conducted in approved laboratories, at NVSL, or at another laboratory to which NVSL has referred a case for confirmatory testing, are considered to be official diagnostic tests for scrapie.
3. The approved laboratory must submit all specimens with an initial positive, suspect, repeat, or inconclusive test result, and all specimens from clinically suspect animals to NVSL for confirmation within 5 business days.

4. Repeat or additional testing is the preferred method for confirming an initial positive or inconclusive test result. NVSL may, however, confirm an initial positive or inconclusive test result based on the review of slides from an IHC test or a developed Western blot if appropriate tissues or tissue blocks are not available or are not suitable for repeat or additional testing.

#### **D. Laboratory Approval**

1. General:
  - a. Requests for laboratory approval should be made in writing to the NAHLN program office at [NAHLN@aphis.usda.gov](mailto:NAHLN@aphis.usda.gov). After the NAHLN program office receives an initial request for approval, staff will provide a copy of the NAHLN Laboratory Qualification Checklist for Membership of a Veterinary Diagnostic Laboratory.
  - b. Participation is contingent on approval from the NAHLN Coordinator, National Scrapie Program Coordinator, and NVSL Reference Laboratory, as well as successfully completing the associated proficiency test. Approval will be based on the need for additional testing capacity and technical ability.
  - c. Approval requires reporting of results for tests supported by VSLs through the VSLs Web page or by using an electronic message in the VS-specified format. Other test results will be reported via spreadsheets or other formats provided by the NVSL Reference Laboratory. Results for IHC testing will be reported within 10 business days of sample receipt. Results for ELISA testing and other assays will be reported as specified in an NVSL Reference Laboratory SOP. Further, all positive, suspect, repeat, and inconclusive results must also be reported by email to the NVSL Reference Laboratory within 1 business day after testing is completed.
  - d. Approval requires that slides, blocks, and other specimens for all submissions are retained for at least 1 year, except when NVSL has authorized shorter retention times for formalin-fixed tissues not in blocks or for fresh or frozen tissue from accessions where no specimens are either pending confirmatory testing or were confirmed positive. All materials for cases with positive, repeat, suspect, and inconclusive test results and materials from clinically suspect animals must be forwarded to NVSL by overnight shipping within 1 business day after testing is completed.
2. Application package: The laboratory must submit the information listed below to the NAHLN program office at [NAHLN@aphis.usda.gov](mailto:NAHLN@aphis.usda.gov).
  - a. The NAHLN Laboratory Qualification Checklist.
  - b. A copy of the laboratory's APHIS VS permit (as required for receipt of proficiency panels and positive controls).
  - c. A description of the specific procedures to be used to report test results.

- d. A description of recordkeeping procedures. Approval requires that records from all specimens be retained for at least 1 year, and records pertaining to cases with positive, suspect, repeat, or inconclusive test results be retained for at least 5 years.
- e. A description of sample/tissue holding and retention procedures.

#### **E. NAHLN Responsibilities**

1. On receiving a request for laboratory approval, the NAHLN Coordinator will inform the NVSL Director, NVSL Reference Laboratory, and the National Scrapie Program Coordinator as well as the appropriate APHIS District Director and AVIC, based on the location of the laboratory. The NAHLN Coordinator will consult with the NVSL Reference Laboratory and National Scrapie Program Coordinator to determine if additional testing capacity is needed.
2. The NAHLN Coordinator or designee will give the requesting laboratory a copy of this document and discuss requirements for laboratory approval with the laboratory director or other appropriate individuals. The NAHLN Coordinator, after consultation with the NVSL Reference Laboratory and National Scrapie Program Coordinator, will advise the requesting laboratory whether capacity is needed at that time.
3. On receiving an application package as described in *D.2*, appropriate NAHLN program and NVSL Reference Laboratory personnel will review the submitted materials.

