



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 17-03

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

**FROM:** Byron Rippke  
Director

**SUBJECT:** Expanded NCAH Portal Functionality: Electronic Outlines of  
Production and Special Outlines

### I. PURPOSE

The purpose of this Notice is to inform licensees, permittees, and applicants that the Center for Veterinary Biologics (CVB) is expanding the functionality of the web-based NCAH Portal by adding to the types of submissions that can be accepted. Outlines of Production and Special Outlines are being added as new submission types under APHIS Form 2049. Submitters must be [portal-enabled](#) to submit electronic Outlines.

### II. BACKGROUND

The NCAH Portal is external-facing and enables web-based electronic submissions and responses between biologics firms and the CVB. To date, all submissions to the CVB's Policy, Evaluation, and Licensing unit (PEL) except Outlines have been accepted via the NCAH Portal. This expansion completes the PEL transition from paper submissions; upon implementation, all PEL submissions may be submitted electronically via the Portal.

### III. ACTION

#### A. Portal-Specific Format and Submission Process Required

The procedure for submitting and reviewing electronic Outlines is substantially different from the traditional paper process. It will leverage efficiencies of electronic document comparison and facilitate document navigation. Therefore it is essential to submit Outlines in the proper electronic format.

*Before submitting an electronic Outline, read the following instructions:*

- [User Guide 17](#)—Template Requirements for Electronic Outlines
- [User Guide 18](#)---Creating and Revising Electronic Outlines
- [User Guide 19](#)—Versioning Electronic Outlines
- [User Guide 20](#)—Submitting Outlines to Policy, Evaluation, and Licensing via the NCAH Portal

The procedure includes:

- Document preparation on CVB-approved template with navigable headings
- Establishment of a “baseline” electronic version from which future revisions may be compared. A baseline **must** be identical in content to the most recent paper Outline and file with the CVB. A baseline must be on file at the CVB before Outline content is revised.
- The same MS Word document will be repeatedly exchanged between the firm and the CVB, with current changes tracked, as revisions are warranted.

Companion videos for each of these User Guides are also available on the [NCAH Portal Guidance page](#) of the CVB website.

Direct any additional questions to [CVB.PIMS@aphis.usda.gov](mailto:CVB.PIMS@aphis.usda.gov).

## **B. Staged Submissions**

The CVB anticipates a substantial influx of submissions as firms file their Baseline versions of electronic Outlines. Please submit only **one** electronic Outline until the CVB has confirmed that the document format and submission details are correct.

Once an initial electronic Outline has been processed by the CVB, please limit electronic Outline submissions for your firm so that there are no more than 10 pending review by the CVB at any given time. The CVB plans to assign extra personnel to process Baseline versions, but it will take time to convert all Outlines to electronic format industry wide. Assistance in providing a manageable submission flow is appreciated.

## **IV. IMPLEMENTATION/ APPLICABILITY**

Detailed procedural instructions and companion training videos are available immediately on the [NCAH Portal Guidance page](#) of the CVB website. Users are expected to read and understand User Guides 17 through 20 *prior to submitting* electronic Outlines.

The NCAH Portal will be updated to accept electronic Outlines on March 16, 2017. Notification of the exact date will be posted to the CVB’s [NCAH Portal Guidance web page](#). Outlines not submitted according to the User Guides will be closed out in the NCAH Portal without review, with a note to resubmit in the proper manner.

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Submit only *one* electronic Outline at first. Once that Outline has been processed successfully by the CVB, it is permissible to submit additional electronic Outlines at reasonably spaced intervals.

The CVB will continue to process paper Outlines for those products that do not yet have an electronic baseline document on file with the CVB, but once converted to electronic format, only electronic revisions will be accepted.