

## General Discussion

This document provides guidance for the management of analytical laboratories including the following:

- Personnel training;
  - Proper handling of samples;
  - Hazardous materials;
  - Control and maintenance of reagents, reference standards, and buffers;
  - Laboratory facilities and equipment; and
  - Documentation and control of test results.
1. Work Surfaces (e.g., benches, fume hoods) should be clean and organized prior to, and after, use.
  2. All Original Sample Solutions, Standard Solutions, Glassware, and Reagents used in the analysis, and in any subsequent investigation, should be retained to the extent possible if an analytical laboratory investigation (LI) is required.

Used testing materials and waste should be disposed of promptly, in a safe manner, and in compliance with local regulatory requirements, after the completion of testing and assurance that neither questionable results, nor Out-of-Specification (OOS) results have been obtained.

3. Analytical Laboratory Personnel Training should include the following, as applicable to the job function:
  - Laboratory safety;
  - Departmental Standard Operating Procedures (SOP);
  - Analytical testing knowledge and skills;
  - Preparation and handling of reagents and reference standards; and
  - Laboratory documentation practices.
4. Calibration and/or Function Verification of laboratory instruments and laboratory equipment (e.g., balances or pH meters) that is performed should be documented and verified prior to use.
5. Laboratory Instruments and Equipment Requiring Repair or Calibration should be clearly marked and, when beyond repair, the equipment should be removed from the laboratory. A description of the malfunction, repair, or calibration of laboratory instruments should be documented.
6. Sample Handling, Testing, and Preparation of Testing Materials should be documented using a controlled documentation system.
7. Control of Laboratory Glassware should include the following:
  - Glassware used for measurements should have the accuracy suitable for its intended use and shall conform to requirements of applicable compendia;
  - A sufficient supply of glassware should be available for the number of tests to be performed;
  - Clean and dirty glassware should be segregated;
  - SOPs for cleaning glassware should be followed;