

§ 54.9

eruption of the second incisor) in slaughter channels; and

(4) Recordkeeping including:

(i) For acquired animals, the date of acquisition, name and address of the person from whom the animal was acquired, any identifying marks or tags present on the animal including 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, tail fold tattoo, and any secondary form of identification the owner of the flock may choose to maintain.

(ii) For animals leaving the premises of the flock, the disposition of the animal, including, for those animals that are required to be identified, any identifying marks or tags present on the animal, including 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.

(iii) Maintenance of these records for 5 years.

(5) Requirements equivalent to those contained in paragraphs (b), (c), (d), and (e) of this section.

(i) *Post-exposure management and monitoring plans for exposed flocks that were not source flocks and in which a scrapie infected animal did not lamb.* A designated scrapie epidemiologist shall determine the testing and monitoring requirements for these flocks based on the exposure risk of the individual flock.

§ 54.9 Waiver of requirements for scrapie control pilot projects.

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

(a) The determination that an animal is a high-risk animal, if the scrapie control pilot project plan contains

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testing or other procedures that indicate that an animal, despite meeting the definition of high-risk animal, is unlikely to spread scrapie; and

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

§ 54.10 Tests for scrapie.

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

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

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

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

(4) Data to support the sensitivity and specificity of the test; and

(5) Any other data requested by the Administrator to determine the suitability of the test for program use.

(b) To be approved, a scrapie test must be able to be replicated at the National Veterinary Services Laboratories, or another reliable, timely, and cost effective method of check testing must be available to APHIS.

(c) A test or combination of tests may be approved for the identification of suspect animals, for the identification of scrapie-positive animals, or for other purposes such as flock certification. For a test to be approved for the identification of scrapie-positive animals, the test must have a specificity comparable to the specificity of the currently approved tests. For a test to be approved as a live animal screening test for the identification of suspect animals, the test must be usually

reliable but need not be definitive for diagnosing scrapie.

(d) Specific guidelines for use of approved scrapie tests within the Scrapie Eradication Program or Scrapie Flock Certification Program will be added to this part as tests are approved and will also be contained in the Scrapie Eradication UM&R and the Scrapie Flock Certification Program standards based on the characteristics of the test, including specificity, sensitivity, and predictive value.

(e) If an owner elects to have an unofficial test conducted on an animal for scrapie, or for the proteinase resistant protein associated with scrapie, and that animal tests positive to such a test, the animal will be designated a suspect animal, unless:

(1) The test was run as part of a bona fide research protocol designed to evaluate an unapproved test in which the owner is not informed of the test result; or

(2) The test protocol includes appropriate measures to prevent the spread of scrapie.

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

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

(1) Employs personnel assigned to supervise the testing who are qualified to conduct the test based on education, training, and experience and who have been trained by the National Veterinary Services Laboratories (NVSL) or who have completed equivalent training approved by NVSL;

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

(3) Follows standard test protocols;

(4) Meets check test proficiency requirements;

(5) Meets recordkeeping requirements;

(6) Will retain records, slides, blocks, and other specimens from all cases for at least 1 year and from positive cases for 5 years;

(7) Will allow APHIS to inspect the laboratory without notice during normal business hours; and

(8) Will report all test results to State and Federal animal health officials within agreed timeframes. An inspection may include, but is not limited to, review and copying of records, examination of slides, observation of the test being conducted, and interviewing of personnel.

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

(c) The Administrator may withdraw approval of any laboratory for failure to meet any of the conditions required by paragraph (a) of this section. The Administrator shall give written notice of the proposed withdrawal to the director of the laboratory and shall give the director an opportunity to respond. If there are conflicts as to any material fact concerning the reason for withdrawal, a hearing will be held to resolve the conflicts.

Subpart B—Scrapie Flock Certification Program

§ 54.20 Administration.

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

§ 54.21 Participation.

Any owner of a sheep or goat flock may apply to enter the Scrapie Flock Certification Program by sending a written request to a State scrapie certification board or to the area veterinarian in charge. A notice containing a current list of flocks participating in