United States Department of Agriculture
Center for Veterinary Biologics

Standard Operating Policy/Procedure

Inspection and Compliance Correspondence (LSRTIS, Mail Log Procedures)

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Contact: Center for Veterinary Biologics, 515-337-6100

United States Department of Agriculture
Animal and Plant Health Inspection Service
P. O. Box 844
Ames, IA 50010

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1. Purpose

Licensees and permittees submit information to the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) for review, and in many cases, authorization for certain functions. Official requests and responses must be in writing. The process used to receive and route the individual submissions is a controlled, yet flexible process.

This document outlines the general policy regarding the receipt, review, and routing of initial submissions, generated either internally or externally. See CVB-SOP-0046, *General Inspection and Compliance Correspondence Guidance,* for additional policy regarding style/format references, template use, and common conventions used by the CVB.

The scope of this document does not include submissions for APHIS Form 2007s, APHIS Form 2008s, Export Certifications, or Facility Documents. Those specific incoming submissions have processes documented in other Quality Management (QM) Standard Operating Procedures (SOPs) and Work Instructions and can be found in the CVB Quality Management program of Decision Tracker.

2. Definitions

2.1 Record

A submission generated by a licensed establishment, or an unlicensed entity, or the CVB-IC while accomplishing the CVB Mission. The submission becomes a record in LSRTIS Mail Log (ML) that is reviewed and processed by the CVB. The submission includes the information entered on the Info tab for each ML Item.

2.2 NCAH Portal

An external-facing application which enables web-based electronic submissions and responses between biologics establishment and the CVB.

2.3 Licensing, Serial Release and Testing Information System (LSRTIS) Mail Log Module (ML)

This database system is the information management system used by the CVB for various regulatory functions. The module most related to correspondence is the ML as it serves as a document tracking system.

2.4 Decision Tracker Quality Management Program

This record's management system maintains quality documents, including templates used for correspondence.

3. Responsibilities

3.1 Specialist

Review incoming correspondence and initiate outgoing correspondence, if needed. When letters are written by other individuals for Specialist signature, the Specialist is responsible for reviewing document. Adds applicable notifications to the ML system.

3.2 Biologics Compliance Assistant (BCA)

Performs a primary review of incoming correspondence, provides any additional information as needed, and finalizes all outgoing. Provides back up to the EDE duties, when needed.

3.3 Export Document Examiner (EDE)

Scans and logs in any Hardcopy correspondence, creates ML Items, and serves as the secondary review of mail prior to Hardcopy correspondences leaving the CVB.

3.4 Section Leader

Provides input on incoming submissions regarding direction or need for response, as needed, reviews outgoing correspondence for policy and consistency in application of policy. Reviews outgoing correspondence for accuracy. Reviews the ML information for accuracy.

3.5 System Administrators (LSRTIS)

Provide support to employees for system functions within LSRTIS.

3.6 Records Management

Provides final review of outgoing CVB-IC correspondence prior to the system uploading the documents to the NCAH Portal.

3.7 Program Coordinator (PC)

This position rotates on a weekly basis [redacted]

4. Procedure Overview

See workflow diagrams (**Appendix I**) for general routing of documents. This workflow is specific for electronic submissions received through the NCAH Portal and initiated by the CVB, usually in the form of Compliance Correspondence. In general, this same workflow is used for submissions received through a courier service or the US Mail, known as Hardcopy, with some differences as to how the submissions are entered into the LSRTIS-ML and the response output.

5. Receipt of Official Correspondence

Official correspondence is received through the NCAH Portal or via a courier service (Hardcopy submissions). Hardcopy submissions must be entered into the ML portion of LSRTIS by the EDE, or their backup.

5.1 NCAH Portal is the recommended method for submission of all records from establishments. The establishments should follow NCAH Portal User Guide 9, *General Guide for E-Submissions of General Correspondence to CVB-Inspection and Compliance.*

5.1.1 Submission via the NCAH Portal is considered an authentic submission and does not require any additional electronic signatures.

5.1.2 The record should include an attachment. This is usually the firm's letter requesting an authorization or providing information. Title 9, *Code of Federal Regulations* (9 CFR), section 116.5, notifications are exceptions.

5.2. Hard copy submissions (via the USPS or other courier service) are also received and considered official. See CVB-WI-0159, *Mail Receipt, Process, and Distribution for CVB – IC Hard Copy Submissions*, Processing mail Sections 2, 3, and 6.

Hard copy submissions are scanned into the Mail Log and the Mail Log becomes the official correspondence for record retention purposes.

