

**SUPPORTING STATEMENT
SCRAPIE IN SHEEP AND GOATS; INTERSTATE MOVEMENT
RESTRICTIONS AND INDEMNITY PROGRAM
OMB NO. 0579-0101**

February 2020

NOTE - The five SF forms formerly included in this information collection are common forms and the burden will be accounted for with Request for Comment Forms (RCFs). The burden for these common forms is not included in this information collection renewal.

NOTE - This information collection includes new burden.

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any such animal or related material if necessary to prevent spread of any livestock or poultry pest or disease. The AHPA is contained in Title X, Subtitle E, Sections 10401-18 of P.L. 107-171, May 13, 2002, the Farm Security and Rural Investment Act of 2002.

Scrapie is a progressive, degenerative, and eventually fatal disease affecting the central nervous system of sheep and goats. Its control is complicated because the disease has an extremely long incubation period. There is no test that can detect the disease early in the incubation period and no treatment. The Animal and Plant Health Inspection Service (APHIS) restricts the interstate movement of certain sheep and goats to control the spread of scrapie within the United States. APHIS also operates an indemnity program to compensate owners of sheep and goats destroyed because of scrapie. APHIS interstate movement, animal identification, flock designation, pilot project provision, and Consistent State regulations are contained in Title 9 of the *Code of Federal Regulations*, part 79, while its scrapie indemnification, flock cleanup, testing, and Veterinary Services (VS) Scrapie Free Flock Certification Program (SFCP) regulations are found in part 54. Parts 54 and 79 and associated program standards constitute the National Scrapie Eradication Program (NSEP) requirements.

APHIS interstate movement requirements minimize any contact between high-risk animals and healthy animals, while the animal identification and recordkeeping requirements help trace scrapie-positive and scrapie-exposed animals. The APHIS indemnity program encourages flock owners to report scrapie signs and to eliminate scrapie from their flocks.

These regulations necessitate the use of a number of information collection activities including applications for participation in the SFCP; flock cleanup plans and Post Exposure Management and Monitoring Plans for infected and source flocks; scrapie test records; applications for indemnity payments; certificates, permits, and owner/hauler statements that allow for the interstate movement

of certain sheep and goats; registry tattoo approval requests; records of animals acquired or disposed of; and applications for premises identification numbers. They also include recording the application of APHIS-approved ear tags, backtags, and/or tattoos. APHIS also uses data entry screens and systems through its employees, contractors, and State cooperators to record and process the collected information. APHIS interstate movement requirements are designed to minimize any contact between high-risk animals and healthy animals, while the animal identification requirements help with investigations of scrapie outbreaks. Implementing these regulations necessitates the use of information collection activities, such as requiring market operators, dealers, accredited veterinarians, and other persons who apply official identification to sheep and goats to submit information on the official identification applied to sheep and goats.

APHIS is asking the Office of Management and Budget (OMB) to approve these information collection activities for an additional 3 years, in connection with APHIS' efforts to contain and eventually eradicate scrapie in the United States.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

APHIS will use the following information collection activities to contain and eventually eradicate scrapie in the United States.

Designated Scrapie Epidemiologist Training and Approval (State/Tribe) - 9 CFR 54.1 and 79.6(a)(8)

Designated Scrapie Epidemiologists (DSEs) are State, Tribal, or Federal veterinarians designated and approved by States and the Administrator to make decisions, in accordance with regulations and guidance, within their geographical areas of responsibility for the disease areas within which they are approved to work. Their activities include, but are not limited to:

- Interpreting diagnostic test results and classifying animals by disease status.
- If necessary or otherwise appropriate, directing additional diagnostic tests to determine animals' disease status.
- Initiating and completing epidemiological investigations.
- Developing and administering herd plans.
- Overseeing the management of exposed and affected animals.
- Monitoring quarantine zones.
- Preparing reports.
- Coordinating the education of producers and accredited veterinarians about disease epidemiology.
- Coordinating disease surveillance.

To be certified as a DSE, a candidate must complete Program Management Training by taking Scrapie Epidemiology Training Modules 1-10. The training modules are available in the Training Materials folder in the National Scrapie Reference Library in the Sheep and Goat Health SharePoint site or from a Sheep and Goat Health Specialist for Epidemiology. Candidates will self-certify completion of this requirement, including the date of review of each module. Alternative scrapie

training sessions, certified by the Sheep and Goat health team (for example, a District sheep and goat health training session), also fulfill the training requirement.

DSEs must also obtain practical experience through mentoring by another DSE or staff specialist on scrapie program management or by taking the Field Skills for Program Diseases training course. The candidate must be able to demonstrate proficiency with aging and classifying sheep and goats, collecting tissues for scrapie testing (drawing blood, FTA cards, rectal biopsy, and postmortem sample collection), submission of scrapie samples, data entry, euthanasia, flock inspections and flock investigations, and infected/source flock management.

To be recertified, a DSE must attend or review 100 percent of the Sheep and Goat Health Webinars held during the 3-year period since the initial certification or most recent recertification. DSEs who miss a webinar may self-certify that they either viewed the recorded webinar or reviewed the presentation provided during the webinar. The State or Tribal animal health official must sign the DSE approval request.

Cooperative Agreements and Grants Workplan (State/Tribe and Not for Profit) - 9 CFR 54.2

The workplan accompanies the cooperative agreements used by States and Tribal governments and not-for-profit institutions. These entities complete the workplan. This document is more fully explained in the accompanying *Grants and Agreements Program Guide*, as well as the accompanying workplan formulation table.

Cooperative Agreements and Grants Financial Plan (State/Tribe and Not for Profit) 9 CFR 54.2

The financial plan accompanies the cooperative agreements used by States and Tribal governments, and not-for-profit institutions. These entities complete the financial plan. This document is more fully explained in the accompanying *Grants and Agreements Program Guide*.

Cooperative Agreement or Grant Quarterly Report (State/Tribe and Not for profit) 9 CFR 54.2

States and Tribal governments and not-for-profit institutions complete quarterly reports on their cooperative agreements. This document is more fully explained in the accompanying *Grants and Agreements Program Guide*.

Memorandums of Understanding Forms (State/Tribe) - 9 CFR 54.2

The memorandum of understanding (MOU) is a written commitment between APHIS and the animal health agency of a State or Tribe to cooperatively administer the National Scrapie Eradication Program (NSEP) and the SFCP. MOUs do not involve the transfer of funds. For more details of this activity, see the *Grants and Agreements Program Guide*.

Table 1 shows scrapie program cooperative agreements and MOUs.

Table 1. Cooperative Agreements and Memoranda of Understanding for the Scrapie Program

| State | Cooperator Name | MOU | CA |
|-------|--|-----|------------------|
| AK | AK Dept. of Environmental Conservation | | AP18VSSPRS00C037 |

