Chronic Wasting Disease

Program Standards

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United States Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services

Chronic Wasting Disease (CWD)
Program Standards

May 2014

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Introduction

The goal of the CWD Program is to assist States, Tribes, and the cervid industry to minimize the risk of introduction, transmission, and spread of CWD in captive cervid populations in the United States. This is accomplished through the establishment of the national CWD herd certification program (HCP) and interstate movement requirements found in title 9 of the *Code of Federal Regulations* (CFR) parts 55 and 81.

The Program Standards are optional guidelines that provide detailed descriptions of suggested methods for complying with the legal requirements in the CWD regulations (9 CFR parts 55 and 81). These methods have been approved by the Administrator of the Animal and Plant Health Inspection Service (APHIS) to meet those requirements. Following the methods described in the Program Standards will facilitate achievement of herd certification status for participants in this voluntary national CWD program.

These Program Standards will be reviewed at least annually by representatives of the cervid industry and appropriate State and Federal agencies. A notice will be published in the *Federal Register* to inform stakeholders of any revisions APHIS plans to the Program Standards. These Program Standards also may be amended in the future by replacing pages or by adding new pages with input from all stakeholders.

Part A. Herd Certification Program. These Program Standards are optional guidelines to meet minimum requirements of the CWD rule adopted and approved by the Deputy Administrator, Veterinary Services (VS), APHIS, United States Department of Agriculture (USDA). They were established for three primary purposes:

1. To assist Federal and State agencies in maintaining CWD-certified herds of deer, elk, and moose (all *Odocoileus* spp. and *Cervus* spp. and their hybrids and *Alces alces*).

2. To provide guidance on procedures to certify herds as a low risk for CWD by remaining in continuous compliance with the CWD Herd Certification Program (HCP) requirements found in 9 CFR 55.

3. To provide guidance on complying with the minimum requirements for interstate movement of cervids found in 9 CFR 81.

Enrollment and participation by cervid herd owners in the national CWD Herd Certification Program may only occur in States that permit cervid farming.

Approved States may have additional or stricter requirements that exceed the national program minimum requirements.

Part B. Guidance on Response to CWD-Affected Herds. The CWD regulations in 9 CFR 55 describe minimum requirements in response to the finding of a CWD-affected herd in accordance with the national CWD HCP. This section further provides optional guidelines on best management practices that may be used by a State and herd owner to investigate and manage CWD-affected herds, including quarantine, depopulation, cleaning and decontamination, and herd plans.

Definitions

Accredited Veterinarian. A veterinarian approved by the Administrator in accordance with Part 161 of this chapter to perform functions specified in subchapters B, C, and D of this chapter.

Administrator. The Administrator of the Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal. Any farmed or captive deer, elk, or moose.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

APHIS Employee. Any individual employed by the Animal and Plant Health Inspection Service who is authorized by the Administrator to do any work or perform any duty in connection with the control and eradication of disease.

Approved State. A State that the Administrator has determined has an Approved State CWD Herd Certification Program.

Approved State CWD Herd Certification Program. A program operated by a State government for certification of cervid herds with respect to CWD that the Administrator has determined to meet the requirements of 9 CFR Part 55.

Approved Laboratory. A diagnostic laboratory approved by the Administrator to conduct official tests for CWD in accordance with 9 CFR 55.8

Assistant District Director (ADD). The APHIS veterinary official assigned by the Administrator to supervise and perform the official APHIS animal health work in the APHIS District and corresponding State(s) concerned.

Certified Herd. A Certified herd is regarded as low risk for CWD because it has attained Certified status as defined in 9 CFR 55.24.

Certified CWD Sample Collector. An individual who has completed appropriate training recognized by his or her State on the collection and preservation of samples for CWD testing and on proper recordkeeping, and who has been certified to perform these activities by his or her State regulatory authority for farmed and captive cervids.

Cervid. All members of the family Cervidae and hybrids, including deer, elk, moose, caribou, reindeer, and related species. For the purposes of this part [rule], the term "cervid" refers specifically to cervids susceptible to CWD. These are animals in the genera *Odocoileus, Cervus*, and *Alces* and their hybrids, i.e. deer, elk, and moose.

Chronic Wasting Disease, (CWD). A transmissible spongiform encephalopathy of cervids.

Commingled, Commingling. Animals are commingled if they have direct contact with each other, have less than 10 feet of physical separation, or share equipment, pasture, or water sources/watershed. Animals are considered to have commingled if they have had such contact with a positive animal or contaminated premises within the last 5 years.

CWD National Database. For the purposes of the CWD rule and the Approved State CWD HCP, a CWD HCP database administered by APHIS or a State database approved by the Administrator as compatible with a "CWD National Database" for the Approved State CWD HCP program.

CWD-Exposed Animal. An animal that is part of a CWD-positive herd, or that has been exposed to a CWD-positive animal or contaminated premises within the previous 5 years.

CWD-Exposed Herd. A herd in which a CWD-positive animal has resided within 5 years before that animal's diagnosis as CWD-positive, as determined by an APHIS employee or State official.

CWD Herd Certification Program. The Chronic Wasting Disease Herd Certification Program established in 9 CFR part 55. This program includes both herds that are directly enrolled in the CWD Herd Certification Program and herds that are included based on their participation in Approved State CWD Herd Certification Programs.

CWD-Positive Animal. An animal that has had a diagnosis of CWD established through official confirmatory CWD testing conducted by the National Veterinary Services Laboratories (NVSL).

CWD-Positive Herd. A herd in which a CWD-positive animal resided at the time it was diagnosed and which has not been released from quarantine.

CWD Source Herd. A herd identified through testing, tracebacks, or epidemiological evaluations to be the source of CWD-positive animals identified in other herds.

CWD-Suspect Animal. An animal for which a State official or APHIS employee has determined that preliminary laboratory tests from an approved laboratory or clinical signs suggest a diagnosis of CWD, but for which official confirmatory laboratory results have been inconclusive, or not yet conducted.

CWD-Suspect Herd. A herd for which preliminary laboratory tests from an approved laboratory, or clinical signs, suggest a diagnosis of CWD, as determined by a State official or APHIS employee, but for which official confirmatory laboratory results have been inconclusive or not yet conducted.

Deer, Elk, and Moose. All animals in the genera *Odocoileus, Cervus*, and *Alces*, and hybrids of these species. This includes white-tailed deer (*Odocoileus virginianus*), mule deer (*Odocoileus hemionus*) and black-tailed deer (*Odocoileus hemionus columbianus*) and any associated subspecies. Also includes North American elk or wapiti (*Cervus canadensis*), red deer (*Cervus elaphus*), and Sika deer (*Cervus nippon*).

Deputy Administrator. The VS Deputy Administrator or any other official to whom the Administrator has delegated authority to act as the Deputy Administrator.

Designated Epidemiologist. A State official or Federal veterinarian with epidemiology training or experience who assists in decision-making about the use and interpretation of diagnostic tests, analysis of field investigation data, and the management of CWD-affected herds.

Enrollment Date. With the exceptions listed in 9 CFR 55.22(a)(1), the enrollment date for any herd that joins the CWD Herd Certification Program after the effective date of this rule will be the date the herd is approved for participation.

Farmed or Captive. Privately or publicly maintained or held for economic or other purposes within a perimeter fence or confined area, or temporarily captured from a wild population for interstate movement and release.

Herd. One or more animals that are:
(1) Under common ownership or supervision and are grouped on one or more parts of any single premises (lot, farm, or ranch) or
(2) All animals under common ownership or supervision on two or more premises which are geographically separated but on which animals have been interchanged or had direct or indirect contact with one another.

Herd Inventory. A herd owner's written record of all of the animals belonging to a herd that includes species, date of birth, age, sex of each animal, the date of acquisition and source of each animal that was not born into the herd, the date of disposal and destination of any animal removed from the herd, and all individual identification numbers (from tags, tattoos, electronic implants, etc.) associated with each animal. Herd inventory can also refer to the process of reconciling a herd owner's written record with the animals physically present in the herd.

Herd Plan. A written herd and/or premises management agreement developed by APHIS in collaboration with the herd owner, State representatives, and other affected parties. The herd plan will not be valid until it has been reviewed and signed by the Adminstrator, the State representative and the herd owner. A herd plan sets out the steps to be taken to control spread of CWD from a CWD-positive herd, to control the risk of CWD in a CWD-exposed or CWD-suspect herd, or to prevent introduction of CWD into that herd or any other herd. A herd plan will require specified means of identification for each animal in the herd; regular examination of animals in the herd by a veterinarian for clinical signs of disease; reporting to a State or APHIS representative of any clinical signs of a central nervous system disease or chronic wasting condition in the herd; maintaining records of the acquisition and disposition of all animals entering or leaving the herd, including the date of acquisition or removal, name and address of the person from whom the animal was acquired or to whom it was disposed; and the cause of death, if the animal died while in the herd.

A herd plan may also contain additional requirements to prevent or control the possible spread of CWD, depending on the particular circumstances of the herd and its premises, including but not limited to depopulation of the herd, specifying the time for which a premises must not contain cervids after CWD-positive, -exposed, or -suspect animals are removed from the premises; fencing requirements; selective culling of animals; restrictions on sharing and movement of possibly contaminated livestock equipment; premises cleaning and disinfection requirements; or other requirements. A herd plan may be reviewed and changes to it suggested at any time by any party signatory to it, in response to changes in the situation of the herd or premises or improvements in understanding of the nature of CWD epidemiology or techniques to prevent its spread. The revised herd plan will become effective after it is reviewed by the Administrator and signed by the Administrator, the State representative, and the herd owner.

Herd Status. The status of a herd assigned under the CWD Herd Certification Program in accordance with 9 CFR 55.24, indicating a herd's relative risk for CWD. Herd status is based on the number of years of monitoring without evidence of the disease and any specific determinations that the herd has contained or has been exposed to a CWD-positive, -exposed, or -suspect animal.

Hold Order. A temporary order issued by a State prohibiting movement of animals from or into a premises for a given period of time.

Hunt Facility. A privately owned ranch or other premises selling commercial hunts. These facilities should have fenced enclosures maintained to prevent ingress and egress of cervids. They may participate in an Approved State CWD HCP if they can comply with all minimum requirements for Approved State CWD HCPs as set forth in the Federal regulations.

Initial Reactor ELISA. The result of a CWD ELISA test conducted at an approved laboratory in which the optical density (OD) of the Bio-Rad ELISA test is above the prescribed cutoff OD value.

Limited Contact. Any brief contact with a farmed animal such as occurs in sale or show rings and alleyways at fairs, livestock auctions, sales, shows, and exhibitions. Limited contact does not include penned animals having less than 10 feet of physical separation or contact through a fence; or any activity where uninhibited contact occurs such as sharing an enclosure, a section of a transport vehicle, sharing equipment, food, or water sources; or contact with bodily fluids or excrement. Pens at fairs, livestock auctions, sales, shows, and exhibitions should be thoroughly cleaned and all organic material removed after use and before holding another animal.

Location-Based Numbering System. The location-based number system combines a State- or Tribal-issued location identification (LID) number or a premises identification number (PIN) with a producer's unique livestock production numbering system to provide a nationally unique and herd unique identification number for an animal.

National Veterinary Services Laboratories (NVSL). The USDA APHIS National Veterinary Services Laboratories.

Official Animal Identification. A device or means of animal identification approved by APHIS for use in the CWD Herd Certification Program to uniquely identify individual animals. For the purposes of the CWD regulations, and in accordance with the Animal Disease Traceability regulations (9 CFR 86.1, *et seq.*), the official identification number must be a nationally unique number that is permanently associated with an animal and that adheres to one of the following numbering systems:
(1) National Uniform Eartagging System (NUES).
(2) Animal Identification Number (AIN).
(3) Location-based number system.
(4) Any other numbering system approved by the Administrator for the identification of animals in commerce.

Official CWD Test. Any test for the diagnosis of CWD approved by the Administrator and conducted in a laboratory approved by the Administrator in accordance with 9 CFR 55.8.

Owner. An individual, partnership, company, corporation, or other legal entity that has legal or rightful title to an animal or herd of animals.

Premises. The ground, area, buildings, water sources, and equipment commonly shared by a herd of animals.

Premises Identification Number. A unique number consistent with official animal identification as set forth in USDA's Animal Disease Traceability framework, used to identify the premises on which a herd resides. This number is recorded in the CWD national database.

Quarantine. An order issued by a State restricting movement of animals from or into a premises for a given period of time.

Research Animal. An animal held captive for research purposes.

SCS – Core One. Surveillance Collaboration Services – Core One is a module of the VS Comprehensive and Integrated Animal Health Surveillance System. SCS –Core One supports routine animal health surveillance and program management under the purview of the VS National Center for Animal Health Programs (VS NCAHP) and the National Surveillance Unit (NSU).

State. Each of the 50 States, the District of Columbia, Puerto Rico, and all territories or possessions of the United States.

State Official. An individual employed in livestock animal health or wildlife activities by a State or a political subdivision of a State who is authorized by the State or political subdivision to perform the activities involved.

State Veterinarian. The veterinary official of a State authorized by the State to supervise and perform the official animal health work of the State concerned.

Status Date. The day, month, and year on which the respective State or APHIS employee approves a change in the status of a herd in regard to CWD.

Suspect Positive ELISA. The result of a CWD ELISA when either of the duplicate wells from repeat testing at an approved laboratory of the initial reactor ELISA homogenate by the Bio-Rad ELISA is above the prescribed cutoff OD values. These results must be confirmed by NVSL.

Suspect Positive IHC Test. The result of an approved CWD IHC test conducted at an approved laboratory in which the presumptive identification of abnormal protease resistant prion protein (PrPres) has been detected in the tissue samples and that result must be confirmed positive by NVSL.

Traceback Herd. A herd in which a CWD-positive animal formerly resided.

Trace-Forward Herd. A herd that has received exposed animals from a CWD-positive herd within 5 years before the diagnosis of CWD in the positive herd or from the identified point of entry of CWD into the positive herd.

Veterinary Services (VS). The APHIS unit authorized to conduct prevention, control, and eradication programs for diseases of livestock and poultry.

Part A. Herd Certification Program

(1) Administrative Procedures

The CWD Herd Certification Program (HCP) is a cooperative effort between APHIS, State animal health or wildlife agencies, and farmed/captive deer, elk, or moose owners. Under the program, APHIS reviews State CWD HCPs and approves the programs if they meet Federal standards, monitors them to ensure consistency with Federal standards, and administers the national CWD HCP, subject to the availability of appropriated funds, in States that do not have an approved State CWD HCP. APHIS will execute a Memorandum of Understanding (MOU) with States having an approved CWD HCP.

Supervision

Routine supervision is provided by full-time State officials or APHIS employees.

Entering Premises

In accordance with the MOU, persons working in the program must be authorized by the State to enter premises to carry out program activities. While on those premises, they must use standard sanitary procedures to minimize the risk of disease transmission to other premises.

Providing Services

Owners may need to engage accredited veterinarians or other appropriate animal health professionals to perform program activities at the owner's expense. Owners are responsible for assembling, handling, and restraining their animals. If resources are available, program services may be rendered by State and Federal agencies without expense to the herd owner.

Reporting Activities

All CWD activities shall be reported as directed in 9 CFR part 55 and further described in the Program Standards.

Designated Epidemiologist

A State official or Federal veterinarian (where applicable) with epidemiology training or experience to: 1) make decisions about the use of CWD diagnostic test results; 2) participate in field epidemiologic investigations; 3) manage CWD-infected herds; and 4) ensure data quality and accuracy for the CWD program in his or her State or District. In each State, a designated epidemiologist may be selected jointly by the State representative with regulatory authority for CWD and the APHIS Assistant District Director. Only persons with the requisite epidemiology training or experience should be selected.

Designated CWD HCP Coordinator

The State has designated at least one State representative, or has worked with APHIS to designate an APHIS employee, to coordinate CWD HCP activities in the State in accordance with 9 CFR 55.23.

Review of Approved State HCP Progress

APHIS may periodically review an approved State's CWD program. Objectives of the review include:

1. Evaluate program activities to verify Approved State status.
2. Identify and provide guidance on State problems in complying with Federal requirements.

3. Review farmed cervid surveillance activities and enrolled herd owner compliance.

4. Review records and documents on enrolled herds, including laboratory reports and herd inventories.

5. Review epidemiological reports submitted by the State-designated epidemiologist to the CWD Epidemiologist and national CWD program manager.

6. Assess compliance and completeness with data entered into the national CWD database or equivalent State database.

7. Review educational and outreach efforts to producers.

8. Evaluate personnel and other resource needs.

9. Conduct site visits in accordance with VS Guidance 5509.1.

Selection of States for Approved State HCP Review

CWD Epidemiologists, with input from District leadership and national program staff, will consider States with compliance or program consistency issues, States with varying sizes of cervid industry, District balance (selecting States from each District), and review intervals (at least once every 5 years).

Approved State Review Report

APHIS will give a State Review report to the Approved State that will include the findings of the review, and a request to the State to develop a response which could include an action plan. The plan will include a list of recommendations or requirements to address specific issues identified and a specified period of time to complete.

(2) Participation

The regulatory authority for the requirements for participation in the national CWD HCP is found in 9 CFR Part 55 Subpart B and describes the surveillance, monitoring, and related actions to determine the CWD status of farmed or captive deer, elk, and moose. Herds that successfully complete 5 years of the program with no evidence of disease will be designated as certified and will be eligible to move interstate.