#### **F. Recommendation for Approval**

1. If the laboratory meets all requirements, the NAHLN Coordinator will notify the NVSL Director, the NVSL Reference Laboratory, the National Scrapie Program Coordinator, and the laboratory director regarding the laboratory's ability to conduct the specific tests on the specified tissues (as listed in the NAHLN Checklist). Approval will be granted if the laboratory:
  - a. Completes proficiency testing for the specific test, as directed by NVSL. Satisfactory performance requires that the laboratory correctly identify the scrapie status of 100 percent of samples in the test panel.
    - 1) If discrepant results are obtained, NVSL, the participating laboratory, and others as required will investigate the cause.
    - 2) If the apparent cause of discrepant results is determined and rectified to NVSL's satisfaction, no additional corrective actions may be needed.
    - 3) At NVSL's discretion, the laboratory may need to train additional personnel or may need additional proficiency testing. NVSL can deny laboratory approval for the specific test after a second proficiency test failure.
    - 4) The NVSL reference laboratory will forward proficiency test results to the National Scrapie Program Coordinator and the NAHLN program office.

- b. Demonstrates the ability to receive submission information and transmit test results by the following methods:
  - 1) Access submission information entered previously by field collectors/submitters and enter submission information for other specimens not submitted electronically on the appropriate VSLS Web site; and
  - 2) Enter test results on the appropriate VSLS Web site or submit test results via electronic messaging to the VS database, as directed; and
  - 3) Supply submission information and test results using a spreadsheet or other NVSL-provided format for tests not supported by VSLS.
2. If the results of a laboratory's proficiency testing are unsatisfactory or the laboratory cannot sufficiently demonstrate its ability to electronically receive and transmit test results, the NVSL reference laboratory will document the deficiencies in writing and send this information to the laboratory director, the NAHLN program office, and the National Scrapie Program Coordinator.
  - a. Laboratories may reapply for approval by contacting the NAHLN program office and the NVSL reference laboratory to discuss retraining and retaking the proficiency test and/or re-evaluation of the laboratory's ability to receive and transmit data electronically. The NVSL reference laboratory may require the lab to submit a satisfactory report detailing the cause of the error or errors and the steps implemented to prevent recurrence before allowing the lab to retake the proficiency test.
  - b. Failure of the subsequent proficiency test or electronic data transmission test will be ground to deny laboratory approval.
    - 1) A laboratory denied approval as a result of failed proficiency testing as described in *1* may be required to wait until the next scheduled round of proficiency testing to complete the testing and submit a new application package.
    - 2) A laboratory denied approval as a result of a failed electronic data transmission test may be approved, within 12 months of a successful diagnostic proficiency panel, after a successful electronic data transmission test. Laboratories failing to demonstrate electronic data transmission proficiency within 12 months must submit a new application package.
    - 3) The new application package must detail the factors associated with the denial of the previous application and the actions implemented to prevent recurrences.

## **G. Changes to Laboratory Approval**

1. A laboratory must notify the NVSL Director and the NAHLN program office of any changes in the information contained in the application package within 30 days of the effective date of the change. Changes in procedures or equipment must be approved in advance. Changes in personnel requiring notification include individuals serving as the responsible laboratory official, laboratory director, and the responsible individual for technical issues regarding scrapie testing or their contact information.

2. The amendments will be reviewed for approval as described in *section E* of this appendix. The NAHLN program may conduct a new site visit or may require additional proficiency testing before approving the amendment, depending on the nature and scope of the requested change.
  - a. If the amended application is approved, the NAHLN Coordinator will notify the NVSL Director and the National Scrapie Program Coordinator.
  - b. If the amended application is not approved, the NAHLN Coordinator will give the laboratory director, NVSL Director, and the National Scrapie Program Coordinator a statement giving the reasons for denying approval. The laboratory can address the deficiencies and resubmit the amendment.

## **H. Maintaining Laboratory Approval**

1. Approved laboratories are required to submit a NAHLN Qualification Checklist annually for re-approval. Continued participation is contingent on approval from the NAHLN Coordinator, National Scrapie Program Coordinator, and NVSL Reference Laboratory.
2. To maintain approval, laboratories must satisfactorily complete proficiency tests annually or as NVSL deems necessary. A final score of 100 percent correctly identified samples is considered a satisfactory score. The procedure described in *F.1* will be used if discrepant results are obtained.
3. As stated in the NAHLN Qualification Checklist, approved laboratories may be required to undergo inspections or audits, or both, as designated by the NAHLN program.

