

Guidance Document for Ensuring Traceability of Measurements

Webster Definition:

Traceability is the ability to verify the history, location, or application of an item by means of documented recorded identification. Other common definitions include the capability of keeping track of a given set or type of information to a given degree, or the ability to chronologically interrelate uniquely identifiable entities in a way that is verifiable.

National Institute of Standards and Technologies (NIST) Definition:

To achieve traceability of measurement results to standards maintained by NIST, you need to reference your measurement results through an unbroken chain of calibrations, including determining the uncertainties at each step, to NIST standards as the specified references. These references may be, for example, standards developed and maintained by NIST: NIST Standard Reference Materials (SRMs), or NIST-Traceable Reference Materials (NTRMs). The chain of calibrations may be short, if the user has instruments or artifacts calibrated by NIST or acquires standards from NIST and references measurement results to those. It may be longer, if the user references other calibrations in a chain of calibrations back to stated references developed and maintained by NIST.

The NELAC Institute

Traceability: The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.

FAQs:

Why does a laboratory have to describe and achieve traceability of measurement?

If the measurement is not traceable or if it is missing one of the components of technical validity, then the numbers could be grossly wrong – without anyone knowing they are wrong because the instruments that provided the measurement have been out of calibration for some time and no one knows they are giving erroneous readings. That is what traceability ensures concerning a calibration. No environmental policy or environmental enforcement action will stand up to judicial scrutiny if it is not supported by traceable measurements and the national metrology infrastructure of the United States of America.

Traceability ensures the legal defensibility of the laboratory's data. DEQ accredited laboratories are required to achieve measurement of traceability per the following citations: Oklahoma Administrative Code (OAC) 252:301-9-4, 252:302 -9-4, 252:307-9-60. Laboratories must describe traceability of measurement in the Quality Assurance Manual. By doing so, it will aid the analyst in troubleshooting an instrument where quality control samples have failed. Accurate traceability also provides the analyst with the capability of investigating failed proficiency testing (PT) results which could further help identify whether the samples were prepared correctly. Being able to identify distinctive patterns in trending QC data is another positive benefit of accurate traceability

How is traceability assessed?

Traceability can be assessed throughout the analysis process by interviewing the analyst, accurate documentation of equipment, certified reference standards and reference materials. Training records are also examined for personnel that are performing internal calibrations and analyses to ensure that they are well trained and capable of performing the procedure.

How does a laboratory develop and implement such policy?

A laboratory can develop and implement such a policy by making sure to document the calibration (all chemicals and reagents utilized within the calibration) and the use of all reference and support equipment. Examples of equipment can include but is not limited to thermometers, weights, balances, autoclaves, mechanical pipettes, and bottle-top dispensers traceable to a National Standard of Measurement. Where commercially available, chemicals shall reference National Standard of Measurement such as NIST.

The following procedures are common approaches used to successfully establish this aspect of traceability:

- Assign a unique identifier and expiration date to each of the prepared reagents and standards. The laboratory should ensure that all standards are included in this process.
 - Calibration standards (including Continuing Calibration Verification (CCV) and second source standards (Initial Calibration Verification (ICV))
 - Spiking standards (Matrix Spike (MS), Surrogate, Internal)
 - Quality control standards (QCS) / laboratory control standards (LCS)
 - Stock standards
 - Intermediate or working standards
 - Instrument performance check (IPC) solutions.
 - The unique identifier and expiration date are recorded in the preparation records as well as on reagent and standard containers.

- **Weight records:**

Laboratory balance verifications must use class 1 weights which are considered as reference weights. This process provides the evaluation of measurement of the instrument. Class 1 weights are considered reference standards and must be calibrated every five years against SI units. Laboratories must provide a link between the class 1 weights and balances in order to make reliable environmental measurements..

- **Thermometer records:**

Accuracy refers to the uncertainty of the measurement relative to the unit (e.g., °C) through the maintenance and documentation of traceability.

A NIST "traceable" thermometer is any thermometer that maintains metrological traceability to the SI through NIST. The NIST "traceable" thermometer can be used to calibrate other thermometers regardless of the type (e.g., platinum resistance, thermocouple, thermistor, analog) as long as the results shows accuracy and precision.

