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INTRODUCTION

This document defines accreditation requirements for ISO/IEC 17025 calibration laboratories (non-forensics). This document is to be used in conjunction with MA 2100, Accreditation Manual for Laboratory-Related Activities (Non-Forensics). Only statements in this document using the word “shall” represent ANAB requirements.

REFERENCES

MA 2100, ANAB Accreditation Manual for Laboratory-Related Activities (Non-Forensics).
JCGM 100 Evaluation of measurement data – Guide to the expression of uncertainty in measurement (GUM).
JCGM 200 International vocabulary of metrology – Basic and general concepts and associated terms (VIM).
ILAC P9, ILAC Policy for participation in proficiency testing activities.
ILAC P10, ILAC Policy on the traceability of measurement results.
ILAC P14, ILAC Policy for uncertainty in calibration.
ISO/IEC 17043, General requirements for proficiency testing.
ISO 17034, General requirements for the competence of reference material producers.
ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.

TERMS AND DEFINITIONS

Adjustment [VIM 3.11]: Set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of a quantity to be measured.

Appropriate PT/ILC: For ANAB purposes, an appropriate PT/ILC is a proficiency test (PT) or inter-laboratory comparison (ILC) that represents the parameters, ranges, measurements, test technologies, inspections, methods, and uncertainty of measurement described in the scope of accreditation.

Authoritative source: For ANAB purposes, an authoritative source is known to be reliable because its authority or authenticity is widely recognized by experts in the field. This may be an organization such as a government regulatory agency (EPA, FDA, USDA, etc.), a standard development organization (AOAC, ASTM, USP, ISO, AABB, etc.), or an organization (APLAC, IAAC, NCSLI, NIST, etc.) considered by experts to be industry leaders.

Calibration [VIM 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.

Calibration and measurement capability (CMC): Calibration and measurement capability available to customers under normal conditions (a) as published in the BIPM key comparison database (KCDB) of the CIPM MRA or (b) as described in the laboratory’s scope of accreditation granted by a signatory of the ILAC Arrangement. [CIPM MRA-D-04, Version 2 (2011), Calibration and Measurement Capabilities in the context of the CIPM.]
Certified reference material [VIM 5.14]: Reference material, accompanied by documentation issued by an authoritative body and providing one or more specific property values with associated uncertainties and traceability using valid procedures.

Conformity assessment activity: For ANAB purposes, these are defined as calibration, testing, inspection, PTP, RMP, or medical as identified in the scope of accreditation.

Inter-laboratory comparison (ILC) [ISO/IEC 17043 3.4]: Organization, performance, and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

Major field: For ANAB purposes, major fields are defined as the types of calibration and testing as identified in the scope of accreditation (e.g. Electrical, Mechanical, Thermodynamic …).

Metrological traceability [VIM 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.

National Metrology Institute (NMI): National Metrology Institutes (NMI) and Designated Institutes (DI) maintain standards in countries (or regions) all over the world. Throughout this document, the term "NMI" is used to cover both National Metrology Institutes as well as Designated Institutes. ILAC has taken note that the results of international comparison carried out in the scope of the Metre Convention are published in Appendix C of the CIPM MRA (www.bipm.org).

OEM: Original equipment manufacturer.


Reference material [VIM 5.13]: Material, sufficiently homogeneous and stable with reference to specific properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.

Related discipline: For ANAB purposes, a related discipline further defines the Major Field.

Uncertainty of measurement (measurement uncertainty, MU) [VIM 2.26]: Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

Verification [VIM 2.44]: Provision of objective evidence that a given item fulfills specified requirements.

- Example 1: Confirmation that performance properties or legal requirements of a measuring system are achieved.
- Example 2: Confirmation that a target measurement uncertainty can be met.

1. PROFICIENCY TESTING

1.1. General Requirements

1.1.1. The laboratory shall participate in appropriate PT/ILC activities representing the parameters, ranges, measurements, test technologies, inspections, methods, and uncertainty of measurement described in the scope of accreditation.
1.1.2. The laboratory shall maintain a documented plan that ensures participation for the current year and at least the next three years covering a representative sampling of activities within each major field identified in the scope of accreditation.

a. The laboratory shall evaluate the risk of the calibrations associated with the scope of accreditation and incorporate that risk analysis as part of the PT plan. This requirement applies to laboratories seeking accreditation to meet ISO/IEC 17025:2017 prior to January 1, 2019. After January 1, 2019, this requirement applies to all ANAB-accredited calibration laboratories.

