



## APPENDIX H METROLOGICAL TRACEABILITY OF MEASUREMENT RESULTS

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## 1. SCOPE

This AIHA Laboratory Accreditation Programs, LLC (AIHA LAP) Policy documents the requirements for laboratories to maintain accreditation to ISO/IEC 17025:2017 regarding metrological traceability of measurement results. This policy applies to all laboratories accredited under the AIHA LAP Laboratory Accreditation Program. AIHA LAP 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 the initial version of 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 Evaluation of Measurement Uncertainty
- CALA A61 - CALA Traceability Policy, [Canadian Association for Laboratory Accreditation](#)
- ISO/IEC 17025:2017, **General requirements for the competence of testing and calibration laboratories**,
- ILAC P10:07/2020, **ILAC Policy on Metrological Traceability of Measurement Results**, <https://ilac.org/publications-and-resources/ilac-policy-series/>
- VIM JCGM 200:2012, **International vocabulary of metrology — Basic and general concepts and associated terms (VIM)** published by (BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML) <https://www.bipm.org/en/publications/guides/>
- **Metrological Traceability Of Measurement Results In Chemistry: Concepts And Implementation (IUPAC Recommendations 2009)**, International Union of Pure and Applied Chemistry (IUPAC), Paul De Bièvre<sup>1</sup>, René Dybkaer, Aleš Fajgelj And D. Brynn Hibbert,
- *EURACHEM/CITAC Guide: Traceability in Chemical Measurement – A guide to achieving comparable results in chemical measurement* (2003)
- Meeting the traceability requirements of ISO 17025: An Analyst's Guide, 3<sup>rd</sup> edition
- ISO 17034:2016, **General requirements for the competence of reference material producers**



### 3. TERMS AND DEFINITIONS

#### **BIPM**

Bureau International des Poids et Mesures

BIPM is the intergovernmental organization through which Member States act together on matters related to measurement science and measurement standards. (ILAC P10:07/2020)

**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 200:2012)

**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 200:2012)

**Certified Reference Material (CRM):** Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. (ISO 17034:2016)

#### **CIPM MRA**

International Committee for Weight and Measures Mutual Recognition Arrangement

The CIPM MRA – is an arrangement between National Metrology Institutes which provides the technical framework to assure the mutual recognition of national measurement standards and for recognition of the validity of calibration and measurement certificates issued by National Metrology Institutes. (ILAC P10:07/2020)

**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. For the purposes of this policy, AIHA LAP considers any contribution that is  $\geq 1/3$  of the largest measurement uncertainty contributor for a test method to be a significant contributor to measurement uncertainty.

#### **JCTLM**

Joint Committee for Traceability in Laboratory Medicine

JCTLM formed by the BIPM, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and ILAC, provides a worldwide platform to promote and give



guidance on internationally recognized and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards. (ILAC P10:07/2020)

### **KCDB**

Key Comparison Database

The KCDB is a publicly available, free web resource related to the CIPM MRA. It contains information on participants of the CIPM MRA, results of key and supplementary comparisons and peer reviewed Calibration and Measurement Capabilities (CMCs) (<https://www.bipm.org/kcdb>). (ILAC P10:07/2020)

**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 200:2012)

**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 200:2012). All laboratories are encouraged to review the VIM in its entirety; however, the following are examples and notes presented in the VIM (as numbered) that may be relevant to the measurements performed by AIHA LAP laboratories:

EXAMPLE 1: 1 kg mass measurement standard with an associated standard measurement uncertainty of 3  $\mu\text{g}$ .

EXAMPLE 4: Standard buffer solution with a pH of 7.072 with 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 200:2012)



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 200:2012)

NOTE 1 Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.

NOTE 2 The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

NOTE 3 Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quality values from series of measurements and can be characterized by standard deviation, evaluated from probability density function based on experience or other information.

NOTE 4 In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

**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 200:2012)

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 P10:2002)

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 200:2012)

NOTE: The expression “traceability to the SI” means ‘metrological traceability to a measurement unit of the International System of Units’.

### **National Metrology Institute**

National Metrology Institute (NMI) and Designated Institutes (DI) maintain measurement standards in countries (or regions) all over the world. Throughout this document, the term “NMI” is used to cover both a National Metrology Institute as well as a Designated Institute. (ILAC-P10:07/2020)

Note that 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](http://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 200:2012)

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.

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 200:2012)



**Reference Material (RM):** Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process. (ISO 17034:2016).

To provide clarity for testing laboratories, AIHA LAP 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 Material Producer (RMP):** Body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference materials it produces. (ISO 17034:2016).

**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 200:2012)

To provide clarity for testing laboratories, AIHA LAP 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 Measurement Standard (secondary standard):** measurement standard established through calibration with respect to a primary measurement standard for a quantity of the same kind. (VIM 5.5 JCGM 200:2012)

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 2.44 JCGM 200:2012)

(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  $\pm 3\%$  or  $\pm 4$  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 200:2012)

#### 4. BACKGROUND

ISO/IEC 17025:2017, section 6.5 requires 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 200:2012).

