



**Animal and Plant
Health Inspection
Service**

Veterinary Services

**Center for Veterinary
Biologics**

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Inspection: Pre-Inspection Activities

Document Number: CVB-SOP-0034

Revision: 04

Previous Number: ICSOP0012.03

Vault: CVB-Released

Section/Area: CVB-SOP-IC

Effective Date: 14 Oct 2022

Notes:

Pre-Inspection Activities

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1. Purpose

An effective and productive on-site inspection starts with advanced preparation. 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. The Specialist should evaluate the site that in being inspected with the aid of previous inspections, consultation with other specialists, and with the support of the Section Leader of Inspections to determine the number of team members, if needed. If a team is required, the Team Leader should select an inspection team and consult on best timing for the inspection. Once dates are selected, the inspection is scheduled and approved; travel preparation can be started.

Please consider the following regarding travel preparations:

1. The Team Leader is responsible for travel reservations.
Submission of travel request is done by Team Leader and submitted to APHIS-CVB Admin Request email address.
If done by the travelers in Concur, this activity needs to be conducted concurrently with each team member. This is to ensure No Traveler is left without a reservation. Not making these reservations concurrently may result in unavailability issues for team members.
2. Determine your travel card is current and ready for use for official business expenses.
3. Before leaving for travel, ensure your travel authorization(s) is/are approved.
4. Prior to any international inspection, the traveler needs to evaluate passport expiration dates and if a Visa or any other documentation is needed. (Work with travel staff)

Please note: There are no clear and consistent directions for international travel inspections. The unit that determines the visa requirements is not located in Ames. The traveler needs to know when does the documents for the Visa application and other requirements such as a current photograph of the required size and background color are to be submitted. The traveler must be on top of these issues even if this process is not to be conducted by him/her.
– See specific SOP and WI for International Travel

It is recommended to ensure any modification to hotel reservations for international travel do not result in a double booking. The international hotels may not cancel your original travel booking resulting in double billing.

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. However, the Specialist should also consult with the previous Team Leader to determine if a courtesy notification is necessary for the firm before arrival. 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 directed by the CVB-Inspection and Compliance (CVB-IC) Director. Pre-licensing inspections, virtual inspections, remote record audits and rabies efficacy study inspections are considered special inspections. Additional information can be found in the quality documents listed below:

CVB-WI-5217 *Prelicensing Process for Newly Establishments/Products*

CVB-SOP-5113 *Virtual Inspections*

CVB-SOP-5116 *Records Audits*

CVB-WI-5283 *Rabies Immunogenicity: Observation of Vaccination and Challenge*

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. Please confirm the travel dates and the Time and Attendance Time Sheet when director asks at the beginning of the travel plans. Ensure the times and travel arrangements will work for you. Consult with the travel officials if any page stamp in your passport will present issues entering other countries. For Example: There may be restrictions to enter the country if your passport has stamps from other adversary countries.

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. Additional input may be added by Inspection Section Leader.

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.

3.4 Biologics Specialists

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

3.5 Investigation and Compliance Specialist

Investigation and Compliance Specialist are responsible for gathering basic data used to prepare for on-site inspections. They are also members of domestic inspection teams.

3.6 Inspection Team Members

3.6.1 Team Leader

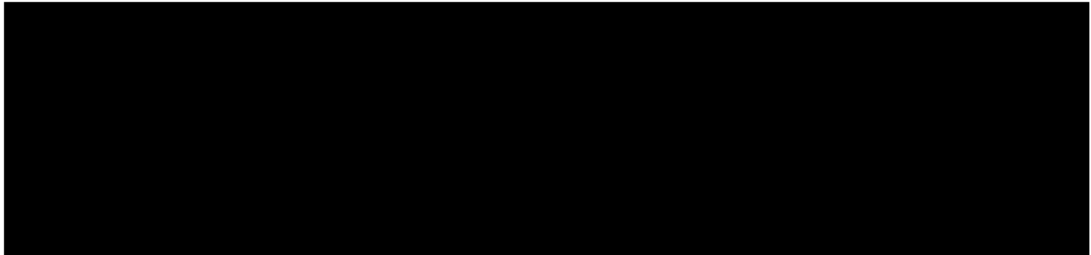
The Team Leader makes the final decision on assignments and ensures that all preparatory aspects of the inspection, including review, assembly of inspection supplies, and travel arrangements have been made for everyone on the team after the inspection request is approved by the Section Leader of Inspections; usually between 3 and 6 months prior to the inspection. Using the individual team member's reports, the Team Leader will assemble, edit, and submit the final inspection report. The team leader needs to confirm the context of team member items.

3.6.2 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, usually within 3 days of returning to the office.

4. Inspection Scheduling

4.1 Frequency



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 (CVB-WI-0080, *Requesting International Inspections*, and CVB-FRM-0097, *International Inspection Checklist*).

4.1.3 Special inspections, such as prelicensing, may be requested (CVB-WI-0093, *Process for Prelicensing Inspection Requests*, and CVB-WI-5219 *Process for Prelicensing Inspection Requests (Inspection Approval and Scheduling)*).

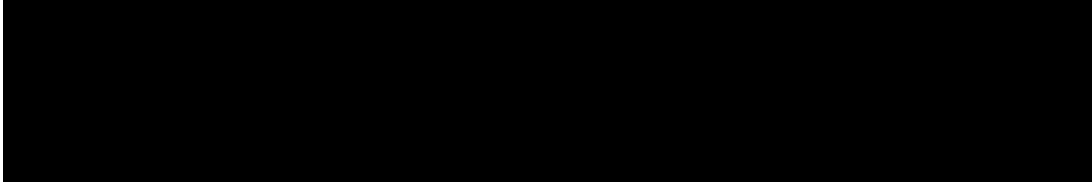
4.2 Scheduling and Approval of Inspections (see current version of CVB-WI-0119)

4.2.1 Inspection priorities will be listed on the Recommended Tab in LSRTIS. Each Specialist prepares a tentative inspection schedule for the year based upon established priorities for the CVB program and the number assigned to each Specialist.

4.2.2 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. It is advised to avoid scheduling inspections during industry meetings such as the Animal Health Institute (AHI) and the Association of Veterinary Biologics Companies (AVBC) as these may be attended by firm's Liaison and/or Alternate Liaison.

4.2.3 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



4.3.1.1 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.



4.3.3 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.

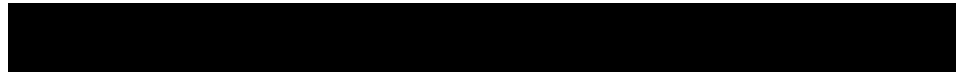
4.4.2 Team Make-up

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.

