

VBI Procedures

1. Determination of Veterinary Biologics Investigation (VBI)

- 1.1. This document is a reference to **ICSOP0016**, *Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act*.
- 1.2. When information concerning an alleged violation of the Virus-Serum-Toxin Act (VSTA) or title 9, *Code of Federal Regulations* (9 CFR), parts 101-118, comes to the attention of the Center for Veterinary Biologics (CVB), that information should be forwarded to the Investigation Manger (IM) or the Compliance Section Leader (CSL).
- 1.3. If neither the IM nor CSL are available, the Director, Inspection and Compliance (IC), or other IC Section Leader should be informed.
- 1.4. The information will be evaluated to determine if the allegation is plausible and would be considered a violation. In some cases, concurrence from the Director, Policy, Evaluation, and Licensing (PEL), is sought to confirm the interpretation by IC warrants an investigation.
- 1.5. If a Concurrence Memorandum is needed, the CSL or the IM prepares a memo for presentation to the Director, PEL.
- 1.6. Authority to open a VBI will be done according to **ICSOP0001**, *Delegation of Authority for Center for Veterinary Biologics – Inspection and Compliance*.

2. Opening a VBI in LSRTIS

- 2.1. Open the VBI after the CVB-IC determines that an alleged violation of the VSTA or 9 CFR may have occurred. See Section 1.6.
 - Assign a Biologics Specialist (Specialist) to investigate the alleged violation(s) or monitor/coordinate the investigation for CVB if Investigative and Enforcement Services (IES), etc., is involved.
 - For investigations involving licensed subjects, the Specialist for that establishment is typically assigned the investigation.
 - For unlicensed subjects, the IM is typically assigned the investigation.
 - Use in the LSRTIS IC Investigations tab to enter initial information.
 - The minimal opening information will be the establishment number or unlicensed subject code, and Specialist assigned.
 - If the subject does not have an establishment number, then assign an unlicensed subject code unique to LSRTIS beginning with the letter 'U' (e.g., Uxxx). The assignment of the unlicensed code must be coordinated with the code master of LSRTIS (PIMS and PEL designee).
 - Click to automatically assign the next available Veterinary Biologics Investigation (VBI) number and save entries.

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- If LSRTIS is unavailable, the opening process can continue with support of email, hardcopy record, and supplemental records to populate LSRTIS when it becomes active.
 - Supplemental records such as the historic Veterinary Biologics Investigation Log (Red Book) or an Excel spreadsheet aid in the tracking of VBIs.
 - Supplemental records do not contain evidentiary information, and can be reproduced from information in LSRTIS or VBI folders.

2.2. Send the “Opening New VBI” email

- ❖ **CRITICAL CONTROL POINT:** A VBI is considered Confidential Business Information (CBI) limiting information to a ‘need to know’ practice.
 - When warranted, this email will flag communication restrictions, such as contact with the investigation subject, or handling a ‘whistleblower’ situation.
- Send to:
 - Director, Inspection and Compliance
 - Director, Policy, Evaluation, and Licensing
 - Other Director depending on staff involved in Determination of Investigation (Section 1)
- Carbon copy to:
 - Assigned Specialist
 - Compliance Section Leader (CSL)
 - Investigation Manager (IM)
 - Investigation and Compliance Specialist (ICS)
 - Other staff, depending on involvement in Determination of Investigation (Section 1)
- The following email content is recommended:
 - **Subject Line:** New (VBI number from LSRTIS)
 - **Date Opened:** day month year
 - **Establishment:** Name, Est. Number or Unlicensed subject code
 - **Product(s) Involved:** product category or specific product
 - **Allegation:** citation or event being investigated
 - **Specialist:** name of assigned Specialist
 - **Plan of Action:** immediate next step

2.3. Assigned Specialist Follow-up

- **The ICS or IM or CSL** fills out the initial information on the Veterinary Biologics Investigation Summary Sheet and delivers the VBI folder to the assigned Specialist.
- Provide all evidentiary or pertinent information, such as; product codes and serial numbers, to be included or referenced in the VBI folder to the Specialist.
- The **Specialist** will complete remaining LSRTIS data entry for the created VBI.

