

**United States Department of Agriculture  
Center for Veterinary Biologics**

**Standard Operating Policy/Procedure**

**Post-Inspection Activities**

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**Post-Inspection Activities**

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## Post-Inspection Activities

### 1. Purpose

An inspection has not been properly completed until four post-inspection activities have been finished.

**1.1** The inspection team, under direction of the Team Leader, meets, critiques, discusses, reviews, and consults with others, including non-team members, Inspection and Compliance (IC) Management, and Policy, Evaluation, and Licensing (PEL) staff, as appropriate, concerning the inspection findings.

**1.2** Each team member prepares her/his part of the report in final format. The Team Leader assembles the draft report, edits it and issues the summary report of the inspection.

**1.3** The Team Leader sends the inspection report to the firm listing exceptions found, arrangements for any corrections agreed upon, and confirms dates for achieving compliance, when appropriate.

**1.4** If needed, the Biologics Specialist (Specialist) arranges follow-up inspections in consultation with their supervisor and the Inspection Section Leader to determine compliance.

### 2. Post-inspection Review and Critique

An inspection will be viewed from a different perspective when the team returns to the IC office in an environment away from the establishment itself.

#### 2.1 Each Member

Reorganize all inspection notes and worksheets. These are the official legal records of the inspection. Be sure:

- all pages are properly identified;
- all sentences, bullet statements, or phrases are completed; and
- all meanings are clear.

Be sure all exhibits or attachments have been properly identified, initialed, and dated. Exhibits or attachments should be initialed and dated on the back of the page. Include who provided the attachment as a part of the notation on the back of the page. Make copies for CVB files, if needed. Attach originals to the notes.

Assemble notes and exhibits and identify for easy retrieval at a later time by stapling a completed "INSPECTION NOTE" slip to the front of the first page.

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## Post-Inspection Activities

### 2.2 Entire Team

Critique the inspection again. Go through each category examined. Carefully review again each exception found.

Be sure each exception is sufficiently documented.

Discuss each action required and previously agreed to by the firm personnel.

Consult with the Section Leaders; the IC Director; PEL personnel; Center for Veterinary Biologics (CVB) Laboratory personnel; or others as appropriate.

Apply the three or four question test to each action:

- Does the action cite the appropriate regulation and the Virus-Serum-Toxin Act (VSTA)?
- Is the action consistent with program policy?
- Is it reasonable?
- Does the action adequately address the exception?

Inform the firm of subsequent decisions made after the wrap-up session at the plant. Document these discussions in a phone log and attach to inspection notes.

Verify previous assignment of categories for report writing with each team member. One person should be responsible for an entire category to ensure that all points are considered.

Begin writing.

### 3. Writing the Report

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 a firm to be licensed under the VSTA. Information documented in the report has profound and long lasting impact on the biologics manufacturer. It is the policy of IC that inspection reports are prepared and mailed promptly to the manufacturer within 15 working days of the team returning to the office. The Team Leader has the responsibility to plan appropriately to assure the report is out on time.

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The inspection report must be:

- Concise,
- Accurate,
- Comprehensive, containing a summary of significant events in the inspection, and
- Supported by notes.

Use the current version of **ICTEM0009**, *Inspection-Report*, APHIS Form 2030 for preparing the final report. This template can be found in the Inspection and Compliance Manual or on the CVB Quality Management SharePoint Site.

Assign each category to at least one team member. (If the categories are split between members, the Team Leader must be sure the entire category has been covered.)

#### **3.1 Each Member**

Prepare a summary report from the inspection notes.

Examine again VS Memorandum 800.91 (*Categories of Inspection for Licensed Biologics Establishments*). Note the items to consider in each category. Use this guideline to prepare the report for the category.

Write concisely, clearly, and explicitly.

Apply this test to what is written: "Are all observations adequately documented?"

Use this format:

**3.1.1** State what actually was done to investigate compliance for the category. Be explicit. Avoid general, vague statements. State quantities and methods used wherever possible.

**3.1.2** State clearly the exceptions found. Applicable regulations must be cited as a part of the Action Item.

**3.1.3** State the action required. Be specific. Phrases such as "use all necessary precautions" are too vague.

**3.1.4** Specify the date the action is to be completed. Do not use "immediately"; this cannot be enforced.

**3.1.5** Always include true name, product code, and serial number if applicable.

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Do not repeat descriptions of repeatedly noted exceptions. If recurring, so note.

Explain abbreviations by fully spelling out words later abbreviated when used the first time. Enclose the abbreviations in parentheses immediately following this first use.

Prepare and properly reference all attachments or appendices used.

Deliver the team members' summary report, exhibits and attachments, and inspection notes to the team leader. This should be delivered to the Team Leader no later than three working days after return to the office.

### 3.2 Inspection Team Leader

Assemble the summary reports into a draft report.