## **I. Removal of Laboratory Approval**

1. The NVSL Director, acting on behalf of the Administrator, may withdraw or suspend approval of a laboratory for any of the following reasons:
  - a. Failure to meet any of the conditions stated in this appendix or in 9 CFR 54.11.
  - b. One or more criteria for obtaining or maintaining approval are no longer being met.
  - c. Submission by the approved laboratory of a request for withdrawal of approval.
  - d. Unsatisfactory performance on regular samples submitted for testing or required proficiency tests as defined in *section H.1* of this appendix.
  - e. A finding of unsatisfactory conditions or procedures at the laboratory.
  - f. Failure to accurately input test data and report results in the manner and within the time frames specified in this appendix, the SOP provided by NVSL, in a contract, blanket purchase agreement, or other binding agreement.
  - g. Loss of NAHLN approval.
2. The NVSL Director, acting on behalf of the Administrator, may withdraw or suspend a laboratory's approval to conduct a specific test kit or method on any or all tissues approved to be tested using the kit or method based on proficiency test failures on any tissue using the kit or method. For example, a laboratory that fails a second proficiency test for approval to conduct the IHC test on the obex may also have its

approval to conduct the IHC test on additional tissue types withdrawn.

3. The NVSL Director, acting on behalf of the Administrator, will provide written notice of a proposed withdrawal to the laboratory director and include an opportunity for the laboratory's response. Any conflicts concerning the reason or reasons for withdrawal will be resolved by holding a hearing. A hearing will include the NVSL Director, the requesting laboratory's director, the National Scrapie Program Coordinator, and their respective subject matter experts.

## **J. List of Approved Laboratories**

The NAHLN program office will maintain a list of approved laboratories conducting official diagnostic tests for scrapie. The list is publicly available [here](#).<sup>29</sup>

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<sup>29</sup> [https://www.aphis.usda.gov/animal\\_health/nahln/downloads/scrapie\\_lab\\_list.pdf](https://www.aphis.usda.gov/animal_health/nahln/downloads/scrapie_lab_list.pdf)

## Appendix C: Program Approval of Diagnostic Tests for Scrapie in Sheep and Goats

### A. Purpose

Following are the procedures for approving new test kits or test methods for diagnosing scrapie in the NSEP or the SFCP, or both. This appendix also provides guidance for implementing the regulations in 9 CFR 54.10).

### B. Definitions

1. Official test:  
A program-approved test for the diagnosis of scrapie conducted at a laboratory VS approves to conduct the test, NVSL, or another laboratory to which NVSL has referred a case for confirmatory testing.
2. Program-approved test:  
A test kit or test method for diagnosing scrapie in a live or dead animal approved for use in the Scrapie Eradication Program or the SFCP, or both in accordance with 9 CFR 54.10, or approved by APHIS for diagnosing scrapie before September 20, 2001.
3. Confirmatory test:  
A test for diagnosing scrapie in a live or dead animal conducted by NVSL or a laboratory to which NVSL has referred a case for such testing. Confirmatory testing may include any of the following methods, used alone or in combination: immunohistochemistry (IHC); Western Blot; histopathology; enzyme immunoassay/enzyme-linked immunosorbent assay (EIA/ELISA) test, if different from the EIA/ELISA test originally performed on the sample and the results are in agreement; or animal inoculation studies (i.e., bioassay). The results of a confirmatory test may be used to designate an animal in accordance with 9 CFR 79.4.

### C. General

1. Routine laboratory diagnosis of scrapie is accomplished by detecting the protease-resistant form of the prion protein, PrP<sup>res</sup>, in CNS or lymphoid tissue, or both.
2. As new test kits or test methods are developed for diagnosing scrapie, APHIS must evaluate their characteristics and intended uses to determine if they are suitable for use in the Scrapie Eradication Program or the SFCP.
3. Only program-approved tests performed in approved laboratories, at NVSL, or at another laboratory to which NVSL has referred a case for confirmatory testing, are considered official diagnostic tests for scrapie.

