Workflow for Initiating a Regulatory Action or Regulatory Correspondence Using the Mail Log System and Portal

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Source Document: CVB-SOP-0037, *Investigation Methods and Processing of Alleged Violations of the Virus-Serum-Toxin Act*

I. Background:

Several avenues are available to initiate the document for a regulatory action or correspondence.

1. **If there are one or more serious actions in an inspection report, the LSRTIS Inspection system will automatically initiate a Mail Log (ML) to the *Team Leader* for addressing the issue(s). The ML will be initiated post finalization of the inspection report. (See Section II)**

   DO NOT INITITATE AN INFRACTION BEFORE THE FINALIZATION OF AN INSPECTION REPORT UNLESS DIRECTED TO DO SO.

2. **Regulatory actions in any other instance can be initiated as a stand-alone ML and may be linked to an inspection report as well as other ML letters. (See Section III)**

A. *Regulatory actions* include the following:
   1. Letter of Advice
   2. Infraction Notice
   3. Letter of Warning
   4. Voluntary Stop Distribution and Sale
   5. Mandated Stop Distribution and Sale
   6. Hold Release
   7. Letter of Guidance

B. *Regulatory correspondence* include the following:
   1. Rescind of a regulatory action
   2. Rescind of a Mandated Stop Distribution and Sale
   3. Lifting of a Hold Release
   4. Acknowledgement of a firm's lifting of a Voluntary Stop Distribution and Sale
   5. Letters related to regulatory actions

6. Letters related to VBI investigations (not Letter of Warning)

II. Serious Action Items Identified from an Inspection

See **CVB-WI-0136**, *Inspection: Specialist Routing of Inspection Reports*. All Serious Action items initiate a ML in "My Queues." Once the inspection report is finalized (post "Pending Finalization"), the Team Leader of the inspection will receive a ML notification.

If there are one or more serious action items post finalization, the Team Leader will receive an email similar to the one below.

From: [redacted]
To: XXXXXXX
Subject: New Mail Items
Date: Wednesday, June 5, 2019, 10:48:06 AM

Hello!

There is a new Mail Item for Inspection [redacted] for your immediate review! Please visit the CVB Mail Log website to see the items awaiting your actions!

MailLog #: XXXXX
Activity: Initial Entry - IC
Type: General Correspondence (IC)

[redacted]

The Inspection Team Leader's Mail log queue will look similar to this:

Mail Log #	Firm	Product	Brief Description	Type	Submitted Date	Status
[redacted]			There are 1 Serious Action Item(s)	General Correspondence (IC)	[redacted]	Completed
[redacted]			There are 1 Serious Action Item(s). [redacted]	General Correspondence (IC)		Completed
[redacted]			There are 3 Serious Action Item(s) - [redacted]	General Correspondence (IC)		Completed

A. The ML will need to be corrected to be more appropriate for the action intended.

1. Correct "Brief Submission Description" to a more appropriate description, such as "Infraction from Inspection".

Mail Log #	Firm	Product	Brief Description	Type	Submitted Date	Status
			INFRACTION -	General Correspondence (IC)		Completed
				Product Correspondence (IC)		Completed
			There are 1 Serious Action Item(s)	General Correspondence (IC)		Active

2. Functionally or Informationally link ML items, if needed.

3. Select the appropriate "Submission Subtype".
   i. Letter of Advice
   ii. Infraction Notice
   iii. Hold Release

4. Regulatory action source should be "Inspection".

5. Select the correct "9 CFR Violations". – Select "+ Add". More than one can be selected.

6. Select "Tag" and add the appropriate tag(s) – at a minimum "Regulatory Action" – Select "+ Add".

7. Select "Update".

B. Search Decision Tracker for the template for the regulatory action/letter that will be written. Write the appropriate regulatory action.
   1. Save the letter
   Note: More than one regulatory letter can be written for an inspection. If needed, create a new regulatory letter from ML system.

C.

