§ 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 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 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.

(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 withdrawal, a hearing will be held to resolve the conflicts. The hearing will be conducted in accordance with rules of

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1 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.
practice that will be adopted by the Administrator for the proceeding.

Subpart B—Chronic Wasting Disease Herd Certification Program

SOURCE: 77 FR 35566, June 13, 2012, unless otherwise noted.

§ 55.21 Administration.

The CWD Herd Certification Program is a cooperative effort between APHIS, State animal health and wildlife agencies, and deer, elk, and moose owners. APHIS coordinates with these State agencies to encourage deer, elk, and moose owners to certify their herds as low risk for CWD by being in continuous compliance with the CWD Herd Certification Program standards.

§ 55.22 Participation and enrollment.

(a) Participation by States. Any State that operates a State program to certify the CWD status of deer, elk, or moose may request the Administrator to designate the State program as an Approved State CWD Herd Certification Program. The Administrator will approve or disapprove a State program in accordance with §55.23(a). In States with an Approved State CWD Herd Certification Program, program activities will be conducted in accordance with the guidelines of that program as long as the State program meets the minimum requirements of this part. A list of Approved State CWD Herd Certification Programs may be obtained by writing to the National Center for Animal Health Program, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737–1235.

(b) Participation by owners. Any owner of a farmed or captive deer, elk, or moose herd may apply to enroll in an Approved State CWD Herd Certification Program by sending a written request to the appropriate State agency. Subject to the availability of appropriated funds for a Federal CWD Herd Certification Program, the owner may apply to the APHIS veterinarian in charge if no Approved State CWD Herd Certification Program exists in the herd's State. APHIS or the State will determine the herd’s eligibility, and if needed will require the owner to submit more details about the herd animals and operations. An application for participation may be denied if APHIS or the State determines that the applicant has previously violated State or Federal laws or regulations for livestock, and that the nature of the violation indicates that the applicant may not faithfully comply with the requirements of the CWD Herd Certification Program. If the enrolling herd is a CWD-positive herd or CWD-exposed herd, immediately after enrollment it must begin complying with a herd plan developed in accordance with §55.24. After determining that the herd is eligible to participate in accordance with this paragraph, APHIS or the appropriate State agency will send the herd owner a notice of enrollment that includes the herd’s enrollment date. Inquiries regarding which herds are participating in the CWD Herd Certification Program and their certification should be directed to the State representative of the relevant State.

(1) Enrollment date. With the exceptions listed in this paragraph, the enrollment date for any herd that joins the CWD Herd Certification Program after August 13, 2012 will be the date the herd is approved for participation.

(i) For herds already participating in State CWD programs, the enrollment date will be the first day that the herd participated in a State program that APHIS subsequently determines qualifies as an Approved State CWD Herd Certification Program in accordance with §55.23(a) of this part.

(ii) For herds that enroll directly in the Federal CWD Herd Certification Program, which is allowed only when there is no Approved State CWD Herd Certification Program in their State and which is subject to the availability of appropriated funds, the enrollment date will be the earlier of:

(A) The date APHIS approves enrollment; or

(B) If APHIS determines that the herd owner has maintained the herd in a manner that substantially meets the conditions specified in §55.23(b) for herd owners, the first day that the herd participated in such a program. However, in such cases the enrollment date may not be set at a date more than 3