



QMS Quick Learning Activity

Traceability

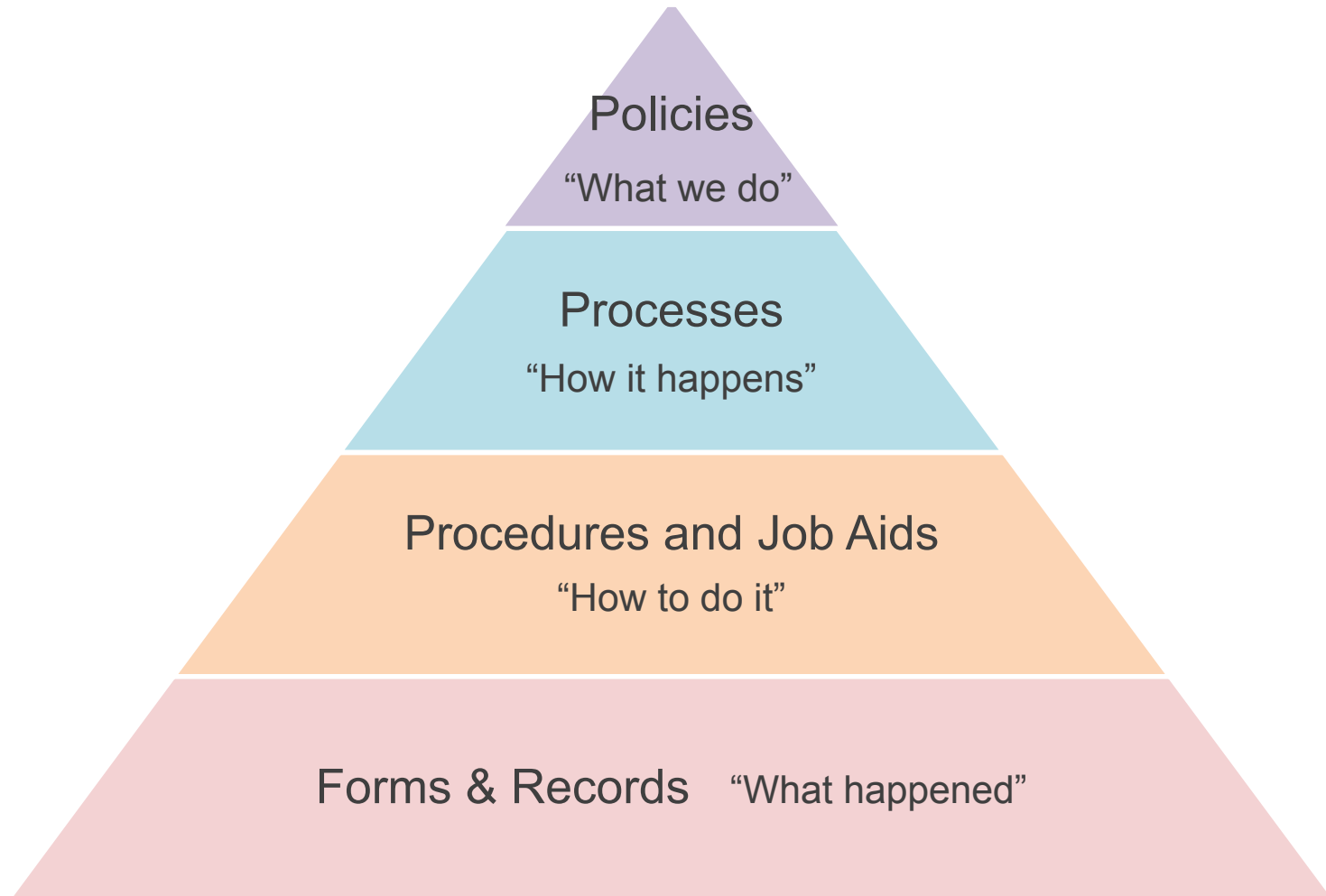
Objectives

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

- Define the terms calibration, certified reference material and 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 requirements



