Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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Post-Inspection Activities

Document Number: CVB-SOP-0036 **Revision: 02**

Previous Number: ICSOP0015.02

Vault: CVB-Released

Section/Area: CVB-SOP-IC

Effective Date: 08 Mar 2022

Notes:

Post-Inspection Activities

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1. Purpose

CVB conducts inspections of sites that prepare veterinary biological products in accordance with title 9 *Code of Federal Regulations*, section 115.1. Inspections require a summary of the findings. The inspection report is a critical document in the Veterinary Biologics Program providing a record of activities of the inspectors and documenting the suitability of an establishment and products to be licensed/permitted under the VSTA.

The type of inspection will determine the inspection report format. [redacted]

This document outlines the general policy related to the output of an inspection; including the report, regulatory actions related to violations documented, and closing action items from the inspection.

2. Responsibilities

2.1 Section Leader (SL), Inspection

Reviews complete report, letter and any other enclosures for program policy and consistency. This may also be done by the Acting Inspection Section Leader or another member of CVB-IC Management. This review is usually done within 3 working days from receipt and can include requested changes or additional information. Reviews final report/letter/enclosures to ensure outgoing Mail Log Item or hardcopy is complete and accurate.

2.2 Inspection Team Members

2.2.1 Team Leader – CVB IC Director, Section Leader, Epidemiologist, Senior Biologics Specialist or Biologics Specialist

Assembles, edits, and submits complete inspection report and associated documents to SL for policy review. Enters Action Items into LSRTIS prior to submitting reviewed report for finalization. Signs cover letter and if needed, inspection report.

Follows up on Action items or regulatory actions as needed, closing actions as information is made available.

If needed, the Biologics Specialist (Specialist) arranges follow-up inspections in consultation with their supervisor and the Inspection Section Leader to determine compliance. A follow up is done within 6 months of the firm receiving the report, similar to the timeframe listed in 9 CFR 105.2 related to infractions.

2.2.2 Team Member

Prepares a report in final format for the items they were assigned; observations made, records audited, and violations documented, usually within 3 working days from the end of the inspection. Completes review of inspection note and submits them to the Team Leader prior to mailing of the final report. Responds to questions and comments regarding the inspection findings they documented as requested.

2.3 Investigation and Compliance Specialist (ICS)

Performs quality review of Action Items entered into LSRTIS against policy reviewed inspection report usually within 1 working day of receipt. Makes changes as needed and informs Team Leader.

Reviews Pending Action Items that are past due on a monthly basis and provide information and input on next steps to the Team Leader.

2.4 Biologic Compliance Assistant (BCA), including Lead BCA

Finalizes outgoing inspection report, cover letter and all other related documents including internal memos as needed, usually within 5 working days of receipt.

3. Review Inspection Notes and Actions

3.1 Inspection Note Review – organization

[redacted]

Each Team Member must ensure inspection notes/worksheets are organized, properly identified, complete and clear.
Prepare and properly reference all attachments or appendices used.
Notes should have been taken in accordance with **CVB-WI-5220,** *How to take Inspection Notes.* The list of review points on **CVB-FRM-5122,** *Inspection Notes – Cover Sheet*, can be used to document this physical review.

3.2 Critique of Inspection Notes/Findings

3.2.1 An inspection will be viewed from a different perspective when the team returns to the CVB-IC office in an environment away from the establishment itself. Critique the inspection observations and record audits. Carefully review again each exception/violation found and be sure each item has sufficient information documented.

3.2.2. Analyze the action agreements made with the liaison, applying the following questions to each action:

3.2.2.1 Does the action cite the appropriate regulation and the Virus-Serum-Toxin Act? See **CVB-REF-5107,** *9 CFR Cross-Reference List*

3.2.2.2 Is the action consistent with program policy?

3.2.2.3 Is the action reasonable?

3.2.2.4 Does the action adequately address the non-compliance and if followed will allow the firm to prepare product in accordance with the regulations and filed outlines of production?

