

(b) All rooms used in connection with the preparation of biological products shall be so constructed and arranged as to prevent cross-contamination of such biological products. Halls or walkways shall be provided for the movement of personnel or materials to each biological products preparation area without going through another such area.

(c) Rooms or compartments separate from the remainder of the establishment shall be provided at licensed establishments for preparing, handling, and storing virulent or dangerous microorganisms and products.

(d) All rooms and compartments at licensed establishments shall have an adequate air handling system to supply proper ventilation sufficient to insure sanitary and hygienic conditions for the protection of the products and personnel.

(e) The supply of hot and cold water at licensed establishments shall be ample and clean. Adequate facilities shall be provided for the distribution of water in each establishment and for the washing of all containers, machinery, instruments, other equipment, and animals used in the preparation of a biological product.

(f) There shall be an efficient drainage and plumbing system for each licensed establishment and premises thereof, and all drains and gutters shall be properly installed with approved traps and vents.

§ 108.9 Dressing rooms and other facilities.

Each licensed establishment shall have dressing rooms, toilet facilities, and lavatory accommodations, including hot and cold running water, soap, towels, and the like. They shall be in sufficient number, ample in size, conveniently located, properly ventilated, and meeting all requirements as to sanitary construction and equipment.

(a) These rooms and facilities shall be separate from rooms or compartments in which biological products are prepared, handled, or stored.

(b) These rooms and facilities shall be so located in the establishment as to be readily accessible to all persons without having to enter or pass through biological products preparation areas.

§ 108.10 Outer premises and stables.

(a) The outer premises of licensed establishments, embracing docks, driveways, approaches, yards, pens, chutes, and alleys shall be drained properly and kept in a clean and orderly condition. No nuisance shall be allowed in any licensed establishment or on its premises.

(b) Stables or other premises for animals used in the production or testing of biological products at licensed establishments shall be properly ventilated and lighted, appropriately drained and guttered, and kept in sanitary condition.

(c) Every practical precaution shall be taken to keep licensed establishments free of flies, rats, mice, and other vermin. The accumulation, on the premises of an establishment, of any material in which flies or other vermin may breed is forbidden. Suitable arrangements, in keeping with the local health practices, shall be made for the disposal of all refuse.

§ 108.11 Water quality requirements.

A certification from the appropriate water pollution control agency, that the establishment is in compliance with applicable water quality control standards, pursuant to section 401 of the Federal Water Pollution Control Act, as amended (86 Stat. 877; 33 U.S.C. 1341), shall be filed with Animal and Plant Health Inspection Service for each licensed establishment.

[39 FR 16854, May 10, 1974, as amended at 56 FR 66783, Dec. 26, 1991]

PART 109—STERILIZATION AND PASTEURIZATION AT LICENSED ESTABLISHMENTS

Sec.

109.1 Equipment and the like.

109.2 Sterilizers.

109.3 Pasteurizers.

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

§ 109.1 Equipment and the like.

(a) All containers, instruments, and other apparatus and equipment, before being used in preparing, handling, or

§ 109.2

storing biological products, at a licensed establishment, except as otherwise prescribed herein, shall be thoroughly sterilized by live steam at a temperature of at least 120 °C. for not less than one-half hour, or by dry heat at a temperature of at least 160 °C. for not less than one hour. If for any reason such methods of sterilization are impracticable, then a process known to be equally efficacious in destroying microorganisms and their spores may be substituted after approval by the Administrator.

(b) Instruments which are found to be damaged by exposure to the degree of heat prescribed in this section, after having been thoroughly cleaned, may be sterilized by boiling for not less than 15 minutes.

[23 FR 10051, Dec. 23, 1958, as amended at 34 FR 18119, Nov. 11, 1969; 56 FR 66783, Dec. 26, 1991]

§ 109.2 Sterilizers.

Steam and dry-heat sterilizers used in connection with the processing of biological products at licensed establishments shall be equipped with automatic temperature recording gauges: *Provided*, That other record keeping systems may be used when approved by the Administrator. When gauges are used, they shall be periodically standardized to assure accuracy. Charts and other temperature records made during production shall be available at all times charts and records shall be kept in accordance with part 116 of this chapter.

[35 FR 16039, Oct. 13, 1970, as amended at 56 FR 66783, Dec. 26, 1991]

§ 109.3 Pasteurizers.

All pasteurizing equipment shall meet the requirements in paragraphs (a), (b), and (c) of this section and be acceptable to Animal and Plant Health Inspection Service.

(a) Metal serum containers shall be used in licensed establishments. During the heating process, each container shall be surrounded by a separate water jacket or equivalent so that the entire container, including its lid, is heated to the required temperature. Each serum container shall be equipped with a motor-driven agitator and a sep-

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arate automatic recording thermometer.

(b) Each water bath shall have an automatic temperature control to limit the temperature of the water to a maximum of 62 °C., an automatic recording thermometer, an indicating thermometer set in a fixed position, and circulating mechanism adequate to insure equal temperatures throughout the bath. The heating unit for the bath shall be separated from the serum container and the water jacket.

(c) Accurate thermometers at licensed establishments shall be used at frequent intervals to check temperatures of the serum as registered by recording thermometers.

[35 FR 16039, Oct. 13, 1970, as amended at 56 FR 66783, Dec. 26, 1991]

PART 112—PACKAGING AND LABELING

Sec.

- 112.1 General.
- 112.2 Final container label, carton label, and enclosure.
- 112.3 Diluent labels.
- 112.4 Subsidiaries, divisions, distributors, and permittees.
- 112.5 Review and approval of labeling.
- 112.6 Packaging biological products.
- 112.7 Special additional requirements.
- 112.8 For export only.
- 112.9 Biological products imported for research and evaluation.
- 112.10 Special packaging and labeling.

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

SOURCE: 38 FR 12094, May 9, 1973, unless otherwise noted.

§ 112.1 General.

(a) Unless otherwise authorized or directed by the Administrator, each biological product prepared at a licensed establishment, or imported, shall be packaged and labeled as prescribed in this part before it is removed from the licensed establishment or presented for importation: *Provided*, That biological products to be imported for research and evaluation shall be subject to packaging and labeling requirements in § 112.9. *Provided further*, That, unless otherwise exempted, all preparation, including packaging and labeling, of biological products shall only be performed in a licensed establishment