(2.1) Approving Existing State CWD Herd Certification Programs

APHIS will accept applications to become an Approved State CWD herd certification program and will review the State's documentation of the CWD programs already existing within the State to determine if the State meets the program requirements. Existing State CWD programs and farmed or captive elk, deer, and moose owners participating in them will be approved if they meet the minimal requirements of the CWD rule (9 CFR part 55). The date that these herds enrolled in a State program that APHIS subsequently determines qualifies as an Approved State CWD herd certification program would be considered their enrollment date in the national CWD HCP. This process will allow herds participating in approved State programs to retain their State status in the APHIS national CWD HCP. A list of Approved State CWD HCPs will be posted on the APHIS CWD Web site.

(2.2) Provisional Approval

Provisional approval may be granted to States that do not meet all the national CWD HCP minimum requirements on application to the program. APHIS and the State will work to develop a plan with an appropriate time frame to meet program requirements.

(2.3) Participating Approved State: Requirements

States must submit an application, including a completed VS Form 11-2 and supporting documentation, describing their ability to meet the national CWD HCP requirements. In reviewing a State program's eligibility to be designated as an Approved State, the Administrator or designee will evaluate the State statutes, regulations, and directives pertaining to the State agency responsible for farmed or captive cervids, as well as relevant reports and publications of the State animal health or State wildlife agency. The Administrator or designee will also review a written statement from the State animal health or State wildlife agency describing State CWD control and farmed or captive elk, deer, and moose herd certification activities. In determining whether the State program qualifies, the Administrator or his or her designee determines whether the State:

1. Has the authority, based on State law or regulation, to quarantine and restrict intrastate movement of all CWD-positive, CWD-suspect, and CWD-exposed animals.

2. Has the authority, based on State law or regulation, to require the prompt reporting of any animal suspected of having CWD; and to forward test results for any animals tested for CWD to APHIS and State representatives, or State wildlife authorities when they are the appropriate regulatory authority.

3. Has signed a Memorandum of Understanding (MOU) between APHIS and the State that delineates the respective roles of each in CWD HCP implementation. A link to the MOU form can be found in Appendix VII.

4. Has placed all known CWD-positive, CWD-exposed, and CWD-suspect animals and herds under movement restrictions, with movement of animals from them only for destruction with appropriate carcass disposal, or under permit.

5. Has effectively implemented policies to:

    a. Promptly investigate all animals reported as CWD-suspect animals within 7 days of notification.

    b. Designate herds as CWD-positive, CWD-exposed, or CWD-suspect and promptly restrict movement of animals from such herds after an APHIS employee or State official determines that the herd contains or has contained a CWD-positive animal.

    c. Remove herd movement restrictions only after completion of a herd plan.

    d. Conduct an epidemiological investigation of CWD-positive, CWD-exposed, and CWD-suspect herds that includes the designation of suspect and exposed animals and that identifies animals to be traced in accordance with recommended guidelines.

    e. Initiate and conduct tracebacks of CWD-positive animals in affected herds and trace-outs of CWD-exposed animals.

    f. Report, within 30 days following notification of a CWD-positive animal, any out-of-State traces to the appropriate State official and APHIS employee.

    g. Conduct tracebacks based on slaughter sampling. Investigation should be initiated promptly following notification of a CWD-positive animal at slaughter.

6. Effectively monitors and enforces State quarantines or hold orders and State reporting laws and regulations for CWD, documenting any noncompliance with quarantines, hold orders, or reporting.

7. Has designated at least one State official to coordinate CWD HCP activities in the State.

8. Has programs to educate those engaged in the interstate movement of farmed or captive elk, deer, or moose regarding the identification and recordkeeping requirements of 9 CFR part 81.

9. Requires, based on State law or regulation, official identification of all animals in herds participating in the CWD herd certification program, effectively enforces this requirement, and documents any noncompliance with this requirement.

10. Maintains the following information in the CWD National Database administered by APHIS (SCS – Core One), or in a State database recognized by the Administrator as meeting the data requirements in the CWD National Database as outlined below:

    a. Premises information and assigned premises numbers.

    b. Individual animal information on all farmed or captive elk, deer, and moose in herds participating in the CWD HCP in the State.

    c. Individual animal information on all out-of-State farmed or captive elk, deer, and moose to be traced.

    d. Accurate herd status data. See Section A3, "Registration, Identification, and Recordkeeping" for detailed information on data requirements.

11. Requires that tissues from all CWD-exposed and suspect animals from affected herds that die or are depopulated or otherwise killed be submitted to a laboratory authorized by the Administrator to conduct official CWD tests.

12. Requires appropriate disposal of the carcasses of CWD-positive, CWD-exposed, and CWD-suspect animals (Appendix V).

13. Enforces all testing and disposal requirements, and documents any noncompliance.

The State further ensures that herds comply with program requirements including physical herd inventories at least every 36 months, annual herd and premises inspections, and verification of required CWD surveillance. Physical inventories may be conducted on unrestrained animals if it is possible to visually inspect and verify at least one CWD HCP required identification number and device on each animal, and that information is matched to herd records. Animals may be temporarily gathered in pens or other means used for viewing. Any animals in which ID cannot be visually inspected will need some form of restraint for confirmation.

Farmed or captive elk, deer, and moose herd owners who do not wish to move their animals interstate or who cannot meet the requirements of the National CWD Herd Certification Program may choose not to participate such as commercial hunt facilities that receive animals from multiple sources.

(2.4) Participating Herd: Requirements for Enrollment

A. Herd owners already participating in an Approved State CWD HCP will maintain the same enrollment date for the National CWD HCP as the first date that the herd participated in the Approved State program.

B. Herd owners may be able to enroll directly in the National CWD HCP, subject to the availability of appropriated funds, if they do not have an Approved State CWD HCP in their State. Their enrollment date will be the earlier of:

   1. The date APHIS approves enrollment; or

   2. A date no more than 3 years before the date APHIS approved enrollment if the owner has demonstrated the herd has been maintained in a manner that substantially meets the requirements listed in Sections A 2.4 (C) and 2.5.

C. Herd owners enrolled in either the Approved State CWD HCP or directly enrolled in the national CWD HCP agree to maintain their herds in accordance with the following requirements:

   1. Each animal in the herd must be identified before reaching 12 months of age using means of identification described in Section A 3.2 of these Program Standards.

   2. The herd premises must have perimeter fencing adequate to prevent ingress or egress of cervids. This fencing must comply with any applicable State regulations, and follow the guidance provided in these Program Standards (See Section 4 – Fencing Requirements).

   3. The owner must immediately report in a prompt and timely manner to a State official of the Approved CWD HCP or to an APHIS employee (where applicable) all deaths of farmed or captive deer, elk, and moose aged 12 months or older (including animals killed on premises maintained for hunting and animals sent to slaughter), and must make the carcasses of such animals available for tissue sampling and testing in accordance with instructions from the State representative (Approved State CWD HCP) or APHIS employee (where applicable).

      States may routinely allow up to 1 week for reporting mortalities. However, State or APHIS employees may approve mortality reporting schedules other than immediate notification when herd conditions warrant it in the opinion of both APHIS and the State. Mortalities also should be reported to the States through laboratory reports of samples tested by the Approved labs. Herd inventory records should be updated and reconciled at least annually for submission to the Approved State Official.

   4. The owner also must immediately report in a prompt and timely manner of discovery to a State official (Approved State CWD HCP) or an APHIS employee (where applicable) animals that have escaped or disappear, or are otherwise missing from the premises and should also immediately report entry of any wild cervids into the facility. States may routinely allow up to 72 hours for reporting such incidents. This also may allow time for the herd owner to recapture the animal and work with the Approved State for decisions on disposition of the animal(s).

   5. Records, including a complete inventory of animals, must be kept in accordance with Section A 3.3 of these Program Standards. Herd owners must make animals and records available to accredited veterinarians, APHIS employees, or State officials for inspection. Owners are responsible for assembling, handling, and restraining animals for physical inventories or other inspections under conditions that will allow the accredited veterinarian, APHIS employee, or State official to safely read all identification on the animals. The owners are responsible for the costs that may be incurred to present the animals for inspection and must agree that any liability or injury to the animals during handling rests with the owner.

6. If an owner wishes to maintain two or more separate herds, he or she must maintain separate herd inventories, records, working facilities, water sources, equipment, and land use. There must be a buffer zone or geographic zone of at least 30 feet between the perimeter fencing around the separate herds, and no commingling of animals may occur. Movement of animals between herds must be recorded as if they were separately owned herds.

   A herd consists of an animal or group of animals that are either under common ownership, control, or supervision and are grouped on one or more parts of any single premises (lot, farm, or ranch) where commingling of animals occurs; or a single herd of all animals under common ownership, control, or supervision on two or more premises which are geographically separated but on which animals have been commingled or had direct or indirect contact with one another.

   Farmed cervids are commingled if they are housed or penned together having direct physical contact with each other, have less than 10 feet of physical separation or any activity where uninhibited contact occurs such as sharing an enclosure, a section of a transport vehicle, or sharing equipment, pens or stalls, pasture, or water sources/watershed (i.e., housed in a pen that receives runoff or shares a natural or manmade body of water with another pen), or being grouped together for bottle feeding (such as in fawn rearing facilities). Commingling includes contact with bodily fluids (blood, saliva, urine), or excrement from other farmed animals. Farmed cervids commingled with other farmed cervids assume the status of the lowest program status animal in the group.

7. New animals may be introduced into the herd only from other herds enrolled in the CWD herd certification plan and under the conditions outlined in Section A 2.6.

Failure to comply with any of the listed HCP requirements will affect the herd status and could result in suspension or removal from the national CWD HCP.

(2.5) Herd Owner Enrollment and Advancement

A. Individual herd owner direct enrollment will be for herds that reside in States that do not have an Approved State HCP and is subject to availability of appropriated funds. Herd owners wishing to participate in the National CWD HCP must first submit a signed application for enrollment form (VS Form 11-1), a current inventory, documentation showing that all animals in the herd 12 months of age or older were inspected and inventoried within the previous 12 months, and a statement attesting to the requirements listed in Section A 2.4 of the Program Standards.

   APHIS will determine the herd enrollment date for HCP participation on receipt and evaluation of the information provided. The enrollment date may include no more than 3 years of credit time if the owner can demonstrate the herd has been maintained in a manner that substantially meets the requirements in Section A 2.4

   The enrollment date will be the day, month, and year in which an owner's herd is officially enrolled in the HCP. This date is important because it would typically be used to calculate when herds may advance to a higher herd status under the HCP after completing successive years without CWD being diagnosed in the herd. For a herd that only adds animals from herds with the same or greater status, the enrollment and status dates will remain the same. However, for herds that add animals from herds with a lesser status the enrollment and status dates for the receiving herd will reflect the lowest status date. The enrollment date is a fixed date, while the status date may change based on herd additions or status progress.

B. When initially enrolled in an Approved State CWD HCP or directly enrolled in the national CWD HCP, all herds will be placed in First Year status. Each year, on the anniversary of the enrollment date or status date (whichever is later) and of meeting the HCP requirements, the herd status is

upgraded by 1 year; i.e., Second Year status, Third Year status, Fourth Year status, and Fifth Year status. One year from the date a herd is placed in Fifth Year status with no findings of CWD in the herd after 5 continuous years of testing, the herd status is changed to Certified, and the herd remains in Certified status as long as continuous enrollment is maintained in the program and the herd continues to meet all of the program requirements. Enrolled herds that have achieved Certified status are eligible to move interstate in accordance with 9 CFR 81.3.

Herds that are established and sourced solely from other Certified herds will be enrolled as Certified herds and must continue to demonstrate compliance with program requirements to maintain Certified status.

Eligibility for advancement from one status to the next is based on compliance with program requirements, including the submission of samples. Should the herd owner not be in compliance with 9 CFR part 55, State officials and APHIS employees will withhold advancement or lower, suspend, or revoke the status.

(2.6) Additions of Animals or Genetic Material (Germplasm) to a Herd: Effects on Status

A herd may add animals from herds with the same or a greater status in the national CWD HCP with no negative impact on the status of the receiving herd.

If animals are acquired from a herd with a lesser status, the receiving herd reverts to the status of that source herd. If a herd participating in the program acquires animals from a nonparticipating herd, the receiving herd reverts to First Year status with a new status date listed as the date of acquisition of the animal. The enrollment date in the national CWD HCP would remain unchanged but the herd status level would be modified (and modification date recorded).

If a herd acquires animals from herds with a lower or nonparticipating status, the owner must notify a Federal or State official within 5 business days of such acquisition.

At this time there is no scientific evidence that germplasm (embryos or semen) may transmit CWD.

New herds assembled from multiple sources will be assigned the status of the lowest status source herd (i.e., will be given the status date of the lowest status herd).

Other sources of equivalent or higher status animals may include cervid herds enrolled and at an appropriate level in a CWD herd certification program in another country where APHIS recognizes the HCP to be at least equivalent to the APHIS national CWD HCP.

(2.7) Inspections and Inventories

Inspections are conducted annually and physical inventories are conducted at least every 3 years as described below. Records are reconciled during inspections and inventories.

An initial complete physical herd inventory in which all animals in the herd are visually inspected and individual identification verified and recorded must be performed on a herd in accordance with this paragraph at the time a herd is initially enrolled in the CWD HCP. APHIS may accept a complete physical herd inventory performed by a State representative, an accredited veterinarian, or an APHIS employee not more than 12 months before the herd's date of enrollment in the CWD HCP as fulfilling the requirement for an initial inventory.

Thereafter, a physical herd inventory must be performed for all herds enrolled in the CWD HCP no more than 3 years after the last complete physical herd inventory for the herd. Physical inventories may be conducted on unrestrained animals providing that it is possible to visually inspect and verify at least one CWD HCP required identification number and device on each animal, and that information is matched to

herd records. Animals may be temporarily gathered in pens or other means used for viewing. Any animals in which ID cannot be visually inspected will need some form of restraint for confirmation.

In addition, herd and premises inspections to include record inventories are conducted and reconciled annually. These annual inspections ensure compliance with the provisions of this program. Herds may not advance in status until the annual inspections have been completed, submitted, reconciled, and approved.

These inspections and inventories will be conducted by State officials, accredited veterinarians, or APHIS employees (subject to the availability of Federal funding), and will consist of inspections of the herd and facilities as well as inventory verification. Inventory verification conducted during the triennial physical inventories includes inspection of the individual animals, verification of identification for each individual, and reconciliation of the animal inspection and identification verification findings to the written records.

(2.8) Loss of Certification Status

Failure to Comply with Program Requirements

Herds may lose national herd certification status if the Administrator or a designee, in consultation with the respective Approved State Official, determines that the herd owner failed to comply with the program requirements. The Administrator will determine owner compliance failures for herds enrolled directly in the national CWD HCP in States without an Approved State CWD HCP.

CWD-Positive or Exposed Herd

If a herd is designated a CWD-positive herd or a CWD-exposed herd, it immediately loses its program status, and may only re-enroll after entering into a herd plan.

CWD Suspect, Traceback, or Trace-Forward Herd

If a herd is designated a CWD-suspect herd, a traceback herd, or a trace-forward herd, it will immediately be placed in suspended status pending an epidemiological investigation by the State animal health agency. A herd may remain in suspended status until the epidemiological investigation ends and appropriate actions are taken.

If the epidemiological investigation determines that the herd was not commingled with a CWD-positive animal, the herd is reinstated to its former program status, and the time spent in suspended status counts toward its advancement to the next herd status level.

If the epidemiological investigation determines that the herd was commingled with a CWD-positive animal, the herd loses its program status and is designated a CWD-exposed herd. (See definitions of "commingled" and "limited contact" in the Definitions Section.)

Farmed cervids are commingled if they are housed or penned together having direct physical contact with each other, have less than 10 feet of physical separation or any activity where uninhibited contact occurs such as sharing an enclosure, a section of a transport vehicle, or sharing equipment, pens or stalls, pasture, or water sources/watershed (i.e., housed in a pen that receives runoff or shares a natural or manmade body of water with another pen), or being grouped together for bottle feeding (such as in fawn rearing facilities). Commingling includes contact with bodily fluids (blood, saliva, urine) or excrement from other farmed animals. Farmed cervids commingled with other farmed cervids assume the status of the lowest program status animal in the group.

If the epidemiological investigation is unable to determine the exposed versus negative status of the herd because the animal or animals of interest are no longer available for testing (for example, a trace animal from a known positive herd died and was not tested) or for other reasons, the herd status would continue

to be considered suspended until a herd plan is developed for the herd and implemented by the Approved State Official.

If the herd plan is implemented and the requirements of the plan are being met, the herd will be reinstated to its former program status, and the time spent in suspended status will count toward its promotion to the next herd status level.

However, if the epidemiological investigation finds that the herd owner has not fully complied with program requirements for animal identification, animal testing, and recordkeeping, then the herd will be reinstated at the First Year status level. The herd owner must comply with all program requirements and the herd plan may require movement restrictions for animals in the herd. Testing of all animal mortalities for any reason and regardless of age and other requirements may also be required to control the risk of spreading CWD.

Approved States may also consider providing an opportunity for a herd involved in the epidemiological investigation that is not already part of the CWD herd certification program to be allowed to immediately enroll in the certification program and conduct surveillance on all animals 12 months of age or older that die in the herd for any reason.

