

February 24, 2017

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

NOTE: This is a reinstatement of a previously approved information collection with change.

The five SF forms 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.

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 and animal identification regulations are contained in Title 9 of the *Code of Federal Regulations*, part 79, while its scrapie indemnification, flock cleanup, testing, and Scrapie Flock Certification Program (SFCP) regulations are found in part 54.

APHIS interstate movement requirements minimize any contact between high-risk animals and healthy animals, while the animal identification 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 Clean-up Plans and Post Exposure Management and Monitoring Plans for infected and source flocks; scrapie test records; applications for indemnity payments; certificates, permits, and owner statements that allow for the interstate movement of certain sheep and goats; and applications for premises identification numbers. They also include recording the application of APHIS-approved eartags, backtags, and/or tattoos. APHIS is also requesting to amend this collection to include new data entry screens used to capture and store the data collected. Data entry

screens are used by USDA employees, contractors, and State cooperators. They are not available to the general public.

APHIS is asking the Office of Management and Budget (OMB) to approve these information collection activities for 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 uses the following information activities to minimize contact between high-risk animals and healthy animals, while the animal identification requirements help trace scrapie-positive and scrapie-exposed animals and encourage flock owners to report scrapie signs and eliminate scrapie from their flocks through the indemnity program.

54.3(b) Request for Information - Record of Animals Moved (VS Form 5-18 or equivalent) and Record of Animals Acquired (VS Form 5-18A or equivalent) (business) (State) - When a flock owner applies for indemnity payments, 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 representatives may complete VS Forms 5-18, 5-18A, and 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.

54.3(b) Individual Animal Information Report (VS Form 5-20 or equivalent) (business) (State) - When a flock owner applies for indemnity payments, 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 representatives may complete VS Forms 5-18, 5-18A, and 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.

54.3(b) and 54.8(f) Flock Inspection and Epidemiology Report (VS Form 5-19) or Scrapie Epidemiology Report (VS Form 5-19D) (business) (State) - An APHIS or State veterinarian records all epidemiological findings of an investigation on these forms. 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. VS Form 5-19D is an updated form and will eventually replace VS Form 5-19.

54.4(a) Appraisal and Indemnity Claim (VS Form 1-23) and Continuation Sheet (VS Form 1-23A) (business) (State) - An APHIS or State 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, this information has already been collected by APHIS 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 including recording identifying tags or marks, species, breed, sex and age of animal (see determination of age, etc., below).

54.5 Written Agreement/Certification (business) - 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). 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. 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.

54.6 Proceeds from Animals Sold for Slaughter (VS Form 1-24) (business) - This form documents salvage value of animals destroyed by slaughter and is required for the calculation of indemnity. The buyer or seller of the animals completes the form.

54.8 Flock Plan and Recordkeeping (business) (State) - A written flock management agreement is signed by the owner of a flock designated as infected or source, a State representative, 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. These records are invaluable if the flock becomes infected and a trace investigation is necessary.

54.8 Post Exposure Management and Monitoring Plan (PEMMP) and Recordkeeping for Plans (business) (State) - This is an agreement between the flock owner, a State 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.

54.8(e) Report Suspect/Dead Animals (business) (State) - Accredited veterinarians or flock owners must immediately report to an APHIS or State animal health official via a telephone call, fax, or e-mail any suspect animals. A suspect animal may be euthanized and tissue specimens submitted for scrapie testing.

54.8(g) Scrapie PEMMP Inspection Report (VS 5-19C) (business) (State)

54.8(h)(4) Recordkeeping for the Plans (business) - This form is used by APHIS or State personnel to record data on flocks inspected as part of a PEMMP. Information is obtained through examining animals and records and by asking questions of flock owners. Flock owners are asked 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, 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 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.

