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P102 - A2LA Policy on Metrological Traceability

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Scope and Field of Application

The quality of products and services is becoming increasingly 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. Relevant definitions are also included. These policies are designed to ensure compliance with [P10:01/2013 ILAC Policy on Traceability of Measurement Results](#). This document is intended for all A2LA-accredited and enrolled calibration and testing laboratories, inspection bodies, proficiency testing providers, and reference material producers. Where these policies differ from an ISO/IEC 17025 or ISO/IEC 17020 requirement or another A2LA Requirement, the more stringent requirement applies.

Specific requirements found in this Policy are numbered as in “(T1)”.

A2LA NOTE 1: A separate document ([P113 - A2LA Policy on Measurement Traceability for Life Sciences Testing Laboratories](#)) has been developed as A2LA’s official interpretation of P102 in the life sciences area specifically. P113 serves as the primary measurement traceability policy for “Life Sciences” testing laboratories (replacing P102 – A2LA Policy on Metrological Traceability). It is meant to explain how measurement traceability may be achieved and how it may be demonstrated for biological, environmental and chemical testing laboratories and accomplishes this through creating a mechanism for determining when such materials and calibrations are required by the laboratories in order to meet the reporting requirements of their customers.

A2LA NOTE 2: A separate document, [P102a - Policy on Reference Material Traceability for Life Sciences Testing Laboratories \(pdf\)](#), has been developed for certain types of reference materials. In the case of Category II and Category III materials P102a serves as the primary measurement traceability policy for “Life Sciences” testing laboratories (replacing *P102 – A2LA Policy on Metrological Traceability*).

A2LA NOTE 3: Separate documents ([P905 - A2LA Metrological Traceability Policy for ISO 15189 Laboratory Testing](#) and *P705 – A2LA Metrological Traceability Policy for CLIA/ISO 15189 Laboratory Testing*) have been developed as A2LA’s official

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interpretation of P102 in the clinical laboratory testing (ISO 15189 and CLIA) area. P905 and P705 serve as the primary measurement traceability policies for clinical testing laboratories (replacing *P102 – A2LA Policy on Metrological Traceability*).

Definition of terms:

Accreditation Body (AB) (ISO/IEC 17000 clause 2.6): Authoritative body that performs accreditation.

Accredited (A2LA): When a Conformity Assessment Body (CAB) is granted accreditation by an accrediting body (e.g. A2LA) that is a signatory to the ILAC mutual recognition arrangement (MRA).

Bureau International des Poids et Mesures (BIPM)

<http://www.bipm.org/en/home/>): The task of the BIPM is to ensure world-wide uniformity of measurements and their traceability to the International System of Units (SI). It does this with the authority of the Convention of the Metre, a diplomatic treaty between fifty-five nations, and it operates through a series of Consultative Committees, whose members are the national metrology laboratories of the signatory States, and through its own laboratory work.

The BIPM carries out measurement-related research. It takes part in, and organizes, international comparisons of national measurement standards, and it carries out calibrations for Member States.

BIPM Key Comparison Database (KCDB) (<http://kcdb.bipm.org/>): supports the Mutual Recognition Arrangement of the CIPM (CIPM MRA) of national measurement standards and of calibration and measurement certificates issued by national metrology institutes. The technical basis of the arrangement is the set of results obtained in the course of time through key comparisons carried out by the [Consultative Committees](#) of the CIPM, the BIPM and the regional metrology organizations ([RMOs](#)), and published by the BIPM and maintained in the [key comparison database](#). Detailed technical provisions are given in the [Technical Supplement](#) to the arrangement.

Calibration (VIM3 clause 2.39): 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, uses this information to establish a relation for obtaining a measurement result from an indication.

VIM NOTE 1 A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.

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VIM NOTE 2 Calibration should not be confused with adjustment of a measuring system, often mistakenly called “self-calibration”, nor with verification of calibration.

VIM NOTE 3: Often, the first step alone in the above definition is perceived as being calibration.

