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Scrapie Eradication Uniform Methods and Rules

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Introduction

Scrapie Eradication Uniform Methods and Rules (UM&R) are cooperative procedures and standards adopted by the Animal and Plant Health Inspection Service (APHIS) and Consistent States for controlling and eradicating scrapie. These UM&R are intended to assist State and Federal animal health personnel in implementing the scrapie eradication program consistently and equitably throughout the United States.

This publication provides the program standards and procedures for the Cooperative State–Federal–Industry Scrapie Program. They are set up for the prevention, monitoring, control, and eradication of scrapie disease from domestic sheep flocks and goat herds and for maintenance of State status in the U.S. Department of Agriculture (USDA) Scrapie Eradication Program. Flock plan agreements or postexposure management and monitoring plan agreements made before the effective date of these standards will remain in force unless changed by mutual agreement of APHIS, the State, and the owner.

The contents of this document have been approved by USDA, APHIS, Veterinary Services (VS), and incorporate recommendations from the Scrapie Working Group, which included State and Federal veterinarians from 17 States, other State animal health authorities, industry representatives, members of the industry, and the United States Animal Health Association.

These UM&R will be reviewed at least annually by representatives of the livestock industry and appropriate State and Federal agencies and will be revised as needed by USDA–APHIS. In addition, this publication may be amended in the future by replacing pages or by adding new pages.

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 in the APHIS Scrapie Program QuickPlace, which is located on the Internet at <https://qp01.aphis.usda.gov/QuickPlace/scrapie/Main.nsf?OpenData>. Access to the QuickPlace is limited to State and Federal employees. To request a QuickPlace user name and password, contact the Scrapie Program Specialist by telephone at (301) 734–6954, or by e-mail at scrapie_program@aphis.usda.gov.

Part I—Definitions

Any definitions pertaining to scrapie published in parts 54 and 79 of the Title 9, *Code of Federal Regulations* (9 CFR), after the date of publication of these UM&R supersede these definitions.

Accredited veterinarian

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

Administrator

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

Animal

Any sheep or goat.

APHIS

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

APHIS representative

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

Approved laboratory

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

Approved test

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

Area Veterinarian in Charge (AVIC)

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

Blackface sheep

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

Breed associations and registries

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

Breeding sheep and goats

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

Certificate

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

Commercial sheep or goat

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

Commingled, commingling

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

Consistent State

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

Deputy Administrator

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

Designation of a flock or animal

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

Designated Scrapie Epidemiologist (DSE)

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

Destroyed

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

Direct movement to slaughter

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

Electronic implant

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

Exposed animal

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

Exposed embryo

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

Exposed flock

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

Female animal

A sexually intact female sheep or goat.

Flock or herd

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

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

Flock ID

See premises identification number.

Flock of origin

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

flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records.

Flock plan

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

Flock under investigation (FUI)

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

Genetically less susceptible exposed sheep

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

Genetically resistant exposed sheep

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

Genetically susceptible animal

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

Genetically susceptible exposed animal

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

- A goat or goat embryo;
- A QQ sheep or sheep embryo;

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

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

Genotypes of sheep

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

RR sheep

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

QR sheep

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

QQ sheep

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

AV sheep

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

VV sheep

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

AA sheep

Any sheep that has tested AA at codon 136 on an official genotype test. APHIS may require

confirmatory testing before designating a sheep as AA.

AA QR sheep

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

AV QR sheep

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

AA QQ sheep

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

AV QQ sheep

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

VV QQ sheep

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

High-risk animal

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

Inconsistent State

Any State other than a Consistent State.

Infected flock

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

Interstate commerce

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

Limited contact

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

Live-animal screening test

Any test for the diagnosis of scrapie in a live animal that is approved by the Administrator as usually reliable but not definitive for diagnosing scrapie and that is conducted in a laboratory approved by the Administrator.¹

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

¹ The names and addresses of laboratories approved by the Administrator to conduct live-animal screening tests will be published in the notices section of the *Federal Register*. A list of approved laboratories is also available upon request from the APHIS, VS, National Animal Health Programs Staff, 4700 River Road, Unit 43, Riverdale, MD 20737-1235. State, Federal, and university laboratories will be approved by the Administrator when he or she determines that the laboratory (a) employs personnel trained by the National Veterinary Services Laboratories (NVSL) assigned to supervise the testing, (b) follows standard test protocols, (c) meets check test proficiency requirements, and (d) will report all test results to State and Federal animal health officials. Before the Administrator may withdraw approval of any laboratory for failure to meet any of these conditions, the Administrator must give written notice of the proposed withdrawal to the director of the laboratory and must give the director an opportunity to respond. If there are conflicts as to any material fact, a hearing will be held to resolve the conflicts.

whiteface crosses born on the premises; that have never contained a scrapie-positive female, suspect female, or high-risk animal; and that have never been an infected, exposed, or source flock or a flock under investigation. The animals are identified with a legible permanent brand or ear notch pattern registered with an official brand registry or with an official premises identification eartag. The term “brand” includes official brand registry brands on eartags in those States whose brand law or regulation recognizes brands placed on eartags as official brands. Low-risk commercial flocks may exist only in a State where in the previous 10 years no low-risk commercial flock has been designated a source or infected flock.

Low-risk commercial goat

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

Low-risk exposed animal

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

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

Low-risk goat

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

- A State in which scrapie has not been identified in a goat during the previous 10 years;
- A State in which scrapie has been identified in a goat during the previous 10 years, but the scrapie-positive goat was not born in the State, resided in the State for less than 72 months, and did not kid while in the State; or

- A State in which scrapie has been identified in a goat during the previous 10 years and the scrapie-positive goat was commingled with sheep and the flock records allowed a complete epidemiological investigation to be completed and all resulting infected, source, and exposed goat herds had completed flock plans and were in compliance with post-exposure monitoring and management plans.

Male animal

A sexually intact male sheep or goat.

Mortgage

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

National Veterinary Services Laboratories (NVSL)

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

Noncompliant flock

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

Official eartag

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

Official genotype test

Any test to determine the genotype of a live or dead animal conducted at either an approved laboratory (see definition) or at NVSL when the animal is officially identified and the samples

are collected and shipped to the laboratory by either an accredited veterinarian or a State or APHIS representative. APHIS may require confirmatory testing before designating an exposed sheep genetically resistant or less susceptible.

Official identification

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

Official test

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

Owner

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

Owner statement

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

Permit

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

Person number

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

Postexposure management and monitoring plan (PEMMP)

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

Premises

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

Premises identification

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

Premises identification number

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

Premises number

A unique number identifying a premises in the SNGD.

Program

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

Scrapie

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

Scrapie control pilot project

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

Scrapie Eradication Program

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

Scrapie Eradication Uniform Methods and Rules (UM&R)

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

Scrapie Flock Certification Program (SFCP)

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

Scrapie Flock Certification Program Standards

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

Scrapie-positive animal

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

- Histopathologic examination of CNS tissues from the animal for characteristic microscopic lesions of scrapie;
- Protease-resistant protein analysis methods including, but not limited to, immunohistochemistry (IHC) and/or Western blotting on CNS and/or peripheral tissue

samples from a live or a dead animal. The method must have been approved by the Administrator for use on that tissue;

- Bioassay;
- Scrapie-associated fibrils detected by electron microscopy; or
- Any other test method approved by the Administrator in accordance with 9 CFR 54.10.

Separate contemporary lambing groups

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

Slaughter channels

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

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

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

Source flock

A flock in which a State or APHIS representative has determined that at least one animal was born that was diagnosed as scrapie positive at an age of 72 months or less or in which a scrapie-positive animal has resided throughout its life. The determination that an animal was born in a flock must be based either on the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records, to show that a scrapie-positive animal originated from the flock combined with the absence of records indicating that the animal was purchased and added to the flock. If DNA from the animal was collected when the animal resided in the flock of birth

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

State

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

State representative

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

State Veterinarian

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

Suspect animal

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

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

Terminal feedlot

- A dry lot approved by a State or APHIS representative or an accredited veterinarian authorized to perform this function where animals are separated from all other animals by at least 30 feet at all times or are separated by a solid wall through, over, or under which fluids cannot pass and contact cannot occur and from which animals are moved only to a

terminal feedlot or directly to slaughter (this means other sheep could be on the same premises if they meet this requirement); or

- A pasture when approved by, and maintained under, the supervision of the State and in which only nonpregnant animals are permitted, where there is no direct fence-to-fence contact with another flock, and from which animals are moved only to another terminal feedlot or directly to slaughter.

Trace

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

Unofficial test

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

Veterinary medical officer (VMO)

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

Part II—Administrative Procedures**A. Supervision of the Cooperative State-Federal-Industry Scrapie Eradication Program**

Full-time animal health officials employed by the State or the Federal Government will supervise the Cooperative State-Federal-Industry Scrapie Eradication Program. APHIS may execute a cooperative agreement and/or memorandum of understanding (MOU) with the animal health agency of any State to administer the scrapie eradication program cooperatively within that State.

