

## IC Inbox Queue

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

### Background

This work instruction gives guidance and information for the IC Inbox queue process. The IC Inbox is a temporary holding place for correspondence awaiting Biologics Compliance Assistant (BCA) attention. Mail Log (ML) items sent to the IC Inbox include:

- Outgoing correspondence from Inspection and Compliance (IC) personnel for finalization (examples: inspection reports, regulatory letters sent to unassigned firm); and
- Submissions through the NCAH Portal from regulated firms for IC review (examples: APHIS Form 2007s, general/product correspondence, Adverse Event Report (AER)).

### A. Access to IC Inbox

1. Go to *My Queues*
2. Click on *IC Inbox* tab
  - a. This is all ML items that have been sent to the IC Inbox for review or finalization.
  - b. Default is set to list Mail Log items numerical by ML number but can be sorted by any of the other categories.
3. Other options
  - a. *Search* function if you know the ML number
  - b. *Advanced Search (IC)* from Search List of Values (LOVs) if you know the info, but not the ML number

### B. BCA IC Inbox Responsibilities

1. BCAs are assigned designated firms (see BCA's Firm Distribution List). Typically, those firms should be self-assigned, unless otherwise noted.
2. BCAs review incoming correspondence from firm personnel received through the NCAH Portal.
3. BCAs finalize documents that may be sent from Specialists to the IC Inbox in priority order of submission type or submission subtypes as listed below and then by date (first in-first out)
  - a. Regulatory Actions (Compliance correspondence)
    - i. Mandated or Voluntary Stop Distribution and Sale
    - ii. Hold Release
    - iii. Infraction Letter
    - iv. Letter of Warning
    - v. Letter of Advice
  - b. Regulatory Correspondence (Compliance Correspondence)
    - i. Rescinding Mandated Stop Sales
    - ii. Lifting of a Hold Release Action
    - iii. Acknowledging of a firm's lifting of a Voluntary Stop Sale
    - iv. Rescind of a Regulatory Action
  - c. Inspection reports
  - d. General correspondence

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- i. Process Deviation requests
- ii. Preliminary facility drawings
- iii. No submission subtype
- e. Personnel (APHIS Form 2007s)
- f. Facility Documents *\*These go into their own Facility Document queue instead of the IC Inbox)*
- g. Administrative Inspection Reviews (AIR)

### C. Movement of ML Items from *IC Inbox*

1. When a BCA is ready to review or finalize ML items for their assigned firms, or next submission in line
  - a. Click Self-Assign
  - b. This moves the ML item from *IC Inbox* to the BCA's *Active* queue
2. The BCA determines which process is needed (work is completed on ML after ML has been self-assigned, not in the Inbox tab)
  - a. Incoming Mail Log Items (not reviewed by a Specialist yet) Review ML item for entries accuracy and move forward to the assigned Specialist (see **CVB-WI-0100**, *BCA Entry and Review of Incoming Correspondence*)
  - b. To Finalize a ML item after receiving from a Specialist (see **CVB-WI-0101**, *Biologics Compliance Assistant (BCA) Finalization of Correspondence*)