



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 18-08

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Byron Rippke
Director

SUBJECT: Expanded NCAH Portal Functionality: Submission of Facility Documents

I. PURPOSE

The purpose of this Notice is to inform licensee and permittees that the Center for Veterinary Biologics (CVB) is expanding the functionality of the web-based NCAH Portal by accepting submissions for facility documents. Submitters must be portal-enabled to submit electronic facility documents.

II. BACKGROUND

The NCAH Portal is external-facing and enables web-based electronic submissions between registered biologics licensees and permittees and the CVB. Adding the facility document submission type accepted via the NCAH Portal completes the CVB-IC transition from paper submissions to electronic submissions.

While there is no “official” pilot project for this new submission type, the process will be evaluated using approximately 40 NCAH Portal submissions. We will start receiving electronic submissions on June 11, 2018, and estimate we should have a sufficient number of submissions for evaluation by August 31, 2018. Based on these documents and user feedback, appropriate changes and document revisions, (such as Veterinary Services Memorandum 800.78), will be made. User feedback regarding this process should be submitted to CVB.PIMS@aphis.usda.gov on or before September 30, 2018, with the subject line: Electronic Facility Document Submission.

Customer help sessions are scheduled every Tuesday at 10:00 am, Central Daylight Time, starting June 5, 2018, through August 21, 2018. We don't expect the sessions to be longer than 30 minutes. Conference call information will be emailed to Liaisons and Alternate Liaisons of NCAH Portal-enabled licensees prior to the first scheduled call.

III. ACTION

A. The Roles of Liaison and Alternate Liaison will be allowed to submit Facility Documents via the NCAH Portal. Portal roles are further explained in the NCAH Portal User Guide, Description of Portal Roles and Privileges.

B. Portal-Specific Format and Submission Process

The procedure for submitting and reviewing electronic Facility Documents is not much different from the traditional paper process, but it will leverage efficiencies of electronic document comparison.

1. Facility documents, (legends, addendums, blueprints, etc.) must be in electronic portable document format (PDF)

2. All pages of legends and addendum must be numbered and identified. Drawings must be identified. Suggested identification in the header of the document includes the following:

- a. Establishment Name and Number
- b. Address of the facility site
- c. Type of document (for example - Plot Plan or Addendum A)
- d. Version number or date – Version 1 will be the first electronic submission for the document

NOTE: One future enhancement will include a field for version number with the NCAH portal submission

- e. Ensure there is a footer; to be used by CVB to “stamp” the file copy

3. Size of each attachment cannot exceed 35 MB.

4. See User Guides 9 and 26 for creating and submitting an Electronic Facility Document.

C. Facility Document Submissions

1. Legends and addenda must be complete revisions, page changes will not be accepted.

2. Blueprint overlays will not be accepted.

3. Individual blueprint legends recommended for each building.

4. Once a document has been submitted and accepted in the electronic format, the document must stay in the electronic format. Intermixing of electronic and paper versions for the same document will not be allowed.

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5. A Summary of Changes is required for all drawings; blueprints and plot plans.
6. A Summary of Changes is required for the first electronic submission of each legend and addendum. After CVB has electronically filed a document, electronic document compare will be used for future submissions, so a Summary of Changes is not required.
7. Based on the credential requirements for submission via the NCAH Portal, signatures of a responsible official of the firm will not be required on the blueprints and/or plot plans.

IV. IMPLEMENTATION/ APPLICABILITY

Detailed procedural instructions and companion training videos are available on the NCAH Portal Guidance page of the CVB Website. Users are expected to read and understand User Guides 9 and 26 prior to submitting electronic facility documents.

Adding the functionality for electronic facility document submission to the NCAH Portal is currently under development and is tentatively scheduled to go live on June 11, 2018.