

Writing a Report of Investigation

The purpose of this document is to provide guidance for the completion of a concise Report of Investigation, which is the official closing document for a Veterinary Biologics Investigation. A formatted template is available.

The report is narrative, do not use bullets. There are six main parts to the Report of Investigation (ROI) and are not numbered or bulleted in the report.

- Title Page
- Synopsis
- Alleged Violations
- Background
- Narrative
- Conclusion

1. Title Page

Title	USDA APHIS CVB title statement and Investigation Report centered on page (formatted on template)
Investigation:	VBI-XX-XXX
Subject(s):	Write the full name, correct address(s), and telephone number(s) of each subject. Boldface the names. Include the dba (bold), and/or the Corporate headquarters address, if there is one.
Investigator:	Type your name and title below the line provided. Electronically sign the PDF version, which will be routed to you after Compliance Section Leader review.
Date of Report:	Date the case report was last prepared or edited by the Investigator, presented in the following format: January 1, 2004
Disposition:	Check (bold X) the applicable disposition: Substantiated allegations, No Violation, Lack of Evidence (formatted in template)
Compliance:	Check (bold X) the applicable compliance result(s): Complied, or To Pre-license (formatted in template)
Concur:	Signature lines for IC Director and Section Leader, Compliance (formatted in template)
Disclaimer	FOR OFFICIAL USE ONLY.... disclaimer (formatted in template)

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Follow this reference guide to name, then refer to a subject for ease of reading.

- A subject person: first name, middle initial and last name, then capitalize last name to declare reference, i.e., John J. Person (PERSON)
 - Add an initial and period to distinguish duplicate last names, i.e., (J. PERSON)
- A subject company: use company full name, then reference as either the capitalized first name or acronym, i.e., Biological Company, Inc. (BIOLOGICAL) or (BCI)

2. Synopsis – Provide a brief summary of the investigation in a narrative format. Identify the subject(s) in the case; include the identity of the regulated product. The expected length of the synopsis is 2-5 sentences per subject or alleged violation.

- Use the reference guide (above) to introduce each subject in regular font.
- The Chronology of Events in **ICFRM0016**, *Veterinary Biologics Investigation Summary Sheet*, should be a helpful outline.

3. Alleged Violations – List the alleged violations in the table provided. Each listed violation will be supported at the end of the Narrative section.

- Subject (s) – may use reference guide.
- Dates(s) – date of violation (if known). If the same citation has been violated repeatedly, write “Multiple.”
- Citation(s) – Cite the most specific subpart of the violation. (VSTA and/or 9 CFR)
 - The citation will be a main citation, or one that supports a main citation.

4. Background – This serves to provide comprehensive background information on the subjects. This may be used to link subjects with previous violation events and enforcement actions (of similar nature). There are two parts:

- Subject(s) Information: List who is pertinent to case and available information, such as; permit status, scope of business (domestic, international), types of products, etc.
- Subject(s) Previous History: List previous similar or related alleged violations.
 - Do not leave blank, state “N/A,” “None,” or the history.

5. Narrative – The purpose is to provide concise explanations of how the investigation started, detail the findings of the investigations, then evaluate any evidence.

The information is organized in two parts:

5.1 Basis for Investigation – Describe the initiation of the investigation: who brought the information forward, who requested the investigation, who authorized the investigation, and date authorized. Typically done in one or two sentences.

Example: BIOLOGICAL promotional materials were received from Dr. Doctor, ARS, Ames, Iowa, on August 9, 2010. Daniel C. Coyle, Section Leader, Compliance, CVB-IC authorized the investigation on August 9, 2010.

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5.2 Investigative Findings –

The introductory paragraph: This paragraph provides an explanation of the initial information. This narrative should:

- Introduce the initial information acted upon in the **Basis for Investigation** and cite the Attachment # or entry date of the information in the VBI.
- Describe the claim(s) or situation the initial information presented to warrant investigation.

The findings paragraph(s): These paragraphs narrate and chronicle when and how the investigation proceeded, what was done, and what was found.

- Upon reading the explanation, the reader should be able to answer the following question: “What are the facts and exhibits that demonstrate a subject met, or failed to meet regulatory requirements?”
- These paragraphs typically start with a date, an action, then lead into facts pertinent to the action. Example: “On August 10, 2010, a Letter of Warning (Attachment#) was issued to BCI informing ...”, then leading to “PERSON responded on August 19, 2010 and stated...”
- Support each fact succinctly, and reference each to a supporting VBI exhibit.
 - To support a violation, introduce all pertinent exhibits.
 - Check referenced exhibits are stamped, secure, and correlated.
 - The reference may be an attachment # or unique date.
- Include any mitigating or aggravating factors and important decisional information.

The transition statement: Provide a transition statement between the **findings paragraphs** and the **citation**. The transition statement typically has three blank lines above and below it to create separation.

Include one of the following transition statements:

- “These findings substantiate the following alleged violations:”
- “These findings indicate that there is insufficient evidence to substantiate an alleged violation.”
- “These findings indicate that there is no violation.”

The regulatory citation: If there is an alleged violation, this section of the Investigative Findings is indented and starts with a bolded CFR/USC code and the entire citation violated. Such as: **9 CFR 114.5 Micro-organisms used as seed.**

- All citations in the Alleged Violations table are presented in this section.
 - Either as the main bolded citation, or in a supportive narrative.
 - Check the citation subpart is specific to the violation.
- Indent this entire section approximately ½ inch from the other text.
- Only bold the citation, not the narrative explaining the allegation.
- Provide blank lines above and below the citation to create separation.

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Follow each bolded regulatory citation with a supportive narrative explaining how the exhibits demonstrate a violation occurred. The narrative may declare a violation has occurred. The reader should be able to answer the following questions:

- “What is the regulatory requirement?”
- “How does this requirement pertain to this incident?”
- “Why is this requirement in effect?”

This may be done through:

- brief reference to the information on the table
- subject(s) involved in violation
- date(s) of violation
- reference to citations in the Alleged Violations table which provide context to your explanation, such as using 9 CFR citations to support a 21 USC 151.

6. Conclusion – This part is used to declare the disposition of the investigation, state compliance actions made by the subject, and recommend closure and/or further actions.

Start with a direct declaration of the disposition and why, such as “BIOLOGICAL was in violation of 9 CFR 114.5 by failure to...”

- If you already declared violation(s) in the regulatory citation portion of the Narrative, then simply repeat only the citation codes “BIOLOGICAL was in violation of 9 CFR 114.5, 9 CFR 116.5 (b), and 21 USC 151.”

State what the subject did to demonstrate compliance to the regulations. This may be brief or detailed depending on the complexity of the issue.

- If applicable, include a follow-up check of date(s) and whether or not the appearance of compliance was observed.

End with applicable closing statements. Such as;

- “Based on the information provided, I recommend closure of the investigation with no further action taken or recommended.”
- “This investigation has been precedent setting (or involved in a court case) and shall be retained permanently and managed according to APHIS Records Management, Program Investigations and Violations.”
 - Routine cases do not need to be declared routine