Some Distinctions



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 Guide 34** - General Requirements for the competence of reference material producers



Terms and Acronyms

- **NIST** - National Institute of Standards and Technology
- **PT** – Proficiency Test
- **QASP** - Quality Assurance Standard Procedure
- **QC** - Quality Control
- **QMS** - Quality Management System
- **Reference Standard** - Hard and not consumable items, such as weights and thermometers, used for calibration measurements that can be traced to a standard unit of the SI (International System of Units)
- **SI** - International System of Units
- **SOP** - Standard Operating Procedure



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 (International System of Units) - metrological traceability to a measurement unit of the International System of Units
- 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 particular quantity that has been measured (e.g. weight, volume, temperature, etc.)
- 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>



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Metrology Systems

ISO/IEC
17025:2005

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

ISO Guide
34

- “Specifies general requirements in accordance with which a reference material producer has to demonstrate that it operates, if it is to be recognized as competent to carry out the production of reference materials.”

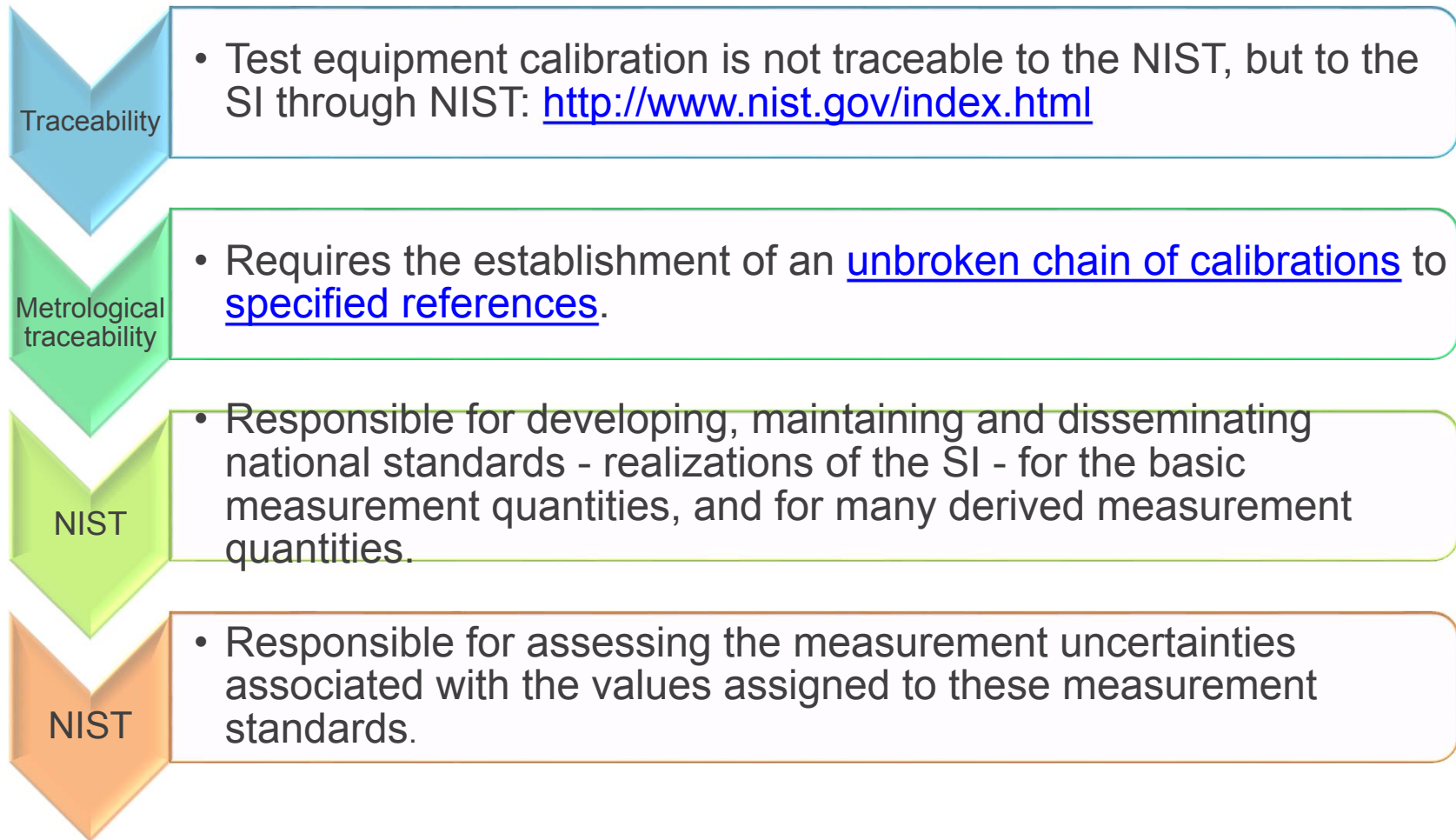
http://www.iso.org/iso/catalogue_detail.htm?csnumber=50174

