

APHIS will publish a notice in the FEDERAL REGISTER advising the public of the Administrator's determination. The notice will describe the proposed revisions and the reasons for the proposed revisions and will invite public comment on the proposed revisions.

(ii) *Immediate process for revising the biosecurity audit tool.* If the Administrator determines that the biosecurity audit tool is no longer sufficient for auditors to use to conduct biosecurity audits pursuant to paragraph (f)(1)(i) or (ii) of this section, APHIS will immediately update the biosecurity audit tool. APHIS will publish a notice in the FEDERAL REGISTER advising the public of the Administrator's determination. The notice will specify the revisions and the reasons for the revisions, provide an effective date for the revisions, and will invite public comment on the revisions.

(g) Proposed updates to the NPIP Program Standards will be announced to the public through a FEDERAL REGISTER notice, as described in § 147.53(e) of this chapter.

(Approved by the Office of Management and Budget under control number 0579-0440)

[81 FR 6750, Feb. 9, 2016, as amended at 83 FR 40438, Aug. 15, 2018; 89 FR 106995, Dec. 31, 2024]

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§ 54.1 Definitions.

Accredited veterinarian. A veterinarian approved by the Administrator in accordance with part 161 of this chapter to perform functions specified in subchapters B, C, and D of this chapter.

Administrator. The Administrator of the Animal and Plant Health Inspection Service or any employee of the United States Department of Agriculture authorized to act for the Administrator.

Animal. A sheep or goat.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

APHIS representative. An individual employed by APHIS in animal health activities who is authorized by the Administrator to perform the function involved.

Approved laboratory. A laboratory approved by the Administrator in accordance with § 54.11 to conduct one or more scrapie tests, or genotype tests, on one or more tissues.

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

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

Classification or reclassification investigation. An epidemiological investigation conducted or directed by a DSE for the purpose of designating or redesignating the status (*e.g.*, scrapie-positive, exposed, high-risk, suspect, infected, noncompliant, source, etc.) of a flock or animal. In conducting such an

investigation, the DSE will evaluate the available records for flocks and individual animals and conduct or direct any testing needed to assess the status of a flock or animal. The status of an animal or flock will be determined based on the applicable definitions in this section and, when needed to make a designation under § 79.4 of this chapter, official genotype test results, exposure risk, scrapie type involved, results of official scrapie testing on live or dead animals, or any combination of these.

Commingle, commingled, commingling. Animals grouped together and having physical contact with each other, including contact through a fence, but not limited contacts. Commingling also includes sharing the same section in a transportation unit where there is physical contact.

Designated scrapie epidemiologist DSE. An epidemiologist who has demonstrated the knowledge and ability to perform the functions required and who has been selected by the State animal health official and the area veterinarian in charge. The regional epidemiologist and the APHIS National Scrapie Program Coordinator must concur in the selection and appointment of the designated scrapie epidemiologist. The designated scrapie epidemiologist must satisfactorily complete training designated by APHIS.

Destroyed. Euthanized and the carcass disposed of by means authorized by the Administrator that will prevent its use as feed or food.

Electronic implant. Any radio frequency identification implant device approved for use in the scrapie program by the Administrator. The Administrator will approve an electronic implant after determining that it is tamper resistant, not harmful to the animal, and readable by equipment available to APHIS and State representatives.

Exposed animal. Any animal or embryo that:

- (1) Has been in a flock with a scrapie-positive female animal;
- (2) Has been in an enclosure with a scrapie-positive female animal at any location;

(3) Resides in a noncompliant flock; or

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

Exposed flock. (1) Any flock that was designated by a DSE as an infected or source flock that has completed a flock plan, and that retained a female genetically susceptible exposed animal;

(2) Any flock under investigation that retains a female genetically susceptible exposed animal or a suspect animal, or whose owner declines to complete genotyping and live-animal and/or post-mortem scrapie testing required by the APHIS or State representative investigating the flock; or

(3) Any noncompliant flock or any flock for which a PEMMP is required that is not in compliance with the conditions of the PEMMP.

Flock. All animals that are maintained on a single premises and all animals under common ownership or supervision on two or more premises with animal interchange between the premises. Changes in ownership of part or all of a flock do not change the identity of the flock or the regulatory requirements applicable to the flock.

Animals maintained temporarily on a premises for activities such as shows and sales or while in marketing channels are not a flock. More than one flock may be maintained on a single premises if:

(1) The flocks are enrolled as separate flocks in the SFCP; or

(2) A State or APHIS representative determines, based upon examination of flock records, that:

(i) There is no interchange of animals between the flocks;

(ii) 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;

(iii) The flocks have separate flock records and identification;

(iv) 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

(v) The flocks do not share equipment without cleaning and disinfection in accordance with § 54.7(e). Additional guidance on acceptable means of cleaning and disinfection is also available in the Scrapie Free Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules.

Flock of origin. The flock in which an animal most recently resided in which it either was born, gave birth, or was used for breeding purposes. The determination of an animal's flock of origin may be based either on the physical presence of the animal in the flock, the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal 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 § 54.8(a) through (j).

Flock sire. A sexually intact male animal that has produced offspring in the preceding 12 months or that was used for breeding during the current breeding cycle.

Flock under investigation. Any flock in which an APHIS or State representative has determined that a scrapie-suspect animal, high-risk animal, or scrapie-positive animal resides or may have resided.

Genetically less susceptible exposed sheep. Any sheep or sheep embryo that is:

(1) An exposed sheep or sheep embryo of genotype AA QR, unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are not less susceptible; or

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

(3) An exposed sheep or sheep embryo of a genotype that has been exposed to a scrapie type to which the Administrator has determined that genotype is less susceptible. In this definition R refers to codon 171 and A refers to codon 136, and Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136.

