

BCA Work Instructions for Processing/Finalizing Inspection Reports

Inspection Reports are routed through the Mail Log (ML) system.

Related Work Instructions

- **ICWI0236**, *Mail Work Flow for Correspondence for Inspection and Compliance: Biologics Specialist Review*
- **ICWI0215**, *Routing Inspection Reports – For Specialist*

A. Prior to finalizing an inspection report in the ML

1. Ensure the inspection has moved from “Pending Report” to “Pending Finalization” in the LSRTIS – IC – Inspections Dashboard screen. **Moving forward and finalizing the report in the ML without having the inspection record in “Pending Finalization” creates errors in the system.**

- If it has not moved to “Pending Finalization”, the Specialist may not have entered action items and/or linked the ML to the inspection record. (Note: the Specialist may NOT move an inspection report to the IC Inbox Pool until the ML has been linked to the inspection record).

2. The ML Workflow Log should indicate Section Leader (SL) Inspection and Compliance (IC) review as approved, “Yes,” prior to finalization by the Biologics Compliance Assistants (BCAs). When there is an Acting SL, there may be a comment indicating the policy review has been done. This is sufficient.

B. Inspection Report in IC Inbox Pool

1. Reports are to be finalized on a first-in, first-out basis. BCAs self-assign the oldest inspection report to their queue for review and formatting. The ML will move to FINALIZATION automatically after an Inspection Report is self-assigned.

2. Any changes to the inspection report should be discussed with the Team Leader/author prior to finalization. If the Team Leader is out, changes can be discussed with the Section Leader, Inspection.

C. Finalize report and cover letter

1. After finalizing, convert the Word documents (inspection report and cover letter) into pdf format

2. Attach pdf documents to ML

- a. Cover letter is identified as Outgoing Correspondence
- b. Inspection Report is identified as Outgoing Inspection Report

3. Add all applicable EM Notifications to ML

4. If firm is not portal enabled

- a. Make hard copy of report and cover letter for Team Leader’s signature
- b. Prepare certified envelope for mailing report and cover letter to firm

5. Complete Submission Response on Info tab of ML

- a. Date of letter
- b. Date mailed
- c. Shipment type – Portal or Certified Mail
- d. Shipment tracking number; only if documents are sent certified mail

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- e. Put inspection report and cover letter in purple folder to Specialist for signature

D. Move the ML item to Specialist for signature

1. If firm is portal enabled, Specialist will
 - a. Do a final review of documents for any final corrections
 - b. Electronically sign inspection report and cover letter
 - c. Move the ML item to SL for Final Authorization
 - d. The SL will review and move the ML to Records Management (RM)
 2. If firm is not portal enabled
 - a. The Specialist will
 - i. Do a final review of documents for any final corrections
 - ii. Sign original inspection report and cover letter
 - iii. Move ML to SL for Final Authorization
 - b. The SL will
 - i. Move the ML item to the BCA under the “Certified Receipt” activity
 - ii. Give the signed hard originals back to the BCA to be mailed
 - c. The BCA will
 - i. Mail original signed report and cover letter to the firm.
 - ii. Follow internal documented procedures for the checking of the mail prior to it being sealed and sent out – see **ICWI0111**, *CVB-IC Mail/Filing*.
 - iii. Keep certified receipt. Verify receipt by the firm. Await green Certified Receipt card’s return.
 - iv. Record the date the green Certified Receipt card was received by the firm in the ML
- Moving the ML out of “Finalization” triggers LSRTIS to move the record out of “Pending Finalization” on the Inspection dashboard.

Consistency Items for Inspection Reports

1. Observations are to be written in past-tense; however, references to liaisons or personnel responsibilities should be written in present-tense.
2. When using **ICTEM0009**, *Inspection – Report*, the location of the firm listed on the cover page should spell out the name of the state rather than the abbreviation. No zip code should be listed in this section.
3. Double space between items within the report and triple space between categories.
4. When referencing 2007 and 2008 forms within the report, the plural should be on “2008s” and “2007s”, not “Forms.”

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5. Spell out acronyms the first time they are used in the report with the initials in parentheses directly following. The initials may be used after that within the report (example: Veterinary Services (VS) Memorandum).

6. The first time a product is referenced in the report, the true name must be included along with the product code. After that, only the product code needs to be used (example: Code 19A5.21).