(2.9) Relocation of a Herd

If a herd moves either within a State or to another State, it must meet all Approved State intrastate or Federal interstate movement requirements. In addition, the appropriate State official or APHIS employee administering the Federal CWD rule should be notified of the relocation within 30 days.

(2.10) Cancellation of Participation

Mandatory Cancellation

The Administrator, in concurrence with the Approved State, may cancel the enrollment of an enrolled herd by giving written notice to the herd owner. The Administrator may cancel enrollment after determining that the herd owner failed to comply with any HCP requirements.

Before enrollment is canceled, an Approved State Official or an APHIS employee will inform the herd owner of the reasons for the proposed cancellation and inform the producer of the 10-day appeal deadline. The herd owner may appeal the proposed cancellation in writing to the Administrator within 10 business days after being informed of the reasons for the proposed cancellation. A timeline for the appeal process will be determined by the Administrator in consultation with the Approved State Official. The appeal must include all of the facts and reasons on which the herd owner relies to show that the reasons for the proposed cancellation are incorrect or do not support the cancellation. The Administrator may grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. The Administrator sets the rules of practice concerning the hearing.

In the event of cancellation, the herd owner may reapply to enroll in the national CWD HCP but will not reach Certified status until 5 years after APHIS approves the herd owner's new application for enrollment regardless of the status of the animals in the herd.

Voluntary Cancellation

An owner may decide to cancel participation in the CWD HCP at any time unless otherwise required by State regulations or a signed herd plan. The cancellation should be in writing. Owners who voluntarily cancel their participation may re-enroll at any time as a First-Year status herd and will receive a new enrollment and status date.

(3) Registration, Identification, and Recordkeeping

The regulatory authority for registration, recordkeeping, and identification for each animal within enrolled herds is found in 9 CFR 55.23.

(3.1) Premises ID

All participating premises must have a unique Premises Identification Number (PIN).

The PIN is a nationally unique number assigned by a State, Tribal, or Federal animal health authority to a premises that is, in the judgment of the State, Tribal, or Federal animal health authority, a geographically distinct location from other premises. It is associated with a physical address (not a post office box), geospatial coordinates, and/or location descriptors which provide a verifiably unique location.

The PIN may be used in conjunction with a producer's own livestock production numbering system to provide a unique identification number for an animal. It may also be used as a component of a group/lot identification number. The premises identification number may consist of:

1. The State's two-letter postal abbreviation followed by the premises' assigned number; or

2. A seven-character alphanumeric code, with the rightmost character being a check digit. The check digit number is based on the ISO 7064 Mod 36/37 check digit algorithm.

(3.2) Animal Identification

In accordance with 9 CFR 55.25, all animals in the herd must be identified with two animal identifications for each individual. One of these animal identifications must be a nationally unique official animal identification.

The official animal identification must be a device using an APHIS-approved animal identification numbering system that uniquely identifies individual animals as described in Appendix I. Information on official animal identification and devices can be found on the APHIS Traceability Web site: http://www.aphis.usda.gov/traceability/downloads/ADT_eartags_criteria.pdf

The official animal identification device must be approved by APHIS, and must be a legible ear tattoo, tamper-resistant eartag, electronic implant, legible flank tattoo, or other approved device (see Appendix I).

The official animal identification must be linked to that animal and herd in the National CWD Database (SCS – Core One) or State database recognized by APHIS as equivalent to the National CWD database.

The second animal identification must be unique for the individual animal within the herd and also must be linked to that animal and herd in the National CWD Database (SCS – Core One) or State database recognized by APHIS as compatible with the National CWD database.

Natural additions to the herd must be identified before 12 months of age. However, any animal must be properly identified as described in this section and Appendix I to move interstate regardless of age (i.e., animals less than 12 months of age that are to be moved interstate must be identified).

If, at the time of enrollment in the CWD HCP, either through the Approved State CWD HCP or by direct enrollment in the national CWD HCP (based on availability of funding), identification of animals in a herd does not meet the above criteria, the herd owner must bring the herd and animal identifications into compliance as soon as possible and no later than the next inventory on a schedule specified by the State official or APHIS employee.

(3.3) Herd Inventory: Records

Each owner must maintain a current complete herd inventory which must include, at a minimum, the following records for each animal:

1. All identification (tags, tattoos, electronic implants, etc.)
2. Age
3. Species
4. Sex
5. The date of acquisition and source of each animal that was not born into the herd (owner name, city, State)
6. The date of removal and destination of any animal removed from the herd (owner name, city, State)

In addition, the following information should be included:

7. Birth date
8. Date of death (and cause, if known) for animals dying within the herd
9. Date of CWD sample submission, submitter, owner, premises, and animal information, and official CWD test results from NVSL or approved laboratory for samples required by the program

(3.4) National Herd Inventory Electronic Recordkeeping

Data will be kept in a CWD National Database (SCS –Core One) or APHIS-approved State database compatible with the CWD program. For the purposes of the CWD rule and the Approved State CWD HCP, the CWD National Database is a CWD HCP database administered by APHIS or a State database approved by the Administrator as compatible with a "CWD National Database" for the Approved State CWD HCP program.

Data for the following should be entered into the National CWD database or equivalent State database in a timely manner:

1. Herds enrolled in the CWD certification program
2. Herds designated as positive
3. Herds designated as exposed, suspect, or epidemiologically linked to positive herds
4. Herds that have achieved certified status

The information should include all items required by these Program Standards, including but not limited to:

1. Premises and owner information (location, addresses, and contact information)
2. Program status of enrolled herds
3. Any restrictions to herds including disease status

4. All program actions such as changes to status, depopulation, and adoption of herd and premises plans

(3.5) Data Security in the Electronic CWD National Database

Data stored in the CWD National Database is secured to protect data at the State level. Users in a State should not be able to review or change data for another State. "Read Only" data viewing privileges between State users may be granted by mutual agreement. CWD program staff should have access to national data for reporting purposes.

(4) Fencing Requirements

The regulatory authority for fencing requirements of enrolled herds is found in 9 CFR 55.23.

The herd premises must have perimeter fencing adequate to prevent ingress or egress of cervids. In herd premises already existing at the time of the effective date of the CWD rule, fencing must comply with any existing State regulations or requirements. For herds established after the effective date of the CWD rule, the fence should be a minimum of 2.4 meters (8 feet) high and must comply with any other existing State regulations or requirements. In either case, the fence should be structurally sound, maintained in good repair, and of sufficient construction to contain the animals.

The program does not intend to have "double fencing" as a comprehensive program standard for farmed cervids. However, the program does recognize the risks of CWD infection to farmed cervids held in facilities that operate in areas known to have CWD in free-ranging cervids. Therefore, the risk of CWD transmission between farmed cervid and free-ranging cervid populations should be assessed by individual States and addressed by additional barrier requirements as necessary. Cervid producers also may elect to include additional barriers or exclusionary fencing to mitigate such risks while enrolled in the HCP.

Approved State officials have the discretion to consider the use of additional barriers or other biosecurity measures to mitigate the risks of CWD transmission. Any requirements for additional barriers or exclusionary fencing to separate farmed and free-ranging cervid populations to minimize risk of CWD transmission between these populations will be addressed by the State officials. Reference information on these topics is located in Appendix II.

In areas where CWD is not known to occur in free-ranging cervids, risk for CWD transmission to captive cervids is recognized as minimal.

Fencing alone does not delineate individual herds, which must be separated by a distance of 30 feet or greater. See "herd" definition in the Definitions section.

(5) Surveillance and Sampling

The regulatory authority for surveillance and sampling of animals in enrolled herds is found in 9 CFR 55.23.

This section outlines surveillance and sampling requirements as well as monitoring principles used with CWD in farmed or captive cervids. The procedures listed below are required for all herds participating in the certification program.

Farmed cervid herds cannot achieve certified status without conducting CWD surveillance on all deaths of cervids aged 12 months or older, including animals in the enrolled herd that are killed on premises maintained for hunting and sent to slaughter for at least 5 consecutive years unless:

1. The herd owner purchases or assembles a herd of animals from known certified status herds and concurrently enrolls in a State HCP.

2. The enrolled herd owner can adequately document that he or she has maintained a closed herd of animals for at least 5 years; had no on-farm mortalities; had no "missing" animals; and did not move any animals off the premises during that time for any reason without testing them for CWD.

If the enrolled herd owner does not have any on-farm animal deaths meeting surveillance criteria for the year and has not moved, transferred ownership, or sold animals as described above, the enrolled owner is considered to be in compliance with surveillance requirements for the year.

(5.1) Reportable Disease

CWD is a reportable disease. The owner must immediately report to a State official, accredited veterinarian, or an APHIS employee all suspected cases of CWD. These are to include any animal exhibiting signs of a neurological or wasting disease as described in Section A 5.2. These animals should be monitored, and if they die, the carcasses must be made available for tissue sampling and testing. Clinical CWD suspects that die or are euthanized should be tested for CWD regardless of age.

(5.2) CWD-Suspect Animals

CWD-suspect animals are defined in the Definitions section of these Program Standards. The clinical signs associated with CWD are nonspecific and could be caused by other diseases affecting farmed or captive elk, deer, and moose; thus, laboratory confirmation is required for CWD diagnosis. Not all animals display all clinical signs of disease. Duration of clinical signs varies from a few days in unusual cases to as long as a year, but is most often 2 to 3 months.

Usually, the earliest clinical signs displayed are behavioral changes which may include alterations in interaction with humans and members of the herd. These subtle changes are often only recognized by caretakers familiar with the individual animal. With disease progression, behavioral changes may include periods of stupor and depression. In addition, progressive weight loss is characteristic of CWD and may occur over a long time. At the terminal stages of disease, animals are emaciated. However, concurrent disease, especially aspiration pneumonia, may cause an affected animal to die while still in good to fair body condition. In the later stages of disease, clinical signs may include increased drinking and urinating, excessive salivation, and lack of coordination and trembling.

Animals with progressive neurological disease or wasting syndromes that are not responsive to treatment may be considered CWD clinical suspects. CWD clinical suspects should be euthanized and tested. If an owner of a clinical suspect refuses to allow euthanasia, the animal should be tested after it dies in accordance with program requirements.

(5.3) On-Farm Surveillance

The owner must report in a prompt and timely manner to a State official of the Approved CWD HCP or to an APHIS employee (where applicable) all deaths of farmed or captive deer, elk, and moose aged 12 months or older (including animals killed on premises maintained for hunting and animals sent to slaughter), and must make the carcasses of such animals available for tissue sampling and testing in accordance with instructions from the State representative (Approved State CWD HCP) or APHIS employee (where applicable).

States may routinely allow up to 1 week for reporting mortalities. However, State or APHIS employees may approve mortality reporting schedules other than immediate notification when herd conditions warrant it in the opinion of both APHIS and the State. Mortalities also should be reported to the States through laboratory reports of samples tested by the Approved labs. Herd inventory records should be updated and reconciled at least annually for submission to the Approved State Official.

Enrolled herd owners are required by these provisions to conduct CWD testing on all on-farm deaths of farmed or captive deer, elk, and moose aged 12 months or older, and those animals under their

ownership sent to hunting operations and slaughter facilities to achieve herd certification status. See additional details in Sections A 5.4 and A 5.5 below.

Once the herd has been certified and to maintain herd certification status, CWD testing of all on-farm deaths of farmed or captive deer, elk, and moose aged 12 months or older must continue. Additional CWD testing of animals from certified herds that are sent to hunting operations and slaughter facilities will be at the discretion of the Approved State officials. However, APHIS intends to evaluate these CWD surveillance parameters for the purposes of assessing CWD risk in these certified herds and to address national efforts in prevention and control of this disease, and may revise these testing requirements in the future.

Exceptions to the testing requirement may be made by APHIS or the appropriate Approved State agency having CWD HCP oversight for extenuating circumstances beyond the control of the herd owner such as extreme weather conditions or mass mortality events not directly related to CWD. (See Section A5.10.)

(5.4) Animal Surveillance on Private Hunt Facilities

All animals on private hunt facilities 12 months or older harvested by hunters as well as natural mortalities on hunt facilities must be made available for testing if the hunt facility is enrolled in the Approved State CWD HCP.

Any cervids 12 months or older that have been sent to hunt facilities from herds enrolled in the Approved State CWD HCP that have not yet achieved certified status and have remained on the owner's enrolled herd inventory must be tested for CWD at time of death or harvest in the hunt facility and test results reported to the Approved State. Testing of animals from certified herds sent to hunting facilities will be at the discretion of the Approved State Officials. APHIS intends to evaluate these CWD surveillance parameters for the purposes of assessing CWD risk in these certified herds and to address national efforts in prevention and control of this disease, and may revise these testing requirements in the future.

In such cases where clinically normal animals are harvested over time on hunt facilities, there may be allowance for reporting groups of animals that have been killed over a specified time period. The delayed notification should include the identification numbers of the animals involved and the actual or estimated time and date of death.

States may consider moving animals from CWD suspect, exposed, or positive herds by permit and under seal to a known CWD-positive hunt facility within the same State for purposes of selective culling and continuity of business, and all animals harvested to be tested for CWD as described in the Herd Plan (See Section B1).

See Section A 8.3 for information on approval by the Administrator for interstate movement of animals from CWD suspect, exposed, or positive herds to hunting operations or terminal slaughter facilities, and requirements for CWD testing.

States also may modify a quarantine to permit movement of apparently healthy cervids onto a CWD-positive, quarantined premises – such as a hunt facility – and all cervids harvested must be tested for CWD. Other stipulations may apply to the modifications.

All animals from enrolled herds that are sent to hunt facilities must retain official identification.

(5.5) Slaughter Surveillance

Any cervids 12 months or older sent to slaughter facilities from herds enrolled in the Approved State CWD HCP that have not yet achieved certified status and have remained on the owner's enrolled herd inventory must be tested for CWD at time of death and test results reported to the Approved State. This includes farmed or captive deer, elk, or moose moving interstate for slaughter. Such animals must be moved directly to a recognized slaughter establishment, must have two forms of animal identification (one

of which is official animal identification), and must be accompanied by a certificate of veterinary inspection (CVI). See Sections A 8.1 and 8.2 for details.

Testing of animals from certified herds sent to slaughter facilities will be at the discretion of the Approved State Official. APHIS intends to evaluate these surveillance parameters to assess risk in these certified herds and to address national efforts in prevention and control of this disease, and may revise these testing requirements in the future.

Samples for CWD testing from animals 12 months or older slaughtered on the farm (custom slaughter) are submitted as part of the on-farm surveillance required for the Approved State CWD HCP.

APHIS recommends that animals moved by permit and under seal to a slaughter facility from a CWD suspect, exposed, or positive herd be tested for CWD as described in the Herd Plan (See Section B1). Owners are responsible for making necessary arrangements for CWD sample collection before moving animals to slaughter. These arrangements could include coordination with an accredited veterinarian, State or Federal animal health official, certified collector, State or Federal meat inspection agency, and the slaughter facility.

(5.6) Sample Collection: Owner Responsibility

Good quality sampling and complete tissue collection of obex and medial retropharyngeal lymph nodes (MRPLN) from dead animals are essential for successful surveillance. It is the owner's responsibility to ensure good quality tissue samples are collected and all required samples are submitted.

Failure to comply with the provisions of this section may result in loss of program status or other actions applicable under Approved State or Federal regulation and based on review and knowledge of the owner's compliance with CWD HCP requirements.

Owners may remove and submit the entire head with all attached identification devices to an approved CWD laboratory. Proper tissue samples will be collected by laboratory personnel.

Samples may not be collected by herd owners unless they are approved by their State authority as a certified or designated CWD sample collector. Samples may only be collected by State officials, APHIS employees, accredited veterinarians, or State-certified or -designated CWD sample collectors.

(5.7) Sample Collection and Submission Procedures

Approved States and enrolled herd owners should follow 9 CFR 55.23(b)(3), which states that owners must make the carcasses of animals that die available for tissue sampling and testing in accordance with instructions from APHIS and the Approved State Official, and should follow 9 CFR 55.8, which refers to using test protocols (including sample submission procedures) provided by NVSL.

The NVSL protocol for CWD testing requires the obex and MRPLN to be submitted and tested from all CWD-susceptible and test-eligible individuals regardless of species. At least one valid CWD test result is necessary on each animal tested to be counted in the required mortality surveillance. Other optional lymphoid tissues such as tonsils and rectoanal mucosa-associated lymphoid tissue (RAMALT) also may be submitted for additional evaluation and at additional cost but are not required tissues. The obex and MRPLN are submitted in 10 percent buffered formalin or as otherwise instructed by an Approved State Official or APHIS employee.

All required tissues should be collected regardless of sample condition (e.g. autolyzed, frozen, etc.) and submitted to the approved laboratory. However, there may be circumstances when only one tissue sample can be collected from an animal. In those circumstances, the producer should notify the Approved State official to explain the reason such as severe tissue autolysis (decomposition), extensive carcass decomposition, or destruction of tissues at slaughter. The Approved State Official may determine on a case-by-case basis if submission of the one tissue is acceptable. If that single sample submission is

determined by the laboratory to be unsuitable or untestable, then it will be recorded as a missed sample (not tested) and that animal will not be counted in the mortality surveillance for herd certification status.

Laboratory diagnosticians will determine the suitability of the samples for CWD testing with guidance from NVSL as necessary. Any concerns for sample quality and suitability, and subsequent interpretation of test results, will be discussed on a case-by-case basis with the Approved State CWD HCP Official and APHIS (See Section A 5.9).