3.2.2.5. Does the action include an active review process to determine effectiveness of the corrective and preventative actions implemented?

3.2.3 If additional direction is needed consult with the IC Section Leaders and/or the IC Director. Other CVB personnel may also be consulted as needed.

3.2.4 The Team Leader will set up a meeting with the responsible Policy, Evaluation, and Licensing (PEL) Reviewer to discuss the inspection findings. It should include the inspection team if possible. This meeting will be beneficial to answer questions directly that may come up as the firm discusses compliance solutions with PEL related to outlines of production, prelicensing issues or labels. Doing this prior to writing the report is beneficial if additional information is needed or discovered.

The preparation will assist you when writing the Inspection Report. Begin Writing.

4. Writing the Inspection Report

The type of inspection determines the inspection template used. Each outgoing inspection report must have an inspection cover letter. [redacted]

4.1 In-depth Inspection Report and Special Inspection - Bench Record Audit

Inspection template **- CVB-TEM-0037,** *Inspection Report (short form) – Attachment of Violations.*
Inspection cover letter template **– CVB-TEM-0038,** *Inspection Report (short form) – Cover Letter.*

If the in-depth inspection is the first one since the establishment has been licensed, use of the long form is required as this provides more instruction to the new establishment.

Inspection template**- CVB-TEM-0018,** *Inspection Report (long form)*
Inspection cover letter template **- CVB-TEM-0019,** *Inspection (long form) – Cover letter.*

4.2 Special Inspection Report

The majority of special inspection reports use the long format as this format provides an opportunity to better describe the observations made, records audited and any special instructions. All categories may not be applicable.

Inspection template**- CVB-TEM-0018,** *Inspection Report (long form)*
Inspection cover letter template **- CVB-TEM-0019,** *Inspection (long form) – Cover letter.*

4.3 Follow-up Inspection Report

This report specifically follows the format of the in-depth report. See the template below.

Inspection template **- CVB-TEM-0046,** *Inspection Report (follow-up) – Attachment of Violations.*
Inspection cover letter template **– CVB-TEM-0045,** *Inspection Report (follow-up) – Cover Letter.*

4.4 Inspection Report Requirements

Inspection Reports should be concise and comprehensive. They must be accurate and supported by the inspection notes. [redacted]

See **CVB-WI-0095,** *Inspection: General Guidelines for Writing an Inspection Report*

4.4.1 Each Team Member

Prepare a summary report from the inspection notes. Use of the correct template is beneficial to the final author (Inspection Team Leader). Use VSM 800.91, Inspection of U.S. Veterinary Biologics Licensed and Permitted Establishments, to determine the inspection category for each observation/audit.

Review notes to make sure all observations/audits (long form) and all non-compliance (every report) are included in the inspection report.

[redacted]

[redacted]

The portion of a team member summary report and inspection notes should be submitted to the Inspection Team Leader no later than an average of three working days after return to the office.

4.4.2 Inspection Team Leader

Create a mail log item for the inspection report, see **CVB-WI-0136,** *Inspection: Routing of Inspection Reports,* Section 4.a. This should be done prior to receiving report summaries from team members.

Assemble the summary reports into a draft report. It should read as if one person wrote the whole report.

Review and edit report – paying attention to repetitive observation and audit items and combining them to reduce/eliminate repetitive items.

Prepare cover letter.

Route inspection ML, see **CVB-WI-0136,** *Inspection: Routing of Inspection Reports*.

Addresses all comments from Section Leader Policy review. [redacted]

[redacted]

[redacted]

4.4.3 Inspection Section Leader (or Acting)

Conducts Policy Review and reviews information in LSRTIS to ensure it is correct. See **CVB-WI-0136,** *Inspection: Routing of Inspection Reports,* Section 5

Reviews ML to ensure the information on the Info Tab matches the information in the report.

[redacted]

5. Entering Action Items in LSRTIS – including Product Destruction Report

5.1 Inspection Team Leader Role

The Inspection Team Leader fills in the action items in LSRTIS, see **CVB-WI-0136,** *Inspection: Routing of Inspection Reports* Section 6.