**D. Request for Program Approval of Tests**

1. Initial requests for program approval of a test kit or test method should be made in writing to the NVSL Director (or his or her designee). Once an initial request for approval is submitted, a copy of this appendix will be sent to the requestor.
2. Program evaluation of tests may also be initiated by the NVSL.
3. Application package: The requestor must submit the following information (electronically in pdf or other format acceptable to NVSL) to the NVSL Director. This information will be referred to as the application package.
  - a. A standardized test protocol that includes a description of the test, a description of the reagents, materials, and equipment used for the test, the specific tissue or tissues on which the test is to be performed, the test methodology, and any control or quality assurance procedures.
  - b. A description of the intended use of the test including if it will be used to test sheep, goats, or both; or live or dead animals or both (i.e., antemortem/postmortem test) for scrapie.
  - c. Data to support repeatability (i.e., the ability to reproduce the same result repeatedly on a given sample).
  - d. Data to support reproducibility (i.e., data to show that similar results can be produced when the test is run at other laboratories).
  - e. Data to support the diagnostic sensitivity and specificity of the test and data to support the analytical sensitivity and specificity for assays, as appropriate.
  - f. A summary of the advantages offered by the new test kit or test method relative to the methods currently approved for a similar use.
  - g. The NVSL Director may request additional data or information at any time during the review process to determine the suitability of the test for program use. This may include but is not limited to past performance, cost of test materials and equipment, ease of test performance, generation of waste, and potential use of existing equipment.
  - h. APHIS-licensed test kit manufacturers may use the data submitted to obtain licensure to support their applications for program approval.

**E. NVSL and National Scrapie Program Coordinator Responsibilities**

1. On receiving a request for program approval, the NVSL Director will inform the National Scrapie Program Coordinator.
2. The NVSL Director, or designee, will provide the requestor a copy of this appendix and discuss the requirements for program approval of a test with the requestor or other appropriate individuals.
3. If the application package is complete and the test kit or test method warrants further consideration, authorized NVSL personnel will coordinate a review of the submitted

materials with the National Scrapie Program Coordinator and, if appropriate, other scientists.

4. The NVSL Director may decline to evaluate any test kit for program approval that has not been licensed for the intended use. The Director may also decline to evaluate any test kit or test method unless the requestor demonstrates the new method offers a statistically significant advantage over currently approved methods, or is likely to provide a savings that will offset the cost of evaluation. If the Director declines further evaluation of the test, the application package will be returned to the requestor with a written statement providing the reason or reasons for the denial. The requestor may address the deficiencies identified and resubmit the application package.

#### **F. Evaluation Criteria for Program Approval of Tests**

1. The approval or disapproval of a test for use in the Scrapie Eradication Program or the SFCP will be based on APHIS' evaluation of the submitted application package and testing at NVSL. APHIS may use outside scientists during the evaluation process, as appropriate. APHIS will use the following evaluation criteria:
  - a. The test must be able to be readily and successfully performed at NVSL.
  - b. The test must have a reliable, timely, and cost-effective method of proficiency testing.
  - c. A test, or combination of tests, may be approved for the identification of suspect animals, for the identification of scrapie-positive animals, or for other purposes, such as flock certification.
    - 1) Test approval for the identification of scrapie-positive animals requires that the test demonstrate a diagnostic specificity comparable to or greater than that of current program-approved tests.
    - 2) Test approval for the removal of high-risk, exposed, or suspect animal designations requires that the test demonstrates a sensitivity comparable to or greater than that of current program-approved tests used for the stated purpose.
    - 3) Test approval for a live animal screening test to identify suspect animals requires that the test be reliable but need not be definitive for diagnosing scrapie.
  - d. Test kits that are not USDA-licensed will be approved only if they offer an advantage over other test methods as determined by NVSL or have a limited use (i.e. such as Western Blot test kits used for discriminatory or confirmatory testing).
  - e. Test procedures must be consistent with established scientific principles and practices for diagnostic testing for scrapie.
2. The NVSL Director may request additional data or information at any time during the review process to facilitate the evaluation of the test's suitability for program approval.