NIST

- The National Institute of Standards and Technology (NIST) was established as the National Metrology Institute (NMI) for the US by Congress in 1901.



NIST and traceability



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

- Reference measurement results can be traced 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:
 - broadcast signals controlled or monitored by NIST (such as standard time and frequency signals)-used to measure timers, for example,
 - 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.



Reference Standards vs. Materials

- Reference Standards

- Hard and 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 body that can provide traceability



- Reference Materials

- Consumables
 - Liquid standards
 - Proficiency testing materials
- 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, CRMs)



QMS Quick Learning Activity

What is Calibration?

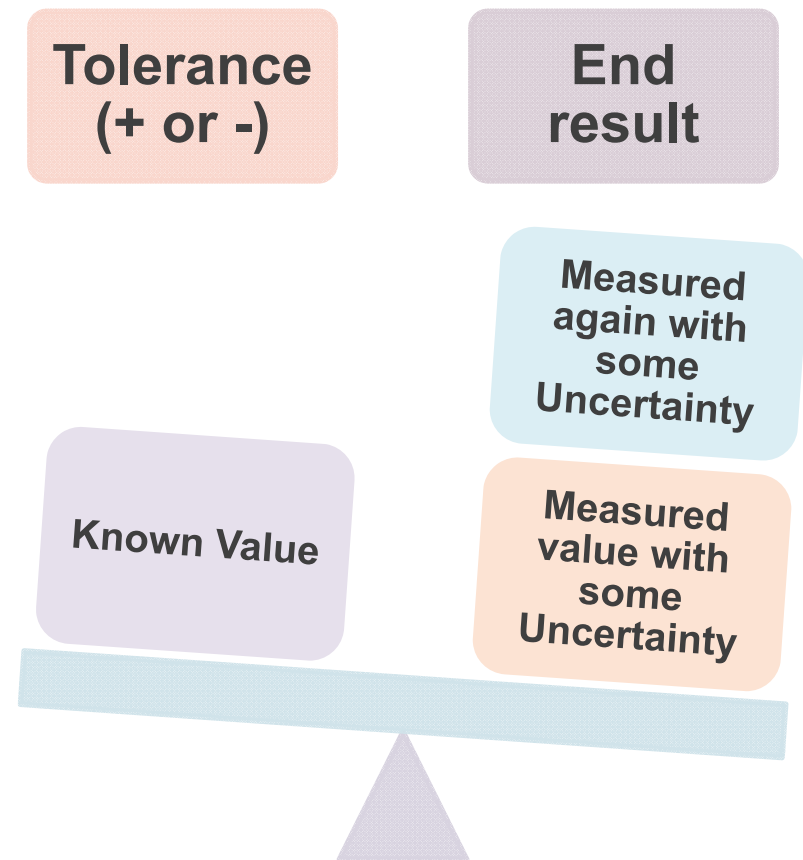
Calibration is the comparison of two measurement devices or systems, one of known uncertainty (reference standard) and one of unknown uncertainty (test equipment)



What is Calibration?

