Animal and Plant Health Inspection Service

Veterinary Services

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Inspection: General Guidelines for Violations Attachment Report (short format)

Document Number: CVB-WI-0095 **Revision:** 02

Previous Number: ICWI0066.02

Vault: CVB-Released

Section/Area: CVB-WI-IC

Effective Date: 20 Aug 2021

Notes:

General Guidelines for Writing an Inspection Report

ITEMS to consider when writing the report (long or short format)

1. Use outline format – do not use bullet points.

2. Do not format – this will be done by the Biologics Compliance Assistant.

3. Observations should be written in past tense.

4. References to Liaisons or Personnel responsibilities should be written in present tense.

5. For long forms, clearly list observations and audits conducted. The descriptions should avoid the phrase, "no exceptions noted". If needed, the phrase "it appeared to meet the purpose intended" can be used. The observation is a moment in time and when the phrase "no exceptions noted" is used, the regulated entity can interpret that as the process is "approved" by CVB. In actuality, CVB had no objection to the process seen at that moment.

6. Clearly describe the non-compliance that was found.
   a. State the specific observations and/or records audited when describing the non-compliant item(s).
   b. Be explicit. Use Product Code and Serial or Lot Numbers
   c. Avoid general, vague statements.
   d. State quantities and methods (e.g. OP references) used wherever possible.

7. Cite the most applicable 9 CFR Regulation for the non-compliance (we can not reference memorandum)

8. Action items **should not** include the following phrases:
   a. *Use all necessary precautions*
   b. *Within __ days*, for items where non-compliance to the Outlines of Production have been determined, as this implies the firm may continue to operate out of compliance for the additional day
   c. *Immediately* as this cannot be enforced – instead use "prior to the next production process" or "prior to the next testing procedure" which can be documented by the production records.

9. List the True Name of the Product and Product Code the first time the product is mentioned in the report. All following references may use just the Code. Remember to include serial or lot numbers as applicable.

10. Spell out all abbreviations followed by the letters the first time the abbreviation is referenced. Enclose the abbreviations in parentheses immediately following this first use. All following references may use the abbreviation only.

11. If the non-conformance is recurring or a repeat observation from a previous inspection, note in the inspection report. This may also increase the severity of the non-conformance.

General Guidelines for Writing an Inspection Report

12. Each author must review their portion of the report for content, grammar, punctuation, complete sentences, and spelling. The Inspection Team Leader is responsible for correct format used and for the overall content, grammar, punctuation, complete sentences, and spelling of the final draft report.

13. While each author's writing styles may vary, it is the Inspection Team Leader's responsibility to combine the team's input into one unified report.

Violations Attachment Report Format (short form)

In-depth inspections, other than the first inspection after licensure, should use the short form to report violations discovered during the on-site inspection.

The violations will be documented using **CVB-TEM-0037**, *Inspection Report (short form) Attachment of Violations.* Violations are placed under one of three categories related to the severity of the non-compliance or observation. Additional observations that are not violations can be listed as Items of Concern.

1. Serious - Violations of this degree will probably affect the quality of the product or products or may be willful. This type of violation will require more thorough documentation and referral to higher authority. Either stop sale or temporary suspension of license should be considered.
2. Less Serious - By repetition or very nature, may affect quality of a product. They may require evaluation at the CVB-IC office before final action is taken.
3. Minor - Are not apt to affect quality of product but indicate laxity or error that could become more serious if not corrected. If numerous minor exceptions are noted during the inspection, it is indicative of poor management and should be considered as having cumulative effect.

Several other work instructions have been developed for use in evaluation of compliance – these include but are not limited to the following:

Inspection Techniques and Reporting Violations Related to 9 CFR 102.5(c)(1) and 114.8(d) - CVB-WI-0140

Findings related to 9 CFR Parts 109.1 and 109.2 exemptions - CVB-WI-0070

CVB Inspection Compliance Policy Concerning Compliance to Title 9 CFR 113.53 - Ingredients of Animal Origin Testing - CVB-WI-0083

CVB Inspection and Compliance Policy Concerning Compliance with Title 9 CFR 114.11 and Out of Cooler Episodes - CVB-WI-0081

Evaluation of 9 CFR 116 related to Electronic Records and Digital Data - CVB-WI-0135

General Guidelines for Writing an Inspection Report

Evaluation of Electronic Record Keeping and Compliance with Title 9, Code of Federal Regulations, Part 116 - CVB-SOP-0050

Assessing Compliance with the Requirement of State Veterinarian Approval- CVB-WI-5215

Each violation will be uniquely identified with a letter, starting with A. If more than 26 violations are identified, the lettering will continue with AA.

The violation should be related to a 9 CFR regulation, but do not restate the regulation or cut and paste the regulation that was violated. Instead, state the general violation. You may use words and phrases from the regulation that was violated to convey the issue.

For example, if you find the product was not prepared in accordance with the Outline of Production, 9 CFR 102.5(c)(1), state:
A. Violation - Several products were not prepared in accordance with the filed Outlines of Production.
[Reference: 9 CFR 102.5(c)(1)]

Then list the observations/audit results to support the violation.

Do not use:
A. Violation - Licensed biological products shall be prepared as required by the regulations and in accordance with the filed Outline of Production as prescribed in 114.8 and 114.9.
[Reference: 9 CFR 102.5(c)(1)]

The most appropriate 9 CFR reference will be cited in the violations attachment. Please refrain from listing more than one 9 CFR reference.

If more than one observation supports the violation, they will be separated by a number. The observations should be brief, but small letters may be used to separate out specific details if needed.