54.11(a)(8) Cooperative State-Federal Scrapie Control Program-Scrapie Test Record (VS Form 5-29) and Continuation Sheet (VS Form 5-29A) (business) (State/Tribe) - Testing of affected and exposed flocks 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 are used for submission of 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 representative or accredited veterinarian completes these forms with assistance from the flock owner and labels the samples and shipping container. In the future, producers will be able to complete 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 provide results of the tests 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 collection of samples and specimens occurs under adverse conditions (see Appendix B-1). The worksheets are also used for filling out VS Form 10-4.

54.11(a)(8) Specimen Submission (VS Form 10-4) (business) (State/Tribe) - An APHIS or State representative 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.

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 Appendix B-2, 3).

54.11(b) Request for Laboratory Approval (State) (business) - 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 Assistant District Director in 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:

- a. Name and address of the laboratory.
- b. Name and contact information (address, telephone number, and email address) of the legally responsible laboratory official and, if different, the name of the laboratory director.
- c. (This and the next 12 items are for testing approval.) A copy of the laboratory's APHIS National Import Export Services permit (as required for receipt of proficiency panels).
- d. A statement that the laboratory participates in the NAHLN or, if not currently a participating NAHLN laboratory, a statement that the laboratory has applied for and is awaiting approval for participation in the network.
- e. A description of the laboratory facilities and equipment that will be used in performing scrapie diagnostic tests.
- f. A list of the specific scrapie diagnostic tests for which laboratory approval is requested.
- g. For each diagnostic test, a list of the types of tissues for which laboratory approval is requested. A laboratory may request approval to conduct one or more types of tests on one or more types of tissue. However, the laboratory may be required to obtain approval for specific types of tissues before they can be used with a specific test kit or test method, as determined by NVSL.

For example, a laboratory will not be approved to test lymph nodes unless they are also approved to test the obex. **Note:** Approval to conduct the same test on additional tissues may require additional proficiency testing, training, or both.

- h. The standing operating procedures (SOP) for each test, including methods, materials, equipment, and other relevant information. Approval requires these procedures be consistent with the SOP provided by NVSL and the manufacturer's instructions for licensed test kits, unless instructed otherwise in the NVSL SOP.
- i. Names of the individuals performing specific tests and a detailed statement of each individual's qualifications. This list should also designate one individual as the laboratory's contact person responsible for technical issues regarding scrapie testing (include address, telephone number, and email address for each individual).
- j. A description of the specific procedures to be used to report test results. Approval requires that results for tests supported by the VS Laboratory Submission (VLS) application be reported through the VLS webpage or by using an electronic message in the format specified by VS. Other test results will be reported via spreadsheets or other formats provided by NVSL. Results for IHC testing will be reported within 10 business days of sample receipt. Results for ELISA testing and other assays will be reported within 3 business days of sample receipt. Further, all positive, suspect, repeat, and inconclusive results must also be reported by email to NVSL within 1 business day after testing is completed.
- k. 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.
- l. A description of sample/tissue holding and retention procedures. Approval requires that slides, blocks, and other specimens for all submissions are retained for at least 1 year, except when NVSL has authorized shorter retention times for formalin-fixed tissues not in blocks or for fresh or frozen tissue from accessions where no specimens are either pending confirmatory testing or were confirmed positive. All materials for cases with positive, repeat, suspect, and inconclusive test results must be forwarded to NVSL by overnight shipping within 1 business day after testing is completed.
- m. Evidence of accreditation or certification by the American Association of Veterinary Laboratory Diagnosticians (AAVLD), the International Organization for Standardization (ISO), or a copy of the laboratory's quality assurance manual or other written documentation of a satisfactory quality control/assurance system.
- n. 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 of records, reviewing slides, observing tests being conducted, and interviewing personnel.
- o. (this and the remaining items are for genotyping approval) A description of the laboratory facilities and equipment that will be used in performing genotype tests.
- p. A list of the types of samples that will be tested.
- q. The standard operating procedure for each test to be used, including methods, materials, equipment, and other relevant information.
- r. A list of the names of individuals performing specific tests and a detailed statement of each individual's qualifications.
- s. A detailed description of the procedures used to satisfy the recordkeeping requirements of the National Scrapie Eradication Program. (**Note:** To satisfy these requirements, the approved laboratory must retain records of all tests performed and all DNA samples for 5 years.)