A response to a known value which establishes a relationship between the known value and an indicator and established tolerance

- I have the result, I know what it should be
- What is my answer in relation to the known value and how much can difference I (and my customer) can tolerate?



Calibration Laboratories

- Establish traceability of its own measurement standards and measuring instruments to the International System of Units (SI) (e.g., NIST, CIPM, CGPM)
- Issue calibration certificates that shall contain the measurement results, including the measurement uncertainty
- Use vendors that have been accredited to ISO Guide 34



INORGANIC VENTURES™

300 Technology Drive
Christiansburg, VA 24073 - USA
info@inorganicventures.com

CERTIFICATE OF ANALYSIS

tel: 800.669.6799 - 540.585.3030
fax: 540.585.3012
info@inorganicventures.com

1.0 INORGANIC VENTURES is an ISO Guide 34 "General Requirements for the Competence of Reference Material Producers" and ISO 9001:2000 registered manufacturer. Our manufacturing laboratory is accredited to ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories."




2.0 DESCRIPTION OF CRM 1000 µg/mL Aluminum in 3% (v/v) HNO3

Catalog Number:	CGAL1-1, CGAL1-2, and CGAL1-5
Lot Number:	C2-AL04078
Starting Material:	Al ingot
Starting Material Purity (%):	99.998788
Starting Material Lot No:	C14S012
Matrix:	3% (v/v) HNO3

3.0 CERTIFIED VALUES AND UNCERTAINTIES

Certified Concentration:	1003 ± 5 µg/mL
Certified Density:	1.017 g/mL (measured at 22° C)

The following equations are used in the calculation of the certified value and the uncertainty. Reported uncertainties represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage factor of k = 2.

$$\text{Certified Value } (\bar{x}) = \frac{\sum x_i}{n}$$

$$\text{Uncertainty } (\pm) = \frac{2(\sum s_i^2 / n)^{1/2}}{(n)^{1/2}}$$

($\bar{x}$) = mean
 x_i = individual results
 n = number of measurements
 $\sum s_i^2$ = The summation of all significant estimated errors
 (Most common are the errors from instrumental measurement, weighing, dilution to volume, and the fixed error reported on the NIST SRM certificate of analysis.)

4.0 TRACEABILITY TO NIST AND VALUES OBTAINED BY INDEPENDENT METHODS

- Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties." (ISO VIM, 2nd ed., 1993, definition 6.10)
- This product is Traceable to NIST via an unbroken chain of comparisons. The uncertainties for each certified value are reported, taking into account the SRM uncertainty error and the measurement, weighing and volume dilution errors. In rare cases where no NIST SRMs are available, the term "in-house std." is specified.

4.1	Assay Method #1	1003 ± 5 µg/mL
	ICP Assay NIST SRM 3101a	Lot Number: 060502
	Assay Method #2	1002 ± 8 µg/mL
	EDTA NIST SRM 528	Lot Number: 528