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3. Conducting the Investigation

- 3.1. The Specialist plans the investigation**, and should within 5 office days of VBI assignment, discuss a plan of action with the IM or CSL if the guidance was not given in the “Opening New VBI email”.
- The “Opening New VBI email” is added to the VBI file.
 - If the plan of action references a CVB Quality Document, that document need not be printed for addition to the VBI folder.
- 3.2. The Specialist adds documents** and LSRTIS references to the VBI folder.
- Use **ICFRM0016**, *Veterinary Biologics Summary Sheet*, to index additions to the VBI folder, see Section 4.
- 3.3. The Specialist gathers and reviews the evidence**, consulting with or forwarding pertinent information to appropriate staff in CVB, Veterinary Services, or externally with those who need to be involved.
- ❖ **CRITICAL JUDGMENT POINT:** Use ‘need to know’ practices and consult with CSL, IM, or IC-Director for guidance as needed.
 - ❖ **CRITICAL CONTROL POINT:** Consult with the CSL prior to purchasing items from the subject of the investigation.
 - This may be demonstrated by email or purchase request authorization.
 - ❖ **CRITICAL CONTROL POINT:** Store physical evidence that can’t be secured in the VBI folder due to size or temperature control in the IC-Evidence Cage.
 - This will be demonstrated by use of **ICFRM0108**, *IC Chain of Custody Form*.
 - The CSL or **ICSOP0001** VBI delegate determines access to the IC-Evidence Cage key by email notification to the NCAH Physical Security Specialist.
- 3.4. The Specialist requests CVB testing** as needed. See **ICWI0103**, *Special Test Requests Initiated by Inspection and Compliance Staff*.
- 3.5. The Specialist drafts correspondence**, acknowledgement letters, investigation summaries, and other reports as appropriate to the case. See **ICSOP0016**, *Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act*.
- A non-CVB employee who reports alleged violations should receive a letter acknowledging that CVB appreciates the information and will take appropriate regulatory actions, if warranted.
- 3.6. The Specialist continues to coordinate** the investigation and follow-up on action items until the issue has been resolved, consulting with the CSL or IM as needed.

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4. Adding hardcopy or electronic documents to the VBI folder and use of the Chronology of Events (CE) section in ICFRM0016, *Veterinary Biologics Summary Sheet*.

- ❖ **CRITICAL CONTROL POINT:** When created in LSRTIS, electronic records are secured by assigning a VBI Number and the failsafe tag “Suppress Response From Portal”. Portable Document Format (PDF) provides best practice for utility and integrity.

4.1. The best practice is to add information to the VBI folder concurrently, whether it is hardcopy, LSRTIS references, or Specialist commentary.

- Arrange additions as information arrives with the most current on top of the previous in the appropriate tab (see Section 4.3).
- Index all events associated with the VBI in the Chronology of Events (CE) section.
- Strap all pertinent hardcopy information in the VBI folder; mailed official correspondence, printed e-mails, requested records, etc.
 - Items difficult to strap may be secured to a sheet of paper for the purpose.
- Index all pertinent electronic information (not added as hardcopy) in the CE, and provide reference in a manner to readily locate the record in LSRTIS.
- Index Specialist commentary in the CE. Such narrative is to provide context to the investigation or information received. Put comments on the backside of the document, call notes below a printed email, or create a separate hardcopy or ML.
 - Do not deface evidence. If needed, make a copy to mark-up.
 - Use “sticky-notes” for temporary purposes.