6. BCA Review of Official Incoming Correspondence

All incoming correspondence is routed through a member of the CVB-IC BCA group for initial review. While it is best if the preliminary review for incoming official correspondence is performed by the BCA assigned to the firm to provide a continuity of information, that is not always possible due to the externally generated workload. See CVB-WI-0102**,** *IC Inbox Queue,* on how to move items to individual mail queues.

The preliminary review is conducted to determine if the submission is complete (technically) and correct. Corrections may be made to the Info Tab if the firm has not adequately followed the instructions listed in NCAH Portal User Guide 9. The preliminary review also allows the BCA to provide additional information related to the submissions. Editing of the Mail Log Info Tab is appropriate, if needed. See CVB-WI-0100, *Correspondence - BCA Entry and Review of Incoming Items.*

7. Specialist Review of Official Incoming Correspondence

All incoming correspondence is routed to either the Specialist assigned to the firm or the Senior Specialist assigned. If the Specialist (and Senior Specialist) is out of the office, submissions that are time sensitive (Voluntary Stop Sales) should be routed to the Program Coordinator, the Specialist's supervisor for most other correspondence including process deviations or compliance related items, or other predetermined routes. Facility documents and APHIS Form 2007s may wait for the assigned Specialist if they are not out for more than 21 business days. Submissions in regard to investigations may be routed to the Specialist assigned to the investigation or the Investigations Manager.

The Specialist will determine if the submission requires a written response. If so, see CVB-WI-0139**,** *Correspondence - Mail Log Work Flow for Inspection and Compliance – Biologics Specialist Review.* Part of this process can include feedback from others in the program.

All correspondence assigned to "Specialist in Training" must be reviewed by their supervisor, Section Leader Review (IC), or designee. Input from their mentor prior to the Section Leader review is advised. Specialists in Training is typically those Specialists who have been in that role less than 18 months. The BCA checks this workflow to determine if the correspondence has been approved by the Section Leader.

Responses to the uncommon submissions, infrequent situations, or Compliance Correspondence should be routed through the responsible Section Leader, Section Leader Review (IC) for review of content and adherence to program policies. See CVB-WI-0105, *Correspondence - Mail Log Work Flow for Inspection and Compliance: Section Leader Review.*

8. BCA or Specialist Generated Outgoing Correspondence

There are specific situations in which the Specialist will initiate outgoing correspondence. These documents (reports/letters) are generated in response to a specific regulatory process, not in response to official incoming submissions. The processes include the following:

8.1 Inspection Reports

See CVB-WI-0136**,** *Inspection: Routing of Inspection Reports - For Specialist*

8.2 Regulatory Letters

See CVB-WI-0155, *Correspondence - Work Flow for Initiating a Regulatory Action or Regulatory Correspondence Using the Mail Log System and Portal*

8.3 AIR (Administration Inspection Review) Processing Documents

See CVB-WI-0145, *AIR - Preparation of Administrative Inspection Reviews*

8.4 CVB Employee Assignment Changes

Upon reassignments of establishments, Personnel change letters are drafted by the BCA and routed through the Director, IC, prior to sending out.
See CVB-TEM-0022, *Personnel Changes - Letter to Firm*

9. Finalization of Correspondence and ML

9.1 BCA Finalization

The BCA reviews the correspondence to ensure the document is readable, conforms to acceptable format/grammar/punctuation standards, is consistent, and includes correct information regarding Product Codes, Serial numbers, Establishment information and personnel names. See **CVB-SOP-0046**, *General Inspection and Compliance Correspondence Guidance,* and CVB-WI-0101, *Biologics Compliance Assistant (BCA) Finalization of Correspondence.*

9.2 Specialist Signature

The author is responsible for signing outgoing correspondence (or ensuring there is a designee for signing) and ensuring the ML item is complete including related submissions, phone calls, or other information. See CVB-WI-0139, *Correspondence - Mail Log Work Flow for Inspection and Compliance - Biologics Specialist Review*, and CVB-WI-0103, *Correspondence - Linking Documents within the LSRTIS, Mail Log System*.

9.3 Section Leader Final Authorization

The Section Leader reviews the ML item for accuracy and completeness. See CVB-WI-0105, *Correspondence - Mail Log Work Flow for Inspection and Compliance: Section Leader Review.*

9.4 Records Management

The staff within PIMS – Records Management will review outgoing correspondence for a final quality check. See CVB-WI-0045, *Records Management, Quality Assurance of Inspection and Compliance Outgoing Correspondence via NCAH Portal.*