Genetically resistant exposed sheep. Any exposed sheep or sheep embryo of genotype RR at codon 171 unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are not resistant.

Genetically resistant sheep. Any sheep or sheep embryo of genotype RR at codon 171 unless the Administrator determines that it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type that affects RR at codon 171 sheep.

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

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

(1) A genetically susceptible animal; or

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

(3) A sheep or sheep embryo of genotype AA QR that the Administrator determines is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are susceptible; or

(4) A sheep or sheep embryo of genotype RR that the Administrator determines is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are susceptible.

(5) *Note:* In this definition R refers to codon 171 and A refers to codon 136, and Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136.

High-risk animal. The female offspring or embryo of a scrapie-positive female animal, or any suspect animal, or a female genetically susceptible exposed animal, or any exposed animal that the Administrator determines to be a potential risk. The Administrator may base the determination that an exposed animal poses a potential risk on the scrapie type, the epidemiology of the flock or flocks with which it is

epidemiologically linked, including genetics of the positive sheep, the prevalence of scrapie in the flock, any history of recurrent infection, and other flock or animal characteristics. An animal will no longer be a high-risk animal if it is redesignated in accordance with § 79.4 of this chapter.

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

Interstate certificate of veterinary inspection (ICVI). An official document issued by a Federal, State, Tribal, or accredited veterinarian certifying the inspection of animals in preparation for interstate movement or other uses as described in this part and in accordance with § 79.5 of this chapter.

Limited contacts. Incidental contacts between animals from different flocks off the flock's premises such as at fairs, shows, exhibitions 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 sterilized between animals for these contacts to be considered limited contacts. Limited contacts do not include any contact, incidental or otherwise, with animals in the same flock or with a female animal during or up to 30 days after she lambed, kidded or aborted or when there is any visible vaginal discharge. Limited contacts do not include any activity where uninhibited contact occurs, such as sharing an enclosure, sharing a section of a transport vehicle, or residing in other flocks for breeding or other purposes. Examples of limited contacts may be found in the Scrapie Free Flock Certification Program 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 exposed animal. Any exposed animal to which the Administrator has determined one or more of the following applies:

- (1) The positive animal that was the source of exposure was not born in the flock and did not lamb in the flock or in an enclosure where the exposed animal resided;
- (2) The Administrator and State representative concur that the animal is unlikely to be infected due to factors such as, but not limited to, where the animal resided or the time period the animal resided in the flock;
- (3) The exposed animal is male and was not born in an infected or source flock;
- (4) The exposed animal is a castrated male;
- (5) The exposed animal is an embryo of a genetically resistant exposed sheep or a genetically less susceptible exposed sheep unless placed in a recipient that was a genetically susceptible exposed animal; or

¹The 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 Animal and Plant Health Inspection Service, Veterinary Services, 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 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.

(6) The animal was exposed to a scrapie type and/or is of a genotype that the Administrator has determined poses low risk of scrapie transmission.

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

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

National Veterinary Services Laboratories (NVSL). The National Veterinary Services Laboratories, APHIS, U.S. Department of Agriculture, or an NVSL cooperating or contract laboratory.

Noncompliant flock. (1) Any source, infected, or exposed flock or flock under investigation whose owner declines to enter into a flock plan or post-exposure management and monitoring plan agreement within 30 days of being so designated, or whose owner is not in compliance with either agreement;

(2) Any exposed flock or flock under investigation whose owner fails to make animals available for testing within 60 days of notification, or as mutually agreed, or whose owner fails to submit required postmortem samples;

(3) Any flock whose owner has misrepresented, or who employs a person who has misrepresented, the scrapie status of an animal or any other information on a certificate, permit, owner/hauler statement, or other official document within the last 5 years; or

(4) Any flock whose owner or manager has moved, or who employs a person who has moved, an animal in violation of this chapter within the last 5 years.

Official genotype test. A test to determine the genotype of a live or dead animal conducted at either the National Veterinary Services Laboratories or at

an approved laboratory. The test subject must be an animal that is officially identified and the test accurately recorded on an official form supplied or approved by APHIS, with the samples collected and shipped to the laboratory using a shipping method specified by the laboratory by:

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

Official test. Any test for the diagnosis of scrapie in a live or dead animal that is approved by the Administrator for that use and conducted either at an approved laboratory or at the National Veterinary Services Laboratories.

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

Post-exposure management and monitoring plan. 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 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 otherwise specified by a State or APHIS representative. As part of a post-exposure management and monitoring plan, the flock owner must provide the facilities and personnel needed to carry out the requirements of the plan. The plan must include the requirements in § 54.8.

Program approved test. A test for the diagnosis of scrapie approved by the Administrator for use in the scrapie eradication or certification program in accordance with § 54.10.

Restricted animal sale or restricted livestock facility. A sale where any animals in slaughter channels are maintained separate from other animals not in slaughter channels unless they are from the same flock of origin and are sold in lots that consist entirely of ani-

mals sold for slaughter only, or a livestock facility at which all animals are in slaughter channels, and where the sale or facility manager maintains a copy of, or maintains a record of, the information from the owner/hauler statement for all animals entering and leaving the sale or facility. A restricted animal sale may be held at a livestock facility that is not restricted.

Scrapie control pilot project. A pilot project authorized by the Administrator in writing, designed to test or improve program procedures or to facilitate research, in order to control and eradicate scrapie. In addition to APHIS, participants may include State animal health agencies, flock owners, and other parties as necessary.

