ANSI National Accreditation Board

ACCREDITATION REQUIREMENTS: ISO/IEC 17025 TESTING LABORATORIES (NON-FORENSICS)

AUTHORITY: ASSOCIATE DIRECTOR OF ACCREDITATION

EFFECTIVE DATE: 2024/04/24

DOCUMENT NUMBER: **AR 2250**

TABLE OF CONTENTS

Introduction....3
Program Scope....3
Scopes of Accreditation....3
References....3
Terms and Definitions....3
1. Proficiency Testing....4
2. Metrological Traceability....6
3. Metrological Traceability Using Reference Materials....7
4. Uncertainty of Measurement....7
5. In-House Calibrations....8
6. Management System Options....8
7. Use of ANAB Accreditation Symbols and Claims of Accreditation....8
Revision History....9

INTRODUCTION

This document defines accreditation requirements for the ISO/IEC 17025 testing laboratories (non-forensics). Additional supplemental program-specific documents may apply. Only statements in this document with a “shall” represent ANAB requirements.

PROGRAM SCOPE

This document specifies the requirements in addition to those identified in ISO/IEC 17025 for the accreditation of testing laboratories by ANAB under the ISO/IEC 17025 accreditation program.

SCOPES OF ACCREDITATION

The policies and scoping fields in PR 2250 ISO/IEC 17025 Testing Laboratories Program Scoping Requirements shall apply to scopes of accreditation for testing laboratories accredited to ISO/IEC 17025.

REFERENCES

MA 2100 Accreditation Manual for Inspection, Laboratories and Related Activities (Non-Forensic)

ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories

ISO/IEC 17043:2010, General requirements for proficiency testing [providers]

ISO/IEC 17043:2023, Conformity assessment – General requirements for the competence of proficiency testing providers

ISO 17034:2016, General requirements for the competence of reference material producers

ILAC P9:01/2024, ILAC Policy for participation in proficiency testing activities

ILAC P10:07/2020, ILAC Policy on metrological traceability of measurement results

ILAC P14:09/2020, ILAC Policy for uncertainty in calibration

JCGM 200, International vocabulary of metrology – Basic and general concepts and associated terms (VIM)

FM 2805 PT/ILC Four-year Plan

FM 2806 ISO/IEC 17025 Accredited PT Alternative Approval

FM 2807 Traceability and In-House Calibration Tracking

FM 2808 Waiver of Traceability Approval

TERMS AND DEFINITIONS

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), or an organization considered by experts to be an industry leader.

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.

Competency: Possession of required skill, knowledge, qualification, or capacity.

Conformity assessment activity: For ANAB purposes, conformity assessment activities are defined as calibration, testing, inspection, provision of proficiency testing (PTP), reference material production (RMP), medical testing, validation, verification, certification of management systems, or certification of management systems, persons, products, processes and/or services as identified in the scope of accreditation.

Inter-laboratory comparison (ILC) [ISO/IEC 17025:2017 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 categories of 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 (NMIs) 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 and 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).

Proficiency testing [ISO/IEC 17025:2017 3.5] Evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons.

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, methods, and uncertainty of measurement described in the scope of accreditation.

1.1.2. The laboratory shall document and submit in writing to ANAB a list of all parameters, ranges, measurements, test technologies and methods on its scope of accreditation, including those for which no appropriate commercial PT is available.

Note: This can be captured on a four-year PT plan (FM 2805 or equivalent)

1.1.3. 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 tests associated with the scope of accreditation and incorporate that risk analysis as part of the PT plan.

1.1.4. 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. Note – This is typically accomplished by email using the ANAB Client Notification Form.

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

c. When appropriate, corrective action shall be performed.

1.1.5. The laboratory shall retain records of their participation for a minimum of 4 years.

1.1.6. 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 ILAC Mutual Recognition Arrangement (MRA) for Proficiency Testing Providers (PTP) with the applicable PT included in the scope of accreditation.