Traceability Includes Specific Requirements for

Calibration & QC Materials



Testing



Reagents, Media, Cultures



Critical & Support Equipment



Reference Standards



Reference Materials



Intermediate Checks



Chemicals

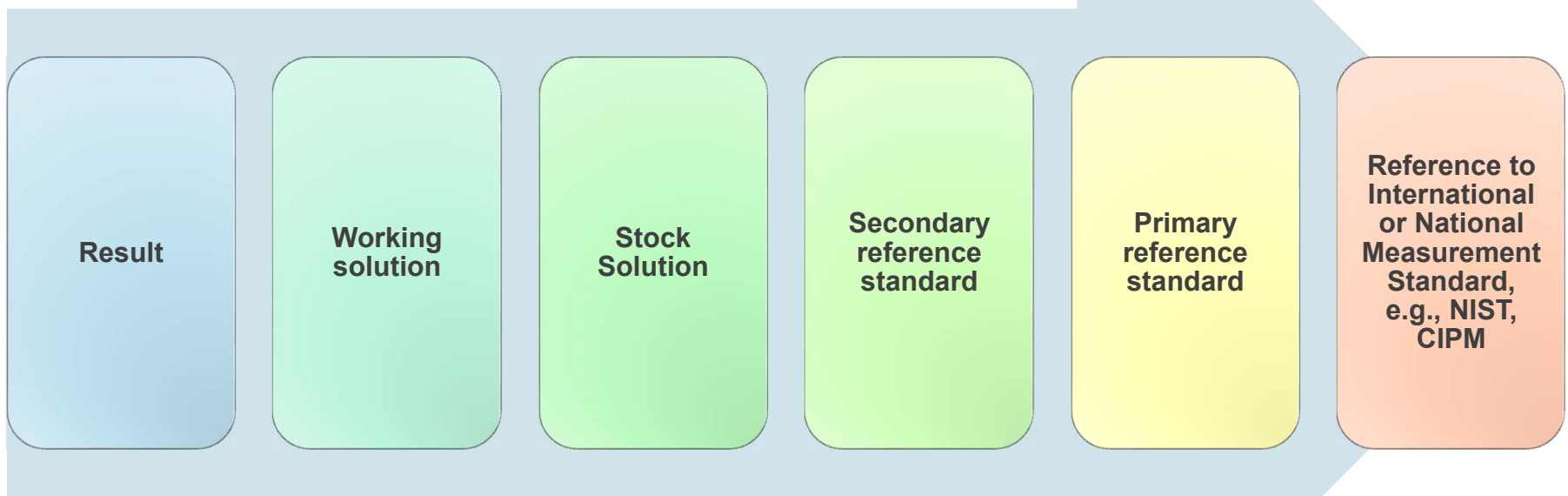


Transport



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)



Intermediate Checks

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

Reference standards

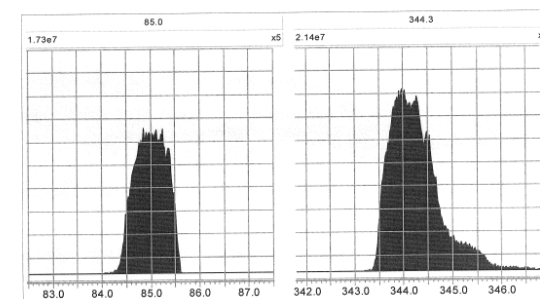
Primary standards

Working standards

Transfer standards

Reference materials

Quattro Micro Tune Parameters MassLynx 4.0 SCN509 Page 1 of 1
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 Printed: Wednesday, April 17, 2013 16:01:38 Central Daylight Time



Type	Start Mass	End Mass	Set Mass
Daughter Scan	83	88	344
Parent Scan	342	347	85
Source (ES+)	Settings	Readbacks	
Capillary (kV)	3.20	3.20	
Cone (V)	35.00	37.73	
Extractor (V)	3.00	3.30	
RF Lens (V)	0.0	0.0	
Source Temperature (°C)	120	118	
Desolvation Temperature (°C)	0	307	
Cone Gas Flow (L/Hr)	0	1	
Desolvation Gas Flow (L/Hr)	810	806	
Analyser	Settings	Readbacks	
LM 1 Resolution	14.0		
HM 1 Resolution	14.0		
Ion Energy 1	1.0		
Entrance	-5	-20	
Collision	25	-25	
Exit	1	-26	
LM 2 Resolution	13.5		
HM 2 Resolution	13.5		
Ion Energy 2	1.0		
Multiplier (V)	700	-700	
Syringe Pump Flow (uL/min)	50.0		
Pressure Gauges			
Gas Cell Pirani Pressure(mbar)	4.49e-3		
MUX Configuration			
Probe	Standard		