Approved State officials should follow NVSL protocols for sample testing but will determine on a case-by-case basis whether consistent patterns of submitting unsuitable samples, submitting only one tissue type, or other noncompliant behavior by the enrolled producer warrant action. Actions may include loss or suspension of status or delay in advancement in the HCP.

Approved State officials also will provide oversight on sample collection by certified sample collectors and address any skill inadequacies which may require additional training or loss of certification as a sample collector.

A positive IHC or ELISA test result on any sample submitted to the approved laboratory will be considered a suspect positive to be confirmed by NVSL. All samples should be submitted using VS Form 10-4 or an equivalent State form (see Appendix VII). Samples collected and preserved in 10 percent buffered formalin for immunohistochemistry (IHC) testing should be submitted to an approved laboratory within 7 days. Samples collected as fresh tissue for ELISA or Western blot testing should be submitted within 24 hours. Detailed instructions regarding sample collection and submissions can be found in Appendices III and VII.

(5.8) DNA Comparison for Verification of Animal Identity

Verification of the animal's identity based on DNA comparison is an option available to enrolled herd owners at the owner's expense. Eartag identification devices that are firmly attached to part of the ear, which is kept chilled or frozen, must accompany the formalin-fixed or fresh tissues for CWD testing from the same animal. If part of the ear cannot be removed (e.g., for taxidermy purposes), then a new identification tag could be affixed to the hide skin and recorded in the animal's official record, and the tagged hide section submitted with the diagnostic specimens. It is critical that the basic principles of chain of custody, such as consistent documentation and sample security, be used to ensure that the samples remain appropriately linked to the source animal from the time of sample collection to the end of the testing process. Chain of custody-type practices must be maintained so that samples submitted can be used to verify the identity of the animal in question with certainty. All specimen containers must be clearly and permanently marked to include official identification of the animal, name of owner, name of collecting official, and date. Laboratory tracking numbers must be included with all corresponding documents.

All requests for DNA comparison testing should be submitted by the owner, in writing, to the Assistant District Director (ADD) in the corresponding District of the State. The ADD will notify NVSL of the request. NVSL will extract DNA from the test specimens and associated skin tissue, and forward the extracts to a laboratory agreeable to NVSL for DNA comparison testing. Results reported by the DNA testing laboratory to NVSL will be forwarded to the appropriate APHIS official, who, in turn, will forward a copy of the test results to the appropriate Approved State Official and the owner.

(5.9) Quality Control

Approved State Officials or APHIS employees have the authority to adjust herd status if incomplete or poor quality samples are repeatedly submitted from an enrolled herd. Poor quality samples include samples that are severely autolyzed, from the wrong portion of the brain, the wrong tissue, or not testable for other reasons.

Approved laboratories should closely monitor sample quality. They are responsible for providing feedback to the producer, State officials, and APHIS employees regarding the receipt of poor quality samples.

(5.10) Consequences of Poor Quality and Missing Samples

Surveillance of all animal mortalities is the key to ensuring valid herd certification status. Owners must report all mortalities to program officials as described in Section A 2.4. Failure to test for CWD of any animal 12 months of age or older in an enrolled herd that dies, is slaughtered, escapes, or is lost resulting in missing samples, or submission of incomplete or poor quality samples, may be cause for delayed advancement, loss of or reduction in status, or cancellation from the program as determined by APHIS or the Approved State Official.

Approved States (in consultation with APHIS) should develop risk-based assessments to address consequences for missed samples of test-eligible animals in enrolled herds. This may include penalties in time by reducing herd status date (with loss, reduction, or delay in herd certification), or a requirement to replace missed animals with an additional percentage of in-kind (test-eligible) animals from the herd such as those sent to slaughter or hunt facilities, or a direct suspension of herd status for some period of time.

Exceptions

Exceptions to the testing requirement and missed samples may be granted by APHIS or the Approved State Official having CWD program oversight for extenuating circumstances beyond the control of the herd owner as described below.

CWD sample collections may be limited to two animals per occasion when APHIS or the Approved State official determines that the animals died from a mass casualty/mortality event (where numerous animals die over a short period of time from the same apparent cause) such as during a natural disaster or an infectious disease outbreak (such as epizootic hemorrhagic disease), or from a known zoonotic disease where sample collection would pose a public health risk. In these cases, the designated sample collector will sample the higher-risk animals. Higher-risk animals would include older animals, males preferentially over females, or those animals having any known pre-existing health conditions or in poor body condition. CWD testing will be at the owner's expense.

(6) Diagnostics

The regulatory authority for official CWD tests and laboratory approval is found in 9 CFR 55.8.

(6.1) Testing Authority and Approved Laboratory

Laboratories will be approved by NVSL, as designated by the APHIS Administrator, to conduct official CWD testing in accordance with 9 CFR 55.8.

A. General Qualifications

Only State, Federal, and university laboratories that are members of the National Animal Health Laboratory Network (NAHLN) will be approved to conduct official CWD diagnostic testing. Only program-approved tests conducted in approved laboratories, at NVSL, or at another laboratory to which NVSL has referred a case for confirmatory testing, are considered to be official diagnostic tests for CWD.

All suspect positive results are reported by email to NVSL within 1 business day after testing is completed.

The approved laboratory submits all specimens (all remaining fixed or frozen tissues, slides, blocks, homogenates, and tags/IDs) from a suspect positive animal to NVSL for confirmation within 24 hours.

B. Laboratory Approval

Requirements for laboratory approval can be found in the "Policy Regarding Evaluation of Veterinary Diagnostic Laboratories for Membership in the National Animal Health Laboratory Network," available at:
http://www.aphis.usda.gov/animal_health/nahln/downloads/Lab%20Evaluation%20Policy.pdf

C. NVSL and National CWD Program Manager Responsibilities

On receiving a request for laboratory approval, the NAHLN Coordinator, or his or her designee, will notify the national CWD program manager. The NAHLN Program office notifies each District Office of any changes to the list of NAHLN approved laboratories in their area.

If the application is complete and testing is approved by the CWD program manager, authorized NAHLN personnel will schedule and conduct a site visit of the applicant laboratory if the laboratory has not been previously inspected by NAHLN or a third party inspector approved by NAHLN. The District Office/ADD will be notified before the site visit. During the site visit, authorized NAHLN personnel will review the test procedures the laboratory intends to use and determine if the applicant laboratory meets the requirements for approval.

If results of the site visit are found to be unsatisfactory, the laboratory will be notified and will be provided the reasons for denying approval. The laboratory can address the deficiencies and resubmit the application package.

D. Recommendation for Approval

After review of the application and the site visit (if required), if the laboratory meets all requirements, the NAHLN Coordinator, or his or her designee, will notify the NAHLN laboratory director and the national CWD program manager that the laboratory is or is not approved to conduct the specific tests. Approval will be granted if the laboratory:

1. Completes proficiency testing for the specific test, as directed by NVSL. Satisfactory performance requires that the laboratory correctly identify the CWD status of all samples in the test panel. If discrepant results are obtained, NVSL, the participating laboratory, and others as required will investigate the cause. If the apparent cause of discrepant results is determined and rectified to the satisfaction of NVSL, no additional corrective actions may be needed.

   At the discretion of NVSL, additional proficiency testing or additional training of personnel may be required. A second failure of a proficiency test is grounds to deny the laboratory approval for the specific test.

   If the results of a laboratory's proficiency testing are unsatisfactory, the NVSL Director (or designee) will indicate the deficiencies in writing and send this information to the laboratory director and the NAHLN program office.

   NVSL will forward proficiency test results to the NAHLN program office.

2. Provides the NAHLN program office with CWD testing numbers and test methods used on a quarterly basis.

E. Changes to Laboratory Approval

A laboratory must notify the NAHLN Coordinator, or his or her designate, of any changes in the information contained in the application package within 30 days of the effective date of the change. Changes in procedures or equipment must be approved by NVSL before they are made.

Changes in personnel requiring notification include individuals serving as the responsible laboratory official, laboratory director, or the individual responsible for CWD testing technical issues; or the contact information for these individuals.

F. Maintaining Laboratory Approval

To maintain approval, laboratories must demonstrate satisfactory completion of proficiency tests annually or as deemed necessary by NVSL. A final score of 100 percent correctly identified samples is considered a satisfactory score. The procedure described in this document will be used if discrepant results are obtained.

G. Removal of Laboratory Approval

Testing approval may be withdrawn or suspended for the following reasons:

1. Failure to meet any of the conditions stated in 9 CFR 55.8
2. Failure to meet one or more criteria for obtaining or maintaining approval
3. A request by the approved laboratory to withdraw approval
4. Unsatisfactory performance on regular samples submitted for testing or required proficiency tests
5. Unsatisfactory conditions or procedures at the laboratory
6. Failure to report results in the manner and within the timeframes specified in these Program Standards, in the SOP provided by NVSL, or in a contract, blanket purchase agreement, or other binding agreement

The NVSL Director, acting on behalf of the Administrator, may withdraw or suspend a laboratory's approval to conduct a specific test kit or method on any or all tissues approved to be tested using the kit or method based on proficiency test failures on any tissue using the kit or method.

The NVSL Director, acting on behalf of the Administrator, will provide written notice of a proposed withdrawal to the laboratory director and will allow the laboratory to respond. Any conflicts concerning the reasons for withdrawal will be resolved through discussions that will include the NVSL director, the requesting laboratory's director, the NVSL laboratory subject matter expert, the national CWD program manager, and the NAHLN coordinator, or designees of any of these.

H. List of Approved Laboratories

The national CWD program manager and the NVSL Director will maintain a list of the types of tests and when appropriate the tissues approved for laboratories that conduct official diagnostic tests for CWD. The list will be available on request to all interested parties.

A list of laboratories approved to conduct CWD testing is available at:
http://www.aphis.usda.gov/animal_health/nahln/downloads/cwd_scrapie_lab_list.pdf

(6.2) Official CWD Test

An official CWD test is approved by the Administrator in accordance with 9 CFR 55.8 and follows NVSL protocols for tests conducted at NVSL, an APHIS-approved laboratory, or another laboratory to which NVSL has referred a case for confirmatory testing. Certain CWD test methods, such as enzyme-linked immunosorbent assay (ELISA) tests, also may require Center for Veterinary Biologics licensure to be used as official CWD tests.

Currently the official tests for routine CWD HCP surveillance in farmed or captive cervids are the immunohistochemistry (IHC) test and the Bio-Rad ELISA when following test protocols provided by NVSL at a laboratory approved to conduct official CWD tests. The Western blot is also an official test when performed at NVSL.

All suspect positive ELISA test and suspect positive IHC test results must be confirmed by NVSL.

The Administrator may approve new official tests for the diagnosis of CWD conducted on live or dead animals, and will base the approval of a new test on criteria described in 9 CFR 55.8. NVSL will provide the protocols including tissues to be tested for all official tests.

(6.3) Confirmatory Testing

All suspect positive samples (either by IHC or ELISA as defined above) are to be submitted to NVSL within 24 hours for confirmatory testing.

The following materials are required for confirmation testing:

1. All remaining homogenate from grinding tubes and wells (if testing by ELISA)
2. Place 1 cm section of brainstem at the obex into formalin with the remaining cranial and caudal ends of the fresh brainstem chilled
3. Place 75 percent of the lymph tissue into formalin and preserve the remaining 25 percent fresh chilled
4. All paperwork, identification tags (with tissue attached), and any remaining tissues

Other optional lymphoid tissues such as tonsils and rectoanal mucosa-associated lymphoid tissue (RAMALT) also may be submitted to NVSL for IHC testing at NVSL's discretion, but are not required tissues.

All suspect positive diagnostic test results from an approved laboratory must be confirmed by NVSL to establish a diagnosis of CWD.

(6.4) Test Results

As described in Section A 5.7, sections of brainstem/obex and MRPLN are evaluated by an official test in an approved laboratory to demonstrate the presence of PrPres. PrPres is a molecular marker for the transmissible spongiform encephalopathies (TSE). PrPres must be detected in at least one of those tissues. Detections of PrPres in samples tested at approved laboratories are considered to be suspect positive pending further testing at NVSL.

A CWD-positive animal is an animal that has had a diagnosis of CWD established by means of official confirmatory CWD testing conducted by NVSL. Brainstem or lymph tissues from an animal in which PrPres is not detected by an official test does not mean absence of disease, only that the disease was not detected in those tissues from that animal at that time. Based on current TSE research and pathogenesis studies, it is possible to have PrPres present at levels below the sensitivity of the test. PrPres also may be present in tissues other than those that were examined. Hence, "not detected" test results may not indicate the true status of the animal if it is in the early stages of the disease.

Several sample quality control concerns are listed in Section A 5.9. A test result of "unsuitable sample" indicates that the submitted sample was not the correct tissue type (e.g., salivary gland collected instead of lymph node). A test result with a "location" statement indicates that the submitted sample was taken from an incorrect area of the brainstem (other than the obex).

(6.5) Autolyzed Samples

Autolyzed samples will be considered to be poor quality samples and may not be acceptable for testing. The sample must be verified as brainstem/obex or peripheral lymphoid tissue by the testing laboratory. Such samples may be tested if in the opinion of the testing laboratory a valid result may still be obtained.

(6.6) Reporting of Results

Positive test results are to be reported by NVSL to the submitter (if a State or Federal animal health official), the Assistant District Director (ADD) in the State where the herd resides, the National CWD Program manager, or designees. The District Office will forward the results to the appropriate State official.

Negative ("not detected") results are to be reported by the testing laboratory to the submitter with copies provided to the corresponding Approved State Official for farmed cervids in the State where the herd resides.

(7) National Reports

This section outlines the recommendations for data entry in the national CWD database (SCS –Core One) or approved State database and the submission of reports. Approved States maintaining data in a State-level database should give CWD HCP information and reports to APHIS on request. The information ensures that Federal and State personnel responsible for administering the CWD Program have the necessary data to do so effectively and efficiently.

(7.1) Data Entry and Purpose

This data will be used to monitor program performance, monitor disease control efforts, and assist States in completing epidemiological investigations. See Section A 3.4 for details regarding data required to be entered into the CWD National Database or equivalent Approved State database.

(7.2) Reporting Intervals

Data on positive and exposed herds should be entered within 5 business days after these designations are made.

Data on enrolled herds and premise identification numbers should be entered within 10 business days after it is available.

Comprehensive annual reports of HCP status and activities of enrolled herds as described in Section A 7.3 are provided to the APHIS Administrator by June 30 each year. Quarterly or midyear status reports may be required as appropriate. Reports are submitted to the respective APHIS District Office and routed to the CWD program manager.

(7.3) Components of Report

Reports should include information related to numbers of enrolled herds by State, status summaries, and summary of the level of mortality surveillance. As the reports will be used to monitor program performance and disease control efforts, the following data will be a component of the reports:

1. CWD samples and tests–number of animals tested during the reporting period, species, herd type (breeder, hunting operation, etc.) and test results.

2. CWD-positive herds–under quarantine, depopulated and released from quarantine, not under quarantine, under herd plans, number of animals in each herd.

3. CWD-exposed herds–under quarantine, depopulated and released from quarantine, not under quarantine, under herd plans, number of animals in each herd.

4. Epidemiological information–traceouts initiated, traceouts pending, and traceouts completed.

5. Enrolled herds–by State and certification status, species, number of animals in each herd, number due for inspection during each reporting period, number actually inspected.

Guidance on annual reporting formats will be provided by the national CWD program.

(8) Interstate Movement

The requirements for interstate movement of live cervids are described in 9 CFR 81.3. The requirements for issuing certificates for interstate movement are in 9 CFR 81.4. Transport of game meat and other products derived from farmed cervids for purposes of interstate commerce are regulated by the Food and Drug Administration and are not addressed in the APHIS CWD regulation or these Program Standards. Similarly, transport of carcasses and other parts derived from hunter-harvested wild cervids, which may contribute to the risk of spread of CWD, are regulated by appropriate State agencies and are not addressed in the APHIS CWD regulation or these Program Standards.

(8.1) Requirement for Interstate Movement

No farmed or captive deer, elk, moose, or other *Cervus, Odocoileus, and Alces* species or their hybrids may move interstate unless the animals meet the following requirements:

For animals in the national CWD HCP: The animal is enrolled in the national CWD HCP and the herd has achieved Certified status. The animal must also be accompanied by a certificate issued in accordance with 9 CFR 81.4 that identifies its herd of origin and states that the animal has achieved Certified status, and that the animal does not show clinical signs associated with CWD.

For cervids captured from a wild population for interstate movement and release: Each animal must have two forms of animal identification, one of which is official animal identification. The certificate issued in accordance with 9 CFR 81.4 that accompanies the animal must state that the source population has been documented to be low risk for CWD based on a CWD surveillance program in wild cervid populations approved by the receiving State and by APHIS. This should include a summary of CWD surveillance data for the source population including estimated population size and statistical parameters used to assess prevalence, and proximity of the source population to any known CWD positive farmed/captive cervid herds or other free-ranging cervid populations. Additional information may include referencing recognized published surveillance strategies for detecting and monitoring CWD in free-ranging cervids on which the surveillance plan was based and/or a review of the surveillance plan by APHIS Veterinary Services.

See Section A 8.3 for exemptions to interstate movement requirements.