| | | | |
|--------------|---|-----------------|--|
| AL | AL Dept. of Ag. and Industries | | No Scrapie funding on CA |
| AR | Arkansas Livestock & Poultry | 17 9705 0073 MU | AP18VSSPRS00C054 |
| AZ | Navajo Nation | | No active FiOps CA |
| AZ | AZ Dept. of Agriculture | 17 9704 0078 MU | AP18VSSPRS00C044 |
| CA | CA Department of Food and Ag. | 17 9706 0088 MU | AP18VSSPRS00C102 |
| CO | American Sheep Industry | | AP17VSSPRS00C122 ; AP18VSSPRS00C117 |
| CO | CO Dept. of Agriculture | 17 9708 0090 MU | AP18VSSPRS00C024 |
| CO | National Institute for Animal Ag. | | No active FiOps CA |
| CT | CT Dept. of Agriculture | 19 9709 D003 MU | AP18VSSPRS00C098 |
| DE | DE Dept. of Agriculture | | No Scrapie funding on CA |
| GA | GA Dept. of Agriculture | 16 9713 0288 MU | AP18VSSPRS00C040 |
| FL | FL Dept. of Ag & Consumer Svc. | | No Scrapie funding on CA |
| HI | HI State Dept. of Agriculture | 16 9715 0068 MU | AP18VSSPRS00C079 |
| IA | IA Dept. of Ag. and Land Stewardship | 17 9719 0077 MU | AP18VSSPRS00C017 |
| ID | ID State Dept. of Agriculture | 17 9716 0079 MU | AP18VSSPRS00C091 |
| IL | IL Dept. of Agriculture | 17 9717 0727 MU | AP18VSSPRS00C025 |
| IN | IN State Board of Animal Health | | No Scrapie funding on CA |
| IN | American Goat Federation | | AP18VSSPRS00C120 |
| KS | KS Animal Health Dept. | 17 9720 0082 MU | AP18VSSPRS00C011 |
| KY | KY Dept. of Agriculture | 17 9721 0874 MU | AP18VSSPRS00C003 |
| LA | LA Dept. of Ag & Forestry | 18 9722 0051 MU | AP18VSSPRS00C057 |
| MA | MA Dept. of Ag. Resource | | AP18VSSPRS00C065 |
| MD | MD Dept. of Agriculture | | No Scrapie funding on CA |
| ME | ME Dept. of Ag., Food and Rural Resources | | AP18VSSPRS00C082 |
| MI | MI Dept. of Agriculture | | No Scrapie funding on CA |
| MN | MN Board of Animal Health | 17 9727 0161 MU | AP18VSSPRS00C045 |
| MO | MO Dept. of Agriculture | | AP18VSSPRS00C089 |
| MS | MS Board of Animal Health | 17 9628 0795 MU | AP18VSSPRS00C100 |
| MT | MT Dept. of Livestock | 17 9730 0085 MU | No Scrapie funding on CA |
| NC | NC Dept. of Ag. and Consumer Service | 17 9737 0750 MU | AP18VSSPRS00C108 |
| ND | ND State Board of Animal Health | 15 9738 0065 MU | No Scrapie funding on CA |
| NE | NE Dept. of Agriculture | 17 9731 0080 MU | AP18VSSPRS00C033 |
| NH | NH Dept. of Ag., Markets and Food | 18 9733 D001 MU | No Scrapie funding on CA |
| NJ | NJ Dept. of Agriculture | 17 9734 0026 MU | No Scrapie funding on CA |
| NM | NM Livestock Board | 17 9735 0110 MU | AP18VSSPRS00C010 |
| NV | NV Dept. of Agriculture | 15 9732 0066 MU | AP18VSSPRS00C119 |
| NY | NY State Dept of Agriculture | 16 9736 0188 MU | No Scrapie funding on CA |
| State | Cooperator Name | MOU | CA |
| OH | OH Dept. of Agriculture | 17 9739 0028 MU | AP18VSSPRS00C068 |
| OK | OK Dept. of Ag. Food & Forestry | 16 9740 0071 MU | AP18VSSPRS00C055 |
| OR | OR Dept. of Agriculture | 16 9741 0074 MU | No Scrapie funding on CA |
| RI | RI Dept. of Environmental Management Division of Agriculture | 18 9744 D004 MU | AP18VSSPRS00C020 |

| | | | |
|----|--------------------------------------|-----------------|--------------------------|
| SC | Clemson University | 16 9745 2514 MU | AP18VSSPRS00C014 |
| SD | SD Animal Industry Board | 17 9746 0075 MU | AP18VSSPRS00C005 |
| TN | TN Dept. of Agriculture | 18 9747 0766 MU | AP18VSSPRS00C016 |
| TX | TX Animal Health Commission | 17 9748 0086 MU | AP18VSSPRS00C072 |
| UT | UT Dept. of Ag. & Food | 16 9749 0072 MU | AP18VSSPRS00C032 |
| VA | VA Dept. of Ag. and Consumer Service | 17 9751 0781 MU | AP18VSSPRS00C029 |
| VI | Virgin Islands Dept. of Agriculture | | No Scrapie funding on CA |
| VT | VT Agency of Ag., Food and Market | 19 9750 D002 MU | AP18VSSPRS00C049 |
| WA | WA State Dept. of Agriculture | 16 9753 0070 MU | AP18VSSPRS00C092 |
| WI | WI Dept. of Ag., Trade and Consumer | 17 9755 0763 MU | AP18VSSPRS00C084 |
| WV | WV Dept. of Agriculture | 17 9754 0782 MU | AP18VSSPRS00C041 |
| WY | WY Livestock Board | 17 9756 0055 MU | AP18VSSPRS00C012 |

(CA = cooperative agreement; MU = memorandum of understanding)

Request for Information: Record of Animals Moved (VS Form 5-18/equivalent) or Record of Animals Acquired (VS Form 5-18A/equivalent) - (Business and State/Tribe) - 9 CFR 54.3(b)

When a flock owner applies for indemnity payments or a flock is under investigation, APHIS may ask the owner for specific information as a condition for receiving the indemnity payments. The owner must submit this information (such as animal registration certificates or sale and movement records) to APHIS within 30 days of the request for the information. State/Tribe representatives may complete VS Forms 5-18 and 5-18A on behalf of APHIS for businesses or provide equivalent information without the use of a form such as on Excel spreadsheets. APHIS needs this information (which includes, specific to these forms, the date the animals were moved, their disposition, flock ID, and the flock owners' names and contact information) to conduct trace investigations in response to an adverse disease event.

Individual Animal Information Report (VS Form 5-20/equivalent) - (Business and State/Tribe) - 9 CFR 54.3(b)

When a flock owner applies for indemnity payments for one or more animals, APHIS may ask the owner for specific information as a condition for receiving the indemnity payments. The owner must submit this information (such as animal registration certificates or sale and movement records) to APHIS within 30 days of the request for the information. State/Tribe representatives may complete VS Form 5-20 on behalf of APHIS for businesses or provide equivalent information without the use of a form such as on Excel spreadsheets. APHIS needs this information (which includes, specific to these forms, the date the animals were moved, their disposition, flock ID, and the flock owners' names and contact information) to conduct trace investigations in response to an adverse disease event.

Scrapie Epidemiology Report (VS Form 5-19D) - (Business and State/Tribe) - 9 CFR 54.3(b) and 54.8(g)

An APHIS or State veterinarian records all epidemiological findings of an investigation on these forms or provides equivalent information without the use of a form such as on Excel spreadsheets. Information is obtained from examining records and animals and through questioning the flock owner regarding flock health, management practices, and animal movements (animals sold for slaughter or breeding, purchased additions, etc). Information collected on VS Form 5-19D is

required under 9 CFR 54.3(b) (see certification listing, below, for the required information) as a prerequisite for receiving indemnity.

Appraisal and Indemnity Claim (VS Form 1-23) and Continuation Sheet (VS Form 1-23A) (Business and State/Tribe) - 9 CFR 54.4(a) and 54.5

An APHIS or State/Tribe representative completes the application for indemnification for the owner. The owner then confirms the information on the application. If a flock is not currently determined to be scrapie affected, the owner may apply directly to APHIS for indemnification. The written application must provide specific information including the name, address, and Social Security number of the flock owner; the number and breeds of animals within the flock; the location of the flock; and reasons the owner believes the flock may be eligible for indemnification. In the case of known infected flocks, APHIS has already collected this information as part of the investigation and request for information. Giving flock owners an opportunity to receive indemnity payments encourages producers to report incidents of scrapie in their animals, which hastens the eradication of scrapie from the United States. This report, containing original signatures of the flock owner and the supervising veterinarians, also serves as the official written record that a specific number of animals in the owner's flock have been destroyed because of scrapie. To complete the VS Form 1-23 the animals must be inventoried by APHIS or the State or Tribe including recording identifying tags or marks, species, breed, sex, and age of animal (see determination of age, etc., in Inventory and Calculation of Animal Value, below). The owner also certifies that if the animal for which indemnity is paid is subject to any mortgage, he or she consents to the payment of the indemnity, up to the value of the mortgage, to the person(s) holding the mortgage; and that the animal may be removed to a USDA facility or a quarantined research facility, slaughtered, or euthanized and necropsied and tissues removed for diagnostic or other purposes.

