GMP 13

Good Measurement Practice for Ensuring Metrological Traceability

1. Introduction

1.1 Purpose

The purpose of this Good Measurement Practice is to enable compliance with essential elements of Metrological Traceability. Traceability ensures that the measurements are accurate representations of the specific quantity subject to measurement, within the uncertainty of the measurement.

To ensure metrological traceability, suitably calibrated standards that are appropriately maintained and cared for, proper standard operating procedures, continuous measurement control, surveillance, and suitable documentation must all be present.

Test numbers issued by NIST should not be used nor required as proof of the adequacy or traceability of a test or measurement. Having a NIST number does not provide evidence that the measurement value provided by another organization has the property of metrological traceability.

1.1.1 **Metrological Traceability** is defined[1] as 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."

NOTE 1: For this definition, a 'reference' can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.

NOTE 2: Metrological traceability requires an established calibration hierarchy.

NOTE 3: Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.

NOTE 4: For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrologically traceable and

1 These definitions are provided in the "International vocabulary of metrology — Basic and general concepts and associated terms (VIM)" JCGM 100:2008.

the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.

NOTE 5: Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

NOTE 6: A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

NOTE 7: The ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (see ILAC P-10:2002).

NOTE 8: The abbreviated term "traceability" is sometimes used to mean 'metrological traceability' as well as other concepts, such as 'sample traceability' or 'document traceability' or 'instrument traceability' or 'material traceability', where the history ("trace") of an item is meant. Therefore, the full term of "metrological traceability" is preferred if there is any risk of confusion.

1.1.2 A **Metrological Traceability Chain** is defined as "traceability chain sequence of measurement standards and calibrations that is used to relate a measurement result to a reference".

NOTE 1: A metrological traceability chain is defined through a calibration hierarchy.

NOTE 2: A metrological traceability chain is used to establish metrological traceability of a measurement result.

NOTE 3: A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement unit .

1.1.3 **Metrological Traceability to a Measurement Unit** is defined as: metrological traceability to a unit metrological traceability where the reference is the definition of a measurement unit through its practical realization

NOTE: The expression "traceability to the SI" means 'metrological traceability to a measurement unit of the International System of Units'. (See section 1.3.3.)

1.2 Prerequisites

Metrological traceability can be characterized by the following seven essential elements:

1.2.1 *Unbroken chain of comparisons.* A documented system of comparisons with each step having the essential elements of metrological traceability going back to a standard acceptable to the parties, usually a national or international standard;

1.2.2 *Documented Measurement Uncertainty.* The measurement uncertainty for each step in the traceability chain must be calculated according to defined methods and must be stated so that an overall uncertainty for the whole chain may be calculated (see SOP 29);

1.2.3 *Documented Measurement Procedure.* Each step in the chain must be performed according to documented and generally acknowledged procedures (see GMP 12) and the results must be documented (i.e., in a calibration report, see SOP 1);

1.2.4 *Accredited Technical Competence.* The laboratories or bodies performing one or more steps in the chain must supply evidence of technical competence (e.g., by maintaining appropriate training records, participating in interlaboratory comparisons, and by demonstrating that they are accredited by a recognized accreditation body);

1.2.5 *Realization of SI Units.* The primary national, international or intrinsic standards must be primary standards for the realization of the International System of Units (SI);

1.2.6 *Documented Calibration Intervals.* Calibrations of standards (and equipment where appropriate) must be repeated at established (may be defined through measurement assurance) and appropriate intervals to preserve metrological traceability of the standard over time and use (see GLP 4, GMP 11); and

1.2.7 *Measurement assurance.* A proper measurement assurance program must be established to ensure the validity of the measurement process and the accuracy of standard used at the time of the measurement (see SOPs 9, 17, 20, 30).

1.3 Responsibility

1.3.1 *Provider.* Providing support for the claim of traceability of the result of a measurement or value of a standard is the responsibility of the calibration provider. Calibration reports and certificates must contain a statement

regarding metrological traceability. See Appedices B and C for a form that may be used to assess evidence supporting metrological traceability.

1.3.2 *User.* Assessing the validity of a claim of traceability is the responsibility of the user of that result or value. Verifying claims of traceability often includes obtaining a calibration directly from a national metrology institute or another laboratory that has achieved recognition or accreditation through a recognized accrediting body.See Appendix D for a form that may be used to assess calibration reports for weights and measures applications.