3. VS may provisionally approve a test method or test kit to allow additional evaluation of its performance during field use.
4. After determining that the test kit or test method meets the criteria for program approval or provisional approval, the National Scrapie Program Coordinator will draft VS Guidance for approval of the test.
5. Specific guidelines for the use of program-approved tests within the Scrapie Eradication Program or the SFCP will be published in the VS Guidance approving the test and may subsequently be incorporated in the NSEPS. These guidelines will be developed according to the characteristics of the test, including specificity, sensitivity, and predictive value in defined groups of animals.
6. If the test kit or test method does not meet the criteria for program approval, the application package will be returned to the requestor with a statement giving the reasons for denying approval. The requestor may address the deficiencies and resubmit the application package.

#### **G. Changes to Test Methodology**

1. The requestor must notify the NVSL Director of any changes or modifications to the test protocol from that contained in the application package. Amendments to the package must be submitted in writing (electronically in pdf or other format acceptable to NVSL) to the NVSL Director.
2. The amendments will be reviewed by NVSL to determine if the proposed changes are approved, disapproved, require additional information or testing before approval, or require a full evaluation for program approval as a new test.
  - a. If the amended protocol does not require full evaluation, the NVSL Director will notify the requestor and the National Scrapie Program Coordinator regarding approval of the modification, additional information needed, or testing required before approval.
  - b. If the amended protocol requires full evaluation, the NVSL Director will notify the requestor and the National Scrapie Program Coordinator that a reapplication is necessary for approval.

#### **H. Removal of Program Approval for a Test**

1. The NVSL Director, acting on behalf of the Administrator, may withdraw or suspend approval of any test kit or test method for the following reasons:
  - a. Failure to meet any of the conditions stated in this document or in 9 CFR 54.10.
  - b. The test kit or test method does not perform as expected following program approval.
  - c. A more effective test kit or test method is subsequently approved.

2. The NVSL Director, acting on behalf of the Administrator, will give written notice of the proposed withdrawal to the director of the laboratories using the test or method, or in the case of test kits, to the manufacturer, and will give the director or manufacturer an opportunity to respond. A hearing will be held to resolve conflicts regarding any material fact concerning the reason for withdrawal.
3. The NVSL Director, acting on behalf of the Administrator, may suspend approval by notifying the laboratory or the kit manufacturer.

## I. List of Program-Approved Diagnostic Tests for Scrapie

Listed in the table below are the following:

- The diagnostic tests approved for diagnosing scrapie in sheep and goats in the United States;
- The tissues on which those tests can be run as official scrapie tests;
- The laboratories authorized to run preliminary (screening) scrapie tests; and
- The laboratories authorized to run confirmatory scrapie tests.

<b>Diagnostic Test</b>	<b>Tissue</b>	<b>Authorized Laboratory: Preliminary Testing</b>	<b>Authorized Laboratory: Confirmation Testing<sup>30</sup></b>
Immunohistochemistry (IHC)	Brain, brainstem (obex)	1. Approved Scrapie NAHLN Laboratories <sup>31</sup> 2. NVSL	NVSL
IHC	Lymph Node (LN) <sup>32</sup>	1. Approved Scrapie NAHLN Laboratories 2. NVSL	NVSL
IHC	Tonsil	1. Approved Scrapie NAHLN Laboratories 2. NVSL	NVSL
IHC	Rectal lymph tissue (RAMALT) <sup>33</sup>	1. RAMALT Approved Scrapie NAHLN Laboratories 2. NVSL	NVSL
IHC	Third eyelid biopsy <sup>33</sup> , other lymphoid tissue	NVSL	NVSL
Western Blot <sup>34</sup>	Brain, obex, LN, tonsil, other lymphoid tissue	NVSL	NVSL
Bioassay <sup>35</sup>	Any tissue		NVSL
ELISA <sup>36</sup>			

<sup>30</sup> Routinely only NVSL conducts confirmatory tests for scrapie in the United States; however, NVSL may refer a sample for confirmatory testing at another laboratory.