Calibration and Measurement Capability (CMC): A CMC per the CIPM MRA-D-04, *Calibration and Measurement Capabilities in the context of the CIPM MRA* is a calibration and measurement capability available to customers under normal conditions:

a) as described in the laboratory’s scope of accreditation granted by a signatory to the ILAC Arrangement; or

b) as published in the BIPM key comparison database (KCDB) of the CIPM MRA.

Calibration and Measurement Capability Uncertainty (A2LA): The uncertainty of measurement described on a scope of accreditation under normal conditions.

Certified Reference Material (ISO Guide 34:2009): Reference material, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA)¹: National Metrology Institutes have been collaborating and carrying out international comparisons of their national measurement standards for more than one hundred years. However, the *ad hoc* recognition that has resulted is now not considered to be sufficient, hence the move towards the MRA.

At a meeting held in Paris on 14 October 1999, the directors of the national metrology institutes (NMIs) of thirty-eight Member States of the BIPM and representatives of two international organizations signed a Mutual Recognition Arrangement (CIPM MRA) for national measurement standards and for calibration and measurement certificates issued by NMIs. A number of other institutes have signed since then.

This MRA is a response to a growing need for an open, transparent and comprehensive scheme to give users reliable quantitative information on the comparability of national metrology services and to provide the technical basis for wider agreements negotiated for international trade, commerce and regulatory affairs.

NMIs who sign an MRA with the CIPM participate in the measurement comparison activities of the BIPM.

¹ <http://www.bipm.org/en/cipm-mra/> 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 (<http://kcdb.bipm.org/>).

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The results of over 200 world-wide participants in key comparisons, such as length, mass, thermometry, electricity, magnetism, ionizing radiation etc., are published in the KCDB and is the basis of traceability of the SI conferred to an NMI from the BIPM.

Conformity Assessment Body (CAB) (ISO17011 2004-09-01): a body that performs conformity assessment services and that can be the object of accreditation.

Designated Institute: Where another institute is responsible for certain national measurement standards and associated services disseminating traceability not covered by the activities of the “traditional” NMI².

ILAC Mutual Recognition Arrangement (MRA) (<http://ilac.org/ilac-mra-and-signatories/>): The ILAC Arrangement provides significant technical underpinning to international trade. The key to the Arrangement is the global network of accredited testing and calibration laboratories and inspection bodies that are assessed and recognized as being competent by ILAC Arrangement signatory accreditation bodies. The signatories have, in turn, been peer-reviewed and shown to meet ILAC's criteria for competence. Now that the ILAC Arrangement is in place, governments can take advantage of it to further develop or enhance trade agreements. The ultimate aim is increased use and acceptance by industry as well as government of the results from accredited laboratories and inspection bodies, including results from facilities in other countries. In this way, the free-trade goal of "a product tested or inspected once and accepted everywhere" can be realized.

Measurand (VIM3 clause 2.3): Quantity intended to be measured.

In-house Calibration (A2LA): The calibration of an A2LA-Accredited CAB's own reference 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.

Note 1: In-house calibration can be performed by testing and/or calibration laboratories.

Note 2: For these measurements to be traceable (T4) of this document applies.

Internal Calibration (A2LA): The calibration of an A2LA-Accredited CAB's own reference standards or measuring and test equipment by the laboratory's own staff for which the calibration measurement parameters **ARE** included on their scope of accreditation.

Note 1: For these measurements to be traceable (T1) and (T5) of this document applies.

² Designate Institutes in the CIPM MRA, version 2, March 2014

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Measurement Uncertainty (VIM3 clause 2.26): Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

Metrological Traceability (VIM 3 clause 2.41): 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.

Metrological Traceability Chain (VIM 3 clause 2.42): Sequence of measurement standards and calibrations that are used to relate a measurement result to a reference.

Metrological Traceability to a Measurement Unit (VIM 3 clause 2.4.3): Metrological traceability where the reference is the definition of a measurement unit through its practical realization.

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

Mutually Recognized Accreditation Body: An accreditation body that is a signatory to the ILAC MRA.

