APPENDIX H

TRACEABILITY OF MEASUREMENT

Table of Contents

1. SCOPE

This AIHA-LAP, LLC Policy documents the requirements for laboratories to maintain accreditation to ISO/IEC 17025 with regard to traceability of measurement. This policy applies to all laboratories accredited under the AIHA-LAP, LLC Laboratory Accreditation Program. AIHA-LAP, LLC wishes to thank and acknowledge the Canadian Association for Laboratory Accreditation (CALA) for its permission to incorporate elements of CALA A61 – *CALA Traceability Policy* in preparing this policy document.

2. REFERENCES

The following documents provide the basis and assist with application of the principles stated in this policy.

- **AIHA-LAP, LLC Policy Appendix G on the Estimation of Uncertainty of Measurement** http://www.aihaaccreditedlabs.org/policymodules/Documents/ApGPolicyEstimationUncertaintyMeasurement.pdf
- **CALA Traceability Policy,** CALA A61 http://www.cala.ca/A61-CALA_Trac.pdf
- **General requirements for the competence of testing and calibration laboratories,** ISO/IEC 17025:2005
- **Guidelines for the determination of calibration intervals of measuring equipment**, ILAC G 24:2007 http://www.ilac.org/documents/ILAC_G24_2007.pdf
- **Guidelines for the Selection and Use of Reference Materials,** ILAC G9:2005 http://www.ilac.org/documents/ILAC_G9_2005_guidelines_for_the_selection_and_use_of_reference_material.pdf
- **ILAC Policy on the Traceability of Measurement Results,** ILAC P10:2002 http://www.ilac.org/documents/ILAC_P10_2002_ILAC_Policy_on_Traceability_of_Measurement_Result.pdf
- **International vocabulary of metrology — Basic and general concepts and associated terms (VIM),** VIM JCGM 200:2008
- **Metrological Traceability Of Measurement Results In Chemistry: Concepts And Implementation (IUPAC Recommendations 2009),** International Union of Pure and Applied Chemistry (IUPAC), Paul De Bièvre1, René Dybkaer, Aleš Fajgelj And D. Brynn Hibbert, http://www.iupac.org/web/ins/2001-010-3-500

3. TERMS AND DEFINITIONS

Calibration: operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, use this information to establish a relation for obtaining a measurement result from an indication. (VIM 2.39 JCGM 200:2008)

Certified Reference Material (CRM): reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures. (VIM 5.14 JCGM 200:2008)

Critical equipment: “Critical” equipment used by testing and calibration laboratories is considered by ILAC to be those items of equipment necessary to perform a test or calibration from the scope of accreditation and which have a significant effect on the uncertainty of measurement of test or calibration results (ILAC-P10:2002). For the purposes of this policy, AIHA-LAP LLC considers any contribution that is ≥ 1/3 of the largest measurement uncertainty contributor for a test method to be a significant contributor to measurement uncertainty.

Measurement Result (result of measurement): set of quantity values being attributed to a measurand together with any other available relevant information. (VIM 2.9 JCGM 200:2008)

Measurement Standard: realization of the definition of a given quantity, with stated quantity value and associated measurement uncertainty, used as a reference (VIM 5.1 JCGM 200:2008) The following are examples and notes presented in the VIM (as numbered) that are relevant to the measurements performed by AIHA-LAP, LLC laboratories:

EXAMPLE 1 1 kg mass measurement standard with an associated standard measurement uncertainty of 3 µg.

EXAMPLE 4 Hydrogen reference electrode with an assigned quantity value of 7.072 and an associated standard measurement uncertainty of 0.006.

EXAMPLE 6 Reference material providing quantity values with measurement uncertainties for the mass concentration of each of ten different proteins.

NOTE 2: A measurement standard is frequently used as a reference in establishing measured quantity values and associated measurement uncertainties for other quantities of the same kind, thereby establishing metrological traceability through calibration of other measurement standards, measuring instruments, or measuring systems.

NOTE 5: Quantity value and measurement uncertainty must be determined at the time when the measurement standard is used.

Measuring System: set of one or more measuring instruments and often other devices, including any reagent and supply, assembled and adapted to give information used to generate measured quantity values within specified intervals for quantities of specified kinds (VIM 3.2 JCGM 200:2008)

NOTE: A measuring system may consist of only one measuring instrument.

Measurement Uncertainty (uncertainty of measurement) (uncertainty): non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used (VIM 2.26 JCGM 200:2008)

Metrological Traceability (traceability): 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 (VIM 2.41 JCGM 200:2008)

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 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.

Metrological Traceability to a measurement unit: metrological traceability where the reference is the definition of a measurement unit through its practical realization. (VIM 2.43 JCGM 200:2008)

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

National Metrology Institute: ILAC considers an "appropriate " national metrology institute to be one that participates regularly and successfully in relevant international interlaboratory comparisons performed by BIPM and/or by regional metrology bodies. ILAC encourages BIPM and regional bodies to conduct and publish details of as broad a range of international comparisons as possible to provide transparency on the equivalence and linkages of national measurement standards, which underpin accreditation activities. ILAC has taken note that the results of international comparisons carried out in the scope of the Metre Convention are published in Appendix B of the CIPM MRA (www.bipm.org).

