GMP 13

Good Measurement Practice for Ensuring Traceability

1. Introduction

1.1 Purpose

Traceability is defined as "the property of a 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".[1] Traceability ensures that the measurements are accurate representations of the specific quantity subject to measurement, within the uncertainty of the measurement.

To ensure 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 is traceable. (See section 1.3.3.)

1.2 Prerequisites

Traceability can be characterized by the following essential elements:

1.2.1 *Unbroken chain of comparisons.* A documented system of comparisons going back to a standard acceptable to the parties, usually a national or international standard;

1.2.2 *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 *Documentation.* 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 ISO VIM, 2nd ed., 1993, definition 6.10

1.2.4 *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 SI units;

1.2.6 *Periodic recalibration.* Calibrations of standards (and equipment where appropriate) must be repeated at established (may be defined through measurement assurance) and appropriate intervals to preserve the 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 (see SOP′s 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 traceability statement.

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.

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 ANSI/NCSL Z 540-1, 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.)

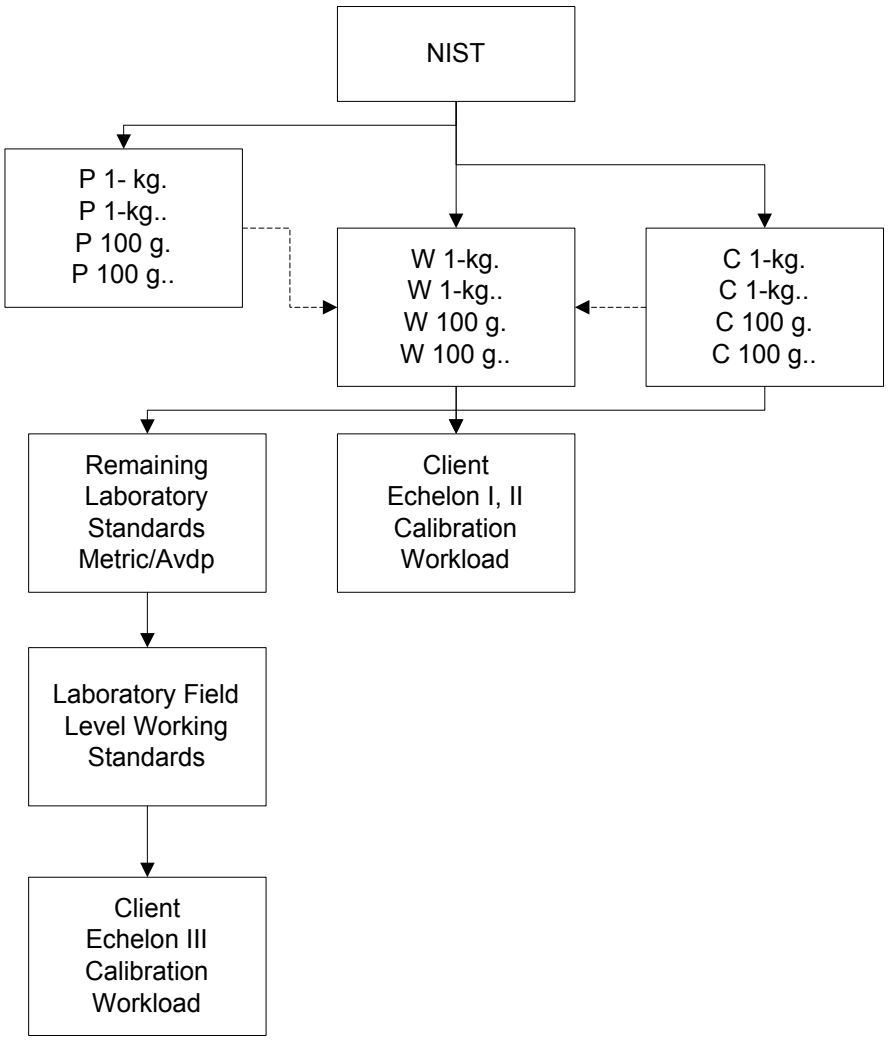
3. Calculations

There are no calculations in this GMP.