- t. A description of the specific procedures used for reporting test results. (**Note:** The results must be reported to the person submitting the sample, as well as to persons designated by NVSL, within 2 working days of completing the test.)
- u. The laboratory quality assurance manual.
- v. 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.

54.11(b) Agreement to Conduct the Official Histopathology Examination for the Diagnosis of Scrapie (VS Form 5-21) (State)

- After the State diagnostic laboratory director requests approval of the laboratory (as discussed above under Request for Laboratory Approval), 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. The laboratory director then signs VS Form 5-21. Once the laboratory has one or more of its pathologists trained at NVSL, then NVSL approves the laboratory as an official laboratory. (A university laboratory not affiliated with a State may also request approval.)

54.21 Application for the Scrapie Free Flock Certification Program (VS Form 5-22) (business)

- 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 on the internet.

54.21 Scrapie SFCP Flock Inspection Report - Initial Flock Inspection (VS Form 5-19A) and Recordkeeping (business) (State)

- APHIS or State 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.

54.21 Scrapie SFCP Flock Inspection Report – Annual Inspection Report (VS Form 5-19B) and Recordkeeping (business) (State)

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

79.2(a) Owner Statement (business)

- An owner statement may be used as an additional or alternative means of identifying regulated sheep and goats to their flock of origin. When these animals are moved across State lines, 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 of animals involved in the movement, the premises identification number assigned to the premises, and other identifying information.

79.3(a) Report for Consignments when Identification is Applied (business) - 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 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 non-compliance.

79.3(a) Agreement to use blue “slaughter only tags” (business) – No animal may be removed from slaughter channels in interstate commerce if it was sold at a slaughter-only auction, is identified with a tag or ear tattoo marking ‘meat’ or ‘slaughter only,’ or was sold with a bill of sale marked for slaughter only, and other animals may be removed from slaughter channels in interstate commerce only if they are identified to their flock of birth.

79.2(d) Recordkeeping, Animals Moved in Interstate Commerce (business) - 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 representative. These records include such information as the number of sheep and/or goats; the breed or cross if known; the name, street address, including city and State, or the township, county, and State, and the telephone number if the telephone number is available, of the owner of the flock of origin and, if different, the person from whom the sheep or goats were purchased or otherwise obtained or to whom they were sold or otherwise disposed; and a copy of any documents required to accompany the animal including any certificate, owner statement, letter, or permit; and in some cases, the identifying marks or tags on the animal. (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.

79.2(f) Request for Approval to Produce Official Identification Devices (business) - Tag manufacturers request by mail or e-mail 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).

79.2(f)(2)(ii)(A) Agreement to Send Official Eartags to Specified Individuals (business) - As part of the request for approval to produce official identification devices, tag manufacturers must provide a signed statement agreeing to send official eartags only to a State or APHIS representative, to a flock owner assigned a premises number or tag sequence by APHIS or a State representative, or as directed by APHIS.

79.2(f)(2)(ii)(B) Monthly Report of Official Identification (business) - Tag manufacturers are required to report by State all tags produced, including the tag sequences produced, the recipient’s name, and shipping address when requested by APHIS. Some voluntarily provide the report monthly since they have automated the report. APHIS is now able to pull similar reports from the APHIS database so

submission is generally not requested. Tag manufacturers working under contracts with APHIS also provide cost reports as required by the contract.

79.2(f)(2)(ii)(C) Data Entry of Official ID Devices Produced (business) - Tag manufacturers enter the sequences of tags shipped into the Animal Identification Management System (AIMS) database through a Web-based interface (see Appendix E-2).

