PROFICIENCY TESTING POLICY

Revision 1

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1.0 SCOPE

All AB accredited laboratories are required to participate in Proficiency Testing (PT) or Inter-laboratory Comparison (ILC) Programmes recognized by AB. This policy is also applicable to inspection bodies, where relevant.

In the context of this document, “laboratories” implies all laboratory types – ie testing, calibration and medical laboratories.

2.0 BACKGROUND

According to ISO/IEC 17025, a laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. This monitoring may include the participation in interlaboratory comparisons or proficiency testing programmes. ISO 15189 also requires that medical laboratories seek confirmation for confidence in their results through participation in suitable interlaboratory comparisons.

This document details AB’s policy on proficiency testing with regard to laboratories and where relevant to inspection bodies accredited by AB.

3.0 SPECIFIC POLICY

3.1 Laboratories shall also participate (as far as available and practicable) in international Inter-Laboratory Comparison/ Proficiency Programmes conducted by APLAC, EA or equivalent organizations. AB provides guidance to the laboratories regarding the proficiency testing programmes through its website, by giving reference to international programmes organised by EPTIS, FAPAS etc. This helps the laboratories in participating in other programmes, in case there are not national programmes available.

3.2 AB is expected to enforce the requirements of APLAC MR 001: ‘Establishing and Maintaining Mutual Recognition Arrangements amongst Accreditation Bodies’ (Cl. 3.3) and ILAC P9: ‘ILAC Policy for Participation in Proficiency Testing Activities’. Accordingly it will be essential for all its accredited laboratories to demonstrate technical competence of its accredited laboratories by satisfactory participation in International/ Regional/ National Proficiency Testing Programmes, including APLAC.

3.4 The PT / ILC program should be conducted in accordance with ISO/ IEC 17043: Conformity assessment -- General requirements for proficiency testing. For this purpose all alternative techniques covered in ISO/ IEC 17043 shall be acceptable.

3.5 At the time of on-site assessment, assessors shall find out whether the laboratories have participated in International/ Regional/ National recognized PT / ILC programme and whether the necessary corrective action were taken, if in terms of Z-Score, En number etc. the laboratory performance has not been satisfactory.

3.6 Satisfactory performance in a Proficiency Testing Programme shall not be considered only criteria for technical competence.

3.7 AB shall nominate its accredited/applicant laboratories for participation in APLAC and other international Proficiency Testing programme, as and when they are available. Following sequential preference shall be given to the laboratories.

- Accredited laboratories not having participated in any other APLAC PT programme.
- Accredited laboratories not having participated in AB PT programme or any other programme recognized by AB.
- Laboratories having unsatisfactory performance in a past PT programme.
- Laboratories with long period of accreditation.
- Applicant laboratories.

3.8 AB shall co-ordinate all activities related to PT programme with APLAC/ other international bodies and the participating laboratories.

3.9 AB sometimes, based on demand, necessity and availability of time, may organize PT/ILC programme by selecting a nodal laboratory according to the procedure described in clause 5.0 of this document.

4.0 PROFICIENCY TESTING (PT) COVERAGE REQUIREMENT

4.1 The PT participation shall be such that each major sub disciplines of a laboratory's scope of accreditation are covered in a cycle of three years. This will of course not apply to those special areas where formal Proficiency Testing Programmes are not available.

4.2 All applicant laboratories are required to successfully participate in PT / ILC in at least one parameter/ type of test/ calibration per discipline at least once, prior to grant of accreditation.

4.3 All accredited laboratories except medical laboratories are required to successfully participate in PT / ILC in at least one parameter/ type of test/ calibration per discipline at least once per year to maintain accreditation.

4.4 The accredited medical laboratories are required to participate, at least once in every quarter (03 months), in the PT / External Quality Assurance Scheme/ ILC, as appropriate.

