

Traceability

APHL Quality Management System (QMS) Competency Guidelines

This course will help staff understand traceability, what is needed to support a claim of traceability, the various metrology systems, how calibration fits into traceability, and key questions to ask about traceability to make sure the laboratory's quality management system is robust.

Objectives:

At the end of this learning activity, the participant will be able to:

- Define the terms calibration, certified reference material and measurement traceability mean in relation to laboratory testing.
- Identify the difference between reference standards and reference materials.
- Describe the items to document in the laboratory to meet traceability.

What is Traceability? It is a Calibration Hierarchy. Reference Standards shall be calibrated by a body that can provide traceability (traced back) to a national standard of measurement (a measurement unit, procedure, or standard)

Public Health Laboratory Competency Guidelines

This learning activity provides content to support high-level competencies (desired skills or behaviors) for a laboratory professional in the listed domains. Also supports related content areas in the National Laboratory Curriculum Standard Framework.

General (GEN) domain

GEN 1.00 General technical and laboratory practice knowledge: demonstrates general knowledge and skills related to the scientific and technical components of laboratory testing (including technical, troubleshooting, mathematical and statistical skills).

- Documents actions and results using established paper or electronic systems

**Traceability
includes
specific
requirements
for:**

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- Calibration
- Testing
- Reagents and Support
- Equipment
- Reference Standards
- Reference Materials
- Intermediate Checks
- Transport and Storage



GEN 2.00 Reagent use and storage: adheres to policies and principles regarding the use and storage of laboratory reagents and supplies.

GEN 3.00 Equipment use: adheres to policies and principles regarding the use, maintenance, and calibration of laboratory equipment.

GEN 7.00 Regulatory compliance: complies with regulations and guidelines governing laboratory testing

Informatics (INF) domain

INF 7.00 Media, reagents, and controls: manages the manufacturing and inventory of media, reagents, and controls electronically.

Terms used in traceability

- **Calibration** - The comparison of two measurement devices or systems, one of known uncertainty (your standard) and one of unknown uncertainty (your test equipment).
- **Certified Reference Material (CRM)** - Reference material that has documentation by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities.
- **NIST** - National Institute of Standards and Technology.
- **Reference Standard** - A standard, generally having the highest metrological quality available at a given location in a given organization, from which measurements are made or derived. Note: Generally, this refers to recognized national or international traceable standards provided by a standards producing body such as NIST.
- **Reference Material** - A material, sufficiently homogenous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process or in examination of nominal properties.
- **Traceability** - The property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.
- **Traceability to the International System of Units (SI)** - Metrological traceability to a measurement unit of the International System of Units.



Reference Standards vs. Reference Materials

- **Reference Standards:**
 - o Hard and non-consumable items
 - o NIST traceable thermometers
 - o Weights
 - o These items should be used for calibration only to maintain accuracy and integrity
 - o They should be calibrated by an ISO/IEC 17025 accredited body that can provide traceability
- **Reference Materials:**
 - o Consumables
 - o Liquid standards
 - o Proficiency testing materials
 - o If they cannot be traced to SI units, then they should be provided by a competent supplier to give a reliable physical or chemical characteristic of a material (e.g., PTs)

Test equipment calibration is not traceable to the National Institute of Standards and Technology (NIST), but to the SI through NIST: <http://www.nist.gov/index.html>

*Only measurement
results can be
traceable*

