



QMS Quick Learning Activity

Traceability

Objectives

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

- Define the terms calibration, certified reference material, and traceability 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 requirements



Terms and Acronyms

- **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
- **CGPM** - Conférence Générale des Poids et Mesures (French: General Conference on Weights and Measures)
- **CIPM** - Comité International des Poids et Mesures (International Committee of Weights and Measures)
- **ISO 17034** - General Requirements for the Competence of Reference Material Producers



Terms and Acronyms

- **NIST** - National Institute of Standards and Technology
- **PT** – Proficiency Test
- **QC** - Quality Control
- **QMS** - Quality Management System
- **Reference Standard** - Substance or item prepared for use as a standard in an assay, identification, or purity test.
- **SI** - International System of Units



What is Traceability?

- Traceability is 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 SI means metrological traceability to a measurement unit of the SI.
- Only measurement results can be traceable.



What do I Need to Support a Claim of Traceability?

*Document the measurement process or system used and provide a chain of calibrations used to establish connection to the reference.

Common elements include:

- a clearly defined quantity that has been measured (e.g. weight, volume, temperature)
- a complete description of the measurement system or working standard used to perform the measurement (What is the measurement based on or compared to: Did you use a CRM, a NIST-traceable thermometer; a calibrated pipette?)
- a stated measurement result, which includes a documented uncertainty. When items have been calibrated or manufactured to certain accredited bodies, they should include an uncertainty measurement.

*From NIST website FAQ I.A.5:

<https://www.nist.gov/traceability/supplementary-materials-nist-policy-review>



QMS Quick Learning Activity

Metrology Systems

ISO/IEC
17025:2017

- Requires laboratories to have calibration systems in place that ensure that their measurements (results) are comparable with any other laboratory.

ISO 17034

- Specifies general requirements for the competence and consistent operation of reference material producers.
- Sets out the requirements in accordance with which reference materials are produced. It is intended to be used as part of the general quality assurance procedures of the reference material producer.
- Covers the production of all reference materials, including certified reference materials. <https://www.iso.org/standard/29357.html>

NIST

- The NIST provides technology, measurement, and standards for the United States.



NIST and traceability



- Test equipment calibration is not traceable to the NIST, but rather to the SI through NIST
- Requires the establishment of an unbroken chain of calibrations to specified references.
- Responsible for developing, maintaining and disseminating national standards - realizations of the SI - for the basic measurement quantities, and for many derived measurement quantities.
- Responsible for assessing the measurement uncertainties associated with the values assigned to these measurement standards.



What does it Mean to be “Traceable to SI”?

- Reference measurement results can be traced through an unbroken chain of calibrations, including determining the uncertainties at each step, to SI units.
- There are seven base units in the SI system:
 - Mass - kilogram (kg)
 - Time - second (s)
 - Temperature - kelvin (K)
 - Electric current - ampere (A)
 - The amount of a substance, mole (mol)
 - Luminous intensity - candela (cd)
 - Length - meter (m)
- The SI is explained more in the following brochure (2019):
<https://www.bipm.org/utils/common/pdf/si-brochure/SI-Brochure-9.pdf>



Use of Reference Material to be Traceable to the SI

- Reference materials are materials or substances, one or more of whose property values are sufficiently homogeneous and well established to be fit for its intended use in measurement or in examination of nominal properties.
- Use CRMs when possible
 - Reference material that has documentation by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities.
- NIST produces reference materials traceable to SI units that can be purchased for use in laboratories to maintain traceability.
 - NIST Standard Reference Materials (SRMs)
 - NIST-Traceable Reference Materials (NTRMs)



Reference Standards vs. Materials

- Reference Standards
 - Non-consumable items
 - NIST traceable thermometers
 - Weights
 - These items should be used for calibration only to maintain accuracy and integrity
 - They should be calibrated by an ISO/IEC 17025 accredited entity that can provide traceability



- Reference Materials
 - Consumables
 - Liquid standards
 - PT materials
 - If they cannot be traced to SI units (CRM), then they should be provided by a competent supplier to give a reliable physical or chemical characteristic of a material (e.g., PT material, other provider)



What is Calibration?

