ACCREDITATION REQUIREMENTS:
ISO/IEC 17020 INSPECTION BODIES
(NON-FORENSICS)
INTRODUCTION

This document defines accreditation requirements for ISO/IEC 17020 inspection bodies (non-forensics). It is to be used in conjunction with the current versions of ISO/IEC 17020 (Conformity assessment – Requirements for the operation of various types of bodies performing inspection), ILAC P15 (Application of ISO/IEC 17020 for the Accreditation of Inspection Bodies), and MA 2100, ANAB Accreditation Manual for Laboratory Related Activities (Non-Forensics). Only statements in this document using the word “shall” represent requirements by ANAB.

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 P15, Application of ISO/IEC 17020 for the Accreditation of Inspection Bodies
ISO/IEC 17043, General requirements for proficiency testing
ISO 17034, General requirements for the competence and consistent operation of reference material producers
ILAC G9, Guidelines for the selection and use of reference materials

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 (inspection body) comparison (ILC) that represents the parameters, ranges, measurements, test technologies, inspections, methods, and uncertainty of measurement described in the scope of accreditation.

**Assuring quality (AQ):** For ANAB purposes, assuring quality is internal quality assurance measurements organized within the inspection body making use of standards and other well-characterised artifacts/equipment (e.g., split-sample analysis, retesting of retained items). Procedures may include but are not limited to inter-analyst comparisons or analysis of a blind reference material.

**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 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.

**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.

**Inspection:** Examination of a product, process, service, or installation or their design and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements.

**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 inspection bodies in accordance with predetermined conditions.

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

**Major field:** For ANAB purposes, major fields are defined as the types of inspection as identified in scope of accreditation (e.g., Electrical, Mechanical, Thermodynamic, Length, Mass).

**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 and Designated Institutes.

**Outlier [17043 3.5]:** Observation in a set of data that appears to be inconsistent with the remainder of that set.

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

**Related Discipline:** For ANAB purposes, related disciplines further defines the major field.

**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.

**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 a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.
- Example 2: Confirmation that performance properties or legal requirements of a measuring system are achieved.
- Example 3: Confirmation that a target measurement uncertainty can be met.
1. IMPARTIALITY AND INDEPENDENCE

1.1. General

1.1.1. Risks to the impartiality of the inspection body shall be considered whenever events occur that might have a bearing on the impartiality of the inspection body or its personnel. (ILAC P15, 4.1.3a)

1.1.2. The inspection body should describe any relationships that could affect its impartiality to the extent relevant, using organizational diagrams or other means. (ILAC P15, 4.1.3b)

Examples of relationships that could influence impartiality include relationships with:

- A parent organization
- Departments within the same organization
- Related companies or organizations
- Regulators
- Clients
- Personnel
- Organizations designing, manufacturing, supplying, installing, purchasing, owning, using, or maintaining the items inspected

1.1.3. The inspection body should have a documented statement emphasizing its commitment to impartiality in carrying out its inspection activities, managing conflicts of interest, and ensuring the objectivity of its inspection activities. Actions emanating from top management should not contradict this statement. (ILAC P15, 4.1.5a)

1.1.4. One way for the top management to emphasize its commitment to impartiality is to make relevant statements and policies publicly available. (ILAC P15, 4.1.5b)

2. STRUCTURAL REQUIREMENTS

2.1. Administrative

2.1.1. The inspection body should describe its activities by defining the general field and range of inspection (e.g., categories/sub-categories of products, processes, services, or installations) and the stage of inspection (see note to clause 1 of the standard) and, when applicable, the regulations, standards, or specifications containing the requirements against which the inspection will be performed. (ILAC P15, 5.1.3a)

2.1.2. The level of provisions should be commensurate with the level and nature of liabilities that may arise from the inspection body’s operations. (ILAC P15, 5.1.4a)

2.2. Organization and Management

2.2.1. Taken together, the size, structure, composition, and management of an inspection body shall be suitable for the competent performance of the activities in the scope for which the inspection body is accredited. (ILAC P15, 5.2.2a)

2.2.2. “To maintain the capability to perform the inspection activities” implies that the inspection body shall take steps to keep it appropriately informed about applicable technical and/or legislative developments concerning its activities. (ILAC P15, 5.2.2c)

2.2.3. Inspection bodies shall maintain their capability and competence to carry out inspection activities performed infrequently (normally with intervals longer than one year). An inspection body
may demonstrate its capability and competence for inspection activities performed infrequently through “dummy inspections” and/or through inspection activities conducted on similar products. (ILAC P15, 5.2.2c)

2.2.4. The inspection body shall maintain an up-to-date organization chart or documents clearly indicating the functions and lines of authority for staff within the inspection body. The position of the technical manager(s) and the member of management referenced in clause 8.2.3 should be clearly shown in the chart or documents. (ILAC P15, 5.2.4a)

3. ASSURING QUALITY/PROFICIENCY TESTING

3.1. General

3.1.1. Inspection bodies shall participate in activities to assure the quality of results through the use of proficiency testing/inter-laboratory (inspection body) comparisons (PT/ILC) when available. While the availability of PT/ILC is limited in the inspection conformity assessment activity area, if available, the inspection body is expected to participate.