Written Agreement/Certification (Business) - 9 CFR 54.5

Before APHIS makes an indemnification payment to a flock owner, the owner must sign a written agreement certifying the following: (1) He or she will make available to APHIS any bills of sale, pedigree registration certificates, and other records regarding movement of animals into and from the flock; and (2) He or she will maintain any current flocks (or any new flocks acquired within 5 years after the last scrapie-positive, scrapie-exposed, or scrapie-suspect animal has been removed from the premises) in accordance with a Post Exposure Management and Monitoring Plan (PEMMP). When a flock plan is also required, this statement is included as part of the flock plan to minimize the number of signatures required. This agreement/certification is a valuable tool in APHIS' efforts to closely monitor sheep and goat operations affected by scrapie.

Inventory and Calculation of Animal Value (State) - 9 CFR 54.6

State employees inventory animals by age, sex, species, breed, registration status, and weight; and determine their value using calculators completed by State/Tribal personnel. If records and identification are inadequate to determine the actual age of animals, a State representative counts all sexually intact animals 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 calculates indemnity for these animals. 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.

Receipt of Disposal Expenses (Payment of Indemnity) - (Business) - 9 CFR 54.7(d)

To obtain reimbursement for disposal costs, animal owners must obtain APHIS' written approval of the costs before disposal. For reimbursement to be made, the owner of the animals must present the Area Veterinarian in Charge (AVIC) 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.

Report for the Environmental Protection Agency (EPA): Exempted Disinfectants Used (Business and State/Tribe) - 9 CFR 54.7(e)(2)(iv), 9 CFR 54.8(j)(1)

When producers enter into a flock plan, they must agree to follow a disinfection protocol requiring use of a product registered by the U.S. Environmental Protection Agency (EPA) specifically for reduction of prion infectivity in accordance with the label or with an emergency exemption issued by EPA for reduction of prion infectivity. On April 29, 2013, the EPA amended 40 CFR 152 to include prions as a "pest" under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Accordingly, only products registered with the EPA specifically for the reduction of prion infectivity can be used to disinfect premises, laboratories, and research facilities after prion exposure. Currently there are no EPA registered products available; EPA therefore granted APHIS an exemption for the use of chlorine and sodium hydroxide (lye) in its prion control and eradication programs. The exemption requires APHIS to submit an annual report to EPA detailing the total amount of bleach and lye used by APHIS, our partners (State laboratories), and TSE-infected premises. For bleach, respondents must report the date of use, the concentration used, the amount used, and any adverse reactions noted in people, livestock, wildlife, or the environment. For lye, respondents must report the date of use, formulation (powder or liquid) used, the amount used, and any adverse reactions noted in people, livestock, wildlife or the environment.

Flock Plan and Recordkeeping (Business and State/Tribe) - 9 CFR 54.8

A written flock plan (management agreement) is signed by the owner of a flock designated as infected or source, a State or Tribal representative (usually the State animal health official), and an APHIS representative. Each participant agrees to undertake actions specified in the flock plan to control the spread of scrapie. These actions include official identification of animals, collection of tissues, availability of records, monitoring for scrapie, and notification of an APHIS or State representative if any animals exhibit signs of possible scrapie infection. The flock owner must maintain records for acquired animals and animals leaving the premises for 5 years. Owners may use VS forms 5-18 and 5-20 to collect some of the information Owners may maintain the information in other ways as long as the required information is maintained. These records are invaluable if the flock becomes infected and a trace investigation is necessary.

Post Exposure Management and Monitoring Plan (PEMMP) and Recordkeeping for Plans (Business and State/Tribe) - 9 CFR 54.8(g)

This is an agreement between the flock owner, a State or Tribal representative, and an APHIS representative describing a plan to carefully monitor a flock for at least 5 years following removal of the last scrapie-positive, scrapie-exposed, or scrapie-suspect animal from the flock. In this plan, the owner agrees to maintain records for 5 years for each animal in the flock, including each animal's sex, breed, date of acquisition, and the source of acquisition (previous flock). The owner also agrees to alert an APHIS or State representative if any animals in the flock show signs of possible scrapie infection. Entering into these agreements with owners of infected flocks or flocks with exposed animals ensures that these flocks will be closely monitored and controlled until 5 years after all scrapie-positive and/or high-risk animals have been removed or died. The records are invaluable if the flock becomes infected and a trace investigation is necessary.

Report Suspect/Dead Animals (Business and State/Tribe) - 9 CFR 54.8 (f) and 54.21

Accredited veterinarians or flock owners must immediately report to an APHIS or State/Tribal animal health official via a telephone call, fax, or email any suspect animals. A suspect animal may be euthanized and tissue specimens submitted for scrapie testing.

**Scrapie PEMMP Inspection Report (VS Form 5-19C) - (Business and State/Tribe)
9 CFR 54.8(d)**

APHIS or State personnel inspect flocks on PEMMPs annually and complete an inspection report detailing compliance with the requirements for flocks on PEMMPs. The flock owner must review and sign the form. Personnel obtain information by examining animals and records and asking questions of flock owners. Personnel ask flock owners about signs of disease, compliance with identification requirements, and records, as follows:

- For acquired animals, the date of acquisition, name and address of the person from whom the animal was acquired, any identifying marks, and any 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 ear tag, 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 9 CFR 79.2 (as further outlined in this collection).
- 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 ear tag, 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 9 CFR 79.2.
- For 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 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.

Flock owners must maintain these records for 5 years. Owners may use VS forms 5-18 and 5-20 to collect some of the information. Owners may maintain the information in other ways as long as the required information is maintained.

**Waiver of Requirements for Scrapie Control Pilot Projects (State/Tribe)
9 CFR 54.9 and 79.7**

APHIS may sign an MOU (9 CFR 54.2) to establish a pilot project with a State/Tribe or modify a flock plan or PEMMP (9 CFR 54.8) with concurrence of the State animal health official to redesignate certain types of exposed animals or to allow certain types of exposed animals to be retained as part of a Flock Plan or PEMMP. This is permitted to evaluate alternate scrapie control methods.

Program Approval of Tests for Scrapie (Business and State/Tribe) - 9 CFR 54.10

Test kit manufacturers or laboratories must apply for approval to use a new test or test method in the program. This ensures that only accurate tests are used in the program. Requestors must submit (1) A standardized test protocol that includes 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.

Appeal of APHIS Decisions (Business and State/Tribe) - 9 CFR 54.10(h), 54.11(c), 54.21, 79.2(b)(5), 79.4(c)(3)

Stakeholders may appeal in writing certain decisions made by APHIS that directly affect them. This provides an extra level of review for decisions that may have significant impacts on individuals, businesses, or States or Tribes. Decisions that may be appealed include not approving or removing approval of a laboratory, a test kit or method, an identification device or method, or an official identification manufacturer; or the designation or status of a flock or animal.

Cooperative State-Federal Scrapie Control Program-Scrapie Test Record (VS Form 5-29) and Continuation Sheet (VS Form 5-29A) - (Business and State/Tribe) - 9 CFR 54.11(a)(8)

Testing of scrapie-exposed and potential exposed animals and other animals for disease surveillance is a key component of the eradication program. The scrapie test record form is used to record the herd being tested; the owner's name and address; official identification numbers, age, breed, and sex of each animal tested; and the type of test required. VS Forms 5-29 and 5-29A or equivalent data entry screens are used to submit samples for genotype testing and/or tissues for antemortem scrapie testing. The sample containers are also labeled with the animal ID number and a preprinted barcode. The shipping container is labeled as required for the method of shipment. An APHIS or State or Tribal representative or accredited veterinarian completes these forms with assistance from the flock owner and labels the samples and shipping container. APHIS also allows producers to complete this form without an accredited veterinarian's help when using a tamper-evident sampling kit to sample animals to test for genetic susceptibility to scrapie. State and private laboratories enter the corresponding test results into an APHIS database and maintain records of tests performed.

APHIS developed worksheets based on the VS Forms 5-29 and 5-29A to provide additional space to apply barcodes used to identify specimens and to serve as a draft copy when collecting samples and specimens under adverse conditions (see the Veterinary Services Laboratory Submission (VSL) worksheets). The worksheets are also used for filling out VS Form 10-4.