79.2(g) Request for Approval of New Device Type (business) - An individual wishing to use or produce an identification device or marking not listed in 9 CFR 79.2(a)(2) must submit to APHIS a written request for approval of the device or marking. If APHIS determines that the device or marking will provide an adequate means of tracing sheep and goats in interstate commerce, APHIS will publish a proposed rule in the Federal Register to add the device or marking to the list.

79.4(C) Herd Owner Notification of Designation of Flocks or Animals (State) - 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.

79.5 Permit for Movement of Restricted Animals (VS Form 1-27) (business) (State) - 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.

79.5 Certificate of Veterinary Inspection (VS Form 17-140 or equivalent) and Recordkeeping (business) (State) - 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 (CVI). Since these animals are not designated exposed or infected, any accredited veterinarian can issue the CVI. The flock owner assists the accredited veterinarian in completing the CVI 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 CVI 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.

79.6 Consistent State Application – Application for Scrapie Classification, Classification Renewal, or Reclassification of a State (VS Form 5-24) (State) - 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.

79.2 Application for ID Numbers Including Blue Tags (business) and Recordkeeping (State/Tribe)

- Flock owners, dealers, accredited veterinarians, and market operators must apply to the appropriate State or Federal representative to be assigned USDA serial 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 or Federal representative can place their orders and create records. These applications are generally made by calling the State or Federal representative. If flock owners, dealers, accredited veterinarians, and market operators give this information to their State representatives, the State representatives would record the application data. This information must be maintained for at least 5 years, and could provide invaluable information to State or Federal personnel conducting a traceback investigation.

79.2(b) Application for Premises ID Numbers (business) and Recordkeeping (State/Tribe) -

APHIS employs an additional (but optional) identification system that allows sheep and goats moving in interstate commerce to be identified with an approved eartag, backtag, or tattoo bearing a premises identification number (also referred to as a flock identification number) assigned by a State 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 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 or Federal representative can create a record. If the flock owners give this information to the State representative, the State would record the information. 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.

79.2(b) - Recordkeeping, Identification (business) - Flock owners, market operators, dealers, slaughter plant owners, tag manufacturers, and accredited veterinarians using official identification devices or methods must record all serial numbers and other identification numbers affixed to the sheep and goats, as well as the location where the identification was applied and the name, address, and when available, telephone number of the animal's owner and the owner of the flock of origin if different. This information must be maintained for at least 5 years, and could provide invaluable information to State or Federal personnel conducting a trace investigation. APHIS does not prescribe a form for recording this information.

79.2 Decline to Participate or Provide Information (business) - 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 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 to remove one or more genetically susceptible exposed animals or suspect animals identified during the investigation; or (2) when under consideration for indemnity, and an 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. In some cases declinations are assumed due to nonresponse. Such declinations generally result in the State issuing movement restrictions to the flock owner and APHIS designating the flock as noncompliant, which restricts the movement of the animals in interstate commerce.

79.2 Determination of Age and Number of Animals (State) - If records and identification are inadequate to determine the actual age of animals, an APHIS or State representative will count 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 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.

79.2 Receipt for Disposal Expenses (business) - To obtain reimbursement for disposal costs, animal owners must obtain written approval of the disposal costs from APHIS before disposal. For reimbursement to be made, the owner of the animals must present the Assistant District Director 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.

54.2 Cooperative Agreements and Grants Workplan (State/Tribe) (not for profit) - 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*.

54.2 Cooperative Agreements and Grants Financial Plan (State/Tribe) (not for profit) - 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*.

54.2 Cooperative Agreement or Grant Quarterly Report (State/Tribe) (not for profit) - 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*.

54.2 Memorandums of Understanding Forms (State) - The memorandum of understanding (MOU) is a written commitment between APHIS and the animal health agency of a State to cooperatively administer the 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* (see Appendix A-4 for the MOU template).

Cooperative agreements and MOUs for the scrapie program are shown in Table 1 below.

