

**United States Department of Agriculture
Center for Veterinary Biologics**

Standard Operating Policy/Procedure

Processing Facility Documents

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Contact: William L. Huls, (515) 337-6193
Approvals:

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Date: 12Oct17

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Entered into CVB Quality Management System by: <u>/s/Linda S. Snavelly</u> <u>12Oct17</u> Linda S. Snavelly Date Quality Management Program Assistant
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Processing Facility Documents

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Processing Facility Documents

1. Purpose

Facility documents are one of the foundational documents required when applying for and maintaining a U. S. Veterinary Biologics Establishment License or U.S. Veterinary Biological Permit for Distribution and Sale. This document clarifies the steps in processing incoming facilities document submissions, and reviewing these documents using title 9, *Code of Federal Regulations* (9 CFR), part 108, and Veterinary Services Memorandum 800.78 as guidance.

2. Definitions

2.1 Plot Plan

A drawing that shows all of the buildings on a particular land area, even if the building is not used in the preparation of biologics.

2.2 Plot Plan Legend

Lists all buildings shown on the plot plan and gives a brief description of the building materials used for, and the functions performed in each building.

2.3 Blueprint

A drawing illustrating, in detail, buildings used for preparation of biologics.

2.4 Blueprint Legend

A listing of rooms on the blueprint; should include room identification, functions performed in room, decontamination/room management for the room and fractions in the room. A listing of stationary and other essential equipment for each room should also be included.

2.5 Addendum

A listing attached to either the Plot Plan Legend or Blueprint Legend for a specific issue; such as an exemption to 9 CFR 109 or movement of products between two premises on the same establishment license. Addendums may also be used if the same information is repeated across several rooms.

2.6 Licensing, Serial Release and Testing Information System (LSRTIS) – Mail Log Module

This database system is the information management system used by the Center for Veterinary Biologics (CVB) to track incoming and outgoing submissions.

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3. Responsibilities

3.1 Document Export Examiner (Biologics Compliance Assistant position to provide backup)

Processes incoming facility documents, enters data, stamps filed facility documents, and mails copies to the establishments.

3.2 Biologics Compliance Assistant (BCA) – including Lead BCA

Performs preliminary review of facility documents to ensure the submission is complete. Finalizes outgoing documentation related to the facility documents.

3.3 Specialist

Performs secondary review of facility documents to ensure submission meets regulatory requirements, usually for establishments assigned to them. Drafts outgoing documentation.

3.4 Facilities Manager

Provides guidance regarding issues for the review of facility document review. Acts as a liaison with Policy, Evaluation, and Licensing (PEL) regarding facility documents. Drafts needed policy and ensures processes are documented.

3.5 Section Leaders

Provides guidance for overarching issues regarding facility document policy

3.6 Records Management

Ensures facility documents are filed in accordance with the current policy.

4. Procedures: Processing Plot Plans, Blueprints, and Legends

4.1 Overview

Prior to permitting or licensure of an establishment, the applicant must prepare and submit facility documents. These documents are reviewed prior to licensure and used during the prelicensing inspection.

Revisions to facility documents are required for, but are not necessarily limited to the following:

1. Adding of an address (buildings) to an existing establishment license

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2. Adding of an address (buildings) for permitted product – as listed in the Outline of Production
3. Adding of a building to an existing address listed on the establishment license
4. Remodeling of an area or building used in the preparation of product
5. Removing a building from the licensed premises
6. Adding/changing functions, fractions, or room management in existing rooms used in the preparation of product (without remodeling)

Remodeling of an existing production building or addition of a new production building most likely will require an on-site inspection prior to filing of the documents or issuance of an updated establishment license.

4.2 Receipt of Incoming Facility Documents - See **ICWI0910**, *Mail Receipt, Process, and Distribution for CVB-IC Hard Copy Submission*, and **ICWI0071**, *BCA Entry and Review of Incoming Correspondence*

4.2.1 Facility document submissions are received hardcopy.

4.2.2 The majority of prelicensing facility documents are submitted to PEL as part of the initial licensing package. They are logged out of the PEL Mail Log (ML) and logged into the Inspection and Compliance ML with an informational link to the original submission.

4.2.3 Preliminary drawings for new construction or remodeling may be submitted for comment prior to construction. These can be submitted via the NCAH Portal. The Submission Type should be General Correspondence (IC) and Submission Subtype should be Preliminary facility drawing.

