

Animal and Plant Health Inspection Service

**Veterinary Services** 

Center for Veterinary Biologics

1920 Dayton Avenue PO Box 844 Ames, IA 50010

(515) 337-6100

# Records Management, Quality Assurance of Inspection and Compliance Outgoing Correspondence via NCAH Portal

Document Number: CVB-WI-0045 Revision: 02

**Previous Number: PIMSWI0045.01** 

Vault: CVB-Released

Section/Area: CVB-WI-PIMS

Effective Date: 13 Dec 2022

**Notes:** 

## Records Management, Quality Assurance of Inspection and Compliance Outgoing Correspondence via NCAH Portal

Records Management will perform a Quality Review audit of electronic Inspection and Compliance (IC) outgoing correspondence sent via the NCAH Portal. Hard copy responses mailed to the firms will follow the process listed in **CVB-WI-0118**, *CVB-IC Mail/Filing*.

Correspondence finalized by CVB-IC will be moved forward in the Mail Log to the Records Management (RM) activity. This activity is a pool that any RM staff has access to in order to perform their duties.

Mail Log items that are received by 4:30 p.m. will be reviewed for sufficiency (see list of "Items to Audit" below) and completed by 3 p.m. the following business day. This will ensure the firms, who will receive this information back through the NCAH Portal, will receive the information in a timely fashion.

- Submission Subtypes that must be completed in the above timeframe include the following (in priority order):
  - Mandatory Stop Sale *Reviewed the same day received, if possible.*
  - Warning Letter
  - o Hold Release
  - o Infraction
  - Letter of Advice
  - Voluntary Stop Sale
  - Inspection Report
  - o Correspondence without a subtype
  - Facility Documents
- Deviations from the above timeframe may be considered with prior notification to the IC staff.

#### **Items to Audit**

- 1. Mail Log Item
  - a. Portal Return? Checked Yes, there should be a "Outgoing Correspondence" that is electronically signed by an IC employee.
  - b. Portal Return? Checked No, the "Outgoing Correspondence" will only have a /s/ on the copy.
  - c. Product Code and/or Serial Numbers match the outgoing correspondence

CVB-WI-0045.02 Page 1 of 2

- 2. Documents Tab there are four document types for outgoing correspondence:
  - a. Outgoing General Correspondence
    - i. May be sent out with
      - 1. Outgoing Inspection Report
      - 2. Outgoing Enclosures
    - ii. Must <u>not</u> be in the same mail log (ML) item as Outgoing Compliance Correspondence
    - iii. Should have digital signature (with USDA Logo), if electronic
  - b. Outgoing Compliance Correspondence
    - i. May be sent out with Outgoing Enclosures
    - ii. Must <u>not</u> be in the same ML as Outgoing General Correspondence
    - iii. Should have digital signature (with USDA Logo), if electronic
  - c. Outgoing Inspection Report
    - i. Must go out with Outgoing General Correspondence
    - ii. May go out with Outgoing Enclosures
  - d. Outgoing Enclosures
    - i. Should go out with another type of outgoing correspondence
    - ii. Cannot go out as a standalone document type, unless it is a part of a Facility Document Submission Type
    - iii. Facility Documents may have Outgoing Enclosures by themselves, or include an Outgoing General Correspondence
    - iv. Outgoing Enclosures for Facility Documents will be stamped with an APHIS File date and invisible digital signature
- 3. Workflow Log
  - a. Section Leader Final Authorization with an Approval Step = Yes

Discrepancies to any of the above items should result in the ML being returned to the last activity. Do this by entering a Sys Admin request\* in LSRTIS requesting a "Revert Move" for the ML#.

\*CVB-SOP-0011, Initiating and Processing System Administrator Requests in the Licensing, Serial Release and Testing Information System (LSRTIS).

CVB-WI-0045.02 Page 2 of 2

### Signature Manifest

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All dates and times are in Central Standard Time.

## CVB-WI-0045 Records Management, QA of IC Outgoing Correspondence via NCAH Portal

#### **Review for Doc Format**

Name/Signature	Title	Date	Meaning/Reason
TIANA BLANCO (TABLANCO)	Quality Management Assistant	12 Dec 2022 11:31:09 AM	Approved

#### **Final Quality Check**

Name/Signature	Title	Date	Meaning/Reason
CROSLEY HERR (CRHERR)	QA Specialist/CVB MC SME	13 Dec 2022, 07:18:52 AM	Approved