P102 - A2LA Policy on Measurement Traceability

October 2008

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Scope and Field of Application[1]

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.

This policy document is intended to explain the concept of measurement traceability, how it can be achieved, and how it can be demonstrated. A2LA requirements pertaining to measurement traceability are described. This document is intended for all A2LA-accredited and enrolled calibration and testing laboratories, inspection bodies, proficiency testing providers, and reference material producers.

Specific requirements found in this Policy are in ***italic*** type and numbered as in "***(T1)***".

NOTE: A separate document (P102a – Policy on Reference Material Traceability for Life Sciences Testing Laboratories) has been developed as A2LA's official interpretation of P102 in the life sciences area specifically. P102a explains how biological, drug, and chemical materials are expected to be processed, and how they can be used within life sciences laboratories to meet traceability requirements. P102a should be consulted in conjunction with P102 by all laboratories within the life sciences discipline.

Introduction- the Concept of "Traceability"

Traceability is 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[2]. 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.

Traceability is characterized by six essential elements[3]:

1. *an unbroken chain of comparisons*: going back to stated references acceptable to the parties, usually a national or international standard;
2. *measurement uncertainty*: 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

[1] See, for example, EA-4/07, *Traceability of Measuring and Test Equipment to National Standards.*
[2] *ILAC P-10:2002, Traceability of Measurement Results.*
[3] *ibid*

that an overall uncertainty for the whole chain may be calculated or estimated;

3. *documentation*: each step in the chain must be performed according to documented and generally acknowledged procedures; and the results must be recorded;
4. *competence*: the laboratories or bodies performing one or more steps in the chain must supply evidence for their technical competence (e.g. by demonstrating that they are accredited);
5. *reference to SI units*: the chain of comparisons must, where possible, end at primary standards for realization of the SI units;
6. *calibration intervals*: calibrations must be repeated at appropriate intervals; the length in of these intervals will depend on a number of variables (e.g. uncertainty required, frequency of use, way of use, stability of equipment).

(T1) A2LA requires that:

(a) All calibrations and verifications of measuring and test equipment and reference standards, be conducted by:

- ***A calibration laboratory accredited to ISO/IEC 17025 by a mutually recognized Accreditation Body; or***

- ***A recognized National Metrology Institute (NMI). Recognition of the NMI is based on the Institute being a signatory to the CIPM (Comité International des Poids et Mesures) MRA (Mutual Recognition Arrangement) and supporting the measurement comparison activities of the CIPM. A listing of these recognized Institutes can be found at http://kcdb.bipm.org/default.asp; or***

- ***A mechanical testing laboratory accredited by A2LA to ISO/IEC 17025 and found to meet the A2LA Calibration Program Requirements (as indicated on their Mechanical Scope of Accreditation). An accredited test report containing appropriate statements of measurement results, measurement uncertainty, and traceability can be considered to satisfy traceability requirements; or***

- ***A laboratory accredited by A2LA to ISO/IEC 17025 and found to meet the T9 requirements of this document for their in-house calibrations.***

(b) When possible, all reference materials shall be obtained from:

- ***A reference material producer accredited to ISO Guide 34 in combination with ISO/IEC 17025 by a recognized Asia Pacific Laboratory Accreditation Cooperation (APLAC) signatory recognized for accrediting reference material producers; or***

- ***A recognized National Metrology Institute (NMI).***

(T2) For those external calibrations and verifications, these must be recorded in a calibration certificate or report endorsed by the recognized Accreditation Body's symbol (or otherwise makes reference to accredited status by a specific, recognized accreditation body) with an indication of the type of entity that is accredited (e.g., via an accreditation certificate number, inclusion of "calibration laboratory" with the symbol, etc.) or endorsed by the National Metrology Institute (NMI). For those internal calibrations and verifications, those requirements outlined in requirement T9 of this document apply. For reference materials, these must be recorded in a certificate meeting the requirements of ISO Guide 31 endorsed by the recognized Accreditation Body's symbol (or otherwise makes reference to accredited status by a specific, recognized accreditation body) with an indication of the type of entity that is accredited or endorsed by the recognized NMI.

(T3) All A2LA-Accredited and enrolled organizations must define their policy for achieving measurement traceability and also for achieving traceability for reference materials if applicable. The policy shall ensure compliance with this policy document.

The Distinction between Calibration and Testing and Achieving Traceability through Dimensional Testing Laboratories

Calibration is defined as the "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"[4]. A test is defined as a "determination of one or more characteristics of an object of conformity assessment, according to a procedure."[5]

In short, "calibration" means determining and documenting the deviation of the indication of a traceable measuring instrument (or the stated value of a material measure) from the conventional "true" value of the measurand. The term "traceability" means a process whereby the indication of a measuring instrument (or a material measure) can be compared, in one or more stages, with a national or international standard for the measurand in question.

