the donor dams and for breeding them (either natural breeding or artificial insemination).

(b) *Embryo collection area.* The embryo collection must have a room or outdoor area for collection of embryos that contains a device or devices for restraining embryo donors during embryo collection. If a room, the floor, walls, and ceiling must be impervious to moisture and constructed of materials that can withstand repeated cleaning and disinfection. If an outdoor area, the area must have a floor that is impervious to moisture and is constructed of materials that can withstand repeated cleaning and disinfection. If the outdoor area also has walls or a roof, the walls or roof also must be impervious to moisture and be constructed of materials that can withstand repeated cleaning and disinfection.

(c) *Embryo processing area.* The embryo collection unit must have an enclosed room, which may be mobile, that is used *only* for processing embryos. The walls, floor, and ceiling of the room must be impervious to moisture and constructed of materials that can withstand repeated cleaning and disinfection. The room must contain a work surface for handling the embryos, such as a table or countertop that is impervious to moisture. The room also must contain a microscope with a minimum of 50x magnification, and equipment for freezing the embryos.

(d) *Embryo storage area.* The embryo collection unit must have one lockable area that is used only for storing frozen embryos intended for importation into the United States.

(e) *Area for cleaning and disinfecting or sterilizing equipment.* The embryo collection unit must have an enclosed room used for cleaning and disinfecting or sterilizing equipment used for artificial insemination or for collection, processing, or storage of embryos. The walls, floor, and ceiling of the room must be impervious to moisture and constructed of materials that can withstand repeated cleaning and disinfection.

[56 FR 55809, Oct. 30, 1991, as amended at 61 FR 15184, Apr. 5, 1996; 62 FR 56025, Oct. 28, 1997]

§ 98.17 Procedures.

(a) *Housing of the donor dam.* (1) Beginning at least 24 hours before a donor dam is bred to produce embryos for importation to the United States, the donor dam must be housed at an embryo collection unit.

(2) The donor dam must remain at the embryo collection unit until the embryos for importation into the United States have been collected.

(3) After collection of embryos, the donor dam must either remain at the embryo collection unit or be returned to the herd of origin and remain there until all examinations and tests required by this subpart have been completed.

(4) During the time the donor dam is in the embryo collection unit, in accordance with paragraphs (a)(1) through (a)(3) of this section, no animals may be in the embryo collection unit with the donor dam unless:

(i) They meet the requirements of § 98.15 of this subpart that are applicable to the donor dam at that time;

(ii) They are part of the donor dam's herd of origin; or

(iii) They are serving as donor sires for the production of embryos to be imported into the United States.

(b) *Oversight and supervision.* (1) All procedures associated with the production of embryos for importation into the United States, including artificial insemination, natural breeding, and cleaning and disinfection, must be performed under the oversight of an APHIS veterinarian. Collecting test samples, and collecting, processing, and storing embryos, must be supervised in person by an APHIS veterinarian.

(2) Officials from the Animal and Plant Health Inspection Service must be given access to all areas of the embryo collection unit and the donor dam's herd of origin during the time the donor dam is housed there, in accordance with paragraphs (a)(1) through (a)(3) of this section.

(c) *Personnel.* All personnel must put on clean outer garments, including disinfected boots, and must scrub their hands with soap and water each time they enter the embryo collection unit and before entering any room or area listed in § 98.16 of this subpart.

(d) *Cleaning, disinfection, and sterilization.* (1) All equipment that comes in contact with embryos or with media used for their collection or processing must be sterile. Equipment used for embryos from one donor dam, or with associated media, may not be used for embryos or associated media from any other donor dam until it has been resterilized.

(2) All equipment that comes in contact with a donor dam's secretions or excretions must be sterile and may not be used with any other donor dam until it has been resterilized.

(3) Containers used for storing embryos or for shipping embryos to the United States must be examined and found free of any organic matter and then disinfected before the ampules or straws are placed inside.

(4) The floor, ceiling, and walls of any room or outdoor area used for embryo collection, and the restraining device(s) used for this procedure, must be cleaned with soap and water and disinfected before the room or area is used to collect embryos intended for importation to the United States, and at least daily while in use for this purpose.

(5) The room and work surface used for processing embryos must be kept free of insects, rodents, trash, manure, and other animal matter and must be cleaned with soap and water and disinfected before the room is used for embryos intended for importation to the United States, and the work surface must be cleaned and disinfected at least daily while in use for this purpose.

(6) The area of the embryo collection unit used to store embryos intended for importation to the United States must be kept free of insects, rodents, trash, manure, and other animal matter and must be cleaned with soap and water and disinfected before being used to store the embryos.

(7) The room used for cleaning and disinfecting or sterilizing equipment used for artificial insemination or for collection, processing, or storage of embryos must be kept free of insects, rodents, trash, manure, and other animal matter and must be cleaned with soap and water and disinfected before being used to prepare equipment for donors of embryos intended for importation into the United States, and at least daily while in use for this purpose.