National Metrology Institute (NMI) (Derived from Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability: 11/09/2011): A national laboratory that is tasked with the realization, maintenance, improvement and dissemination of the SI units via traceable calibration and measurement services based on their Calibration and Measurement Capabilities (CMCs) for the metrology activities (ex. fundamental metrology, applied, technical or industrial metrology and legal metrology) within a particular country. This includes designated institutes that are empowered by an NMI for specified functions.

Reference Material (ISO Guide 34:2009): 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.

Reference Standard (ISO Guide 30:1992): Standard, generally having the highest metrological quality available at a given location or in a given organization, from which subsequent measurements are derived.

Traceability (VIM3 clause 2.41): Property of a measurement result whereby the result can be related to a reference through documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

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I. A2LA Metrological Traceability Policies

(T1) External Calibration Service

For equipment and reference 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 MRA³; 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 (see Policy: 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 standard(s) used to perform the calibration;
 - c) The CAB maintains evidence that the reference standard(s) noted on the calibration certificate are traceable to the SI through NIST (or equivalent) or an accredited laboratory;
 - d) The CAB maintains evidence of the calibration interval⁴ for the measuring and test equipment (M&TE) or reference standard.

³ 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 (<http://kcdb.bipm.org/>).

⁴ See, for example, NCSLI RP-1 "Establishment & Adjustment of Calibration Intervals" (3/96).

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Policy: Special Circumstances

A2LA recognizes that there are circumstances where a non-accredited laboratory must be used even when an accredited laboratory is available to perform the calibration. An exception to (T1) is allowed under the following special circumstances:

1. Cases where the reference standard or M&TE warranty from the Original Equipment Manufacturer (OEM) will be deemed null and void should another calibration provider other than the OEM be used. Evidence of the warranty shall be maintained by the CAB. In this case (T2.2) still applies.
2. Cases where the calibration must be performed by the OEM since proprietary software is needed to perform the calibration which is not made available by the OEM to the public through policy or pricing. Evidence that use of such software is required for the performance of the calibration shall be maintained by the CAB. In this case (T2.2) still applies.
3. Cases where a piece of equipment is newly purchased with a non-accredited OEM calibration or where a piece of equipment is repaired and provided with a non-accredited OEM calibration. Where an accredited calibration is available from the OEM the laboratory shall obtain the accredited calibration.

Policy: Exceptions and Calibration Interval

Exceptions to A2LA (T1) are valid for the length of the calibration interval. After the interval is complete another search for an accredited provider shall be conducted and documented.

In cases where the calibration interval of the reference standard or M&TE is set at greater than two years, and it exceeds the manufacturer's recommended interval, documented evidence (e.g. records of intermediate checks) indicating that the reference standard or M&TE continues to remain within the manufacturer (or applicable) specification is also required.

Note: this does not apply for reference standards or M&TE where traceability is established through the use of certified reference materials, intrinsic standards or consensus standards.

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(T3) Reference Materials⁵

When possible, all reference materials shall be obtained from:

1. An Accredited⁶ reference material producer; or,
2. A National Metrology Institute⁷ (NMI) or designated institute.

(T4) In-house Calibrations

An in-house calibration is the calibration of an A2LA accredited CAB's own reference 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.

Note: This should not be confused with an internal calibration. 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;
3. 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 NMI⁷ for the reference standard used to perform the in-house calibration;

⁵ See also *P102a – Policy on Reference Material Traceability for Life Sciences Testing Laboratories*.

⁶ An accredited reference material producer is one that is accredited to ISO Guide 34 by an AB that is recognized by the Asia Pacific Laboratory Accreditation Cooperation (APLAC) www.aplac.org for accrediting reference material producers.

⁷ 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 (<http://kcdb.bipm.org/>).

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6. Where available, the CAB shall use reference materials from accredited⁸ reference material producers or an NMI⁷;
7. Measurement uncertainty:
 - a) The CAB shall have and apply a procedure for evaluating measurement uncertainty;
 - 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;
 - d) At a minimum, all uncertainty analysis shall take into consideration the following contributors and documentation of the consideration shall be made.
 1. Repeatability;
 2. Resolution⁹;
 3. Reference standard uncertainty;
 4. Reference standard stability;
 5. Environmental factors

Note: It is recommended to also consider reproducibility per A2LA [R205 - Specific Requirements: Calibration Laboratory Accreditation Program](#).