5.0 PROCEDURES OF PT/ILC ORGANIZED BY AB

5.1 For Testing Laboratories

- AB identifies various areas of testing where in Proficiency Testing Programme are required to be initiated. Normally, accredited laboratories/ competent shall be selected as nodal laboratories to conduct the PT programmes. In case, the accredited laboratories are not available for a particular test then non-accredited laboratories with sufficient infrastructure and resources may be considered by AB to act as nodal laboratories.
- AB will evaluate each proposal, received from the applicant laboratory w.r.t its merit as per requirements of **ISO/ IEC 17043** and select a nodal laboratory.
- The applicant laboratories may be invited to present their proposals in AB to provide clarification and technical details of the PT program.
- The nodal laboratory in consultation with AB shall design the programme and their testing specification on PT for the participating laboratories.
- Procurement of materials with appropriate precautions for PT programme shall be the responsibility of the nodal laboratory. The nodal laboratory shall ensure that the source of material is authentic and that the producer certifies the composition & properties of the PT material.
- Nodal laboratories under the guidance of AB shall conduct homogeneity testing of the materials before dispatching the samples to the participating laboratories.
- The nodal laboratories shall carry out proper packaging and dispatching of the samples to participating laboratories. The sample should be accompanied with the instruction sheet, sample receipt form and result proforma.
- The participating laboratories shall conduct the required test, complete the result sheet and dispatch it to AB.
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- After receiving the results from the participating laboratories, AB will allot a laboratory code number to each participating laboratory, to maintain confidentiality. The result sheet with code number of all the participating laboratories shall be dispatched by AB to the nodal laboratory for analysis of test data and statistical calculations for performance evaluation. The analysis and calculations shall be done in consultation with AB.
- Nodal laboratory shall prepare a report of the specific PT programme. The Nodal laboratory shall also prepare laboratory summary sheets for each participating laboratory indicating the performance score, satisfactory / unsatisfactory (outlier) performance and laboratory code number. The same shall be submitted to AB.
- The summary sheet of each participating laboratory shall be communicated to the participating laboratories on confidential basis by AB in form of a report.
- The outlier laboratory shall take necessary corrective actions within two months from the date of receipt of communication from AB.

5.2 For Calibration Laboratories

- AB identifies a nodal laboratory either NMI or AB accredited laboratories or any competent laboratory determined by AB to conduct Proficiency Testing (PT) / Inter-Laboratory Comparisons (ILC) as per **ISO/ IEC 17043**.
- The nodal laboratory coordinating the PT / ILC program regularly interacts with AB at every stage of ILC.
- The nodal laboratory shall acquire the artefacts required for conducting the PT / ILC program. The nodal body shall assign the value of the artefacts based on its own characterization.
- The nodal laboratory shall submit the technical protocol of the PT / ILC program to AB for approval and AB will send a list of accredited / applicant laboratories for participation in PT / ILC program.
- The artefact shall be circulated by nodal laboratory to participating laboratories in sequence following a round robin route.
- Each laboratory shall be required to perform measurement with the Calibration and measurement capability (CMC) following the specific calibration procedure and conditions.
- The laboratory shall send the measurement result to the nodal laboratory within a fixed time allotted to each laboratory.
- At any stage during the round robin test, the nodal laboratory may require the artefacts to be brought back for assessing the stability, if needed. At the end of the round robin test the artefact shall be brought back to the nodal body for final measurement to assess its stability and to detect any change if that is taken place.
- Results received from participating laboratory shall be analyzed statistically by the nodal laboratory. The En number in absolute terms shall be the indicating factor to ascertain the performance of the participating laboratory.
- The nodal laboratory shall submit interim reports to AB at appropriate intervals, where necessary. Besides above, the nodal laboratory shall submit a final report to AB on completion of the programme.
- The nodal laboratory shall maintain confidentiality and communicate the results directly to the participating laboratories and AB.
- The laboratory shall take necessary corrective action in terms of En number.
- AB shall monitor the progress of corrective actions taken by the Calibration laboratories and shall be in regular correspondence with the participating laboratories in this matter.

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