1.1.3. The laboratory shall investigate any results found outside of predefined performance criteria, such as unsatisfactory results.

a. The laboratory shall promptly notify ANAB of unsatisfactory results.

b. When appropriate, corrective action shall be performed.

c. A record of the investigation summary and conclusion shall be retained.

1.1.4. The laboratory shall maintain records of their participation on a rolling four-year basis.

1.1.5. The laboratory shall ensure that PT activities are not always performed by the same person if other qualified personnel in the system perform accredited work.

1.2. Types of Participation

1.2.1. If other factors are similar, the laboratory shall select, when available and appropriate, PT/ILC providers that are accredited to ISO/IEC 17043 by ANAB or another accreditation body that is a signatory of the APLAC or IAAC MRA for PTP.

1.2.2. When ISO/IEC 17043 accredited PT/ILC providers are not used and the laboratory develops its own ILC, the laboratory shall seek written ANAB approval for each PT/ILC scheme. This written ANAB approval shall be documented prior to participation.

1.2.3. When ensuring the validity of results internally, a plan and procedure shall be applied to meet the requirements of ISO/IEC 17025. The plan and procedure will be evaluated by the assessor(s) during assessment activities for the effectiveness of the results.

1.3. Frequency of Participation

1.3.1. The laboratory shall participate in at least one approved PT/ILC activity or alternative each calendar year.

1.3.2. The laboratory shall perform a PT/ILC activity or alternative covering a representative sampling of activities within each major field in their scope of accreditation for each rolling four-year period.

1.4. Initial Accreditation Requirements

1.4.1. Before accreditation can be granted, the applicant laboratory shall have performed satisfactorily in at least one approved PT/ILC within the previous 12 months. The applicant laboratory shall provide reported results as evidenced by either a preliminary or final report issued by an approved provider. Evidence of PT participation and submission of data may be sufficient for initial accreditation. In such cases, failure to submit to ANAB an official report of results within six months of accreditation will risk suspension of accreditation by the laboratory.

1.4.2. Major fields with related parameters for calibration scopes can be found in PR 2351, Preparing a Draft Scope of Accreditation for Calibration Laboratories.
2. METROLOGICAL TRACEABILITY

2.1. The laboratory shall ensure that all testing and calibration results are traceable whenever possible through NIST or another National Metrology Institute (NMI) to the International System of Units (SI). The hierarchy of acceptable sources of traceability is:

2.1.1. **Metrological Traceability from an NMI:** Applicant and accredited laboratories can submit appropriate physical standards and measurement and test equipment (M&TE) directly to NIST, a designated institute (DI), or, when appropriate, to another National Metrology Institute (NMI) to the International System of Units (SI units). Measurement services provided by NIST as described in SP 250 are considered traceable to the SI.

2.1.2. **Traceability from an ISO/IEC 17025 Accredited Calibration Laboratory:** Applicant and accredited laboratories can use ISO/IEC 17025 accredited calibration laboratory services whenever available. ISO/IEC 17025 accredited calibration laboratories are those accredited by ANAB or another accreditation body that is recognized as a signatory of the International Laboratory Accreditation Cooperation (ILAC) MRA. A list of ISO/IEC 17025 laboratories accredited by ANAB is available on ANAB’s website. When using accredited calibration laboratory services, the calibration certificates shall be accompanied by a recognized accreditation body symbol or otherwise refer to accredited status to be considered satisfactory for traceability purposes.

2.1.3. **Traceability Using Intrinsic Standards:** The laboratory shall demonstrate traceability by measurement-assurance techniques, inter-laboratory comparison, or other suitable means that its intrinsic-measurement results are correlated with an NMI (e.g., Josephson Junction or Triple-Point Devices).

2.1.4. **Traceability from Weights and Measures Lab:** Prospective customers and accredited laboratories can use a national, state, or provincial weights and measures laboratory that is recognized and/or traceable to any recognized NMI. Evidence of recognition and/or traceability shall be available during the assessment.

2.2. When an applicant or accredited laboratory seeks to submit reference standards and equipment to a calibration provider that is not covered by the traceability hierarchy above, the laboratory shall apply for the approval of that non-accredited calibration provider by submitting the following:

2.2.1. An unbroken chain of comparisons going back to a standard acceptable to the parties, usually a national or international standard.