NIST Standard Reference Material® (SRM) - A CRM issued by NIST that also meets additional NIST-specific certification criteria and is issued with a certificate or certificate of analysis that reports the results of its characterizations and provides information regarding the appropriate use(s) of the material (NIST SP 260-136).

Note: An SRM is prepared and used for three main purposes: (1) to help develop accurate methods of analysis; (2) to calibrate measurement systems used to facilitate exchange of goods, institute quality control, determine performance characteristics, or measure a property at the state-of-the-art limit; and (3) to ensure the long-term adequacy and integrity of measurement quality assurance programs. The terms "Standard Reference Material" and the diamond-shaped logo which contains the term "SRM," are registered with the United States Patent and Trademark Office. (NIST Definitions)

Primary measurement standard (primary standard): measurement standard established using a primary reference measurement procedure, or created as an artifact, chosen by convention (VIM 5.4 JCGM 200:2008)

EXAMPLE 1 Primary measurement standard of amount- of-substance concentration prepared by dissolving a known amount of substance of a chemical component to a known volume of solution

EXAMPLE 3 Primary measurement standard for isotope amount-of-substance ratio measurements, prepared by mixing known amount-of-substances of specified isotopes

EXAMPLE 4 Triple-point-of-water cell as a primary measurement standard of thermodynamic temperature. [for temperature]

EXAMPLE 5 The international prototype of the kilogram as an artifact, chosen by convention [for mass].

Reference Material (RM): material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties (VIM 5.13 JCGM 200:2008) (To provide clarity for testing laboratories, AIHA-LAP, LLC uses the term reference material to be those related to chemical and microbiological references. Reference materials include neat materials, chemical solutions, and microbiologic cultures.)

Reference Measurement Standard (reference standard): measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location (VIM 5.6 JCGM 200:2008) (To provide clarity for testing laboratories, AIHA-LAP, LLC uses the term reference standard to be those related to physical attributes such as mass, length, and temperature that are defined by convention as traceable to the SI through an NMI such as NIST).

Secondary Reference Standard: measurement standard established through calibration with respect to a primary measurement standard for a quantity of the same kind (VIM 5.5 JCGM 200:2008)

NOTE 1 Calibration may be obtained directly between a primary measurement standard and a secondary measurement standard, or involve an intermediate measuring system calibrated by the primary measurement standard and assigning a measurement result to the secondary measurement standard.

NOTE 2 A measurement standard having its quantity value assigned by a ratio primary reference measurement procedure is a secondary measurement standard.

SI (International System of Units): System of units. The name adopted by the 11th General Conference on Weights and Measures (1960) for the recommended practical system of units of measurement. The base units are a choice of seven well-defined units: the metre, the kilogram, the second, the ampere, the Kelvin, the mole, and the candela.

Verification: provision of objective evidence that a given item fulfils specified requirements. (VIM 2.26 JCGM 200:2008)

(CALA/AIHA-LAP, LLC) A procedure normally associated with the acquisition of data regarding an instrument to provide some indication as to whether it is operating within expected tolerances. For example, weights may be placed on a balance and the reading can provide some indication as to whether the balance is operating within expected tolerances. This operation should not be confused with **calibration**. Verification does not establish traceability. Verification seeks only to determine whether or not the instrument is operating within its expected tolerances. It is not a method of establishing the expanded uncertainty, which is the core issue in a *calibration*.
Note that manufacturer's tolerances, as provided in data sheets and instrument manuals, will use the same method of expression as an uncertainty, such as +/- 3% or +/- 4 grams. These are still only *tolerances* and should not be confused with the expanded *uncertainties* associated with the measurement result.

Working measurement standard (working standard): measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems. (VIM 5.7 JCGM 200:2008)

4. BACKGROUND

ISO/IEC 17025, section 5.6 requires conformant laboratories to demonstrate that the results produced by their measuring systems are traceable in accordance with the international definition of that term. See the definition for metrological traceability above and the ***International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*** (VIM JCGM 200:2008).

This allows

- Laboratories to support the validity of test results.
- Laboratories and users to make objective comparison of different test results.
- Laboratories and users to make sound interpretation of individual test results.

Traceability is characterized (in ILAC documents and the VIM) by:
(a) **an unbroken chain of comparisons** going back to stated references acceptable to the parties, usually a national or international standard;
(b) **uncertainty of measurement;** the uncertainty of measurement for each step in the traceability chain must be calculated or estimated according to agreed methods and must be stated so that an overall uncertainty for the whole chain may be calculated or estimated
(c) **documentation;** each step in the traceability chain must be performed according to documented and generally acknowledged procedures; the results must be recorded;
(d) **competence;** the laboratories or bodies performing one or more steps in the traceability chain must supply evidence for their technical competence (e.g. by demonstrating that they are accredited for that activity);
(e) **reference to SI units;** the chain of comparisons must, where possible, end at primary standards for the realization of the SI units;
(f) **calibration intervals;** calibrations must be repeated at appropriate intervals; the length of these intervals will depend on a number of variables (e.g. uncertainty required, frequency of use, way of use, stability of the equipment).