Scrapie Eradication Program. The cooperative State-Federal 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. The UM&R will be reviewed at least annually by representatives of the livestock industry and appropriate State and Federal agencies and the public and will be revised, and published as needed by APHIS.

Scrapie Free Flock Certification Program (SFCP). The cooperative Federal-State-industry voluntary program for the control of scrapie conducted in accordance with this subpart.

Scrapie Free 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 flock certification.²

Scrapie-positive animal. An animal for which a diagnosis of scrapie has been made by the National Veterinary Services Laboratories or another laboratory authorized by the Administrator

²Individual copies of the Scrapie Flock Certification Program standards may be obtained on the World Wide Web at URL <http://www.aphis.usda.gov/animal-health/scrapie>, or from the Animal and Plant Health Inspection Service, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737–1235.

to conduct scrapie tests in accordance with this part, through:

(1) Histopathological examination of central nervous system (CNS) tissues from the animal for characteristic microscopic lesions of scrapie;

(2) The use of proteinase-resistant protein analysis methods including but not limited to immunohistochemistry, and/or ELISA, and/or western blotting on CNS and/or peripheral tissue samples from a live or a dead animal for which a given method has been approved by the Administrator for use on that tissue;

(3) Bioassay;

(4) Scrapie associated fibrils (SAF) detected by electron microscopy; or

(5) Any other method or combination of methods approved by the Administrator in accordance with § 54.10.³

Slaughter channels. Animals in slaughter channels include any animal that is sold, transferred, or moved either directly to or through a restricted animal sale or restricted livestock facility to an official slaughter establishment that is under Food Safety and Inspection Service (FSIS) jurisdiction per the Federal Meat Inspection Act (FMIA) or under State inspection that FSIS has recognized as at least equal to Federal inspection or to a custom exempt slaughter establishment as de-

finied by FSIS (9 CFR 303.1) for immediate slaughter or to an individual for immediate slaughter for personal use or to a terminal feedlot.

Source flock. A flock in which a State or APHIS representative has determined that at least one animal was born that was diagnosed as a scrapie-positive animal at an age of 72 months or less. The determination that an animal was born in a flock will be based on such information as 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 was born in the flock, combined with the absence of records indicating that the animal was purchased from outside and added to the flock. If DNA from the animal was previously collected by an accredited veterinarian and stored at an approved genotyping laboratory, or if DNA collection and storage are 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. The owner will be responsible for all costs for the DNA comparison. 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 and who is authorized by the State or political subdivision to perform the function involved.

Suspect animal. An animal will be designated a suspect animal in accordance with § 79.4 of this chapter if it is:

(1) A mature sheep or goat as evidenced by eruption of the first incisor that has been condemned by FSIS or a

³The names and addresses of laboratories approved by the Administrator to conduct tests are published in the Notices Section of the FEDERAL REGISTER. A list of approved laboratories is also available upon request from the Animal and Plant Health Inspection Service, Veterinary Services, 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 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 conflict.

State inspection authority for central nervous system (CNS) signs, or that exhibits any of the following clinical signs of scrapie and has been determined to be suspicious for scrapie by an accredited veterinarian or a State or USDA representative, based on one or more of the following signs and the severity of the signs: Weakness of any kind including, but not limited to, stumbling, falling down, or having difficulty rising, not including those with visible traumatic injuries and no other signs of scrapie; behavioral abnormalities; significant weight loss despite retention of appetite or in an animal with adequate dentition; increased sensitivity to noise and sudden movement; tremors; star gazing; head pressing; bilateral gait abnormalities such as but not limited to incoordination, ataxia, high stepping gait of forelimbs, bunny-hop movement of rear legs, or swaying of back end, but not including abnormalities involving only one leg or one front and one back leg; repeated intense rubbing with bare areas or damaged wool in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; abraded, rough, thickened, or hyperpigmented areas of skin in areas of wool/hair loss in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; or other signs of CNS disease. An animal will no longer be a suspect animal if it is redesignated in accordance with § 79.4 of this chapter.

(2) A sheep or goat that has tested positive for scrapie or for the proteinase resistant protein associated with scrapie on a live-animal screening test or any other test, unless the animal is designated a scrapie-positive animal.

(3) A sheep or goat that has tested inconclusive or suggestive on an official test for scrapie.

Tamper-resistant sampling kit. A device or method for collecting DNA samples from sheep or goats that is approved by the Administrator and that identifies both the sample and the animal at the time the sample is collected. These devices or methods must ensure that the sample, its corresponding label, and the official ID device or method applied to the animal meets the requirements

of § 79.2(k) of this chapter and that the sample is from the same animal to which the official ID device or method was applied. The kit must include an APHIS-approved official form or another form, device, or method acceptable to APHIS for transmitting the information required to APHIS and the approved laboratory.

Terminal feedlot. (1) A dry lot approved by a State or APHIS representative or an accredited veterinarian who is authorized by the Administrator to perform this function where animals in the terminal feedlot are separated from all other animals by at least 30 feet at all times or are separated by a solid wall through, over, or under which fluids cannot pass and contact cannot occur and must be cleaned of all organic material prior to being used to contain sheep or goats that are not in slaughter channels, where only castrated males are maintained with female animals and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(2) A dry lot approved by a State or APHIS representative or an accredited veterinarian who is authorized by the Administrator to perform this function where only animals that either are not pregnant based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, an ICVI issued by an accredited veterinarian stating the animals are not pregnant, or the animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, and all animals in the terminal feedlot are separated from all other animals such that physical contact cannot occur including through a fence and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(3) A pasture when approved by and maintained under the supervision of the State and in which only nonpregnant animals are permitted based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, or an ICVI issued by an accredited veterinarian stating the animals are not pregnant, or the

animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, 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.