B. Appointing DSEs

The selection and appointment of DSEs will be made jointly by the State animal health official and AVIC with the concurrence of the APHIS Regional Scrapie Epidemiologist and the APHIS National Scrapie Program Coordinator. (See VS Memorandum No. 557.3.)

C. Administrative review of program activities and progress

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

- Ongoing review by VS personnel at the local and national levels of program activities and records, including evaluation of information entered into the SNGD by State and/or Federal animal health officials in each of the States.
- Review of epidemiological reports submitted by the DSE(s) in the State to the Regional and National Scrapie Epidemiologists.
- Review of applications for renewal or reclassification of a State as described in part IV of these UM&R.
- Site visits conducted in accordance with VS Memorandum No. 515.1.

D. Identification and recordkeeping compliance

The State must have the authority and take regulatory action to ensure that the following persons maintain records to enable State or APHIS authorities to trace exposed, high-risk, and/or scrapie-positive or suspect animals to all flocks in which they have resided and to determine their final disposition:

- Persons who purchase, deal in, or sell sheep over 18 months of age as well as breeding sheep or goats;
- Persons who act as commission representatives or brokers of such animals; and
- Persons who operate or conduct an auction at which sheep or goats are sold.

Action must be taken in the following cases:

- There is adequate evidence to establish that the person had the intent to violate or circumvent recordkeeping or identification requirements of this section, other animal health regulations, or both;
- The person has repeatedly demonstrated an unwillingness to keep required records or to identify animals, thus impeding the tracing of exposed, high-risk, or scrapie-positive or suspect sheep or goats that he or she has handled.

Under the State's authority, State's must have provisions so that State animal health officials can institute any action at law or in equity that appears necessary to enforce compliance with animal identification and recordkeeping requirements under these UM&R. Possible actions include the authority to subpoena appropriate records and persons who allegedly have violated these standards. The appropriate State officials must also have authority to petition the local court that has jurisdiction for an order to enforce these subpoenas.

E. Requirements for program personnel entering premises

Persons working on the Scrapie Eradication Program 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 sanitary procedures to minimize the risk of physically transmitting scrapie and other diseases to other premises.

F. Providing services to livestock owners

Program services 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 collecting blood or tissue samples, in identifying animals, and in performing other specified activities.

G. Exceptions to the deadline(s)

Program officials must follow deadlines for the flock plan, investigation, 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 Scrapie Eradication Program.

H. Whole-flock depopulation

State or Federal officials of the Scrapie Eradication Program will review sheep and goat flocks for whole-flock depopulation, with indemnity, based on the prevalence and epidemiology of the infection. In States that have been classified as free of scrapie, all newly disclosed affected flocks must be reviewed for possible depopulation with indemnity.

I. 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 in accordance with 9 CFR 54.4. Federal indemnity may be paid only for the following:

- Destruction of high-risk animals and male genetically susceptible exposed animals. If a genetic plan is used, exposed ewes will be genotyped, and only those designated as genetically susceptible exposed animals or that are restricted or requested for sampling by the DSE will be indemnified. If a 9 CFR plan is used, the 9 CFR definition of high-risk will be used;
- Destruction of animals based on an epidemiological investigation when the authorized APHIS representative determines that destroying these animals will contribute to eradicating scrapie;
- Destruction of live scrapie-positive animals;
- Destruction of animals that test positive on a live-animal screening test;
- Destruction of suspect animals that are destroyed at the request of an APHIS representative.

2. Requirements of flock owners to receive indemnity

Before any indemnity is paid to owners, they must be in compliance with the flock cleanup and monitoring plans, including the provision of records and a signed request for release of all records from any breed association with which they have registered animals.

3. Amount of indemnity payments

Federal indemnity: Federal indemnity will be paid in accordance with 9 CFR, part 54, and will be based on price reports provided by USDA's Agricultural Marketing Service as described in 9 CFR 54.6. Spreadsheets are posted on the APHIS Scrapie Program QuickPlace to assist Federal and State representatives with calculation of indemnity.

State-Industry indemnity: State and/or industry indemnity may be paid in addition to Federal indemnity in accordance with State regulations and/or industry guidelines up to the fair market value of the animal.

4. Indemnity procedures for animals destroyed

Animals for which indemnification is sought must be destroyed in accordance with 9 CFR 54.7. Animals that are not scrapie positive, or suspect animals for which indemnification is sought, may be slaughtered when moved in accordance with 9 CFR, part 79, and with the prior written approval of the APHIS representative involved.

The destruction of animals and disposition of their carcasses must be monitored by an APHIS representative. State personnel may conduct or supervise these activities including signing the valuation portion of VS form 1-23 when authorized and monitored by APHIS. The AVIC must review and sign VS form 1-23. Prior to the destruction of any animal for which indemnity will be claimed, the AVIC must submit a request for indemnity and get approval from the Regional Scrapie Epidemiologist. APHIS may pay, when approved in advance in writing, the reasonable and customary costs of disposal for scrapie-positive and suspect animals. The owner of the animals must present to APHIS a copy of either a receipt for expenses paid or a bill for services rendered.

J. Certificates of Veterinary Inspection (CVI) for sheep and goats in interstate commerce

State importation requirements may vary, so you should check each State's importation requirements prior to sending the animals. CVIs are required by USDA for breeding² sheep and goats that cross State lines except for:

- Sheep and goats being moved for grazing without change of ownership;

² Breeding sheep and goats are any sexually intact sheep or goat that is not moving directly to slaughter, through slaughter channels to slaughter, or to a feedlot to enhance its condition for movement to slaughter.

- Low-risk commercial sheep that require an owner and veterinary statement instead of a CVI; and
 - Low-risk commercial breeding goats. (Note: An owner and veterinary statement is **not** required unlike low-risk commercial sheep.)
- Note: CVIs may be required for other classes or types of sheep or goats by some States.

CVIs will be considered to meet the intent of 9 CFR 79.5(a) if they include:

- Either the animal's official individual identification number(s) or the flock of origin's premises identification number;
- The number of animals covered by the CVI;
- The purpose of the movement;
- The points of origin and destination;
- The name and address of the consignor and consignee; and
- A statement by the issuing accredited, State, or Federal veterinarian that the animals were not exhibiting clinical signs associated with scrapie at the time of examination. (CVIs that have certification statements indicating that "the animals have no history of clinical signs or exposure to contagious or infectious diseases," or words to that effect, will suffice in lieu of the specific scrapie statement.)

Note: These requirements apply only to the classes of animals that are required to have CVI by USDA.

K. Permits

A permit (VS form 1–27 or State equivalent) is required for movement of high-risk, suspect, scrapie-positive, and some exposed animals. (See section M of this part for exposed animals that require a permit to move.) Such animals moving intrastate may move under conditions specified by the State Veterinarian that ensure that these animals are destroyed or maintained under restriction.

L. Records of terminal feedlots

Records of all animals entering and leaving a terminal feedlot must be maintained for 1 year after the animal leaves the feedlot and must include the person from whom the animals were acquired and the slaughtering facility in which they were slaughtered. Records must be made available for inspection by an APHIS or State representative during normal business hours.

M. 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. No sexually intact animal will be permitted to move from an infected or source flock, except under permit, and then only to slaughter, for destruction, or to a research or diagnostic facility until a flock plan agreement has been signed and the owner is in compliance. The movement restrictions on the flock and criteria for release of these restrictions will be specified as part of the flock plan or PEMMP.
2. The following animals may be moved unrestricted once they have been officially identified and entered into the SNGD:
 - Genetically resistant exposed sheep;
 - Genetically less susceptible exposed male sheep;
 - Genetically less susceptible exposed female sheep that are not restricted by the DSE; and
 - Low-risk exposed animals in flocks that are in compliance with a plan, or that are in flocks not required to be on a plan.

These animals are not required to be listed as exposed animals on certificates of veterinary inspection. They must meet the other CVI requirements for animals of their species, age, and intended use as listed in 9 CFR 79.3.

3. Genetically less susceptible exposed female sheep that are restricted by the DSE may move only as permitted in the flock plan or PEMMP. The DSE, with the concurrence of the AVIC and State Veterinarian, 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, and/or other characteristics that may make these sheep a potential risk. If removal with indemnity is being considered, the Regional Scrapie Epidemiologist must be consulted to determine if indemnity is available.
4. Genetically susceptible exposed female animals and female offspring of any genotype of a scrapie-positive female animal, scrapie-positive animals, and scrapie-suspect animals must be restricted to the premises where found or moved under permit for destruction or to a research or diagnostic facility. These animals

will be submitted for testing when they die or are euthanized in accordance with APHIS policy.

5. Genetically susceptible exposed male animals may be moved only as exposed animals in accordance with 9 CFR, part 79, including being listed as exposed animals.
6. Animals from noncompliant flocks may be moved only in accordance with 9 CFR, part 79.
7. Animals that have been designated for test 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 a research or diagnostic facility. These animals will be submitted for testing if they die or are euthanized prior to completion of the required testing in accordance with APHIS policy.
8. Exposed wethers of any species or genotype may move unrestricted once they have been officially identified and entered into the SNGD. Exposed wethers in slaughter channels at under 18 months of age do not require official identification.