(8.2) Issuance of Certificates (CVI) for Interstate Movement

The certificate of veterinary inspection (CVI) issued for interstate movement must contain the following information:

1. Identification numbers of each animal in the shipment

2. Total number of animals being moved in the shipment

3. Purpose of animal movement

4. Consignor and herd of origin with complete address

5. Consignee and point of destination with complete address

6. CWD HCP herd program status of the animals in the shipment

7. A statement by the issuing accredited veterinarian or State or Federal veterinarian that the animals have achieved Certified status in the CWD HCP and that the animals were not exhibiting clinical signs associated with CWD at the time of examination

The consignor or owner should contact the State official in the State of destination to determine if there are any additional requirements.

(8.3) Exemption for Interstate Movement

Animals Moved Directly to Slaughter
Farmed or captive deer, elk, moose, or other species of *Cervus, Odocoileus, or Alces* and their hybrids may move interstate directly to a recognized slaughter establishment for slaughter if they meet the import requirements of the state of destination.

Specifically, owners should notify their State official having CWD authority and their APHIS District Office for approval of their eligibility to transport directly to slaughter (see Section A 5.5 for details). The consignor or owner also should contact the State official in the State of destination to determine if they meet all import requirements. While it is not required, APHIS recommends producers and transporters provide courtesy notification to any States through which these animals may transit en route to their destination. See Section A 8.4 on transiting.

Research Animals
A research animal permit is required for interstate movement of cervids for research purposes. The VS Form 1-27, "Permit to Move Restricted Animals," may be used for movements of CWD-exposed, CWD-suspect, and CWD-infected animals.

Interstate Movements Approved by the Administrator
Interstate movement of farmed or captive deer, elk, and moose may be allowed on a case-by-case basis when the Administrator determines that adequate survey and mitigation procedures are in place to prevent the dissemination of CWD and issues a permit for the movement. The animals also must meet the import requirements of the State of destination.

Approved States may request approval by the Administrator on a case-by-case basis for interstate movement under seal and by permit (VS Form 1-27) of farmed cervids from CWD-exposed, -suspect, and -positive herds to a recognized slaughter facility, to a known CWD-positive hunt facility, or to a hunt facility located in a CWD endemic region in another State if the source Approved State has considered other intrastate options for disposition and the receiving State officials agree to permit entry of these animals. The receiving State officials are to have adequate mitigation measures in place to ensure identification and containment of these animals, to limit their time in residence and termination, and to prevent dissemination of CWD. These animals are to be accompanied by a certificate issued by an APHIS or State representative or accredited veterinarian. The certificate is to state the destination of the animals, the purpose for which they are being moved, the number of animals covered by the certificate, the point from which the animals are moved interstate, and the name and address of the owner or shipper. All animals must retain official identification until death and all should be tested for CWD.

(8.4) Transiting

Cervids eligible to move interstate in accordance with the CWD rule, and meeting the conditions specified in 9 CFR 81.5, can transit States en route to their destination. These conditions are: (a) The farmed or captive deer, elk, or moose must be eligible to move interstate under Part 81.3; (b) the farmed or captive deer, elk, or moose must meet entry requirements of the destination State listed on the certificate or permit accompanying the animal(s); and (c) except in emergencies, the farmed or captive deer, elk, or

moose must not be unloaded until their arrival at their destination. The rule ensures farmed or captive cervids moved interstate are considered low risk for being infected with CWD based on defined farmed cervid herd and wild cervid population surveillance. Prior requirements that States may have had for transiting are preempted by this rule.

While it is not required, APHIS recommends producers and transporters provide a courtesy notification to any State through which they may transit en route to their final destination. This may be a benefit should emergencies arise and State assistance is needed.

Part B. Guidance on Responding to CWD-Affected Herds

The CWD regulations in 9 CFR part 55 describe minimum requirements in response to the finding of a CWD-affected herd in accordance with the national CWD HCP. The Program Standards also provide detailed descriptions of optional guidelines for complying with the legal requirements in the regulations in 9 CFR parts 55 and 81 and have been approved by the APHIS Administrator to meet the Federal rule requirements.

Information in this section further provides suggested best management practices and other mitigation methods recognized as effective that may be used by an Approved State and herd owner to investigate and manage CWD-affected herds. APHIS will serve in an advisory capacity on details presented in this section. Suggested best management procedures include quarantine, depopulation, cleaning and decontamination, epidemiology investigations, and development of herd plans.

In accordance with 9 CFR 55.1, only animals present in the original inventory at the time the herd was determined to be CWD-positive or exposed may be eligible for Federal indemnity on depopulation should Federal funding be available. Signed herd plans are required to receive Federal indemnity, to restore status to a herd in suspended status if exposed animals are not available for CWD testing, and to re-enroll in the Approved State CWD HCP if designated a CWD-positive or CWD-exposed herd.

(1) Herd Plan

A written herd plan is required for any CWD-positive and CWD-exposed herds that intend to re-enroll in the Approved State CWD HCP, and for release of quarantine on completion of the herd plan requirements. These individual plans are based on a risk evaluation of the affected premises and herd by State officials and provided to the owner for agreement. The plans may be reviewed by APHIS and State officials. Herd plans are to be signed by APHIS, the herd owner and the appropriate State officials, and should be adopted within 60 days of a confirmed diagnosis of CWD.

In general, a herd plan includes:

1. Specified means of identification for each animal in the herd.

2. Regular examination (time period as determined by a State official or APHIS employee) of animals in the herd by a veterinarian for signs of disease.

3. Reporting to a State official or APHIS employee of any signs of central nervous system or wasting disease in herd animals.

4. Maintaining records of births and deaths as well as of the acquisition and disposition of all animals entering or leaving the herd, including the date of acquisition or removal, name and address of the person from whom the animal was acquired or to whom it was disposed, and the cause of death, if the animal died while in the herd.

5. Testing of all mortalities 12 months of age or older. Records should be maintained for all samples submitted for CWD testing.

A herd plan may also contain additional requirements to prevent or control the possible spread of CWD, depending on the particular condition of the herd and its premises, including but not limited to:

1. Depopulation of the herd if funds for indemnity are available. Depopulation also may be accomplished by moving animals from CWD-positive, -suspect, and -exposed herds by permit

and under seal to a slaughter facility or to an appropriate hunt facility either within the State or to an appropriate hunt facility in CWD-endemic areas at the discretion of the State officials.

2. Specifying the time for which a premises must not contain cervids after CWD-positive diagnosis.
3. Removal of exposed or suspect animals from the premises if funds for indemnity are available or at the discretion of State officials.

4. Fencing requirements.

5. Selective culling of animals.

6. Restrictions on use and movement of possibly contaminated livestock equipment.

7. Cleaning and disinfection or other requirements. If a positive or exposed herd is depopulated, the written herd plan will consist only of premises cleaning and disinfection and restocking requirements.

A herd plan may be reviewed and changes proposed at any time by any party signatory to it in response to changes in the situation of the herd or premises. The plan may also be changed if the understanding of the nature of CWD epidemiology, or techniques to prevent its spread, improves. However, any proposed changes must be reviewed and approved by all signatories before they are adopted.

Additional information on CWD environmental contamination and recommended procedures for disinfection and decontamination of premises to be included in herd plans is provided in Appendix IV.

(1.1) Herd Plan: CWD-Positive Herds

A. Whole-Herd Depopulation With or Without Repopulation

1. If funds for indemnity are available, depopulation of the whole herd may be the preferred option for response to CWD-positive herds.

2. CWD-positive and exposed animals that are depopulated must be tested and disposed of according to VS guidelines for CWD carcass disposal (Section B.2 and Appendix V of these Program Standards) and all applicable Federal, State, and local regulations.

3. Herd plans are required to receive Federal indemnity for depopulation, disposal, and cleaning and disinfection of the premises; and for release of quarantine on completion of the herd plan requirements. Herd plans should include the information listed in Section B.1 and may also include a premises plan because of possible environmental contamination. Premises plans may include cleaning and disinfecting actions, future land use in terms of restocking, maintenance of perimeter fencing to prevent ingress or egress of cervids, and the time period for surveillance before interstate animal movement is allowed if restocking occurs.

B. Quarantine With or Without Selective Culling of Animals

If long-term quarantine of the affected herd instead of depopulation is implemented by State officials in discussion with the owner, then additional restrictions may be required on the cervids remaining on the premises.

1. After a risk evaluation of the quarantined herd, this plan may include euthanasia of selected animals depending on exposure if funds for indemnity are available or at the discretion of State officials. This will be followed by testing and disposal of those carcasses. Any CWD-positive animals must be disposed of according to VS guidelines for CWD carcass disposal (Section B.2 and Appendix V of these Program Standards) and all applicable Federal, State, and local regulations.

2. The herd may remain in quarantine for 60 months (5 years) from the last case or for a period of time as determined by the risk evaluation. The owner may be required to remove and CWD test any suspect animals at the discretion of the State officials.

3. The herd will have lost its program status and may only re-enroll in the Approved State CWD HCP after entering into a herd plan. Herd plan requirements must be completed for release of quarantine, and to regain certified status in accordance with the CWD regulations and Section A 2.5 in these Program Standards.

4. The owner should maintain an inventory complete with the following information for each individual animal:

   a. All identification (tags, tattoos, electronic implants, etc.)

   b. Date of birth and age

   c. Species

   d. Sex

   e. The date of acquisition and source of each animal that was not born into the herd

   f. The date of removal and destination of any animal removed from the herd (animals in quarantined positive herds may only be removed for destruction or under permit)

   g. Mortality date for animals dying within the herd and CWD official test results for all animals tested

   h. Method and location of carcass disposal

   i. Date of submission, submitter, and official CWD test results for samples required by the herd plan

   The inventory for a newly identified positive herd should be verified by a State official or accredited veterinarian and provided to APHIS within 30 days of the notification of the positive diagnosis. The owner will help complete the inventory verification. State or Federal personnel will verify this inventory annually.

5. The herd premises must have perimeter fencing adequate to prevent ingress and egress of cervids in accordance with 9 CFR 55.23. This fencing also must comply with any applicable State regulations. The fence should be structurally sound, maintained in good repair, and of sufficient construction to contain the animals. APHIS recommends the perimeter fencing to be a minimum of 2.4 meters (8 feet) high (See Appendix II).

   The program does not intend to have "double fencing" as a comprehensive program standard for farmed cervids. However, the risk of CWD transmission between farmed cervid and free-ranging cervid populations should be assessed by individual States and addressed by additional barrier requirements as necessary. In areas where CWD is not known to be present in free-ranging wild cervids, a second barrier is recommended that is adequate to prevent fenceline contact of wild cervids with a CWD-exposed farmed cervid herd. Examples of barriers are described in Appendix II.

   The effectiveness of these fencing requirements for the species included in the CWD rule is being evaluated and requirements may change based on future research findings.

6. The owner also must immediately report to an Approved State official or an APHIS employee (where applicable) any quarantined cervids that have escaped or disappear, or are otherwise missing from the premises as well as entry of any wild cervids into the facility. State officials may allow time for the herd owner to recapture the animal and work with the Approved State for decisions on disposition of the animal(s).

7. Herd surveillance (mandatory mortality reporting and CWD testing of animals of all ages that die or are euthanized) is to be conducted during the quarantine period. If the herd has re-enrolled in the Approved State CWD HCP, mortality reporting and CWD testing of animals 12 months of age or older must continue for 5 years to regain certified status.

8. If CWD continues to be detected and the producer decides that he or she will not be able to successfully manage the herd out of the disease, herd depopulation may be considered if funds for indemnity are available.

(1.2) Herd Plan: CWD-Exposed Herds

A trace-forward exposed herd is a herd that has received an animal from a CWD-positive herd within 5 years before the diagnosis of CWD in the positive herd. A traceback exposed herd is a herd in which a CWD-positive animal had formerly resided before diagnosis of CWD in the positive herd. If the positive animal was a natural addition to the CWD-infected herd being investigated, the origins of all purchased animals for the previous 5 years should be evaluated to locate a possible source herd for introduction of the CWD infection.

Trace-forward and traceback herds will immediately be placed in Suspended status pending an epidemiological investigation by APHIS or a State official. If the epidemiological investigation determines that the herd was not commingled with an animal from the CWD-positive herd, the herd will be reinstated to its former program status, and the time spent in Suspended status be counted in its herd status.

If the epidemiological investigation determines that the herd was commingled with an animal from the CWD-positive herd, the herd will lose its program status and be designated a CWD-exposed herd.

A. Herd Plans for Trace-Forward Exposed Herds

1. APHIS recommends that exposed animals traced to a herd be removed and tested:

   a. If the animal is CWD-positive, the herd is considered to be positive and handled as in Section B 1.1.

   b. If the animal is negative (not detected), no additional actions are required.

2. If an exposed animal traced forward to the herd is not removed, the herd plan should stipulate the following:

   a. The whole herd in which the trace-forward animals reside may remain in quarantine for 60 months (5 years) from the last case or for a period of time as determined by a risk evaluation at the discretion of the State officials. During this time the herd may undergo monthly inspections by State or Federal personnel with removal and CWD testing of any suspect animals. Exceptions to the inspection schedule may be allowed by the designated epidemiologist in consultation with the State or the ADD.

   b. If the herd has been participating in surveillance as part of the herd certification program, surveillance performed after arrival of the exposed animal may count as time in quarantine to establish or re-establish herd certification status at the discretion of the State official and APHIS.

c. The owner should maintain an inventory with the following information for each individual animal in the exposed herd:

- All identification (tags, tattoos, electronic implants, etc.)
- Date of birth and age
- Sex
- Species
- The date of acquisition and source of each animal that was not born into the herd
- The date of removal and destination of any animal removed from the herd (animals in quarantined exposed herds may be removed only for destruction or under permit)
- Mortality date for animals dying within the herd and CWD test results for all animals tested
- Method and location of carcass disposal
- Date of submission, submitter, and results for samples required by the herd plan

The inventory for a trace-forward exposed herd that chooses quarantine should be verified by a State official or accredited veterinarian and provided to APHIS within 30 days of the notification to the producer of the trace-forward exposed animals. The owner will provide the necessary assistance to complete the inventory verification. State or Federal personnel will verify this inventory record annually.

d. Exposed herd premises must have perimeter fencing adequate to prevent ingress or egress of cervids in accordance with 9 CFR 55.23. This fencing must comply with any applicable State regulations. The fence should be structurally sound, maintained in good repair, and of sufficient construction to contain the animals. APHIS recommends the perimeter fencing to be a minimum of 2.4 meters (8 feet) high. (See Appendix II).

The program does not intend to have "double fencing" as a comprehensive program standard for farmed cervids. However, the risk of CWD transmission between farmed cervid and free-ranging cervid populations should be assessed by individual States and addressed by additional barrier requirements as necessary. In areas where CWD is not known to be present in free-ranging wild cervids, a second barrier is recommended that is adequate to prevent fenceline contact of wild cervids with a CWD-exposed herd. Examples of barriers are described in Appendix II.

The effectiveness of these fencing requirements for the species included in the CWD rule is being evaluated and requirements may change based on future research findings.

e. Herd surveillance (mandatory mortality reporting and CWD testing of animals 12 months of age or older which die or are euthanized) is to be conducted during the quarantine.

f. If the producer chooses quarantine and CWD is diagnosed during the quarantine period, herd depopulation should be considered based on availability of Federal funds.

3. If an exposed animal traced to a herd has died and was not tested for CWD, was sold or moved elsewhere, and no longer resides in that herd, a risk evaluation should be conducted to determine the level of CWD risk associated with the length of time the exposed animal was in residence. This may include a review of all aspects of the producer's management, compliance, and recordkeeping to determine how best to manage the exposed herd, the extent of restrictions to movement of animals in the herd, and release of quarantines. A herd plan should be established to describe required surveillance activities and management practices to re-establish herd status. State officials and epidemiologists should determine if the herd in which the exposed animal currently resides will be subject to any quarantines or movement restrictions.

B. Herd Plans for Traceback Exposed Herds

1. If funds for indemnity are available, the preferred action in herds identified as traceback exposed may be whole-herd depopulation and testing. However, if the epidemiological investigation is able to determine the likely point of infection of the positive animal, depopulation of herds in which the animal resided before that point may not be necessary. If not already participating, these herds should be encouraged to enroll in the Approved State CWD HCP. Movement of exposed animals by permit and under seal to a slaughter facility or appropriate hunt facility should be considered as options for disposition.

   Animals that moved from traceback herds during the time the positive animal was in residence also should be traced.

2. If the herd owner decides against depopulation, the herd will remain under quarantine for 60 months (5 years) from the last case or for a period of time determined by a risk evaluation at the discretion of the State officials. The owner should agree to a herd plan which must be completed before release of quarantine. During this time, the herd plan will include:

   a. Periodic inspections by State or Federal personnel with removal and CWD testing of any suspect animals. Exceptions to the inspection schedule may be allowed by the designated epidemiologist in consultation with the State, the ADD, or both.

   b. If the herd has been participating in surveillance as part of the herd certification program, time in surveillance following the departure from the herd of the animal which becomes CWD-positive may count as time in quarantine to establish or re-establish herd certification at the discretion of the designated epidemiologist, APHIS employees, and State officials.

   c. The owner should maintain an inventory complete with the following information for each individual animal:

      - All identification (tags, tattoos, electronic implants, etc.)
      - Date of birth and age
      - Sex
      - Species
      - The date of acquisition and source of each animal that was not born into the herd
      - The date of removal and destination of any animal removed from the herd (animals in quarantined exposed herds may be removed only for destruction or under permit)
      - Mortality date for animals dying within the herd and CWD test results for all animals tested
      - Method and location of carcass disposal
      - Date of submission, submitter, and results for samples required by the herd plan

      The inventory for a traceback exposed herd that chooses quarantine must be verified by a State official or accredited veterinarian and provided to APHIS within 30 days of the notification to the producer of the herd as a traceback exposed herd. The owner will help complete the inventory verification. State or Federal personnel will verify this inventory annually.

   d. Exposed herd premises must have perimeter fencing adequate to prevent ingress or egress of cervids in accordance with 9 CFR 55.23. This fencing must comply with any applicable State regulations. The fence should be structurally sound, maintained in good repair, and of sufficient construction to contain the animals. APHIS recommends the perimeter fencing to be a minimum of 2.4 meters (8 feet) high. (See Appendix II).

