Scope and Field of Application

This document serves as the application of requirements contained in P102-A2LA Policy on Metrological Traceability. The Life Sciences Traceability Policy (P113) has been withdrawn and the requirement previously in this document are now included in P102. This policy is meant to explain how metrological traceability may be achieved and how it may be demonstrated for conformity assessment bodies.

Specific Guidance on Application of P102 Clauses

P102 T2 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 A2LA P102 (T1) is allowed under the following special circumstances when all of the (T2) requirements of P102 are also verified to be met:

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.

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.

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.

P102 T2 Exceptions and Calibration Interval

Exceptions to A2LA P102 (T-1) 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.

P102 T4 In House Calibrations

In-House Calibrations and Measurement Uncertainty

Required in-house calibrations of test equipment requiring traceability through reference materials (e.g. gas chromatographs, atomic absorption spectrophotometers and pH meters) require the CAB to calculate measurement uncertainty to support the calibration. The method measurement uncertainty may be based on the entire process such as the laboratory control sample or may be based on each step of the analysis

process. The estimation of uncertainty may be accomplished with the effective use of and analysis of control charts, control limits and other processes. Examples of this can be found in A2LA P103 – Policy on Estimating Measurement Uncertainty for Testing Laboratories.

P102 T5 Statements of Traceability

This statement will affirm that the calibration reported was conducted using reference measurement 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.

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 metrological traceability and do not meet P102.

P102 T5 Measurement Uncertainty

Measurement uncertainty analysis is required for all calibrations and dimensional tests in cases where the dimensional artifact serves as a link in the traceability chain. 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 ; P103b - Annex: Policy on Estimating Measurement Uncertainty for Life Sciences Testing Lab; P103c - Annex: Policy on Estimating Measurement Uncertainty for Electromagnetic 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 metrological traceability has been achieved.

General Guidance on Application of P102 Clauses

Intrinsic Standards

Where an intrinsic standard or system is used as a reference measurement standard, the following applies:

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 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) and (3).

Consensus Standards

The use of specified methods and/or consensus standards are deemed metrologically 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.

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. However, the presentation of dimensional testing on scopes does not include all possible dimensional calibrations. Calibration for dimensional reference measurement standards and equipment shall be called out as parameters on a calibration scope of accreditation to establish traceability.

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 17025:2017 Section 7.8, 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.

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.

Acceptable Accreditors of Calibration and Testing Providers

Currently, the primary mutual recognition agreements (MRAs/MLAs) among accrediting bodies are is the International Laboratory Accreditation Cooperation (ILAC), with the Asia-Pacific Accreditation Cooperation (APAC), and the Inter-American Accreditation Cooperation (IAAC) serving as the primary regional recognition arrangements.

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/MLAs 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 ILAC or APAC MRAs, or the IAAC MLA. Furthermore, it is required that the results be reported in a certificate or product information sheet meeting ISO 17034 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.

NIST Test Report Numbers and Traceability

The NIST Calibration Program[1] 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[2].

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 ISO 9000 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.

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[1] http://www.nist.gov/traceability/nist_traceability_policy_external.cfm.

[2] NCSLI Position Statement 96-1.

APPENDIX I: Example Calibration Certificate Related to P102 T5 Requirements

CALIBRATION CERTIFICATE

T5.1.a →

Cert# 0000.01

T5.1.b

ABC Company
1234 Main Street
Anytown, ME 00000

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

| Description of Item: | Famous Widget | Serial Number:0001 | Date of Calibration: 01/02/2021 |

T5.1.d

| Environmental Conditions: | 25 °C | | |

| As Found: | 1.0 inch | | |
| As Left: | 1.0 inch | Measurement Uncertainty | ±0.025 inch |

Found to be in tolerance

| Reference Measurement Standards Used | Steel Ruler | Report Number 1234 | |

T5.1.c

T5.1.d

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.

T5.2

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

Page 1 of 1

DOCUMENT REVISION HISTORY

Date	Description
11/20/24	➢ Added the caveat to the P102 (T2) exception examples that the requirements of P102 (T2) must be still be met for the examples to apply