Table 1—Restrictions on Exposed Animals

Positive animal(s)	-----Exposed animals-----				
	Goats	QQ Sheep	AVQR Sheep	AAQR Sheep	RR Sheep
AAQQ sheep and goats	Doe — X Buck — EX	Ewe — X Ram — EX	Free	Free	Free
AV and VV sheep	Doe — X Buck — EX	Ewe — X Ram — EX	Ewe — X Ram — Free	Free	Free
AAQR sheep	Doe — X Buck — EX	Ewe — X Ram — EX	Ewe — X Ram — Free	Ewe — X Ram — Free	Free
RR sheep	XX	XX	XX	XX	XX

Positive animal(s) = Positive animal(s) 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.

Free = Move unrestricted (rare exceptions to this general class are listed in part II, M, 3 and 4).

X = Removed or permanently restricted.

EX = Removed, retained, or moved as exposed animals.

XX = Whole flock depopulation (all animals removed or permanently restricted).

N. SNGD – Data entry requirements

Complete information is available to data entry persons in the SNGD tutorial.

Information that must be entered by State or APHIS animal health personnel

Each premises or person that either (1) is or has been enrolled in the SFCP; (2) is or has been designated an infected, source, exposed, flock under investigation, or noncompliant flock; (3) owns or has, or has had an exposed, scrapie-suspect, or scrapie-positive animal residing there; or (4) has been issued a premises identification number for use as official identification (such as

ear tags, back tags, or tattoos) or has been issued tags must have a premises form accurately completed and maintained in the SNGD. (Note: The flock's premises identification number must be completed in user field 1 of the premises supplemental form.)

Each set of serial numbers assigned to a person for use as official identification (such as ear tags, back tags, or tattoos) and each set or serial of tags issued must be accurately recorded and maintained in the miscellaneous form of the SNGD. 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 that is tested or designated for test must have an individual animal record completed and maintained in the SNGD. Individual records should, when practical, be completed and maintained for animals in SFCP flocks. A test record must be completed and maintained for each animal tested for scrapie or for genetic resistance to scrapie.

Part III—Identification Requirements

A. Identification of sheep and goats in commerce

1. Identification requirements

Animals required to be identified in 9 CFR 79.3 must be officially identified to the flock of birth upon change of ownership. In cases where the flock of birth cannot be determined, the animal is to be officially identified to the flock of origin (flock in which an animal most recently resided for breeding). Allowed identification methods are provided in 9 CFR 79.2. (Note: Check with the receiving State to ensure that both State and Federal requirements are met.)

Animals required to be officially identified include:

- a. All breeding sheep;
- b. All sexually intact animals for exhibition;
- c. All sheep over 18 months of age;
- d. All 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;
- e. All suspect and test-positive animals;
- f. Animals from noncompliant flocks; and
- g. Breeding goats, except low-risk commercial goats.

Animals not required to be individually identified include:

- a. Slaughter sheep (sheep in slaughter channels) under 18 months. Note: If a sexually intact sheep is sold at an unrestricted sale (any sale that is not a slaughter or feeding for slaughter sale), it must be identified. If these animals cannot be identified to flock of origin, they must be identified with slaughter only tags;
- b. Wethers for exhibition and wethers under 18 months of age;
- c. Slaughter goats (goats in slaughter channels);
- d. Low-risk commercial goats;
- e. Animals shipped directly to an approved slaughter facility or an approved market when all the animals in a section of a truck are from the same premises of origin and are accompanied by an owner's statement. Note: The owner's statement must contain the information needed for the plant or market to identify the animals; and
- f. Animals moved for grazing or similar management reasons whenever 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.

2. Issuance of premises identification numbers

The VS Area Office or the State Veterinarian's office will issue a premises identification number to each sheep or goat owner who requests one. The office will fill out a premises information form in the SNGD and permanently assign a premises number and a premises identification number that will be used on tags or as the premises portion of the tattoo; in some States the numbers will be the same.

All two- and three-character alphabetical sequences must be reserved for use by producers who use registered tattoo prefixes. All two- and three-character numeric and alphanumeric sequences must be reserved for flocks that participate in the SFCP or that use tattoos. When possible, the premises identification number for premises with registered tattoo prefixes will be the State postal abbreviation followed by the producer's registered tattoo prefix. Alpha and alphanumeric sequences that contain I, O, or Q may not be assigned.

3. Allowed tags

Only USDA provided or approved tags will be used. USDA provided tags will either have a unique alphanumeric sequence or a premises number and a production (animal) number unique within a flock, or a premises number and a unique alphanumeric sequence. The premises identification number will be the Postal Service State abbreviation followed by up to five alphanumeric characters or the national premises identification number. All tags must have the U.S. shield. Premises tags produced by approved tag companies will have the premises number and a unique production number. Series of alphanumeric USDA eartags and backtags may be assigned as premises identification if they are linked to the premises in the SNGD.

4. Issuance of official identification tags to persons other than producers

The VS Area Office or the State Veterinarian's office for the State in which that person maintains his or her place of business will assign a person number, when requested, to each accredited veterinarian or regulatory person and a premises number and premises identification number to persons who handle sheep and goats in commerce and will issue official USDA serial number backtags or eartags to these persons when requested. Premises eartags will not be issued to persons who do not maintain breeding flocks.

The official responsible for issuing eartags in a State may assign serial numbers of official eartags to other responsible persons if the State animal health official and the AVIC agree that such assignments will improve scrapie control and eradication within the State and if appropriate records are maintained to permit traceback of animals to the flock of origin and flock of birth.

5. The owner of the flock of origin is the primary person responsible for officially identifying animals

The owner of the flock of origin or his or her agent must officially identify any animal that requires official identification before putting it in the same enclosure with animals from a different flock of birth. 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.

Producers are strongly encouraged to identify their animals officially before the animals leave their premises whenever it is practical to do so to prevent any error from occurring in the later identification of the animals and to ensure that they will meet the interstate movement requirements.

If official identification has not been placed on the animal by the owner before leaving the flock of origin, the owner must ensure that the animal is officially identified before it is put in the same enclosure with animals from a different flock of origin and before change of ownership.

6. Responsibility of persons handling sheep and goats in commerce to identify animals

A person who **delivers** an animal that is required to be identified to a place where it will be put in the same enclosure with animals from a different flock of origin must ensure that the animal is officially identified to its premises of origin before putting it in the same enclosure with animals from a different flock and before a change of ownership.

A person who **receives** an animal that is required to be identified at a site where it will be commingled must ensure that the animal is officially identified to its premises of origin before putting it in the same enclosure with animals from a different flock and before change of ownership.

A person cannot move animals lacking the required identification that have been put in the same enclosure with animals from a different flock of origin unless they are identified in accordance with 9 CFR 79.2(a)(3). (This section requires that all possible flocks of origin be recorded.)

7. **Premises and individual identification**
Premises identification may be used as official individual animal identification if the premises identification method either includes a unique production number or is combined with a flock eartag that has a unique production number. Official individual animal identification may be used as premises identification if the tag numbers have been assigned to the flock of origin by a State or Federal animal health official and have been linked to the premises of the flock of origin in the SNGD and the animals are accompanied by an owner statement.
8. **Restrictions on the application of premises identification**
No person will apply a premises identification number or a brand or ear notch pattern to an animal that is not from the flock of origin to which the number was assigned by a State or APHIS representative or to which the brand or ear notch pattern has been assigned by an official brand registry. This prohibition includes individual identification (such as USDA tags and backtags) that has been assigned to a premises for use as premises identification and registration tattoos that contain prefixes that have been assigned to a premises for use as premises identification. This procedural requirement does not prevent an owner from applying his or her premises identification to an owned animal as long as it is also identified to its premises of origin or birth.
9. **Restrictions on the removal of official identification**
No person will remove or tamper with any official identification device. At the time of slaughter, animal identification must be maintained throughout postmortem inspection in accordance with regulations of USDA's Food Safety and Inspection Service.
10. **Loss of ability to apply official identification**
Any person who fails to comply with part III, Identification Requirements, must not be assigned serial numbers of USDA backtags, official sheep and goat tattoos, official eartags, or premises identification numbers.
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 metal eartag, official tamper-resistant 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 of ears or similar problems. Animals other than RR sheep that are not removed will also be identified with an electronic identification device (EID) and be recorded in the SNGD.
- b. Animals that are positive on an official live-animal test will be identified with a red metal tag. Only APHIS or State representatives may acquire official red metal tags.
- c. All other animals will be identified with either a white or blue eartag. Blue tags are for animals in slaughter channels only.
- d. 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.

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 SNGD.

B. Records of animals handled

Persons who maintain records as indicated below will be considered in compliance with the intent of the recordkeeping requirements described in 9 CFR 79.2, Identification of sheep and goats in interstate commerce.

