

(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: