

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

Standard Operating Policy/Procedure

Pre-Inspection Activities

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Entered into CVB Quality Management System by: <u>/s/Linda S. Snavelly</u> <u>23Jan17</u> Linda S. Snavelly Date Quality Management Program Assistant
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Pre-Inspection Activities

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Pre-Inspection Activities

1. Purpose

An effective and productive on-site inspection starts with preparing properly before the actual on-site inspection. This preparation is key to a quality inspection of the facilities, equipment, personnel and processes for a particular site.

Planning starts with selecting the inspection dates for an in-depth inspection at a recommended site, an assigned special inspection, or a follow-up inspection. Then, when needed, the Team Leader should select an inspection team. The inspection is scheduled and travel preparation is done by the Team Leader. Team assignments are made by the Team Leader; this can be done by product or inspection category. Team members review the Center for Veterinary Biologics (CVB) files (hard copy and electronic) to gather needed information for the on-site inspection. Each team member makes sure they have the supplies needed to conduct a safe and effective inspection.

2. Definitions

2.1 Types of Inspection

2.1.1 In-Depth

An in-depth inspection is an unannounced, detailed inspection in which overall compliance with title 9, *Code of Federal Regulations* (9 CFR), and other requirements is systematically examined. The time required for this type of inspection is normally the longest of the three types of inspections, but does not exceed two weeks in length. The size of the plant, the number of inspectors on the team, and problems encountered determine the length of time expended. As many inspection categories as possible are examined.

2.1.2 Follow-Up

Follow-up inspections are conducted to determine if corrections required as a result of a previous in-depth (or follow-up) inspection have been made. Need for a “follow-up” and length of time for the inspection are recommended by the Biologics Specialist (Specialist) based on the seriousness of the corrections required. Follow-up inspections are discussed with the Inspection Section Leader prior to being scheduled. Follow-up inspections are within six months from the in-depth inspection or notification of infractions as required by 9 CFR 105.2.

2.1.3 Special

A special inspection is any inspection not of the previous two types. This type of inspection is requested by CVB personnel or other government officials, or as

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directed by the CVB-Inspection and Compliance (CVB-IC) Director. Pre-licensing inspections are considered special inspections.

2.2 Licensing, Serial Release and Testing Information System (LSRTIS) and Mail Log (ML)

This database system is the information management system used by CVB for listing, scheduling, and notifying specific CVB personnel regarding on-site inspections. Non-compliant actions, agreements, and outcomes are also stored in this database. In concert with the ML (a document routing system used for inspection reports and related correspondence), data can be entered and retrieved across the entire program.

3. Responsibilities

3.1 IC Director

The IC Director requests the funds and the manpower needed to accomplish the goals set. The IC Director conducts domestic and international on-site inspections, especially those related to the North American Foot and Mouth Disease Bank and National Vaccine Stockpile.

The IC Director is responsible for the management of the Cooperative Service Agreements for international inspections.

3.2 Section Leader, Inspection

The Inspection Section Leader is responsible for determining the frequency of site inspections, approval of special inspections, and providing the list of recommended inspections each fiscal year. The Inspection Section Leader (the Compliance Section Leader and the IC Director can serve as the Acting) is responsible for approving requested inspections in LSRTIS. They also conduct domestic and international on-site inspections for establishment sites and permittees assigned to them.

The Inspection Section Leader acts as the backup for drafting Cooperative Service Agreements.

3.3 Section Leaders, Senior Epidemiologists, and Senior Biologics Specialists

Section Leaders, Senior Epidemiologists, and Senior Biologics Specialists are responsible for conducting domestic and international on-site inspections for establishment sites and permittees assigned to them.

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3.4 Biologics Specialists

Biologics Specialists are responsible for conducting domestic on-site inspections for establishment sites assigned to them.

3.5 Inspection Team Members

3.5.1 Team Leader

The Team Leader makes the final decision on assignments and ensures that all preparatory aspects of the inspection, including review, assembly of inspection supplies, and travel arrangements have been made for everyone on the team. Using the individual team member's reports, the Team Leader will assemble, edit, and submit the final inspection report.

3.5.2 Team Member

Each team member is responsible for obtaining and evaluating the information accumulated from the various sources and sharing that information with the rest of the team. At the end of the inspection, each team member reports her or his findings to the Team Leader for editing and enclosing in the final report. Inspection notes and summaries are provided to the Team Leader within a specified time upon returning to the office.

4. Inspection Scheduling

4.1 Frequency

4.1.1 The frequency of inspection at specific sites is determined by using an Inspection Risk Matrix or as required by other issues not associated with the risk matrix. A listing of in-depth inspections for the fiscal year is prepared and posted in [REDACTED].

4.1.2 International manufacturing sites are required to be inspected on a two year cycle (\pm 6 months).

These inspections are conducted under a Cooperative Service Agreement, in accordance with a restriction listed on the United States Veterinary Biological Product Permit for Distribution and Sale. The international inspections are conducted by the IC Director, Section Leaders, or Senior Biologics Specialist (see

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current version of **ICWI0045**, *Requesting International Inspections*, and **ICFRM0045**, *International Inspection Checklist*).

4.1.3 Special inspections, such as prelicensing, may be requested (see current version of **ICWI0064**, *Process for Prelicensing Inspection Requests*).

4.2 Scheduling and Approval of Inspections (see current version of ICWI0112)

4.2.1 Each Specialist prepares a tentative inspection schedule for the year based upon established priorities for the CVB program. Inspection priorities will be listed on the Recommended Tab in LSRTIS. Schedule inspections in LSRTIS as soon as possible in the fiscal year so any gaps between work and resources can be reviewed and a plan put in place.

4.2.2 Approval of domestic inspections will be done by the Inspection Section Leader approximately three months prior to the start of the inspection. Approval for international inspections will be done as soon as the dates are set with the permittee.

4.3 Notification of Inspections

4.3.1 Approval of the inspection in LSRTIS automatically emails Center Directors, IC and Program Information Management and Security (PIMS) Section Leaders, the Policy, Evaluation, and Licensing (PEL) Reviewer(s) assigned to the firm, the IC Specialist(s) assigned to the firm, the inspection Team Leader and team members.

4.3.1.1 It is CVB policy for all domestic in-depth and most follow-up inspections to be unannounced. We, therefore, limit notifications to only those persons that need to know.

4.3.1.2 Exception to the notification restriction is possible for small firms with limited personnel. After consulting with the IC supervisor, it may be acceptable to contact these firms just prior to incurring travel expenses if it is suspected that critical personnel may be away from the firm during the inspection. Since this contact is contrary to program policy, concurrence of the supervisor is required.

4.3.2 Maintain security over the dates and locations of unannounced inspections. Notify the IC Director and Inspection Section Leader immediately if it is found that the information was leaked to anyone without the need to know.

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4.3.3 Pre-licensing inspections are announced. A mutually agreed upon time is set by the Team Leader and the firm Liaison prior to scheduling the inspection in LSRTIS.

4.3.4 Some other special inspections, such as efficacy trials, may also be announced if notification will improve the inspection.

4.3.5 International inspections are announced. A mutually agreed upon time is set by the Team Leader and the Liaison for the permittee prior to scheduling the inspection in LSRTIS.

4.4 The Inspection Team

4.4.1 A Biologics Specialist, Senior Biologics Specialist, Senior Epidemiologist, Section Leader, or IC Director leads the inspection team and coordinates the inspection. Usually the Specialist assigned to the firm is the Team Leader, but others may be designated this responsibility. The Team Leader assembles the team.

4.4.2 Team Make-up

Team composition and size depends on the size of the plant, the type of inspection, the number and types of products produced, and special problems likely to be encountered.

4.4.2.1 Limit the team size to no more than four. Use fewer people if the plant is small or if few products are involved. Do not take more people than the firm Liaison(s) can adequately handle.

4.4.2.2 Identify special problems prior to the inspection and consider who is best suited to research these issues.

4.4.2.3 Consider including a CVB-Laboratory scientist on the team if testing problems are foreseen. Make requests for CVB-Laboratory personnel to the appropriate Section Leader. Coordinate this request with the IC Director, since CVB-IC may have to cover the travel expenses for the CVB member.

4.4.2.4 Consider including a member of CVB-Policy, Evaluation, and Licensing (CVB-PEL) on the inspection team whenever advantageous. Make the request to the appropriate Section Leader. Coordinate this request with the IC Director, since CVB-IC may have to cover the travel expenses for the CVB member.

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5. Travel and Time

5.1 Travel Preparation

Inspections are usually conducted at locations remote from the official duty station.

5.1.1 The Team Leader prepares one CVB Pre-Travel Worksheet for the entire team.

5.1.2 The CVB Pre-Travel Worksheet may be signed by the Team Leader's supervisor or the Inspection Section Leader.

5.1.3 Travel may be submitted as soon as the trip is scheduled. Consider the area you are traveling to; travel requests may need to go in sooner if the area does not have many hotels or if it is in a tourist location.

5.2 Inspection Time

5.2.1 The Team Leader proposes the time schedule for the team during the inspection. Normally 9 hour work days are scheduled for most inspections. This includes travel time to and from the inspection location, on-site inspection, daily review of inspections notes, and preparing for the next day's inspection.

5.2.1.1 No credit time is allowed for on-site inspections.

5.2.1.2 Comp time must be pre-approved by IC management.

5.2.1.3 It is expected that inspections will be conducted within the normal 80 hours per pay period under the flexible schedule. If needed, an employee may request premium pay in WebTA (Transaction 32 – Comp Time/Travel Worked) for traveling back from an inspection. This allows IC to make best use of inspection time with the current resources. This should be approved by the employee's supervisor or Inspection Section Leader prior to the inspection or as needed.

5.2.2 If advantageous to the agency, travel to or from the inspection site may be conducted on a weekend, with the appropriate employee premium pay request in WebTA (Transaction 32 – Comp Time/Travel Worked). This should be approved by the employee's supervisor or Inspection Section Leader prior to the inspection.