Create Attachment Screen

D. Select the "Documents" tab of the ML to upload the letter.

1. Select "Type" arrow.
   Select "Outgoing Compliance Corr".

2. Select "Save and Add Another Document".

3. Upload the WRP document. ([redacted]

4. Select on "Type" arrow.
   Select "[redacted]".

5. Select "Save and Return to Item Record" Button.

Note: The Specialist should edit the Mail Item to include any requested follow-up within the content of the regulatory action or letter.

Mail Log Move Item Screen

E. Select the "Move Forward" tab.

F. Select "OK" to move the document(s).

G. On the drop down select "Section Leader Review (IC)."

H. On the drop down, select "Section Leader Review (IC)." Compliance Correspondence is sent to the Compliance Section Leader [redacted]

I. Select "Move Item."

J. Select "OK" to move the document(s).

K. The item is now in the Queue of the person selected.

III. Initiating a Regulatory Action (Not from Inspection)

Note: If the regulatory action is associated with a current ML item, the regulatory action may be added to that ML, only if all the required information (i.e. investigation report) has been submitted or there must be an informational link to that ML item if a new ML is generated.

- Review ML to confirm requested or required information has been submitted, such as the investigation report.
- If pushed under a current ML, then add the Submission Subtype for the applicable regulatory action.
- Review the Serial Stat for an APHIS Form 2008, if applicable to check if a 2008 has been submitted, released, or exported.

A. Search Decision Tracker for the template for the regulatory action/letter that will be written.
   1. Write the regulatory action/letter.

   2. [redacted]

   3. Save the letter [redacted]

B. On ML home page, choose "Create Mail Item."
   1. Enter the establishment.

   2. Enter product code, if applicable – then select "Add," enter serial number if appropriate. Then select "Set Serial Number."

      a. If no serial number – then select "No Serial Number" (multiple products and/or serials may be added).
      b. **Note**: an infraction, voluntary stop sale, mandated stop sale, hold release requires a product code.

   3. Enter the VBI number, if applicable.

   4. Select the "Date Submitted" – this will be the current date.

   5. Select "Submission Type." Even with no incoming submission, a selection needs to be made. Select "General Correspondence," "Investigation," or "Product Correspondence," whichever one is the most appropriate.

   6. Select the appropriate "Submission Subtype."

      a. If you are writing a **regulatory action**:
         i. Letter of Advice
         ii. Infraction Notice
         iii. Letter of Warning
         iv. Voluntary Stop Distribution and Sale
         v. Mandated Stop Distribution and Sale
         vi. Hold Release
         vii. Letter of Guidance

b. If you are writing **regulatory correspondence** "Submission Subtype" is not required.

7. Select the "Add" button.

8. Select the "Regulatory Action Source" from drop down LOV.
   a. Firm Submission
   b. Inspection
   c. Investigation

9. Select the "9 CFR Violations" from drop down list (multiple violations may be added), click "Add."

10. Select the "Tag", "Regulatory Action" for these actions **only**:
    a. Letter of Advice
    b. Infraction Notice
    c. Letter of Warning
    d. Voluntary Stop Distribution and Sale
    e. Mandated Stop Distribution and Sale
    f. Hold Release
    g. Letter of Guidance

11. Select the "Tag", "Regulatory Correspondence" for correspondence associated with a regulatory action. **(See Section I.B for examples)**

12. Select the "Tag" "No Incoming submission" if not associated with ML letter.

13. If the Level of Regulatory Action is either of the following two actions:
    a. Voluntary Stop Distribution and Sale
    b. Mandated Stop Distribution and Sale

    Select the level of the regulatory action.
    i. All Known Persons
    ii. All Wholesalers or Distributors
    iii. Licensed Premises
    iv. Firm Owned Distribution Points

14. Select "Tag", "Voluntary Stop Distribution and Sale Acknowledged" or "Partial Voluntary Stop Sale". If product was distributed, select "Product Distributed" tag.