3.2. Initial Requirements (if Available to the Inspection Body)

3.2.1. Before accreditation can be granted, applicant inspection bodies shall have performed satisfactorily in at least one approved PT/ILC or quality assurance activity.

3.2.1.1. Applicant inspection bodies shall provide reported results as evidence by a preliminary or final report issued by an approved PT/ILC provider, or an internal round-robin/qualification program. Qualifying results typically are no more than one year old from the initial assessment date to be considered acceptable.

3.3. General Requirements

3.3.1. Inspection bodies shall maintain a documented plan that ensures performance of appropriate PT/ILC activities or qualification activities covering each major field identified in the scope of accreditation.

3.3.2. Inspection bodies shall investigate any PT/ILC results found outside of predefined performance criteria, such as unsatisfactory results.

a. Inspection bodies are required to immediately notify ANAB of unsatisfactory PT/ILC results;

b. When necessary, corrective action shall be performed.

3.3.3. Inspection bodies shall maintain records of participation in PT/ILC or qualification activities.

3.3.4. Inspection bodies shall ensure that PT/ILC or qualification activities are distributed equally among trained and qualified personnel, such that one single person is not performing the majority of PT/ILC or qualification activities.

3.4. Types of Assuring Quality/Proficiency Testing Activities

3.4.1. Commercially Available PT/ILC

a. When available, inspection bodies shall select acceptable PT/ILC providers that can demonstrate their programs meet the requirements of the current version of ISO/IEC 17043. Acceptable PT/ILC providers are those accredited to ISO/IEC 17043 by ANAB or another accreditation body that is a signatory of the ILAC, APLAC, or IAAC MRA for PTP.
b. When accredited PT/ILC providers are not available, inspection bodies should use commercial programs that operate in accordance with ISO/IEC 17043 and programs that use as the reference inspection body an inspection body accredited to ISO/IEC 17025 by an ILAC, APLAC, or IAAC signatory accreditation body.

c. If the PT/ILC provider is not accredited or not listed on the ANAB website, the inspection body shall seek ANAB approval for the organization conducting the PT/ILC.

d. Any inspection body that is unable to locate a suitable PT/ILC provider shall contact ANAB for assistance.

3.4.2. Commercially PT/ILC Unavailable

a. If commercial PT/ILC is not available for a specific major field, the inspection body shall use internal performance-based assuring quality (AQ) procedures in accordance with ISO/IEC 17020 and ILAC P15.

3.5. Frequency of Assuring Quality/Proficiency Testing Activities

3.5.1. Inspection bodies shall participate in at least one approved PT/ILC activity each calendar year.

3.5.2. Inspection bodies shall perform a PT/ILC activity for each major field in their scope of accreditation within a four-year period.

4. METROLOGICAL TRACEABILITY

4.1. Inspection bodies shall ensure that all quantifiable results are traceable whenever possible through NIST or another National Metrology Institute (NMI) to the International System of Units (SI units).

4.2. When equipment and standards are used, calibration certificates shall, when applicable, provide indication of traceability by inclusion of the following information clearly visible on the certificate:

a. Uncertainty of measurement associated with a specified range of measurement for a specified measurement parameter (e.g., force, mass, temperature);

b. Statement regarding the confidence region of the data applicable to the uncertainties estimated and the coverage factor (k) used by the calibration facility;

c. Symbol of an ILAC-recognized accreditation body that has recognized the competence of the laboratory through accreditation, or equivalent.

d. Information regarding traceability through an NMI or intrinsic standard, and/or a statement of compliance with an identified metrological specification.

4.3. Equipment and reference standards that must be calibrated shall demonstrate traceability through one of the following:

a. Metrological traceability from an NMI: NIST or, when appropriate, to another NMI. Accredited inspection bodies can obtain certified reference materials from NIST (called Standard Reference Materials or SRM under trademark) or another NMI. Use of an NMI other than NIST must be documented as the appropriate NMI relevant for the scope of accreditation and stated uncertainties. An NMI whose service is suitable for the intended need and is covered by the CIPM MRA. Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB which includes the range and uncertainty for each listed service.

b. Traceability from an ISO/IEC 17025 accredited calibration laboratory: Inspection bodies shall use ISO/IEC 17025 accredited calibration laboratory services whenever available. ISO/IEC 17025...
accredited calibration laboratories are those accredited by ANAB or an accreditation body that is recognized as a signatory of the ILAC MRA.

i. When using accredited calibration laboratory services, the calibration certificates shall be accompanied by a recognized accreditation body symbol or otherwise make reference to accredited status to be considered satisfactory for traceability purposes. An accredited calibration laboratory whose service is suitable for the intended need (i.e., the scope of accreditation specifically covers the appropriate calibration) and the accreditation body is covered by the ILAC MRA or by Regional Arrangements recognized by ILAC.