2.2.2. Proof that measurement uncertainty throughout the traceability chain has been calculated according to accepted methods and stated so an overall uncertainty for the whole chain can be calculated.

2.2.3. Proof that each step in the chain has been performed according to documented and generally acknowledged procedures, including documenting results (before and after data).

2.2.4. Evidence of technical competence of the non-accredited providers.

2.2.5. Proof that traceability is to the SI.

2.2.6. Evidence that calibrations have been repeated at appropriate intervals.

2.3. Calibration certificates and reports for reference standards and equipment shall provide indication of traceability.
2.3.1. Uncertainty of measurement associated with a specified range of measurement for a specified measurement parameter (e.g., force, mass, temperature). The unit of the uncertainty shall always be the same as that of the measurand or in a term relative to the measurand (e.g., percentage). The inclusion of the relevant unit gives the necessary explanation;

2.3.2. Symbol of an ILAC-recognized accreditation body that has recognized the competence of the laboratory through accreditation or equivalent; and

2.3.3. Information regarding traceability through an NMI or intrinsic standard, and/or a statement of compliance with an identified metrological specification to the SI unit.

2.3.4. Calibration certificates and reports provided for customers shall contain a traceability statement indicating traceability to the International System of Units (SI).

- Example: “The calibrations within the certificate/report are traceable through NIST or another National Metrology Institute to the International System of Units (SI).”

2.3.5. Calibration certificates and reports shall provide evidence of traceability. This includes identification of all reference standards and equipment disseminating traceability.

2.3.6. NIST numbers shall not be reported unless traceability has been achieved directly from NIST.

2.4. The laboratory shall complete ANAB form **FM 2807, Traceability and In-House Calibration Tracking**, or equivalent, documenting the traceability of the measurements associated with the scope technologies.

2.4.1. This form must be kept up to date and available when requested by ANAB or an approved ANAB representative.

### 3. TRACEABILITY USING REFERENCE MATERIALS

3.1. The laboratory shall ensure that all testing and calibration results are traceable whenever possible through NIST or other National Metrology Institute (NMI) to the International System of Units (SI units). When this is not feasible or possible, traceability to consensus standards, reference materials, or defined methods shall be sought.

3.2. Demonstration of Metrological Traceability Using Reference Materials

3.2.1. When the laboratory obtains measurement traceability by using reference materials, it shall use one of the following:

- a. Certified Reference Materials (CRM) from a reference material producer (RMP) accredited to ISO Guide 34 or ISO 17034 by ANAB or another MRA signatory accreditation body.
- b. Standard Reference Materials® (SRM) from NIST (called under trademark).
- c. CRM from another National Metrological Institute (NMI). Use of any CIPM-active NMI may be acceptable.

3.2.2. If traceability per 3.2.1 is not possible, the laboratory shall obtain measurement traceability from authoritative sources.

- a. The laboratory shall determine that reference materials obtained from authoritative sources are fit for intended uses in accordance with established and validated procedures.

3.2.3. If traceability per 3.2.1 or 3.2.2 is not possible, or when no methods or reference materials are available, the laboratory shall develop reference methods or materials from internal validation.
a. The laboratory shall validate methods and determine fitness for use.

3.3. Reference materials shall not be altered from their original state from the manufacturer without validation that they are still suitable for use. Documentation shall be available of this validation.

3.4. Because many CRMs and RMs are qualitative or have nominal values, traceability is still relevant for the CRM or RM but not for the associated quantitative uncertainty.

### 4. UNCERTAINTY OF MEASUREMENT

**4.1. Scope of Accreditation**

4.1.1. Accredited calibration laboratories shall estimate and maintain expanded uncertainties for each line item in the scope of accreditation having a specific coverage probability of approximately 95%.

**4.2. Reporting Measurement Uncertainty**

4.2.1. Calibration laboratories shall report the measurement uncertainty (MU) on all accredited certificates and reports. The measurement uncertainty shall include all significant contributors including those attributed to the unit under test.

4.2.2. When the customer requests a report to be issued in a simplified manner excluding the measurement uncertainty, evidence of the request shall be available for review at the time of an assessment.

4.2.3. Regardless of whether the laboratory’s client wants the uncertainty of measurement reported, the laboratory shall retain documentary evidence of the measured quantity values and uncertainty of measurement to be provided upon request.

4.3. A statement of the measurement result and the associated uncertainty must be accompanied by an explanation of the coverage probability and coverage factor \((k)\).