[redacted]

5.2 Investigation and Compliance Specialist Role

The ML is routed to the Investigation and Compliance Specialist for a Quality Review of the data entered into LSRTIS. [redacted]

5.3 Documentation of Product Disposal

The firm may have products that require disposal under the supervision of APHIS employees. The disposal during an inspection is certified using an APHIS Form 2045, PRODUCT DESTRUCTION RECORD.

The Specialist who observed the serial destruction is responsible for entering the information into LSRTIS using the White copy of the APHIS Form 2045. The White copy is filed as an attachment to the inspection notes. -

5.3.1 Entry Process

[redacted]

[redacted]

5.4 Quality Review Prior to Finalization

Follow **CVB-WI-0136** *Inspection: Routing of Inspection Reports.*

6. Finalization of Inspection Report CVB-WI-0101, *Biologics Compliance Assistant (BCA) Finalization of Correspondence* and CVB-WI-0121 *BCA Process for Finalization of Report*

The BCA reviews the report and the cover letter for format and make required changes. The Team Leader is responsible for spelling and grammar but if there are issues, the BCA may make those corrections. The BCA reads the report for understandability and any changes should be discussed with the Inspection Team Leader. The Team Leader will make the final decision on changes in the text of the report.

Note: If the Team Leader is not available for signing, the report should be signed by the supervisor and if the supervisor is not available, by any Section Leader or the Director. Whenever possible, the alternate signer should be a person who reviewed the report.

Hard copy reports are sent by U.S. Mail using Certified Mail with a return receipt requested or equivalent via a commercial carrier. [redacted]

7. Closing Action Items

7.1 Corrective and Preventative Actions

VSM 800.91, Section 6.B.3. requires a written response regarding corrective and preventative actions (CAPA) that are taken to correct the violation and maintain future compliance. This may require more than one submission from the regulated entity.

The regulated entity should have a review process for effectiveness as CAPAs may not result in maintaining compliance.

7.2 Specialist Review

Review the response to the Action items to see if the corrective action resolved the immediate compliance issues. In some cases, the actions taken don't address the violation observed, so additional information or clarification may be required. Use **CVB-TEM-5115,** *Inspection – Follow-up to Action Item Completion Template* requesting additional information.

Determine if the firm has reviewed similar processes globally as a part of the corrective action.

If the regulated entities response appears to have addressed the issue observed during the inspection, the action item should be closed. **Closing an action item does not mean CVB-IC confirms the action taken is guaranteed to resolve the issue.** See **CVB-WI-0089,** *Inspection Report – Closing Action Items in LSRTIS.* A written confirmation the action items were close using **CVB-TEM-5106,** *Inspection - Response to Action Item Completion Template*.

Preventative measures may not be included in the information submitted by the firm. If it was a repeat violation from previous inspections, the action requirement should include a plan for prevention and may require multiple submissions prior to closing the action item.

7.3 Closing Actions related to Prelicensing Inspections or New Sites to be added to Establishment License

The inspection report ML serves as the notification to PEL what issues must be addressed prior to issuance (or re-issuance) of the establishment license. Once all action items have been adequately addressed, PEL is notified the site is acceptable and the establishment license may be issued. Use **CVB-TEM-0020,** I*nspection Prelicensing – IC Site Approval Memo*.

See **CVB-WI-5217,** *Prelicensing Inspections for New Establishments/Products,* Section on Post-Inspection Activities

See **CVB-SOP-5113,** *Inspections – Virtual Inspections* Section 7 for new or remodeled facilities of an existing licensee.

7.4 Open Action Items Prior to Next Inspection

If action items are not closed prior to the next inspection, the act of conducting the next inspection should allow all previous action items to be closed with a reference to the recent inspection. If repeat items are found, the previous item should be closed with a reference to the item in the recent inspection.

8. Summary of Revisions

Revision .02

- Document format and identification numbers updated.