Biologics Compliance Assistant (BCA) Finalization of Correspondence

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
    b. your H:\drive

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)

...ail Log...	1/6
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 and Yellow file copy
   a. Print original letter on bond paper (watermark, eagle facing up)
   b. Attach supporting documents to the Yellow
   c. Notate in top right-hand corner of the Yellow
   - Mail Log # (in red ink)
   - Est. #
   - Product Code or VBI #
   - Specialist/Author's name
   d. Give to Specialist for signature in purple folder
   - Specialist is responsible to pass it onto the Section Leader to initial the Yellow
   e. Upon receipt of the signed final letter, proceed on to Sections B through F.

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 <u>Sign Correspondence Activity</u>
       - 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 F:\Licensed Firms

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 Edit 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 Update

E. Send notifications to all individuals listed under the "em:" in your document (Electronic and Hard Copy)
  1. Click on *Notifications* tab
  2. Click +Add Notifications
    a. Select "Immediate Notification – ALL" from LOVs
    b. Click on all applicable "em" names
    c. Add the IC PSA's name (or alternate)
- For all MLs with WARP Correspondence
- They will not be a formal em on the letter

  3. Click Create Notifications
  4. Verify all names selected are listed under the *Notifications* tab

F. Move mail log record for filing of Outgoing Correspondence (Hard Copy only)
  1. Go back to *Active* tab
  2. Click Move Forward
  3. Click OK in pop-up box
  4. Select appropriate destination from LOVs
    a. Select "Records Management (RM)" if it is ready to be filed in mail room
    b. Select "Workflow completed-no records management" for
- VBI documents
- Documents you will file yourself

    c. Select "Certified Receipt" to await delivery notification of overnight or Certified Mail
- Select Assigned Individual" from the LOVs
- Click Move Item
- Click OK to accept your choice
- This should remove Mail Log item from your *Active* listing

  5. Put outgoing letter in appropriate envelope to the correct addressee
  6. Put envelope and Yellow in "Outgoing Mail" basket for Export Document Examiner (EDE) to do a mail check, initial Yellow, seal envelope, and mail
  7. When Yellow is returned from EDE
    a. Put Yellow with any attachments in "IC Correspondence to be Filed" tray for file room personnel to pick up and file
    b. If certified or overnighted, hold Yellow 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 (see Step F.4. above)