1.3.3 *Use of, or reference to, official test numbers of a national metrology institute.* Having an authentic test number does not provide assurance or evidence that the measurement value provided by another organization is traceable. Not only must there be an unbroken chain of comparisons, but each measurement must be accompanied by a statement of uncertainty associated with the value. Test report numbers should not be used nor required as proof of the adequacy or traceability of a test or measurement. National and international standards dealing with test and measurement quality requirements, such as ISO 10012, ISO/IEC 17025 and the ISO 9000 series do not require the use or reporting of specific test numbers to establish traceability.

1.4 Safety

No outstanding safety concerns

2. Methodology

2.1 Summary

Traceability is maintained through comparison to appropriate standards with suitable procedures and measurement uncertainties. Procedures are outlined in SOPs and GMPs. Examples of possible hierarchies of the standards leading to the traceability of a calibration are provided in this document.

2.2 Procedure

The charts in this GMP show examples of the traceability hierarchy for mass, length, volume, and temperature measurement disciplines. Each laboratory must define the exact traceability system in their operating quality manual. (A worksheet is included as an Appendix to help in the definition of the traceability system.)

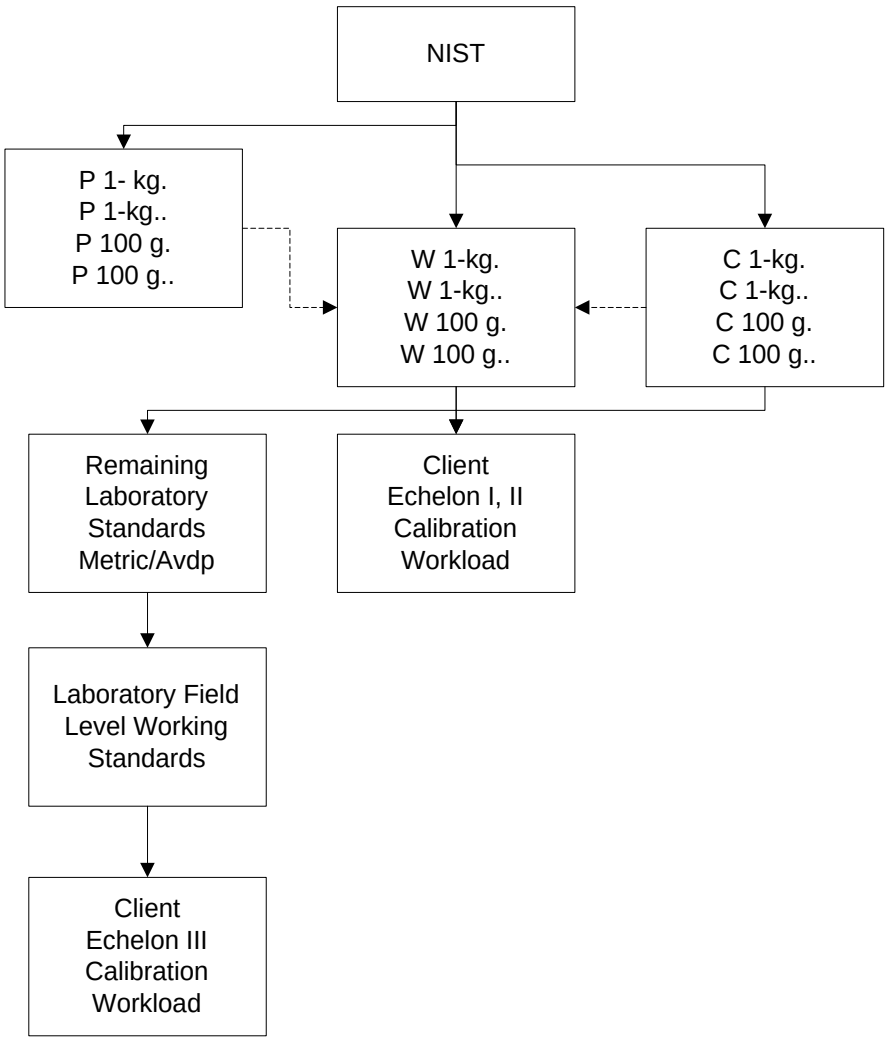
3. Calculations

There are no calculations in this GMP.

