

cervids unless the cervids have been appraised as prescribed in this part and the owners have signed the appraisal form indicating agreement with the appraisal amount as required by § 55.3(c) of this part.

(b) The Department will not allow claims arising out of the destruction of cervids unless the owners have signed a written agreement with APHIS in which they agree that if they maintain cervids in the future on the premises used for cervids for which indemnity is paid, they will maintain the cervids in accordance with a herd plan and will not introduce cervids onto the premises until after the date specified in that herd plan. Persons who violate this written agreement may be subject to civil and criminal penalties.

(c) The Department will not allow claims arising out of the destruction of cervids that have been moved or handled by the owner or a representative of the owner in violation of a law or regulation administered by the Secretary regarding animal disease, or in violation of a law or regulation for which the Secretary has entered into a cooperative agreement.

(Approved by the Office of Management and Budget under control number 0579-0189)

§ 55.8 Official CWD tests and approval of laboratories to conduct official CWD tests.

(a) An official CWD test is:

(1) Histopathological examination of central nervous system (CNS) tissues from the animal for characteristic microscopic lesions of CWD, using test protocols provided by the National Veterinary Services Laboratories (NVSL);

(2) The use of proteinase-resistant protein analysis methods including but not limited to immunohistochemistry and/or western blotting on CNS and/or peripheral tissue samples from a live or a dead animal, using test protocols provided by NVSL; or

(3) Any other test method approved by the Administrator in accordance with this section.

(b) The Administrator may approve new tests for the diagnosis of CWD conducted on live or dead animals, and 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.

(c) Specific protocols for official CWD tests are available upon request to NVSL.

(d) State, Federal, and university laboratories will be approved by the Administrator to conduct official CWD tests 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 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 inspect¹ 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.

¹An 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.

§ 55.8

(e) The Administrator may withdraw approval of any laboratory for failure to meet any of the conditions required by paragraph (d) 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 with-

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drawal, a hearing will be held to resolve the conflicts. The hearing will be conducted in accordance with rules of practice that will be adopted by the Administrator for the proceeding.

Subpart B [Reserved]

PART 56 [RESERVED]