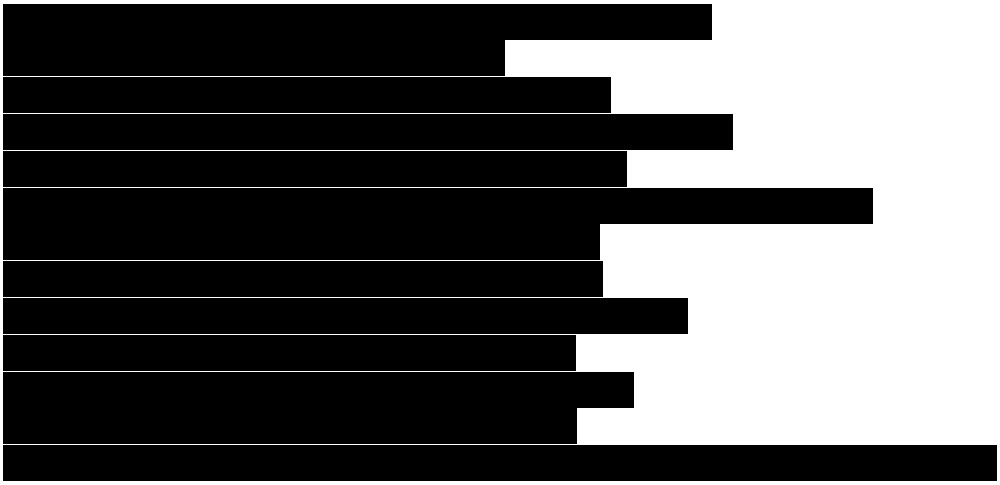
10. Types of Correspondence – Common WI and TEM Index

10.1 General Correspondence

See CVB-WI-0139, *Correspondence - Mail Log Work Flow for Inspection and Compliance - Biologics Specialist Review.*

10.2 Compliance Correspondence

See CVB-WI-0105, *Correspondence - Mail Log Work Flow for Inspection and Compliance: Section Leader Review*



10.3 Inspection Correspondence

See CVB-SOP-0036, *Post-Inspection Activities* and
CVB-WI-0121, *Inspection: BCA Process for Finalization of Inspection Reports*

10.4 Processing Administrative Inspection Reviews (AIR)

See CVB-WI-0144, *AIR - Processing Incoming Administrative Inspection Review Documents by CVB* and
CVB-WI-0145, *AIR - Preparation of Administrative Inspection Reviews*

10.5 Miscellaneous Correspondence

11. System Functions/Releases to NCAH Portal

See the System Administrators for LSRTIS for functionality in which the normal process needs to be halted or updated.

11.1 Daily Email to the firms

11.1.1 Included Items:

- Inspection and Compliance – Correspondence
  Serial release notifications are <u>not</u> included – these will remain in their individual emails at 11 a.m. and 3 p.m., Central time.

- Policy, Evaluation, and Licensing – Correspondence, Labels

- CVB Laboratory – Information of Serials put on Test once an APHIS Form 2008 has been received by the firm.

- Sample Processing – Samples received, with the corresponding Sample Code assigned.

11.1.2 How to update this Email Address:

See instructions within CVB-WI-0142, *Serial Release - Process for Email Address for Electronic Notification of Serial Release*.

11.2 Documents/Information Released to NCAH Portal –
See NCAH Portal Guide #3, Submission History (CVB) and Account Details

The Liaison/Alternate Liaison, Quality Review role at the firm may search on IC Correspondence. Updates to the NCAH Portal are sent at 11 a.m. and 3 p.m., Central time. Updates include a status change with the applicable CVB Response or CVB Initiated Correspondence.

Status Changes for the Firm (within the NCAH Portal):

- **Submitted** – Submission been sent from the NCAH Portal to the CVB ML and is an Active ML item.

- **Awaiting Update from Submitter** – Upon request by the firm to the CVB (either by email or phone call to the Biologics Specialist or other IC employee).

- **Complete** – The Mail activity has been completed for the ML with one of the following outcomes:

  1) *CVB Response* – the Outgoing Correspondence Files (Outgoing General Correspondence, Outgoing Compliance Correspondence, Outgoing Enclosure document types) will be displayed within the Portal.

  2) *No Outgoing Correspondence* – The submission does not require an immediate response from the CVB-IC. The incoming document has been received and filed.

  3) *CVB Initiated Correspondence* – Any correspondence that initiated at the CVB, such as Outgoing Inspection Report.

  4) *Response is linked to a different Mail Log Item* – the CVB may link multiple MLs together, where only one submission will contain the CVB Response (Functionally linked ML items). The ML item that does not have the outgoing correspondence will have a CVB Response of "See ML xxxxxx for CVB Response to this Submission."

All "open" submissions remain in the NCAH Portal until they are completed. Completed submissions are available for 60 days after their last action date. Firms are required to download the CVB responses to their own system.

