Corrective Action

Definitions:

- *Corrective Action* means any measure taken to eliminate or prevent the recurrence of the causes of an existing nonconformity, defect or undesirable condition.
- *Nonconformance* means a documented or verifiable deviation from the requirements of chapter NR149.

What does NR149 require now?

- If a problem exists, some sort of follow-up is required to verify that the corrective action taken to resolve the problem was successful.
- If the resolution was not successful, then additional corrective action is required.
- Your corrective action documentation must include a follow-up to ensure that the corrective action taken did indeed resolve the problem.

A good corrective action report addresses and documents the following issues:

Date: **Analyst:** **Test:** **Samples affected:**
1. What problem exists? **2. What corrective action was taken to fix the problem?** **3. Did the action taken to fix the problem work?** **4. Does any data need to be qualified or rejected due to this problem?**

Examples of when corrective action is required.

- Anytime any quality control sample, including proficiency testing samples, fails to meet their acceptance limits or evaluation criteria.

  Note that changes taken to address quality control sample failures must be those that resolve or address the failure in a timely manner – before affected results are released or reported by a laboratory.

- To address deficiencies noted during internal or external audits.
- If quality assurance or quality systems policies and procedures are not providing the desired effects.
- Discrepancies are noted.
- Any nonconformance situation is observed.

Corrective Action Form

Source or Nature of the Nonconformance

A. Quality Control sample issues:

☐ Blank ☐ LCS ☐ ICV ☐ CCV ☐ Spike ☐ Replicate ☐ QCS ☐ PT ☐ Other

Blank: What is the LOD? _____ What level was detected in the blank? _____
Spikes/replicates: Acceptance criteria? _____ Your result? _____
Is this a matrix interference problem? _____
How do you know that? _____

LCS/QCS/PT: True Value: _____ Acceptance criteria? _____ Your result? _____

B. Departures from Quality System Policy or Procedure:
Describe the departure (What was the departure from policy? Why?)

Other problems (equipment malfunctions, etc.)

Describe the situation (how did you know something was wrong?)

Corrective Action Mechanism

List any activities or checks you performed to identify the source and resolve the problem.

Action	What did you conclude?	Initials/Date

Documentation of Resolution

Date: _____

Briefly document how you know this problem has been corrected. What changes have you made to prevent it from recurring?

Data Qualification Required?

Will any sample data be qualified? (Identify affected samples and qualifier)