15. Write a brief description of the regulatory action taken by including in CAPITAL LETTERS the type of regulatory action at the beginning of the sentence, for example:
    a. INFRACTION
    b. VOL STOP

c. **Note**: This description shows up in the "Brief Description" and must be performed for a timely response in Section Leader queue.

16. Informationally link Mail Items if any ML is associated with this new ML.

C. Select "Create".

D. Note "Mail Item" number created.

Create Attachment Screen

Follow the same process as **Section II**.

Mail Log Move Item Screen

Follow the same process as **Section II**.

IV. Section Leader or Acting Review and Approval – Word Document

Portal Notes:

A. It is important to review the "Type" of document as this will determine which document is delivered via the portal to the firm, if applicable.

B. The final version of each "Outgoing" document type is the document delivered to the firm other than internally routed documents.

C. If a document has an incorrect type, it must be changed to the correct type. This is performed by editing the ML.

D. Go to "My Queries," "Active Tab" and check if there is a folder with corresponding ML number.

E. Select the appropriate ML number.

Mail Log Item Screen

A. Select "Documents" tab, select the regulatory document to review under the "File Name."
   1. Save the attachment and include your initials in the naming convention.
   2. Open the attachment for review.
   3. Utilize the "Review" tab. Select "Track Changes" and/or add comments.
   4. Save the reviewed document.

B. If no changes are needed, go to **Step D**.

C. If review changes require addressing, send the document back to the author for revision.
   1. Select "Create New Document Record".
   2. Select "Browse" to find the reviewed and edited document.
   3. Select "Type" as "Outgoing Compliance Correspondence".
   4. Select "Save and Return to Item Record" [redacted] by following the last series of steps through "Save and Add Another Document".
   5. Select the "Move Forward" button to move the document(s) back to the author for revision. Click "OK" if appropriate.
   6. Select the role – normally "Review Specialist".
   7. Select the author.
   8. Select "Move Item".
   9. IMPORTANT: a message appears that asks: "Are you moving this item because you are giving final approval? Press OK to give final approval. Press Cancel if you are routing for revisions or otherwise have concerns that prevent your approval."
      a. If the revisions are minor and you are comfortable in approving, select "OK" as this will allow the documents to be revised and subsequently moved for finalization [redacted]
      b. If the revisions are major, select "Cancel" and the process will go through Section Leader revision again once the documents are updated.

D. If no changes are needed in the regulatory [redacted]:
   1. Move forward to "Finalization (IC)".
   2. Select the Biologics Compliance Assistant (BCA) assigned to the firm or IC In-box Pool for investigations dealing with unlicensed entities.
   3. Note: For status, check your Mail Log tabs, such as Reviewed - Not Completed.

V. BCA Finalization

A. The BCA finalizes the document as per normal procedures.

B. [redacted]

C. The outgoing product will be a pdf document.

VI. Follow-Up – Role: Section Leader, Investigation Manager, Inspection Team Leader, or Biologics Specialist

A. At the final approval, the Section Leader, Investigation Manager, Team Leader, or Biologics Specialist may edit the Mail Log item for follow-up.
   1. Select Mail Log to edit.
   2. Select "Edit Mail Log item #"
   3. Scroll to "Follow-Up" and select "Yes".

4. Enter follow-up Due Date.
5. Select "Update"

VII. Follow-Up Completed – Role: Section Leader, Investigation Manager, Inspection Team Leader, or Biologics Specialist

A. The "For Follow-Up" tab will list the Mail Log items requiring a follow-up.

B. When the follow-up is satisfactorily completed:
   1. Select the Mail Log Item #
   2. Select "Edit Mail Item #"
   3. Scroll to "Follow-Up" and enter completion date.
   4. Enter follow-up description.
   5. Select "Update"

VIII. Final Authorization: Delivery to Recipient – Portal or Certified Mail

A. Portal Delivery
   1. Review all types.
   2. Move to Records Management for Portal Delivery.

B. Certified Mail
   1. Review
   2. Send to Section Leader for Approval.
   3. Move to Certified Receipt.