the State of production pursuant to a license granted by such State under a program determined by the Administrator to be consistent with the intent of the Act to prohibit the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful biological products.

(b) A request for exemption under this section must be made by the appropriate State authority and shall include information demonstrating that:

(1) The State has the authority to license viruses, serums, toxins, and analogous products and establishments that produce such products; and

(2) The State has the authority to review the purity, safety, potency, and efficacy of such products prior to release to the market; and

(3) The State has the authority to review product test results to assure compliance with applicable standards of purity, safety, and potency prior to release to the market; and

(4) The State has the authority to deal effectively with violations of State law regulating viruses, serums, toxins, and analogous products; and

(5) The State effectively exercises the authority specified in paragraphs (b)(1) through (4) of this section consistent with the intent of the Act prohibiting the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful viruses, serums, toxins, or analogous products.

(c) Each product to be exempted and each establishment preparing such product shall be identified by the State and the State shall give written notification to the Administrator of each such product and establishment. The State shall also give written notice to the Administrator of each new license issued and of each license terminated.

(d) In order to determine whether a State exercises its authority with respect to biological products and establishments and whether its laws and regulations are being achieved, the Administrator, in cooperation with proper State authorities, may conduct an onsite evaluation of the State's program which may include inspection of establishments and/or products to be included under the exemptions in this section.

[52 FR 30131, Aug. 13, 1987, as amended at 56 FR 66783, Dec. 26, 1991]

PART 108—FACILITY REQUIREMENTS FOR LICENSED ESTABLISHMENTS

Sec.

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

SOURCE: 39 FR 16854, May 10, 1974, unless otherwise noted.

§ 108.1 Applicability.

Unless otherwise authorized by the Administrator, all buildings, appurtenances, and equipment used in the preparation of biological products shall be in compliance with the regulations in this part. Each land area on which such buildings and appurtenances are located shall be identified by an address which shall appear on the establishment license.

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

§ 108.2 Plot plans, blueprints, and legends required.

Each applicant for an establishment license shall prepare a plot plan showing all buildings for each particular land area, blueprints for each building used in the preparation of biological products and legends containing a brief description of all activities in each room or area.

§ 108.3 Preparation of plot plans.

Plot plans shall show all of the buildings on a particular land area, whether or not they are all used for the preparation and initial shipping of biological products: *Provided,* That, when a great

number of buildings are on the same premises, only those surrounding the buildings used for preparation and initial shipping of biological products shall be shown. The presence of the remainder of the buildings may be accounted for by a single statement denoting the total number of such buildings not used for the preparation or shipping of biological products.

(a) Reduce the entire premises to any standard scale on one sheet of paper which meets any of the American standard trimmed sizes. Indicate the scale used.

(b) Clearly mark the boundaries of the licensed premises and indicate what marking denotes the boundaries. Such boundaries shall coincide with some readily apparent perimeter line. Identify all fences, walls, or streets.

(c) Show buildings as reduced dimensional drawings in the proper scale distance relationship with each other.

(d) Number, letter, or otherwise identify all buildings so that they may be correlated with the respective blueprints and legends.

(e) Describe on the plot plan the use of immediate adjacent properties such as, residential area, pasture, box factory, or the like.

(f) Show compass points.

(g) Show date of preparation.

(h) Apply signature of responsible official of the firm.

§ 108.4 Preparation of blueprints.

(a) Blueprints, drawn to any suitable scale, on regular blueprint paper or a good grade of white paper of any one of the American standard trimmed sizes shall be acceptable: *Provided*, That the same scale shall be used for future revisions unless the entire blueprint is revised. Indicate the scale used.

(b) Use a single sheet of paper for each floor of all buildings in which biological products are prepared. Illustrate in detail the areas in each building utilized for such preparation.

(c) If only a portion of a floor is used in the preparation of a biological product, the blueprint shall illustrate the entire floor in essentially the same detail throughout. All functions or activities performed in the remainder of the floor shall be indicated.

(d) Identify the floors if the drawing is not for all floors in a multiple-story building and identify activities on each floor.

(e) Identify all rooms by letters or numbers.

(f) Show the location of important stationary equipment by a suitable code which will be further identified on legends.

(g) Explain on the blueprint or on the legend, by a statement or listing, which rooms are equipped with water outlets, drains, and lighting. Show the location of doors and windows.

(h) Show compass points.

(i) Show building number.

(j) Show date of preparation.

(k) Apply signature of responsible official of firm.

§ 108.5 Preparation of legends.

A brief description of the activities performed in each room or area shall be prepared as provided in this section and shall be referred to as a legend. Legends shall be provided for each plot plan and each blueprint or drawing. All pages of the legends shall be numbered, identified with corresponding plot plan or blueprint, and submitted in booklet form either stapled together or clipped into a suitable folder.

(a) Plot plan legends shall show the following:

(1) Number of each building and the functions performed in each: *Provided*, That if it is a multiple-story building in which biological products are prepared or handled, briefly describe functions performed on each floor.

(2) A practical and nontechnical description of construction materials used throughout those buildings used entirely or partially for production and handling of biological products.

(b) Blueprint legends shall show the following:

(1) A listing of all rooms by identifying letters or numbers and the fractions prepared in each. Exceptions may be listed for general purpose areas or rooms. Functions performed in each area and room shall be described, whether the licensed or unlicensed products. In rooms where products are exposed to the surroundings, a description of decontamination procedures

and other precautions against cross contamination shall be included.

(2) A listing of the coded stationary equipment.

(3) A general listing of other essential biological equipment such as mills, centrifuges, mixing tanks, bottling and sealing equipment, and the like, which are not regarded as stationary but are maintained in certain rooms.

[39 FR 16854, May 10, 1974, as amended at 40 FR 51413, Nov. 5, 1975; 50 FR 50764, Dec. 12, 1985]

§ 108.6 Revision of plot plans, blueprints, and legends.

Preliminary drawings may be submitted to Animal and Plant Health Inspection Service for comment prior to construction of new facilities or when remodeling is anticipated, old facilities are to be torn down, or other changes affecting the workflow are to be made. The licensee shall:

(a) Prepare revised plot plans, blueprints, or legends and submit to Animal and Plant Health Inspection Service for review and filing when changes have been completed. Also prepare a statement to accompany each revision to identify, by date of the superseded item, what is being superseded.

(b) Prepare a drawing of the revised rooms, unit, or section to the same scale as the blueprint on file which shall be stamped and applied to the existing blueprint. If changes are numerous, prepare a new blueprint.

(c) Drawings of new buildings may be added to existing plot plans. Indicate the distance from surrounding buildings and boundary lines.

(d) Any change prescribed in this section shall necessitate a change in one or more pages of the respective legends. The revised pages shall carry the same numbers as superseded pages.

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

§ 108.7 Filing of plot plans, blueprints, and legends.

Two copies of all plot plans, blueprints, and legends, including revisions, shall be submitted to Animal and Plant Health Inspection Service for review and filing. When the reviewer takes exception to a submitted item, such item shall be returned with appropriate comments for correction and resubmission. Acceptable submissions shall be stamped as filed and the date noted. One stamped copy shall be returned and two copies retained for Animal and Plant Health Inspection Service files.

[39 FR 16854, May 10, 1974, as amended at 56 FR 66783, Dec. 26, 1991; 75 FR 20772, Apr. 21, 2010]

§ 108.8 Construction of buildings.

(a) The floors, walls, ceilings, partitions, posts, doors, and all other parts of all structures, rooms, or facilities used for the preparation of biological products or ingredients of biological products at licensed establishments shall be of such material, construction, and finish as may be readily and thoroughly cleaned.

(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 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