- Example: “The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor \(k=2\), which for a normal distribution corresponds to a coverage probability of approximately 95%.”

4.4. When the measurement result is determined (or verified) to be within a specified tolerance or limits, the associated uncertainty of the measurement result shall be taken into account with respect to the tolerance or limits in accordance with a documented agreement established during contract review.

4.4.1. The calibration certificate is not intended to be used in support of the further dissemination of metrological traceability (i.e., to calibrate another device).

4.5. As the definition of CMC implies, the accredited calibration laboratory shall not report a smaller uncertainty of measurement on their accredited certificates than the uncertainty of the CMC for which the laboratory is accredited.

4.6. The unit of measure for the MU reported on calibration certificates and reports normally shall be the same as that of the measurand or in a term relative to the measurand.

4.7. Uncertainties reported on calibration certificates and reports shall be limited to two significant digits unless justified.

4.8. Measurement data shall not be reported beyond the resolution of the reported uncertainty of measurement.
Note: Exceptions are made when OEM software does not permit the laboratory control of the display resolution of the measurement data or reported expanded uncertainties.

5. IN-HOUSE CALIBRATIONS

5.1. For the purpose of ensuring traceability of measurement, an accredited laboratory can calibrate its own reference standards or equipment that supports an accredited parameter in the scope of accreditation if the appropriate requirements of ISO/IEC 17025 and the following requirements are met:

5.1.1. Appropriate environment for carrying out the calibration.
5.1.2. Appropriately trained personnel to both carry out and check the calibrations.
5.1.3. Demonstration of competency to perform the calibrations it undertakes.
5.1.4. Traceable reference standards, certified reference materials, or reference measuring instruments are traceable with appropriate measurement uncertainties.
5.1.5. Documented procedure for each type of calibration.
5.1.6. Appropriate means of recording and reporting the data and results of any calculations according to the requirements of ISO/IEC 17025.
5.1.7. The laboratory shall estimate, evaluate, and maintain records of uncertainties for traceability realized internally that support measurements associated with the scope of accreditation.

5.2. The laboratory shall complete and keep up to date ANAB form FM 2807, Traceability and In-House Calibration Tracking, or equivalent, documenting the traceability of the measurements associated with the scope technologies.

6. MANAGEMENT SYSTEM OPTIONS (ISO/IEC 17025:2017 REQUIREMENTS)

6.1. If the laboratory claims conformity with ISO/IEC 17025:2017 section 8.1.3 option B, it shall demonstrate that it has established a management system that complies with ISO 9001 and that the management system can support the consistent fulfillment of the requirements of ISO/IEC 17025:2017.

6.2. ANAB shall verify compliance with option B through representative sampling and review of objective evidence against clauses 8.2 to 8.9 of the standard, as relevant to its testing and calibration activities.

6.3. If the laboratory claims conformity to option B but the sampling results in the identification of nonconformities, multiple findings will be written against clause 8.1.3 and the relevant clauses 8.2 to 8.9 of ISO/IEC 17025:2017.

7. USE OF ANAB ACCREDITATION SYMBOLS AND CLAIMS OF ACCREDITATION

7.1. When using the ANAB accreditation symbol or making claims of accreditation, the laboratory shall comply with PR 1018, Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status, effective January 1, 2019.¹

¹AR 2201, Control and Use of the Accreditation Symbol, remains in effect through December 31, 2018.
7.2. ANAB allows the use of its symbol by accredited entities on calibration labels attached to calibrated items.

7.2.1. Labels bearing the ANAB symbol shall be used only in conjunction with methods and/or services covered by the approved scope of accreditation.

7.2.2. Calibration labels bearing the ANAB symbol shall include the following:

- Name of the accredited entity and the accreditation certificate number
- Equipment identification
- Date of current calibration
- Cross-reference to the calibration certificate issued in respect of the calibration

### REVISION HISTORY

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<tr>
<td>Original Release</td>
<td>Original release to combine legacy ANAB and L-A-B requirements.</td>
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<tr>
<td>1</td>
<td>Added section 6 to address management system options of ISO/IEC 17025:2017.</td>
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<td>2</td>
<td>Added additional definitions; added section 1.1.2 a. addressing risk when developing a PT plan; and added section 1.2.3. about ensuring the validity of results internally to meet ISO/IEC 17025 and ILAC requirements.</td>
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<td>3</td>
<td>Added section 7 regarding use of ANAB accreditation symbols and claims of accreditation.</td>
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