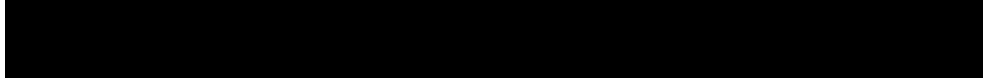


4.4.2.2 Identify special problems prior to the inspection and consider who is best suited to research these issues.

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



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

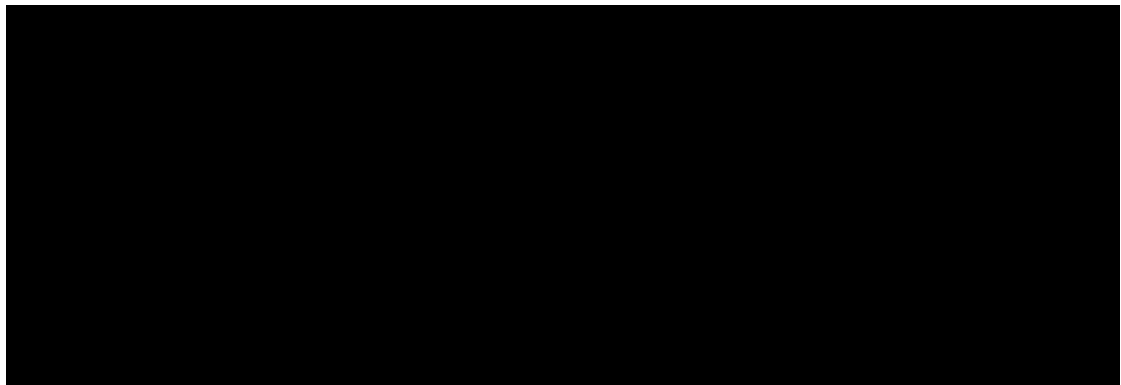


5. Travel and Time

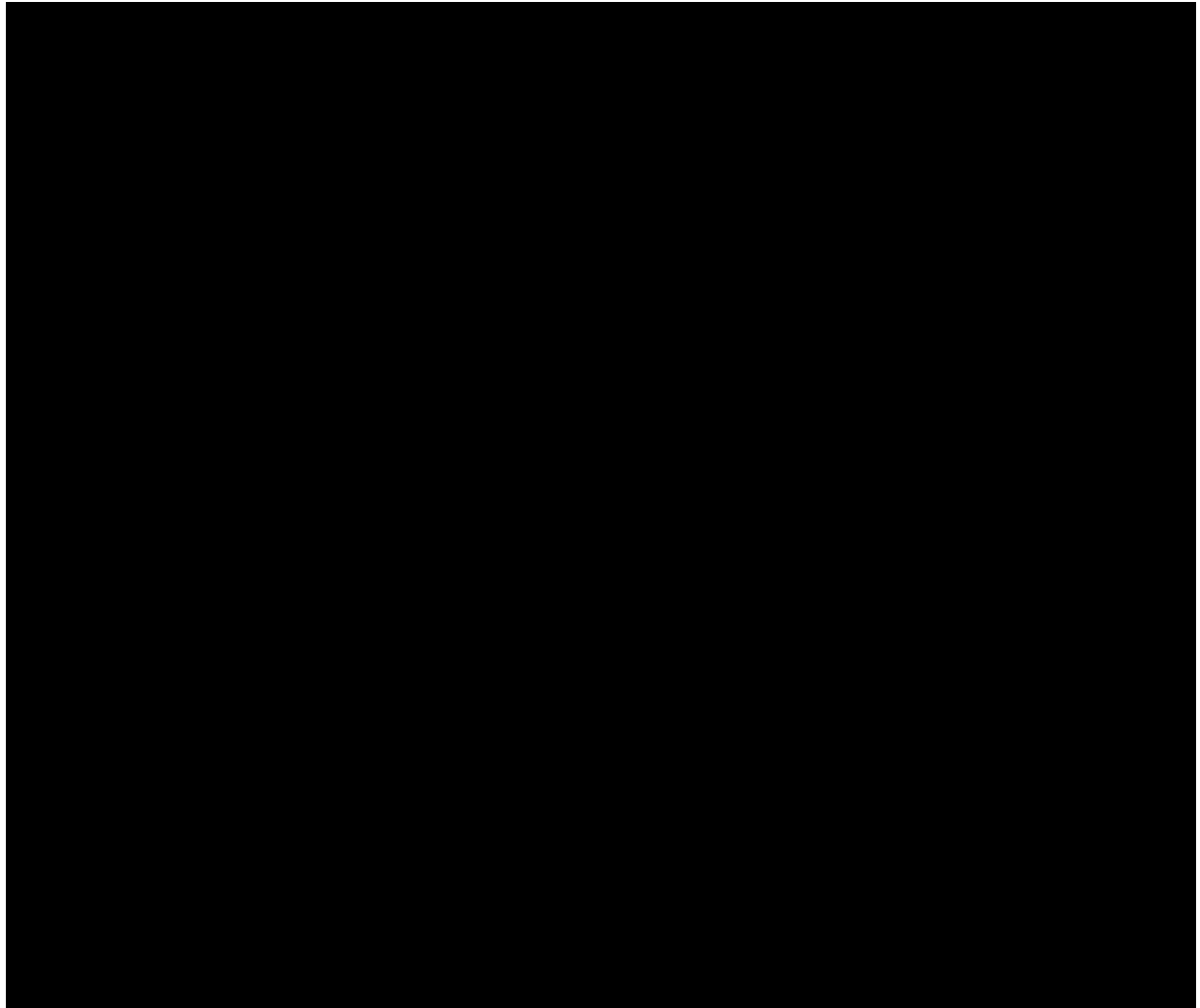
5.1 Travel Preparation

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

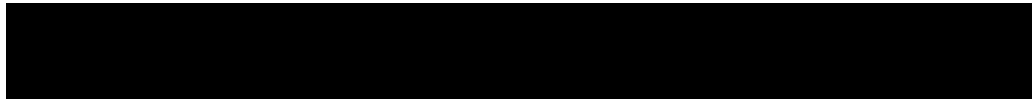
5.1.1 Domestic Inspection travel can be arranged by D&B Administration, Travel Staff via a request sent to APHIS-CVB Admin Request email group or can be booked by the team members in ConcurGov. The team should meet and book the trip at the same time to ensure the same flights and hotels are reserved.



5.2 Inspection Time



5.2.1.5 The requirement to take a minimum of 30 minutes for lunch applies to travel days as well as inspection days.



6. Inspection Assignments

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 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.


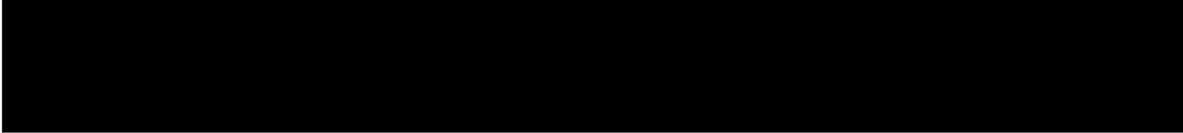
6.1.5 Discuss assignments with all team members so overlapping duties may be coordinated.

