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	P102 - Policy on Metrological Traceability	

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Scope and Field of Application

The quality of products and services continues to be dependent on reliable measurements. The importance attached to measurements is reflected in relevant standards by the requirement that measurements must be "traceable" to national or international standards of measurement. Different definitions and explanations of the term "traceability" exist in standards and various literature, giving rise to differing interpretations and misinterpretations.

Metrological traceability is defined by the International Vocabulary of Metrology (VIM) 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.' The purpose of requiring traceability is to ensure that measurements are accurate representations of the specific quantity subject to measurement, within the uncertainty of the measurement.

A2LA policies pertaining to metrological traceability are described in this document. These policies are designed to ensure compliance with P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results. This document is intended for all A2LA-accredited and enrolled calibration and testing laboratories, inspection bodies, proficiency testing providers, reference material producers and biobanks. Where these policies differ from an ISO/IEC 17025 or ISO/IEC 17020 requirement or another A2LA Requirement, the more stringent requirement applies. Guidance on application of the requirements of P102 can be found in G135 - Guidance for application of P102.

I. **A2LA Metrological Traceability Policies**

(T1) External Calibration Service

For equipment and reference measurement standards that must be calibrated, the calibration shall be conducted by:

- 1. A calibration laboratory accredited to ISO/IEC 17025 by a mutually recognized Accreditation Body; or,
- 2. A National Metrology Institute (NMI) including designated institutes whose services are covered by the CIPM MRA1; or,
- 3. A U.S. State Weights and Measures facility with a current certificate of measurement traceability. Please see http:/www.NIST.gov for a copy of current certificates.

(T2) Exceptions on External Calibration Service

- 1. For cases where the National Institute of Standards and Technology (NIST) service is suitable for the intended need but is not covered by the CIPM MRA, A2LA will accept services covered under the NIST SP 250 Series on NIST Measurement Services.
- 2. A CAB may use a calibration laboratory whose service is suitable for the intended need, but is not covered by the ILAC MRA under the following conditions:
 - a) The CAB maintains evidence that there is no other accredited calibration laboratory available to perform the calibration or maintains evidence of qualification for special circumstances; and
 - b) The CAB maintains evidence of a calibration certificate that contains all of the following
 - 1. The calibration result; and,

2. An indication of the reference measurement standard(s) used to perform the calibration;

c) The CAB maintains evidence that the reference measurement standard(s) noted on the calibration certificate are traceable to the SI through NIST (or equivalent) or an Accredited Laboratory; and

¹ Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB which includes the range and uncertainty of each listed service (https://www.bipm.org/kcdb/).

d) The CAB maintains evidence of the calibration interval² for the measuring and test equipment (M&TE) or reference measurement standard.

(T3) Reference Materials

When possible, all reference materials used for the purpose of establishing and maintaining metrological traceability (calibration and recalibration, also referred to as standardization) shall be obtained from:

- 1. A reference material producer accredited to ISO 17034 that is covered by the ILAC Arrangement or by a Regional Arrangement recognized by ILAC; or,
- 2. A National Metrology Institute (NMI) that is included in the BIPM KCDB or designated institute; or,
- 3. Those certified values that are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.

(T4) In-house Calibrations

An in-house calibration is the calibration of an A2LA accredited CAB's own reference measurement standards or measuring and test equipment by the laboratory's own staff for which the calibration measurement parameters *ARE NOT* included on their Scope of Accreditation.

<u>Note</u>: This should not be confused with an "internal calibration" of the CAB's own equipment (e.g. secondary or working standards) which <u>is</u> included on their scope of accreditation. In this case (T4) is not applicable; rather (T1) and (T5) of this document applies.

For all in-house calibrations having a significant effect on the accuracy or validity of the result of the accredited test, calibration or sampling on the CAB's A2LA Scope of Accreditation:

- 1. The CAB shall maintain documented procedures for the in-house calibrations;
- 2. The in-house calibrations shall be evidenced by a calibration report, certificate, or sticker, or other suitable method;
- Calibration records shall be retained minimally for the length of time between full A2LA assessments;
- 4. The CAB shall maintain training records for calibration personnel and these records shall demonstrate the technical competence of the personnel performing the calibrations: evidence of competence includes, for example, documented training and the results of measurement audits;
- 5. The CAB shall be able to demonstrate traceability to national or international standards of measurement by procuring calibration services from appropriately accredited calibration labs or an NMI for the reference measurement standard used to perform the in-house calibration;
- 6. Where available, the CAB shall use reference materials from accredited reference material producers or an NMI, per the requirements of (T3) of this document;
- 7. Measurement uncertainty:

- a) The CAB shall evaluate measurement uncertainty; when evaluating measurement uncertainty, all contributions that are of significance shall be taken into account using appropriate methods of analysis.
- b) The data from which the origin of the uncertainty was determined shall be documented and the assumptions made for the determination of the uncertainty shall be specified and documented.
- c) Measurement uncertainty shall be taken into account when statements of compliance with specifications are made;

² See, for example, NCSLI RP-1 "Establishment & Adjustment of Calibration Intervals" (2010).