Traceability is typically achieved through calibration services. However, in some instances, traceability can be achieved through test results. For example, since A2LA enforces the same requirements on dimensional testing laboratories (including traceability requirements and requirements pertaining to the calculation and reporting of measurement uncertainty) as it does for dimensional calibration laboratories, the distinction between calibration and testing can be lost.

Therefore, a mechanical testing laboratory performing dimensional testing that issues an accredited

[4] *International Vocabulary of Basic and General Terms in Metrology (VIM)*, Definition 2.39.
[5] *ISO/IEC 17000-2004*, Definition 4.2.

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*** and the ***A2LA Calibration Program Requirements*** can be considered as having produced a "calibration" report or certificate for the dimensional artifact in question regardless of the title of the document. This can be particularly useful for complex dimensional artifacts that most dimensional calibration laboratories will not be accredited to calibrate.

Scopes of Accreditation

Scopes of accreditation are documents that define specifically the 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 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 must ensure that the organization's measurement uncertainties are suitable for their needs.

Accredited Calibration and Test Reports

For the purpose of demonstrating measurement traceability, calibration certificates shall, wherever applicable, indicate the traceability to national or international standards of measurement and should provide the measurement result and associated uncertainty of measurement.

Wherever applicable, and when suitable for customer requirements, a statement of compliance with an identified method or procedural specification can be accepted instead of measurement results and associated uncertainties.

Only calibration certificates or reports endorsed by a recognized accreditation body's symbol (or which otherwise makes reference to accredited status by a specific, recognized accreditation body) that is accompanied by an indication of the type of entity accredited (e.g., "calibration laboratory", "reference material producer") are considered to satisfy traceability requirements. By definition, such an endorsed certificate or report will contain an appropriate statement of measurement results and/or a statement of compliance with an identified metrological specification accompanied by an appropriately defined uncertainty statement and a suitable statement of traceability.

Determination and Statement of Uncertainty

A crucial element of the concept of measurement traceability is measurement uncertainty**.**

(T4) Where measurement uncertainty analysis is applicable[6], A2LA requires laboratories to calculate measurement uncertainty in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement." These uncertainties, when reported, 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).

(T5) If a calibration certificate or test report contains a statement of the measurement result and the associated uncertainty, then the uncertainty statement must be accompanied by an explanation of the meaning of the uncertainty statement. An example of such an explanation 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.

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 can be adequate for the purpose of demonstrating measurement traceability since they are implicit statements of the uncertainty: knowing the tolerance ratio allows one to determine the largest possible value of the measurement uncertainty. However, ***(T6) TURs must be calculated using the expanded uncertainty of the measurement, not the "collective uncertainty of the measurement standards"***[7].

(T7) Implicit uncertainty statements must be accompanied by words to the effect that the uncertainty ratio was calculated using the expanded measurement uncertainty. In addition the coverage factor and confidence level must be stated.

Statements of Traceability

(T8) In addition to the information required in the above sections, calibration reports and certificates must contain a traceability statement[8]. 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 laboratory 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.

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[6] Measurement uncertainty analysis is required for all calibrations and dimensional inspections. For applicability of testing, please see the *P103 - Policy on Estimating Measurement Uncertainty for Testing Laboratories* and the relevant Annexes *P103a-P103d*.

[7] This is the language in ANSI/NCSL Z540-1-1994 section 10.2.b.

[8] See ANSI/NCSL Z540-1-1994, section 13.2.q.

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 (see below) are insufficient to demonstrate measurement traceability.

In-house Calibrations[9]

An in-house calibration system ensures that all measuring and test equipment used in a company is calibrated regularly against its own reference standards. The in-house calibration system shall ensure traceability of measurement by having its reference standards calibrated at an accredited calibration laboratory or a national metrology institute.

The nature and scope of the metrological control of in-house calibration is at the discretion of the parent organization. They must be adapted to the particular applications so that the results obtained with the measuring and test equipment are sufficiently accurate and reliable. Accreditation of organizations to perform in-house calibrations is not always necessary to satisfy the requirements of ISO/IEC 17025. However, in light of the definition of measurement traceability, ***(T9) all in-house calibrations must be supported by the following minimal set of elements:***

- ***a) The in-house laboratory must maintain documented procedures for the in-house calibrations and the in-house calibrations must be evidenced by a calibration report, certificate, or sticker, or other suitable method, and calibration records must be retained for an appropriate, prescribed time;***
- ***b) The in-house laboratory must maintain training records for calibration personnel and these records must demonstrate the technical competence of the personnel performing the calibrations: evidence of competence includes, for example, documented training and the results of measurement audits;***
- ***c) The in-house laboratory 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 and/or purchasing reference materials from appropriately accredited reference material producers or an NMI;***
- ***d) The in-house laboratory must have and apply procedures for evaluating measurement uncertainty. Measurement uncertainty shall be calculated for each type of calibration and records of these calculations shall be maintained. (Note: Records of these calculations must be maintained for calibrations done as of 8/1/06.) Measurement uncertainty must be taken into account when statements of compliance with specifications are made;***
- ***e) Reference standards must be recalibrated at appropriate intervals to ensure that the reference value is reliable. Policy and procedures for establishing and changing calibration intervals must be based on the historical behavior of the reference***