In the area of chemistry, traceability of all measurements is problematic due to recent changes in terminology, difficulties in melding of chemical concepts with metrological traceability as required by ISO/IEC 17025, and lack of reference materials from metrological organizations. The IUPAC Committee has been working towards a recommendation document addressing traceability in chemical measurements since 2001. The latest version (2009) has been reviewed to help establish the concepts presented in this document along with the other references (Section 2). The concepts used in chemistry may also be applied to microbiological measurements. As the international community in the fields of chemistry and biology continues to develop consensus statements, AIHA-LAP, LLC will adopt those that are appropriate to its scope of accreditation activities.

AIHA-LAP, LLC provides this policy and associated general guidance on acceptable and appropriate methods for accredited laboratories to:

- Ensure the continuing conformance to the requirements of the standard.
- Demonstrate traceability of all accredited results.
- Include traceability requirements in the performance of equipment calibration.
- Make sound decisions on the purchasing of services and supplies in support of accredited testing.

5. TRACEABILITY OF MEASUREMENT POLICY

The requirement which underlies this policy is given in ISO/IEC 17025, Clause 5.6.

5.1 Laboratories accredited by AIHA-LAP, LLC shall demonstrate, when possible, that calibrations of critical equipment and hence the measurement results generated by that equipment, relevant to their scope of accreditation, are traceable to the SI through an unbroken chain of calibrations.

5.2 External calibration services shall, wherever possible, be obtained from providers accredited to ISO/IEC 17025 by an ILAC recognized signatory. Calibration certificates shall be endorsed by a recognized accreditation body symbol. Certificates shall indicate traceability to the SI or reference standard and include the measurement result with the associated uncertainty of measurement.

5.3 Where traceability to the SI is not technically possible or reasonable, the laboratory shall use certified reference materials provided by a competent supplier (refer to ISO/IEC 17025 4.6.4), or use specified methods and/or consensus standards that are clearly described and agreed to by all parties concerned. A competent supplier is an NMI or an accredited reference material provider (RMP) that conforms with ISO Guide 34 in combination with ISO/IEC 17025, or ILAC Guidelines for the Competence of Reference Material Producers, ILAC G12. Conformance is demonstrated through accreditation by an ILAC recognized signatory.

NOTE: There are many gaps in the measurement traceability of the calibration infrastructure in the world and there are a relatively small number of accredited reference material providers. In recognition of this situation, AIHA-LAP, LLC will not require the use of accredited reference material providers, where applicable, until January 2012.
AIHA-LAP, LLC assessors will, at present, note any nonconformity with this requirement of Section 5.3 of this policy as a suggestion for improvement.

5.4 Reference materials shall have a certificate of analysis that documents traceability to a primary standard or certified reference material and associated uncertainty, when possible. When applicable, the certificate must document the specific NIST SRM® or NMI certified reference material used for traceability.

5.5 Calibrations performed in-house shall be documented in a manner that demonstrates traceability via an unbroken chain of calibrations regarding the reference standard/material used, allowing for an overall uncertainty to be estimated for the in-house calibration.

5.6 Calibrations shall be repeated at appropriate intervals, the length of which can be dependant on the uncertainty required, the frequency of use and verification, the manner of use, stability of the equipment, and risk of failure considerations. Table 5-1 provides the **minimum** frequencies that are required.

5.7 Periodic verifications shall be performed to demonstrate the continued validity of the calibration at specified intervals between calibrations. The frequency of verifications can be dependent on the uncertainty required, the frequency of use, the manner of use, stability of the equipment, and risk of failure considerations. Table 5-1 provides the **minimum** frequencies that are required.

5.8 The laboratory shall have procedures describing their external and internal calibration and verification activities and frequencies, and the actions to follow if the equipment is found to be out of acceptable specification.

5.9 Laboratory staff performing in-house calibrations and verifications shall have received documented training.

Table 5-1
Minimum Calibration/Verification Frequency Requirements for Common Reference Standards and Support Equipment

Reference Standard / Equipment	Calibration Frequency	Verification Frequency
Reference Thermometer	Initial and every 5 years	Not applicable
Working Thermometer	Initial and when verification fails	Annually
Reference Masses	Initial and every 5 years	Not applicable
Working Masses	NA	Initial and then annually
Stage Micrometer	Initial and if damaged	Not applicable
Balance	Initial and following service/repair or when verification fails	Each day of use
Mechanical Pipettes	Initial and when verification fails	Annual
Volumetric Containers for critical functions (non-Class A)	Not applicable	Each lot prior to use

NOTE: It is imperative laboratories understand that this table is **not** a list of recommended frequencies. Rather, they are the **minimum** frequencies that will be accepted by AIHA-LAP, LLC assessors. It is the laboratory's responsibility to establish a suitable schedule.

6. GUIDANCE ON IMPLEMENTING THIS POLICY

Refer to the AIHA-LAP, LLC Guidance on the Traceability of Measurement document for additional background information and guidance regarding reference standard and equipment calibrations, and locating accredited calibration laboratories and reference material providers.