<sup>31</sup> For a list of NAHLN laboratories approved for scrapie diagnostic testing, please visit [https://www.aphis.usda.gov/animal\\_health/nahln/downloads/scrapie\\_lab\\_list.pdf](https://www.aphis.usda.gov/animal_health/nahln/downloads/scrapie_lab_list.pdf). NVSL is included on this list.

<sup>32</sup> The most commonly tested lymph tissue is the retropharyngeal lymph node (RLN).

<sup>33</sup> The RAMALT and third eyelid lymph tissues can be tested on either live or dead animals. The RAMALT test is the preferred live-animal test due to increased sensitivity, reliability, repeatability, and animal comfort. While NVSL may authorize NAHLN labs to run RAMALT tests, they are currently conducted only at NVSL.

<sup>34</sup> Western blot is generally reserved for scrapie-exposed animals, scrapie suspect, and test-positive animals.

<sup>35</sup> Bioassay, while rarely used, may be used by NVSL for confirmatory testing.

<sup>36</sup> Although other countries use ELISA for scrapie testing and it is used for bovine spongiform encephalopathy testing in the United States, APHIS has not currently approved an ELISA test for use in the NSEP. NVSL may use ELISA as a supplemental test.

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## Appendix D: Scrapie Surveillance

### A. General

The national performance goal for scrapie surveillance is to collect samples from at least 40,000 mature targeted sheep or goats each year. Mature animals are those with at least one completely erupted first permanent incisor. The AVIC and SAHO are responsible for ensuring that surveillance minimums for their State or area of responsibility are met and that targeted sheep and goats slaughtered in their area are sampled. The National Scrapie Surveillance Plan published in 2010 is currently being revised. When it is finalized it will supersede sections B-D below and will replace the [2010 National Scrapie Surveillance Plan](#).

### B. Animals Targeted for Surveillance Sampling

1. All mature blackfaced sheep and clinical suspects should be sampled regardless of traceability, including those from flocks on the “Do Not Collect” list.
2. Mature sheep that are not blackfaced and mature goats should only be sampled if they are traceable, are not from a flock on the “Do Not Collect” list, and meet at least one of the additional criteria listed below.
  - a. The animal is a Southdown or Montadale sheep.<sup>37</sup>
  - b. The animal is dead before slaughter or condemned on antemortem inspection for any reason.
  - c. The animal is nonambulatory:
    - 1) Down and unable to rise, or able to rise but only for brief periods.
    - 2) Nonambulatory animals can include those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral columns, or metabolic conditions.
  - d. The animal exhibits signs of CNS disease, including any of the following:
    - 1) Weakness of any kind, including stumbling, falling down or having difficulty rising (not including those with visible traumatic injuries, which should be recorded as nonambulatory animals).
    - 2) Behavioral abnormalities.
    - 3) Increased sensitivity to noise and sudden movement.
    - 4) Tremors.
    - 5) Star gazing.
    - 6) Head pressing.
    - 7) Bilateral gait abnormalities, including incoordination, ataxia, high stepping gait of forelimbs, bunny-hop movement of rear legs, or swaying of back end, but not including abnormalities involving only one leg or one front and one

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<sup>37</sup> Southdowns have wool-covered gray to mouse-brown faces. Montadales cannot be readily identified by observation of the head, so these can only be selected if advised by the plant. The Montadale is typically bright white with a clean head and black nose, similar to the Cheviot.

- back leg.
- 8) Other CNS signs.
- e. The animal shows signs of intense rubbing, abrasions, or rough, thickened, and/or hyperpigmented skin:
- 1) Repeated intense rubbing with bare areas in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; and/or
  - 2) Abraded, rough, thickened, or hyperpigmented areas of skin in areas of wool or hair loss in similar locations on both sides of the animal's body or, if on the head, both sides of the poll.
- f. The animals are scrapie-exposed animals not in source or infected flocks (i.e., those identified with a yellow "Exposed" eartag or received on a VS 1-27 permit).
- g. Any goat or sheep, including hair sheep, that is 2, 3, 4, or 5 years of age as evidenced by examination of the teeth.
- h. Condemned postmortem for emaciation.
- i. Animals of higher risk than the general population or needed to achieve State sampling minimums as determined by the SGHSE.
- j. Sheep or goats identified with an SFCP tag.