(4) Records of all animals entering and leaving a terminal feedlot must be maintained for 5 years after the animal leaves the feedlot and must meet the requirements of § 79.2 of this chapter, including either a copy of the required owner/hauler statements for animals entering and leaving the facility or the information required to be on the statements. Records must be made available for inspection and copying by an APHIS or State representative upon request.

Unofficial test. Any test for the diagnosis of scrapie or for the detection of the proteinase 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 laboratory or at the National Veterinary Services Laboratories.

[66 FR 43982, Aug. 21, 2001, as amended at 84 FR 11179, Mar. 25, 2019]

§ 54.2 Cooperative agreements and memoranda of understanding with States.

APHIS will execute cooperative agreements and/or memoranda of understanding with the animal health agency of any State in order to cooperatively administer the Scrapie Eradication Program and the Scrapie Free Flock Certification Program within that State. These agreements will describe the respective roles of APHIS and State personnel in implementing the Scrapie Eradication Program and the Scrapie Free Flock Certification Program. Each agreement may specify the financial, material, and personnel resources to be committed to these programs and other scrapie control measures by APHIS and the State; assign specific activities related to the control of scrapie within a State to APHIS or State personnel; establish schedules for APHIS representatives or State representatives to visit flocks; establish procedures for maintaining

and sharing program records specified in this part, and specify other responsibilities of State representatives and APHIS representatives in support of the Scrapie Eradication Program and the Scrapie Free Flock Certification Program.

(Approved by the Office of Management and Budget under control number 0579-0101)

[66 FR 43982, Aug. 21, 2001, as amended at 84 FR 11182, Mar. 25, 2019]

Subpart A—Scrapie Indemnification Program

§ 54.3 Animals eligible for indemnity payments.

(a) Indemnity may be paid for an animal only after the owner of the animal has applied for indemnification and been approved in accordance with § 54.4. Indemnity may be paid only for the following:

- (1) Destruction of high-risk animals;
- (2) Destruction of animals based on an epidemiologic investigation, when the Administrator determines that the destruction of these animals will contribute to the eradication of scrapie;
- (3) Destruction of live scrapie-positive animals;
- (4) Destruction of animals that test positive on a live-animal screening test; and
- (5) Destruction of suspect animals that are destroyed at the request of an APHIS representative.

(b) Indemnity will be paid to an owner only for animals actually in a flock at the time indemnity is first offered in writing, and for offspring born to animals in that flock within 60 days after the time indemnity is first offered in writing. Animals removed from the flock as part of an investigation or a post-exposure management and monitoring plan (PEMMP) will be paid indemnity based on the calculated prices at the time an APHIS representative designates, in writing, the animals for removal. If an owner declines to remove an animal within 60 days of when indemnity is first offered the owner will receive the lower value of when indemnity was first offered in writing or when the animal was actually removed. APHIS may withdraw an indemnity offer if an owner does not

§ 54.4

9 CFR Ch. I (1–1–25 Edition)

make animals available for inventory, gestational assessment, and testing within 30 days, does not remove an animal within 60 days of the written indemnity offer or by the date specified in a flock plan or PEMMP, or fails to provide APHIS animal registration certificates, sale and movement records, or other records requested in accordance with § 54.5. No indemnity will be paid for any animal, or the progeny of any animal, that has been moved or handled by the owner in violation of the requirements of the Animal Health Protection Act or the regulations promulgated thereunder. No indemnity will be paid for an animal added to the premises while a flock is under investigation or while it is an infected or source flock other than natural additions. No indemnity will be paid for natural additions born more than 60 days after the owner is notified they are eligible for indemnity unless the Administrator makes a determination that the dam could not be removed within the allowed time as a result of conditions outside the control of the owner. No indemnity will be paid unless the owner has signed and is in compliance with the requirements of a flock plan or post-exposure management and monitoring plan (PEMMP) as described in § 54.8 unless the requirement for a flock plan or PEMMP has been waived by the Administrator. No indemnity will be paid until the premises, including all structures, holding facilities, conveyances, and materials contaminated because of occupation or use by the depopulated animals, have been properly cleaned and disinfected in accordance with § 54.7(e), unless premises or portions of premises have been exempted from the cleaning and disinfecting requirements per § 54.8(j)(1); Except that, partial indemnity may be paid when the Administrator determines that weather or other factors outside the control of the owner make immediate disinfection impractical. No indemnity will be paid to an owner for any animals if the owner established or increased his

flock for the purpose of collecting or increasing indemnity.

(Approved by the Office of Management and Budget under control number 0579-0101)

[66 FR 43982, Aug. 21, 2001, as amended at 84 FR 11182, Mar. 25, 2019]

§ 54.4 Application by owners for indemnity payments.

(a) Normally, an application for indemnification will be initiated by a State or APHIS representative who is working with the owner of a flock that has already been determined to be an infected flock or source flock, or that is already under a State movement restriction. In such cases, the flock owner will confirm information about the flock's eligibility for indemnity that is contained in the application submitted by the State or APHIS representative. However, the owner of any flock may apply directly to receive indemnification by submitting to the Administrator a written request containing the following information:

(1) Name, address, and social security number of the flock owner;

(2) Number and breed(s) of animals in the flock, including a current inventory;

(3) Location of flock premises;

(4) Reasons the owner believes animals in his or her flock may be eligible for indemnification, including any diagnosis of scrapie made for animals in the flock; any signs of scrapie observed in the flock by the owner; and any movement of animals into the flock from flocks infected with or exposed to scrapie;

(5) A copy of the registration papers issued in the name of the owner for any registered animals in the flock (registration papers are not required for the payment of indemnity for animals that are not registered); and

(6) Signed release letters addressed to any sheep or goat registry associations that maintain records of the owner's sheep or goats requesting the associations to release to APHIS all records maintained by the association on sheep or goats currently or formerly owned by the applicant.