[9] See EA-4/07, *Traceability of Measuring and Test Equipment to National Standards.*

***standard*[10].**

It is not always easy to define the precise circumstances under which a given calibration should be considered to be an in-house calibration that is not subject to accreditation requirements. However at least two cases can be distinguished:

1) If the calibration service is performed within the same physical location as the customer[11], and if the calibrations are performed in a permanent calibration laboratory (i.e., customer equipment to be calibrated is transported to the calibration laboratory), then the calibration should be considered to be an in-house calibration not subject to accreditation requirements;
2) If the calibration service is performed at a location other than a permanent calibration laboratory (i.e., if reference standards are being transported to the customer equipment to be calibrated), then such a calibration service should be accredited.

Acceptable Accreditors of Calibration and Testing Providers

A2LA has signed multi-lateral recognition agreements or arrangements (MLAs) with numerous accreditation bodies throughout the world. The import of these agreements is that the signatories promote the recognition and acceptance of certificates and reports issued by organizations accredited by accreditation bodies who have signed the MLA. Through the vehicle of the MLA, a uniform level of competence of the accredited bodies involved is assured and the need for multiple assessments is diminished or eliminated. This means that a supplier should only need one certificate or report to satisfy the markets and governments represented by MLA signatories.

Currently, the primary multi-lateral recognition agreements amongst accrediting bodies are the Asia-Pacific Laboratory Accreditation Cooperation (APLAC[12]), the European cooperation for Accreditation (EA[13]), the International Laboratory Accreditation Cooperation (ILAC[14]) and the Inter-American Accreditation Cooperation (IAAC[15]). As signatories to these multi-lateral agreements, A2LA is committed to promoting the recognition and acceptance of accreditations granted by its fellow signatories.

Accredited test and calibration results, reported by laboratories that are accredited by the accreditation bodies recognized by any of these multi-lateral agreements, and reported in a test or calibration report endorsed by the accrediting body's symbol (or which otherwise makes reference to accredited status

[10] See, for example, NCSL RP-1 "Establishment & Adjustment of Calibration Intervals" (3/96).
[11] "customer" refers to the recipient of the in-house calibration service.
[12] http://www2.wave.co.nz/~ianz/aplac/index.htm
[13] http://www.european-accreditation.org/
[14] http://www.ilac.org/
[15] http://iaac-accreditation.org/intro.html

by a specific, recognized accreditation body, for example through use of a statement that the organization is accredited by XYZ) that is accompanied by an indication of the type of entity accredited (e.g., through inclusion of an accreditation certificate number, words such as "calibration laboratory", etc.), are recognized by A2LA as satisfying the requirements pertaining to measurement traceability.

A2LA recognizes reference material certificates that are issued by reference material producers that are accredited by the accreditation bodies recognized by the APLAC mutual recognition arrangement for reference material producer accreditation, and reported in a certificate meeting ISO Guide 31 and endorsed by the accreditation body's symbol (or which otherwise makes reference to accredited status by a specific, recognized accreditation body) and an indication of the type of entity accredited.

Use of NIST Test Report Numbers as Evidence of Traceability

The NIST Calibration Program[16] 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 measurement[17].

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.

[16] http://ts.nist.gov/ts/htdocs/230/233/calibration/trace/index.html.
[17] NCSL Position Statement 96-1.

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.

Summary of Specific Requirements

(T1) A2LA requires that:

(a) All calibrations and verifications of measuring and test equipment and reference standards, be conducted by:

- A calibration laboratory accredited to ISO/IEC 17025 by a mutually recognized Accreditation Body; or
- A recognized National Metrology Institute (NMI). Recognition of the NMI is based on the Institute being a signatory to the CIPM (Comité International des Poids et Mesures) MRA (Mutual Recognition Arrangement) and supporting the measurement comparison activities of the CIPM. A listing of these recognized Institutes can be found at http://kcdb.bipm.org/default.asp; or
- A mechanical testing laboratory accredited by A2LA to ISO/IEC 17025 and found to meet the A2LA Calibration Program Requirements (as indicated on their Mechanical Scope of Accreditation). An accredited test report containing appropriate statements of measurement results, measurement uncertainty, and traceability can be considered to satisfy traceability requirements; or
- A laboratory accredited by A2LA to ISO/IEC 17025 and found to meet the T9 requirements of this document for their in-house calibrations.

