Veterinary Services
Safeguarding Animal Health

Animal and Plant Health Inspection Service

Veterinary Services

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Items to Consider When Processing Preliminary Drawings

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Source Document: Title 9, *Code of Federal Regulations*, part 108; Veterinary Services Memorandum No. 800.78

Reference: Veterinary Services Memorandum No. 800.78

Licensees, permittees, and applicants may submit preliminary drawings for comment before construction of new facilities when the company anticipates renovation of existing facilities or other facility changes affecting workflow.

Background

Preliminary facility documents submitted under title 9, *Code of Federal Regulations* (9 CFR), part 108.6, are frequently received from licensees/permittees. When evaluating each submission, continue to consider the question, 'is the use of the new area/building adequately described, and is the proposed use appropriate based on the information provided?' Use 9 CFR 108, Veterinary Services (VS) Memorandum No. 800.78, and any filed Outlines of Production for your review, as necessary. In order to improve the review of these submissions and the consistency of our response back to the firm, the following items should be evaluated/considered:

1. Does the preliminary drawing and any associated verbiage provided with the submission adequately explain what the function(s) of the new/renovated room(s) will be, and in the case of renovation, describe what will be changed in relation to the existing layout? You may need to request more information from the firm before an adequate assessment can be made.

2. Are rooms adjacent to, but not directly involved in the construction/renovation area(s) shown or described? Has the firm adequately described physical barriers and any other processes and procedures which will be used to protect product/rooms/spaces from cross contamination during the construction/renovation? If not, let the firm know that we expect this to be done.

3. It may be beneficial for the firm to indicate where key items of equipment will be located or used within the new room(s) even if the equipment is not considered to be stationary.

4. Specific methods to mitigate cross contamination, e.g., airlocks, HEPA filtered rooms, laminar flow clean rooms or cabinets, directional airflow, backflow prevention of air and drainage systems, personnel, material, and equipment flows may all be important information to have to adequately assess the proposed facility changes.

5. Inform the firm that our expectation is that equipment and processes be validated for effectiveness prior to use.

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6. The site (manufacturing), especially if new, should be entered within LSRTIS, Establishment Site Management. The firm should have submitted an APHIS Form 2001 or 2003 to initiate this process.

7. It is beneficial to know the products/processes to be used in the rooms; double check the Outlines of Production for the specific production step(s). Review to ensure the new equipment or process is in compliance with the Outline.

8. Inform the firm that an inspection of the new/renovated facility/building/room(s) may be required prior to use/release of product to the marketplace (the firm may decide to go forward with use of the new area at-risk). See **CVB-WI-0112**, *Facility Documents: Specialist Review and Outgoing Correspondence*, for guidance on when Inspection and Compliance (IC) would inspect a facility before use. If an inspection is necessary prior to approving the use of the new rooms/area/building(s), let the firm know our expectation is items such as walk-in coolers, incubators, clean rooms, and the like should be in place and validated prior to the inspection. If we choose not to inspect prior to use, inform the firm we will inspect at our next regularly scheduled inspection. In lieu of an inspection, we may request that the firm submit commissioning data for our review and approval prior to use.

9. Based on the information in the firm's submission, and possibly other communications between the firm and IC (make note of these in our letter), it is acceptable to inform the firm that what they are proposing appears to be acceptable.

10. Remember that preliminary drawings are not considered to be or filed as a regular facility document submission would be. Preliminary drawings may be submitted electronically. Also keep in mind a firm is **not required** to submit preliminary facility documents.

11. Remind the firm that once the construction/renovation is completed revised facility documents should be submitted to CVB-IC.

12. The items to consider as noted above are not intended to be an all-inclusive listing. Other considerations/assessments may be required depending on individual circumstances. Refer to ML [redacted] and [redacted] for examples of previous correspondence related to IC responses to preliminary document submissions.

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