### 3. Note:

- a. Below is the list of options for age in VSLS:

AGE	DESCRIPTION
12 to < 18 months	First permanent incisor erupted, but lower than remaining deciduous teeth
18 to < 24 months	First permanent incisor level with or extends above remaining deciduous teeth; second permanent incisor erupted
2 years	Second permanent incisor erupted and level with first permanent incisor; third permanent incisor <b>not</b> erupted
3 years	Third permanent incisor erupted; fourth permanent incisor <b>not</b> erupted
4 years	Fourth permanent incisor erupted; no dental wear on fourth incisor
Full mouth – min.	Animal has full mouth, all incisors fully erupted, with minimal dental wear
Full mouth – mod.	Animal has full mouth; all incisors fully erupted, with moderate dental wear. No broken, missing or markedly splayed teeth
Full mouth – sev.	Animal has full mouth; all incisors fully erupted, with severe dental wear. Teeth may be broken, missing, or markedly splayed

- b. In plants where the collector does not see the live sheep or goat, arrangements should be made with the FSIS inspector in charge to identify the heads from animals meeting the clinical signs criteria.
- c. The targeted groups may be revised based on ongoing analysis of RSSS data.
- d. Reminder: Unlike other sheep and goats, **all** mature sheep that have a black face should be sampled regardless of traceability and "Do Not Collect" list status so that the NSEP can accurately measure program effectiveness.

### C. Surveillance Minimums

1. To ensure that the last remaining classical scrapie cases in the United States are detected, each State must test a minimum number of sheep and goats for scrapie annually. Both sheep and goat sampling minimums are calculated based on each State's breeding ewe and breeding doe populations, as reported by NASS annually in its *Sheep and Goat* report (usually released the last week of January each year).
2. For sheep, the minimum annual sample numbers required by a State are the lesser of the following:
  - a. Twenty percent of the number of samples needed to detect classical scrapie at a prevalence of 0.1 percent with 95 percent confidence; or
  - b. 1 percent of the breeding sheep population in the State based on NASS data.
3. For goats, the minimum annual sample numbers are determined based on the occurrence of classical scrapie in a goat since 2001.
  - a. For States that have had at least 1 case of classical scrapie in a goat since 2001, the sampling minimum is calculated the same as it is for sheep, using the breeding doe population, and is the lesser of:
    - 1) Twenty percent of the number of samples needed to detect classical scrapie at a prevalence of 0.1 percent with 95 percent confidence; or
    - 2) 1 percent of the breeding goat population in the State based on NASS data.
  - b. For States that have not had a case of classical scrapie in a goat since 2001 or that have met the 5-year sampling minimum since their last case, the sampling minimum is the State's prorated share of the national goal of 3,000 goats based on NASS data.
4. Annual Sampling Minimum
  - a. NSEP staff determines the annual sampling minimums for the upcoming fiscal year based on the most recent NASS data available on March 1, and the minimums are distributed to the VS Area Offices by April 1.
5. For further information about the NSEP surveillance strategy, please refer to the [National Scrapie Surveillance Plan](#)<sup>38</sup>.

### D. Surveillance at Sources Other Than Slaughter

1. State-of-origin minimums may be fulfilled by submitting surveillance specimens from mature dead, disabled, or suspect animals from non-slaughter sources. Such sources include, but are not limited to, the following:
  - a. Veterinary diagnostic laboratories (even if another diagnosis was achieved).
  - b. Public health laboratories (rabies-negative submissions).
  - c. Renderers.
  - d. Dead-stock haulers.

