1. Use Template ICTEM0040, *Attachment of Violations*
Remember to use cover letter, **ICTEM0041**, *New Inspection Report – Cover Letter*

2. Use Template ICTEM0009, *Inspection Report*, for special inspections, the first inspection after licensure, and in-depth inspections for international manufacturers
Remember to use cover letter, **ICTEM0010**, *Inspection – Cover Letter*

3. For BOTH inspection reports

The report or Attachment of Violations should read as if one person wrote the whole document. It is the responsibility of the Inspection Team Leader to organize the information from the team members in a readable/understandable document.

REMINDER – 9 CFR listing must be included with each action item.

The "Priority" of the Violation must be noted.

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. If more than one of the same issue, all items may be considered Less Serious.

Less Serious – By repetition or very nature, may affect quality of a product. They may require evaluation by Inspection and Compliance (IC) management before final action is taken. Holding release of serials or products may be required.

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.

4. Preparation of Mail Log – Inspection Team Leader

    a. Create mail log item - See Mail Log (ML) Work Instructions, **ICWI0236**, *Work Flow for Correspondence for Inspection and Compliance: Using the Mail Log System,* **Section VIII**.

    b. Documents are attached to the ML and labeled with the following document types:
        1. Completed inspection report - <u>Outgoing Inspection Report</u>
        2. Cover Letter - <u>Outgoing General Corr</u>
        3. Listing of observations/records audited – <u>Inspection Notes</u>
            Each Team Member should have a list.
        4. Draft Report from Team Members – <u>Internally Routed</u>
            This is *optional* – may be easier for the team leader to have them all in one place.

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5. **Policy Review – Section Leader or Acting**

    a. Move forward to the Section Leader for Policy Review – Comments and edits will be captured using track changes.

    Additional Section Leader review responsibilities:
    1. Review inspection notes for complete information. Note dates of inspection.
    2. Ensure report reflects the dates noted on inspection notes.
    3. Go to LSRTIS – Pending Report, if the start date and end date listed do not match the dates of the inspection, click on "Edit" to Modify Inspection dates.
    4. Ensure IC Calendar has correct inspection dates (this will include the travel dates).

    b. The ML item will be routed back to the author (Review (Specialist)) for needed changes and for LSRTIS loading of Action Items.

6. **Loading Action Items into LSRTIS – Inspection Team Leader**

    a. Go to [Pending Report (18)] Tab under Inspection Dashboard and find the inspection.

    b. Click on [Info] for the inspection

    c. Add Action Items – Initiate by clicking on Add Action Item

    ## Action Items

    Add Action Item No Action Items For This Inspection - Add Action Item

    This takes you to Create Action Item

d. Fill in * boxes – Note, some are drop downs

Action Item Category *

| LICENSES | ⌄ |

Action Item Priority *

| MINOR | ⌄ |

Action Item Due Date *

| |

Violation *

| 101.2 | ⌄ | - OR - [🔍 **Search & Select**]

Observation *

| |

> Note – there is only room for one violation reference – choose the most relevant

Action *

| |

[✔ **Create**]

e. Then click on

NOTE – If there are no action items, click on "Mark with No Action Items"

Action Items

Add Action Item No Action Items For This Inspection - Add Action Item

[✏ **Edit**] [✏ **Mark With No Action Items**] [✏ **Link To Regulatory Letter**] [✉ **Create Regulatory Letter**]

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7. Link Inspection to Inspection Report in Mail Log – Inspection Team Leader

    a. Click on Link to Inspection Report

✎ Edit	✎ Link To Inspection Report	✎ Link To Regulatory Letter	✉ Create Regulatory Letter	✎ Close Selected Action Items

    b. Enter ML number – this will move the record from Pending Report to Pending Finalization

This MUST be done prior to moving the ML item for finalization by Biologics Compliance Assistants (BCAs). If it is not done, the inspection record will not close even if the ML is finalized. Also, ML for serious action items will not be created.

8. Move ML item to IC Inbox Pool – Inspection Team Leader

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