QMS Quick Learning Activity

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

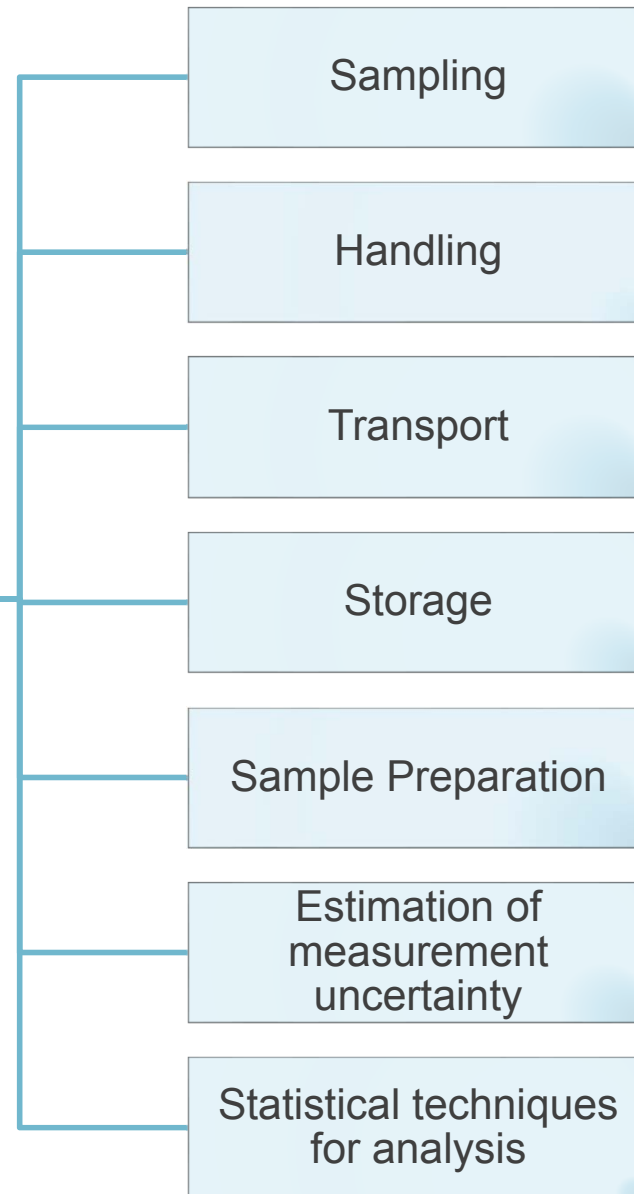
Where traceability to SI units is not possible or relevant, the laboratory should