1. General requirements

- a. Persons who purchase, acquire, sell, or dispose of sheep and goats that are required to be identified by the regulations in 9 CFR 79.2 and 79.3 must officially identify the animals as to their premises of birth or origin if they are not already officially identified. (Persons may not sell or dispose of unidentified animals that are 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. Persons may not purchase or acquire unidentified animals that are required to be identified unless they identify them 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 number 3 below, "Records required of persons who purchase, acquire, sell, or dispose of animals."

- c. For the purpose of officially identifying animals that are changing ownership, the person purchasing or acquiring the animals may act as an agent for the person disposing of or selling these animals.
- d. Animals that lose their official identification may be retagged, provided that all possible flocks of origin are listed in the record describing the new identification that is applied.
- e. Low-risk commercial sheep, as well as goats that would qualify as commercial low-risk goats except for their being commingled with low-risk commercial sheep, may be identified using an official premises eartag rather than a registered brand.

2. Records required of persons who apply official identification to animals

- a. Persons who apply official identification assigned directly to the owner of the premises of origin of the animal must maintain the following records:
 - (1) The date the animals were officially identified;
 - (2) The number of sheep and the number of goats identified;
 - (3) The premises number or serial numbers applied. (Note: Preexisting tags do not have to be recorded, although this is encouraged.); and
 - (4) For animals born after January 1, 2002, in another flock and not already identified to flock of birth, the name and address of the owner of the flock of birth, if known.
- b. Veterinarians, dealers, or market personnel who apply official identification that is not assigned to the owner of the premises of origin of the animal in the SNGD must maintain the following records:
 - (1) For animals that have official identification:
 - (a) The date tagged;
 - (b) The number of sheep and the number of goats identified;
 - (c) The serial numbers applied. (Note: Preexisting tags do not have to be recorded although recording is encouraged); and
 - (d) The name and address of the person who owns the animals.
 - (2) For animals without official identification:
 - (a) The date tagged;

- (b) The number of sheep and the number of goats identified;
 - (c) The serial numbers applied;
 - (d) The name and address of the owner of the flock of origin;
 - (e) If the person who currently owns the animals is different from the owner of the flock of origin or birth, the current owner's name and address; and
 - (f) If the owner of the flock of birth is different from the owner of the flock of origin, and if the animals were born after January 1, 2002, the name and address of the owner of the flock of birth, if known.
- 3. Records required of persons who purchase, acquire, sell, or dispose of animals**
- a. Persons who purchase or acquire sheep or goats must maintain normal business records that include the following information:
 - (1) The number of animals purchased or acquired;
 - (2) The date of purchase or acquisition;
 - (3) The name and address of the person from whom the animals were purchased or otherwise acquired;
 - (4) The species and breed or class of animal;
 - (5) A copy of the brand inspection certificate for animals officially identified with brands or ear notches; and
 - (6) CVI when required.
 - b. Persons who sell or dispose of sheep or goats must maintain normal business records that include the following information:
 - (1) The number of animals sold or disposed of;
 - (2) The date of sale;
 - (3) The name and address of the buyer or person who acquired the animals;
 - (4) The species and breed or class of animal;
 - (5) A copy of the brand inspection certificate for animals officially identified with brands or ear notches; and
 - (6) CVI when required.
- 4. Keeping of records**
- Each person required to keep records under this paragraph 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 records-retention requirement may be extended for such further period as the Administrator 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 USDA or State employee upon that employee's request and presentation of his or her official credentials.

Part IV—Shows and Sales

Official identification is required for any sexually intact animal to be exhibited.

Whenever practical, ewes over 12 months of age (as evidenced by eruption of the first 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.

All sheep and goats from SFCP-enrolled flocks must be housed and handled to prevent direct contact with female sheep and female goats from other flocks of lower status. Spacing sufficient to prevent contact or solid partitions 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.

If sheep or goats (other than low-risk goats, see definition) that are within 30 days of parturition (or that are postpartum, have aborted, or are pregnant and have a vaginal discharge) are allowed at a show, special arrangements must be made to keep them 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.

Should a lambing or kidding occur at the show, the placenta, placental fluids, and soiled bedding must be removed immediately and disposed of in a sanitary landfill or by another method approved by the State. The dam and her offspring will 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 must be thoroughly cleaned and disinfected before use by another animal.

Part V—Program Stages

A. 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.

B. Scrapie classification, renewal, or reclassification of State or zone

1. **Purpose:** This application is for the annual classification, classification renewal, or reclassification of a State for national scrapie status recognition.
2. **Data source:** Area and State offices and the SNGD.
3. **Action:** A completed VS form 5–24 application and report or equivalent must be filed by the VS Area Office for each State annually. The completed VS form 5–24 should be submitted to the Regional Scrapie Epidemiologist within 1 month after the renewal due date. The application must be signed by both the State Veterinarian and AVIC. The required data include certification statements and reports on sheep flock and goat herd-monitoring and testing results in the State; the number of positive, high-risk, exposed (broken down by type), and suspect animals; quarantines or movement restrictions issued (if any) and release dates; slaughter test results; animal tracebacks; a brief summary of the history of scrapie in the State; and success in the identification of sheep and goats.
4. **Regional level:** The Regional Scrapie Epidemiologists will review the VS form 5–24 applications for their region for completeness to determine if the State meets the requirements in accordance with 9 CFR, part 79, and these UM&R for scrapie control and eradication and forward them with a recommendation for approval or disapproval to the National Center for Animal Health Programs, Ruminant Health Programs (NCAHP RHP).
5. **National level:** The NCAHP National Scrapie Program Coordinator will approve all VS form 5–24 applications based on the recommendations of the regional epidemiologist. The National Scrapie Program Coordinator will inform the State Veterinarian of any change in status or of the renewal of status by letter with copies to the Regional Director, Regional Epidemiologist, and AVIC . In cases that involve a change in status, the National Scrapie Program Coordinator will provide a copy of the application for information and comment to the Scrapie Committee of the United States Animal Health Association. APHIS will publish changes in status in the *Federal Register* as an interim rule.

Part VI—Monitoring and Surveillance

A. SFCP

Copies of the SFCP standards may be obtained on the Internet at <http://www.aphis.usda.gov/vs/naphs/scrapie> or from APHIS, NCAHP RHP, 4700 River Road, Unit 43, Riverdale, MD 20737–1235.

B. Scrapie surveillance

Suspect animals at markets or slaughter facilities

Clinically suspect and test-positive 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 should be placed under movement restriction until an investigation can be done. If the investigation concludes the animal is a scrapie suspect, the animal should either be purchased for diagnostic purposes and necropsied or maintained under restriction until it either recovers and is released, or dies and is necropsied (see part VII, C).

Mature traceable sheep that are dead or down at a market will be sampled and tested when practical to do so.

Clinically suspect animals at slaughter facilities must be condemned in accordance with regulations of USDA's Food Safety and Inspection Service, and they must be reported to the AVIC so that samples can be collected for diagnosis and the carcass can be removed from the food chain.

Regulatory Scrapie Slaughter Surveillance (RSSS)

APHIS coordinates sampling and testing of mature traceable sheep at slaughter that have a higher than average probability of being scrapie infected. (See VS Memorandum No. 557.11 for sampling goals and selection criteria and the Regulatory Scrapie Slaughter Surveillance Handbook for detailed sample collection instructions.)

C. Live-animal surveillance testing

States may pilot live-animal sampling programs for at-risk populations on farms, at markets, or as a condition to participate in a sale in areas of high scrapie prevalence or in high-prevalence classes within an area or for other appropriate reasons. Movement beyond the pilot stage will be based on the relative cost of identifying new infected flocks through the piloted method as compared with slaughter surveillance.

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 UM&R, H, K, or any amino acid other than R at codon 171 is considered the same as Q at codon 171.

Research indicates that QQ sheep and goats are the most susceptible to scrapie infection; whereas QR sheep are much less susceptible, and RR sheep are resistant. Therefore, when determining the status of the flock, it is only necessary to test for scrapie in QQ sheep and goats unless insufficient QQ sheep and goats are available. In this case, the DSE may require the 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.)

“Exposed and high-risk animal,” as defined in 9 CFR, part 79, will be used to determine which animals to trace out of infected or source flocks. In addition, all sheep and goats residing in source or infected flocks whose owners elect to conduct genetic flock plans will be considered exposed animals. All high-risk and exposed animals will be further designated as one of the following: genetically resistant exposed sheep, genetically less susceptible exposed sheep, genetically susceptible exposed animals, or low-risk exposed animals.

B. Redesignation of high-risk and exposed animals

High-risk and exposed animals that meet the definition of genetically resistant exposed sheep, genetically less susceptible exposed sheep, genetically susceptible exposed animals, or low-risk exposed animals will be designated as such. These animals must be officially identified and individually listed in the SNGD.