- d) At a minimum, all uncertainty analysis shall take into consideration the following standard contributors and documentation of the consideration shall be made.
 - 1. Repeatability;
 - 2. Resolution³;
 - 3. Reference measurement standard uncertainty;
 - 4. Reference measurement standard stability;
 - 5. Environmental factors.
- 8. Reference measurement standards shall be recalibrated at appropriate intervals to ensure that the reference value is reliable. The CAB shall have a policy or procedure for establishing and changing calibration intervals which shall be based on the historical behavior of the reference measurement standard⁴.

(T5) Accredited (Endorsed) Calibration Certificates (or equivalent)

A2LA requires that:

- 1. The external calibration of all reference measurement standards and M&TE having a significant effect on the accuracy or validity of the result of the accredited test, calibration or sampling shall be recorded in a calibration certificate or report and shall include:
 - a) An endorsement by the recognized AB's symbol (or other reference to accredited status by a specific, recognized AB); and
 - b) The accreditation certificate number for A2LA-accredited CABs, or an indication of the type of entity accredited for CABs accredited by MRA signatory ABs; and
 - c) A statement of traceability; and
 - d) A statement of the measurement result and the associated uncertainty that meets the requirements of <u>ILAC P14:09/2020 ILAC Policy for Uncertainty in Calibration</u> These uncertainties shall include an explanation of the meaning of the uncertainty statement and be reported as the expanded uncertainty with a defined coverage factor, k (typically k = 2) and the confidence interval (typically to approximate the 95% confidence level).
- 2. When Test Uncertainty Ratios (TURs) are reported, they shall be calculated using the expanded uncertainty of the measurement, not the "collective uncertainty of the measurement standards"; these implicit uncertainty statements shall be accompanied by words to the effect that the TUR was calculated using the expanded measurement uncertainty. In addition, the coverage factor and confidence interval shall also be stated (e.g. expressed at approximately the 95% confidence level using a coverage factor of k=2). Please note that a TUR does not satisfy the requirement of T5 1 d) above as you must report the associated uncertainty with the measurement result.
- 3. For external calibrations performed by an NMI, these shall be recorded in a calibration certificate or report and shall include:
 - a) An endorsement by the NMI; and
 - b) A statement of the measurement result; and
 - **c)** The associated measurement uncertainty.

(T6) Accredited (Endorsed) Reference Material Certificates

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³ It should be noted that uncertainty components, such as resolution, may also contribute to other components such as repeatability. Therefore, simply combining all components on an equal basis could result in an overstatement of the measurement uncertainty.

⁴ See, for example, NCSLI RP-1 "Establishment & Adjustment of Calibration Intervals" (2010).

- 1. Accredited reference materials shall be accompanied by a certificate or product information sheet meeting the requirements of ISO 17034 Appendix A. This certificate or product information sheet shall also include:
 - a) An endorsement by the AB's symbol (or other reference to accredited status by a specific, recognized AB); and
 - b) The accreditation certificate number for A2LA-accredited CABs or an indication of the type of entity accredited for CABs accredited by MRA signatory ABs.
- 2. Reference materials obtained from an NMI shall include an endorsement by the NMI.

<u>Note</u>: It is common practice for a reference material producer to package their reference materials under a different organization's name. In these instances, it is possible for the reference materials to meet A2LA P102 if the accompanying certificate includes reference to the specific, recognized accreditation body, and the accreditation certificate number.

DOCUMENT REVISION HISTORY

Date	Description
2/9/2021	Updated to include latest revision of ILAC P10 and P14
	Updated to revision history to include last published date.
	> Removed reference to Guide 34.
09/13/21	Rewrite of document for unified traceability policy to apply to all types of
	conformity assessment body. The fundamental requirements for
	metrological traceability remain unchanged.
11/28/22	Updated reference to ILAC P10 to match ILAC website
	➤ Updated link for G135
	> Editorial updates