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INTRODUCTION

This document defines accreditation requirements for ISO 15189 medical test laboratories (non-forensic). This document is to be used in conjunction with MA 2100, Accreditation Manual for Laboratory Related Activities (Non-Forensics). Additional supplemental program-specific documents may apply.

REFERENCES

ANAB MA 2100, Accreditation Manual for Laboratory Related Activities (Non-Forensics)

ISO 15189:2012, Medical laboratories – Requirements for quality and competence

ISO 22870:2016, Point-of-care testing (POCT) – Requirements for quality and competence

ISO/IEC 17043:2010, Conformity assessment – General requirements for proficiency testing

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

TERMS AND DEFINITIONS

**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 industry leaders.

**Competence:** Possession of required skill, knowledge, qualification, or capacity.

**Complexity:** Test categorization based on measure of the following: (1) scientific and technical knowledge, (2) training and experience, (3) reagent and material preparation, (4) characteristics of operational steps, (5) calibration, quality control, and proficiency testing materials, (6) test system troubleshooting and equipment maintenance, and (7) interpretation and judgment.

**Conformity assessment activity:** For ANAB purposes, calibration, testing, inspection, PTP, RMP, or medical test as identified on the scope of accreditation.

**Inter-laboratory comparison (ILC):** Organization, performance, and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions. [ISO/IEC 17043:2010 3.4]

**Specialty:** For ANAB purposes, specialties are the categories of medical testing as identified on scope of accreditation.

**National Metrology Institute (NMI):** National Metrology Institutes 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.

**Participation (proficiency testing):** Making the measurements or observations and submitting for evaluation.

**Related discipline:** For ANAB purposes, a related discipline further defines the specialty.
1. PROFICIENCY TESTING

1.1. General Requirements

1.1.1. The laboratory shall participate in appropriate proficiency testing (PT) activities or alternatives that represent the test, analyte, method, and matrices described on the scope of accreditation, regardless of test complexity level. Providers of PT activities and alternatives must provide performance evaluation according to predefined criteria appropriate to the laboratory’s needs.

1.1.2. The laboratory shall maintain a documented plan that ensures participation for the current year and ongoing four-year cycle, and at a minimum the laboratory’s PT program shall:

   1.1.2.1. Identify to ANAB the approved program or programs in which it chooses to participate to meet PT requirements (see section 1.2).
   1.1.2.2. Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this section.
   1.1.2.3. Submit all PT program data required to ANAB for determination of the laboratory’s compliance with this section (see section 1.4).

1.1.3. The laboratory must examine or test, as applicable, the PT samples it receives from the PT program in the same manner it tests patient specimens. If the laboratory’s patient-specimen-testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the PT sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

1.1.4. The samples must be examined or tested with the laboratory’s regular patient workload by personnel who routinely perform testing in the laboratory (preferably rotating analysts), using the laboratory’s routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory’s routine methods.

1.1.5. The laboratory must test samples the same number of times that it routinely tests patient samples.

1.1.6. Laboratories that perform tests on PT samples must not engage in any inter-laboratory communication pertaining to the results of PT sample(s) until after the date by which the laboratory must report PT results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communication or discussion across sites or locations concerning PT sample results until after the date by which the laboratory must report PT results to the program.

1.1.7. The laboratory must not send PT samples or portions of PT samples to another laboratory.

1.1.8. The laboratory must document the handling, preparation, processing, and examination, and each step in the testing and reporting of results for all PT samples. The laboratory must maintain a copy of all records, including a copy of the PT program report forms used by the laboratory to record PT results, including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that PT samples were tested in the same manner as patient specimens, for a minimum of four years from the date of the PT event.

1.1.9. PT is required for all test systems, assays, and examinations identified on the scope of accreditation and used for patient testing during the PT event. The laboratory shall not perform PT on secondary testing systems using the same PT materials obtained for the primary testing system.
1.1.10. The laboratory shall investigate any results found outside of predefined performance criteria, such as unsatisfactory results.

- The laboratory shall immediately notify ANAB of unsatisfactory results.
- When appropriate, corrective action shall be performed.
- A record of the investigation summary and conclusion shall be retained.

1.2. Types of Activities

1.2.1. If other factors are similar, the laboratory shall select, when available, PT/inter-laboratory comparison (ILC) providers accredited to ISO/IEC 17043 by ANAB or another accreditation body that is a signatory of the APLAC or IAAC MRA for PTP. In addition, PT providers that can demonstrate their programs meet the criteria in Subpart I of 42 CFR § 493 and are approved by CMS may be used. A list of CMS-approved PT providers is available at [http://www.cms.hhs.gov/clia/](http://www.cms.hhs.gov/clia/).

1.2.2. When ISO/IEC 17043 accredited PT/ILC providers or CMS-approved PT providers are available but not used, 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 ISO/IEC 17043 accredited PT/ILC or CMS-approved PT providers are not available or appropriate, the laboratory shall seek to use programs that operate in accordance with ISO/IEC 17043, if available. The laboratory shall seek written ANAB approval for each PT/ILC or alternative scheme. This written ANAB approval shall be documented prior to participation. Acceptable alternatives include but are not limited to:

- Split sampling or blind testing of patient samples within or between laboratories
- Analysis of manufacturer’s calibration material
- Evaluation of interlaboratory quality control data
- Re-evaluation of interpreted results
- Direct observation
- Clinical correlation studies

A useful reference is CLSI document QMS24, Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality.

1.3. Frequency of Activities

1.3.1. Proficiency and ILC samples shall mimic patient samples when possible and have the effect of checking the entire examination process and across the reportable range. For all laboratories, POCT, and satellite sites, the minimum participation required is two activities per calendar year, preferably with multiple samples in each. The laboratory is highly encouraged to participate more frequently as individual circumstances may dictate.

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 or alternative activity.

1.4.2. The applicant laboratory shall provide reported results as evidenced by a preliminary or final report issued by an approved provider. Qualifying results typically are no more than six months old from the initial assessment date to be considered acceptable.

1.5. PT Review

1.5.1. The laboratory shall review and evaluate the results obtained from the PT provider.
1.5.2. The laboratory shall keep a record of the results of reviews and any action taken in response to risks identified during the review.

1.6. Accuracy Review

1.6.1. The laboratory also shall verify the accuracy of the following:

- Any analyte or subspecialty without analytes listed in Subpart I of the Clinical Laboratory Improvement Amendments (CLIA) requirements, 42 CFR § 493, that is not evaluated or scored by an approved PT program
- Any analyte, specialty, or subspecialty assigned a PT score that does not reflect laboratory test performance (that is, when the PT program does not obtain the agreement required for scoring, as specified in Subpart I of the CLIA requirements, or the laboratory receives a zero score for nonparticipation or late return of results)
- At least twice annually, the laboratory shall verify the accuracy of the following:
  o Any test or procedure it performs that is not included in Subpart I of the CLIA requirements or for which compatible PT samples are not offered by an approved PT program
  o All PT evaluation and performance verification activities shall be documented

2. METROLOGICAL TRACEABILITY

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

2.2. Demonstration of Metrological Traceability

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

a) National Metrology Institute (NMI). The laboratory can use NIST or, when appropriate, another NMI. The accredited laboratory can obtain certified reference materials [called Standard Reference Materials (SRM) under trademark] from NIST 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.
   i) The laboratory shall use 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) Intrinsic Standard. When intrinsic standards are used, the laboratory shall demonstrate by measurement assurance techniques, ILC, or other suitable means that the intrinsic measurement results are correlated with an NMI.

c) Traceability from Weights and Measures Lab. Prospective customers and accredited laboratories can use national, state, or provincial weights and measures laboratories recognized and/or traceable to the country NMI. Evidence of recognition and/or traceability shall be available during the assessment.

d) External ISO/IEC 17025 Accredited Calibration Laboratory. If external calibration is used, the laboratory 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 recognized as a signatory of the International Laboratory Accreditation Cooperation (ILAC) MRA.

e) 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.

f) Reference Materials. See sections 2.5 through 2.8.

g) For NMI, calibration provider, or reference standard not covered in sections a, b, c, d, or e above, the laboratory shall contact ANAB for written approval.

2.3. Calibration Certificates

2.3.1. Calibration certificates that support the equipment and reference standards used in testing when applicable shall provide indication of traceability through inclusion of the following information clearly visible on the certificate:

- The uncertainty of measurement associated with a specified range of measurement for a specified measurement parameter (e.g., force, mass, temperature)
- A statement regarding the confidence region of the data applicable to the uncertainties estimated and the coverage factor (k) used by the calibration facility
- The symbol of an ILAC-recognized accreditation body that has recognized the competence of the laboratory through accreditation or equivalent
- Information regarding traceability through an NMI or intrinsic standard and/or a statement of compliance with an identified metrological specification

2.4. The laboratory shall maintain a list documenting how traceability of measurement is achieved (e.g., accredited calibration provider, SRM) for measurement equipment types associated with the scope of accreditation.

2.5. Using Reference Materials

2.5.1. 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).

2.5.2. Demonstration of Metrological Traceability Using Reference Materials

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

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

2.5.2.2. If traceability per ISO 15189 section 5.3.1.4 is not possible, the laboratory shall obtain measurement traceability from authoritative sources.