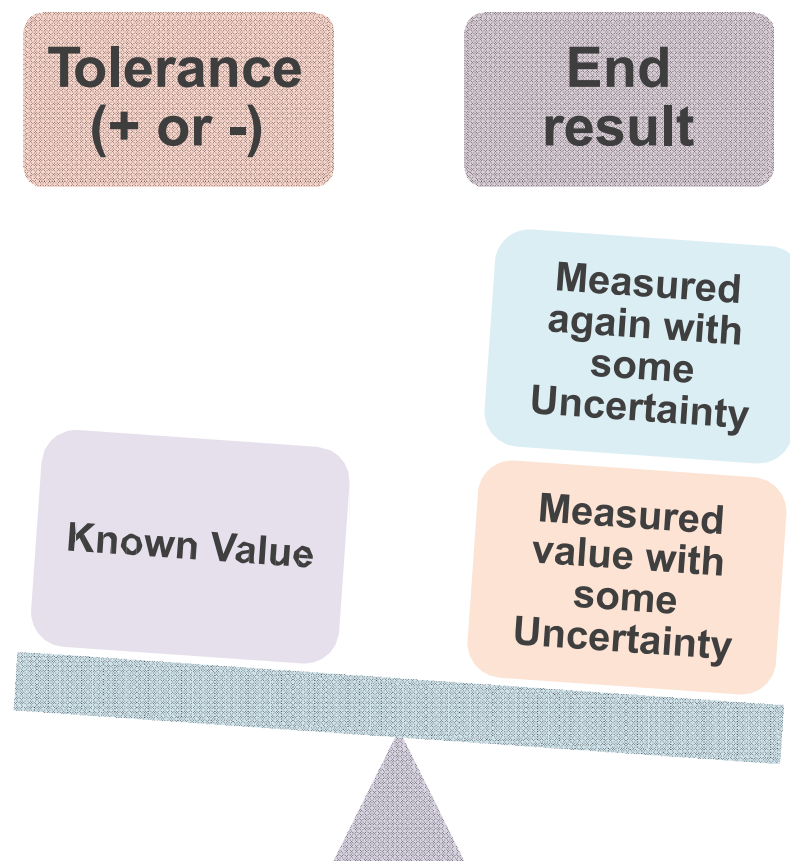
Calibration is the comparison of a measurement device or system under test with one of known uncertainty (limits which contain the true value at specified confidence limits).



What is Calibration?

Calibration is a process in which a physical measurement or physical response is compared to a known standard

- What is my answer, plus or minus my error, in relation to the known value, plus or minus established tolerance?
- How much error can by customer tolerate?



Calibration Laboratories

- Establish traceability of its own measurement standards and measuring instruments to SI units (e.g., NIST, CIPM, CGPM)
- Issue calibration certificates that contain the measurement results, including the measurement uncertainty
- Use vendors that have been accredited to ISO 17034- check certificate!

TRACEABLE®

ISO 17034 pH Certified
Reference Materials



QMS Quick Learning Activity

Traceability Includes Specific Requirements for

Calibration & QC Materials



Testing



Reagents, Media, Cultures



Critical & Support Equipment



Reference Standards



Reference Materials



Intermediate Checks



Chemicals

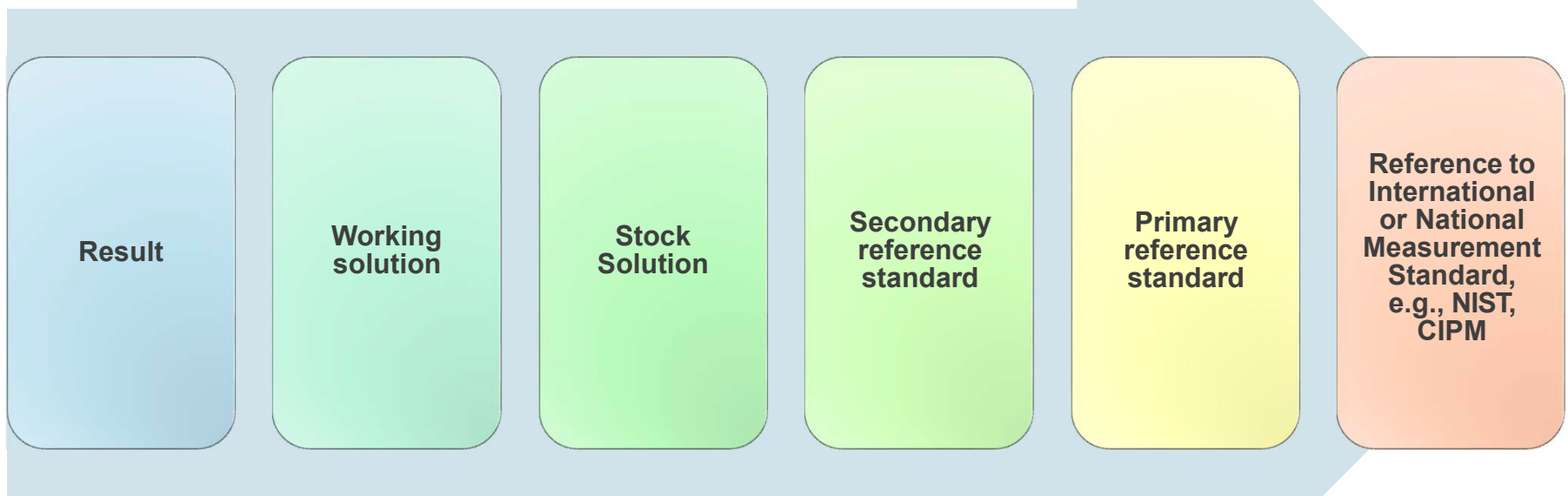


Transport



What is Traceability? A Calibration Hierarchy

For example: 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)