5. TRACEABILITY UTILIZING REFERENCE MATERIALS

5.1. Inspection bodies shall ensure that all inspection and calibration results are traceable whenever possible through NIST or another NMI to the International System of Units (SI units).

5.2. Demonstration of Metrological Traceability Using Reference Materials

5.2.1. Inspection bodies shall obtain measurement traceability by using reference materials from accredited reference material producers (RMPs) and a National Metrological Institute (NMI).

a. Certified Reference Materials (CRMs) from an RMP accredited to ISO 17034 by an ILAC MRA signatory;

b. Standard Reference Materials® (SRM) from NIST (called under trademark);

c. National Metrological Institute (NMI). Use of an NMI other than NIST must be documented as the appropriate NMI relevant for the scope of accreditation and stated uncertainties.

5.2.2. If traceability per 5.2.1 is not possible, inspection bodies shall obtain measurement traceability from authoritative sources.

a. Inspection bodies are responsible for determining that reference materials obtained from authoritative sources are fit for intended uses in accordance with established and validated procedures.

5.2.3. If traceability per 5.2.1 or 5.2.2 is not possible, or when no methods or reference materials are available, inspection bodies shall develop reference methods or materials from internal validation.

a. Inspection bodies are responsible for validating methods and determining fitness for use.

5.2.4. The inspection body shall have a policy concerning measuring and monitoring devices having no significant influence on the results of inspection activities. Such exclusions shall be defined and documented.

5.3. Records for Reference Materials, Supporting Standards, Reagents, and Media

5.3.1. Inspection body records that support traceability for all reference materials and supporting standards, reagents, and media shall clearly provide the following information when applicable:

a. Chemical name or description;

b. Manufacturer’s lot number;

c. Assigned laboratory number;

d. Purchase orders;

e. Date received;

f. Recommended storage conditions;

g. Manufactures Certificate of Analysis (CoA) or purity;
h. Expiration date from manufacturer or laboratory-determined expiration date;
i. Inspection bodies shall not use the reference material past their expiry without validation that they are still suitable for use. Documentation shall be available of this validation.
i. Uncertainty of measurement associated with a specified range of measurement for a specified measurement parameter (e.g., analyte concentration in its matrix);
j. Statement regarding the confidence region of the data applicable to the uncertainties estimated and the coverage factor (k) used by the calibration facility;
k. Statement regarding the homogeneity and stability of the reference material;
l. Certificate of analysis that indicates reference to accreditation.

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

6. DEMONSTRATION OF COMPETENCY

6.1. Initial accreditation and re-assessments shall include witnessing of live or mock inspections carried out by inspection body personnel. In special cases when no such inspection witnessing can be arranged, a mock interview to assess the technical competence of inspection staff may be used subject to communication with the ANAB Accreditation Manager.

7. MANAGEMENT SYSTEM OPTIONS

7.1. If an inspection body claims conformity with Option B of ISO/IEC 17020, it shall demonstrate that it has established a management system that complies with ISO 9001 and that the management system is capable of supporting the consistent fulfillment of the requirements of ISO/IEC 17020.

7.2. ANAB shall verify the claims made by sampling the ISO 9001 management system relevant to its inspection activities.

7.2.1. ANAB will verify compliance with 8.1.3 through representative sampling and review of objective evidence against clauses 8.2 to 8.8 of the standard, as relevant to its inspection activities.

7.3. If the inspection body uses and has claimed conformity to Option B but the verification results in the identification of nonconformities, there will be multiple finding written, one set cited against clause 8.1.3 and others against the relevant clauses 8.2 to 8.8 of ISO/IEC 17020.

8. USE OF ANAB ACCREDITATION SYMBOLS AND CLAIMS OF ACCREDITATION

8.1. 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

8.2. ANAB allows the use of its symbol by accredited entities on inspection labels attached to inspected items.

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

1AR 2201, Control and Use of the Accreditation Symbol, remains in effect through December 31, 2018.
8.2.2. Inspection labels shall clearly indicate that the item has been inspected (e.g., “inspected by...” or “inspected on...” or equivalent).

8.2.3. Inspection labels bearing the ANAB symbol shall include the following:

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

### REVISION HISTORY

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<tr>
<td>Original Release</td>
<td>2017/05/11</td>
<td>Combined legacy ANAB and L-A-B accreditation requirements.</td>
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<tr>
<td>1</td>
<td>2017/12/20</td>
<td>Adds section 7 on Management System Options.</td>
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<td>2</td>
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<td>Added section 8 regarding use of ANAB accreditation symbols and claims of accreditation.</td>
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