C. Procedures for investigating a report of a clinically suspicious animal

1. APHIS and State representatives will notify each other of a report of a clinically suspicious animal.
2. The flock will be assigned a number; and if it is not already in the SNGD, it will be entered as a premises. A status record will be created that lists the flock status as being under investigation (INVEST) with the reason for the investigation status coded as suspect (SUSPECT).

3. A VMO will contact the flock owner. The suspect animal and, when determined to be appropriate by the DSE with the concurrence of the State Veterinarian, the flock will be placed under a hold order or other appropriate restrictions until the status of the animal is determined.
4. The owner will be provided with information about scrapie.
5. A premises visit will be scheduled as soon as possible but within 7 days of initial notification. The visit is to allow the VMO to examine the animal and conduct an investigation.
6. 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.
7. If upon 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 State Veterinarian concurs, the State will maintain movement restrictions on susceptible animals in the flock until the animal's status has been determined.
8. If the owner declines euthanasia of the suspect animal, the VMO will require that the animal be held for observation. 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 State Veterinarian concurs, movement restrictions will also be maintained on susceptible animals in the flock until the animal's status has been determined.
9. Suspect sheep that are not euthanized must be third-eyelid tested and genotyped at codons 171 and 136 at VS cost, if funds are available.
10. 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 an appropriate sample 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 or if he or she moves the animal without a permit.

11. 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.
12. If the VMO determines the animal does not have scrapie, movement restrictions will be lifted; the investigation status will be closed in the SNGD.
13. An individual animal record will be created in the SNGD; if scrapie or genetic testing is done, a test status will also be opened in the SNGD. (See the APHIS Scrapie QuickPlace Web site, <https://qp01.aphis.usda.gov/QuickPlace/scrapie/Main.nsf?OpenDatabase>, for additional data entry and tissue collection instructions.) Access to the QuickPlace is limited to State and Federal employees. To request a QuickPlace user name and password, contact the Scrapie Program Specialist at (301) 734-6954, or by e-mail at scrapie_program@aphis.usda.gov.

D. Procedures for investigating a report of a live test-positive animal

1. APHIS and State animal health officials will be notified by the veterinarian or laboratory that conducted the test, and the first notified will notify his/her counterpart.
2. If the flock does not already have an assigned premises number, it will be assigned a number in the SNGD. A status record, with status INVEST and reason SUSPECT, will be generated. (See the APHIS Scrapie QuickPlace for data entry instructions.)
3. If the test was an official test, the flock will be handled as in part VII, E, of this document. If the test was an unofficial APHIS-sponsored test, the animal will be purchased under the provisions of the APHIS live-animal test agreement.
4. If the test was an unofficial test, the animal will be classified as suspect in accordance with 9 CFR, part 79.
 - a. If the animal is exhibiting clinical signs, it should be handled as in part VII, C.
 - b. If the animal is a sheep, it will be third-eyelid tested and genotyped at codons 171 and 136 with the owner's consent. (Note: If the owner refuses to test, the flock will be designated noncompliant.)

- c. The suspect designation of an animal may be removed by the DSE if:
 - (1) The animal is not showing clinical signs of scrapie; the animal is over 18 months of age and is negative on an official test; or
 - (2) If an epidemiological investigation shows the animal is not likely to be infected and an official third-eyelid test cannot be done due to lack of sufficient tissue or because the animal is a goat. (Note: If the unofficial test has a reasonable scientific basis, such as a third-eyelid test at a laboratory that has not been approved, or IHC on lymph node or tonsil, the animal should not be redesignated unless prion protein scrapie (PrP^{sc}) cannot be detected in any tissue at necropsy. 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 will be created in the SNGD. If the animal is necropsied or third-eyelid tested, a test status will also be opened in the database. (See the APHIS Scrapie QuickPlace for additional data entry and necropsy tissue collection instructions.)
 6. The DSE will submit a summary report to the Regional Scrapie Epidemiologist of suspect animals investigated each month by the 15th of the following month. The report will include number of suspects investigated and 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 third-eyelid testing in a live sheep

1. Responsibilities of NVSL:
 - a. Notify the AVIC, either directly or through the RSSS coordinator, that a tissue submitted for scrapie testing was positive by an official scrapie test.
 - b. Submit tissue for genotyping at codons 171 and 136 and report results to the VS AVIC directly or through the RSSS coordinator.
2. Responsibilities of AVIC/Area Office:
 - a. Keep State animal health officials informed.
 - b. Assign a field VMO.
 - c. Request approval for indemnity from the Regional Office.
 - d. Make sure SNGD is updated with accurate flock status, event, and animal data. (See section on SNGD.)

- e. 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.
 - (1) The notification should include, when known:
 - (a) Information about the positive animal(s), including date of birth, sex, date of death, date of diagnosis, genotype at codons 171 and 136, the flock of origin and date of entry into the flock if purchased, and whether the animal(s) was born on or lambed on the premises where the exposed animal resided and the date of each lambing;
 - (b) 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
 - (c) 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, 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, and maintained in separate group.
 - (d) 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, below.
- f. Assign additional field VMOs if needed to investigate within area traceouts.
- g. Request records from breed registries.
- h. Officially notify the owner of the flock under investigation of infected and/or source status designation as required by 9 CFR, part 79.
- i. 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 same VS area, 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 VS area, notification must be made to the AVIC and the Regional Scrapie Epidemiologist of the birth flock's State

as soon as possible, but within 45 days. The receiving VS Area Office will initiate data entry and the investigation of the birth flock. The receiving VS Area Office will notify the Regional Scrapie Epidemiologist and the sending VS Area Office of the outcome of the investigation.

- j. 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 of out-of-area potentially infected flocks will be handled the same as out-of-area potential birth flocks described above.
3. Responsibilities of the State Veterinarian:
- 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(s) of the flock and/or premises until the owner has signed and is in compliance with a flock plan. Once an owner is in compliance with a flock plan, the State Veterinarian may modify the order to include only those sheep or goats that are required to be restricted or destroyed under the flock plan.
 - b. Others as mutually agreed or as provided for in an MOU or cooperative agreement.
4. Responsibilities of field VMO:
- a. The VMO will contact the owner and schedule a visit within 7 days of receipt of the NVSL report. Before the initial visit the VMO should:
 - (1) Review the flock cleanup plans in part VIII so that he or she can advise the producer of the options that are available. The species and genotype of the positive animal and the epidemiology of the flock will determine the type(s) of 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 if the producer wants to stay in the sheep business.);
 - (2) Determine whether indemnity funds are available; and
 - (3) Review requirements and procedures for approval of plans with the DSE.
 - b. During the initial visit, the VMO will complete c-f(6) below.
 - 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 embryo's on the premises and when appropriate for all sheep and goats including embryos owned by the owner(s) of the flock and/or premises.
 - (2) Inventory all sheep and goats and sheep and goat embryos on the premises and apply official ear tags to the animals. An 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 SNGD with an event summary 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 cleanup plan options that are available.
 - (5) Confirm the status with the DSE and report the information to the Area Office for entry into SNGD. If the status cannot be immediately determined, a PDESIG status should be entered.
 - (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 APHIS Scrapie QuickPlace and have the DSE approve the plans. Once the DSE has approved the plans, the VMO will review the plans with the producer and have the producer sign the plans. If the producer has owned any registered sheep, he or she must also sign a records 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 PLAN and PPLAN status entered in SNGD.
 - (9) Determine whether each animal is suspect, high-risk, scrapie positive, or exposed. Animals that are no longer in the flock for which there is insufficient information to designate them 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 source flocks, it should be the beginning of the lambing season in which the positive animal was born or 5 years whichever is earlier.

- (12) VS form 5–19, or an electronic equivalent, will be completed, and additional information, as listed in part X, will be collected for the epidemiologist’s 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, and registration information, and the name and address of the person who acquired the animal. Document all steps. Provide this documentation, copies of all documents, and either the completed epidemiological investigation report or the information needed to complete the epidemiological investigation report (as directed by your DSE), the signed original flock plan, PEMMP, and request for registration records to the Area Office with a copy to the DSE.
- g. If the flock does not meet the definition of an infected or source flock, the pending designation status in the database will be closed. If the flock meets the definition of a source or infected flock, the pending designation status will be closed, and an infected or source status and a hold status will be opened in the database.
5. Responsibilities of DSE:
- a. Ensure that the VMO assigned to conduct an investigation understands the process.
 - b. Review and approve:
 - (1) The status of flocks.
 - (2) Flock plans.
 - (3) PEMMPs.
 - (4) Designation of animals.
 - (5) Release of exposed, infected, or source flock status.
 - c. If the DSE believes that genetically less susceptible ewes should be restricted, the DSE must consult with the State Veterinarian and the AVIC prior to taking action. With their concurrence, the DSE may require the restriction of some or all of the exposed QR ewes in the flock. Removal with indemnity must be approved by the Regional Scrapie Epidemiologist. 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 QuickPlace. (Note if the codon 136 genotype of the positive animals is unknown AVQR sheep may be removed at the discretion of the DSE.)
 - d. Animals that meet the definition of high-risk or exposed animals and that, due to unusual circumstances, are not a significant risk may be redesignated

low-risk exposed animals by the DSE. (See definition of low-risk exposed animal.)