Revise and edit as necessary for consistency and to assure that the entire report is not repetitive. Consult with team members as necessary. The Team Leader is responsible for:

- content,
- format (using the "Inspection Report and Cover Letter" template),
- grammar,
- punctuation,
- complete sentences, and
- spelling (run the spell check on the computer).

Please do not paginate the report. Do not format the report. The Biologics Compliance Assistant (BCA) will do that.

Prepare a draft of the appropriate cover letter and/or memo for the report.

Deliver the draft report with the covers, exhibits or attachments, and the inspection notes to the Inspection Section Leader for policy review. The Acting Inspection Section Leader or IC Director may also review the draft in the absence of the Inspection Section Leader.

### 3.3 The Inspection Section Leader

Review the draft report and covers to assure that:

- appropriate policy is followed,
- actions are consistent with findings,
- the report is understandable,
- categories are complete,

### Post-Inspection Activities

- proper editing was done by the inspection team leader,
- actions are consistent with previous actions taken by IC, and
- the date the Team Leader returned to the office is documented.

Review the inspection notes to be sure they are in proper form; they have been completed; the findings in the report are well documented; and attachments and exhibits are properly identified; and copies are attached to the report.

Write comments as appropriate on the draft report and covers. Comments on inspection notes should be given directly to the person who made the notes; comments on the report and covers with the Team Leader. Each review should be completed within 24 hours. A copy of the Inspection Section Leader comments on the initial review will be provided to the Team Leader's supervisor for information.

### 3.4 Team Leader

Revise and edit the draft report and the covers, if necessary. Check the revisions for grammar, completeness of sentences, and run the spelling checker on the whole document. If there are significant changes suggested by the Inspection Section Leader, the Team Leader will discuss these changes with the author of that section of the inspection report. If further clarification is needed, they will discuss this with the Inspection Section Leader.

Email the final draft report and covers to the CVB-IC Inbox. The hardcopy, with appropriate initials and date submitted for finalization, must be delivered to the BCA Inbox.

### 3.5 Biologics Compliance Assistant

Review the report and the covers for format and make required changes. The Team Leader is responsible for spelling and grammar. If the BCA notices any problems with the report, it is discussed with the Team Leader. The Team Leader will make the final decision on changes in the text of the report.

Make revisions. Paginate and print one copy of the final report.

Finalize and print all copies of the cover letters, memos, etc.

Present inspection report and covers to the Team Leader for signature.

**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.**

### Post-Inspection Activities

Present the signed report and covers to the Inspection Section Leader for initials. **ICSOP0001** describes delegation of authority for final review if the Inspection Section Leader is not available.

Send by U.S. Mail using Certified Mail with a return receipt requested or equivalent via a commercial carrier. Internal APHIS copies may be sent electronically. The BCA must complete and mail the final report within five days of submission to the inbox.

## 4. Cover Letters and/or Memos for the Report

### 4.1 Cover Letter to the Firm

A short letter to the inspected firm is used as a cover for the inspection report. Use the current version of **ICTEM0010**, *Inspection Cover Letter*.

#### 4.1.1 Required

Address the letter to the official liaison of the firm. If there is difficulty getting compliance through the liaison, the letter may be addressed to another official with sufficient authority to insure corrective actions can be made. The APHIS Form 2001 lists the principal officers that CVB holds responsible for management of the facilities. Consult with the IC Director before invoking this authority.

Regulatory actions (infractions, stop sale, warnings) taken and sampler authorization as a result of the inspection will be noted in separate letters.

Send by U.S. Mail using "Certified Mail with a return receipt request." See above

#### 4.1.2 Optional

Request a written reply from the licensee confirming that corrective actions have been completed if this would help in gaining compliance and save for a follow-up inspection.

### 4.2 Cover Memo to PEL for Prelicensing or New Facilities

If the inspection was a prelicensing or new facilities inspection done at the request of PEL, a cover memo to the PEL Reviewer is sent with the PEL copy of the report.

Include brief recommendations for PEL action in the memo using **ICTEM0028**. Once action item have been completed, follow up with PEL using a memo, **ICTEM0012**.

### Post-Inspection Activities

#### 4.3 Responsibilities for Cover Letters and Memos

##### 4.3.1 Inspection Team Leader

Prepare the draft cover(s).

Deliver to Inspection Section Leader with the draft inspection reports.

##### 4.3.2 Inspection Section Leader

Review following the review guidelines for inspection reports.

Revise and edit, if necessary, and check grammar, completeness of sentences, and run the computer spelling check on the document.

Return with the inspection report to the Team Leader so it may be emailed with the report to the CVB-IC Inbox. Submit a hard copy to the BCA Inbox.

##### 4.3.4 BCA

Follow the procedures for finalizing as listed for inspection reports.

#### 5. Distribution of Report and Covers

##### 5.1 Distribution by BCA

The report and the cover letters should be mailed or electronically sent out of the office on the day they are signed and dated. The BCA obtains the final signatures and initials and is responsible for distribution of the report and the covers.