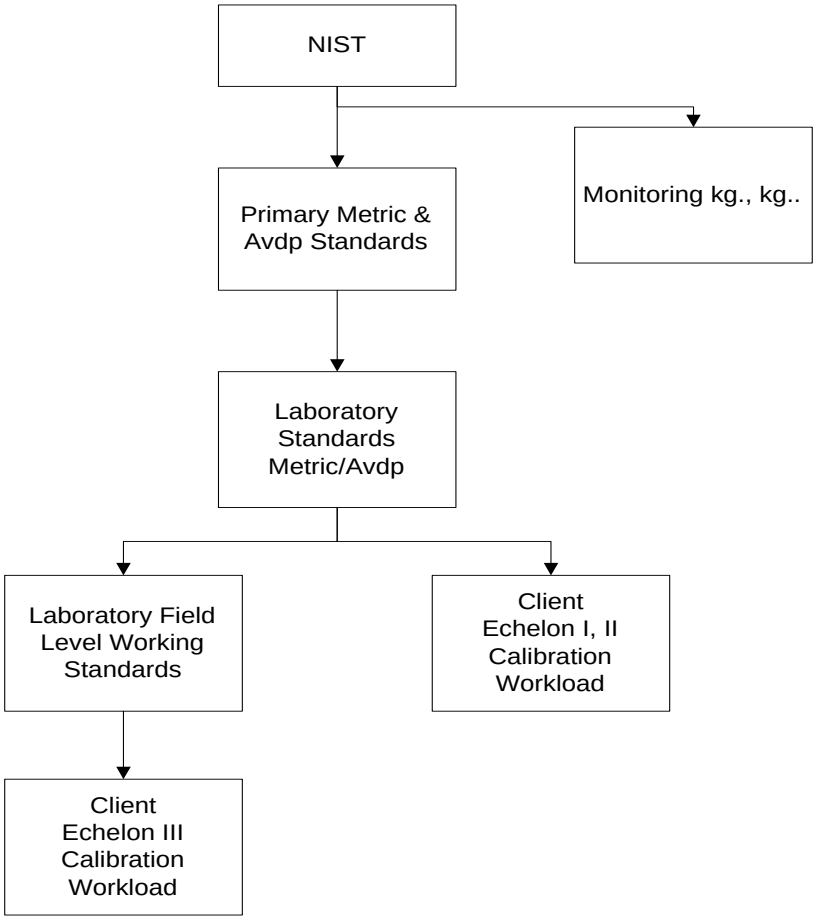
4. Assignment of Uncertainty

The uncertainty associated with reported calibration values is included within the uncertainty analysis for each SOP and in SOP 29, Calculating and Reporting Uncertainties.