(b) APHIS will evaluate each application to determine whether the owner's

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flock contains animals eligible for indemnity in accordance with § 54.3.

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§ 54.5 Certification by owners.

Before any indemnity is paid to an owner, the owner must sign a written agreement with APHIS, certifying the following:

(a) The owner will make available for review upon request by a State or APHIS representative all bills of sale, pedigree registration certificates, and other records regarding movement of animals into and from the flock;

(b) If the owner maintains any flock after the payment of indemnity or acquires a new flock that is housed on the same premises within 5 years after the last high-risk or scrapie-positive animal is removed, the owner will maintain the flock in accordance with a post-exposure management and monitoring plan for 5 years;

(c) If the animal for which indemnity is paid is subject to any mortgage, the owner consents to the payment of the indemnity, up to the value of the mortgage, to the person(s) holding the mortgage;

(d) That the animal may be removed to a U.S. Department of Agriculture facility or a quarantined research facility, or euthanized and necropsied and tissues removed for diagnostic or other purposes.

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[66 FR 43982, Aug. 21, 2001, as amended at 84 FR 11183, Mar. 25, 2019]

§ 54.6 Amount of indemnity payments.

(a) *Indemnity.* Indemnity paid for sheep and goats in accordance with § 54.3 will be the fair market value of the animals. APHIS' determination of fair market value will be based on available price report data that most accurately reflect the type of animal being indemnified and the time at which the animal was indemnified. Premiums will be paid for certain types of sheep and goats, including, but not limited to: Registered animals, flock sires, pregnant animals and early-ma-

turing ewes; Except that, no premium will be added for animals of any age that were in slaughter channels when indemnity was offered. To calculate indemnity, APHIS will use price information provided by the Agricultural Marketing Service (AMS) or other available price information and any other data necessary to establish the value of different types of sheep and goats. A detailed description of the methods APHIS uses to calculate indemnity for sheep and goats is available at <http://www.aphis.usda.gov/animal-health/scrapie>.

(b) *Age and number of animals.* If records and identification are inadequate to determine the actual age of animals, an APHIS or State representative will count all sexually intact animals that are apparently under 1 year of age, and those that are apparently at least 1 and under 2 years of age, based on examination of their teeth, and the indemnity for these animals will be calculated. The total number of these animals will be subtracted from the total number of sexually intact animals in the group to be indemnified, and indemnity for the remainder will be calculated based on the assumption that the remainder of the flock is 80 percent aged 2 to 6 years and 20 percent aged 6 to 8 years.

(c) *Animal weights.* If the owner disagrees with the average weight estimate, he may have the animals weighed at a public scale at his own expense, provided that the animals may not come in contact with other sheep or goats during movement to the public scales, and will be paid based on the actual weight multiplied by the price per pound for the class of animal as calculated in paragraph (a) of this section.

(Approved by the Office of Management and Budget under control number 0579-0101)

[84 FR 11183, Mar. 25, 2019]

§ 54.7 Procedures for destruction of animals.

(a) Animals for which indemnification is sought must be destroyed on the premises where they are held, pastured,

or penned at the time indemnity is approved or moved to an approved research facility, unless the APHIS representative involved approves in advance of destruction moving the animals to another location for destruction.

(b) The carcasses of animals destroyed in accordance with this section are authorized by the Administrator to be buried, incinerated, or disposed of by other methods in accordance with local, State, and Federal laws. The carcasses of scrapie-positive and suspect animals may not be processed for human or animal food.

(c) The destruction of animals and disposition of their carcasses in accordance with this part must be monitored by an APHIS representative who will prepare and transmit to the Administrator a report identifying the animals and showing their disposition.

(d) APHIS may pay the reasonable costs of disposal for animals that are indemnified. To obtain reimbursement for disposal costs, animal owners must obtain written approval of the disposal costs from APHIS, prior to disposal. For reimbursement to be made, the owner of the animals must present the Veterinary Services, Field Operations, Area Veterinarian in Charge (AVIC) responsible for the State involved with a copy of either a receipt for expenses paid or a bill for services rendered. Any bill for services rendered by the owner must not be greater than the normal fee for similar services provided by a commercial hauler or disposal facility.

(e) *Cleaning and disinfection of premises and equipment.* When required, cleaning and disinfection shall be conducted under the supervision of a State or APHIS representative as follows. Additional guidance on acceptable means of cleaning and disinfection is also available in the Scrapie Program Standards Volume 1: National Scrapie Eradication Program and Scrapie Program Standards Volume 2: Scrapie Free Flock Certification Program (SFCEP):

(1) *Drylot areas.* When required, remove the manure and top 1–2 inches of soil to reduce contamination. Bury, till under, or compost the removed material in areas not accessed by domestic or wild ruminants.

