

General Guidelines for Violations Attachment Report Format

An outcome from the 2015 “Just Do It” Business Process Improvement (BPI) project on Inspection Reports, the format for in-depth domestic inspections has changed to just reporting the violations discovered during the on-site inspection.

The violations will be documented using **ICTEM0040**, *Attachment of Violations*, and placed under one of four categories related to the severity of the non-compliance or observation:

1. Serious
2. Less Serious
3. Minor
4. Items of Concern

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.

Use outline format – do not use bullet points.

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

Observations should be written in past tense.

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