##### 5.1.1 IC Original

The original inspection report, attachments, exhibits, and yellow copies of all letters and memos are to be placed in the IC file right away for safe keeping. .

##### 5.1.2 Firm Copy

A copy of the report, attachments and exhibits, and the original cover letter is sent to the firm, certified mail, return receipt requested. Do not send a copy of the PEL memo to the firm unless instructed to do so by the Specialist.

### Post-Inspection Activities

#### 5.1.3 PEL Copies

Send a copy of the report, attachments, and exhibits to PEL.

#### 5.1.4 Additional Copies

Send copies to other persons designated on the report or cover letter.

#### 5.1.5 Special Copies

The APHIS Animal Care personnel need to know the status of animal welfare at the firms that are visited. Send a copy of the front page and the pages with the category "XII ANIMALS" of the report to the Animal Care Regional Director responsible for the site inspected. This is not necessary if the firm has no animals. If unsure, check with the Specialist.

Keep one copy of the report, attachments, exhibits and covers for office circulation and after circulation return to the Specialist responsible for the firm for her/his desk file.

Notify the Inspection Section Leader, that an inspection report has been completed by providing a copy of the front page of the report.

## 6. Final Activities

### 6.1 Follow-up Inspections

The detection of non-compliance is only a start. Compliance is the desired end result. If the firm knows their progress will be monitored, there is more incentive for compliance. The Team Leader, with the inspection team, should recommend if a follow-up inspection is needed. The Specialist responsible for the firm should schedule the follow-up inspection.

Schedule follow-up inspections in consultation with the Inspection Section Leader to determine if corrections have been made. Set tentative dates.

**Note: The 9 CFR 105.2 provides that product infractions may be considered willful if repeated within 6 months after written notification. It is a good idea to re-inspect within that time.**

Monitor to see that compliance is achieved.

## Post-Inspection Activities

### 6.2 Inspection Notes

The inspection notes are the official record of the inspection and become part of the IC records. They are kept in files separated from the firm and product files. The IC Director is the custodian of these records. The inspection team leader is responsible for filing all the notes with the original attachments and exhibits attached.

File all the team members' inspection notes with the original exhibits and attachments in the special inspection note files in the secure files within five days of finalization of the inspection report.

### 6.3 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.

#### 6.3.1 Inspection Team Leader

Check to see that the APHIS Form 2045 has been completed and signed.

Distribution: PINK - Specialist's copy - attach to notes for that day.  
YELLOW - Firm copy.  
WHITE - IC copy - Note in computer and place in the PRODUCT DESTRUCTION folder in the firm's file.

Check to see that the pink copy has been attached with the notes. If the yellow copy is still attached, send it to the firm.

Deliver the white copy to the BCA for entry of information into the computer system.

#### 6.3.2 BCA

Enter the destruction in the computer for each serial.

File the form in the firm's PRODUCT DESTRUCTION folder.

### 6.4 Updating the Firm Pre-Inspection Computer File

Inspection and Compliance keeps a file for each firm in the computer commonly referred to as the "PI Package." The BCA is responsible for updating part of the information. The Team Leader and the inspection team are responsible for providing new and additional information and correcting old information that is no longer correct.

### Post-Inspection Activities

#### 6.4.1 BCA

Enter new or revised information on permits, prelicensing products, inspections conducted, and personnel.

Revise as requested by the Team Leader.

#### 6.4.2 Team Leader, Specialist, and/or Inspection Section Leader

Accumulate information to update the package during the inspection.

Correct/update information.

Mark changes on a copy of the package.

Deliver changes to the BCA.

#### 6.5 Tally of Inspections

In the Biologics Program, the number of inspections conducted is one criterion used to evaluate program effectiveness in achieving our objectives. The BCA will make a copy of the front page of the report and deliver it to the Inspection Section Leader. That copy will be used to document the completion of an inspection and the information will be used to provide planning and analysis information for program management.

##### 6.5.1 Inspection Section Leader

Provide the monthly reports to the IC Director.

##### 6.5.2 IC Director

Report information on inspection of firms to the other CVB Directors, and to IC, on a quarterly basis.

#### 7. Summary of Revisions

- The Contact information has been updated.
- **3:** The location of template letters has been updated.
- **1.4:** "If needed" has been added.

**Post-Inspection Activities**

- **2.1:** The need to include who provided the attachment to the inspection team member has been clarified.
- **3:** The reference to performance elements has been removed.
- **3.1.2:** The need to cite regulations for all action items has been clarified.
- **3.2:** “Do not format report” has been added to the instructions.
- **4.1.1:** “Sampler authorization” has been added.
- **4.2:** The references to ICTEM0028 and ICTEM0012 have been added for prelicensing inspections.
- **6.4.2:** The information concerning hotels and restaurants has been deleted.