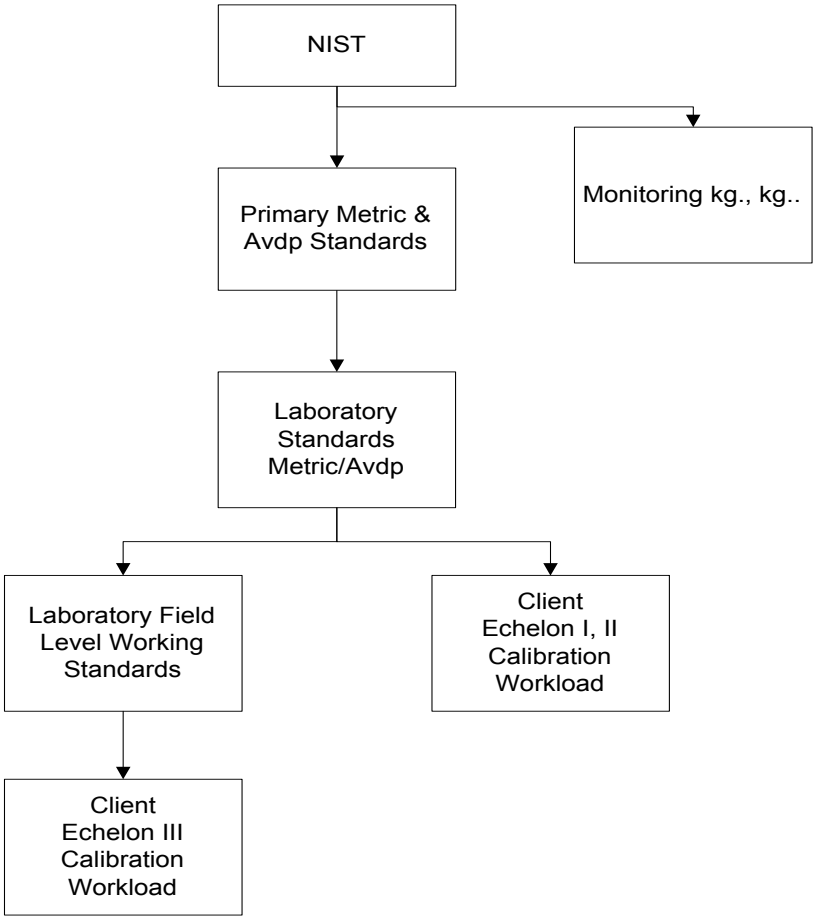
4. Assignment of Uncertainty

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

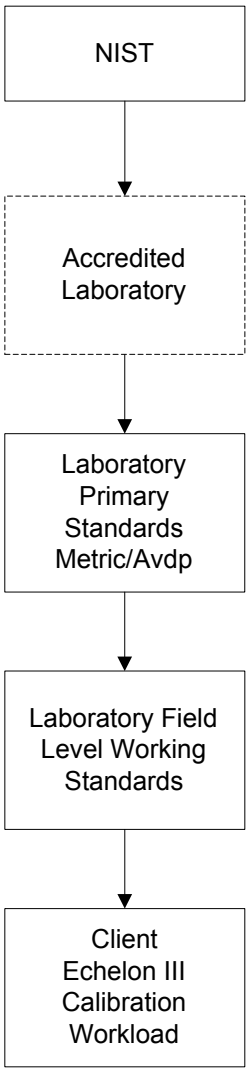
Mass - Option A



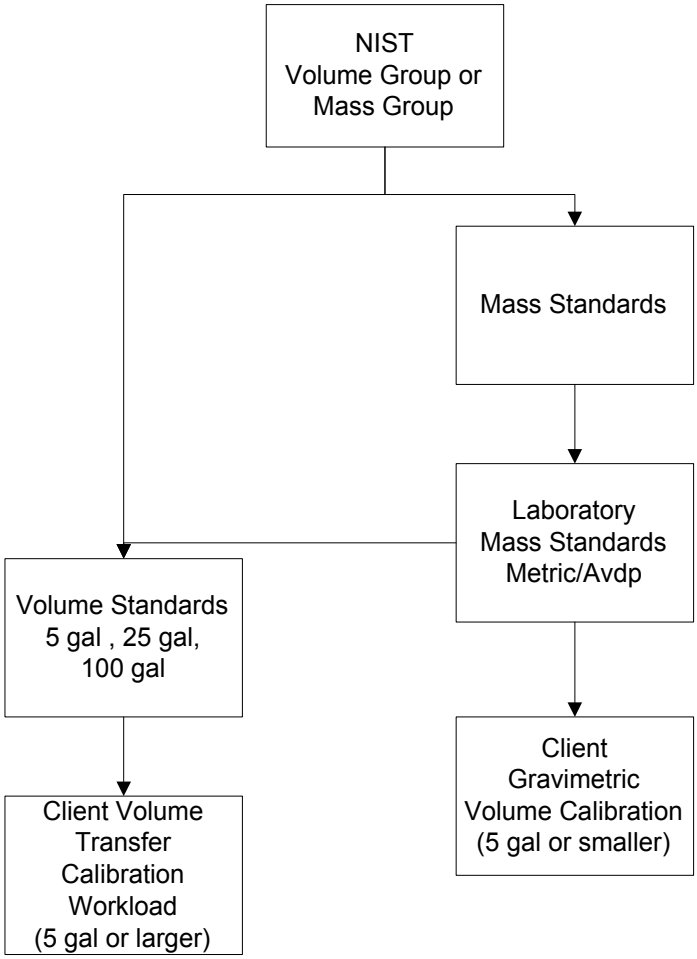
Mass - Option B