8. Reference 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 standard¹⁰

(T5) Accredited (Endorsed) Calibration Certificates (or equivalent)¹¹

A2LA requires that:

1. The external calibration of all reference standards and M&TE having a significant effect on the accuracy or validity of the result of the accredited test, calibration or

⁸ An accredited reference material producer is one that is accredited to ISO Guide 34 by an AB that is recognized by the Asia Pacific Laboratory Accreditation Cooperation (APLAC) www.aplac.org for accrediting reference material producers.

⁹ 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.

¹⁰ See, for example, NCSLI RP-1 "Establishment & Adjustment of Calibration Intervals" (3/96).

¹¹ See Appendix A for an example accredited (endorsed) calibration certificate.

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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 uncertainty¹² that meets the requirements of [ILAC P14:01/2013 ILAC Policy for Uncertainty in Calibration](#). 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).
 3. For external calibrations performed by an NMI¹³, these shall be recorded in a calibration certificate or report and shall include:
 - a) An endorsement by the NMI¹³; and
 - b) A statement of the measurement result; and
 - c) The associated measurement uncertainty.

Policy: Statements of Traceability

This statement will affirm that the calibration reported was conducted using standards whose values are traceable to an appropriate national, international, intrinsic, or mutual consent standard. For example, if the traceability chain for a given CAB originates at NIST, then the statement will affirm that “This calibration was conducted using standards traceable to the SI through NIST”, or words to that effect.

¹² See A2LA R205 for exceptions on including the measurement uncertainty.

¹³ 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 (<http://kcdb.bipm.org/>).

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Accredited calibration certificates and reports which do not contain equivalent statements of traceability, or which only refer to NIST report of test numbers as evidence of traceability are insufficient to demonstrate measurement traceability and do not meet this traceability policy.

Policy: Measurement Uncertainty

Measurement uncertainty analysis is required for all calibrations and dimensional tests. A2LA requires measurement uncertainty to be calculated in accordance with the JCGM 100:2008 [*Evaluation of measurement data – Guide to the expression of uncertainty in measurement*](#) (GUM).

For applicability of measurement uncertainty analysis in testing see A2LA [P103 - Policy on Estimating Measurement Uncertainty for Testing Laboratories](#) and the relevant Annexes [P103a - Annex: Policy on Estimating Measurement Uncertainty for Automotive & Materials Testing Labs \(pdf\)](#); [P103b - Annex: Policy on Estimating Measurement Uncertainty for Life Sciences Testing Lab](#); [P103c - Annex: Policy on Estimating Measurement Uncertainty for Electro-Mechanical Testing Labs](#); [P103d - Annex: Policy on Estimating Measurement Uncertainty for Construction Materials & Geotechnical Testing Labs](#); [P103e - Annex: Policy on Estimating Measurement Uncertainty for Forensic Conformity Assessment Bodies](#)

An example of an explanation of the meaning of the uncertainty statement might be the statement “Reported uncertainties represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage factor of $k = 2$ ”. Statements of uncertainty which do not specify at least the coverage factor and the confidence level are incomplete and they are inadequate for the purpose of demonstrating that measurement traceability has been achieved.

Policy: Implicit Statement of Uncertainty

It is often the case that a calibration certificate will contain the statement “in tolerance”, or words to that effect, along with a statement to the effect that the measurement uncertainty does not exceed a certain fraction of the tolerance. Such fractions are often called “test uncertainty ratios”, TURs for short. Uncertainty statements phrased in terms of TURs are implicit statements of the uncertainty: knowing the tolerance ratio allows one to determine the largest possible value of the measurement uncertainty. Implicit statements of uncertainty are acceptable on accredited calibration certificates as long as the measurement uncertainty and the measurement results are also provided.