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 17025:2017, 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 2009 version was 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 will adopt those that are appropriate to its scope of accreditation activities.

AIHA LAP 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 metrological traceability of all accredited results.
- Include metrological traceability requirements in the performance of equipment calibration.
- Make sound decisions on the purchasing of services and supplies in support of accredited testing.

## 5. METROLOGICAL TRACEABILITY OF MEASUREMENT RESULTS POLICY

The requirement which underlies this policy is given in ISO/IEC 17025:2017, Clause 6.5

- 5.1** Laboratories accredited by AIHA LAP 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 an ISO/IEC 17025 accredited calibration laboratory whose service is suitable for the intended use (i.e., the scope of accreditation specifically covers the appropriate calibration)

and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC, a National Metrology Institute (NMI) whose service is suitable for the intended use and is covered by the International Committee for Weight and Measures Mutual Recognition Arrangement (CIPM MRA), or a State Weights and Measures Facility that is part of the NIST Laboratory Metrology Program. Calibration certificates shall be endorsed by a recognized accreditation body symbol or otherwise make reference to accredited status by a specific, recognized accreditation body, or contain endorsement by the NMI. Certificates shall indicate metrological 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 or use specified methods and/or consensus standards that are clearly described and agreed to by all parties concerned. Certified values assigned to CRMs are considered to have established valid metrological traceability when:
- 1) CRMs are produced by NMIs using a service that is included in the BIPM KCDB, or
  - 2) CRMs are produced by an ISO 17034 accredited RMP under its scope of accreditation and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC, or
  - 3) The certified values assigned to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.

NOTE There are many gaps in the measurement traceability of the calibration infrastructure in the world and there are a relatively small, but increasing, number of accredited reference material producers. In recognition of this situation, AIHA LAP requires the use of accredited reference material producers for newly purchased reference materials with known accredited RMPs (e.g., many metals, inorganic anions, some organic mixtures, some microbial organisms). Existing reference materials may be used until expired or exhausted. This requirement is not enforced for reference materials not readily available from an accredited RMP.

- 5.4** Reference materials shall have a certificate of analysis that documents metrological traceability to a primary standard or certified reference material and associated uncertainty, when possible. When applicable, the certificate must document the specific NIST SRM<sup>®</sup> or NMI certified reference material used for traceability.
- 5.5** Calibrations performed in-house shall be documented in a manner that demonstrates metrological traceability via an unbroken chain of calibrations regarding the reference standard/material used, allowing for an overall uncertainty to be evaluated for the in-house calibration.



- 5.6** Calibrations shall be repeated at appropriate intervals, the length of which can be dependent 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 includes a list of reference standards and support equipment, commonly found in AIHA LAP accredited laboratories that require calibration and/or verification.
- 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.
- 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. Although the frequency of recalibration can be extended, it cannot be eliminated. The procedures shall describe the action(s) that will be taken when recalibrations or verifications fail to meet the established criteria, including the use of the nonconformance and corrective action system to identify the root cause, prevent recurrence, and evaluate the impact to data reported since the last passing calibration or verification, including data recall where appropriate.
- 5.9** Laboratory staff performing in-house calibrations and verifications shall have received documented training.

**Table 5-1**  
**Common Reference Standards and Support Equipment Requiring Calibration and/or Verification**

Reference Standard / Equipment	Calibration Frequency	Verification Frequency
Reference Thermometer	Initial and as determined by the laboratory	Not applicable
Working Thermometer	Not Applicable	As defined by the laboratory
Reference Masses	Initial and as determined by the laboratory	Not applicable



Working Masses	Not Applicable	As defined by the laboratory
Stage Micrometer	Initial and as determined by the laboratory	As defined by the laboratory
Balance	Initial and as determined by the laboratory	As defined by the laboratory
Mechanical Pipettes	Initial and as determined by the laboratory	As defined by the laboratory
Volumetric Containers for critical functions	Initial and as determined by the laboratory	As defined by the laboratory

NOTE 1: For some laboratories, this list may not be complete. It is the responsibility of each laboratory to identify all reference standards and support equipment whose calibration has a significant impact on analytical uncertainty.

NOTE 2: It is the laboratory's responsibility to establish a calibration and verification schedule suitable to the use of equipment. (See Section 5.6 and 5.7 above)

NOTE 3: Laboratories should be mindful of ISO/IEC 17025, clause 6.4.7 when developing the schedule, "The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration."

NOTE 4: Laboratories should be prepared to show supporting data and rationale for the schedule chosen.

## **6. AOAC ADDITIONAL FOOD LABORATORY REQUIREMENTS**

Laboratories that are seeking compliance to the AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food and Pharmaceuticals are expected to meet the criteria defined in Appendix A of the aforementioned document.

The criteria outlined in the AOAC International document supersede the requirements noted in Table 5-1 above for equipment used under this scope of accreditation, only.

## **7. GUIDANCE ON IMPLEMENTING THIS POLICY**

Refer to the AIHA LAP Guidance on the Metrological Traceability of Measurement Results



document for additional background information and guidance regarding reference standard and equipment calibrations and locating accredited calibration laboratories and reference material producers.