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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.

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(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

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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