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

State	Cooperator Name	Number
AK	AK Dept. of Environmental Conservation	11-9702-0069-MU
AL	AL Dept. of Ag. and Industries	15-9601-1003-MU
AR	Arkansas Livestock & Poultry	15-9705-2205-CA
AZ	Navajo Nation	10-9704-1983-CA
AZ	AZ Dept. of Ag.	12-9704-0078-MU
AZ	AZ Dept. of Ag.	15-9704-2207-CA
CA	CA Department of Food and Ag.	15-9706-2223-CA

CA	CA Department of Food and Ag.	12-9706-0088-MU
CO	American Sheep Industry	14-9100-1231-CA
CO	CO Dept. of Ag.	15-9708-2206-CA
CO	CO Dept. of Ag.	12-9708-0090-MU
CO	National Institute for Animal Ag.	14-9794-1316-CA
CT	CT Dept. of Ag.	12-9609-0873-MU
DE	DE Dept. of Ag.	13-9610-0807-MU
GA	GA Dept. of Ag.	12-9613-0228-MU
FL	FL Dept. of Ag & Consumer Svc.	12-9612-0316-MU
HI	HI Dept. of Ag.	15-9715-2224-CA
HI	HI State Dept. of Ag.	11-9715-0068-MU
IA	IA Dept. of Ag. and Land Stewardship	15-9719-2217-CA
IA	IA Dept. of Ag. and Land Stewardship	12-9719-0077-MU
ID	ID State Dept. of Ag.	15-9716-2210-CA
ID	ID State Dept. of Ag.	12-9716-0079-MU
IL	IL Dept. of Ag.	15-9717-1269-CA
IL	IL Dept. of Ag.	12-9617-0727-MU
IN	IN State Board of Animal Health	15-9718-1259-CA
IN	IN State Board of Animal Health	10 9618 0696-MU
IN	American Goat Federation	14-9100-1447-CA
KS	KS Animal Health Dept.	12-9720-0082-MU
KS	KS Dept. of Ag., Division of Animal Health	15-9720-2212-CA
KY	KY Dept. of Ag.	15-9721-1257-CA
KY	KY Dept. of Ag.	11-9621-0874-MU
LA	LA Dept. of Ag. & Forestry	15-9722-12544-CA
LA	LA Dept. of Ag & Forestry	13-9622-1249-MU
MA	MA Dept. of Ag. Resource	12-9625-0890-MU
MD	MD Dept. of Ag.	13-9624-0806-MU
ME	American Goat Federation	14-9100-1447-CA
ME	ME Dept. of Ag.,	12-9623-0894-MU

	Food and Rural Resources	
MI	MI Dept. of Ag.	15-9726-1278-CA
MI	MI Dept. of Ag.	12 9626 0779-MU
MN	MN Board of Animal Health	15-9727-1253-CA
MN	MN Board of Animal Health	12 9627 0796-MU
MO	MO Dept. of Ag.	14-9729-2226-CA
MO	MO Dept. of Ag.	15-9729-0064-MU
MS	MS Board of Animal Health	15-9728-1256-CA
MS	MS Board of Animal	12 9628 0795 MU
MT	MT Dept. of Livestock	12-9730-0085-MU
MT	MT Dept. of Livestock	15-9730-2208-CA
NC	NC Dept. of Ag. and Consumer Service	12 9637 0750 MU
ND	ND State Board of Animal Health	10-9738-0065-MU
NE	NE Dept. of Ag.	15/9731-2218-CA
NE	NE Dept. of Ag.	12-9731-0080-MU
NH	NH Dept. of Ag., Markets and Food	12 9633 0764-MU
NJ	NJ Dept. of Ag.	12 9634 0026-MU
NM	NM Livestock Board	15-9735-2227-CA
NM	NM Livestock Board	12-9735-0081-MU
NV	NV Dept. of Ag.	15-9732-1541-CA
NV	NV Dept. of Ag.	11-9732-0066-MU
NY	NY State Dept of Ag.	10 9636 1018-MU
OH	OH Dept. of Ag.	15-9739-1285-CA
OH	OH Dept. of Ag.	12 9639 0028 MU
OK	OK Dept. of Ag. Food & Forestry	15-9740-2219-CA
OK	OK Dept. of Ag. Food & Forestry	11-9740-0071-MU
OR	OR Dept. of Ag.	11-9741-0074-MU
RI	RI Dept. of Environmental Management Division of Ag.	13 9644 0828-MU
SC	Clemson University	10 9645 0883-MU
SD	SD Animal Industry Board	11-9746-0075-MU