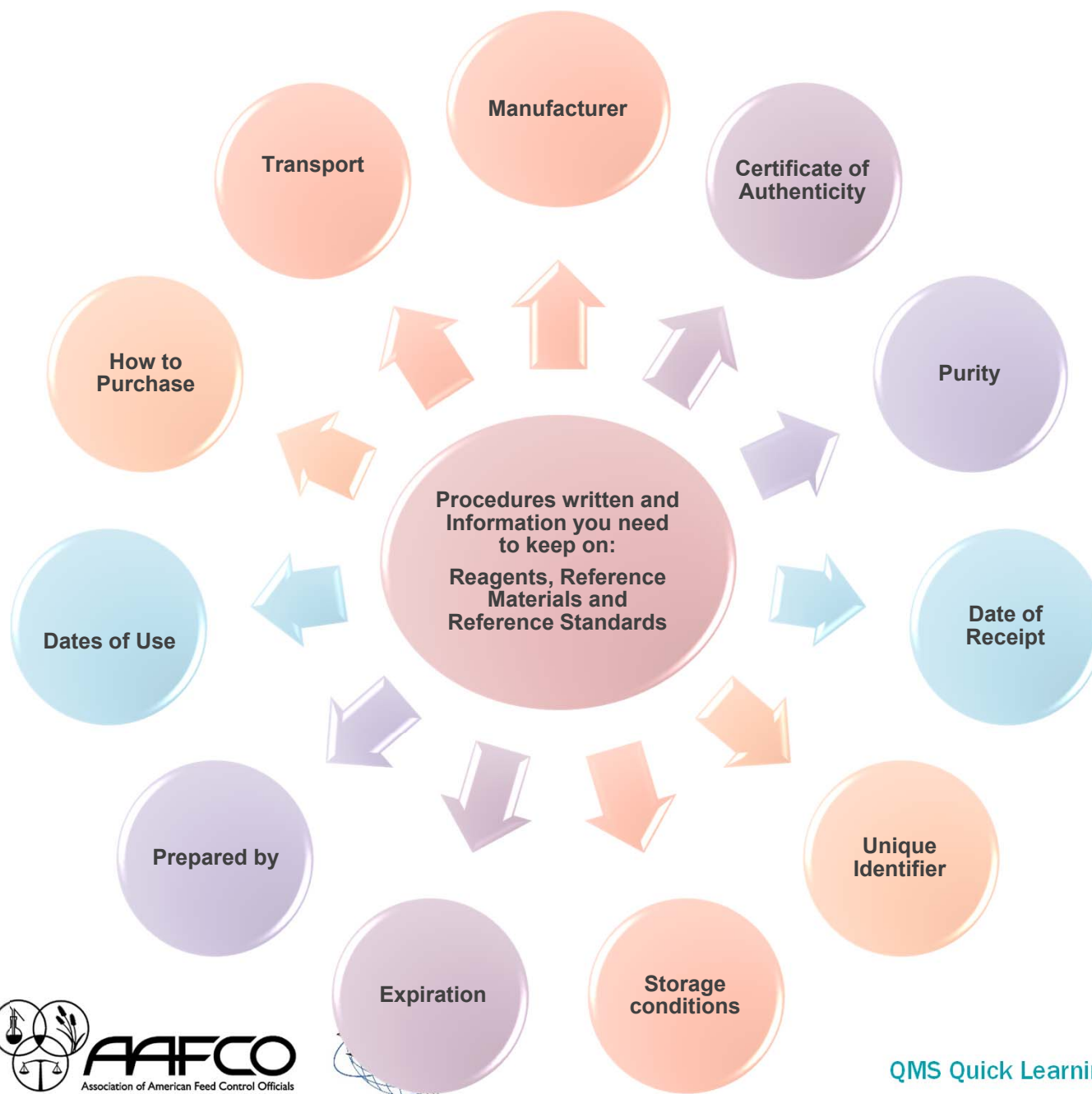
- Use Certified Reference Materials provided by a competent supplier to give a reliable physical or chemical characterization of a material
- Use specified methods and/or consensus standards that are clearly described and agreed by all parties concerned



Methods

5.4.2: 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 it been properly calibrated in a manner that provides traceability to the international measurement system?
- 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 other acceptable source (such as a consensus standard)?



Key Questions to Ask in the Laboratory

- Does the laboratory hold a master reference thermometer?
 - If so, did the thermometer come with a calibration certificate issued by an accredited calibration laboratory? Is it in need of recalibration?
- 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 (stock or CRM)
- Equipment used (pipettes, thermometers, balances)
- Including their associated uncertainties



References

- ISO/IEC 17025-www.iso.org/39883.html
- NIST-<http://www.nist.gov/>
- NIST Mercury Thermometer Alternatives: What Is Traceability?-
http://www.nist.gov/pml/mercury_traceability.cfm
- ISO Guide 34-
http://www.iso.org/iso/catalogue_detail.htm?csnumber=50174 ‘
- Complying with ISO 17025: A Practical Guidebook for meeting the requirements of laboratory accreditation schemes based on ISO 17025:2005 or equivalent national standards by the United Nations Development Organization, Vienna, 2009
https://www.unido.org/fileadmin/user_media/Publications/Pub_free/Complying_with_ISO_17025_A_practical_guidebook.pdf

