Laboratory Quality Systems Homework # 4 – Out of Specification/Corrective Actions

Due by Midnight on Monday, March 3, 2025

A corrective action program is an essential management tool for quality assurance/ quality control activities and for addressing errors or defects at any point in the generation of data

Corrective actions can either be taken on-the-spot to correct or repair non-conforming data or equipment or be a long-term effort to eliminate causes of non-conformance. A corrective action program should consist of the following steps:

a. Define the problem

b. Assign responsibility for investigating the problem

c. Assign and accept responsibility for implementing the corrective action

d. Establish the effectiveness of the corrective action and implement the correction

e. Verify that the corrective action has eliminated the problem

For more information on a corrective action program for out-of-specification results, see:

- Out-of-Specification Results - Chapter 11 from A laboratory quality handbook of best practices by Donald Singer
- The Laboratory Quality Assurance System Manual by Thomas Ratliff (pps 139 – 146)
- Office of the Texas State Chemist SOPs on:
    - Control of Non-conforming Work
    - Corrective Action Procedure

Assignment Directions

Consider the situation described below:

> **After a series of tests have been run using the Salt in Feed method (see SOP on Salt in Feeds), an analyst in your lab finds that the most recent test results for the control samples are out of specification.**

In a brief essay, answer the following questions (See class readings and lectures in Unit II):

1. How would you investigate the problem with the control samples? (2 pts)
2. Identify at least 3 factors that could have caused the problem (3 pts)
3. Describe the corrective actions you would implement to address the problem in the future. (5 pts)