

§ 54.8 Requirements for flock plans and post-exposure management and monitoring plans.

(a) The owner of the flock or his or her agent must identify all animals 1 year of age or over within the flock. All animals less than 1 year of age must be identified when a change of ownership occurs, with the exception of those animals under 1 year of age moving within slaughter channels that must be identified in accordance with §§ 79.2 and 79.3 of this chapter. The form of identification must be an electronic implant, flank tattoo, ear tattoo, or tamper-resistant ear tag approved for this use by APHIS. In the case of goats, the form of identification may alternatively be a tail fold tattoo. The official identification must provide a unique identification number that is applied by the owner of the flock or his or her agent and must be linked to that flock in the National Scrapie Database.

(b) Upon request by a State or APHIS representative, the owner of the flock or his or her agent must have an accredited veterinarian collect tissues from animals for scrapie diagnostic purposes and submit them to a laboratory designated by a State or APHIS representative.

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

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

(e) The owner of the flock or his or her agent must immediately report the following animals to a State represent-

ative, APHIS representative, or an accredited veterinarian, and not remove them from a flock without written permission of a State or APHIS representative:

(1) Any sheep or goat exhibiting weight loss despite retention of appetite; behavioral abnormalities; pruritus (itching); wool pulling; biting at legs or side; lip smacking; motor abnormalities such as incoordination, high stepping gait of forelimbs, bunny hop movement of rear legs, swaying of back end; increased sensitivity to noise and sudden movement; tremor, “star gazing,” head pressing, recumbency, or other signs of neurological disease or chronic wasting illness; and

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

(f) *Requirements for flock plans only.*

(1) An epidemiologic investigation must be conducted to identify high-risk and exposed animals that currently reside in the flock or that previously resided in the flock, and all high-risk animals, scrapie-positive animals, and suspect animals must be removed from the flock. The animals must be removed either by movement to an approved research facility or by euthanization and disposal of the carcasses by burial, incineration, or other methods in accordance with local, State, and Federal laws, or, in the case of high-risk animals, by movement to slaughter in accordance with the provisions of part 79 of this chapter, or upon request in individual cases by another means determined by the Administrator to be sufficient to prevent the spread of scrapie;

(2) The premises of a flock under a flock plan must be cleaned and disinfected in accordance with § 54.7(e). Additional guidance on acceptable means of cleaning and disinfection is also available in the Scrapie Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules. Premises or portions of premises may be exempted from the cleaning and disinfecting requirements if a designated scrapie epidemiologist

determines, based on epidemiologic investigation, that cleaning and disinfection of such buildings, holding facilities, conveyances, or other materials on the premises will not significantly reduce the risk of the spread of scrapie, either because effective disinfection is not possible or because the normal operations on the premises prevent transmission of scrapie. No area where a scrapie-positive animal lambed or aborted may be exempted;

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

(4) The flock owner must agree to conduct post-exposure management and monitoring.

(g) *Requirements for post-exposure management and monitoring plans only:* The plan must require that a State or APHIS representative inspect the flock and flock records at least once every 12 months. The owner of the flock or his or her agent must maintain, and keep for a minimum of 5 years after an animal dies or is otherwise removed from a flock, the following records for each animal in the flock:

(1) 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;

(2) Sex, year of birth, breed, and when possible to determine, the following: sire, dam, and offspring of the animal;

(3) Date of acquisition and previous flock, if the animal was not born in the flock; and

(4) Disposition of the animal, including 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.

(h) *Modification of flock plans and post-exposure management and monitoring plans.*

A designated scrapie epidemiologist may modify the requirements of a flock plan or post-exposure management and monitoring plan to accommodate the situation of a particular flock if the modified plan requires:

(1) That a State or APHIS representative inspect the flock and flock records at least once every 12 months;

(2) The testing of animals at a level that will result in 99 percent confidence of detecting a 1 percent prevalence in the flock (for flock plans only);

(3) The official identification of all animals upon leaving the premises of the flock for purposes other than slaughter and of all animals over 18 months of age (as evidenced by the 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 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: