product or longer as may be required by the Administrator.

(Approved by the Office of Management and Budget under control number 0579–0013)

[83 FR 22836, May 17, 2018]

§ 116.9 Recording and reporting adverse events.

(a) Licensees and permittees must maintain a detailed record for every adverse event report the licensee or permittee receives for any biological product it produces or distributes. These records shall be maintained for a period of 3 years after the date the adverse event report is received. The adverse event report form and guidance on how to complete it, including guidance specific to the various information blocks on the form, is available on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics* or by writing to APHIS Center for Veterinary Biologics, 1920 Dayton Avenue, P.O. Box 844, Ames, Iowa 50010.

(b) A report of all adverse events reports received by a licensee or permittee must be compiled and submitted to the Animal and Plant Health Inspection Service. The frequency of report submission is as follows:

(1) Immediate notification is required if at any time there are indications that raise questions regarding the purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding the preparation, testing, or distribution of a product.

(2) Adverse event reports determined by the licensee or permittee to be product-related, serious, and unexpected must also be reported immediately.

(3) All other adverse event reports must be reported within 90 calendar days of the date the report was first received.

(Approved by the Office of Management and Budget under control number 0579–0209)

[83 FR 22836, May 17, 2018]

PART 117—ANIMALS AT LICENSED ESTABLISHMENTS

Sec.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 38 FR 15499, June 13, 1973, unless otherwise noted.

§ 117.1 Applicability.

(a) All animals used in licensed establishments in the preparation or testing of biological products shall meet the regulations in this subchapter and special requirements as may be prescribed by the Administrator to prevent the preparation, sale, and distribution of worthless, contaminated, dangerous, or harmful biological products.

(b) Unless otherwise authorized or directed by the Administrator, animals used in the preparation or testing of biological products shall be admitted to and maintained at the licensed establishment and ultimately disposed of in accordance with the regulations in this part, and with the Act of August 24, 1966 (Pub. L. 89–544) as amended by the Animal Welfare Act of 1970 (Pub. L. 91–579) and the regulations in parts 1, 2, and 3 of this chapter. Personnel who supervise the care and welfare of such animals shall be qualified by education, training, and experience to carry out the regulations in this part.

[38 FR 15499, June 13, 1973, as amended at 56 FR 66784, Dec. 26, 1991]

§ 117.2 Animal facilities.

Animal facilities shall comply with the requirements provided in part 108 of this chapter.

§ 117.3 Admittance of animals.

(a) No animal which shows clinical signs or other evidence of disease shall be admitted to the premises of licensed establishments, except as provided in paragraphs (d) and (e) of this section. The health status of all animals offered for admission shall be determined by or under the direction of a veterinarian prior to admission. If the determination cannot be made prior to admission, the animals shall be kept separate from animals already on the premises and in a quarantine area to be provided by the licensee for this purpose

until the animal's health status is determined.

(b) If special test requirements for admittance of the animals are specified in the Outline of Production for the product to be produced, the animals shall remain in the quarantine area until such tests have been performed and the results obtained. Animals which do not meet the requirements shall not be admitted to the production area or allowed to contact production animals.

(c) All animals admitted to the premises of a licensed establishment shall be permanently identified either collectively or individually by the licensee with tags, marks, or other means acceptable to the Administrator.

(d) When an animal which has a disease is to be used to prepare a biological product for control of such disease, the animal shall be admitted directly to the processing facilities in which the product is to be prepared but shall not be permitted contact with other animals on the premises.

(e) The Administrator may authorize the maintenance of diagnostic facilities at the licensed establishment: *Provided*, That safeguards proposed by the licensee are adequate to prevent diseased or dead animals brought into such facilities from being a threat to biological products prepared in such establishment or to other animals on the premises used in the preparation of biological products.

[38 FR 15499, June 13, 1973, as amended at 56 FR 66784, Dec. 26, 1991]

§ 117.4 Test animals.

(a) All test animals shall be examined for clinical signs of illness, injury, or abnormal behavior prior to the start of a test and throughout the observation period specified in the test protocol.

(b) All animals used for test purposes shall be identified either collectively or individually in a manner conducive to an accurate interpretation of the results of the test.

(c) No test animals shall be given a biological product during the preconditioning period which would affect its eligibility according to the test requirements. No treatment, with a biological product or otherwise, shall be administered to a test animal during a test period which could interfere with a true evaluation of the biological product being tested.

(d) During the course of a test, animals that are injured or show clinical signs of illness or unfavorable reactions that are not due to the test may be removed from the test and treated or humanely destroyed. If sufficient animals do not remain for the test to be evaluated, the test shall be declared inconclusive and may be repeated.

(e) Test animals that show clinical signs of illness that are due to the test may be treated or humanely destroyed if the illness has progressed to a point (defined in the filed Outline of Production) when death is certain to occur without therapeutic intervention. When interpreting the results of the test, the animals that were treated or humanely destroyed because of illness due to the test and the animals that have died from illness due to the test prior to being humanely destroyed shall be combined into a common statistic of mortality due to the test.

[38 FR 15499, June 13, 1973, as amended at 60 FR 43356, Aug. 21, 1995]

§ 117.5 Segregation of animals.

Animals which have been infected with or exposed to a dangerous, infectious, contagious, or communicable disease shall be kept effectively segregated at a licensed establishment until such time as they are humanely destroyed or successfully treated and removed as healthy animals.

§ 117.6 Removal of animals.

Production animals or ex-test animals which are no longer useful at the licensed establishment may be removed from the premises of the licensed establishment; provided, such removal is accomplished in a manner as shall preclude the dissemination of disease and in accordance with the following conditions:

(a) Meat-producing animals which received a biological product containing inactivated microorganisms and adjuvants within 21 days shall not be removed; or

(b) Animals which received virulent microorganisms within 30 days shall not be removed; or

(c) Only animals that are in a healthy condition as determined by a veterinarian shall be removed, except as provided in paragraph (d) of this section.

(d) Other animals that are injured or otherwise unhealthy, except when affected with a communicable disease, may be removed for immediate slaughter to an abattoir operated in accordance with the Federal Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended by the Wholesome Meat Act of 1967, 81 Stat. 585 (21 U.S.C. sec. 601 *et seq.*): *Provided*, That such animals shall be properly marked for identification and the inspector in charge of slaughter operations is given due notice in advance.

(e) All animals on the premises shall be disposed of in accordance with the provisions of the regulations in this part and where specific provision is not made therefor shall be disposed of as required by the Administrator.

[38 FR 15499, June 13, 1973, as amended at 56 FR 66784, Dec. 26, 1991]

PART 118—DETENTION; SEIZURE AND CONDEMNATION

Sec.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 52 FR 30135, Aug. 13, 1987, unless otherwise noted.

§ 118.1 Administrative detention.

Whenever any biological product which is prepared, sold, bartered, exchanged, or shipped in violation of the Act or regulations is found by any authorized representative of the Administrator upon any premises, it may be detained by such representative for a period not to exceed 20 days, pending action under §118.4, and shall not be moved by any person from the place at which it is located when so detained, until released by such representative.

[52 FR 30135, Aug. 13, 1987, as amended at 56 FR 66784, Dec. 26, 1991]

§ 118.2 Method of detention; Notifications.

An authorized representative of the Administrator shall detain any biological product subject to detention under this part by:

(a) Giving oral notification to the owner of the biological product if such owner can be ascertained, and, if not, to the agent representing the owner or to the immediate custodian of the biological product; and

(b) Promptly furnishing the person so notified with a preliminary notice of detention which shall include identity and quantity of the product detained, the location where detained, the reason for the detention, and the name of the authorized representative of the Administrator.

(c) Within 48 hours after the detention of any biological product, an authorized representative of the Administrator shall, if the detention is to continue, give written notification to the owner of the biological product detained by furnishing a written statement which shall include the identity and quantity of the product detained, the location where detained, specific description of the alleged noncompliance including reference to the provisions in the Act or the regulations which have resulted in the detention, and the identity of the authorized representative of the Administrator; or, if such owner cannot be ascertained and notified within such period of time, furnish such notice to the agent representing such owner, or the carrier or other person having custody of the biological product detained. The notification, with a copy of the preliminary notice of detention shall be served by either delivering the notification to the owner or to the agent or to such other person, or by certifying and mailing the notification, addressed to such owner, agent, or other person, at the last known residence or principal office or place of business.

[52 FR 30135, Aug. 13, 1987, as amended at 56 FR 66784, Dec. 26, 1991]