



AMERICAN
ACCREDITATION
ASSOCIATION

Proficiency Testing policy



Document No.

P-LAB-01

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1. Scope:

- 1.1 AAA considers the participation of laboratories in external proficiency testing / inter-laboratory comparisons an important mechanism for demonstrating the technical competence of a laboratory and monitoring the integrity of test / calibration results. This statement sets out the policy of the American Accreditation Association with respect to participation in proficiency testing / inter-laboratory comparisons. This document relates to applicant and accredited laboratories, including medical, testing, and calibration laboratories (ISO 15189 and ISO/IEC 17025) with specific requirements re ISO 15189 and ISO 17025 laboratories respectively.
- 1.2 This document may also relate to Inspection Bodies (ISO 17020) as proficiency testing may also be applicable in many types of Inspection.
- 1.3 It is the responsibility of laboratories and inspection bodies to source suitable proficiency test providers or arrange inter-laboratory comparisons as needed.

2. Definitions

2.1 Proficiency testing (PT)

Evaluation of participant (testing or calibration laboratory) performance against pre-established criteria by means of inter-laboratory comparisons. (ISO/IEC 17043 3.7)

2.2 External Quality Assurance (EQA)

EQA is considered to be equivalent to Proficiency Testing.

2.3 Inter Laboratory comparison (ILC)

Organization, performance, evaluation of calibrations/tests (measurements) on the same or similar calibration / test items by two or more laboratories in accordance with predetermined conditions

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3. AAA general policy for Proficiency Testing

- 3.1 It is AAA policy that all applicant and accredited testing/calibration laboratories are required to participate in appropriate PT/ILCs and achieve a satisfactory performance.
- 3.2 AAA recommends that proficiency testing scheme providers accredited to ISO 17043 are used by laboratories, where possible.
- 3.3 Laboratories shall develop a plan for the level and frequency of participation in PT, over the re-assessment cycle. The plan shall be regularly reviewed and shall be updated when:
- 3.3.1 Changes in staffing, volume of work
 - 3.3.2 Changes to work activities, extensions to scope
 - 3.3.3 Change in laboratory equipment, methodologies etc.
 - 3.3.4 Location of testing for example; site laboratory, main laboratory
- 3.4 The plan shall be based on a comprehensive risk assessment which will consider (among other measures) the volume of testing/calibration, the frequency of testing/calibration, the significance and final use of the testing/calibration result where a higher level of assurance may be required (e.g. medical testing, forensic science), accreditation of flexible scopes.
- 3.5 The plan shall be developed in consideration of all regulatory or professional body requirements.
- 3.6 The plan shall ensure all applicant and accredited measurement techniques are included. All staff performing accredited testing/calibration shall be included in the plan
- 3.7 Laboratories preparing for initial accreditation or wishing to extend their scope of accreditation are required to participate in and achieve satisfactory performance in a PT/ILC where such schemes are available and relevant to

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their scope of accreditation before a recommendation for accreditation can be considered.

- 3.8 Where no appropriate proficiency testing or inter-laboratory comparison is available, the laboratory will be required to demonstrate the validity of its tests and calibrations by other means such as replicate testing, use of certified reference materials, calibrations using the same or a different method, analysis of blind samples etc.
- 3.9 The AAA assessment team will review at each surveillance visit the laboratory's plan and performance in proficiency testing / inter-laboratory comparisons. Laboratories are required to monitor and review their on-going PT/ILC participation and performance and have appropriate acceptance criteria and a procedure for investigating flagged (or anomalous) results and implementing corrective actions when these acceptance criteria are not met. A written record of these activities shall be maintained.
- 3.10 If at any time the laboratory's performance in proficiency testing / inter-laboratory comparisons in the opinion of AAA, casts doubt on the integrity of test results, AAA may suspend the relevant tests from the laboratory's scope of accreditation. The laboratory will be required to provide AAA with written evidence that the problem has been identified and satisfactorily rectified (which may include demonstrated satisfactory performance in subsequent proficiency testing/inter laboratory comparisons) before re-instatement of accreditation can be considered.

4. Proficiency Testing policy for Medical Laboratories

- 4.1 ISO 15189 requires laboratories to participate in an inter-laboratory comparison program(s) (such as an external quality assessment program or proficiency testing program) appropriate to the examination and

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interpretations of examination results. The laboratory shall establish a documented procedure for inter-laboratory comparison participation that includes defined responsibilities and instructions for participation, and any other performance criteria that differ from the criteria used in the - comparison program. Wherever an ILC is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results.

5. References:

- ISO/IEC 17025:2005/2017 General requirements for the competence of testing and calibration laboratories
- ISO 15189:2012 Medical laboratories - Particular requirements for quality and competence
- ISO/IEC 17043:2010 Conformity assessment - General Requirements for Proficiency Testing
- ISO/IEC 17020:2012 Conformity assessment - Requirement's for the operation of various types of bodies performing inspection
- ILAC P9:11/2010 Policy for Participation in Proficiency Testing Activities
- ISO/IEC 17011:2017 Requirements for bodies providing assessment and accreditation of conformity assessment bodies

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