The program does not intend to have "double fencing" as a comprehensive program standard for farmed cervids. However, the risk of CWD transmission between farmed cervid and free-ranging cervid populations should be assessed by individual States and addressed by additional barrier requirements as necessary. In areas where CWD is not known to be present in free-ranging wild cervids, a second barrier is recommended that is adequate to prevent fenceline contact of wild cervids with a CWD-exposed herd. Examples of barriers are described in Appendix II.

The effectiveness of these fencing requirements for the species included in the CWD rule is being evaluated and requirements may change based on future research findings.

e. Herd surveillance (mandatory death reporting and CWD testing animals 12 months of age or older which die or are euthanized) is to be conducted during the quarantine.

f. If the producer chooses quarantine and CWD is diagnosed during the quarantine period, herd depopulation should be considered.

(2) Quarantine

CWD-positive or exposed herds are to be issued quarantine or hold orders by the State official. Exposed animals in a positive or trace herd must remain on the premises unless a State or Federal permit for movement (such as VS Form 1-27) has been obtained.

APHIS defines quarantine as an order issued by a State prohibiting movement of animals from or into a premises for a given period of time.

If a captive cervid herd in which CWD is confirmed is not depopulated, the herd may remain in quarantine for 60 months (5 years) from the last case or for a period of time as determined by a risk evaluation at the discretion of the State official. State officials may modify a quarantine to permit cervid movement onto CWD-positive quarantined premises, such as a hunting facility, and all cervids harvested must be tested for CWD. Other stipulations may apply to the modifications.

The herd will have lost its program status and may only re-enroll in the Approved State CWD HCP after entering into a herd plan. Herd plan requirements must be completed to regain certified status.

(2.1) Release from Quarantine

Quarantine may be released only after all herd plan requirements have been met and completed, or as determined by the State official.

(3) Depopulation

If funds for indemnity are available, whole-herd depopulation and testing of all cervids on the premises may be the preferred action to be taken in response to a positive herd provided a signed herd plan is in place. A signed herd plan is required to receive Federal indemnity for depopulation, disposal, and cleaning and disinfection of the premises, and for release of quarantine once the herd and/or premises plan requirements are completed.

If funds for indemnity are available, depopulation and testing may be the preferred action for trace-forward exposed animals and traceback herds that are epidemiologically implicated as source herds or exposed herds. As determined by the State official, quarantined animals may be moved by permit (such as VS Form 1-27) under seal to a recognized slaughter establishment for slaughter. Quarantined animals may be approved by the APHIS Administrator to move interstate to a slaughter facility or to an appropriate hunting facility in a CWD-endemic region with the approval of the receiving State officials. These animals must have two forms of identification, one of which must be official, in accordance with 9 CFR 81.3. Meat and other cervid products derived from commercial slaughter for interstate commerce

are under Food and Drug Administration (FDA) jurisdiction and are not discussed in these Program Standards.

(4) Carcass Disposal

This section outlines the guidelines that States and herd owners may use for the disposal of carcasses from positive or exposed herds or from trace-exposed animals.

(4.1) Suitable Disposal Methods

Remains of CWD-positive animals should be disposed of in compliance with all Federal, State, and local regulations. Incineration, alkaline digestion, disposal of materials in appropriate landfills, and burial onsite are the most suitable options. Detailed disposal guidelines can be found in Appendix V.

(5) Sanitary Precautions and Biosecurity Practices for Herd Plans and Depopulations

Cleaning, disinfection, and decontamination recommendations for CWD-positive herds are located in the Herd Plan guidelines in Appendix IV. The following information on biosecurity should be included as general best management practices and is applicable for CWD-infected herds.

Delivery vehicles, such as feed trucks, should always follow good biosecurity and disinfection practices between premises. Owners should restrict entry of such vehicles onto infected premises or provide disinfection stations on exiting the premises.

Any third-party vehicle used to transport cervids should be cleaned and disinfected before and after transporting CWD-susceptible cervids. The owner should require the transporter to provide a statement that the truck or trailer was cleaned and disinfected, and should keep a copy of the statement.

Producer-owned vehicles such as cars, pickup trucks, and tractors only may be shared among herds or premises under common ownership. Producer-owned equipment for transport of animals should be cleaned and disinfected if it is to be used for multiple herds managed by the same producer. Other farm equipment that tends to be heavily contaminated with soil or feces, such as manure spreaders and drags, should not be shared among herds or premises unless it is cleaned and disinfected with each use. Producers should keep records of these activities which involve commingling of animals in those herds.

Other equipment that should not be shared unless herds are commingled includes, but is not limited to, feed bunks, water troughs, chutes, buckets, and multiple-use medical equipment (antler removal equipment, bolus guns, multiple-dose syringes, etc.).

For herds managed by the same owner, personnel working with these herds should wear different outerwear (e.g., boots and coveralls) when moving from one herd to another.

(6) Epidemiology

This section is an outline for States on epidemiological investigation methods and responsibilities for determining the source of infection as well as the extent of exposure when an infected animal has been identified.

(6.1) Responsibility

An epidemiological investigation will be conducted by a State representative once an animal has been confirmed to have CWD. When appropriate, and when there are available Federal funds, VS personnel will assist with the investigations. The investigation should be started within 7 business days of the laboratory confirmation by a State official or designee.

Where possible, VS personnel will work with the State and the District Office to prepare educational materials about CWD that can be provided to owners to mitigate future disease transmission.

(6.2) Investigation

The investigation identifies the source of infection in a herd as well as other animals that may have been exposed to CWD. See Appendix VI for an example of an Epidemiology Report template.
The investigation should identify:

1. Source of infection in a positive herd when the positive animal was a natural addition (born in the infected herd and resided there for its lifetime). The focus should be on how CWD may have been introduced into the herd (e.g., movement of other animals into the herd or potential exposure to infected wild cervids). The origin of all purchased animals into the herd should be evaluated to determine if the source of CWD infection can be identified.

2. Traceback herds – An exposed herd in which a CWD-positive animal resided in any of the 60 months before the diagnosis. If the positive animal was a natural addition, the origins of all purchased animals for the previous 60 months should be evaluated to locate a possible source herd for introduction of the CWD infection.

3. Trace-forward herds – A herd that has received exposed animals from a positive herd within 60 months before the diagnosis of CWD in the positive herd or from the identified point of entry of CWD into the positive herd.

4. Any other susceptible animals which may have been exposed to CWD from direct or indirect contact (e.g., wild cervid exposure).

(6.3) Traceback and Trace-Forward Notifications

Traceback and trace-forward herd owners and their respective State officials should be notified within 15 business days after their herds are identified as exposed. All notification should be provided in writing to the respective State or States and a copy provided to the ADD in the corresponding District Office even if the initial contact was verbal.

If these herds reside in States different than the positive herd, notification will be accomplished through the respective Federal or State official. On notification, actions regarding traceback and trace-forward herds enrolled in the national CWD HCP should be taken as prescribed in these Program Standards.

Appendix I: Animal Identification

The requirements for Official Animal Identification are described in 9 CFR 55.25.

Each animal required to be identified must have at least two forms of identification attached to its body. One of the animal identifications must be official animal identification with a nationally unique animal identification number that is linked to that animal in the CWD National Database (SCS –Core One) or equivalent State database.

The type of official identification device must be approved by APHIS. The devices can be an electronic implant (electronic identification device/EID), legible flank tattoo, legible ear tattoo, tamper-resistant eartag, or any other device approved by APHIS.

In accordance with 9 CFR 86.4, removal of official identification devices is prohibited except at the time of slaughter, at any location on the death of an animal, or as otherwise approved by the State or Tribal animal health official or a VS Assistant District Director when a device needs to be replaced.

In accordance with 9 CFR 86.1, an official eartag is defined as an identification tag approved by APHIS that bears an official identification number for individual animals. Beginning March 11, 2014, all official eartags manufactured must bear an official eartag shield. Beginning March 11, 2015, all official eartags applied to animals must bear an official eartag shield. The design, size, shape, color, and other characteristics of the official eartag will depend on the needs of the users, subject to the approval of the Administrator. The official eartag must be tamper-resistant and have a high retention rate in the animal.

The official identification number must use one of the APHIS-approved numbering systems to provide a nationally unique identification number. For the purposes of the CWD rule, and in accordance with 9 CFR 86.1, the official identification number must be a nationally unique number that is permanently associated with an animal and that adheres to one of the following numbering systems:

(1) National Uniform Eartagging System (NUES)
(2) Animal Identification Number (AIN)
(3) Location-based number system
(4) Any other numbering system approved by the Administrator for the identification of animals in commerce

The device should be applied by the owner of the herd or his or her agent and be linked to that herd in the National CWD Database (SCS –Core One) or equivalent State database. If a microchip is used and the animals are slaughtered under State or Federal meat inspection, it should be used in compliance with applicable State or Federal regulations.

The second animal identification must be unique to the individual animal within the herd and also be linked to that animal and herd in the National CWD Database (SCS –Core One) or equivalent State database. As an example, the unique Animal Identification Number may be used on two separate identification devices on the same animal to fulfill the identification requirements if desired.

Although not required in the CWD rule, it is recommended that all animal identification devices be visible on the animal from an appropriate distance to allow visual verification of the identification number on the device without animal restraint. Any animals in which identification cannot be visually inspected will need some form of restraint for confirmation during herd inventories.

The FDA Center for Veterinary Medicine regulates the marketing of implantable transponder devices (electronic identification devices/EID) for use in animals. Please contact the FDA or the manufacturer or distributor for information on approved EIDs. USDA's Food Safety and Inspection Service (FSIS) should be contacted regarding anatomic placement of the EIDs in animals that may be presented for slaughter in official slaughter facilities to determine if these devices pose a potential physical food safety hazard.

See APHIS Web site link for additional information on animal identification:
http://www.aphis.usda.gov/traceability/downloads/ADT_eartags_criteria.pdf

Appendix II: Fencing Requirements and References

The herd premises must have perimeter fencing adequate to prevent ingress or egress of cervids. In herd premises already existing at the time of the effective date of the CWD rule (August 13, 2012), fencing must comply with any existing State regulations or requirements. For herds established after the effective date of the CWD rule, the fence should be a minimum of 2.4 meters (8 feet) high and must comply with any other existing State requirements. In general, the fence should be structurally sound, maintained in good repair, and of sufficient construction to contain the animals.

Selected Studies on Farmed Cervid Fencing

VerCauteren, et al. (2010) evaluated the ability of wild-caught white-tailed deer to jump progressively taller woven-wire fences. They documented a 100 percent deterrence rate when the test fence was 2.4 m tall, suggesting that a 2.4 m fence will contain or exclude most deer under similar conditions. Other factors that may reduce a fence's effective height include topography, snow depth, and the motivation level of the cervid to penetrate the fence.

VerCauteren, et al. (2007a and b) also measured behaviors and contacts through game-farm fences between farmed and wild white-tailed deer in Michigan and between farmed elk and wild elk and mule deer in Colorado. All sites in Michigan employed a single 3 m high woven-wire fence. Fence types in Colorado included a single woven-wire fence (2.4 m high), double woven-wire fences separated by 1 to 4 m (2.4 m high), and a single woven-wire fence (2.4 m high) plus a 3-strand offset electric fence either inside or outside the woven-wire fence. The study recorded only two direct naso-oral contacts between wild and farmed deer in Michigan during more than 77,000 hours of camera monitoring. Conversely, 77 interactions were documented between wild and farmed elk involving naso-oral contact. No direct contacts were observed through double woven-wire fences. Risk of direct contact was about 3.5 times greater for single woven-wire fences compared to an offset electric fence attached to the single woven-wire fence.

Expanding on the offset electric fence type, Fischer, et al. (2011) examined the effectiveness of a baited electric fence, as an addition to an existing single woven- wire fence (2.4 m high), for reducing fenceline contact between captive elk. They reported 426 direct contacts between elk through the existing woven-wire fence during trials without the electric fence; 0 direct contacts occurred between adult elk or the woven-wire fence when the baited-electric fence was in place.

Literature Cited

Fischer, J.W., G.E. Phillips, D.M. Baasch, M.J. Lavelle, and K.C. VerCauteren, 2011. "Modifying elk (*Cervus elaphus*) behavior with electric fencing at established fencelines to reduce disease transmission potential." Wildlife Society Bulletin 35:9-14.

VerCauteren, K.C., M.J. Lavelle, N.W. Seward, J.W. Fischer, and G.E. Phillips, 2007a. "Fenceline contact between wild and farmed cervids in Colorado: Potential for disease transmission." Journal of Wildlife Management 71:1594-1602.

VerCauteren, K.C., M.J. Lavelle, N.W. Seward, J.W. Fischer, and G.E. Phillips, 2007b. "Fenceline contact between wild and farmed white-tailed deer in Michigan: Potential for disease transmission." Journal of Wildlife Management 71:1603-1606.

VerCauteren, K.C., T.R. Vandeelen, M.J. Lavelle, W. Hall, 2010. "Assessment of abilities of white-tailed deer to jump fences." Journal of Wildlife Management 74:1378-1381.

Appendix III: Sample Collection

When CWD is suspected in a live or dead animal, or when an animal dies and is 12 months of age or older, the owner must immediately report to a State official and ensure samples are submitted for CWD testing in accordance with APHIS instructions. State officials or APHIS employees may approve reporting schedules other than immediate notification when herd conditions or circumstances warrant it in the opinion of both the State and APHIS.

It is the responsibility of the herd owner to have samples collected and preserved properly or to preserve the head by refrigeration for sampling. Refrigerated heads may be shipped to an APHIS-approved CWD laboratory for this purpose. Prior notification and approval is required from the laboratory before shipping whole heads. Owners must ensure that fresh samples or heads can be refrigerated over weekends and holidays. A link to CWD approved labs is:
http://www.aphis.usda.gov/animal_health/lab_info_services/approved_labs.shtml

The obex and medial retropharyngeal lymph nodes (MRPLNs) are collected on all CWD-susceptible species. Scientific evidence shows that although MRPLNs may be early indicators of CWD in deer and the obex may be an early indicator of CWD in elk, the sensitivity for early CWD detection is increased in both deer and elk when both obex and MRPLNs are tested. The obex and MRPLNs should be fixed in 10 percent neutral buffered formalin for IHC or submitted as fresh tissues for ELISA as described in this Appendix and instructed by the CWD approved laboratory.

Animal identification (eartags, tattoos, etc.) is submitted with a portion of the skin (hide) or ear attached fresh or frozen, and must be kept linked to the diagnostic specimens. Skin (hide) samples with attached identification may be used in lieu of ear sections to avoid any complications in taxidermy procedures. Including animal identification provides verification of sample identity. The skin (hide or ear) samples can be used for DNA testing if there is some dispute regarding origin of the sample. Chain of custody principles should be followed in the field and the laboratory to assure sample integrity. The owner may observe the sampling and labeling procedures to assure his or her sample is properly identified.

A link to VS Form 10-4 can be found in in Appendix VII.

The collector will include the following with each diagnostic submission:

1. Completed VS Form 10-4 or an equivalent form with the same information found on the 10-4. (**Note:** Complete VS Form 10-4 with the approval of the State official or accredited veterinarian who will in turn obtain the approval of the Assistant District Director).

   In the case of whole heads submitted to a laboratory by the owner, the owner's name, address, phone number, herd ID, and the animal's ID numbers, age or date of birth, breed, sex, and any clinical signs observed should be included with the shipment.

   All ID devices, tattoos, and any brands on the animal taking care to avoid complications in taxidermy.

2. Age of animal based on owner records.

3. Herd ID, species, breed, and sex of animal.

4. Obex/brainstem and MRPLN collected and packaged as described below.

5. Any additional samples as requested by the State veterinarian or Assistant District Director, including samples requested for research. (Any research will be done at no charge to the owner.)

A. Safety Precautions

It is the responsibility of the collector to take appropriate safety precautions. Measures should be taken to avoid contact with specimens. To minimize exposure to pathogens, the following precautions should be taken:

1. Wear personal protective equipment (PPE) at all times. (See Section B below.)

2. Cover cuts, abrasions, and wounds with waterproof dressing if not covered by PPE.

3. Wear gloves while handling specimens and formalin. Optionally, use face and respiratory protection, including a well-fitted respiratory mask and face shield or goggles to protect from infective droplets or tissue particles.

4. Use 10 percent neutral buffered formalin in a well-ventilated area.

5. Take steps to avoid creating aerosols, splashes, and dusts.

6. Wash hands and exposed skin following collection procedures.

7. Wash and disinfect protective clothing and instruments thoroughly after use. Use 50 ounces (6 1/4 cups) bleach to enough water (78 ounces or 9¾ cups) to make 1 gallon of disinfectant solution; this solution will remain effective at room temperature (at least 18.3 °C or 65 °F) for 1 hour.