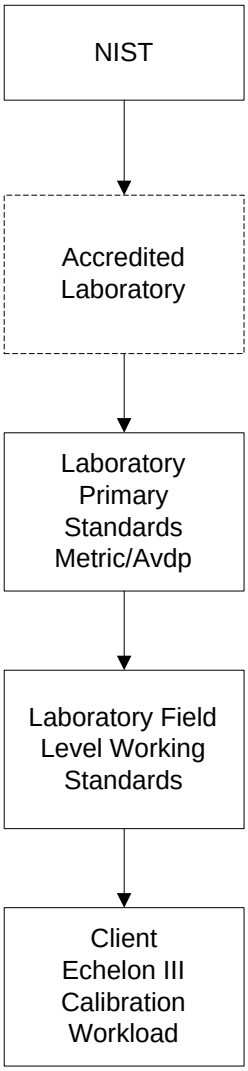
Mass - Example A



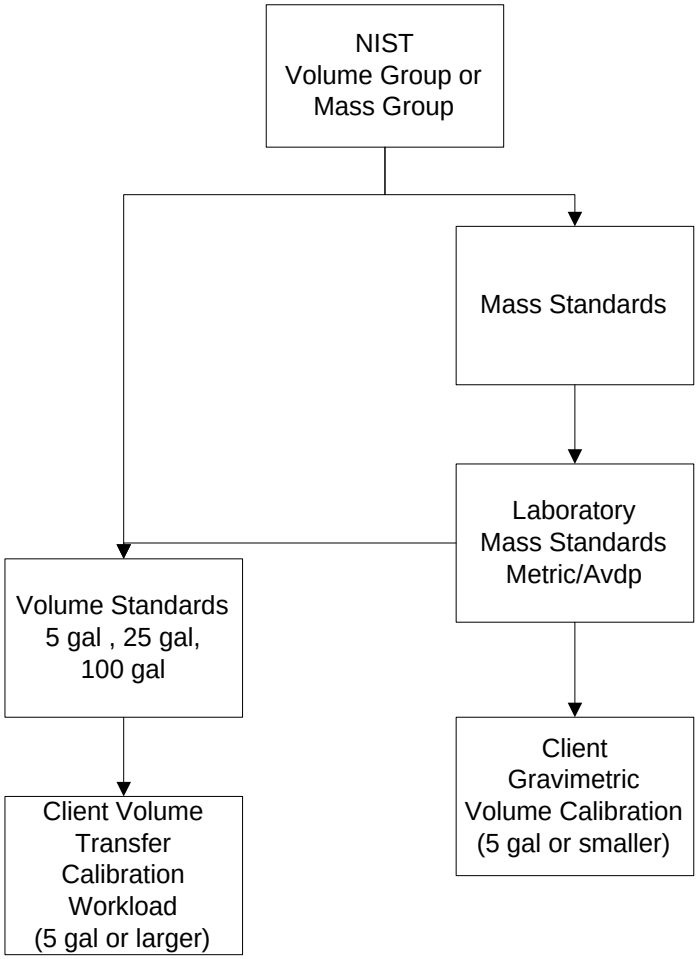
Mass - Example B



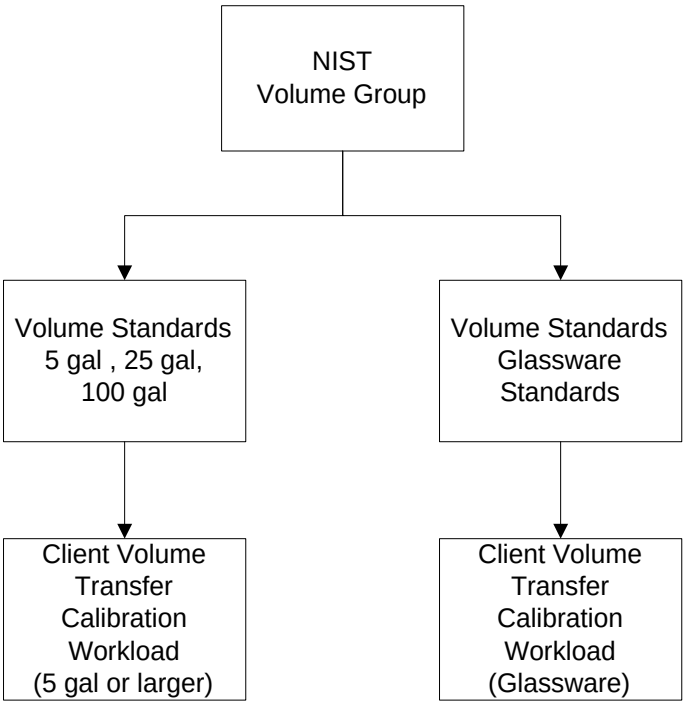
Mass - Example C



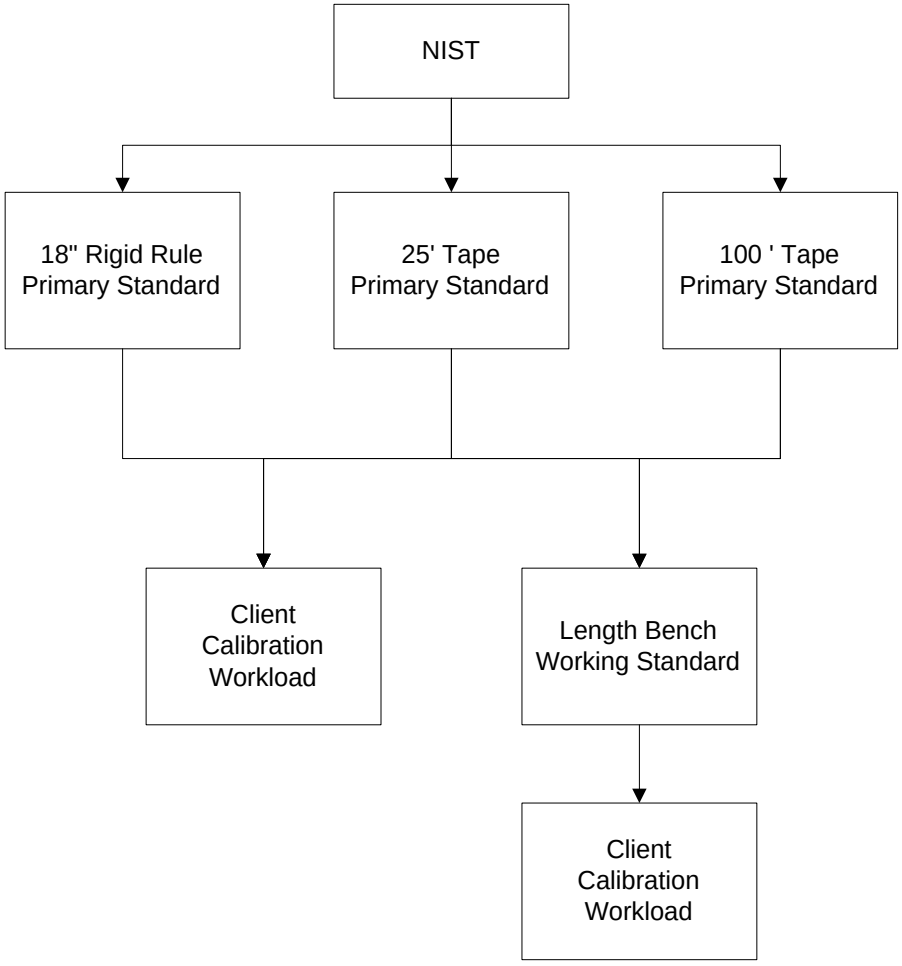
Volume - Example A



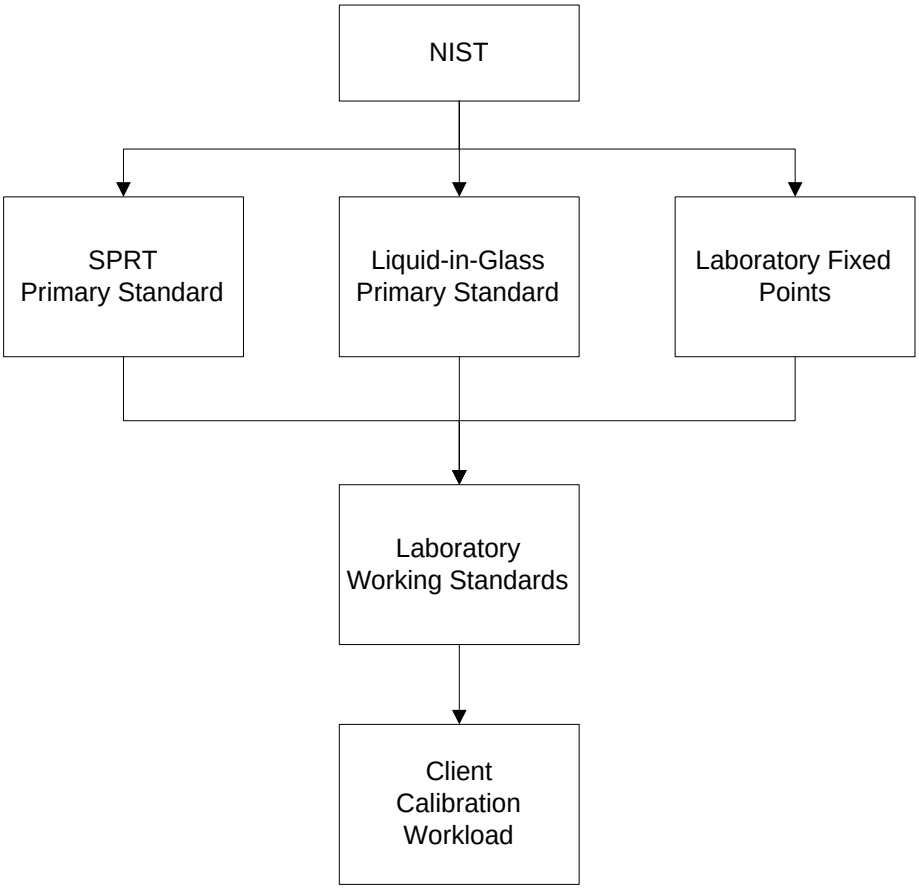
Volume - Example B



Length Example



Temperature Example



Appendix A - Traceability worksheet

Parameter: Mass, Volume, Length, Temperature, Other

R		Metric (g, L, m, °C)	Cal. date	Cal. Lab	Interval
	Range				
		Customary (lb, gal, ft, °F)			
	Range				