12. Summary of Revisions

Version CVB-SOP-0049.03

- Added Hard Copy specific processes
- Added routing procedures for specific regulatory letters.
- Updated out-dated links to MasterControl

Version CVB-SOP-0049.02

- File name changed
- Added sections 5-11 with detailed descriptions of the roles of the BCA review, Specialist review of incoming correspondence, Specialist generate outgoing correspondence, finalization of correspondence and ML, and types of correspondence
- Updated MasterControl filenames and numbers to reflect current numbering in MasterControl system
- Removed majority of information in Section 4. Overview and renamed to "Procedures." Removed items are being incorporated into other QM documents
- Flow chart updated

Version ICSOP0045.02

- Updated flow charts
- Added Facility Document Pool Queue (Section 4.3.2)

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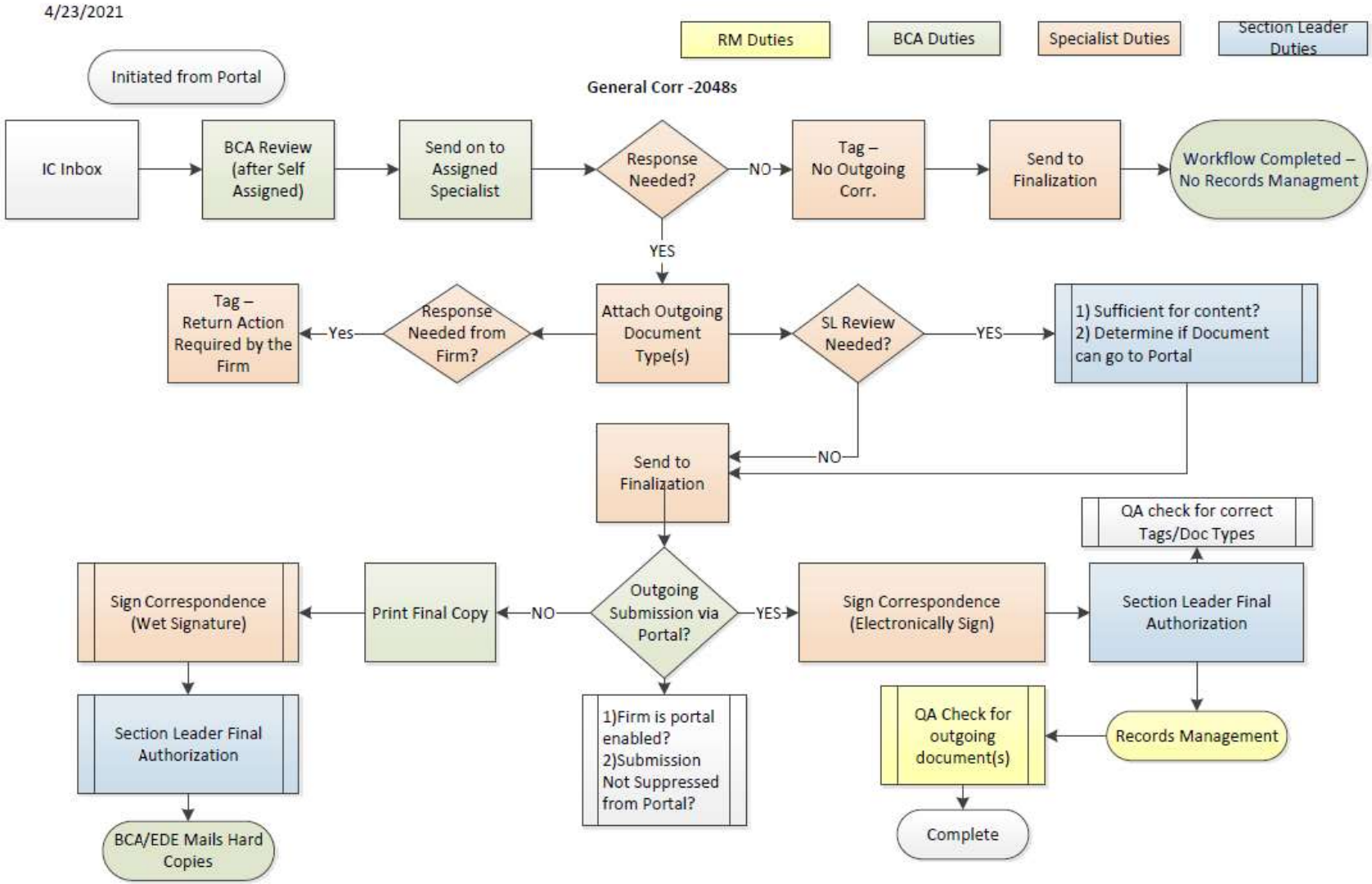
Appendix I



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