4.3 Preliminary Review – See **ICWI0081**, *Preliminary Review of Facility Documents (BCA)*, and **ICFRM0018**, *Facility Document Form Plot Plan/Plot Plan Legend – Preliminary Review (BCA)*, and **ICFRM0019**, *Facility Document Form Blueprint/Blueprint Legend – Preliminary Review (BCA)*

The function of the BCA review serves as a quality check on data entry and technical review of the documents for accuracy and complete submissions.

4.3.1 If data entry errors are noted, the BCA corrects them during the review.

4.3.2 If the facility document submission is incomplete, the BCA may return the submission to the establishment without further review.

4.3.3 BCA may not return a Prelicensing Facility Document Submission. Deficiencies will be documented and the submission will be sent forward to the responsible Specialist.

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4.2.4 Provides completed **ICFRM0018** and/or **ICFRM0019** to the Specialist with the facility documents for their review.

4.4 Specialist Review (see **ICWI0083**, *Facility Documents: Specialist Review and Outgoing Correspondence*)

4.4.1 The Specialist reviews facility documents for acceptability of the facility, processes, and equipment as related to the functions performed in the preparation of product. This includes review of the equipment listed, functions performed, fractions, decontamination procedures, methods to mitigate cross-contamination, biosecurity and biosafety practices related to all activities in the licensed premises.

4.4.2 The Specialist provides outgoing correspondence.

4.4.2.1 Fill out Facility Document Submission Form, sign and date.

4.4.2.2 If needed, attach completed **ICTEM0045**, *Facility Document Correspondence*.

4.5 Facility Document Finalization, see **ICWI0072**

A copy of the filed facility document(s) are maintained by CVB for reference. A copy is returned to the licensee/permittee.

4.6 Filing – See **PIMSWI1004**, *IC Miscellaneous Filing - General Correspondence, Inspection Reports, Blue Print Correspondence, Certificates of Licensing and Inspection, Import/Export, and Product Information*

5. Summary of Revisions

Version .04

- Complete revision of document based on business process improvement.

Version .03

- Changed “agenda” to addenda.
- 2.2.1 Changed IC OAA to IC BOA or designee.
- 2.2.1 First bullet added, All plot plans, blueprints, legends and associated addenda.

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- **2.2.1** Added a new bullet point, “Logs the facility documents into the LSRTIS Mail Log (see ICWI0236, Work Flow for Correspondence for Inspection and Compliance: Using the Mail Log System)”.
- **2.2.1** Added (see Section 6 of ICWI0910.02, Mail Receipt, Process and Distribution) to third bullet point.
- **2.2.2** Added a new bullet stating, “Self assigns mail log item”.
- **2.2.2** Added statement, “Moves mail log item to Specialist Review”.
- **2.2.3** Removed “The submission is not split into separate accepted or rejected parts” under the fourth bullet point.
- **2.2.3** Removed “...a hard copy of the draft cover letter,...” Added “Using the mail log system an.....” under the sixth bullet point.
- **2.2.4.** Added “...and/or rejected...” under first bullet point.
- **2.2.4** Added to second bullet, “A third copy may be approved and stamped if submitted and requested by the firm in a cover letter”.
- **2.2.6** Changed IC OAA to IC BOA under second bullet point.
- **2.2.6** Added to first bullet, “Cover letter is saved to the APHIS Mail Log and mailing information is entered. Electronic “notifications are sent.”
- **2.2.6** Added to second bullet, “with the stamped legends, plot plan, and/or blueprints....to await the certified return receipt green card...future...”.
- **2.2.7** Changed IC OAA to IC BOA
- **2.2.7** Removed first bullet point
- **2.2.7** Added, “Updates the Mail Log with the date documents received by the establishment and the name of person who signed the Certified Mail Return Receipt,” to the second bullet point.

Version .03

- Moved details of each step to a more detailed work instruction
- Updated to reflect outcome of business process improvement project.

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Version .02

- The Contact has been changed from Ronald Owen to William Huls.
- **2:** The location of template letters has been updated.
- **2.2.3:** This section has been revised to provide minor clarifications to the steps involved.
- **3:** This section has been revised to further define the facilities involved in the process.

Version .03

- Moved details of each step to a more detailed work instruction
- Updated to reflect outcome of business process improvement project.