W		Metric (g, L, m, °C)	Cal. date	Cal. Lab	Interval
	Range				
		Customary (lb, gal, ft, °F)			
	Range				

S_c		Metric (g, L, m, °C)	Cal. date	Cal. Lab	Interval
	Range				
		Customary (lb, gal, ft, °F)			
	Range				

R = Reference Standards; W = Working Standards; S_c = Check Standards.

Appendix B: Traceability Evaluation Form

Assess whether all of the essential elements of traceability are available for the entire Scope by completing the table below. Specific Analysis: Include specific comments on what was observed and what evidence is available.

Manual Reference	Description	Specific Example or Evidence	Complies? Yes/No
	Unbroken Chain of Evidence. Standards (Reference, Working, and Check or Control) demonstrate an unbroken chain to SI references.		
	Documented Uncertainty. Needed for each step in the hierarchy.		
	Documented Procedures. Suitable, applicable, documented and validated procedures.		
	Accredited Technical Competency. Demonstration of competency is documented.		
	Realization to SI Units.		
	Calibration intervals.		
	No calibration intervals are "past due."		
	Measurement Assurance.		

Appendix C: Sample Technical Audit for Traceability Evidence

Select 3 calibration reports for the past year, and identify the following specific information to support traceability for each calibration. On each chart, next to each block for your primary and working standards, please list evidence that is available in your laboratory:

Item Evaluated	Evidence
Calibration selected (Measurement Type, Lab Test Number)	
Test Number(s) for all standards used	
Calibration Date(s) for the standards	
Calibration Interval	
Uncertainty analysis components included(s)	
Uncertainty file name where data is stored	
Documented SOP used	
Evidence of competency	
Measurement assurance type	
Measurement Assurance file name where data is stored	
Report contains a Traceability Statement	

You should be able to identify any gaps and corrective action needed in your laboratory in the area of traceability, uncertainty analysis, and measurement assurance. Note it below.

Appendix D: Evaluating Supplier Calibration Reports for Metrological Traceability for Weights and Measures Applications

Step	Notes	Accept (Yes/No)
Legal	Does your law allow acceptance of reports for the applicable use (laboratory standards, field standards, service company standards)? Does your law specify traceability to NIST? To the SI? Is there a required calibration interval?	
Specifications	Does your law require assessment against published specifications like the NIST Handbook 105-series documentary standards? IF SO, have the customer standards been evaluated for compliance to specifications (are the standards suitable for use?) Note: This is NOT common for non-governmental laboratories, even when accredited, and cannot be done if there are no applicable specifications. *Accreditation has nothing to do with evaluating compliance to specifications.*	
Documented Calibration Report	Is there a valid calibration report for *all of* the standards? Does it (do they) comply with laboratory requirements? (Checklist available.) Specifically, traceability components: reference to SI and standards used, traceability statement, uncertainty statement, measurement results, measurement uncertainty, reference to documented procedures.	
Is the report from a National Metrology Laboratory (NMI) like NIST?	Can you accept a calibration report for a standard that was tested by Measurement Canada that is traceable to NRC for example? Has that NMI signed the CIPM MRA and is this range/scope/uncertainty of measurements published in the Appendix C listing maintained by BIPM? (List available.)	
Is the report from a NIST OWM Recognized laboratory?	OWM is NOT a recognized Accreditation Body and has not signed the ILAC MRA. Is the measurement parameter on their Scope? Is the reported uncertainty acceptable for your needs? (Posted on our website, includes those Accredited by NVLAP.)	
Is the report from an Accredited laboratory?	Is the Accreditation Body a signatory of the ILAC MRA? (List available.) Is the measurement parameter on their Scope *now*? Is the *currently* reported uncertainty small enough to meet requirements for the laboratory or for Fundamental Considerations (less than 1/3 the applicable tolerance)?? (Directories available.)	