

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

**Standard Operating Policy/Procedure**

**Outgoing Correspondence**

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Contact: Becky R. Rasmussen, (515) 337-6138  
Approvals:

/s/Steven A. Karli Date: 24May17  
Steven A. Karli, Director  
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Entered into CVB Quality Management System by: <u>/s/Linda S. Snavelly</u> <u>25May17</u> Linda S. Snavelly Date Quality Management Program Assistant
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**Outgoing Correspondence**

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## Outgoing Correspondence

### 1. Purpose and Scope

This document provides work instructions to facilitate the movement of correspondence from origination to finalization.

### 2. General Instructions

Current templates are to be used. See the Inspection and Compliance Manual located on the CVB Quality Management SharePoint site for the current template. (Documents not on current templates will be returned to the author for revision.)

The author drafts the document for finalizing and includes distribution by email (em) and/or hardcopy (cc). All Center for Veterinary Biologics (CVB) recipients will be emailed.

Drafted correspondence should be prepared by the author to conform to acceptable standards for format, readability, consistency, grammar, and punctuation.

Any incoming correspondence and any other related/relevant information (i.e., phone logs, emails) is to accompany the correspondence-in-progress.

The Biologics Compliance Assistant (BCA) will review the document for format, readability and consistency in word usage, checking for grammar and punctuation, and finalize for signature. All content changes suggested are discussed with the author or supervisor prior to incorporation.

Regulatory letters with financial impact on licensees or permittees (such as mandated stop distribution and sale, infraction notices) are to be signed by the Compliance Section Leader or other designated person (see the current version of **ICSOP0002**, *The Inspection and Compliance Development Process for Veterinary Biologics Program Documentation Intended for Publication*).

### 3. Instructions for All Draft Stage Correspondence from Biologics Specialists in Training (or whenever a second opinion is required or desired by a trained Biologics Specialist)

#### 3.1 Author

All outgoing correspondence is submitted through the supervisor for review, Section Leader Review (LSRTIS Mail Log).

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### 3.2 Supervisor

The supervisor reads the document for content and adherence to program policies and may make suggestions and corrections to the draft document.

If significant changes are to be made, the supervisor may return the document to the author for revision before applying initials.

Draft correspondence that has been initialed and dated will be submitted for finalization after revision according to the supervisor's comments.

## 4. Instructions for All Finalized Correspondence

The draft document is placed in the appropriate inbox, if needed, or to the electronic CVB IC Inbox within the Mail Log system.

**4.1** The BCA will make any needed corrections/revisions to the document.

Any changes other than spelling or format are to be reviewed with the author prior to finalizing.

The BCA finalizes the document for signature and returns the document and accompanying documentation to the author. If the outgoing correspondence is electronic, the BCA will PDF the document prior to signature.

**4.2** The signee (author or other designated person) signs the original (white) copy of the finalized document, if needed. Otherwise the signee electronically signs the document with the appropriate USDA signature block.

The signee ensures the yellow copy is initialed above the legend line by the **supervisor or CVB-IC management**, indicating that the document has been reviewed and is acceptable, if needed. Otherwise, the signee sends the electronic document to the Section Leader Final Authorization for final review within the Mail Log.

If the outgoing document was hard copy, the documentation is returned to the appropriate BCA. If the outgoing document was electronic, the documentation is sent directly to Records Management. Records Management employees perform a quality inspection of outgoing documents prior to being pushed to the NCAH Portal.

**4.3** If the outgoing documentation is hard copy, the BCA completes the processing, converts the final version to PDF format, and files it in the appropriate electronic folder. The word document is deleted after the yellow is initialed off by the supervisor or

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management and the hard copy of the letter is sent out. The PDF electronic copy is the official electronic copy.

The BCA designates the physical file location in the upper right-hand corner of the hard copy of the yellow. This information should include Establishment number, Specialist last name and the physical designation for the hard copy. The electronic path must include author/person formatting letter/path/main folder/# of licensed establishment subfolder under establishment folder/yymmdd (for example – [REDACTED]).

**4.4** Prior to mail being sealed, a secondary review of contents is performed to verify the correspondence is being mailed to the correct address/addressee.

The Serial Release BCA or other designee performs this review and initials and dates in the left margin by the legend line on the yellow copy.

## 5. Summary of Revisions

### Version .03

- Updated to include NCAH Portal processes.

### Version .02

- The Contact information has been updated.
- **4.3:** This section has been updated for clarification