(2) *Cement, wood, metal and other non-earth surfaces, tools, equipment, instruments, feed, hay, bedding, and other materials.* Organic and/or inorganic materials may be disposed of by incineration or burial. Inorganic material and wood structures may be cleaned and disinfected. To disinfect, remove all organic material and incinerate, bury, till under, or compost the removed organic material in areas not accessed by domestic or wild ruminants until it can be incinerated, buried, or tilled under. Clean and wash all surfaces, tools, equipment, and instruments using hot water and detergent. Allow all surfaces, tools, equipment, and instruments to dry completely before disinfecting and sanitizing using one of the following methods:

(i) Autoclave instruments, small tools, and other items at 136 °C for 1 hour;

(ii) To clean dry surfaces, apply a 2-percent chlorine bleach solution at room temperature (at least 18.3 °C for 1 hour, or apply a 1-molar solution of sodium hydroxide (approximately 5 oz. of sodium hydroxide dissolved in 1 gallon water) at room temperature for at least 1 hour. Note: A 2-molar solution is more effective than a 1-molar solution and should be used when circumstances permit.

(iii) Use a product registered by the U.S. Environmental Protection Agency (EPA) specifically for reduction of prion infectivity at these sites in accordance with the label.

(iv) Use a product in accordance with an emergency exemption issued by the EPA for reduction of prion infectivity at these sites.

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[66 FR 43982, Aug. 21, 2001, as amended at 84 FR 11183, Mar. 25, 2019]

§ 54.8 Requirements for flocks under investigation and flocks subject to flock plans and post-exposure management and monitoring plans.

(a) For animals in a flock under investigation, flock plan, or post-exposure management and monitoring plan (PEMMP), the official identification must provide a unique identification number that is applied by the owner of the flock or his or her agent and must

be linked to that flock in the National Scrapie Database. APHIS may specify the type of official identification that may be used in order to maximize retention of the means of identification, identify restricted or test positive animals or to facilitate the testing or inventory of the animals. The owner of the flock or his or her agent must officially identify and maintain the identity of:

(1) All animals in the flock while it is subject to a flock plan or PEMMP;

(2) Any high-risk or genetically susceptible exposed animals in the flock and any other restricted animals;

(3) Any animals designated for testing by an APHIS representative or State representative until testing is completed, results reported, and animals classified; and

(4) All sexually intact animals, all exposed animals, and animals 18 months of age and older (as evidenced by the eruption of the second incisor) prior to a change in ownership and before they are moved off the premises of the flock.

(b) For flocks under a flock plan or PEMMP, the flock owner must maintain the following records for 5 years or until the flock plan and/or PEMMP is completed, whichever is longer.

(1) For acquired animals, the date of acquisition, name and address of the person from whom the animal was acquired, any identifying marks, or identification devices present on the animal including but not limited to the animal's individual official identification number(s) from its electronic implant, flank tattoo, ear tattoo, tamper-resistant eartag, or, in the case of goats, tail fold tattoo, and any secondary form of identification the owner of the flock may choose to maintain and the records required by § 79.2 of this chapter.

(2) For animals leaving the premises of the flock, the disposition of the animal, including, any identifying marks or identification devices present on the animal, including but not limited to the animal's individual official identification number from its electronic implant, flank tattoo, ear tattoo, tamper-resistant eartag, or, in the case of goats, a tail fold tattoo, and any secondary form of identification the

owner of the flock may choose to maintain, the date and cause of death, if known, or date of removal from the flock and name and address of the person to whom the animal was transferred and the records required by § 79.2 of this chapter.

(c) Upon request by a State or APHIS representative or as required in a PEMMP, the owner of the flock or his or her agent must have an accredited veterinarian collect tissues from animals for scrapie diagnostic purposes and submit them to a laboratory designated by a State or APHIS representative or collect and submit samples by another method acceptable to APHIS.

(d) Upon request by a State or APHIS representative, the owner of the flock or his or her agent must make animals in the flock available for inspection and or testing and the records required to be kept as a part of these plans available for inspection and copying.

(e) The owner of the flock or his or her agent must meet requirements found necessary by a DSE to monitor for scrapie and to prevent the recurrence of scrapie in the flock and to prevent the spread of scrapie from the flock. These other requirements may include, but are not limited to: Utilization of a live-animal screening test; reporting animals found dead and collecting and submitting test samples from them; restrictions on the animals that may be moved from the flock; use of genetically resistant rams; segregated lambing; cleaning and disinfection of lambing facilities; and/or education of the owner of the flock and personnel working with the flock in techniques to recognize clinical signs of scrapie and to control the spread of scrapie.

(f) The owner of the flock or his or her agent must immediately report the following animals to a State representative, APHIS representative, or an accredited veterinarian; ensure that samples are properly collected for testing if the animal dies; allow the animals to be tested, and not remove them from a flock without written permission of a State or APHIS representative:

(1) Any sheep or goat exhibiting weight loss despite retention of appetite; behavioral abnormalities; pruritus

(itching); wool pulling; wool loss; 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; rubbing, or other signs of neurological disease or chronic wasting illness; and

(2) Any sheep or goat in the flock that has tested positive for scrapie or for the proteinase resistant protein associated with scrapie on a live-animal screening test or any other test.

(g) An epidemiologic investigation must be conducted to identify high-risk and exposed animals that currently reside in the flock or that previously resided in the flock, and all high-risk animals, scrapie-positive animals, and suspect animals must be removed from the flock except as provided in paragraph (h) of this section. The animals must be removed either by movement to an approved research facility or by euthanasia and disposal of the carcasses by burial, incineration, or other methods approved by the Administrator and in accordance with local, State, and Federal laws, or upon request in individual cases by another means determined by the Administrator to be sufficient to prevent the spread of scrapie.