(T6) Accredited (Endorsed) Reference Material Certificates

1. Accredited¹⁴ reference materials shall be accompanied by a certificate meeting the requirements of ISO Guide 31. This certificate shall also include:

¹⁴ Accredited reference materials are those provided from a reference material producer that is accredited to ISO Guide 34 by an AB that is recognized by the Asia Pacific Laboratory Accreditation Cooperation (APLAC) www.aplac.org.

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- 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 NMI¹⁵ shall include an endorsement by the NMI¹⁵.

Note: 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.

(T7) Intrinsic Standards

Where an intrinsic standard or system is used as a reference standard, the following requirements apply:

1. Direct intrinsic standard or system-to-intrinsic standard or system comparison with NIST or an accredited laboratory shall be conducted at appropriate intervals to ensure the correct realization of the measurand;
2. Documented calibration history of the device used to measure differences between intrinsic standard or system and unknown values shall be maintained;
3. Documented calibration history of the intrinsic standard or system components (e.g., the time base of the reference frequency counter in a Josephson voltage array system) shall be maintained;
4. Documented evidence of periodic checks on system precision and stability (e.g., leakage currents, ground loops, thermal emf's, step integrity, trapped magnetic flux, noise, and microwave power impinging on a Josephson voltage array) shall be maintained.

Note: For those laboratories using saturated salt solutions for the purposes of traceability, those solutions mixed on demand from reagent grade salts and distilled water may be treated as comparable to an intrinsic standard. In these instances, the laboratories are not required to meet item (1) as listed above, but must be able to provide evidence of meeting (2) through (4).

¹⁵ 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 (<http://kcdb.bipm.org/>).

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Policy: Consensus Standards

The use of specified methods and/or consensus standards are deemed traceable when they are clearly described and agreed by all parties concerned in the contract for service and where participation in a suitable program of interlaboratory comparisons (where possible) is successfully completed,

(T8) Dimensional Testing

A2LA requires that the dimensional testing laboratory shall comply with A2LA [R205 - Specific Requirements: Calibration Laboratory Accreditation Program](#) in cases where the dimensional artifact serves as a link in the traceability chain.

Policy: Achieving Traceability through Dimensional Testing

Traceability for measuring and test equipment is typically established through the procurement of accredited calibration service. In cases where a dimensional artifact serves as a link in the traceability chain, such as when it will be used by the owner to measure another item, traceability is also established. Therefore it is necessary for the dimensional testing laboratory to be evaluated for compliance with A2LA R205.

Where a testing laboratory performing dimensional testing is deemed compliant with A2LA R205 and this policy document, the accredited test report issued serves as the de facto calibration certificate.

For example, a mechanical testing CAB that performs dimensional testing and that issues an accredited test report or certificate containing appropriate statements of measurement results, measurement uncertainty, and traceability, in accordance with the requirements of ISO/IEC 17025:2005 Section 5.10, A2LA R205 and this policy document can be considered as having produced a traceable calibration regardless of the title of the report issued. This can be particularly useful for complex dimensional artifacts that most calibration laboratories will not include on their Scope of Accreditation.

See APPENDIX D from A2LA [R205 - Specific Requirements: Calibration Laboratory Accreditation Program](#) and APPENDIX B from [G118 - Guidance for Defining the Scope of Accreditation for Calibration Laboratories](#) for more information.

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II. General Policies

Policy: Calibration Scopes of Accreditation

Scopes of Accreditation are documents that define the specific measurements an organization is accredited to make. In addition, the Scope defines the ranges of the accredited measurand along with the associated best measurement capability (under normal conditions) expressed as an uncertainty for each measurand and range.

Before placing work with an accredited organization, it is important that the customer request a copy of the organization's Scope (*not the Certificate of Accreditation*) so that the customer can ensure that the organization is accredited to perform the needed measurements. In addition, customers shall ensure that the organization's measurement uncertainties are suitable for their needs.