- e. If the DSE determines that additional testing is needed to designate the flock, a test status will be opened, and the flock will be tested as described in VII, G, below. (The DSE may use this option only in cases where the scrapie exposure was minor or could not be confirmed.)
 - f. Review SNGD to ensure that flock statuses were accurately entered and released and animal designations and information were correctly entered in SNGD.
 - g. Prepare or review indemnity requests for transmittal through the AVIC to the Regional Scrapie Epidemiologist.
 - h. Prepare or approve the epidemiological investigation report and summary for each infected, source, and exposed flock (see part X) and transmit them to the Regional Epidemiologist.
6. Responsibility of Regional Scrapie Epidemiologist 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 the region are properly trained.
 - c. Review all epidemiological investigations for compliance with policy and maintain a copy of the report for the National Coordinator on the shared drive.
 - d. Prepare a regional summary report each month that will be submitted to the National Scrapie Program Coordinator summarizing the epidemiology, status, and final disposition of each infected and source flock. (See APHIS Scrapie Program QuickPlace for summary format.)
 - e. Review and approve requests for indemnity.
 - f. Identify animals to be moved to research facilities.
7. Additional details concerning handling of infected and source flocks:
- a. The infected or source status will be reopened and a noncompliant status opened if the flock is found not to be in compliance with the plan.
 - b. All actions required by the plan that are under the control of the flock owner will be completed within 60 days.

F. Procedures for investigating and monitoring a flock that has received an exposed or high-risk animal (See flowchart in figure 1)

- 1. The flock must be assigned a premises identification number and entered in the SNGD as a premises, if not already entered. A status record must be created

listing the flock status as investigation (INVEST) with the reason for the investigation status coded as TRA (trace).

2. APHIS and State animal health officials will notify their State or Federal counterpart.
3. The flock owner will be contacted by a regulatory VMO.
 - a. The high-risk animal(s), any other animals required for testing as part of the investigation, and, when the State Veterinarian determines the circumstances warrant it, the flock will be restricted by an authorized representative of the State until the status of the high-risk animal and animals required for testing is determined.
 - b. The owner will be provided information about scrapie, and a premises visit will be scheduled for a VMO to examine the animal(s) and conduct an investigation as soon as possible but within 7 days of notification of 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 and exposed sheep traced to the flock can be positively identified and are present in the flock, they will be officially identified and either genotyped at codon 171 or in the case of QR sheep, both 171 and 136.

Approval from the NCAHP National Scrapie Program Coordinator must be first obtained before genotype samples can be submitted to a laboratory for testing. An e-mail message must be sent reflecting the following information: name of flock, flock premises identification number, type of test requested, reason for test, any previous genotype tests performed on the sheep, number of sheep to be tested, 10-day/5-day turnaround requested. Approval for the codon testing will then be e-mailed back to the requestor, as well as which laboratory to send the samples. Please see Scrapie Quickplace for further details on this procedure.

Once a sheep is genotyped, it will be indemnified only if it is designated genetically susceptible or needed for study. The genotype of high-risk and exposed sheep that the owner wants to keep will be determined at two (Note: The need for two tests is under review, and a decision will be made based on an analysis of test data) different contract laboratories using samples collected on two separate dates unless same day collection is authorized by the Regional or National Epidemiologist. In the case of infected flocks, the second collection should occur after the genetically susceptible animals have been removed. When

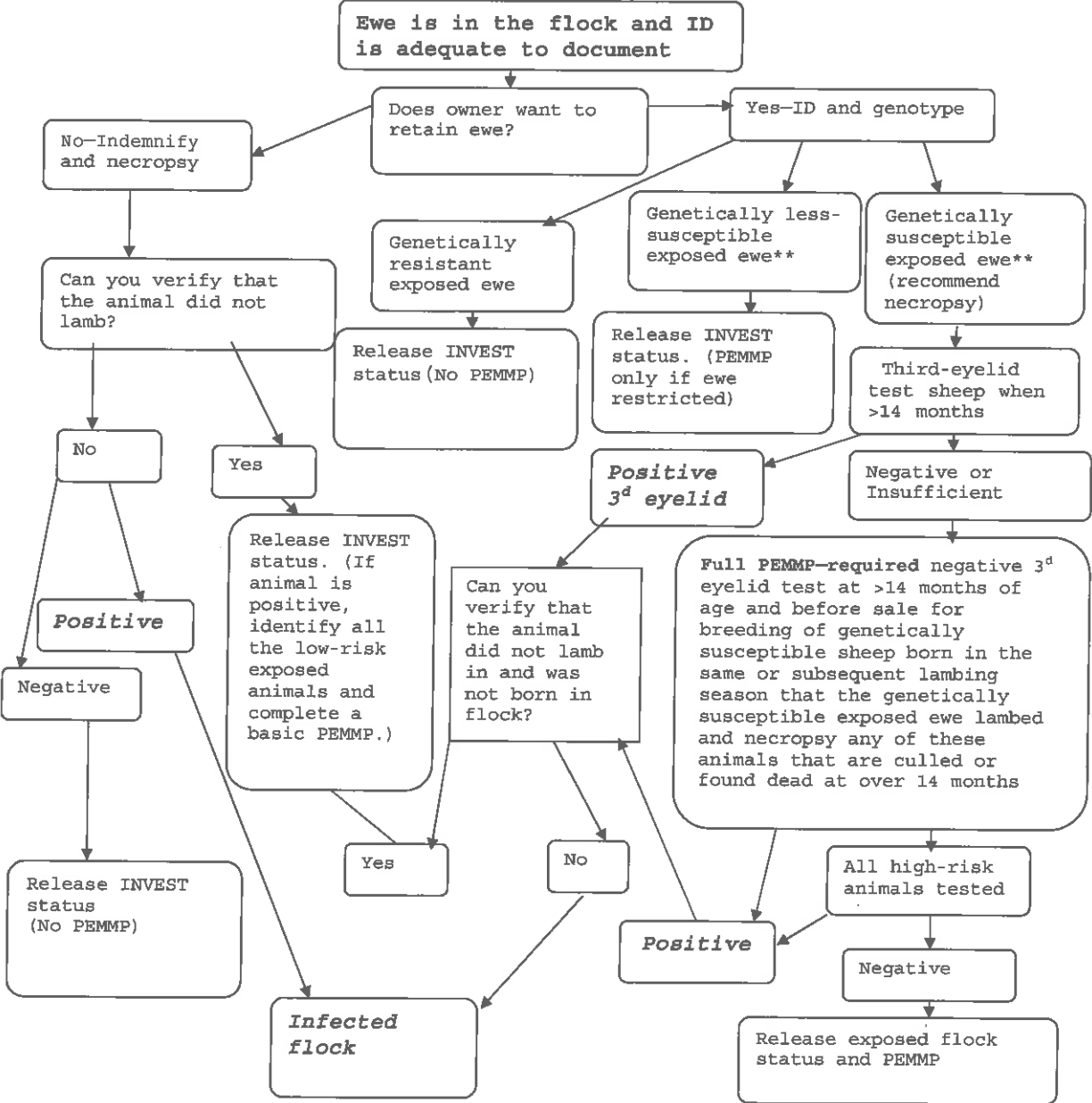
separate collection cannot reasonably be done, the eartag numbers and sample labels must be read and checked for accuracy by both the owner or owner's representative and a State or APHIS representative.

5. Animals that meet the definition of genetically resistant exposed sheep, genetically less-susceptible exposed sheep, genetically susceptible exposed animal, or low-risk exposed sheep will be designated as such and may move only as allowed in part II, M, of this document.
6. The presence of an exposed male animal 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 status is closed. If the animal is a genetically susceptible exposed male animal, it will be restricted to movement by permit only or when requested by the owner indemnified and destroyed.
7. INVEST status can be released if:
 - a. All female traced exposed animals can be positively identified and are present in the flock; and
 - b. All the 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 the exposed female goats are tested by IHC at necropsy and found negative.
8. These release reason codes will be used for flocks under investigation that received exposed animals:
 - a. LO (flocks in which all traced animals were RR sheep or unrestricted QR sheep, or flocks in which some sheep were RR or unrestricted QR and some were necropsied);
 - b. QRRES (flocks that retain genetically less-susceptible exposed sheep that are restricted); or
 - c. ESN (flocks in which all traced animals were necropsied).
9. LO and ESN flocks will not have PEMMPs.
10. The INVEST status will be closed, an exposed flock status will be opened, and a full PEMMP will be done if a genetically susceptible exposed female sheep is retained. The PEMMP (see format posted in the APHIS Scrapie QuickPlace) will require:
 - a. The testing of all the genetically susceptible exposed female animals and any restricted genetically less susceptible exposed sheep by third eyelid,