(e) *Media; cryogenic agent.* (1) All media containing products of animal origin and used for embryo collection and processing must be from sources in the United States or Canada.

(2) The liquid nitrogen used to freeze embryos may not have been used previously for any other products of animal origin.

(f) *Collection and processing of embryos.* (1) If embryos are collected in an outdoor area, they must be collected by using a closed collection system so that the embryos are not exposed to open air until they are inside the embryo processing room.

(2) Embryos from donors that do not meet the requirements of §98.15 of this subpart that are applicable at the time of embryo collection may not be in the processing room at the same time as embryos intended for importation into the United States.

(3) Each embryo must be washed at least 10 times. Each wash must be accomplished by transferring the embryo into an aliquot of fresh medium that is 100 times the volume of the embryo plus any fluid transferred from the previous wash. No more than 10 embryos from the same flush may be washed together. A sterile micropipette must be used for each transfer, and the embryos must be well agitated throughout the entire volume of the wash before the next transfer. Embryos from different donors may not be washed together.

(4) After the last wash, each embryo must be microscopically examined over its entire surface at not less than 50× magnification. An embryo may not be imported into the United States unless its zona pellucida is found to be intact and free from any adherent material.

(5) After washing and examination of the zona pellucida, embryos must be individually packaged in sterile ampules or straws and frozen in liquid nitrogen. The donor dam's and sire's identifications and breed, the date of embryo collection, the name and address of the place where the embryos were collected, and an identification number for the straw or ampule must be recorded with indelible markings on

each ampule or straw. If any of this information is provided in code, deciphering information must be attached to the health certificate for the embryos.

(6) The Administrator may require additional measures to be taken in processing embryos after collection (for example, adding trypsin to the washes) if he or she determines that such measures are necessary to ensure the embryos freedom from infectious agents that may cause communicable diseases. Circumstances that may result in such additional measures being required include, but are not limited to:

(i) The existence of communicable diseases of livestock, other than those diseases specifically listed, in the region of origin; and

(ii) A high prevalence or an increase in the incidence of a communicable disease in the region of origin.

(g) *Preparation of test samples; tests.* (1) All nontransferrable embryos and unfertilized eggs from each collection of embryos intended for importation into the United States must be pooled, frozen in liquid nitrogen, and sent to the Foreign Animal Disease Diagnostic Laboratory for testing under the personal supervision of an APHIS veterinarian. The collection and last two wash fluids from the collection of embryos must be frozen and sent to the Foreign Animal Disease Diagnostic Laboratory for testing under the personal supervision of an APHIS veterinarian. Samples from different collections may not be mixed.

(2) All samples collected in accordance with paragraph (g)(1) of this section must be tested and found negative for viral contamination. The wash fluids also must be found negative for bacterial contamination. The only official results for these tests will be those provided by the Foreign Animal Disease Diagnostic Laboratory.

(h) *Storage of embryos.* (1) Frozen embryos to be imported into the United States must be stored in a locked area or must remain in the custody of an official veterinarian until they are sealed in accordance with paragraph (h)(2) of this section and released for shipment to the United States in accordance with § 98.18(a) of this subpart; except that, the embryos may be moved to a U.S. Department of Agriculture-operated animal import center in either New York, Hawaii, or Florida, under seal and in the custody of that individual, and remain in quarantine there until all tests and examinations required by this subpart have been completed and all test results have been provided by the Foreign Animal Disease Diagnostic Laboratory.

(2) Containers in which embryos will be imported into the United States must be sealed by an official veterinarian with the official seal of the region of origin or, if the official veterinarian is an employee of the Animal and Plant Health Inspection Service, with an official seal of the United States Department of Agriculture. The seal number must be recorded on the health certificate that accompanies the embryos to the United States.

(Approved by the Office of Management and Budget under control number 0579–0040)

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§ 98.18 Shipment of embryos to the United States.

(a) *Release from the embryo collection unit.* Except as provided in § 98.17(h)(1) of this subpart, embryos may not be moved from the embryo collection unit until all tests and examinations required by this subpart have been completed and the Import-Export Animals Staff, Veterinary Services, APHIS, has received written notification of all test results from the Foreign Animal Disease Diagnostic Laboratory.

(b) *Route.* The sealed shipping containers must be routed directly to the U.S. port of entry designated on the import permit.

(c) *Ports of entry.* The embryos may be imported into the United States only through a port of entry listed in § 93.203(a) of this chapter.

(d) *Date of arrival in the United States.* Embryos that arrive at the port of entry more than 14 days after the proposed date of arrival stated in the import permit will not be eligible for importation into the United States.

[56 FR 55809, Oct. 30, 1991, as amended at 62 FR 56026, Oct. 28, 1997]