8. If rabies is suspected, do **not** proceed with any tissue collection. Instead, contact the approved laboratory for instructions on submission of the entire head to the laboratory for rabies testing. After rabies testing is completed, the laboratory will proceed with CWD sampling on rabies-negative brains.

B. Personal Protective Equipment

Personal protective equipment (PPE) is designed to minimize exposure to pathogens while collecting samples.

According to the Occupational Safety and Health Administration, PPE is defined as "specialized clothing or equipment worn by employees for protection against health and safety hazards." PPE is designed to protect many parts of the body (i.e., eyes, head, face, hands, feet, and ears.).

PPE is selected based on the environment, physical hazards, and ability to complete the task. PPE is a balance between protection and comfort. PPE should protect an individual from the physical hazards of the collection environment while allowing the individual to comfortably collect specimens. Even though the environment where collecting specimens will differ, the following PPE should be worn at all times during collection of CWD specimens:

1. Skin Protection

   Protect your skin from contact with fluids during specimen collection. Wear waterproof coveralls, preferably disposable, or coveralls with a waterproof apron and forearm protectors.

2. Eye and Face Protection

   Protect your eyes and face from any aerosols, splashes, or dusts that may be created while collecting specimens. Eye protection includes safety glasses, safety goggles, or a face shield.

3. Hand Protection/Gloves

   a. Wear metal or mesh gloves. Always wear the cut-resistant glove (Hantover, Koch, or Packer) on the hand that is not holding the knife. Find a cut-resistant glove that fits against your skin and then wear a rubber glove on top of it.

   b. Wear latex or nitrile examination gloves or thick rubber gloves that extend halfway up the forearm. Many people prefer the long, thick rubber gloves for the added protection.

4. Foot Protection

   Protect your feet from injuries such as spills or splashes, impact, compression, or exposure. Wear steel-toed rubber boots when collecting specimens. If steel-toed boots are not available, pullover rubber boots are acceptable.

5. Respiratory Protection

   Face masks or respirators are recommended if the environment includes aerosols, splashing, or flying debris as may be encountered with certain methods of brain removal or tissue handling. CWD cannot be transmitted through the air or to humans. However, other zoonotic diseases such as rabies may be present during CWD collection. Also, *Listeria monocytogenes* and *Arcanobacterium pyogenes* are each known to cause brain abscesses in cervids; *Listeria* sp. should be considered a potential zoonotic agent.

Instructions for Veterinarians and Animal Health Technicians:

1. Collector's Responsibility

   Specimens submitted to NVSL or the approved laboratories should be traceable to the source animal and farm. The sample collector should follow all instructions for sample collection, completing VS Form 10-4 or its equivalent and labeling sample containers. The sample collector must accurately complete the specimen collection and submission process. When collecting specimens:

   a. Properly collect brainstem with obex, and at least one MRPLN. Both left and right MRPLN are preferred.

   b. Correctly label specimen collection containers.

   c. Correctly package specimens to meet Federal transportation guidelines. For Category B (UN3373) packaging and shipping details, contact the receiving laboratory, or NVSL, or visit the following Web site: www.aphis.usda.gov/animal_health/lab_info_services/packaging_labeling.shtml

   d. Properly complete the specimen submission form (VS Form 10-4 or electronic 10-4, or equivalent submission form). Be sure to indicate whether the animal was an exposed animal or an animal with no known exposure. Also indicate whether the animal was exhibiting clinical signs. If the animal exhibited clinical signs, list the signs in the Additional Data Section of the VS Form 10-4 or equivalent form.

   e. Make four copies of the completed VS Form 10-4 or equivalent form:
      - One for your files (submitter's copy)
      - One for the animal owner or collection site
      - One for the VS District Office
      - One to be submitted with the specimen

f. Follow the laboratory's procedure for notifying the laboratory of incoming specimens.

g. Contact the delivery service. Ensure that the package containing any fresh tissues for CWD testing will be shipped with ice packs for overnight delivery to the laboratory.

2. Sample Quality

A list of laboratories approved to conduct CWD testing is available at: http://www.aphis.usda.gov/animal_health/lab_info_services/approved_labs.shtml

All samples should be collected and submitted to the lab irrespective of the state of autolysis. Approved labs should evaluate the condition of the autolyzed samples to determine if the samples are of sufficient quality to be reliably tested or if the samples should be sent directly to NVSL.

3. Labeling Sample Containers

Properly label all specimen collection containers. The information on the label provides detailed information to the laboratory regarding the specimens. The sample number or sample bar code on the container must be the same as on the completed VS Form 10-4 (or equivalent form).

Clearly label both the top and the sides of the sample container. Identify the sample by typing the information, using a permanent marker, or affixing the bar code (if available). Verify that the sample number that appears on the top and side of the sample container and the completed VS Form 10-4 (or equivalent form) are identical.

The side label includes:

a. Date of collection

b. Producer name

c. Species

d. Type of specimen

e. Official animal ID number

f. Sample ID number (number assigned to this sample on the VS Form 10-4 or equivalent form)

4. Samples and Sample Packaging

Properly preserve CWD specimens to ensure accurate test results. CWD diagnosis may require the submission of fresh and fixed specimens.

Fresh tissue specimens are used for Western blot and ELISA assays. *Fresh tissue specimens must be kept chilled.* While dry ice may be used, it is usually best to ship the chilled tissues overnight on ice packs.

Formalin-fixed specimens are used for IHC testing, histopathology, and may be acceptable for DNA comparison (although fresh or frozen tissues are preferred for DNA testing). Submerge the specimen in 10 percent neutral buffered formalin (follow the guideline of 10 parts buffered formalin per 1 part specimen). ***Do not freeze the formalin-fixed specimens.***

Use the following table as a guide for proper tissue specimen collection for routine testing, and for exposed animals, suspect animals, and animals with specific clinical signs suggestive of CWD.

Animals with "specific clinical signs" include those that are nonambulatory, antemortem condemned or die before slaughter, or are ataxic. Suspect animals are highly suspicious for CWD because they are exhibiting central nervous system (CNS) signs.

Suspect and presumptive-positive animals should be submitted on separate VS Form 10-4s and shipped promptly to allow NVSL to prioritize testing these cases. **Note:** If rabies testing is required, contact the laboratory for instructions on submitting the entire head. After rabies testing is completed, the laboratory will proceed with CWD sampling on rabies-negative brains from animals presenting with neurologic symptoms, and/or are unthrifty (debilitated), may be salivating, or exhibiting nonspecific respiratory signs.

Ensure the sample container correctly lists all specimens included.

Tissue specimens for CWD testing – Use single container for each animal

10 percent neutral buffered formalin: Histopathology and IHC	**Fresh: Western blot and ELISA**
Left and Right MRPLNs	Left and Right MRPLNs
Obex with 1-2 cm brain stem (including the apex of the "V" in the obex)	Obex with 1-2 cm brain stem (including the apex of the "V" in obex)
Tonsils (optional)	Tonsils (optional)
Animal ID device(s) Collect all animal ID devices with a quarter-sized piece of tissue (ear, hide, etc.) attached to each device. This will allow DNA verification if necessary. This should be kept fresh, but some laboratories will accept ID tissue samples in formalin. Verify with the receiving laboratory.	Animal ID device(s) Collect all animal ID devices with a quarter-sized piece of tissue (ear, hide, etc.) attached to each device. This will allow DNA verification if necessary. This should be kept fresh, but some laboratories will accept ID tissue samples in formalin. Verify with the receiving laboratory.

5. Collection Procedures

The collection of the obex and MRPLNs can be completed using several methods. However, these collection procedures describe the preferred methods to prevent inadvertent damage to the tissues during collection. Other methods may be used. Contact an experienced professional for more information regarding alternative collection methods.

The link to the APHIS CWD Web site to find the CWD Program Sample Collection Guidance with dissection photos and instructions can be found in Appendix VII.

The following equipment will help ensure proper specimen collection:

a. Sharp boning knives

b. Disposable scalpel blades or disposable scalpels (a large scalpel blade is acceptable)

c. Brown-Adson or rat-tooth forceps

d. Meat-cutting bone saw, hacksaw, or electric saw when brain removal is required

e. Disposable cutting surfaces such as cardboard, plastic, or Styrofoam

f. Small hand nippers can be used on the hyoid bones or you may cut through at the soft cartilage of the joint using a knife

g. Sharp stainless steel scissors

h. Brain stem/obex spoon, grapefruit knife, or other brain stem scoop

6. Obex Collection Procedure (Via Foramen Magnum)

a. Incise the head of the animal at the atlanto-occipital joint (between skull and first vertebra). Cut behind the back of the ears and extend the cut around and through the front of the larynx. Sever the brain stem as far to the posterior as possible during the removal process.

b. Position the head upside down (ventral side up). Locate the occipital condyles and foramen magnum (FM). Locate the brain stem inside the FM. Trim the dura mater around the brainstem and cut the attached cranial nerve trunks.

c. Gently lift the brain stem with forceps and insert the spoon into the **dorsal** aspect of the FM between the brainstem and **dorsal** calvarium.

d. Advance the spoon 2-3 inches rostrally until it contacts bone to sever the cerebellum.

e. Reposition the spoon in the **ventral** aspect of the FM between the brainstem and the **ventral** calvarium. Advance the spoon until it contacts bone and transversely sever the brain stem.

f. Remove the brain stem using the spoon and forceps. Examine to ensure the proper obex sample (bifurcation or "V") is preserved.

g. Further trim the brain stem section by making a transverse cut 3/4 inch in front of the "V" shape bifurcation and an equal distance behind the bifurcation for good fixation.

For IHC testing: Place the trimmed obex and brainstem pieces in a jar of 10 percent neutral buffered formalin (10:1 ratio of formalin to tissue sample).

For ELISA testing: Place the fresh obex sample and trimmed pieces in a conical tube (do NOT use formalin).

7. Medial Retropharyngeal Lymph Node (MRPLN) Collection Procedures

The MRPLNs are medial to the stylohyoid bones on the dorsolateral surface of the pharyngeal muscles and dorsal to the carotid artery.

a. With the head positioned upside down, locate the esophagus and trachea in relation to the FM.

b. Lift the trachea and dissect muscles forward of the FM (rostrally). Locate the left and right medial retropharyngeal lymph nodes (RPLN) halfway between each corner of the jaw bone and the FM, caudal to the nasopharynx, and deep to the salivary gland. Lymph node consistency is much firmer and rounder than the surrounding tissue.

c. Remove each left and right medial RPLN and longitudinally incise each LN to confirm lymphoid tissue.

For IHC testing: Place the medial RPLNs in the same formalin jar with the obex.

For ELISA testing: Place the fresh medial RPLNs in labeled whirl-pak bags (do NOT use formalin).

8. Head Removal and Whole Head Packaging Procedure That May be Used by Owners for Submission to Laboratory

It is best to first contact the approved laboratory for instructions on submission of whole heads for CWD testing. Some laboratories may not accept whole heads.

Tools:

a. Sharp boning knife

b. Two heavy duty plastic bags and ties

c. If shipping the head, use shipping container with cooler, large heavy-duty plastic bag, absorbent material and four frozen cool packs. Contact your inspector or the VS office serving your State for shipping containers. A list of State contacts can be found at www.aphis.usda.gov/animal_health/downloads/vs_poc.pdf

Procedures

a. If the carcass is intact, remove the head. This is done at the atlanto-occipital joint, which is where the skull meets the first cervical vertebrae.

b. Position the animal in ventral recumbency (lying on its abdomen).

c. Remove the head at the hinge joint where the skull meets the first cervical vertebrae (just behind the ears) using the following steps:

- To locate the "hinge" area where the skull meets the first cervical vertebrae, grasp the nose and move the head up and down to locate the joint.
- Insert the knife into the neck between the first cervical vertebrae and the throat. Cut downward (ventrally) with blade directed away from you through the throat tissue and skin. (Cutting down through the skin readily dulls the blade.)
- Cut down to the membrane that covers the spinal cord; cut through the membrane exposing the spinal cord. Then cut the spinal cord as far from the head (caudally) as possible so that it is kept as long as practical.
- Cut the lateral ligaments connecting the skull to the vertebra in a ventral to dorsal direction on both sides. This is usually best accomplished with the tip of the knife directed between the skull and vertebra.
- Once the lateral ligaments have been severed, cut through the remaining tissue to remove the head from the carcass.

Maintain any animal identification attached to the ears (eartags, etc) in place and double bag the head. Secure each bag in a manner that will prevent leakage by tying a knot in the bag or using twist ties, string, or cord.

Chill the head before placing in the cool box and refrigerate the head until and during shipment to the laboratory in the cool box.

d. To pack the cool box: Put cool packs in the bottom, insert large plastic bag, insert absorbent material, insert double-bagged heads, and seal the outer plastic bag. Place cool packs on top of bag and close cooler top. Insert submission form between cooler top and exterior box. Ship overnight. Use at least four chill packs per box and an additional chill pack for each additional head if more than two heads are shipped in the same cool box.

Appendix IV: Guidelines on Environmental Contamination and Recommended Procedures for Disinfection and Decontamination of Premises

Chronic wasting disease (CWD) is an infectious disease of cervids. The agent is believed to be transmitted laterally. Current models show that environmental contamination may be important in transmitting and perpetuating the disease. Once a CWD-positive animal is identified on a premises, the premises should be quarantined until cleaning and decontamination procedures have been performed. This is recommended to reduce the risk of CWD exposure to and infection in cervids that are restocked on that site and as described in the herd plan.

These guidelines base the suggested preferred herd plan on depopulation of the entire herd following detection of the index positive animal. If a producer chooses long-term quarantine, additional restrictions on the herd may be required and will be specified in the herd plan. The State will give the plan to the owner of the premises for agreement. The basic guidelines below provide a framework for developing these herd plans.

None of the following cleaning and inactivation procedures guarantees elimination or inactivation of the infectious prion agent; however, the methods listed below are the most effective procedures to reduce prion levels and activity based on current information. These recommended procedures may be altered as new information becomes available.

Principles and Approach

The primary methods of CWD transmission and the time from infection to shedding are not known. Therefore, it is assumed that animals may shed the CWD prion into the environment before the onset of clinical disease. Published scientific studies have reported that the CWD prion may be shed into the environment via saliva, urine, and feces. Prions resist breakdown in the environment (i.e. to exposure to sunlight, freezing, or desiccation) but may slowly break down with time.

Decontamination procedures are directed at portions of the facility or items most likely to harbor the agent. Areas where animals (particularly CWD-positive animals) have resided will be the most contaminated. These areas should be evaluated by:

1. Assessing the facility in detail to document areas of animal congregation or particular movement patterns.

2. Characterizing the entire facility in terms of concentration of animals over time. This includes identification of fence lines (past and present), pens, corrals or handling facilities, watering and feeding areas (including natural water sources), points of concentration in a landscape (i.e. sheltered areas, woodlots etc.), drainage areas, and calving areas.

3. Identifying where known positive or suspicious animals resided relative to the areas of animal concentration. In the case of clinical animals, identify those areas where they resided during the time they were clinical.

4. Considering the physical nature of surfaces as well as topography and drainage of the area that might create concentration of the agent.

Categorization of Premises

Premises are categorized as premises with "No to Minimal Environmental Contamination" or "Moderate to Severe Environmental Contamination". Where applicable, the State or Federal designated epidemiologist, with concurrence of the State or APHIS veterinarians, will assess the premises.

Factors Used in Decisionmaking

1. Origin of the positive animals (born to the premises or introduced).

2. Herd history verified through records to give confidence in the herd CWD status (i.e., degree of certainty, or uncertainty, in relation to possible unreported cases).

3. The number of CWD cases (clinical and preclinical) originating from or occurring over time on a premises.

Basic Definitions for Categories

1. No to Minimal Environmental Contamination: A premises where there is little evidence that there has been transmission on the premises and there is no evidence of longstanding infection of the herd. The number of cases is minimal and history and records indicate that the animals likely contracted the disease on another premises (i.e., purchased or trace animals). The animals are preclinical at the time of CWD diagnosis or are early in the clinical course of the disease.

2. Moderate to Severe Environmental Contamination: Those premises where there is evidence that CWD has been identified in multiple animals; or those premises where a positive animal was exposed in another herd and dies of CWD or is euthanized late in the clinical course of the disease (i.e., animals are not removed from the herd while they are preclinical or early in the clinical course of the disease).

Recommended Procedures for Disinfection and Decontamination of Premises

None of the following suggested disinfection and inactivation procedures will guarantee elimination or inactivation of the infectious prion agent. However, based on current information on the efficiency under laboratory conditions of the disinfection methods listed, it is likely that these procedures will reduce the amount of infectivity in the environment. Until more specific information becomes available, good sanitary practices are recommended for all cervid husbandry activities. The following methods below should be applied where infected or exposed animals have been housed or maintained.

A. No to Minimal Environmental Contamination Premises

<u>Pastures</u>
Intensive measures are not required.

<u>Dry Lot Where CWD-Positive Animals Have Been Held in Close Confinement</u>
Remove organic materials (manure, feed, bedding, and other organic material) and bury the removed material in areas not accessed by farmed or wild animals. Composting may be used to reduce the volume of organic materials. Composted material should be buried deeply, incinerated, or digested by alkaline hydrolysis after composting is complete. Composting alone does not inactive prions.