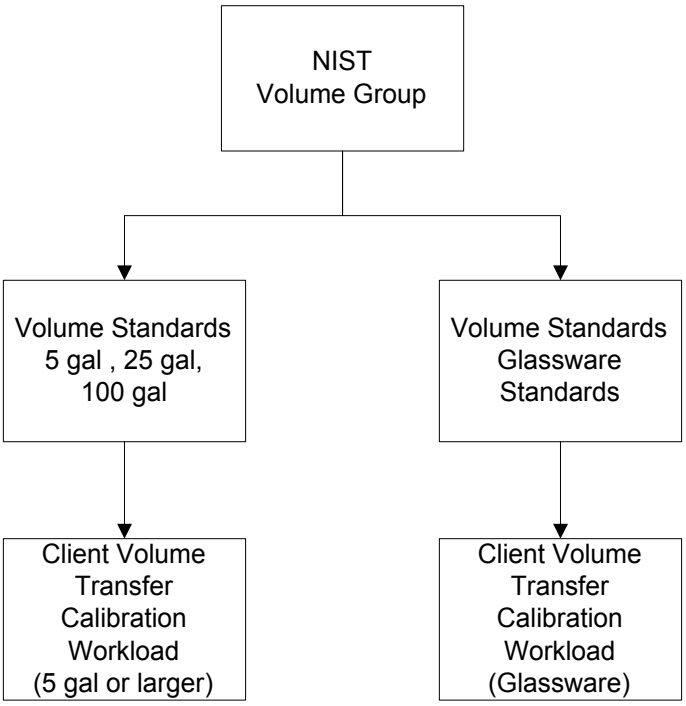
Mass - Option C



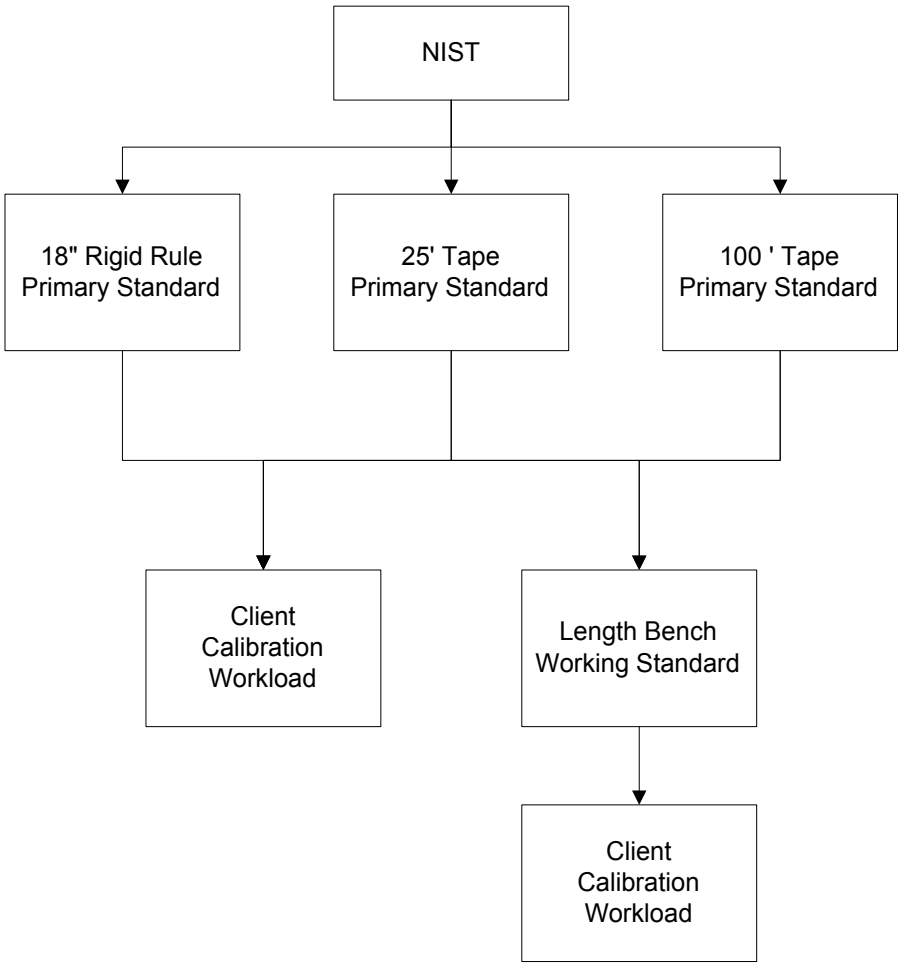
Volume - Option A



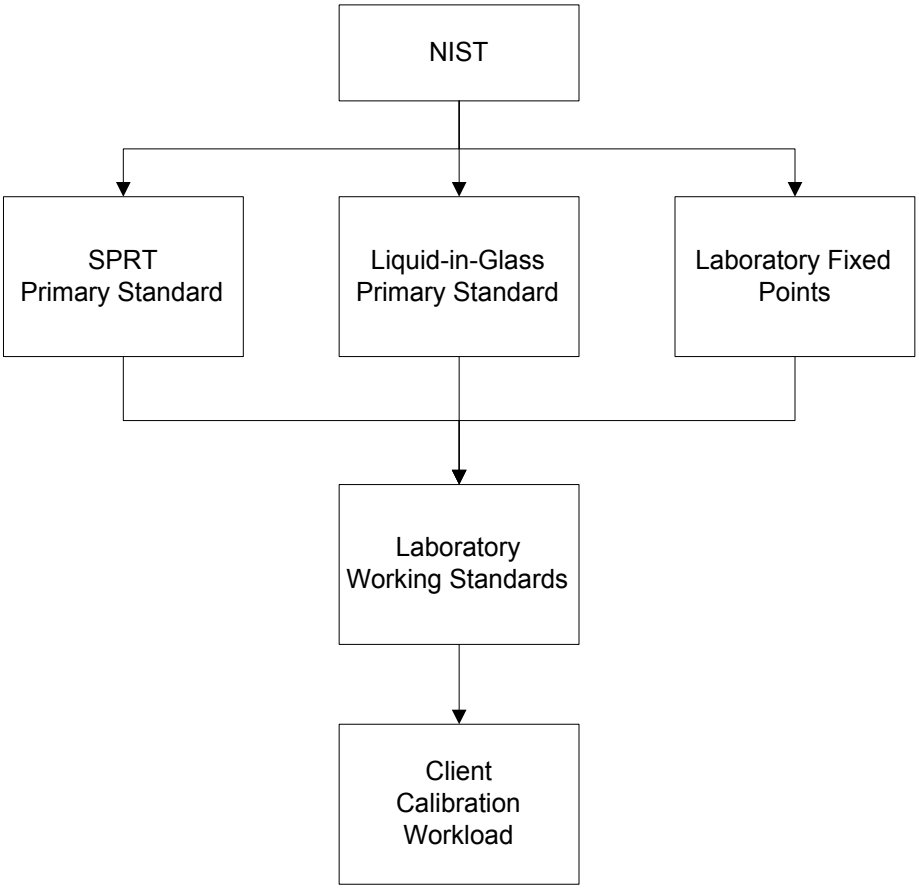
Volume - Option B



Length


NIST
18" Rigid Rule Primary Standard
25' Tape Primary Standard
100 ' Tape Primary Standard
Client Calibration Workload
Length Bench Working Standard
Client Calibration Workload

Temperature



Appendix A - Traceability worksheet

Parameter: Mass, Volume, Length, Temperature, Other

P		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				