4.2. The CE section serves as a rough timeline and table of contents for the investigation.

- The “Date Occurred” column need not be consecutively dated. Variance is expected due to lag in various communication methods and adding records.
- The “Attachment Number” column may point to a hardcopy attachment number or LSRTIS reference, such as ML#.
- Each entry into the CE must correspond to information in the VBI folder or held in LSRTIS.
- The Specialist may maintain the CE electronically and add the initialed/signed printout to the VBI folder.
- The entry into the CE should be a short explanation of what the document added to the investigation file is, i.e., phone log between “Person A and Person B,” Letter of Warning, etc. Do not write an extensive explanation of the attachment.
- All blank lines in CE section will be lined-out during VBI closure.

4.3. The Veterinary Biologics Investigation Summary Sheet has Tab use requirements.

- The A Tab is used for the Investigation Summary Sheet.
- The B Tab holds all correspondence, paper evidence, telephone logs, etc., and is headed by the “Investigation Report – For Official Use Only.”
- The C Tab is used for reports from IES or other Agencies.
- The D Tab, on the back of the folder, is used to hold test requests and results.
- The CE must specify which Tab holds information other than B Tab.

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4.4. Recording receipt information for physical items

- Add receipt information to evidentiary hardcopy documents if not intrinsic or obvious on each page of the document. A stamp may be used.
- Record remaining receipt information on backside of document.
 - Attachment number indexed in the CE
 - VBI number
 - Page number control (i.e., page 1 of X)
 - Source or Submitter
 - Date of receipt
 - Initials of recipient, or if applicable, initials and date of person adding record
- Large documents (i.e., over 10 pages) may have receipt information on first and last page, instead of each page. Indicate the total number of pages. Physically staple, if possible.
- Record receipt information for items that can't be held in VBI folder, such as actual animal biologics, evidence needing return to IES, etc.
Use the following options:
 - Procurement records (hardcopy or ML upload)
 - **ICFRM0108**, *IC Chain of Custody Form*
 - Scan item and upload image to ML
 - Upload electronic file to ML
 - Add photocopy/picture of the item to VBI folder

5. Closing the VBI

5.1. The Specialist writes a draft Report of Investigation (ROI) after determining all issues have been resolved by all parties involved.

- The Specialist is considered the “Investigator” on the ROI.
- See **ICWI0416**, *Writing a Report of Investigation*
- Use **ICTEM0039**, *Report of Investigation*

5.2. ROI Routing: Mail Log (ML) is the standard method, hardcopy may be used.

- **Draft ROI** (Word document) for review and editing:
 - Moves from Specialist → IM → CSL → ICS
 - Rejected draft is returned to the Specialist
 - A revised draft may skip the IM after the initial round
- **“Final” ROI** (PDF) for concurrence signatures:
 - ICS child-loop ↔ Specialist. Then ICS → CSL → IC-Director → ICS
 - Rejected ROI is returned to the Specialist
- The recipient of the any ROI may request the VBI folder.
 - Notify the ICS for VBI folder tracking

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5.3. The Specialist will create a ML for the ROI to upload the draft ROI.

- **Create Mail Item** in LSRTIS Mail Log
 - Add ML# to draft ROI **ICTEM0039**, *Report of Investigation*

- Refer to table for **ROI ML Values** when creating ML
 - Select value by typing first characters, then selecting from choices
 - Pick value from drop down list of values
 - Enter text not formatted by ML
 - click Add to populate ML after selection or pick

ML Parameter	ROI ML Values select, pick or enter	Note
Select Category	select IC	
Establishment	select Establishment # or Unlicensed Code	
Product	select Product then enter Serial Number	Complete if Product and Serial Numbers referenced in ROI are not already linked to VBI.
VBI Number	select VBI #	
Date Submitted	select date	
Date Received	select date	
Submission Type	pick Investigation	
Submission Subtypes	pick Report of Investigation	
Regulatory Action Source	pick Investigation	
9CFR Violations	pick 9CFR code or VSTA	Add each applicable code referenced in ROI.
Tags	pick Suppress Response from Portal	
Brief Description	enter ROI VBI-FY-XXX	This formatting is preferred.
Informationally Linked Mail Item		Typically not used.