<u>Earth Surfaces Inside Structures or Used for Confinement</u>
Remove and dispose of the organic material as described for dry lot. Bury the removed material in areas not accessed by farmed or wild cervids.

Nonearth Surfaces
(These include cement, wood, metal, tools, equipment, instruments, and other artificial items)
Remove all organic material or items (such as wooden feed bunks) and incinerate by high temperature incineration methods if possible.
Clean and wash surfaces and other items using hot water and detergent.
Allow all surfaces, tools, and equipment to dry completely before disinfecting and sanitizing using the methods outlined in Section B below.

Restocking
The premises may be restocked with non-cervid species immediately after decontamination. The premises may be restocked with cervids after decontamination but the cervid herd should immediately enroll in the Approved State CWD HCP. All mortalities 12 months of age or older must be reported, investigated, and CWD tested. If the premises are located in a CWD-endemic area, or any area where CWD has been found in free-ranging cervids, restocking with cervids is not recommended. If restocking with cervids is done, then additional biosecurity practices such as additional fencing or other barriers to minimize CWD exposure should be considered.

Fencing Requirements
Fences should be maintained to prevent ingress and egress of cervids.

B. Moderate to Severe Environmental Contamination Premises

Pastures
Attempts to inactivate the prion agent on the landscape using caustic chemicals will destroy vegetation and should only be considered where exclusion of animals from high-use areas is not an option. Such decisions should be approached on a case-by-case basis.

Small pastures where CWD-positive animals have resided or particular areas in a pasture where animals are known to have congregated may be treated as follows:

1. If practical, till soil under or do not use area to graze susceptible animals.

2. If this is not practical, do not use the pasture until the animal waste has decomposed and the weather has had an opportunity to dilute any infectivity.

3. Organic material (hay, accumulations of manure, etc.) in areas of congregation should be buried. Congregation areas include animal shelters, feeding grounds, and water sources (if applicable).

Dry Lot Where CWD-Positive Animals Have Been Held in Close Confinement (this includes but is not limited to corrals, pens, stalls, and alleyways or pathways)
Remove organic materials (manure, feed, bedding, and other organic material). This material may be buried deeply onsite in areas not accessed by farmed or wild animals, incinerated, or chemically digested. Composting may be used to reduce the volume of organic materials. Composted material should be buried deeply, incinerated, or digested by alkaline hydrolysis after composting is complete. Composting alone does not inactive prions.

In addition, removal of the top 1 to 2 inches of soil may help to reduce surface contamination. The soil removed may be buried deeply or incinerated.

Earth Surfaces Inside Structures or Used for Confinement
Remove and dispose of the organic material as described for dry lot. When practical, remove the top 1 to 2 inches of soil to help reduce surface contamination. Bury the removed material in areas not accessed by farmed or wild cervids.

Nonearth Surfaces
(These include cement, wood, metal, tools, equipment, instruments, grain feeders, hay feeders, panels, chutes, and working facilities).

1. Remove all organic material and deeply bury the removed material onsite in areas not accessed by farmed or wild cervids.

2. Clean and wash surfaces of items using hot water and detergent. A high-pressure washer after initial manual removal of organic debris and cleaning surfaces is recommended for thorough cleaning of large equipment items. Allow all surfaces, tools, and equipment to dry completely before disinfecting and sanitizing using the following suggested methods:

   a. Autoclave instruments, small tools, and other items at 136° C (277° F) for 1 hour. This method is more effective when preceded by the treatment described in b or c, below.

   b. To clean dry surfaces, apply a 2 percent-available chlorine solution (equivalent to about 20,000 ppm available chlorine at room temperature (at least 18.3° C [65° F]) for 1 hour. This can be achieved by mixing 50 ounces [6 1/4 cups] of household bleach (sodium hypochlorite) with enough water (78 ounces or 9¾ cups) to make 1 gallon of solution. Rinse to remove solution after 1 hour of contact time.

   c. For environmental purposes, use this disinfection method when the preceding methods are not available: Expose dry surfaces by applying a 1-molar solution of sodium hydroxide (an approximately 4 percent solution [5 ounces sodium hydroxide dissolved in one gallon of water]) at room temperature (at least 18.3° C [65° F) for at least 1 hour. Rinse equipment to remove solution after 1 hour of contact time.

Precautions: Professional judgment should be exercised in the choice and use of disinfectants. All disinfectants are hazardous to humans, animals, and the environment. Label directions should be carefully read and followed. If corrosive disinfectants are used directly on metal items, the items must be thoroughly rinsed with fresh water to minimize damage.

Synonyms for sodium hydroxide (NaOH) are caustic soda, soda lye, and sodium hydrate. Sodium hydroxide is a white, brittle solid that dissolves readily in water to form a strong alkaline and caustic solution and is used as an alkalinizing agent. Sodium hydroxide is very caustic and in solution is ***extremely corrosive***. For environmental reasons, only use this disinfection method when the preceding method is not available.

Disinfectants, especially in concentrated form, may irritate the skin, eyes, and respiratory systems. Protective equipment such as coveralls, rubber boots, rubber gloves, masks, or respirators as well as eye protection should be worn while mixing and applying some disinfectants. If areas of the body are exposed directly to a disinfectant, they should be washed thoroughly with water. Any employee should notify his or her supervisor if excessive human or animal exposure to disinfectants occurs or if there is an accidental release into the environment.

Restocking
The premises may be restocked with non-cervid species immediately after decontamination. If the premises is restocked with cervids after decontamination, the cervid herd should immediately enroll in the Approved State CWD HCP. CWD test mortalities aged 12 months or older. If the premises are located in an endemic area, or any area where CWD has been found in free-ranging cervids, restocking with cervids is not recommended. If restocking with cervids is done, then additional biosecurity practices such as additional fencing or other barriers to minimize CWD exposure should be considered

Fencing Requirements

Fences should be maintained to prevent the ingress and egress of cervids.

Appendix V: Carcass Disposal of CWD-Positive Animals or Animals of Unknown Status

Destruction or inactivation of PrPres is difficult and few treatments have been documented as completely successful. In addition, there are currently no quality assurance or quality control methods to ensure successful prion inactivation. For that reason, we have provided a list of processes reported to reduce the amount or activity of the infectious prion material.

The following is a list of acceptable options for disposal of animals infected with chronic wasting disease (CWD) and animals from CWD-positive or exposed herds euthanized as part of a diagnostic or depopulation effort.

Options:

1. Incineration of carcasses in an Environmental Protection Agency-approved conventional incinerator, air curtain incinerator, or cement kiln. After incineration, ashes should be buried in an active, licensed landfill at a depth that meets local and State regulations to prevent scavenging or contamination of groundwater. Incineration of animals onsite with a mobile incinerator is an option as it presents the least risk of spreading contaminated materials by moving animals. However, mobile incinerators require large amounts of fuel to maintain an even, high temperature appropriate for prions.

2. High-pressure alkaline hydrolysis of carcasses followed by burial of the treated material in an active, licensed landfill at a depth that meets local and State regulations.

3. Removal of high-risk materials such as heads (with brain), spinal cords, and lymphoid tissues (including entire gastrointestinal tract) for incineration or alkaline hydrolysis followed by burial of the treated high-risk materials as well as the remainder of the carcass in an active, licensed landfill at a depth that meets local and State regulations for animal carcass disposal. Please note that CWD prions may be found throughout the body including skeletal muscle; therefore, this approach is not the most effective for prion reduction.

4. Rendering of carcasses. If a rendering facility is used, it must be one that does not provide rendered material for use in animal feeds. Food and Drug Administration Center for Veterinary Medicine guidance on rendering can be found at: www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052506.pdf

   Burial of carcasses in a licensed, active landfill or burial onsite at a depth that meets local and State regulations for animal carcass disposal are options for disposal of CWD-infected carcasses, but these methods do not inactivate prions. Furthermore, composting does not inactivate prions.

   With all of the recommended methods, carcasses must be carefully transported between the collection location and treatment or burial sites to prevent the spread of potentially contaminated and infectious materials. Precautions should be taken to prevent ashes, blood, tissues, or feces from leaking from transport vehicles.

   APHIS recommends first testing individual animals for prion protein by IHC or other official test and delaying disposal until test results are obtained. Subsequently, disposal options involving incineration, alkaline hydrolysis, or rendering with burial of the treated materials can be used for the positive animals, and simple carcass burial in a landfill or onsite may be used for the negative animals.

These options provided are based on the available science of CWD inactivation. Changes will be made as appropriate as new information on CWD becomes available.

Appendix VI: CWD Epidemiology Investigation and Report Template

A. Outline of Information

Preliminary Information: The following format is used to generate a summary of pertinent premises information. This summary typically precedes each situation report and does not change unless new or additional information becomes available.

(1) Information about **Owners:**
- (a) Owner name or names.
- (b) Owner physical addresses (if different from facility address) including county.
- (c) Other contact information (i.e. home phone, cell phone, or email address).
- (d) Herd or farm manager names and contact information (if applicable).
- (e) Facility or premises owners and contact information (if applicable).

(2) Information about the **Index Case**:
- (a) Index animal: Species, age, gender, breed, color, all forms of identification, other information or descriptions if applicable.
- (b) Clinical signs exhibited by index animal? If so, list signs, duration, and whether died or euthanized.
- (c) Location of index animal when clinical signs first observed (mortality/slaughter surveillance, on-farm, first-point, or other)
- (d) CWD test confirmed positive (date, screening laboratory, other necessary information)?

(3) Information about the **Facility or Premises:**
- (a) Physical location of facility (i.e., street address, GPS coordinates).
- (b) Type of facility (i.e. breeding, feeding, exhibition, hunt preserve, other).
- (c) Other facilities associated with index facility or premises?
- (d) When was facility established?
- (e) General description of facility (i.e., total acreage, confinement or modified confinement, type and condition of fencing and enclosure, flooring, traffic in and out of facility, other necessary information).
- (f) A map or schematic of the facility will help officials understand the situation.
- (g) Biosecurity of facility? Risks? Implementation?
- (h) Handling facilities available on premises?

(4) Information about **other animals** in the index facility or adjacent to the facility or premises:
- (a) Number and type of animals housed at facility or premises (**physical inventory with identification**).
- (b) Other susceptible animals or species located on facility.
- (c) Any other animals or species on facility affected? Clinical signs observed?
- (d) Number of other animals on facility affected?
- (e) Transmission believed to have occurred on premises?
- (f) Testing history and level of testing for disease of concern (required monitoring or surveillance, etc.)
- (g) Proximity of other susceptible species in adjacent facilities or enclosures or susceptible wild species. Potential for exposure to affected animals at facility?
- (h) Types of facilities adjacent to the index premises and related information (i.e., distance, number of animals, type of facility, nature of exposure).
- (i) Facility quarantined? Conditions of quarantine? Level of biosecurity?

(5) Facility Management Information:
   (a) Identification systems used at facility? Any official identification in use?
   (b) Level of management regarding but not limited to recordkeeping and availability of herd records.
   (c) Management practices such as vaccination programs, feed sources and storage, sources of herd additions, marketing practices, animal movements, level of biosecurity maintained, and other areas.

Follow-up Information to be Included in Situation Reports or Final Narrative:

(1) Records/Regulatory issues:
   (a) Record review: Herd additions and dispositions in preceding years; confirm existing inventory.
   (b) If State requires an annual inventory, are owner's records consistent with State's records?
   (c) Date of last regulatory inspection and findings.
   (d) Has the owner complied with applicable regulatory requirements?

(2) **Animal Movements** (i.e., traces):
   (a) Movements in and out of the facility without change in ownership and reasons for movements (such as exhibition, breeding, or seasonal grazing).
   (b) Movements into facility
      i. Purchase of herd additions or trades to acquire new additions.
   (c) Movements out of facility
      i. Sale or marketing of animals (slaughter, exhibition, etc.) and channels (such as auction market, private treaty, commercial feeding or slaughter, or hunting).
      ii. Mortalities
   (d) Identification of other facilities that animals may have moved to (trace forwards).
   (e) Identification of source facilities, especially if linked to index cases (tracebacks).
   (f) Dates of movements (acquisitions, dispositions). Investigation should extend back at least 5 years for CWD.
   (g) Disease status of other linked facilities? Quarantine status of linked facilities?

(3) **Additional premises information** that might affect disease control, depopulation, or cleaning and disinfection:
   (a) Pen layouts, pen sizes, structures (types and construction), equipment (types and materials), enclosure materials, and cover vegetation.
   (b) Accessibility of animal pens.
   (c) Soil types, general terrain.
   (d) Surface and groundwater proximity and vulnerability.
   (e) Proximity to other residences, businesses, and other entities and nature of these entities.
   (f) Presence of other nonsusceptible species (domestic or wild) or human traffic that could compromise biosecurity.
   (g) Access by index animals to various areas (such as pens) in facility.
   (h) Other activities that may contribute to the risk of disease introduction (such as taxidermy, offsite hunting, breeding loans, or other hobbies).

(4) Other facilities:
   (a) If epidemiologically linked to index premises, are these other facilities under State quarantine?
   (b) Linked premises' regulatory compliance, testing history, monitoring, etc.
   (c) Any animals on linked premises exhibiting clinical signs?

Herd Summary Information:

(1) If selected animals or entire herd is depopulated, what is the suspected disease **prevalence** in the herd?
(2) What is the **distribution** of disease in the herd (i.e., restricted to certain areas in the facility or certain classes of animals)?
(3) Cleaning and disinfection considerations related to suspected level and distribution of environmental contamination in the facility.

Summary of Various Reports:
Situation Reports:
Situation reports (sitreps) are generally reserved for incidents or situations related to identification of newly infected herds or changes in State status (i.e., newly documented CWD in captive herds or wildlife). Information accrues rapidly early in an incident. The corresponding need for information is critical; a situation report may be necessary daily or semiweekly.

Supplemental Epidemiological Reporting:
Additional epidemiological information may be requested if not provided in sitreps or other reports from the State. This information can be used for planning or additional risk assessment related to herd plan development and could include information such as:

- Map or schematic of facility, pens, structures, etc.
- Proximity to surface water or groundwater.
- Availability of handling facilities.
- Terrain/soil types/surrounding land use.
- Identification used on susceptible species.
- Testing history.
- Any other information including, but not limited to, the information specifically mentioned in pages 1-3 of this document.

Final Epidemiological Report Narrative:
The final epidemiological report should contain sufficient detail to convey the known epidemiology of the outbreak or incident to the intended audience. The final report should also comment on elements of the herd plan and how these elements correspond to epidemiological findings, or how the herd plan is substantiated by epidemiological findings.

B. Situation Report (Sitrep) Format and Content

Facility/Premises Information:
A sitrep is always preceded by an initial summary of the farm or facility information. Most of this information should not change substantially from one sitrep to the next; however any changes or corrections identified should be noted.

This section briefly provides relevant background information and history related to the facility and index animal and may include information such as:

- Owner name, address, geographic information system/global positioning system (GIS/GPS) information, farm name, and other information (depending on level of disclosure).
- Name of county or State where premises is located.
- Primary species (susceptible species), index case information (species, breed, age, sex, etc.)
- Disease identified, date of testing or confirmation, laboratory where testing occurred, and reason for testing.
- Type of facility (such as breeding, hunt preserve, or other) and when established.
- Type and condition of enclosure.
- Number of susceptible animals remaining at index premises.
- Proximity to other susceptible animals.

Current Status:
This section contains relevant information and findings that have developed since the previous sitrep. Information in this section includes:

- New laboratory results of interest from the index herd.
- Notable activities by producer.
- Changes in quarantine status of farm or breaks in quarantines.
- Completion of final depopulation plan or herd plan.
- Activities being conducted such as appraisal, depopulation, or cleaning and disinfection.
- Signature of herd plan, VS Form 1-23, and other necessary documents by owner and related State officials.
- Additional issues not previously identified.

Epidemiological Investigation
This section should relate information such as:

- Findings of record reviews.
- Progress of traceouts.
- Identification of new traces and how they are associated with index premises.
- Identification of new risk factors (biosecurity risks).
- Closed-out traces.

Planning:
This section should provide information related to planned or pending activities such as:

- Contingency planning for newly identified risks.
- Plans for additional surveillance (traceout herds).
- Plans for wildlife surveillance.
- Plans for depopulation, cleaning and disinfection, and other needed activities.

Note: In addition to the information specifically mentioned above, preparers should maintain an archive of previous sitreps, and attach them to any current sitrep to serve as a historical reference to the reader if needed.

Appendix VII. Links to Forms and Documents

Forms and documents for application to the Approved State CWD Herd Certification Program include:

- VS Form 11-2
- MOU Between State and APHIS for CWD HCP
- Guidance to States on Application

These documents can be found on the APHIS CWD Web site at:
http://www.aphis.usda.gov/animal_health/animal_diseases/cwd/apply.shtml

A list of Approved State CWD HCPs can be found at:
http://www.aphis.usda.gov/animal_health/animal_diseases/cwd/downloads/list_approved_st_cwd_herd_cert_programs.pdf

VS Form 10-4 laboratory submission forms can be found at:
http://www.aphis.usda.gov/library/forms/pdf/VS_Form10_4.pdf

VS Form 10-4A laboratory submission forms can be found at:
http://www.aphis.usda.gov/library/forms/pdf/VS_Form10_4a.pdf

CWD Program – "CWD Sample Collection Guidance" can be found at:
http://www.aphis.usda.gov/animal_health/animal_diseases/cwd/diagnostics.shtml