Organizations are not permitted to claim a CMC uncertainty on their Scope of Accreditation that is smaller than the CMC uncertainty claimed by the NMI (as stated in the KCDB listed on the BIPM website, www.bipm.org) through which traceability is achieved unless allowance is made by A2LA. A2LA may accept uncertainties smaller than the NMI's "commercial" uncertainty that is provided to its own customers on a case-by-case basis.

Policy: Acceptable Accreditors of Calibration and Testing Providers

Currently, the primary mutual recognition agreements (MRAs) among accrediting bodies are the International Laboratory Accreditation Cooperation (ILAC¹⁶), the Asia-Pacific Laboratory Accreditation Cooperation (APLAC¹⁷), and the Inter-American Accreditation Cooperation (IAAC¹⁸). As signatories to these MRAs, A2LA is committed to promoting the recognition and acceptance of accreditations granted by its fellow signatories.

A2LA will recognize accredited test and calibration results reported by laboratories that are accredited by ABs that are a signatory to the above noted MRAs as satisfying the requirements pertaining to measurement uncertainty as long as the results also meet this policy document.

A2LA recognizes reference material certificates that are issued by reference material producers that are accredited by the accreditation bodies recognized by the APLAC MRA. Furthermore it is required that the results be reported in a certificate meeting ISO Guide 31 and endorsed by the AB's symbol (or which other reference to accredited status by a specific, recognized AB) and an indication of the accreditation certificate number assigned by the AB.

¹⁶ <http://www.ilac.org/>

¹⁷ <http://www.aplac.org>

¹⁸ <http://iaac.org.mx>

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Policy: NIST Test Report Numbers and Traceability

The NIST Calibration Program¹⁹ often receives calls to verify the authenticity of a NIST Report of Test numbers appearing on another organization's report. Although NIST can verify the authenticity of its report numbers, having an authentic number does not provide assurance or evidence that the measurement value provided by another organization is traceable. Not only should there be an unbroken chain of comparisons, each measurement should be accompanied by a statement of uncertainty associated with the farthest link in the chain from NIST, that is, the last facility providing the measurement value. NIST does not have that information; only the facilities that provided the measurement values to the customer can provide the associated uncertainties and describe the traceability chain.

To establish an audit trail for traceability, a proper calibration result should include: the assigned value, a stated uncertainty, identification of the standards used in the calibration, and the specification of any environmental conditions of the calibration where correction factors should be applied, if the standard or equipment were to be used under different environmental conditions.

Similarly, it is the policy of the National Conference of Standards Laboratories International (NCSLI) that test report numbers issued by NIST are intended to be used solely for administrative purposes. Although they are often used to uniquely identify documents which bear evidence of traceability, test report numbers shall not be used nor required as proof of the adequacy or traceability of a test or measurement²⁰.

It should also be noted that nationally and internationally recognized standards dealing with test and measurement quality requirements such as ANSI/NCSL Z540-1, ISO 10012, ISO/IEC 17025 and the ISO9000 series do not require the use or reporting of NIST test report numbers to establish traceability.

Consequently, A2LA neither requires nor accepts the presence of NIST test report numbers on test or calibration reports as sufficient evidence of the traceability of a measurement result.

¹⁹ http://www.nist.gov/traceability/nist_traceability_policy_external.cfm.

²⁰ NCSLI Position Statement 96-1.

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III. Summary of Specific Requirements

(T1) External Calibration Service

All measuring and test equipment (M&TE) and reference standards having a significant effect on the accuracy or validity of the result of the accredited test, calibration or sampling shall be calibrated before being put into service. The calibration shall be conducted by:

1. A calibration laboratory accredited to ISO/IEC 17025 by A2LA or a mutually recognized Accreditation Body; or
2. A National Metrology Institute (NMI) including designated institutes whose services are covered by the CIPM MRA²¹; 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 Requirements

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 (see Policy: 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 standard(s) used to perform the calibration.
 - c) The CAB maintains evidence that the reference standard(s) noted on the calibration certificate are traceable to the SI through NIST (or equivalent²¹) or an accredited laboratory;
 - d) The CAB maintains evidence of the calibration interval for the measuring and test equipment (M&TE) or reference standard.