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<sup>38</sup> [http://www.aphis.usda.gov/animal\\_health/animal\\_diseases/scrapie/downloads/national\\_scrapie\\_surv\\_plan.pdf](http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/national_scrapie_surv_plan.pdf)

- e. Markets.
  - f. Cull ewe feedlots.
  - g. Research facilities.
  - h. Farms (including home slaughter of targeted animals, up to 30 per flock of origin).
  - i. Other sites.
2. In addition, surveillance specimens may include approved live-animal tests on codon 171 QQ sheep or goats over 14 months of age that are:
    - a. Black-faced;
    - b. Southdowns;
    - c. Montadales; or
    - d. Reside in flocks that contain or contained female animals of these types or that are at higher risk than the average population or as needed to meet surveillance objectives, as identified by the DSE.

Note: Contact the SGHSE for guidance on live animal testing for surveillance.

## **E. Sampling Procedures and Forms**

1. Specimens must be collected using the sampling procedure provided in the National Scrapie Reference Library, which is available to State and Federal animal health employees on the APHIS-NSEP [Scrapie SharePoint](#) site (see *E.6*).
2. Sampling supplies to collect scrapie samples are available from NVSL by e-mailing [NVSLshipping@aphis.usda.gov](mailto:NVSLshipping@aphis.usda.gov). Boxes for shipment of whole heads are available by e-mailing [Remington.Locker@aphis.usda.gov](mailto:Remington.Locker@aphis.usda.gov).
3. All on-farm necropsy and live animal submissions must be made electronically through the VSLS on-farm module. Guidance for entering submissions in VSLS is available in the National Scrapie Reference Library, which is available to State and Federal animal health employees on the APHIS-NSEP site (see *E.6*).
4. All specimens collected at slaughter plants or other concentration points, where the owner information is not known at the time of collection, must be submitted electronically through the VSLS RSSS module.
5. Whole head submissions shipped to the Remington Locker in Indiana must include a completed RSSS or On-Farm Submission Worksheet as appropriate. The worksheet is used by collection personnel to enter the submission in VSLS. Refer to the Whole Head Collection Manual for a copy of the worksheet and for additional information. A copy of the Manual is available in the National Scrapie Reference Library (see *E.6*).
6. The Scrapie SharePoint site is available to State and Federal animal health employees at <https://share.aphis.usda.gov/sites/vs-sgh/>. Information from this site is also available on CD or hard copy for Federal and State employees who cannot access the

Scrapie SharePoint site, and can be obtained by contacting the Scrapie Program Specialist by email at [scrapie@aphis.usda.gov](mailto:scrapie@aphis.usda.gov).

7. The AD for the collecting State is responsible for initiating traces for positive animals in accordance with *part VII* of these Program Standards.

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## Appendix E: Scrapie Cleaning and Disinfection Guidelines

The following procedures do not guarantee total and complete disinfection and inactivation of the infectious agent. Nonetheless, current information regarding the efficacy 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 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 one of the following 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*.

- b. To clean dry surfaces, apply a 2 percent available chlorine solution<sup>39</sup> (equivalent to about 20,000 p/m; available chlorine: 50 ounces or 6-1/4 cups of normal strength (5.25 percent) bleach) to enough water (78 ounces. or 9 3/4 cups) to give 1 gallon of solution) at room temperature (at least 65 °F) for 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 before use and use appropriate personal protective equipment or hire trained personnel to do the work.

- c. To clean dry surfaces, apply a 1-molar solution of sodium hydroxide<sup>39</sup> (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 before use and use appropriate personal protective equipment or hire trained personnel to do the work.

Use of chlorine and sodium hydroxide must be reported to [scrapie@aphis.usda.gov](mailto:scrapie@aphis.usda.gov) or directly to the designated individual for compilation into a report for submission to EPA.

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<sup>39</sup> 40 CFR part 152 declares prions a pest under the *Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)*. Accordingly, only products registered with the EPA specifically for the reduction of prion infectivity can be used to disinfect these sites. Currently there are no EPA-registered products available; EPA has therefore granted APHIS an exemption for the use of chlorine and sodium hydroxide for use in its prion control and eradication programs. These instructions conform to those provided in the exemption labels.