



**Animal and Plant
Health Inspection
Service**

Veterinary Services

**Center for Veterinary
Biologics**

**1920 Dayton Avenue
PO Box 844
Ames, IA 50010**

(515) 337-6100

Biologics Compliance Assistant (BCA) Finalization of Correspondence

Document Number: CVB-WI-0101

Revision: 02

Previous Number: ICWI0072.01

Author: LENNIS

Section/Area: CVB-WI-IC

Release Date: 12 Nov 2019

Notes:

Biologics Compliance Assistant (BCA) Finalization of Correspondence

Source Document: CVB-SOP-0049, *Inspection and Compliance Correspondence (LSRTIS, Mail Log Procedures)*

Background

This document is to give guidance and information in the process of finalizing Inspection and Compliance (IC) correspondence that is first received by the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) through the NCAH Portal or by mail, such as USPS, and overnight courier. Hand-delivery is discouraged due to processes required to enter the National Centers for Animal Health campus. It is then reviewed by the BCA and Specialist before coming to the BCA for finalization.

Finalization is usually performed by the BCA assigned to the firm. However, Inspection Reports and correspondence not relating to a specific firm is finalized on a first in/first out basis. Exceptions to this procedure may be during absence of an employee.

The BCA will review the correspondence for format, readability, and consistency in word usage, will check for grammar and punctuation, and finalize the correspondence for signature. Any changes other than format are to be reviewed with the author prior to finalizing the electronic version.

A. Finalize document

1. Go to *My Queues*
 - a. Click on *Active* tab
 - This is all Mail Log items that have been sent to you for finalization
 - Default is set to list them by the date the Mail Log item entered into its current tab, but can be sorted by other categories by clicking the up or down arrow of the column heading
 - b. Other options
 - *Search* function if you know the ML#
 - *Advanced Search (IC)* from Search LOVs if you know particular info, but not the ML#
2. Click on Mail Item # you wish to select
3. Click on *Workflow Log* tab
 - a. Verify Section Leader reviewed and approved document (if applicable)
 - b. If not approved, move ML# back to Specialist with comment
4. Click on *Documents* tab
5. Click on the document link under *File Name* to open attachment
 - a. Verify document is on correct template (if applicable)
 - b. If not, move ML# back to Specialist with comment
6. Click "Enable Editing" in the Protected View bar at the top of the document
7. Finalize document
 - a. Edit document for grammar, formatting, and readability
 - b. Review any questionable needed edits with author
8. Save document to a temporary holding location
 - a. F:\Documents for Review or your [REDACTED]

9. Determine if the submission should be mailed **Hard Copy** or sent out **Electronically**.

a. *Is the Firm Portal Enabled?*

- Yes: Go on to 9b
- No: STOP - the submission should be sent hard copy.

Mail Log Item

Open Activities:
 - Finalization (IC) for Watson, Jeanette

This item is currently active in the queue of Watson, Jeanette for Finalization (IC)

Mail Log ID	170
Status	Active
Establishment	999
Is Firm Portal Enabled?	Yes
Products - Serial Number	• 264853 - 1234A

b. *Is the Mail Log Item tagged to SUPPRESS Response from Portal?*

- Yes: STOP - the submission should be sent hard copy – go to step 10
- No: The submission may be sent back electronically – go to step 11.

Submission Classification

Submission Subtypes

Regulatory Action Source

Special Inspection Type

9CFR Violations

Tags

- No incoming submission
- SUPPRESS Response From Portal

Licensing Plans NA

10. **Hard Copy:** Print original

- Print original letter on bond paper (watermark, eagle facing up) (See Sections B, C, & D)
- Add Ems to mail log Notifications (Section E)
- Move to Specialist in LSRTIS as Sign Correspondence-IC and give to Specialist for signature in purple folder

- Specialist is responsible to pass it onto the Section Leader as Section Leader-Final Authorization.
- Section Leader will choose Certified Receipt if going out certified or overnight. They will choose the BCA who processed the mail log. It will go back into that BCA's que.
- If the letter is going out regular mail, the Section Leader will choose Work Flow Completed-No Records Management.

- d. Upon receipt of the signed final letter, put outgoing letter in appropriate envelope to the correct addressee.
- e. Put envelope in “Outgoing Mail” basket for Export Document Examiner (EDE) to do a mail check, seal envelope, and mail.
- f. If certified or overnighted, hold ICs copies of documents until delivery notification is received.
 - Go back to Active tab
 - Click **Edit** at bottom of screen
 - Enter receipt date and (optional) name of individual signing for it
 - Click **Update**
 - Go back to **Move Forward** on *Active* tab
 - Select final destination for document – Workflow Completed-No Records Management

11. Electronic document

- a. Upload final formatted pdf document (see Sections B and C)
 - Do not include a legend line in the document
 - Include the Mail Log item at the bottom of the document
- b. Add ems to ML Notifications (see Section E)
- c. Review ML for Tags
 - Ensure that No outgoing correspondence is not selected. (If this is, no outgoing document type should be added)
 - Suppress Response from Portal is not selected (if selected, must go out hard copy)
- d. Send to Specialist to sign as Sign Correspondence Activity
 - The Specialist will digitally sign the document and send to Section Leader for Final Authorization
 - This ends BCA portion of the electronic process

B. PDF the document (Electronic and Hard Copy)

1. Bring up document from temporary holding location
2. If finalizing an electronic document, remove the legend lines and the /s/ (signatory info) to allow for digital signatures.
3. Save pdf document on XXXXXXXXXX

C. Attach PDF document (Electronic and Hard Copy)

1. Go back to *My Queues, Active* tab
2. Click on the Mail Log Item #
3. Click on *Documents* tab
4. Click on **+Create New Document Record**
5. Select File Location as “Uploaded File”
6. Click on “Browse”
 - a. Find your PDF document
 - b. Click “Open” (or double click) to attach the PDF file
7. Click on Document Type by using the drop down arrow – this should be the same document type as what the Specialist used for their draft.
 - **See Specialist/Section Leader for discrepancies.****
 - a. Outgoing General Correspondence

- b. Outgoing Compliance Correspondence
 - c. Outgoing Inspection Report
 - d. Outgoing Enclosures
8. Click on “Save and Return to Item Record”

D. Complete Submission Response in Mail Log (Hard Copy only)

1. Go back to *Active* tab
2. Click button at bottom of screen
3. Enter pertinent information
 - a. Date of Letter
 - b. Date Mailed
 - c. Shipment Type
 - d. Shipment Tracking Number (if applicable)
4. Click

E. Send notifications to all individuals listed under the “em:” in your document (Electronic and Hard Copy)

1. Click on *Notifications* tab
2. Click
 - a. Select “EM – ALL” from LOVs
 - b. Click on all applicable “em” names
 - c. Add the IC PSA’s name (or alternate)
 - For all MLs with WRP Correspondence
 - They will not be a formal em on the letter
3. Click
4. Verify all names selected are listed under the *Notifications* tab