²¹ 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 (<http://kcdb.bipm.org/>).

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(T3) Reference Materials

When possible, all reference materials shall be obtained from:

1. An Accredited²² reference material producer; or,
2. A National Metrology Institute²³ (NMI) or designated institute.

(T4) In-house Calibrations

An in-house calibration is the calibration of an A2LA accredited CAB's own reference 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.

Note: This should not be confused with an internal calibration. 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;
3. 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 NMI²⁴ for the reference standard used to perform the in-house calibration;
6. Where available, the CAB shall use reference materials from accredited²² reference material producers or an NMI²⁵;

²² An accredited reference material producer is one that is accredited to ISO Guide 34 by an AB that is recognized by the Asia Pacific Laboratory Accreditation Cooperation (APLAC) www.aplac.org for accrediting reference material producers.

²³ See also *P102a – Policy on Reference Material Traceability for Life Sciences Testing Laboratories*.

²⁴ 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 (<http://kcdb.bipm.org/>).

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7. Measurement uncertainty:

- a) The CAB shall have and apply a procedure for evaluating measurement uncertainty;
- 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;
- d) At a minimum, all uncertainty analysis shall take into consideration the following contributors and documentation of the consideration shall be made:
 1. Repeatability;
 2. Resolution²⁵;
 3. Reference standard uncertainty;
 4. Reference standard stability;
 5. Environmental factors;

Note: It is recommended to also consider reproducibility per A2LA [R205 - Specific Requirements: Calibration Laboratory Accreditation Program](#).

8. Reference standards shall be recalibrated at appropriate intervals to ensure that the reference value is reliable;
9. 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 standard²⁶

(T5) Accredited (Endorsed) Calibration Certificates (or equivalent)²⁷

A2LA requires that:

1. The external calibration of all M&TE and reference standards 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 AB's symbol (or other reference to accredited status by a specific, recognized AB); and

²⁵ 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.

²⁶ See, for example, NCSLI RP-1 "Establishment & Adjustment of Calibration Intervals" (3/96).

²⁷ See Appendix A for an example accredited (endorsed) calibration certificate.

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- 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 uncertainty²⁸ that meets the requirements of [ILAC P14:01/2013 ILAC Policy for Uncertainty in Calibration](#). These uncertainties shall 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).
 3. For those external calibrations performed by an NMI²⁹, 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

1. Accredited³⁰ reference materials shall be accompanied by a certificate meeting the requirements of ISO Guide 31. This certificate 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.

²⁸ See A2LA R205 6.4.1 for exceptions on including the measurement uncertainty.

²⁹ 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 (<http://kcdb.bipm.org/>).

³⁰ Accredited reference materials are those obtained from a reference material producer that is accredited to ISO Guide 34 by an AB that is recognized by the Asia Pacific Laboratory Accreditation Cooperation (APLAC) www.aplac.org.

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Note: 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.

(T7) Intrinsic Standards

Where an intrinsic standard or system is used as a standard, the following requirements apply:

1. Direct intrinsic standard or system-to-intrinsic standard or system comparison with NIST or an accredited laboratory shall be conducted at appropriate intervals to ensure the correct realization of the measurand;
2. Documented calibration history of the device used to measure differences between intrinsic standard or system and unknown values shall be maintained;
3. Documented calibration history of the intrinsic standard or system components (e.g., the time base of the reference frequency counter in a Josephson voltage array system) shall be maintained;
4. Documented evidence of periodic checks on system precision and stability (e.g., leakage currents, ground loops, thermal emf's, step integrity, trapped magnetic flux, noise, and microwave power impinging on a Josephson voltage array) shall be maintained.

Note: For those laboratories using saturated salt solutions for the purposes of traceability, those solutions mixed on demand from reagent grade salts and distilled water may be treated as comparable to an intrinsic standard. In these instances, the laboratories are not required to meet item (1) as listed above, but must be able to provide evidence of meeting (2) through (4).