Specimen Submission (VS Form 10-4) and Continuation Sheet (VS Form 10-4A) or equivalent data entry screen - (Business and State/Tribe); Recordkeeping (State/Tribe) 9 CFR 54.11(a)(8)

An APHIS or State representative, contractor, or accredited veterinarian completes this form to submit specimens from dead animals to an approved laboratory for scrapie testing. These individuals usually obtain information to complete this form from the flock owners or other business owners, such as slaughter plant owners. This form is critical for identifying infected and source flocks or for releasing exposed flock status, as it contains information identifying the

individual animal from which specimens were taken, the animal's herd or flock, the type of specimen submitted, and the purpose for submitting the specimen. The sample containers are labeled with the animal ID number, preprinted barcode, and tissue type, and the shipping container is labeled as required for the method of shipment. State laboratories enter the corresponding test results into an APHIS database and maintain records of tests performed.

To facilitate the collection of information at sheep or goat slaughter plants and when producers submit whole heads from individual animals for scrapie testing, APHIS developed a simplified worksheet. Use of the worksheet decreases the time that would be needed to complete VS Form 10-4 and also serves as a draft copy when collection of samples occurs under adverse conditions (see Appendices B-2, 3).

Request for Laboratory Approval (Business and State/Tribe) - 9 CFR 54.11(a and b)

State or university diagnostic laboratory directors may request approval for their laboratory to conduct an official test for the diagnosis of scrapie or for scrapie susceptibility genotyping. Private laboratories may also request approval for scrapie susceptibility genotyping. The request can be made by letter or e-mail through the VS Area Veterinarian in Charge for the State in which the laboratory is located or to the Director of the National Veterinary Services Laboratory (NVSL). A laboratory must send the NVSL Director an application package consisting of an original document and three copies containing the information listed below:

For scrapie testing laboratories:

- a. The National Animal Health Laboratory Network Laboratory Qualification Checklist.
- b. A copy of the laboratory's VS permit (as required for receipt of proficiency panels and positive controls).
- c. A description of the specific procedures to be used to report test results.
- d. A description of recordkeeping procedures. Approval requires that records from all specimens be retained for at least 1 year, and records pertaining to cases with positive, suspect, repeat, or inconclusive test results be retained for at least 5 years.
- e. A description of sample/tissue holding and retention procedures.

For scrapie genetic susceptibility testing laboratories:

- a. Name and address of the laboratory.
- b. Name of the legally responsible official and, if different, the director of the laboratory.
- c. A description of the laboratory facilities and equipment that will be used in performing genotype tests.
- d. A list of the types of samples that will be tested.
- e. The standard operating procedure for each test to be used, including methods, materials, equipment, and other relevant information.
- f. A list of the names of individuals performing specific tests and a detailed statement of each individual's qualifications.
- g. A detailed description of the procedures used to satisfy the recordkeeping requirements of the NSEP.
- h. A description of the specific procedures used for reporting test results.
- i. The laboratory quality assurance manual.
- j. A statement authorizing APHIS to inspect the laboratory, without prior notice, during normal business hours. The inspection may include, but is not limited to, reviewing and copying records, observing tests, and interviewing personnel.

After the State diagnostic laboratory director requests approval of the laboratory, APHIS inspects the laboratory to determine that it has the proper physical facilities and equipment. The inspector reviews the laboratory's responsibilities (both regulatory and technical) with laboratory officials. Once the laboratory has one or more of its pathologists trained at NVSL, NVSL approves the laboratory as an official laboratory. (A university laboratory not affiliated with a State may also request approval.) VS formerly used VS Form 5-21 for this activity, but no longer does so.

Application for the SFCP (VS Form 5-22) - (Business) - 9 CFR 54.21

Any flock owner desiring to participate in the SFCP must sign an application form, agreeing to follow the provisions of the program. This pre-printed form requires the flock owner to provide his or her name and address, the location of the flocks, and the number of animals in each flock. The information on the form is entered into the Surveillance Collaborative Services (SCS) website to inform potential buyers of the location and current status of animals in the program and to allow APHIS to manage the program. The form serves as the owner's agreement to comply with SFCP requirements and to have the flock's information published online.

Scrapie SFCP Flock Inspection Report (Initial Flock Inspection) (VS Form 5-19A) and Recordkeeping - (Business and State/Tribe) - 9 CFR 54.21

APHIS or State or Tribal personnel use this form to collect information from flock owners as part of their application to enroll in the SFCP. Flock owners assist the State or Federal employee in completing VS Form 5-19A and must keep these records for 7 years. The information describes their inventory, location, and type of operation; documents education regarding compliance with program requirements; and includes their contact information.

Scrapie SFCP Flock Inspection Report - Annual Inspection Report (VS Form 5-19B) and Recordkeeping - (Business and State/Tribe) - 9 CFR 54.21

Flock owners assist State or Federal employees in completing the VS Form 5-19B. This form records data regarding subsequent SFCP inspections. The information describes the flock owner's inventory, location, type of operation, and management practices, including additions and disposition of animals; documents compliance with program requirements; and includes the owner's contact information. Flock owners must keep these records for 7 years.

Approval of Terminal Feedlots (VS Form 5-10 or equivalent) - (Business and State/Tribe) 9 CFR 54.1 and 79.1

APHIS approves terminal feedlots for animals in slaughter channels to document the agreement of the owners to comply with the requirements for terminal feedlots and APHIS' approval of the feedlot. The template asks for the owner's name, facility name, premises address and identification number, the owner/premises phone number, the owner's email address, and contact information if the owner is not the main contact and includes the owner's agreement to keep the required records and separate the animals as required. Approval requires that records be kept of animals moving through the feedlot.

Owner/Hauler Statement and recordkeeping (VS Form 5-13 or equivalent) - (Business) 9 CFR 79.2 (a)(1) and 79.3(a)

An owner/hauler statement must be used as an additional form of ID for movement of certain classes of regulated sheep and goats or as an alternative means of identifying certain other classes of regulated sheep and goats to their flock of origin. When these animals move in interstate commerce,

it is vital that APHIS has documentation that will enable it to trace animals back to their flock of origin. The flock owner completes this form with the owner's name, signature, address, telephone number, the date the animals left the flock of origin, the number and class of animals involved in the movement, the premises identification number assigned to the premises, and other identifying information.

Interstate Certificate of Veterinary Inspection (VS Form 17-140 or equivalent) and Recordkeeping (Business and State/Tribe) - 9 CFR 79.5

A flock owner wishing to move sheep or goats in interstate commerce for reasons other than for slaughter or feeding for slaughter must be issued a certificate of veterinary inspection (ICVI). Since these animals are not designated exposed or infected, any accredited veterinarian can issue the ICVI. The flock owner assists the accredited veterinarian in completing the ICVI by having the animals available for inspection and providing the purpose for which the animals are being moved, the points of origin and destination, the consignor, and the consignee. The issuance of the ICVI requires examination of the animals for clinical signs of scrapie or other communicable diseases and listing of official identification, and gives APHIS important information if a trace investigation must be conducted.

Request by a Breed Registry to Have its Tattoos Approved as Official ID (Business) 9 CFR 79.2 (a)(2)

Sheep or goat breed registries wishing to have their tattoos considered official ID for interstate commerce must make a written request for approval. Approval is required to ensure that tattoos are unique and that the registry will provide the information needed to trace the animals if needed for a disease investigation.

Requests for Approval of Sheep or Goat Identification Device Types or Methods not Currently Approved (Business) - 9 CFR 79.2 (a)(2)

An individual wishing to use or produce an identification device or method not already approved must submit to APHIS a written request for approval of the device or method. If APHIS determines that an identification device or method will provide an effective means of tracing sheep and goats in interstate commerce, APHIS will provide public notice that the device type or method, along with any restrictions on its use, has been added to the list of approved devices and methods of official sheep and goat identification.

Application for and Assignment of ID Numbers or Official Tags Including Blue Tags (VS Forms 5-11, 5-11A, 5-12, and 5-12A, or equivalent) - (Business) and Recordkeeping (State/Tribe) - 9 CFR 79.2 (b)

Flock owners, dealers, accredited veterinarians, breed registries, and market operators must apply to the appropriate State or Federal representative (usually the designee of the State or Tribal animal health official or AVIC) to be assigned USDA serial or flock identification numbers that correspond to official animal identification devices. They must provide their name, address, phone number, number of animals, and type of operation so that the State/Tribal or Federal representative (a contractor or direct employee) can place their orders and create records. These applications are generally made by calling the State/Tribal or Federal representative or official ear tag manufacturer. If flock owners, dealers, accredited veterinarians, and market operators give this information to their State/Tribal representatives, breed registry or official ear tag manufacturer, these individuals record the assignment in the APHIS Animal Identification Management System (AIMS) database or by alternative methods acceptable to APHIS (such as a State database). This information is maintained

in the AIMS database, and could provide invaluable information to State/Tribal or Federal personnel conducting a traceback investigation.

