

Mail Log Work Flow for Correspondence for Inspection and Compliance – Biologics Specialist Review

This is a main activity queue in which the Biologics Specialist does a review of compliance issues or firm requests. They may also determine if a response is needed or not.

Hard Copy Incoming Submissions

1. Biologics Compliance Assistant (BCA) places purple folder on your desk with correspondence from the firm. Review items in folder and determine if a written response is required.
2. If no written response is required
 - a. My Queues, Active Tab and click on Mail Log (ML) number link.
 - Can also use mail item # search function to find document
 - b. Click the “Edit Mail Item” tab at the bottom of the screen.
 - c. Go to the middle of the page under “Submission Classification” and click on the drop down box beside “Tags”. Select “No Outgoing Correspondence” in drop down and then click the add button to the side of the drop down box. Then click the “Update” box at the bottom of the screen.
 - d. Move Forward to Finalization (IC), click on BCA who provided the correspondence to you.
 - e. Initial and date document in upper right hand corner and return purple folder to BCA.
3. If written response is required
 - a. Write response and save to your computer drive.
 - b. Go to My Queries, Active Tab and click on ML number link.
 - Can also use mail item # search function to find document
 - c. Click on Documents tab.
 - d. Click on “Create New Document Record” button.
 - i. Select File Type as Uploaded File (This is the default and is usually already selected.)
 - ii. Click on “Choose File” button to find document, click on document, and then click open to attach document

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- iii. Click on the drop down box beside “Type”. Select one of the following types of correspondence:
 - Outgoing General Correspondence
 - Outgoing Compliance Correspondence
 - Outgoing Inspection Report
 - Outgoing Enclosure
 - WARP Correspondence
- iv. Click on “Save and Return to Item Record Button”

IMPORTANT: TWO SITUATIONS IN WHICH MORE THAN ONE DOCUMENT MUST BE ATTACHED TO A MAIL LOG ITEM prior to Section Leader Review:

 1. Inspections
 - a. Attach the report as Outgoing Inspection Report
 - b. Attach the cover letter as Outgoing General Correspondence
 - c. Attach the list of records audited and processes observed as Inspection Notes
 2. Regulatory Actions
 - a. Attach regulatory letter as Outgoing Compliance Correspondence
 - b. Attach WARP item (Weekly Activity Report to the Secretary) as WARP Correspondence.
- v. If Response by the Firm is required:

Tag the Mail log with– Return Action Required by the Firm. This will notify the firm through their daily email notification and NCAH Portal.
- e. If wanted or needed, move forward for Specialist Review for another Specialist to review the document.
 - i. Initial and date document in upper right hand corner and give purple folder to Specialist for review
 - ii. After review, open document by clicking on document link under “Document” tab, modify as needed, and Save As on your computer drive
 - iii. Then repeat steps under 3.d.

IMPORTANT: When uploading a modified document, make sure it is tagged as the same type of correspondence as the original version.
- f. Move forward to Section Leader Review (IC), if required.
 - Facility documents letters – Bill Huls (Facility Manager) has Section Leader functionality for Facility Documents
 - Controversial letters and outgoing correspondence during training period
 - NOTE –Doug Murtle (Investigation Manager) has Section Leader functionality for Compliance Correspondence in Dan Coyle’s absence – see **ICSOP0001**, *Delegation of Authority for Center for Veterinary Biologics - Inspection and Compliance*
 - See **ICWI0076**, *Mail Log Work Flow for Correspondence for Inspection and Compliance: Section Leader Review*, for specifics regarding this review

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- g. Move Forward to Finalization (IC) if no Section Leader review is required or if letter has been reviewed and approved by Section Leader previously.
4. If a response was written, the BCA will finalize the document.
- a. The BCA will provide the finalized document in a purple folder for the Specialist to sign.
 - b. After signing the document, the Specialist needs to get Section Leader initials on the yellow copy of the correspondence.
 - c. The Specialist returns the purple folder to the BCA whose name is on the folder, and the BCA mails letter and submits correspondence and supporting information to Records Management.

PORTAL – Electronic Submissions

1. BCA will electronically assign the mail log to appropriate Specialist in the LSRTIS, Mail Log. Specialist may receive an email that an item has been assigned.
2. If no written response is required

See Item 2.a. – 2.d. under Hard Copy Incoming Submissions
3. If more information is needed from the firms, request the information by initiating a child workflow through the “Request Info from Submitter” activity.
 - a. If bench records, additional information, or corrected information is needed, specify the request within the Routing Comments.
 - b. Once this request has been received by the firm, they may append additional attachments to the Mail Log item. This may be additional information or replacing an incorrect document.
 - i. The CVB user(s) who are assigned to the Mail Log item will receive an email notification with the subject “Submitter has appended documents to Mail Item xxxxxx”.
 - ii. Upon receiving this email, the CVB User must complete the child workflow, which will be found in the Pending Other Input tab in Mail Log.

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4. If written response is required

- a. See Item 3.a. – 3.e. under Hard Copy Incoming Submissions, with the exception that there are no hard copy documents to initial.
CRITICAL! When uploading a modified document, make sure it is tagged as the same type of correspondence as the original version.
- b. Move forward to Section Leader Review (IC) if required. See Item 3.f. under Hard Copy Incoming Submissions.
- c. Move Forward to Finalization (IC) if no Section Leader review is required or if letter has been reviewed and approved by Section Leader previously.

5. If a response was drafted, the BCA will finalize the document and push to you as the Specialist for Signature under Sign Correspondence (IC) activity.

- a. The Specialist should open the pdf document and Digitally Sign the document with the approved USDA Logo Signature block.



- b. Save this document on a designated drive, and re-upload that signed document into the Mail Log. **ENSURE THIS IS THE SAME DOCUMENT TYPE.**

6. Section Leader Final Authorization

- a. The Section Leader will review the document for policy if it is the first time reviewing the letter and ensure the letter is signed by the Specialist and meets the criteria for a portal document as under **ICSOP0045, *Inspection and Compliance Correspondence (LSRTIS, Mail Log Procedures)***. Upon acceptance, move the mail log to Records Management (RM).

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- b. The document is moved to Records Management. Records Management will perform a Quality Review Audit, and upon completion (Filing), the Record will be complete.

7. CVB Responses to Portal

Responses and completed records without CVB responses will be sent back to the firms through the NCAH Portal after the mail log is complete (through Records Management review).

11 a.m. and 3 p.m. Central time, daily

- a. All final versions (highest document number) of any Outgoing Attachment, regardless if the document initiated in the NCAH Portal or with CVB
- b. Tag of “No Outgoing Correspondence”
- c. Awaiting Update from Submitter (from CVB child workflow of Request Info from Submitter)

3:30 p.m. Central time, daily – NCAH Portal Daily CVB Submission email, Submissions to CVB-IC with the following status:

- a. Update from Submitter Received
- b. Awaiting Update from Submitter
- c. Completed items