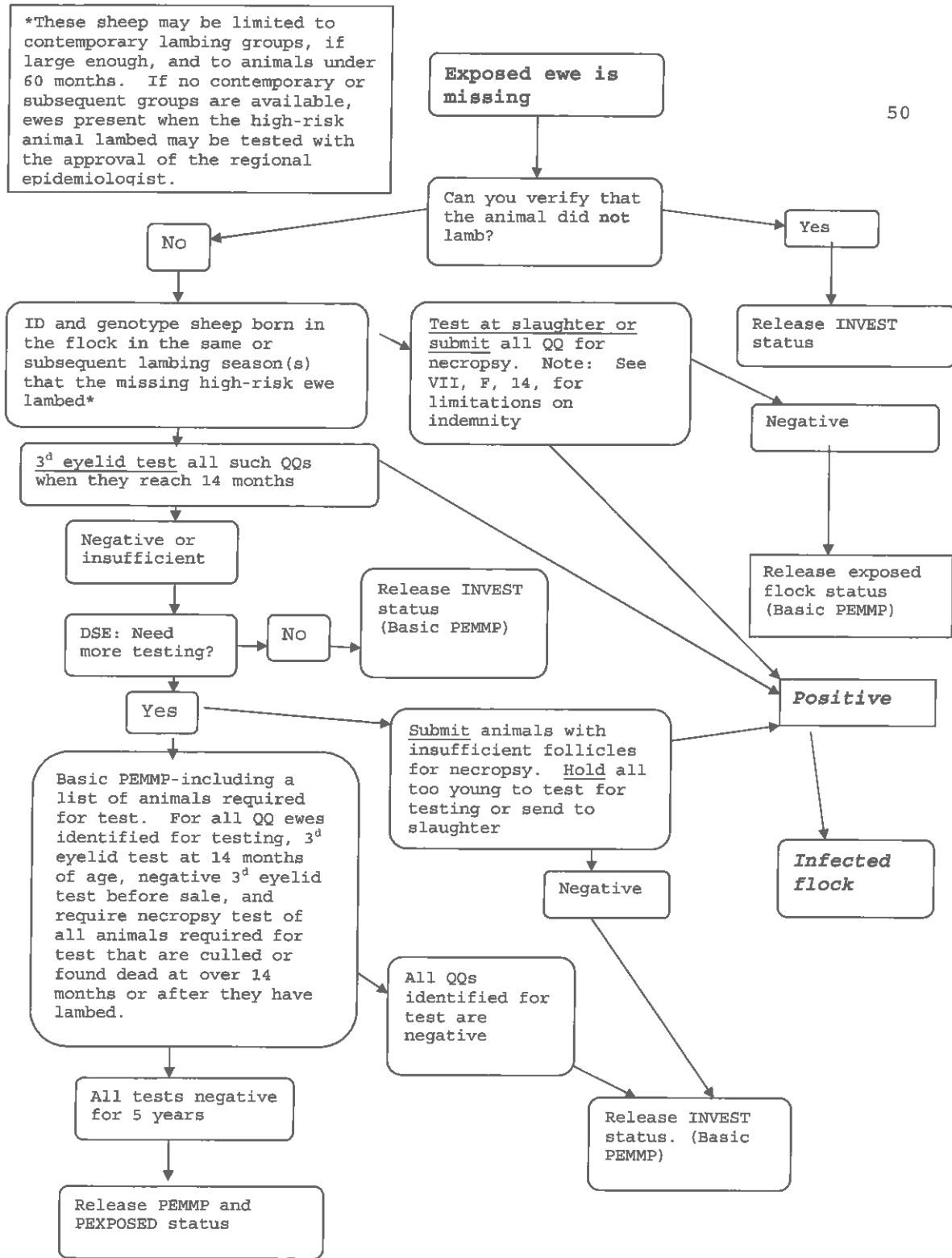
- immediately, and by IHC when they die or are culled, and any genetically susceptible female animals born after the high-risk animal was introduced that die at over 14 months of age; and
- b. A negative third-eyelid test before sale of any genetically susceptible female sheep born in the same or subsequent lambing season that the high-risk animal lambled unless sent direct to slaughter.
 - c. These flocks will remain in exposed flock status until the PEMMP is completed.
11. If all exposed female goats are not tested by an approved test at necropsy, the flock will be placed on a full PEMMP and remain in exposed status for 5 years or until all the exposed female goats die and are tested by an approved test.
 12. If high-risk female animals that may have lambled in the flock (“may have lambled” refers to any ewe 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. In cases where the exposed animal is believed to be present but could be one of several animals, genotype testing of these animals may be approved by the Regional Epidemiologist. In cases where there are insufficient lambing cohorts to test, the Regional Epidemiologist may approve testing of ewes present during the lambing seasons in which the missing ewe(s) lambled.
 - b. All the QQs, and, when appropriate, other susceptible sheep over 14 months of age will be tested by third-eyelid test or IHC at necropsy. (Note: Necropsy testing with indemnity must be approved by the Regional Epidemiologist, see 14 below for approval criteria.) 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 INVEST and TEST status until all animals required for test have been tested. (See figure 1.) Once testing is completed, the INVEST status will be closed with reason code INFECT or STS (statistical sampling).
 - c. All animals required for test will be restricted until testing is completed.

* If ID is not adequate, use animal missing flowchart.
 ** Apply EID.

Figure 1—Trace High-Risk Animals



*These sheep may be limited to contemporary lambing groups, if large enough, and to animals under 60 months. If no contemporary or subsequent groups are available, ewes present when the high-risk animal lambed may be tested with the approval of the regional epidemiologist.



13. If testing is done, a test status will be opened in the SNGD and released when the test results have been entered into the SNGD. Individual records will be made in the SNGD for each tested, genotyped, exposed, and high-risk animal. The exposed and high-risk animals and any other animals required for test 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.
14. 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 Regional Epidemiologist:
 - a. Sheep with insufficient third-eyelid follicles to test. (Note: In the case of high-value sheep, two attempts should be made to collect third-eyelid biopsies.)
 - b. Sheep designated for testing in cases in which the sheep are under 1 year of age (too young to test by third eyelid) and the owner does not want to retain the sheep until they are old enough to test.
 - 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 Regional or National Scrapie Epidemiologist, and the State Veterinarian.
 - e. Any suspect animal.
 - 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.

15. 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.
16. The DSE must provide a monthly report to the Regional Scrapie Epidemiologist detailing the status of, and final disposition of, all high-risk and exposed animals traced to the State.
17. The Regional Scrapie Epidemiologist will prepare a monthly summary report of the investigation and disposition of all traces in the region for the National Scrapie Epidemiologist.

Note: All SNGD flock status information should be entered within 1 week and individual animal information within 3 weeks of the designation being made by the DSE.

G. Testing a flock that is pending designation as a source or infected flock to determine whether the flock is infected

1. Testing of a flock that is pending designation as a source or infected flock to determine whether the flock is currently infected, other than by necropsy of all genetically susceptible exposed female animals, will be conducted only when the DSE determines such testing is needed to properly designate a flock to be a source or infected flock. The DSE should make such a determination only when there is reasonable doubt that the flock is infected.
2. Such testing will require genotyping of all sexually intact sheep 14 months of age and older. Only genetically susceptible exposed animals will be tested for scrapie. (Note: Only QQ sheep and goats are considered genetically susceptible unless a positive QR or RR sheep was identified in the flock of origin of the exposed animal.)
 - a. QQ sheep may be tested by third-eyelid biopsy. Goats and other genetically susceptible animals will only be tested at necropsy.
 - b. Goats and genetically susceptible sheep that are not QQ should be tested at necropsy if there are less than 30 QQ sheep that are available for test or if the QQ sheep are not representative of the flock. Examples would include animals born on the premises in cases where the QQ sheep are purchased additions and goats when the positive animal was a goat or if the goats were in a contemporary lambing/kidding group to the positive animal or the positive animal's offspring.
3. To detect disease at 1 percent prevalence with 95 percent confidence with live-animal testing (third eyelid), refer to Table 2 for the number of animals to test for various flock sizes. Due to a 40 percent average nontestable rate when the live-animal test is conducted, 40 percent more animals have been added to each sample size.
4. When the potential exposure to a flock was the result of a purchased positive female animal possibly lambing in the flock, only animals born after the positive animal might have lambed and ewes present during the lambing seasons in which the positive female animal resided on the premises will be tested. Such ewes must be tested at least 18 months after the last possible lambing of the infected animal. If the exposure event occurred recently, and thus high-risk animals have not lambed in a subsequent lambing season, a flock plan that requires destruction

of all female genetically susceptible exposed animals from that birth cohort should be strongly considered along with testing or removal of other female genetically susceptible exposed animals.

5. To detect disease at 1 percent prevalence with 95 percent confidence by IHC of the third eyelid 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. Goats and 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 third-eyelid testing.

Table 2—Testing Schemes

Number of sheep* greater than 14 months of age of QQ genotype	Number to be sampled by third-eyelid test
<215	Sample and necropsy all animals that have invalid third-eyelid tests results.**
215-300	Sample all (minimum of 215 valid tests)
301-400	335 (minimum of 239 valid tests)
401-500	358 (minimum of 256 valid tests)
501-1,000	410 (minimum of 293 valid tests)

* Goats must be tested by necropsy only.