1.2.2. When an ISO/IEC 17043 accredited PT/ILC provider is available, and offers appropriate schemes, but the laboratory instead chooses to develop its own ILC, the laboratory shall seek written ANAB approval for each PT/ILC scheme. This written ANAB approval shall be documented on the ANAB FM 2806 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 each calendar year.

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

1.3.3. Major fields with related parameters for testing scopes can be found in PR 2250 ISO/IEC 17025 Testing Laboratories Program Scoping Requirements.

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.

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 units). The hierarchy of acceptable sources of traceability is:

2.1.1. **Metrological Traceability from a NMI**: Applicant and accredited laboratories can submit appropriate physical standards and measurement and test equipment (M&TE) directly to a NMI or a designated institute (DI). A NMI whose service is suitable for the intended use but not covered by the CIPM MRA shall be approved by ANAB as stated in section 2.2.

2.1.2. **Traceability from an ISO/IEC 17025 Accredited Calibration Laboratory**: Applicant and accredited laboratories should use ISO/IEC 17025 accredited calibration laboratory services whenever available. Acceptable ISO/IEC 17025 accredited calibration laboratories are those accredited by ANAB or another accreditation body that is a signatory of the International Laboratory Accreditation Cooperation (ILAC) MRA with the appropriate calibration services listed in the scope of accreditation. 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 not covered by the traceability hierarchy above, the laboratory shall use the ANAB form FM 2808 Waiver of Traceability Approval and 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 SI.

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

2.3. 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.

3. METROLOGICAL 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 (CRMs) from a reference material producer (RMP) accredited to ISO 17034 by ANAB or another accreditation body that is a signatory of the ILAC Mutual Recognition Arrangement (MRA) for RMP with the applicable reference material in the scope of accreditation.

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.

d. The certified values assigned to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.

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 the associated quantitative uncertainty.

4. UNCERTAINTY OF MEASUREMENT

4.1. The uncertainty requirements of the relevant version of ISO/IEC 17025 apply.

5. IN-HOUSE CALIBRATIONS

5.1. For the purpose of ensuring traceability of measurement, an accredited testing laboratory can calibrate its own equipment that supports an accredited parameter in the scope; in this case, the laboratory shall follow the relevant requirements ISO/IEC 17025 and shall meet the following requirements:

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 undertaken.

5.1.4. 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 tests 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

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 the testing and calibration activities.

6.3. If the laboratory has claimed 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.

REVISION HISTORY

Revision Level	Description
Original Release	Combines legacy ANAB and L-A-B requirements.
1	Added sections 2.3 and 5.2; revised section 4 to refer to relevant sections of ISO/IEC 17025 and added section 6 to address management system options of ISO/IEC 17025:2017.
2	Added additional definitions; added section 1.1.2 a. addressing risk when developing a PT plan; added section 1.2.3. about ensuring the validity of results internally; added section 1.3.3 clarifying the major fields; and deleted section 4.2 about dimensional measurement uncertainty, which is now in an AR for dimensional measurement. Revised section 5.1.7 for clarity.
3	Added section 7 regarding use of ANAB accreditation symbols and claims of accreditation.
4	Updated logo.
5	Removed reference to 17025:2005. Added reference to ILAC P9, ILAC P10, ISO/IEC 17034. Removed outdated reference to a risk plan timeline in section 1.1.2 a. Section 1.1.3a added a note for clarity. Section 1.1.4 clarified the retention time of PT records. Section 1.2.2 reworded for clarity. Section 2.1.1 reworded for clarity. Added reference to a NMI whose service is suitable for the intended use but not covered by the CIPM MRA. Section 3.2.1 d. added reference to traceability through the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database. Other administrative changes.
6	Aligned with AR 2255 and AR 2253, updated PR 2350 to PR 2250. Updated title of MA 2100 to remove Product Certification and added section 1.1.2. Updated issuing authority.