(b) When possible, all reference materials shall be obtained from:

- A reference material producer accredited to ISO Guide 34 in combination with ISO/IEC 17025 by a recognized Asia Pacific Laboratory Accreditation Cooperation (APLAC) signatory recognized for accrediting reference material producers; or
- A recognized National Metrology Institute (NMI).

(T2) For those external calibrations and verifications, these must be recorded in a calibration certificate or report endorsed by the recognized Accreditation Body's symbol (or otherwise makes reference to accredited status by a specific, recognized accreditation body) with an indication of the type of entity that is accredited (e.g., via an accreditation certificate number, inclusion of "calibration laboratory" with the symbol, etc.) or endorsed by the National Metrology Institute (NMI). For those internal calibrations and verifications, those requirements outlined in requirement T9 of this document apply. For reference materials, these must be recorded in a certificate meeting the

requirements of ISO Guide 31 endorsed by the recognized Accreditation Body's symbol (or otherwise makes reference to accredited status by a specific, recognized accreditation body) with an indication of the type of entity that is accredited or endorsed by the recognized NMI.

(T3) All A2LA-Accredited and enrolled organizations must define their policy for achieving measurement traceability and also for achieving traceability for reference materials if applicable. The policy shall ensure compliance with this policy document.

(T4) Where measurement uncertainty analysis is applicable, A2LA requires laboratories to calculate measurement uncertainty in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement." These uncertainties, when reported, 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).

(T5) If a calibration certificate or test report contains a statement of the measurement result and the associated uncertainty, then the uncertainty statement shall be accompanied by an explanation of the meaning of the uncertainty statement. (For example, "This uncertainty represents an expanded uncertainty expressed at approximately the 95% confidence level using a coverage factor of k=2.)

(T6) TURs shall be calculated using the expanded uncertainty of the measurement, not the "collective uncertainty of the measurement standards".

(T7) Implicit uncertainty statements must be accompanied by words to the effect that the uncertainty ratio was calculated using the expanded measurement uncertainty. In addition the coverage factor and confidence level must be stated.

(T8) Calibration reports and certificates issued by A2LA-accredited calibration laboratories shall contain a traceability statement.

(T9) All in-house calibrations shall be supported by the following minimal set of elements:

a) The in-house laboratory shall maintain documented procedures for the in-house calibrations and the in-house calibrations shall be evidenced by a calibration report, certificate, or sticker, or other suitable method, and calibration records shall be retained for an appropriate, prescribed time;
b) The in-house laboratory shall maintain training records for calibration personnel and these records shall demonstrate the technical competence of the personnel performing the calibrations;
c) The in-house laboratory 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 and/or purchasing reference materials from appropriately accredited reference material producers or an NMI;
d) The in-house laboratory shall have and apply procedures for evaluating measurement

uncertainty. Measurement uncertainty shall be calculated for each type of calibration and records of these calculations shall be maintained. (Note: Records of these calculations must be maintained for calibrations done as of 8/1/06.) Measurement uncertainty shall be taken into account when statements of compliance with specifications are made;

e) Reference standards shall be recalibrated at appropriate intervals to ensure that the reference value is reliable. Policy and procedures for establishing and changing calibration intervals shall be based on the historical behavior of the reference standard.

APPENDIX A - Document Revision History

Date	Description
08/28/2000	**Original Issue of this document. This document replaces the A2LA Calibration Accreditation Policy**
10/01/2003	• **Minor editorial changes and clarifications added.** • **Document Revision History section added.** • **No other changes made.**
11/15/2004	• **Revised 'Concept of Traceability'** • **Modified T1 – added "to ISO/IEC 17025"; defined recognized national metrology institute** • **Modified / Clarified T4** • **Modified T5 – added "test" so that testing laboratories that are reporting measurement uncertainty properly define the uncertainty statement. Removed discussion on accuracy ratios.** • **Modified T7 – removed "accuracy ratio" since it is not a statement about measurement uncertainty.**
01/10/2005	• **Updated list of Recognition Arrangements of which A2LA is a signatory.**
05/19/2006	• **Added Inspection Bodies, Reference Material Producers, and Proficiency Testing Providers to the Scope and Field of Application** • **Updated the requirements of T1 and T2 to clarify the means available to achieve traceability; minor edit of T3 in the summary list to agree with T3 in the beginning of the document** • **Modified T9d – added "record" of the measurement uncertainty for each type of in-house calibration; minor edit for renumbering list in T9d**
10/22/08	• **Clarified what must accompany an accreditation body's symbol on certificates or reports.** • **Clarified in T3 that the organization's policy shall ensure compliance with P102.** • **Clarified the role of accredited reference material producers.** • **Clarified the role of accredited reference material producers in T9 (c).** • **Updated references to current versions.** • **Reference to P102a added.**