7. Pre-Inspection Review

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

7.1.1.1 See **CVB-WI-0076**, *IC Pre-Inspection Packet Checklist – LSRTIS Information and Preparation*. This is received as an email with attachments from the Investigation and Compliance Specialist.

7.1.1.2 See **CVB-WI-0096**, *Inspection Items to Consider (electronic desk file on the Mail Log)*.

7.2 Discussions with the PEL-Reviewer(s) responsible for the firm site are beneficial. The PEL-Reviewer may know of current activities relating to licenses, outlines, labels, and research activities at the licensee. 


7.3 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-



7.3.2 The inspector may choose to follow **CVB-SOP-5116** *Records Audit* to choose records to review

7.3.3 **CVB-WI-5282** *Pre-Inspection Tool* to provide items to consider in evaluating compliance provides information regarding review and understanding of an Outline of Production prior to inspection.

7.4 Facility Document Review – review the facility documents on file for the site you are inspecting. See **CVB-FRM-0082**, *Preinspection Blueprint Worksheet*.

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

7.4.4.2 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.

7.5 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 ensure 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.
- An example of items to request and initial questions can be found in **CVB-WI-5253** *Inspection Tools - Items Requested During Opening Meeting - Template*

8. Inspection Supplies

8.1 Computers

8.1.1 Laptop computers may be used during inspections.

8.1.2 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 discouraged, but due to connectivity may be the only means of connecting to VPN. Always be prepared to conduct inspections without connections to LSRTIS.

8.1.3 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.

8.2 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 **CVB-SOP-0035**, *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 (**CVB-FRM-0084**)
 2. Inspection Product Check-Off Sheet (**CVB-FRM-0083**)
 3. Product Destruction Form (**APHIS Form 2045**) (**CVB-SOP-0031**)
 4. On-site Inspection Meeting Sign-In Sheet (**CVB-FRM-0085**)
 5. Inspection, Requested Document Worksheet (**CVB-FRM-0096**)
 6. Inspection, Processes Observed Worksheet (**CVB-FRM-0095**)
 7. Items Requested During Opening Meeting (**CVB-TEM-5117**)
- Blank note paper, pens, paperclips, sticky notes, highlighters, and other stationary supplies
- Pre-inspection packet as noted in **CVB-WI-0076**, *IC Pre-Inspection Packet Checklist – LSRTIS Information and Preparation* and other reference material prepared during the pre-inspection period.

8.3 Additional Personal Equipment

- Flashlight
- Safety glasses

8.4 Travel Packet

- Travel itinerary
- Travel authorization
- Government credit card
- Accident report kit
- State Tax Exemptions forms as applicable – links found in Concur

9. Summary of Revisions

Version CVB-SOP-0034.04

- Section 5.2.1.5 was changed to state that “The requirement to take a minimum of 30 minutes for lunch applies to travel days as well as inspection days.” Previously it stated it did not apply.

Version CVB-SOP-0034.03

- Reviewed as a part of the Inspection Tool Kit Business Process Improvement (BPI) project of FY2021
- Included new quality documents created in response to the BPI

Version CVB-SOP-0034.02

- The document alphanumeric number has changed from ICSOP0012.03 to CVB-SOP-0034.02 due to the transition to MasterControl.
- Updated document numbers throughout the document and added hyperlinks to the documents stored within MasterControl.

Version ICSOP0012.03

- Complete revision of the document to reflect current practices.
- Updated work instruction numbers to reflect Master Control document numbers

Version ICSOP0012.02

- 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.

Signature Manifest

Document Number: CVB-SOP-0034

Revision: 04

Title: Inspection: Pre-Inspection Activities

Effective Date: 14 Oct 2022

All dates and times are in Central Standard Time.

Inspection: Pre-Inspection Activities

Review for Doc Format

Name/Signature	Title	Date	Meaning/Reason
TIANA BLANCO (TABLANCO)	Quality Management Assistant	13 Oct 2022, 11:13:46 AM	Approved

Section Leader Final Approval

Name/Signature	Title	Date	Meaning/Reason
KENDALL GRABER (KGRABER)	Inspection Section Leader	13 Oct 2022, 01:23:44 PM	Approved

Final Quality Check

Name/Signature	Title	Date	Meaning/Reason
CROSLEY HERR (CRHERR)	QA Specialist/CVB MC SME	14 Oct 2022, 01:56:29 PM	Approved