Application for and Assignment of Identification Numbers (Business) and Recordkeeping (State/Tribe) - 9 CFR 79.2 (b)

APHIS employs an additional (but optional) identification system that allows sheep and goats moving in interstate commerce to be identified with an approved ear tag, backtag, or tattoo bearing a flock identification number assigned by a State/Tribal or Federal animal health official to the premises on which the sheep or goats originated. Obtaining and applying these premises identification numbers, which could be used in lieu of official USDA serial numbers, is the responsibility of flock owners. To apply for these numbers, the flock owners contact the State/Tribal or Federal representative by telephone or other means and give their name, address, phone number, number of animals, and type of operation so that the State/Tribal or Federal representative can create a record. If the flock owners give this information to the State/Tribal representative, the representative records the information. The representatives use SCS (see below) or a local log book per the State/Tribal standard operating procedure (SOP) for this purpose. The State/Tribal SOP is a discretionary document. These premises identification numbers help APHIS and States monitor sheep and goats moving in interstate commerce and provide APHIS and States with critical information if a trace investigation is necessary.

Assignment of Official ID Numbers

Official identification numbers for use on animals not in slaughter channels may be assigned as follows:

- Directly to the owner of a breeding flock;
- In the case of official serial numbers or serial number devices, to APHIS or State representatives or accredited veterinarians or other responsible individuals (such as 4-H leaders) for reassignment to owners of breeding flocks, if the State animal health official and the District Director agree that such assignments will improve scrapie control and eradication within the State; or
- To any federally recognized tribe that maintains sheep or goats on tribal lands (Tribal codes).

APHIS or State representatives or accredited veterinarians that reissue official serial numbers or devices must provide data associating assigned serial sequences to the flock of origin and, when required, the flock of birth. This can be done by entering the data into the Animal Identification Management module of the National Scrapie Database.

Persons assigned serial numbers may either directly apply eartags to animals, or may reassign eartag numbers to producers. Such persons must maintain records that permit traceback of animals to their flock of origin, or flock of birth when required, and must either reassign the tags in the National Scrapie Database or, if permitted by the VS District office, provide a written record of the reassignment when requested to the District Office or the State Office for entry into the National Scrapie Database. APHIS may also assign sets of unique individual identification numbers to breed registries that agree to reassign the sequences to the flock of origin and, when required, the flock of birth; and to provide associated registry identifiers such as registry tattoo numbers to APHIS when requested in the Animal Identification Management module of the National Scrapie Database.

Livestock facilities may identify animals after sale if the facility maintains unidentified animals from different flocks of origin or, when required, birth in separate enclosures until officially identified.

Assignment of Unique Identification Numbers to Persons Who Do Not Own Breeding Flocks (9 CFR 79.3(a)(5))

Sets of unique individual identification serial numbers may be assigned to persons who handle sheep and goats, but who do not own breeding flocks, if they apply to and are approved by the State animal health official or the District Director in the State in which the person maintains his or her business location. The assigning entity should be the one responsible for issuing official identification devices or numbers in the State where the applicant maintains business and for assigning flock identification numbers and premises identification numbers in that State in the National Scrapie Database. Such persons must, if requested, provide data associating assigned serial sequences to the flock of origin and, when required, the flock of birth. This can be done by entering the data into the Animal Identification Management module of the National Scrapie Database.

Reporting when Identification is Applied (Business and State/Tribe) - 9 CFR 79.2 (b)(1-3)

Persons applying official ID to animals that did not originate in a flock owned by them (as may be required by regulation) or that assign official ID numbers to other people, flocks, or premises must report the assignment to APHIS.

Recordkeeping when Identification is Applied (Business) - 9 CFR 79.2 (g)

Persons such as flock owners, market operators, dealers, slaughter plant owners, and accredited veterinarians who apply official individual or group/lot identification to animals must maintain records for 5 years. These persons must make the records available for inspection and copying by any authorized USDA or State/Tribal representative upon that representative's request and presentation of his or her official credentials. The records must include the following information: (1) The flock identification number of the flock of origin, the name and address of the person who currently owns the animals, and the name and address of the owner of the flock of origin if different; (2) The name and address of the owner of the flock of birth, if known, for animals in another flock and not already identified to flock of birth; (3) The date the animals were officially identified; (4) The number of sheep and the number of goats identified; (5) The breed and class of the animals. If breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead; (6) The official identification numbers applied to animals by species or the group identification number (GIN) applied in the case of a group lot; (7) Whether the animals were identified with "Slaughter Only" or "Meat" identification devices; and (8) Any GIN with which the animal was previously identified.

Recordkeeping, Animals Moved in Interstate Commerce (Business) - 9 CFR 79.2(f)

Flock owners must maintain specific records on each animal for at least 5 years after the animal is moved or sold, and make these records available for inspection by an authorized APHIS or State/Tribal representative. These records include the following information: (1) The number of animals purchased or sold (or transferred without sale); (2) The date of purchase, sale, or other transfer; (3) The name and address of the person from whom the animals were purchased or otherwise acquired or to whom they were sold or otherwise transferred; (4) The species, breed, and class of animal. If breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead; (5) A copy of the brand inspection certificate for animals officially identified with brands or ear notches; (6) A copy of any certificate or owner/hauler statement required for movement of the animals purchased, sold, or otherwise transferred; and (7) If the flock of origin or the receiving flock is under a flock plan or PEMMP, any additional records required by the plan. (Much of this recordkeeping is part of normal business records that people maintain for tax and other purposes.) These records would be invaluable if an exposed or infected animal needs to be located.

Request to Replace Official ID and Recordkeeping for Lost or Replaced Official ID (Business and State/Tribe) - 9 CFR 79.2 (h)(3)

Any time an official identification device is replaced, as authorized by the State or Tribal animal health official or the AVIC responsible for the State involved, the person replacing the device must record the following information about the event and maintain the record for 5 years: (1) The date when the device was removed; (2) The address of the location and the name, phone number, and email address of the person responsible for the location where the device was removed; (3) The official identification number (to the extent possible) on the device removed; (4) The type of device removed (e.g., metal ear tag, RFID ear tag); (5) The reason for the removal of the device; (6) The new official identification number on the replacement device; and (7) The type of replacement device applied. Persons must keep the records for 5 years.

Request for Approval to Produce or Renew Approval to Produce Official Identification Devices (Business) - 9 CFR 79.2(k)(2)

Tag manufacturers request by mail or email approval to produce official identification devices. Approval packages include data supporting the durability of the tag, durability and legibility of the identification numbers, and high retention rates of the tags in animals, preferably sheep or goats; and a signed agreement (see below). This can also be accomplished by using the VS Form 1-64 to request approval to manufacture a particular device. The form requires the submitter to describe the type of device, provide the company and manufacturing plant name and address, and contact person information (name, address, phone number, email); contact information for the manufacturing plant's information technology person; the product name, code number, and anticipated production capacity and inventory; and the species to which the tag or device is to be applied. The company must also document tag production, performance, and testing.

**Agreement to Send Official Ear Tags to Specified Individuals (Business)
9 CFR 79.2(k)(2)(iii)**

As part of the request for approval to produce official identification devices, tag manufacturers must provide a signed statement agreeing to: (1) Send official identification devices only to a State/Tribal or APHIS representative, to the owner of a premises or to the contact person for a premises at the address listed in the National Scrapie Database, or as directed by APHIS; (2) When requested by APHIS, provide a report by State or Tribe of all tags produced, including the tag sequences produced and the name and address of the person to whom the tags were shipped, and provide supplemental reports of this information when requested by APHIS; (3) Maintain the security and confidentiality of all tag recipient information acquired as a result of being an approved tag manufacturer and use the information only to provide official identification tags; and (4) Enter the sequences of tags shipped in the National Scrapie Database through an internet web page interface or other means specified by APHIS prior to shipping the identification device.