Thermometers used for daily temperature readings (of incubators, ovens, etc...) are considered support equipment and require annual calibration.

The laboratory must be able to provide a documented link between the support equipment used and the NIST traceable thermometer which shows the measurement uncertainty.

- **Mechanical volumetric dispensing device records:**

When quantitative results are dependent on the equipment accuracy, the laboratory may benefit by demonstrating traceability to each mechanical volumetric dispensing device used. Mechanical volumetric dispensing devices such as non-Class A burettes, mechanical pipets, and bottle-top dispensers shall be checked for accuracy on at least a quarterly use basis. Glass microliter syringes are to be considered in the same manner as Class A glassware, but shall come with a certificate attesting to established accuracy or the accuracy shall be initially demonstrated and documented by the laboratory. One approach to managing this aspect of traceability is by recording on the bench sheet the serial number or other assigned identification number of the dispensing device.

- **Analytical instruments**

Analytical records must uniquely identify the instrument determinative parts. Traceability of analytical instrumentation is such an integral part of the analysis, that the maintenance and replacement of instruments such as pH meters, dissolved oxygen meter electrodes, probes, discrete analyzers, spectrophotometers, ICPs, etc. must be documented.

- **Instrument Calibration**
 - All reagents and standards utilized in instrument calibrations must be documented and traceable to a National Standard of Measurement (such as NIST).
 - Documentation must include but is not limited to the following information:

- Manufacturer/Vendor
 - Certificate of analysis (if available)
 - Date of receipt,
 - Date of put into use
 - Date of disposal
 - Expiration dates
 - Lot #'s
 - Time and date of calibration
 - Slope (if applicable)
 - Temperature (if applicable)
 - Calculations, spike amounts, etc.
- **Purchased standards, reagents, and consumables** such as pH buffers and sample bottles must have documentation for receipt and use. A laboratory purchasing policy may reference or utilize a purchasing department, but usually, the laboratory must be specific in purchase specifications that require the purchase of standards, reagents, and consumables that are traceable to a national standard of measurement (such as NIST).
 - **Common approaches used to help successfully establish this traceability aspect:**
 - Keep certificates of analysis (if available).
 - The laboratory may request the certificate of analysis when ordering, or go to the company's website and download the current certificate of analysis.
 - Retain records for all standards, reagents, reference materials, and media include the following information:
 - Manufacturer/ vendor
 - Certificate of analysis (if available)
 - Date of receipt
 - Recommended storage conditions
 - Expiration date
 - Media only, records must also contain lot number, type and amount of media received, and the pH of the media.
 - Assign a unique identifier to each reagent and standard received. This unique identifier is recorded in the receipt records as well as on the container. If more than one container of the same lot is received, a letter can be added to the end of the unique identifier to distinguish each container.
 - Establish documentation that facilitates historical reconstruction and identification of the purchased standards and reagents used for each analysis. A unique identifier can be recorded on the laboratory's bench sheets or sample preparation logs, providing a link to the preparation information so that a data reviewer can trace back to the origin of stock chemicals. An alternative to listing individual unique identifiers on bench sheets is to note in the reagent log "Date In Use" and "Date Out of Use."
 - Maintain records that show supply, reagent, and consumable purchases are checked upon receipt to ensure that they comply with standard or method specifications. In other words, verify that you received what you actually ordered and that you ordered the correct product. This verification may be documented on the packing slip which is kept on file, or in some other manner. Maintain records of all sample preparation including but not limited to cleanup, digestion, incubation (times in and out), sample volumes or weights used, instrument printouts, meter readings, and calculations.

Lastly, summarize the laboratory's traceability procedures within the Quality Assurance Manual. If traceability procedures are described in individual standard operating procedures, this quality manual requirement can be met with a brief summary referencing the associated documents. This unique identifier approach can be recorded on the

laboratory's bench sheets or sample preparation logs, providing a link to the preparation information so that a data reviewer can trace back to the origin of stock chemicals.

Notes:

Traceability may be accomplished using other approaches other than what is described here. Also unique identifiers may be assigned using other documented approaches.