** Sensitivity = 88 percent and specificity = 100 percent are assumed. The confidence level in small flocks (fewer than 300) will be less than 95 percent.

Part VIII—Flock Cleanup Plans

A. Movement restrictions on animals in flocks in plan status

See part II, M, of this document and the standard flock plan formats provided by APHIS.

B. Requirements for flock plans and PEMMPs

1. A flock plan and PEMMP will be prepared by the VMO using the standard plan formats posted in the APHIS Scrapie QuickPlace. The species and genotype of the positive animal and the epidemiology of the flock will determine the type(s) of flock plan that may be offered to the producer. The PEMMP selected will be determined based on whether any high-risk animals are retained. If no high-risk animals are retained, a basic PEMMP should be used. If high-risk animals are retained, a full PEMMP will be used. If any retained animals that are required for test are not high risk, a basic PEMMP will be used with an attachment listing all animals required for test and the type of test(s) required.
2. When a flock plan requires an animal to be destroyed, the Regional Scrapie Epidemiologist must approve the indemnity and determine if the animals are needed for research or developmental projects.
3. There are three basic types of flock plans:
 - a. Genetics-Based Flock Plans – General guidelines (see step-by-step instructions in part VIII, B, 3, b, below, for standard genetic plan):
 - (1) A genetic plan is preferred for most flocks. When a genetics-based flock cleanup plan is used, owners can retain or sell RR sheep, QR rams, and most QR ewes without restriction.
 - (2) Genetics-based plans require the removal of all:
 - (a) Genetically susceptible exposed female animals;
 - (b) All test positive and suspect animals; and
 - (c) The 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.
 - (4) Exposed QQ rams and bucks may be removed at the owner's request. Exposed QQ rams and buck goats that are not removed will be treated as exposed animals and must move on a permit.
 - (5) Animals that are not designated genetically susceptible may also be

- removed when requested by the Regional Epidemiologist and agreed by the owner in order to provide animals or tissues for study.
- (6) Any animals that are removed may qualify for indemnity. These animals must be euthanized or moved to a quarantine facility for research.
 - (7) Genetically resistant and genetically less susceptible exposed sheep may be retained or sold without restriction after they have been officially identified as described in part VIII, B, 3, (a), (10), below, entered in the SNGD, and had their genotype confirmed.
 - (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 third-eyelid testing and genetic selection will be used.
 - (10) Exposed animals will be identified with an official eartag.
 - (a) The eartag number and the genotype will be recorded in SNGD.
 - (b) Animals, other than RR sheep, that are not removed will also be identified with electronic microchips provided by APHIS.
 - (11) Flocks where all genetically susceptible exposed female animals, female offspring of positive female animals, and test positive or suspect animals are not removed will be exposed flocks. Accordingly, until the PEMMP is completed, these flocks will have movement restrictions placed on these animals and in some cases less susceptible female animals residing in the flock, including such animals born or brought into the flock.
- b. Steps for completing a Standard Genetic Based Flock Plan – For source and infected flocks that retain only QR, HR, and RR ewes and male sheep and goats:
- (1) 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 goats” posted on the APHIS Scrapie QuickPlace. Have completed form reviewed by the DSE and then have the owner sign form.
 - (2) Provide an estimate of indemnity and disposal costs through the AVIC to the Regional Epidemiologist in the format provided by the regional office. Request authorization to submit blood for genotyping. (See instructions on the APHIS Scrapie QuickPlace.)
 - (3) Bleed all sexually intact sheep for genotyping and send blood to the authorized APHIS contract genotyping laboratory. Request codons 171 and 136 testing on all sheep unless instructed to do otherwise. Do not genotype goats.

- (4) Designate all animals in the flock as suspects, genetically susceptible exposed animals, genetically less susceptible exposed animals, genetically resistant exposed sheep, high-risk animals (see UM&R definition), and/or low-risk exposed animal.
 - (5) Have DSE review and approve the designations.
 - (6) Work with the DSE and AVIC to develop a necropsy (see necropsy instructions on the APHIS Scrapie QuickPlace) and disposal plan.
 - (7) Complete an indemnity request (VS form 1–23) that includes all suspect and high-risk animals; when requested by the owner, male genetically susceptible animals; and any other animals required to be in the flock plan. Then, have the request reviewed and approved by the AVIC and forwarded to the Regional Epidemiologist.
 - (8) Depopulate and necropsy indemnified animals. In most cases, all animals over 14 months of age should be sampled for scrapie testing and postmortem genotyping as described in the necropsy protocol posted on the Scrapie QuickPlace. When a large number of animals are involved and it is not practical to sample them all, an appropriate statistical sample may be taken. In addition, all test positive and suspect animals, any QR or RR animals that are destroyed, any animals that may implicate another flock, and all offspring of positive female animals must be sampled. Animals moved for destruction must move on a VS form 1–27 or State equivalent.
 - (9) Request authorization to submit blood from remaining sexually intact sheep at another contract laboratory to confirm the result at codon 171. Sheep and goats, other than RR sheep, that are not removed are identified with electronic microchips provided by APHIS. In most cases, this should be done at the same time the second bleeding is done.
 - (10) Observe and document cleaning and disinfection of premises.
 - (11) Release infected or source flock status.
- c. Exposure-Based Flock Plans: These plans require the depopulation of high-risk animals as defined in 9 CFR and any other animals that are required to be removed under a genetic based plan for the flock. This should be done only when requested by the owner.
- d. 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, State Veterinarian, and the Regional Epidemiologist or National Scrapie Program Coordinator. Such concurrence will be based on the availability of funds and whether a particular depopulation will enhance scrapie eradication. Examples of when whole-

flock depopulation should be recommended by the DSE for further consideration include:

- (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;
 - (3) Goat herds;
 - (4) Flocks where infection has recurred after a flock plan was completed in animals born on the premises and where the owner agrees not to restock with sheep or goats on the premises for at least 5 years;
 - (5) Flocks in States that have been classified as free of scrapie; and
 - (6) 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 official and/or an APHIS official (this is dependent on the delegation of duties within the State).
 - b. A plan status will be entered in the SNGD. Plan status means that a plan has been signed and the owner is in compliance with the flock plan.
 - c. All high-risk, exposed, suspect animals, and all animals under the plan will also be entered in the SNGD animal sample information form, 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. Prior to releasing the flock's plan and infect or source status, completion of the flock plan requirements must be verified by the VMO through an inspection, inventory, and records review. Upon verification, some or all of the movement restrictions may be removed and the flock's plan and infected or source status will be released. The infected, source, hold (hold will remain in place if any restricted animals are retained), and plan statuses will be released in the SNGD. A new status will be entered (PEPLAN) to indicate that the flock is on a PEMMP.

Part IX—Diagnostic Laboratory Approval Procedures and Test Interpretation

Laboratories will be approved in accordance with 9 CFR and applicable VS memorandums.

Part X—Reports

Reports will be made in accordance 9 CFR and applicable VS memorandums. Also see part V, B, and part VII of this document.

Epidemiological Investigation Report

The epidemiological report is prepared by the VMO or the DSE and used 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. The report will include:

- A. Information about the owner(s):
 - 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 animal(s), including:
 - 1. Date and place of birth or approximate age if date of birth is unknown;
 - 2. Sex, breed (if breed or cross is unknown, the animal's color);
 - 3. Official identification, any other identification, and any distinguishing marks or features;
 - 4. Date of death;
 - 5. Genotype at codons 171 and 136;
 - 6. All flock(s) in which the animal has resided and the dates during which the animal resided on each premises, and whether the animal lambed on any of the premises and the date of each lambing; and
 - 7. Results of all scrapie tests conducted.

C. Information about the flock, including:

1. Address and geographic location;
2. An inventory of sheep and goats owned at the time of the first visit and any animals added prior to completion of the flock plan. (The 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 available, third-eyelid test results; the designation of each animal; whether the animal will be indemnified, otherwise disposed of, or retained; any restrictions on animals that are not or will not 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 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 5 years if a date cannot be determined. The inventory will include all information required in part X, C, 2, above, 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, 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 identification numbers and marks, sex, breed, flock of origin if different, date of acquisition, date of birth or approximate age, if available genotype and third-eyelid test results, 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.

The information required for the epidemiological report may be gathered using VS forms 5–19, 5–20, and 5–18, or the equivalent information may be submitted in Microsoft Access.

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. The DSE will summarize the report and provide a copy to the Regional Scrapie Epidemiologist.

A copy of the epidemiological report, a copy of the VS form 1-23, and a summary (see APHIS Scrapie Program QuickPlace for the summary format) will be provided to the Regional Scrapie Epidemiologist by the DSE within 14 days of completion of the flock plan.

The DSE will send an interim summary report to the Regional Scrapie Epidemiologist for each month by the 15th of the following month until the complete report is provided.