Title: Mail Log Work Flow for Correspondence for Inspection and Compliance: Section Leader Review
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# Mail Log Work Flow for Correspondence for Inspection and Compliance: Section Leader Review

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**Notes:** 

## Mail Log Work Flow for Correspondence for Inspection and Compliance: Section Leader Review

Section Leader Review is a step for policy review and consistency with Inspection and Compliance.

Section Leader Final Authorization is a step to ensure all documented comments have been incorporated if applicable, and that the correct document is being sent to the firms.

**NOTE** – Managers have Section Leader functionality for Facility Documents. The Investigation Manager has Section Leader functionality for Compliance Correspondence when the Section Leader, Compliance is not available.

#### I. PORTAL – Electronic

### A. Section Leader Review (IC)

- 1. Specialist pushes the Mail Log documents to the **Section Leader Review (IC)**.
- 2. Review items for consistency.
- **3.** Edit document using Track Changes. Use New Comment for questions and comments.
- **4.** If needed, Click on "Create New Document Record" button.

  a. Select File Type as Uploaded File (This is the default and is usually already

a. Select file Type as Uploaded file (This is the default and is usually already selected.)

IMPORTANT: When uploading a modified document, make sure it is tagged as the same type of correspondence as the original version. You may have to change the type on the initial document.

- **5.** Move Forward to **Review (Specialist)** if changes are required. If no changes are need and the Specialist is not in training status, send the Mail Log to Finalization.
- 6. After Finalization, the BCA will move the Mail Log item to the Specialist under the activity **Sign Correspondence** and digitally sign the document. The Specialist should move the Mail Log item back to the Section Leader under the activity **Section** Leader Final Authorization.

#### B. Section Leader Final Authorization -

- 1. 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 NCAH Portal document:
  - a. Review of the signed electronic document including the following:
  - b. The content of the letter meets the policy of CVB-IC,
  - c. The letter is digitally signed with the USDA Logo added,

- d. The attachment type of the document matches the intended document (i.e., Compliance Correspondence),
- e. All versions of the draft documents are the same document type.
- f. The last item the Section Leader needs to determine is if the Mail Log item may go back to the NCAH Portal or should be suppressed from the Portal (in these cases, a hard copy document must be printed).
- **2.** Upon acceptance, move the Mail Log to Records Management (RM).
- 3. Note: The comment box asks, "Are you moving this item because you are giving final approval..." If you are giving final approval (with or without edits), click ok. If you need to review it again, click Cancel.

## II. Hard Copy (Incoming and/or Outgoing)

## A. Section Leader Review (IC)

- 1. All Steps are the same as if it was an electronic document (above) except The BCA will print a copy of the completed outgoing letter and provide to the specialist or designee for signing upon finalization.
- 2. Move Forward to Review (Specialist) if changes are required. Move Forward to Finalization (IC) if no changes are needed and click on the Biologics Compliance Assistant (BCA) who performed the activity of Review (BCA) or IC In-box Pool for investigations. E-mail the Specialist to let them know where their document is located.

Note: The comment box asks, "Are you moving this item because you are giving final approval..." If you are giving final approval (with or without edits), click ok. If you need to review it again, click Cancel. The BCAs will look for Section Leader approval prior to finalization of the document as needed.

3. After the Specialist signs the hard copy correspondence, they will send to the Section Leader as Section Leader Final Authorization.

#### B. Section Leader Final Authorization –

- 1. 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 NCAH Portal document:
  - a. Review of the signed electronic document including the following:
  - b. The content of the letter meets the policy of CVB-IC,
  - c. The hard copy letter is signed. This may take contacting the Specialist or BCA to ensure it is signed.
  - d. The attachment type of the document matches the intended document (i.e., Compliance Correspondence),
  - e. All versions of the draft documents are the same document type.
  - f. The last item the Section Leader needs to determine is if the Mail Log item may go back to the NCAH Portal or should be suppressed from the Portal.
- **2.** Upon acceptance, move the Mail Log to Records Management (RM).

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