(T8) Dimensional Testing

A2LA requires that the dimensional testing laboratory shall comply with A2LA [R205 - Specific Requirements: Calibration Laboratory Accreditation Program](#) in cases where the dimensional artifact serves as a link in the traceability chain.



APPENDIX A: Example Calibration Certificate

CALIBRATION CERTIFICATE

ABC Company
1234 Main Street
Anytown, ME 00000

Description of Item: Famous Widget

Environmental Conditions: 25 °C

As Found: 1.0 inch
As Left: 1.0 inch

Reference Standards Used: Steel Ruler

Customer:
XYZ Company
1234 Circle Court,
Anytown, AL 00001

Serial Number:0001 Date of Calibration: 01/01/2014

Measurement Uncertainty: ±0.025 inch

Report Number: 1234



Cert# 0000.01

T5.1.a

T5.1.b

T5.1.c

T5.1.d

T5.2

This calibration was conducted using standards traceable to the SI through NIST. Reported uncertainties represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage factor of k = 2.

TUR reported as 4:1 and the uncertainty ratio was calculated using the expanded measurement uncertainty expressed at approximately the 95% confidence level using a coverage factor of k=2.

Authorized by: John Q. Public

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APPENDIX B: Document Revision History

Date	Description
5/7/2014	<ul style="list-style-type: none"> • Editorial changes as a result of A2LA P101 change to R105 (clauses T1.a., T2.a.2., T2.d.2). • T1.a, 2nd bullet, deleted ‘R205c’ • T1.b, 1st bullet, deleted ‘in combination with ISO/IEC 17025’ • Added Annex P103e to footnote 6 • References to P605 updated to P905/P705.
3/5/2015	<ul style="list-style-type: none"> • Title change to “A2LA Policy on Metrological Traceability” • Scope and Field updated for metrological traceability concepts • Addition of many new definition of terms (only calibration was previously defined) • T1: <ul style="list-style-type: none"> ✓ updated to include standards and equipment having a significant effect on the accuracy or validity of the result ✓ T1.3 and reference to T9 removed ✓ Changed website to NIST.gov ✓ Added a note on traceability via A2LA scope of accreditation • T2: New Section pertaining to exceptions on external calibration service • T3 renamed for reference materials



Date	Description
	<ul style="list-style-type: none">• T4 renamed for in-house calibrations:<ul style="list-style-type: none">✓ Redefined in-house calibration✓ Removed paragraph 2, 3 and the last paragraph✓ Changed “must” to “shall”✓ Changed record retention minimum to the time between renewal assessments✓ Added minimum contributor requirements for measurement uncertainty✓ Changed requirement for the calibration interval as needing either a policy or procedure✓ Added a note on traceability via an A2LA scope of accreditation✓ Moved T9 elements to T4• T5 renamed for accredited (endorsed) calibration certificates (or equivalent):<ul style="list-style-type: none">✓ updated to include standards and equipment having a significant effect on the accuracy or validity of the result✓ updated to include measurement result and uncertainty that meets ILAC P14✓ Moved old T4, T5, T6 and T7 to T5• Acceptable Accreditors of Calibration and Testing Providers:<ul style="list-style-type: none">✓ Removed paragraph 1✓ Revised paragraph 3 & 4• Revised to Use of NIST Test Report Numbers as Evidence of Traceability header to NIST Test Report Numbers and Traceability• Revised the Summary of Specific Requirements for all the noted changes• Added Appendix A Example Calibration Certificate• Changed old Appendix A to Appendix B
5/14/15	<ul style="list-style-type: none">• Clarified T5 and T6 with regard to information required with the AB’s accreditation symbol.



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6/9/16

- T1 changed the first paragraph to “For equipment and reference standards that must be calibrated, the calibration shall be conducted by...”
- Removed the implementation periods
- Removed (T2)2.b.2
- Removed (T4)7.b, first sentence
- Added a note to (T4)7.d
- Added “or where a piece of equipment is repaired and provided with a non-accredited OEM calibration. Where an accredited calibration is available from the OEM the laboratory shall obtain the accredited calibration” to “Policy: Special Circumstances”