TN	TN Dept. of Ag.	12 9647 0766-MU
TX	TX Animal Health Commission	15-9748-2225-CA
TX	TX Animal Health Commission	12-9748-0086-MU
UT	UT Dept. of Ag. & Food	11-9749-0072-MU
VA	VA Dept. of Ag. and Consumer Service	10 9651 078- MU
VT	VT Agency of Ag., Food and Market	13 9650 0776-MU
WA	WA State Dept. of Ag.	11-9753-0070-MU
WI	WI Dept. of Ag., Trade and Consumer Protection	15-9755-1263-CA
WI	WI Dept. of Ag., Trade and Consumer	12 9655 0763-MU
WY	WY Livestock Board	15-9756-2204-CA

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

54.2 Designated Scrapie Epidemiologist Training (State) - Designated Scrapie Epidemiologists (DSEs) are State or Federal veterinarians designated by 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 session, certified by the Sheep and Goat health team (for example, District sheep and goat health training session), also fulfills the training requirement.

DSEs must also obtain practical experience by shadowing another DSE 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% of the Sheep and Goat Health Webinars held during the 3 year period since the initial certification/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.

54.2 Epidemiology and Identification Compliance Report (State) - This report is used to track compliance with the requirements for Consistent States. 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.

As mentioned in the Note at the beginning of this Supporting Statement, the five SF forms included in this information collection are common forms, and the burden will be accounted for with Request for Comment Forms. The burden for the common forms is not accounted for in this information collection. The last page of the APHIS 71 reflects the common forms used in this collection; however, none of the burden figures for the SF forms was added into this information collection.

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:

The request for information (VS Forms 5-18, 5-18A, 5-19, 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, they are not candidates for electronic submission.

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 is 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 Proceeds from Animals Sold for Slaughter, VS Form 1-24, requires an original signature of the buyer or seller to document salvage value of animals destroyed by slaughter, which is required for the calculation of indemnity. Therefore, this form 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 authorities. This information can also be e-mailed or faxed.

The Scrapie PEMMP Inspection Report (VS Form 5-19C) requires an original signature by the flock owner and is, therefore, not 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 VSLS, 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 Form 5-29 and 5-29A or worksheets containing the same information (Appendix B-1) 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 personnel who do not have e-Authentication 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 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 personnel with e-Authentication 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 a signature-only agreement.

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, therefore, not 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, therefore, not a candidate for electronic submission.

The owner statement is a hard copy document that identifies the flock of origin of sheep or goats in a shipment. The document must accompany the shipment across State lines and therefore is not a candidate for electronic submission.

The agreement to use blue tags 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 e-mail, fax or regular mail. Submitting this information electronically is 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 eartags to specified individuals is not a candidate for electronic submission because it requires original signatures to be valid.

The Monthly Report of Official Identification Devices Produced is currently submitted by CD, e-mail, or hard copy. APHIS is revising 9 CFR to remove this requirement since the information can now be obtained from an APHIS database.

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

The Herd Owner Notification (provided by State 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 hard copy document requiring an original signature by the veterinary medical officer providing the notification. While this notification is frequently less formal (via fax, telephone, or e-mail), a signed hard copy is also sent to document that the flock owner received the notification.

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 since it requires original signatures.

The workplan, the financial plan, and quarterly reports associated with cooperative agreements are also not candidates for electronic submission. They are submitted with other forms that require original signature.

Paperwork for Designated Scrapie Epidemiologist Training must be completed at the time of training and so is not under consideration for electronic submission.

