CONTROLLED//PROPIN//BASIC

Source Document: CVB-SOP-0036, *Post-Inspection Activities*

1. Inspection Report Templates

a. Short Form: CVB-TEM-0037**,** *Inspection Report (short form) - Attachment of Violations*
Remember to use cover letter, CVB-TEM-0038, *New Inspection Report – Cover Letter*

b. Long Form: CVB-TEM-0018**,** *Inspection Report*
Used for special inspections and the first inspection after licensure
Remember to use cover letter, CVB-TEM-0019, *Inspection – Cover Letter*

2. Follow CVB-WI-0095, *General Guidance for Writing an Inspection Report*

Key Points: The report or Attachment of Violations should read as if one person wrote the whole document. It is the responsibility of the Inspection Team Leader to organize the information from the team members in a readable/understandable document.

REMINDER – 9 CFR listing must be included with each action item.

The "Priority" of the Violation must be noted.

3. Preparation of Mail Log – Inspection Team Leader

a. Create mail log item:
   1. Enter Establishment number
   2. Date Submitted should be the date you returned to the CVB Office
   3. Submission Type is **Inspection**
   4. Submission Subtype is **Inspection Report** – must click on +Add button
   IMPORTANT – if the subtype is not entered, the inspection record will not move through the process in LSRTIS, even if the ML is completed and sent to the firm.
   5. Tags is **No Incoming Submission**
   6. Establishment Site is the main manufacturing site listed for the inspection in LSRTIS
   7. If needed, add additional sites inspected, usually ancillary or testing as described in LSRTIS. Remember to click on +Add button.
   8. Brief Description should be Type of Inspection (In-depth, Follow-up, or Type of Special), and the city and state of the main inspection site. The city and state may seem redundant but when you do a search on inspection reports in ML, the brief description shows but the address of the inspected site does not.

b. Child-Loop the ML to each Team Member
   1. Each Team Member and Team Lead will scan their notes with CVB-FRM-5122 and upload them and along with a complete listing of records reviewed and procedures observed.
   2. If electronic notes are used, they must be converted to pdf, signed and locked.

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Documents are attached to the ML and labeled with the following document types:
1. Listing of observations/records audited – <u>Inspection Notes</u>
2. Scanned notes from each Team Member – <u>Inspection Notes</u>
3. Draft Report from Team Members – <u>Internally Routed</u>
This is *optional* – however it is easier for the team leader to have them all in one place.

c. Documents are attached to the ML by Team Lead and labeled with the following document types:
1. Completed inspection report - <u>Outgoing Inspection Report</u>
2. Cover Letter - <u>Outgoing General Corr</u>

4. Policy Review – Section Leader or Acting

a. Move forward to the Section Leader for Policy Review **–** Comments and edits will be captured using track changes. Inspection Notes for in-depth inspections are also provided to the Section Leader (hardcopy).

b. The Section Leader will review the letter and report for the following:
1. Appropriate application of policy and correct regulation cited.
2. Correct category is cited.
3. Actions are consistent with the findings and previous actions taken by IC.
4. Severity of the action is documented and in-line with previous actions taken by IC.
5. Report is understandable and appears to be written by one person.

c. The Section Leader will review the inspection notes for the following:
1. Notes are on the proper form and all attachments are properly identified.
2. Notes are complete with dates and initials.

COMPARE INFORMATION TO LSRTIS-INSPECTION AND ML ITEM
*The Inspection Certificate is generated for in-depth inspections using this information, when requested by the licensee/permittee. LSRTIS and ML must be accurate.

3. The date of the inspection listed on the report and letter matches the dates listed on the inspection notes and is correct in LSRTIS.
4. All sites listed in the notes are also selected in LSRTIS Inspection and ML Item.

d. The ML item will be routed back to the author (Review (Specialist)) as needed for changes and for LSRTIS loading of Action Items.

5. Loading Action Items into LSRTIS – Inspection Team Leader

    a. Go to the Pending Report Pending Report (18) Tab under Inspection Dashboard and find the inspection.

    b. Click on Info <u>Info</u> for the inspection

    c. Add Action Items – Initiate by clicking on Add Action Item

Action Items

Add Action Item No Action Items For This Inspection - Add Action Item

This takes you to Create Action Item

    d. Fill in * boxes – Note, some are drop downs

Action Item Category *
LICENSES

Action Item Priority *
MINOR

Action Item Due Date *

Violation *
101.2 - OR - 🔍 Search & Select

Observation *

Action *

> Note – there is only room for one violation reference – choose the most relevant

    e. Then click on Create ✔ Create

    f. The Action Item Due Date for Items of Concern can be the date of the closing meeting.

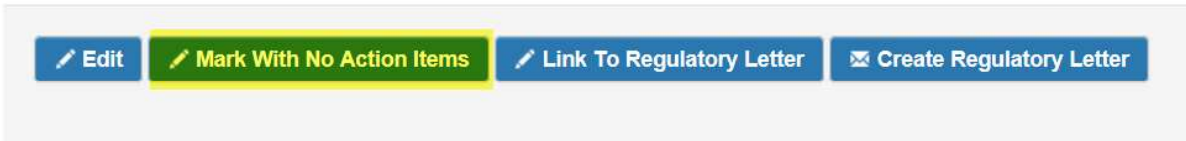   **g.** Action for Items of Concern can be listed as N/A

NOTE – If there are no action items, click on "Mark with No Action Items

Action Items

Add Action Item No Action Items For This Inspection - Add Action Item

[✎ Edit] [✎ Mark With No Action Items] [✎ Link To Regulatory Letter] [✉ Create Regulatory Letter]

6. **Link Inspection to Inspection Report in Mail Log – Inspection Team Leader**

   a. Click on Link to Inspection Report

[✎ Edit] [✎ Link To Inspection Report] [✎ Link To Regulatory Letter] [✉ Create Regulatory Letter] [✎ Close Selected Action Items]

   b. Enter ML number – this will move the record from Pending Report to Pending Finalization

   This MUST be done prior to moving the ML item for finalization by Biologics Compliance Assistants (BCAs). If it is not done, the inspection record will not close even if the ML is finalized. Also, ML for serious action items will not be created.

7. **Quality Review of LSRTIS Action Items**

   a. Route ML to the Investigation and Compliance Specialist (ICS) assigned to the Inspection group. Use Activity "Quality Review"

   b. The ICS will compare the Inspection Report to the Action Items entered in LSRTIS.
   1. If items are missing from LSRTIS, the ICS will add them
   2. If items are duplicated in LSRTIs, the ICS will delete the duplication
   3. The category, citation, priority must match.
   4. Grammar and format in LSRTIS are not important, but the item in the inspection report and the action item in LSRTIS should have the similar language and same meaning

   c. If there are significant quality issues, the ICS may route the ML back to the Inspection Team Leader for corrections.

8. **Move ML item to IC Inbox Pool – ICS or Inspection Team Leader**

See Attachment 1, Inspection Report Flow. This will include flow of hard copy notes as well.

Attachment 1