Reexamine traceability periodically

There should be defined *procedures and schedules* for carrying out regular checks needed to maintain confidence in the calibration status of:



The Calibration Traceability Pyramid



Testing Laboratories

Traceability applies to measuring and test equipment unless you can prove that it is a minor component of measuring uncertainty. In this case, you must provide the uncertainty of the instrument.



Testing Laboratories

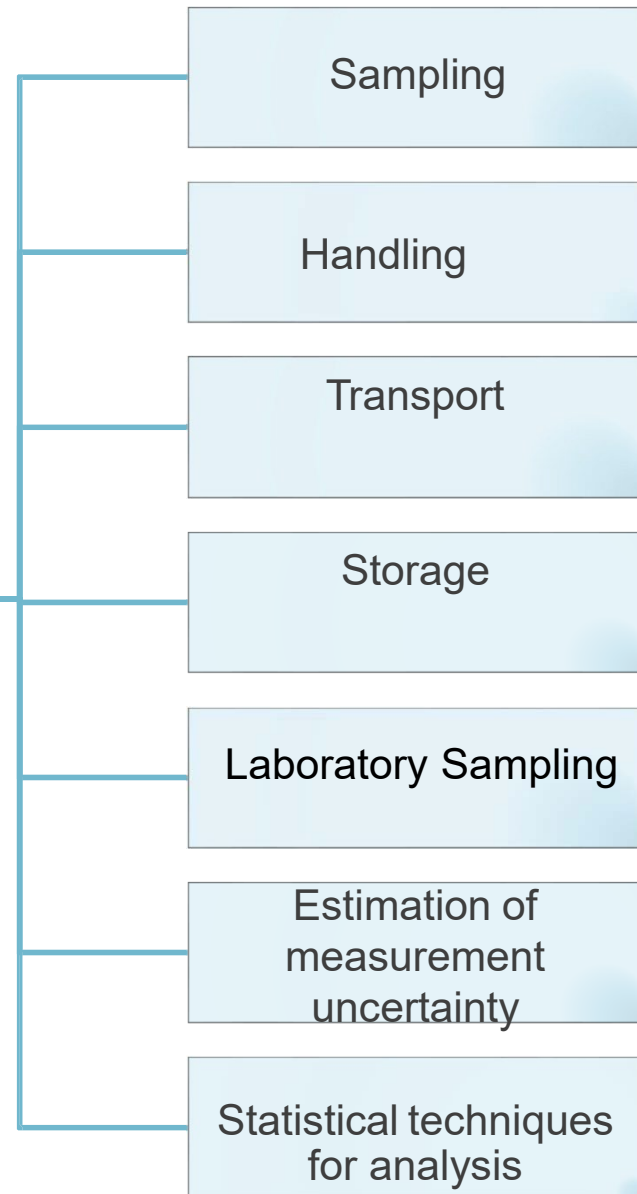
Where traceability to SI units is not possible or relevant, the laboratory should