Overview of the Scrapie program databases:

Surveillance Collaborative Services (SCS) - APHIS or State 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 (SFCP or disease) are entered into the SCS. Data is also transferred to SCS from VS Laboratory Submissions (VLS) 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 (VLS) - VLS is a Web-based interface for submission of various specimens for testing by APHIS and contract laboratories. Three VLS 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 cooperators, contract laboratories, and contract sample submitters have access to one or more VLS modules. Specific forms from which information is collected and entered into the VLS 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 eartags. This database is used by APHIS and State 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 and Federal personnel.

The identification requirement allows the use of several devices including electronic eartags. 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 an APHIS website and stored in an APHIS database.

The CVI (VS Form 17-140), 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 CVI.

The application for identification numbers and application for premises identification can be made to APHIS via a telephone call, e-mail, mail, or fax. These requests are then processed through an APHIS website and stored in an APHIS database.

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.

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.

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 95 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.

- **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 engaged in productive consultations with the following individuals concerning the information collection activities with this program:

Joan Dean Rowe, DVM
American Association of Small Ruminant Practitioners
P.O. Box 3614
Montgomery, AL 36109
515-306-1129

Mr. Paul Rodgers
American Sheep Industry Association
Route 2, Box 94
Ronceverte, WV 24970
304-647-9981

Leo Tammi
American Polypay Sheep Association
Route 1, Box 274-A
Mt. Sidney, VA 24467
540-234-8526

On Friday, April 29, 2016, pages 25640-26541, APHIS published a proposed rule (APHIS-2016-0019) in the Federal Register. The rule states APHIS' plans to request a 3-year renewal of this information collection, described its proposed information gathering requirements, and also provided a 60-day comment period. During that time, APHIS received one comment from a member of the public which did not involve paperwork burden.

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.

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 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 \$37,234,695.60. APHIS arrived at this figure by multiplying the hours of estimated response time (1,021,528 hours) by the estimated average hourly wage of the above respondents (\$36.45).

Flock owners: \$22.86 [11-9012 Farmers and Ranchers]

Market owners, operators, or managers: \$34.89 [11-9011 Farm, Ranch, and Other Agricultural Managers]

Dealers: \$29.02 [13-1021 Purchasing Agents and Buyers, Farm Products]

Slaughter plant owners, operators, or managers: \$34.89 [11-9011 Farm, Ranch, and Other Agricultural Managers]

Feedlot owners, operators, or managers: \$34.89 [11-9011 Farm, Ranch, and Other Agricultural Managers]

Managers of producer organizations: \$52.99 [11-0000 Management Occupations – Managers, All Others]

Tag manufacturers: \$18.33 [51-0000 Production Occupations (Metal Workers and Plastic Workers)]

Accredited veterinarians: \$47.23 [29-1131 Veterinarians]

State animal health authorities: \$52.99 [11-0000 Management Occupations – Managers, All Others]

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>.

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 \$3,250,315.33. (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.

This reinstatement is a program change of 57,000 respondents; 854,721 annual responses; and 1,021,528 burden hours.

New burden in this collection that was inadvertently omitted in the previous collection is as follows: (1) Request for Laboratory Approval (Business); (2) Agreement to Use Blue “Slaughter Only Tags” (Business); (3) Certificate of Vet Inspection – United States Origin Health Certificate and Recordkeeping (State); (4) Application for Premises ID Numbers and Recordkeeping (State/Tribe); (5) Declination to Participate or Provide Information (Business); (6) Determination of Age/Number of Animals (State); (7) Receipt of Disposal Expenses (Business); (8) Cooperative Agreement or Grant Quarterly Report and Recordkeeping (State/Tribe); (9) Cooperative Agreement or Grant Quarterly Report and Recordkeeping (Not for profit); (10) Designated Scrapie Epidemiologist Training (State); and (11) Epidemiology and Identification Compliance Report (State).

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, 1-27, 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.