- **Upload the draft ROI** to the ML# using internally routed procedures
- Open ML# for ROI, click Documents tab
- Click + Create New Document Record
 - Select File Location button = “Upload File”
 - Select File to Upload = Browse and find draft ROI
 - Type* = pick “Internally Routed”
 - Tags field is not required
 - Comments = “For review” or anything similar
 - click Select Save and Return to Item Record
- Click → Move Forward, add Routing Comment, route according to Section 5.2, then ✓ Move Item

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5.4. The Specialist will prepare the VBI Folder

- Check all evidentiary documents are present (Section 4.1)
 - Remove “sticky-notes”. If important, add Specialist commentary (Section 4.1)
 - Secure loose documents/pages.
- Check the CE is complete (Section 4.2)
 - Do not line through remaining blanks in CE. Done by the ICS (Section 6)
 - Check ML# tags are legible and correct
- Check documents are in proper tab (Section 4.3)
- Check documents have receipt information (Section 4.4)
- Check work email pertinent to VBI has either a hardcopy or ML# tag in VBI folder

5.5. The IM will conduct review of the draft ROI by either:

- Promote approval: the draft ROI to the CSL
- Request rework: return draft ROI to the Specialist with routing comment

5.6. The CSL will conduct concurrence reviews of both draft and PDF ROI by either:

- Give Approval: according to Section 5.2
- Request rework: return ROI to the Specialist with routing comment

5.7. Adding Signatures to the ROI and tags for work counts

- Follow Section 5.2 for electronic or hardcopy routing
- Upload ROI to corresponding ML as “Internally Routed”
- **ICS will convert approved ROI to a PDF**
 - , pick “Request Misc Info from CVB Employee” and select Specialist to sign
 - to CSL, pick “Section Leader- Final Authorization” after child-loop completed
- **The Specialist will sign**, upload and
- **The CSL will sign**, upload
 - to IC Director
 - pick “Director’s Review/Approval”, add comment then

5.8. The IC Director will conduct concurrence Review/Approval by:

- May request the VBI folder from the ICS for further review.
- May grant Final Approval to close the VBI per date signed:
 - Sign ROI, upload to ICS
 - pick “Review (BCA)”, select ICS, then
- May request rework:
 - Does not sign ROI.pdf
 - , to return to Specialist
 - pick “Review (Specialist)”, add denial comment, then

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5.9. The ICS will perform a quality check of the VBI folder.

- Check all evidence referenced in ROI exists in VBI folder or LSRTIS
- Check all evidentiary documents/items demonstrate chain of custody with receipt information
- Check all evidentiary documents for missing pages
- Check all hardcopy pages are secured
- Spot Check CE entries correspond to numbered document or item
- Spot Check for documents not indexed in the CE
- Spot Check for ML# not indexed in the CE using VBI# in LSRTIS
- Request Specialist to correct and complete VBI folder
 - The ICS may **Initiate Child Workflow** to track the request and transfer of the VBI folder
 - The ICS may correct and complete instead of the Specialist

6. Finalization Steps in Closing the Investigation

6.1. The ICS performs a final review and closure of ICFRM0016, *Veterinary Biologics Investigation Summary Sheet*.

- Print the signed Final ROI.pdf as a yellow file-copy and add it to the VBI folder.
 - May handwrite ML# on the ROI yellow, if needed
- Correct and/or complete remaining ICFRM0016 entries using information from the final ROI, such as; disposition, close date, etc.
- Add final ROI entry to the CE
- Line through remaining CE blank spaces

6.2. The IM or CSL or ICS will incorporate any other needed information into the Investigation Module in LSRTIS, and **Close** the VBI.

6.3. The ICS will mark the VBI folder closed with the destruction date noted.

- **Close** the VBI in LSRTIS if not already closed by the IM or CSL
- File the VBI folder in the power files with the closed cases