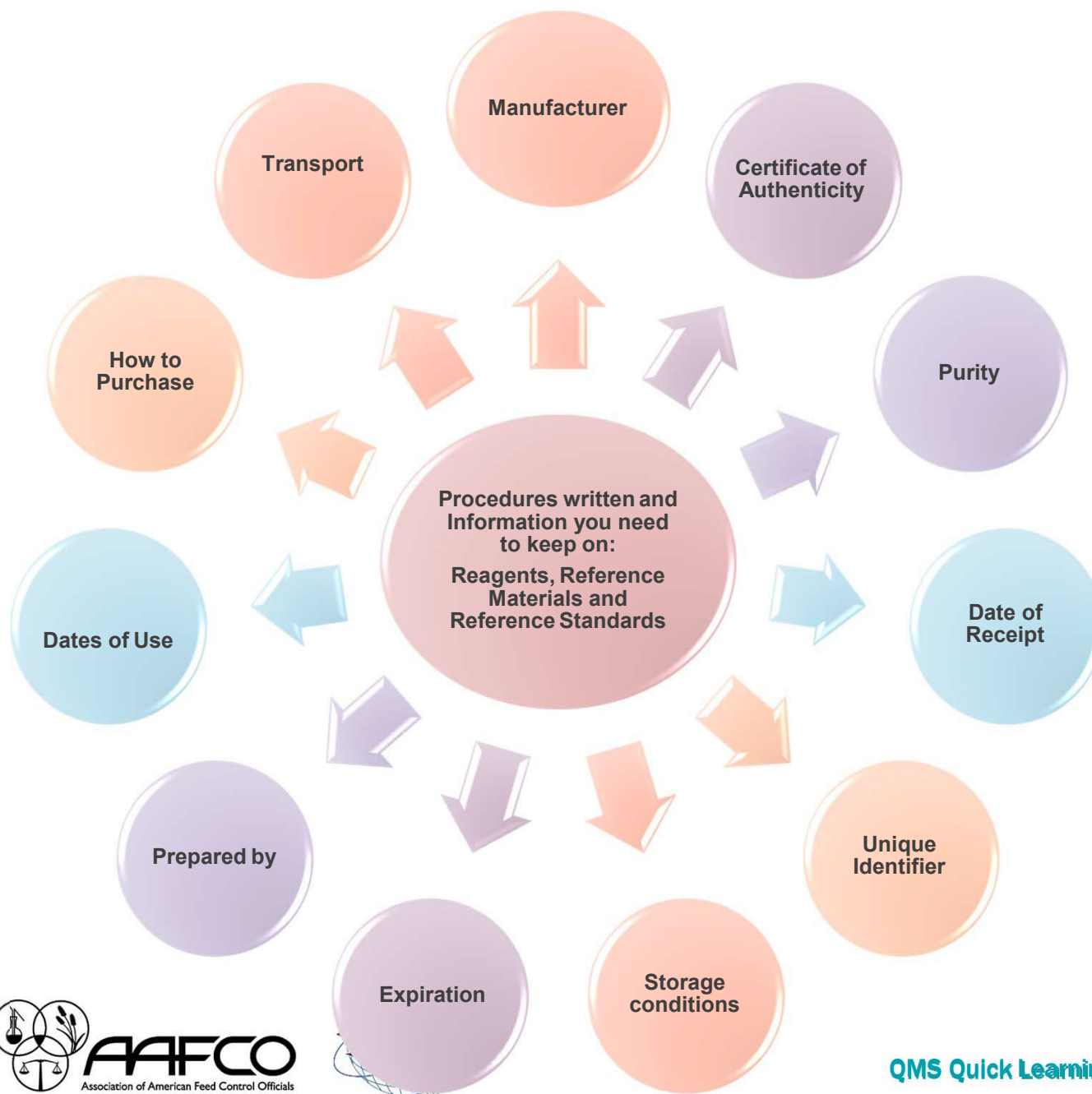
- Use reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material
- Use specified methods and/or consensus standards that are clearly described and agreed by all parties concerned



Methods

ISO17025:2017 7.2.1:
The laboratory shall use appropriate methods that meet the needs of the customer and are appropriate for tests and use procedures for all tests that should include these items:





Key Questions to Ask in the Laboratory

- Has the laboratory identified all the measuring equipment that would affect the validity of measurements?
- Has the equipment been properly calibrated in a manner that provides traceability to the SI?
- Does the QMS address that calibration is maintained and monitored? Is drift detected?
- Does the laboratory keep records of the calibration status of the equipment? Would an auditor be able to trace the calibration status to any point in the past?
- Are all reagents traceable to a CRM or reference material from other acceptable source (such as a consensus standard)?



Key Questions to Ask in the Laboratory

- Is the laboratory able to trace temperature calibrations to the SI unit?
 - If used, did the reference thermometer come with a calibration certificate issued by an accredited calibration laboratory? Is it being used within the expiration date of the certificate?
- Does the laboratory have a written procedure and training program for carrying out calibration of working thermometers with adequate applied quality controls?
- Are there records that show an auditor that these criteria are met on a routine basis?



Summary

Traceability is an unbroken record of documentation of measurement that can be related to stated references

- Tracing reagents back to their source (CRM)
- Equipment used (pipettes, thermometers, balances)
 - Including their associated uncertainties



References

- ISO/IEC 17025:2017 - <https://www.iso.org/standard/66912.html>
- NIST-<http://www.nist.gov/>
- NIST Mercury Thermometer Alternatives: What Is Traceability?-
http://www.nist.gov/pml/mercury_traceability.cfm
- ISO 17034- <https://www.iso.org/standard/29357.html>
- Supplementary Materials related to NIST Policy on
Metrological Traceability
http://members.aoac.org/aoac_prod_imis/Programs/RMG_files/Page322.htm
- BIPM: The International System of Units
<https://www.bipm.org/utis/common/pdf/si-brochure/SI-Brochure-9.pdf>