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6. Inspection Assignments and Pre-Inspection Review

6.1 Tasks related to each of the major categories to be covered on an in-depth inspection are assigned to at least one member of the team approximately 2-4 weeks prior to the inspection. Assignments are made by the Team Leader and are based upon the training, experience, and expertise of each team member. Team assignments may be changed as warranted by findings during pre-inspection review or during the inspection. Assign a mentor to team members that are not fully trained inspectors to assure they are used efficiently and have a productive experience. The assignment may be made at a face-to-face meeting or through other means of communication.

6.1.1 Review the categories of inspection.

6.1.2 Set the priorities for categories to be examined during inspection.

6.1.3 Assign tasks to team member.

6.1.4 Record assignments made.

6.1.5 Discuss assignments with all team members so overlapping duties may be coordinated.

6.2 Review of Documents and Other Preparation

6.2.1 The Team Leader will either provide background documents or require each team member to gather documents related to their assignments.

6.2.1.1 See current **ICWI0041**, *IC Pre-Inspection Packet Checklist – LSRTIS Information and Preparation*.

6.2.1.2 See current **ICWI0067**, *Inspection Items to Consider (electronic desk file on the Mail Log)*.

6.2.2 Discussions with the PEL-Reviewer(s) responsible for the firm site are beneficial. The PEL-Reviewer will know of all current activities relating to licenses, outlines, labels, and research activities at the licensee. Prior to each discussion, remind the PEL-Reviewer that the inspection is unannounced and they must maintain confidentiality.

6.2.3 Discussions with the CVB-Laboratory may also be beneficial. The detailed report of serials will provide information to post-licensing problems that may require CVB-Laboratory consultation. Prior to each discussion, remind the

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CVB-Laboratory personnel that the inspection is unannounced and they must maintain confidentiality.

6.2.4 Facility Document Review – review the facility documents on file for the site you are inspecting. See current version of **ICFRM0001**, *Preinspection Blueprint Worksheet*.

6.2.4.1 List the current buildings and legend pages, including the Stamp Date.

6.2.4.2 Pay special attention to addendums. Review them prior to the inspection so you are familiar with the disinfection processes, biosecurity and biosafety procedures in place. These are some of the observations you may make during the initial tour of the facilities.

6.3 Final Pre-inspection Meeting

When each team member has completed their portion of the office files review and details of scheduling, lodging, transportation, and equipment needs have been arranged, the Team Leader may call a team meeting. The following is a checklist for the conference:

- Redefine the objectives of the forthcoming inspection.
- Review worksheets to insure needed information has been written down and will be available in useful form at the inspection site.
- Review schedules, supply needs, etc.
- Answer questions.
- Go over the final work plan. Be sure everyone is aware and prepared to fulfill their role on the inspection team.

7. Inspection Supplies

7.1 Computers

7.1.1 Laptop computers may be used during inspections.

7.1.2 Connecting to LSRTIS (via VPN) at the inspection location should only be done with a government issued “hot spot.” Use of the firm’s WIFI is prohibited.

7.1.3 Computers must be secured against theft or loss. Pay special attention when going through security lines at airports as many laptop computers look the same. If the computer is lost or stolen, call the 24-hour hotline at 1-277-744-2968 and then contact your supervisor.

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7.2 Inspection Supplies

- Badge and valid USDA Identification Card. Identification is always required.
- Business cards
- A calculator for records audit
- A current 9 CFR 101-118 and other policy documents related to the inspection with latest revisions.
- A copy of the current version of ICSOP0013, *The Inspection Proper*
- Veterinary Services Memorandum No. 800.91, *Categories of Inspection for Licensed Biologics Establishments*
This information can also be found on the CVB Website under Regulations and Regulatory Guidance.
- Pre-printed inspection forms:
 1. Daily Inspection Note Forms and Daily Notes Continuation Sheets (**ICFRM0004**)
 2. Inspection Product Check-Off Sheet (**ICFRM0002**)
 3. Product Destruction Form (**APHIS Form 2045**)
 4. On-site Inspection Meeting Sign-In Sheet (**ICFRM0005**)
- Blank note paper, pens, paperclips, sticky notes, highlighters, and other stationary supplies
- Pre-inspection packet as noted in **ICWI0041** and other reference material prepared during the pre-inspection period.

7.3 Additional Personal Equipment

- Flashlight
- Safety glasses

7.4 Travel Packet

- Travel itinerary
- Travel authorization
- Government credit card
- Accident report kit

8. Summary of Revisions

Version .03

- Complete revision of the document to reflect current practices.

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Version .02

- The Contact information has been updated.
- **3.1.6:** This section has been added to include Biological Compliance Inspectors as possible inspection team members.
- **4.2:** Changed timeframe from three days to five days to meet current performance standards.
- **5.1:** The method of determining inspections based on a risk based approach is described. This replaced the old standard of inspecting each site once every 36 months
- **8.2:** Added “if assigned” to telephone credit cards since it is no longer our policy to assign these to each new Specialist.

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