Monthly Report of Official Identification Produced (Business) - 9 CFR 79.2(k)(2)(iii)(B)

Tag manufacturers are required to report by State all tags produced, including the tag sequences produced, the recipient's name, and shipping address when APHIS asks for it. Some manufacturers voluntarily provide the report monthly as they have automated it. APHIS is now able to pull similar reports from the APHIS AIMS database so submission is generally not requested. Tag manufacturers working under contracts with APHIS also provide cost reports as required by the contract.

**Data Entry of Official Identification Devices Produced and Assigned (Business)
9 CFR 79.2(k)(2)(iii)(D)**

Currently tag manufacturers enter the sequences of tags shipped into the Animal Identification Management module of the National Scrapie Database through a Web-based interface. APHIS anticipates the number of responses will increase significantly the first 2 years following publication due to the requirement to officially identify more classes of goats and then drop off substantially since only 12 percent of producers typically request official tags each year.

Compliance Agreement and Report for Consignments when Identification is Applied (Business) - 9 CFR 79.3(k)

As part of the agreement to use blue slaughter-only tags, dealers or owners, operators, or managers of livestock markets, slaughter plants, or other concentration points agree to report consignments of animals that arrive without identification and are not eligible for certain forms of official

identification because the flock of origin cannot be determined. The representatives report to APHIS or the State or Tribal representative a list of official identification numbers applied; date or receipt, consignor name and address; number, species, and breed or class of animal; number of unidentified animals; and a statement (or photographs of the teeth and ears of the unidentified animals), noting whether the second permanent incisor of the unidentified animals had erupted. The agreement and report enable the facility to accept the animals that arrived without identification. These documents also avoid having to return the animals to the truck and reship them. These agreements ensure that untraceable animals are moved only to slaughter and allow APHIS to identify individuals or entities not complying with the regulations so APHIS can correct the noncompliance.

Decline to Participate or Provide Information (Business) - 9 CFR 79.4

A flock owner can, at several points in a flock designation or investigation, decline to provide information or carry out a task: (1) When a flock is under investigation and the owner declines to complete genotyping and live-animal and/or post-mortem scrapie testing required by the APHIS or State/Tribal representative investigating the flock, or to remove one or more genetically susceptible exposed animals or suspect animals identified during the investigation; or (2) when under consideration for indemnity, and the owner declines to remove an animal within 60 days of when indemnity is first offered. These declinations may be made verbally or in writing, and must be given to the appropriate APHIS representative. APHIS assumes declination in some cases due to nonresponse. Such declinations generally result in the State or Tribe issuing movement restrictions to the flock owner and APHIS designating the flock as noncompliant, which restricts the movement of the animals in interstate commerce.

Herd Owner Notification of Designation of Flocks or Animals (State/Tribe) - 9 CFR 79.4(c)(2)

When an APHIS or State representative determines a flock or animal has or may have been exposed to scrapie, the APHIS representative must notify the flock owner in writing of this determination and provide the owner with a description of APHIS interstate movement restrictions and identification requirements. APHIS or the State representative communicates this information to flock owners so they will be fully and promptly advised of their flock's new status with regard to interstate movement. The flock owner is not required to respond to this notification.

Permit for Movement of Restricted Animals (VS Form 1-27) - (Business and State/Tribe) 9 CFR 79.5

Authorized APHIS or State personnel or authorized accredited veterinarians issue permits for the interstate movement of scrapie-exposed, scrapie-positive, or other high-risk animals. A permit lists the owner's name and address, the origination and destination of the animals, how many animals are involved in the movement, the purpose of the movement, the transportation vehicle's license number, and all official identification on each animal being moved.

Consistent State Application - Application for Scrapie Classification, Classification Renewal, or Reclassification of a State (VS Form 5-24) - (State/Tribe) - 9 CFR 79.6

States wishing to remain classified as having an effective scrapie management program must submit to APHIS an annual application for renewal describing the State's scrapie management actions during the preceding fiscal year. These include inspections done to monitor compliance with official identification and recordkeeping requirements, reports of disease events, actions taken in response to these events, and surveillance activities. In addition, the VS Form 5-24 requires signatures by the State animal health official. The current version of this form simplifies the application and relies on

transmission of an electronic spreadsheet as part of the reporting process rather than summarizing the information on a hard copy form.

Epidemiology and Identification Compliance Report (State/Tribe) - 9 CFR 79.6 (4 and 12)

APHIS uses this report to track compliance with Consistent State requirements. APHIS' State partners carry out inspections relating to ID compliance at several points during the progress of sheep and goats through production channels. They visit livestock concentration points such as markets and slaughter facilities to determine compliance with the identification requirements. Reporting is typically done on State forms and APHIS receives summarized data which is used for the Epidemiology and ID Compliance Report. In a few cases States compile the report under a cooperative agreement or MOU. States also provide information for the epidemiology portion of the report, which is gathered from responses previously described.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Justification for continued use of hard copy forms is spelled out as appropriate in the list below:

The requests for information (VS Forms 5-18, 5-18A, 5-19D, and 5-20) contain information supplied by the flock owner to APHIS necessary for the flock owner to receive indemnity payments. The flock owner attests to the accuracy of this information by signing the forms. Since an original signature is necessary for these forms to be valid, the forms themselves are not candidates for electronic submission unless the owner is working with a VS employee who can prepare the forms and submit them through eAuthentication. Also, owners can submit information informally using Excel, Word, or PDF files, which VS then enters into an electronic database (see below).

The Application for Payment of Indemnity (VS Forms 1-23 and 1-23A) is completed for and signed by flock owners whose sheep are being destroyed because of exposure to scrapie. This form is not a candidate for electronic submission because it requires original signatures to be valid.

The Written Agreement/Certification by Owners has been incorporated into the VS 1-23 and flock plan agreements which constitute a hard copy agreement requiring an original signature by the flock owner to be valid. Therefore, it is not a candidate for electronic submission.

The Flock Plan and PEMMP are hard copy agreements requiring an original signature by the flock owner to be valid. They are not candidates for electronic submission.

Reporting the presence of suspect animals is usually accomplished by the flock owner or accredited veterinarian with a telephone call to Federal or State/Tribal authorities. This information can also be emailed or faxed.

The Scrapie PEMMP Inspection Report (VS Form 5-19C) requires an original signature by the flock owner and is not, therefore, a candidate for electronic submission.

The Scrapie Test Record (VS Form 5-29) and its Continuation Sheet (VS Form 5-29A) are used for submission for testing for genetic susceptibility to scrapie and tissue biopsies (third eyelid or rectal biopsy). All genotype and scrapie tests are entered into Veterinary Services Laboratory Submissions (VSLS, described further below) and the information is submitted electronically to APHIS and contract laboratories for resulting. Data may be scanned into VSLS (RFID tags or specimen barcodes) or entered manually. Hard copies of VS Forms 5-29 and 5-29A or worksheets containing the same information (the VSLS worksheets) are still needed when the form is completed on the flock owner's property or in other outdoor locations where computer access may not be readily available. State or Tribal personnel who do not have eAuthentication accounts and accredited veterinarians will continue to use hard copies of these forms as these individuals do not have access to VSLS.

The Specimen Submission (VS Form 10-4) is typically completed onsite by Federal or State/Tribal veterinary authorities. This form has been adapted for electronic submission of slaughter and on-farm surveillance samples. (Refer to Appendix D for screenshots of VSLS electronic forms.) Electronic submission is required for APHIS personnel and State/Tribal personnel with eAuthentication accounts. Hard copies of VS Form 10-4 or worksheets containing the same information (Appendices B-2, 3) are needed when the form is completed in slaughter facilities, on the flock owner's property, or in other outdoor locations where computer access is not available.

A laboratory's request to APHIS to conduct official scrapie tests can be accomplished with a telephone call. (The subsequent documentation supporting the laboratory's request can be submitted to APHIS electronically or in hard copy.)