(h) The Administrator may allow high-risk animals that are not suspect animals to be retained under restriction if they are not genetically susceptible animals or if they have tested “PrPsc not detected” on a live animal scrapie test approved for this purpose by the Administrator and are maintained in a manner that the Administrator determines minimizes the risk of scrapie transmission, *e.g.*, bred only to genetically resistant sheep, segregated for lambing, and cleaning and disinfection of the lambing area. Such animals may be retained only if the exempted animal’s official identification and the requirements for minimizing the risk of scrapie transmission are documented in the PEMMP and the owner is in compliance with the PEMMP. All such animals must be tested for scrapie when they are

euthanized or die or if they are later determined to be suspect animals.

(i) The owner of the flock, or his or her agent, must request breed associations and registries, livestock facilities, and packers to disclose records to APHIS representatives or State representatives, to be used to identify source flocks and trace exposed animals, including high-risk animals.

(j) The flock plan will include a description of the types of animals that must be removed from a flock, the timeframes in which they must be removed and any other actions that must be accomplished in order for the flock plan to be completed. Flock plans shall require an owner to agree to:

(1) Clean and disinfect the premises in accordance with § 54.7(e). Premises or portions of premises may be exempted from the cleaning and disinfecting requirements if a designated scrapie epidemiologist determines, based on an epidemiologic investigation, that cleaning and disinfection of such buildings, holding facilities, conveyances, or other materials on the premises will not significantly reduce the risk of the spread of scrapie, either because effective disinfection is not possible or because the normal operations on the premises prevent transmission of scrapie. No confined area where a scrapie-positive animal was born, lambled or aborted may be exempted;

(2) Agree to conduct a post-exposure management and monitoring plan (PEMMP); and

(3) Comply with any other conditions in the flock plan;

(k) A PEMMP will be required for exposed flocks and may be required for flocks under investigation that were not source or infected flocks. A PEMMP may also be required for flocks that formerly were exposed flocks or flocks under investigation as a condition for being redesignated. A designated scrapie epidemiologist shall determine when to require a PEMMP and the monitoring requirements for these flocks based on the findings of the classification or reclassification investigation.

(l) Provided that, the Administrator may waive the requirement for a flock plan or PEMMP or waive any of the requirements in a flock plan or PEMMP

after determining that the flock poses a low risk of scrapie transmission.

(Approved by the Office of Management and Budget under control numbers 0579-0101 and 0579-0469)

[84 FR 11183, Mar. 25, 2019]

§ 54.9 Waiver of requirements for scrapie control pilot projects.

The Administrator may waive the following requirements of this part for participants in a scrapie control pilot project by recording the requirements waived in the scrapie control pilot project plan:

(a) The determination that an animal is a high-risk animal, if the scrapie control pilot project plan contains testing or other procedures that indicate that an animal, despite meeting the definition of high-risk animal, is unlikely to spread scrapie; and

(b) The requirement that high-risk animals must be removed from a flock if the scrapie control pilot project plan contains alternative procedures to prevent the further spread of scrapie without removing high-risk animals from the flock.

§ 54.10 Program approval of tests for scrapie.

(a) The Administrator may approve new tests or test methods for the diagnosis of scrapie conducted on live or dead animals for use in the Scrapie Eradication Program and/or the Scrapie Free Flock Certification Program. The Administrator will base the approval or disapproval of a test on the evaluation by APHIS and, when appropriate, outside scientists, of:

(1) A standardized test protocol that must include a description of the test, a description of the reagents, materials, and equipment used for the test, the test methodology, and any control or quality assurance procedures;

(2) Data to support repeatability, that is, the ability to reproduce the same result repeatedly on a given sample;

(3) Data to support reproducibility, that is, data to show that similar results can be produced when the test is run at other laboratories;

(4) Data to support the diagnostic and in the case of assays the analytical

sensitivity and specificity of the test; and

(5) Any other data or information requested by the Administrator to determine the suitability of the test for program use. This may include but is not limited to past performance, cost of test materials and equipment, ease of test performance, generation of waste, and potential use of existing equipment.

(b) To be approved for program use, a scrapie test must be able to be readily and successfully performed at the National Veterinary Services Laboratories.

(c) The test must have a reliable, timely, and cost effective method of proficiency testing.

(d) The Administrator may decline to evaluate any test kit for program approval that has not been licensed for the intended use and may decline to evaluate any test or test method for program use unless the requester can demonstrate that the new method offers a significant advantage over currently approved methods.

(e) A test or combination of tests may be approved for the identification of suspect animals, or scrapie-positive animals, or for other purposes such as flock certification. For a test to be approved for the identification of scrapie-positive animals, the test must demonstrate a diagnostic specificity comparable to that of current program-approved tests, and the sensitivity of the test will also be considered in determining the approved uses of the test within the program. For a test to be approved for the removal of high-risk, exposed, or suspect animal designations the test must have a diagnostic sensitivity at least comparable to that of current program-approved tests used for this purpose. Since the purpose of a screening test is usually to identify a subset of animals for further testing, for a test to be approved as a screening test for the identification of suspect animals, the test must be usually reliable but need not be definitive for diagnosing scrapie.

(f) Specific guidelines for use of program-approved tests within the Scrapie Eradication Program or Scrapie Free Flock Certification Program will be made available on the scrapie website

at <http://www.aphis.usda.gov/animal-health/scrapie>. Guidelines will be based on the characteristics of the test, including specificity, sensitivity, and predictive value in defined groups of animals.

(g) If an owner elects to have an unofficial test conducted on an animal for scrapie, or for the proteinase resistant protein associated with scrapie, and that animal tests positive to such a test, the animal will be designated a suspect animal, unless the test is conducted as part of a research protocol and the protocol includes appropriate measures to prevent the spread of scrapie.