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

2.5.3. The laboratory shall define the specification and tolerance requirements for reference materials.

2.5.4. Reference materials shall not be altered from the original state from the manufacturer without validation that they are still suitable for use. Documentation of this validation shall be available.
2.6. Traceability to the Method

2.6.1. When it is not possible to demonstrate metrological traceability using reference materials, the laboratory shall develop reference methods or materials from internal validation.

2.7. Traceability by Other Means

2.7.1. When traceability cannot be established per 2.5 or 2.6, the laboratory shall use other means to provide confidence that it meets the requirement of ISO 15189.

2.8. Records for Reference Materials Traceability

2.8.1. Laboratory records that support traceability for all reference materials shall clearly provide the following information, when applicable:

- Chemical or microbiological name or description
- Manufacturer’s lot number
- Assigned laboratory number
- Date received
- Recommended storage conditions
- Manufacturer’s Certificate of Analysis (CoA) or purity
- Expiration date from manufacturer or laboratory-determined expiration date
  - The laboratory shall not use a reference material past its expiry without validation that it is still suitable for use. Documentation of this validation shall be available.
- Uncertainty of measurement associated with a specified range of measurement for a specified measurement parameter (e.g., analyte concentration in its matrix)
- Statement regarding the homogeneity and stability of the reference material
- Certificate of analysis that indicates reference to accreditation

3. UNCERTAINTY

3.1. The laboratory shall have a documented uncertainty of measurement procedure and be able to demonstrate to ANAB during an assessment that they can apply their uncertainty of measurement calculation procedure as required by ISO 15189 section 5.5.1.4.

4. IN-HOUSE CALIBRATIONS

4.1. To ensure traceability of measurement, the accredited testing laboratory may calibrate its own equipment that supports an accredited parameter on the scope if the relevant requirements ISO 15189 and the following requirements are met:

4.1.1. Appropriate environment for carrying out the calibration
4.1.2. Appropriately trained personnel to both carry out and check the calibrations
4.1.3. Laboratory shall demonstrate competence to perform the calibrations it undertakes
4.1.4. Reference standards, certified reference materials, or reference measuring instruments are traceable with appropriate measurement uncertainties
4.1.5. Documented procedure for each type of calibration
4.1.6. Appropriate means of recording and reporting the data and results of any calculations according to the requirements of ISO/IEC 17025

4.1.7. Procedure for calculating the measurement uncertainty for each calibration and ability to demonstrate to ANAB during an assessment that they have applied their uncertainty measurement calculations

4.2. The laboratory shall maintain a list of in-house calibrations documenting the traceability of the measurements associated with the scope technologies (see section 2.4).

4.3. If the laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

5. SAFETY PROGRAM

5.1. ISO 15189 includes specific requirements for safe handling of biological specimens, equipment, and facilities; because of the nature of specimens examined by medical laboratories, safety considerations cannot be ignored. All medical laboratories accredited by ANAB shall have and follow a documented environmental health and safety program, with an individual designated as the manager or safety officer overseeing the operations of that program. ISO 15190, Medical laboratories – Requirements for safety, is a useful reference in determining safety requirements.

6. CODE OF ETHICS

6.1. Previous versions of ISO 15189 included an annex to provide insight into ethical considerations in the practices of laboratory medicine. The current version of ISO 15189 requires laboratory management to provide ethics training and ensure the ethical conduct of all personnel.

6.2. The American Medical Association, the American Society for Clinical Pathology, and other professional organizations have codes of ethics that can provide guidance for ethics training and conduct. When none of these apply, or when none apply to all personnel, the agency shall develop its own code of ethics based on these or similar examples or similar. The code shall include a description of the action to take when a breach is encountered.

6.3. The code adopted shall be incorporated in the organization’s management system and communicated to all employees.

7. PROFESSIONAL QUALIFICATIONS

7.1. ISO 15189 accreditation supplements specific government regulations and professional governance documents with which medical laboratories may be required to comply. The laboratory must meet professional qualifications and educational and other specified requirements as required by government regulations. When no such regulation exists, it is recommended that the laboratory use the requirements of CLIA, 42 CFR § 493.
8. POINT-OF-CARE TESTING

8.1. For medical laboratories seeking accreditation of testing performed near or at the site of a patient, ISO 22870, Point-of-care testing (POCT) – Requirement for quality and competence, applies and ANAB may incorporate these requirements in the assessment.

9. USE OF ANAB ACCREDITATION SYMBOLS AND CLAIMS OF ACCREDITATION

9.1. 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

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<tr>
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<tr>
<td>1</td>
<td>Added section 10 regarding use of ANAB accreditation symbols and claims of accreditation.</td>
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<td>2</td>
<td>Added ILC under Definitions, expanded sections on PT and traceability, and combined sections 2 and 3.</td>
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