The Agreement to Conduct Official Histopathology Examinations for the Diagnosis of Scrapie (VS Form 5-21), a document signed only after the laboratory has received APHIS approval to conduct the tests, is no longer being used.

The Application for the Scrapie Flock Certification Program (VS Form 5-22) is pre-printed requiring an original signature from the flock owner. These formal agreements are not candidates for electronic submission.

The Flock Inspection and Epidemiology Report: Initial Flock Inspection for Complete or Export Monitored Status in the SFCP (VS Form 5-19A) requires an original signature from the flock owner and is not, therefore, a candidate for electronic submission.

The Flock Inspection Report: Annual Inspection Report for Scrapie Flock Certification Program Enrolled or Certified Flocks (VS Form 5-19B) requires an original signature from the flock owner and is not, therefore, a candidate for electronic submission.

The owner/hauler statement is a hard copy or pdf document that identifies the flock of origin of sheep or goats in a shipment. The document must accompany the shipment across State lines or when moving in interstate commerce and while it may be carried electronically most people prefer a hard copy. The compliance agreement is also not a candidate for electronic submission as it requires original signatures.

The report for consignments does not use a standard form and may be submitted by email, fax, or regular mail. Submitting this information electronically is allowed but not practical based on stakeholder preferences.

The request for identification approval is not a candidate for electronic submission because it requires original signatures to be valid.

The agreement to send official ear tags to specified individuals is not a candidate for electronic submission because it requires original signatures to be valid.

The Report of Official Identification Devices Produced may be submitted by CD, email, or hard copy when requested by APHIS.

The request for approval of a new device type requires an original signature and is not, therefore, a candidate for electronic submission.

The Herd Owner Notification (provided by State/Tribal or Federal personnel to the flock owner as a means of notifying the owner that he or she has or may have had a scrapie-positive or scrapie-exposed animal in his or her flock) is a written document that may be sent by fax, mail, or email. A signed hard copy is often sent to document that the notification was received if other means of communication are unavailable, if the notification was made by phone, or when other forms of communication have not been responded to.

The Permit for Movement of Restricted Animals (VS Form 1-27) to move scrapie-exposed or other high-risk animals across State lines must contain original signatures from various personnel involved in the movement at both the point of origin and the point of destination, and must accompany the shipment. This form is not a candidate for electronic submission.

Information contained in the Consistent State Application (VS Form 5-24) is currently submitted to APHIS in hard copy by the States. This form is not a candidate for electronic submission as it requires original signatures.

Paperwork for Approval of Designated Scrapie Epidemiologists and verification of training must be signed.

Overview of the Scrapie Program Databases:

Surveillance Collaborative Services (SCS) - APHIS or State (or Tribal) personnel enter information provided by producers and nonproducer entities (livestock markets, slaughter plants, and dealers) into the SCS. Information is from the various official forms and other listed activities, such as owner name, address, contact information, premises identification numbers, premises name, address, type of premises (production unit, market, slaughter plant, etc.), and species. Specific forms from which information is collected and entered into the SCS are the VS Forms 5-18, 5-18A, 5-19A-D, 5-20, and 5-22. In addition to this information, events (inspections or testing), test results, and flock status (SFCEP or disease) are entered into the SCS. Data is also transferred to SCS from VSLS for long-term storage and to correlate test data with the associated flock and animal record (see Appendix C for screenshots of these electronic forms).

Veterinary Services Laboratory Submissions (VSLS) - VSLS is a Web-based interface for submission of various specimens for testing by APHIS and contract laboratories. Three VSLS modules are used by the scrapie program: (1) Regulatory Scrapie Slaughter Surveillance (RSSS); (2) Genotyping; and (3) On-farm surveillance. In addition to APHIS employees, State or Tribal cooperators, contract laboratories, and contract sample submitters have access to one or more VSLS modules. Specific forms from which information is collected and entered into the VSLS modules are the VS Forms 5-29, 5-29A, and 10-4 (see Appendix D for screenshots of these electronic forms).

Animal Identification Management System (AIMS) - This is a Web-based system used to manage the distribution of official ear tags. This database is used by APHIS and State/Tribal employees and approved tag manufacturers (see Appendix E for screenshots of forms).

The cooperative agreements, MOUs, and grants can now be handled electronically with verified digital signatures of State/Tribal and Federal personnel.

The identification requirement allows the use of several devices including electronic ear tags. By using the electronic devices, APHIS employs an official animal identification that can be read electronically, can be listed by a computer, and can be used to facilitate the completion of forms requiring animal identification to be listed, such as the VS Forms 5-29 and 10-4.

Data entry of official identification devices produced is done through the AIMS website and stored in AIMS.

The ICVI (VS Form 17-140, or U.S. Origin Health Certificate), which authorizes the movement of breeding animals in interstate commerce, may be completed and submitted electronically. This form can be submitted through the VS Process Streamlining database, which has an electronic ICVI.

The application for identification numbers and application for premises identification can be made to APHIS via a telephone call, email, mail, or fax. These requests are then processed through and stored in AIMS and SCS.

Recordkeeping for identification can be accomplished either by maintaining a hard copy or an electronic record of official identification applied to sheep or goats. APHIS encourages recordkeepers to store the information electronically as much as possible and provides optional templates that can be used.

General recordkeeping can be accomplished either by maintaining hard copies of records (such as bills of sale and copies of movement permits or certificates) or electronically storing certain information (such as the name and address of the individual from whom an animal was purchased; the animal's sex, year of birth, breed; date the animal entered the flock; and the animal's final disposition). APHIS encourages recordkeepers to store the information electronically as much as possible and provides optional templates that can be used.

Owner/Hauler Statement and Bill of Sale (VS Forms 5-13)

Owners will typically use hard copies but may use other methods if acceptable to the person receiving the animals. Any method must accompany the animals and be shown to regulatory officials when requested. These documents can be submitted electronically as long as the technology includes a legally acceptable electronic signature.

**Data Assigning Official Identification to Flocks (VS Forms 5-11, 5-11A, 5-12, and 5-12A)
(includes Data Entry of Official Identification Devices Produced; Application for Official and Unofficial ID, PINs, and Flock Identification Numbers)**

Market operators, dealers, accredited veterinarians, and other persons who apply official identification to sheep and goats can submit the information in hard copy, by email, electronically through the animal identification number management system module of the National Scrapie Database at <http://nais.aphis.usda.gov/ainmngt/>, or in another manner acceptable to APHIS.

Concurrence with APHIS/State Animal Designations

Notification of such concurrence can be done via a phone call or email.

Flock Plan Disinfection Worksheet

APHIS has specific Excel spreadsheets for completing these worksheets; these may be submitted by email or in hard copy.

Applications for Approval of New Test Methods, Official ID, Alternate Forms of ID, and Assignment of ID

These may be done in hard copy or by emailing pdf files or other electronic file formats acceptable to APHIS.

Appeals of Withdrawal or Suspension of Approval of Test Method, ID Number Assignment and Approval

These may be done in hard copy or by emailing pdf files or other electronic file formats acceptable to APHIS.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

The information that APHIS collects in connection with this program is not available from any other source. APHIS is the only Federal agency responsible for controlling the interstate spread of domestic animal diseases. Some information APHIS is requesting is already being recorded by flock owners as part of routine business practices. This program, however, requires flock owners to engage in a number of additional activities before moving their animals interstate and that certain information be maintained for 5 to 7 years after an animal dies or is sold.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

APHIS estimates that 97 percent of the business respondents in this information collection are small businesses. Only the information needed to conduct a successful program is being collected. APHIS minimizes the burden on flock owners by having its own personnel complete as many of the required forms as possible.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If the information was collected less frequently or not collected, APHIS efforts to aggressively prevent the spread of scrapie would be severely hindered. APHIS would be unable to fulfill its mission of eradicating this economically damaging disease from the United States.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years;**

Certain records must be maintained for a minimum of 5 years after the death of an animal or the sale of an animal from the flock. In some cases, records need to be kept for more than 5 years. This is because of the 2- to 5-year incubation period of scrapie; the disease may not appear in a live animal until 5 years or longer after the death or departure of a transmitting animal, but would still have to be traced to that transmitting animal. Keeping records for long periods of time enables animal health officials to trace infected animals. Moreover, the international standard (set by the World Organization for Animal Health) for scrapie-free certification programs is 7 years.