(h) The Administrator may withdraw or suspend approval of any test or test method if the test or method does not perform at an acceptable level following approval or if a more effective test or test method is subsequently approved. The Administrator shall give written notice of the suspension or proposed withdrawal to the director of the laboratories using the test or method or in the case of test kits to the manufacturer and shall give the director or manufacturer an opportunity to respond. Such action shall become effective upon oral or written notification, whichever is earlier, to the laboratory or manufacturer. If there are conflicts as to any material fact concerning the reason for withdrawal, a hearing may be requested in accordance with the procedure in § 79.4(c)(3) of this chapter. The action under appeal shall continue in effect pending the final determination of the Administrator, unless otherwise ordered by the Administrator. The Administrator's final determination constitutes final agency action.

(Approved by the Office of Management and Budget under control number 0579–0469)

[84 FR 11185, Mar. 25, 2019]

§ 54.11 Approval of laboratories to run official scrapie tests and official genotype tests.

(a) State, Federal, and university laboratories, or in the case of genotype tests, private laboratories will be approved by the Administrator when he or she determines that the laboratory:

(1) Employs personnel assigned to supervise and conduct the testing who are qualified to conduct the test based

on education, training, and experience and who have been trained by the National Veterinary Services Laboratories (NVSL) or who have completed equivalent training approved by NVSL;

(2) Has adequate facilities and equipment to conduct the test;

(3) Follows standard test protocols that are approved or provided by NVSL;

(4) Meets check test proficiency requirements and consistently produces accurate test results as determined by NVSL review;

(5) Meets recordkeeping requirements;

(6) Will retain records, slides, blocks, and other specimens from all cases for at least 1 year and from positive cases and DNA from all genotype tests for at least 5 years and will forward copies of records and any of these materials to NVSL within 5 business days of request; Except that, NVSL may authorize a shorter retention time in a standard operating procedure or contract;

(7) Will allow APHIS to inspect the laboratory without notice during normal business hours. An inspection may include, but is not limited to, review and copying of records, examination of slides, review of quality control procedures, observation of sample handling/tracking procedures, observation of the test being conducted, and interviewing of personnel;

(8) Will report all test results to State and Federal animal health officials and record them in the National Scrapie Database within timeframes and in the manner and format specified by the Administrator; and

(9) Complies with any other written guidance provided to the laboratory by the Administrator.

(b) A laboratory may request approval to conduct one or more types of program-approved scrapie test or genotype test on one or more types of tissue. To be approved, a laboratory must meet the requirements in paragraph (a) of this section for each type of test and for each type of tissue for which they request approval.

(c) The Administrator may suspend or withdraw approval of any laboratory for failure to meet any of the conditions required by paragraph (a) of this section. The Administrator shall give

written notice of the suspension or the proposed withdrawal to the director of the laboratory and shall give the director an opportunity to respond. Such action shall become effective upon oral or written notification, whichever is earlier, to the laboratory or manufacturer. If there are conflicts as to any material fact concerning the reason for withdrawal, a hearing may be requested in accordance with the procedure in § 79.4(c)(3) of this chapter. The action under appeal shall continue in effect pending the final determination of the Administrator, unless otherwise ordered by the Administrator. The Administrator's final determination constitutes final agency action.

(d) The Administrator may require approved laboratories to reimburse APHIS for part or all of the costs associated with the approval and monitoring of the laboratory.

(Approved by the Office of Management and Budget under control numbers 0579-0101 and 0579-0469)

[84 FR 11185, Mar. 25, 2019]

Subpart B—Scrapie Free Flock Certification Program

§ 54.20 Administration.

The Scrapie Flock Certification Program is a cooperative effort between APHIS; members of the sheep and goat industry, including owners of flocks, slaughtering and rendering establishments, and breed associations and registries; accredited veterinarians; and State governments. APHIS coordinates with State scrapie certification boards and State animal health agencies to encourage flock owners to certify their flocks as free of scrapie by being in continuous compliance with the Scrapie Flock Certification Program standards.

§ 54.21 Participation.

Any owner of a sheep or goat flock may apply to enter the Scrapie Free Flock Certification Program by sending a written request to a State scrapie certification board or to the Veterinary Services, Field Operations, AVIC responsible for the State involved. A notice containing a current list of flocks participating in the Scrapie

Free Flock Certification Program, and the certification status of each flock, may be obtained from the APHIS website at <http://www.aphis.usda.gov/animal-health/scrapie>. A list of non-compliant flocks and a list of flocks that sold exposed animals that could not be traced may also be obtained from this site, and these lists may be obtained by writing to the National Scrapie Program Coordinator, Strategy and Policy, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1235.

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[84 FR 11185, Mar. 25, 2019]

§ 54.22 State scrapie certification boards.

An area veterinarian in charge, after consulting with a State representative and industry representatives, may appoint a State scrapie certification board for the purpose of coordinating activities for the Scrapie Flock Certification Program, including making decisions to admit flocks to the Scrapie Flock Certification Program and to change flock status in accordance with the Scrapie Flock Certification Program standards. These boards are not appointed for the purpose of providing APHIS with consensus advice or policy recommendations. No more than one State scrapie certification board may be formed in each State. Each State scrapie certification board shall include as members the area veterinarian in charge, one or more State representatives, one or more accredited veterinarians, when possible, and one or more owners of flocks, and, at the discretion of the area veterinarian in charge, may include other members.

PART 55—CONTROL OF CHRONIC WASTING DISEASE

Sec.

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