The retention of records associated with this rulemaking is required for 5 years. This requirement is based on the fact that livestock animals typically live to be more than 3 years old and animal diseases can affect all ages and classes of livestock. Further, the incubation period for scrapie on average is 44 months (roughly 3 and a half years) and is often longer. Therefore, information that fully supports disease control, eradication, and surveillance needs to be maintained for longer than 3 years. APHIS also requires 5-year retention of records associated with animal movement kept by producers and operators of feedlots, markets, buying stations, and slaughter plants. The 5-year requirement brings consistency throughout APHIS regulations.

- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies**

that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

There are no other special circumstances associated with this information collection that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

APHIS contacted the following respondents by email and phone to discuss the information APHIS collects to administer its scrapie control and eradication program. We discussed with them how we and they obtain the necessary data and how frequently; how much data is available; the convenience and clarity of reporting formats and other collection instruments; and the clarity of, and necessity for, any recordkeeping requirements. The respondents stated via email or phone that they had no concerns with any of these items and had no further recommendations.

Pierce Bennett
Government and Industry Affairs Associate
Livestock Marketing Association
10510 N Ambassador Drive
Kansas City, MO 64153
pbennett@lmaweb.com
(937) 541-1287

Amy Hendrickson
American Sheep Industry Association Consultant
Wyoming Wool Growers Executive Director
811 North Glenn Rd.
Casper, WY 82602
amy@wyowool.com
(307) 265-5250

Joan Rowe, DVM, Past President
American Association of Small Ruminant Practitioners
American Dairy Goat Association Board Member
University of California Davis College of Veterinary Medicine
(Professor, Population Health & Reproduction)
jdrowe@ucdavis.edu
24580 Cache Street

Capay, CA 95607-3225
(530) 752-4926

On Tuesday, DEC 3, 2019, pages 66146-66147, Vol. 84, No. 232, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. No comments were received from the public. However, there was a comment received during the 30-day comment period from a concern citizen about how scrapie affect the soil and other animals. Her comment has no relevance to the purpose of the collection.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

APHIS may require approved laboratories to reimburse it for part or all of the costs associated with the approval and monitoring of the laboratory. No additional assurance of confidentiality is provided with this information collection. However, the confidentiality of information is protected under 5 U.S.C. 552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no questions of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**

See APHIS Form 71. Burden estimates were developed from discussions with flock owners; livestock market owners, operators, or managers; dealers; slaughter plant owners, operators, or managers; feedlot owners, operators, or managers; managers of producer organizations; tag manufacturers; accredited veterinarians; and State and Federal animal health officials.

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**

Respondents are flock owners; livestock market owners, operators, or managers; dealers; slaughter plant owners, operators, or managers; feedlot owners, operators, or managers; managers of producer organizations; tag manufacturers; accredited veterinarians; and State and Federal animal health officials. APHIS estimates the total annual cost to these respondents to be \$53,167,783.10. APHIS arrived at this figure by multiplying the hours of estimated response time (1,006,509 hours) by the estimated average hourly wage of the above respondents (\$35.92) and then multiplying the result (\$36,153,803.28) by 1.4706 to capture benefit costs.

Flock owners: \$24.42 [45-1011 First-Line Supervisors of Farming, Fishing, and Forestry Workers]
Market owners, operators, or managers: \$38.43 [11-9013 Farm, Ranch, and Other Agricultural Managers]

Dealers: \$32.47 [13-1020 Buyers and Purchasing Agents]

Slaughter plant owners, operators, or managers: \$38.43 [11-9013 Farm, Ranch, and Other Agricultural Managers]

Feedlot owners, operators, or managers: \$38.43 [11-9013 Farm, Ranch, and Other Agricultural Managers]

Managers of producer organizations: \$55.57 [11-9199 Management Occupations – Managers, All Others]

Tag manufacturers: \$20.17 [51-4011 Production Occupations (Computer-Controlled Machine Tool Operators, Metal and Plastic)]

Accredited veterinarians: \$50.59 [29-1131 Veterinarians]

State animal health authorities: \$55.57 [11-9199 Management Occupations – Managers, All Others]

Animal scientists: \$33.10

Veterinarians: \$48.81

Animal breeders: \$20.89

First-line supervisors of production and operating workers: \$30.13

Slaughters and meat packers: \$13.38

Farmers, ranchers, and other agricultural managers: \$38.62

The average hourly rate is derived from the most recent U.S. Department of Labor; Bureau of Labor Statistics Report – National Occupational Employment and Wage Estimates United States. See <http://www.bls.gov/oes/#tables>. According to DOL BLS news release USDL-18-1499, dated September 18, 2018 (see <https://www.bls.gov/news.release/pdf/ecec.pdf>), benefits account for 32 percent of employee costs, and wages account for the remaining 68 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.4706.”

13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

No annual cost burden is associated with capital and startup costs, operation and maintenance expenditures, or purchase of services.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

The annual cost to the Federal Government is estimated at \$1,524,435.45. (See APHIS Form 79.)

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

| | Requested | Program Change Due to New Statute | Program Change Due to Agency Discretion | Change Due to Adjustment in Agency Estimate | Change Due to Potential Violation of the PRA | Previously Approved |
|----------------------------|-----------|-----------------------------------|---|---|--|---------------------|
| Annual Number of Responses | 1,785,229 | 0 | 478,886 | 451,622 | 0 | 854,721 |
| Annual Time Burden (Hr) | 1,006,509 | 0 | 129,260 | -114,241 | 0 | 1,021,528 |
| Annual Cost Burden (\$) | 0 | 0 | 0 | 0 | 0 | 0 |

This is a program change of +478,886 annual responses and +129,260 burden hours.

There is a slight decrease in burden hours that can be attributed to rolling in the activity represented by the VS Form 5-21 into the existing Request for Laboratory Approval, as well as combining the Agreement to Use Blue Tags into the Application for and Assignment of ID Numbers or Official Tags Including Blue Tags. This eliminated two items. VS also removed the Determination of Age/Number of Animals as a separate activity.

For the Owner/Hauler Statement and Bill of Sales (Private Sector) it is a **program change** of +310, responses resulting in an increase +24,800 burden hours. The Bill of Sales is new to this information collection.

For the Application for Premises Identification Numbers and Flock Identification Numbers and Request to Change Information Associated with these Numbers - State, Local, and Tribal Governments there is a **program change** of +6,000 responses resulting in an increase of +12,000 burden hours. This is also new to this information collection. It takes the state 2 hours to complete this task where as it only takes the businesses around 10 minutes to complete their portion.

However, VS combined this information collection with new burden requirements, which added the several activities (See attached Document (Working Comparison APHIS 71 - Inventory and Calculations).

Many of these additional items did not take much time, but did increase the total number of respondents. Further, addition of the owner/hauler statement as a separate item from the ICVI accounted for a number of extra respondents.

There is an adjustment increase of +451,622 annual responses and a decrease of -114,241 burden hours. The decrease is due to the adjustment of in the time it take complete activies.

For the Owner/Hauler Statement - (business) and recordkeeping is an **adjustment** of +55,000 Respondents and +420,000 responses resulting in an increase of +87,000 burden hours.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS routinely publishes summary information in monthly and yearly reports at http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie. This information may also be published in newsletters or scientific journals. Further, APHIS presents summary information at various scientific and industry meetings that is occasionally published in a meeting compendium or posted by the meeting sponsor on the web. Finally, APHIS posts information at the above site listing the status in the program of participants in the SFCP and listing noncompliant flocks as described in 9 CFR 54.21.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

VS Forms 1-23, 1-23A, 1-24, 1-27, 10-4, and 17-140 are used in multiple collections; therefore, it is not practical to include OMB expiration dates because of the various expiration dates for each collection. APHIS is seeking approval to not display the OMB expiration date on these forms.

APHIS has no plans to seek approval for not displaying the OMB expiration date on the remaining forms.

18. Explain each exception to the certification statement identified in the “Certification for Paperwork Reduction Act.”

APHIS is able to certify compliance with all the provisions in the Act.

B. Collections of Information Employing Statistical Methods

Statistical methods are not used in this information collection.