

POLICY FOR PARTICIPATION IN PROFICIENCY TESTING ACTIVITIES

1. Scope :

This document describes the policies that SLAB has formulated in relation to the participation in Proficiency Testing (PT) activities in order to comply with ILAC-P9 -06: 2014, ILAC Policy for Participation in Proficiency Testing activities.

This document stipulates the minimum requirements of PT participation for accreditation of testing, calibration, medical laboratories and inspection bodies (Where relevant).

This document provides guidelines for SLAB decision making committees, assessors and laboratories on participation in PT activities.

This also gives information about the measures against poor performance of laboratories in a defined Proficiency Testing program and information on potential PT providers.

2. Reference :

ILAC P9-06 -2014 - ILAC Policy for Participation in Proficiency Testing activities

3. Procedure:

Proficiency Testing is one of the important tools to determine the technical competence of the testing /calibration laboratories, medical laboratories and inspection bodies.

According to ISO/IEC 17025:2005, participation in Proficiency Testing programs /Inter laboratory comparison is significant means for assuring the quality of test/calibration results. Where relevant, Inspections bodies involve in inspection and testing activities are also required to comply with ISO/IEC 17025 requirements for testing activities.

According to ISO 15189:2012, medical laboratories shall participate in inter-laboratory comparisons such as those organized by external quality assessment schemes.

3.1 Participation

3.1.1 Applicant testing laboratories and calibration laboratories except medical testing laboratories shall successfully participate in at least one PT program to cover at least one parameter prior to gaining accreditation in each product group applied. All parameters/ types of tests included in the accredited scope of each discipline of testing and calibration laboratories except medical testing shall be covered at least once every three years.

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3.1.2 In medical testing, laboratories shall participate in at least one Proficiency Testing / External Quality Assurance Scheme to cover at least one parameter/ type of test per major discipline prior to gaining accreditation and all parameters/ types of tests included in the accredited scope of each discipline in at least three times a year.

3.1.3 In inspection, applicant inspection bodies shall participate in at least one PT programme (where relevant and applicable) prior to applying for accreditation and accredited inspection bodies shall cover all inspections under the scope within three years.

3.1.4 Accredited testing laboratories including medical testing & calibration laboratories and Inspection bodies shall have a three year PT plan for Proficiency Testing participation which shall cover all the accredited scope under each product group/ field of testing/ type of inspection.

3.1.5 Laboratories including testing, medical & calibration and inspection bodies are encouraged to participate in more than one PT programme and also programmes organized by accredited PT providers as per ISO/IEC 17043 where relevant and available or PT providers recognized by SLAB.

3.1.6 Generally, the choice of programmes rests with the laboratory. The laboratory may select any programme from APLAC PT 003 ‘Proficiency Testing Directory’. This directory may be accessed by <http://www.aplac.org>. This list is not exhaustive and is constantly revised to include new programmes. ILAC has endorsed the use of European Information System on Proficiency Testing Schemes (EPTIS) database for use by laboratories. This database may be accessed by <http://www.eptis.bam.de>. In addition, SLAB has posted lists of recognized PT providers which could be accessed by <http://slab.lk/PTProgrammes.aspx>.

3.1.7 Grouping of tests or inspections for PT participation is accepted based on the technically valid justification and such justifications are subjected to review by the SLAB accreditation committees and assessors.

3.1.8 Where no programme is available for a particular field of testing including medical, calibration, or inspection, the laboratory shall participate in inter-laboratory comparisons preferably with at least 2 accredited laboratories (where applicable & relevant). Laboratories should refer to AC-GL(P)-08: Guideline for Proficiency Testing Programmes or any other guideline published by ILAC MRA Partner or APLAC PT 001 ‘Calibration Inter-laboratory Comparisons’ and APLAC PT 002 ‘Testing Inter-laboratory Comparisons’ when organizing inter-laboratory comparison. APLAC documents are available at <https://www.aplac.org>.

3.1.9 In case for a particular test parameter, when accredited laboratories are not available for Inter-laboratory comparison, if laboratories compare its results with non-accredited laboratories, such laboratories shall prove their competence through traceability of measurement, competent personnel, availability of equipment with required accuracy, test methods, satisfactory performance in, internal Quality Control and ILC or PT with an evaluation as per ISO/IEC 17025/ ISO 15189/ISO/IEC 17020 requirements.

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3.2 Evaluation of Performance

3.2.1 The laboratory/ inspection body shall keep the records of raw data including original observations with work sheets or similar records, personnel involved in testing, and results of all proficiency testing programmes that it has participated and evidence for the reviewing PT reports and investigations & actions taken for the outliers or questionable results and trend analysis.

3.2.2 These records are to be formally reviewed as part of the assessment by SLAB during on-site assessment visits as well as SLAB Accreditation Committee and SLAB staff where required.

3.2.3 At the time of on-site assessment, assessment team shall verify whether the laboratories have participated in recognized Proficiency Testing Program as per the PT plans and whether the necessary corrective actions were taken.

3.2.4 For testing programmes, the criteria for performance is typically z-score (to be less than 3) and En ratio (less than [1]) for calibration programme or criteria defined by the PT provider.

3.2.5 Corrective actions for outliers and questionable results shall be taken within a month. It is recommended to show through participating in another PT or ILC or other means to verify the effectiveness of actions taken for outliers.

3.2.6 Failure to investigation and taking actions within a month may result in a temporary suspension of particular parameter. Reinstatement of suspended test parameters is done only after on site witness assessment and satisfactory performance in another PT or ILC programme or other means within three months.

3.2.7 If satisfactory actions are not taken within three months, particular test parameters will be withdrawn from the accredited scope.

3.3 APLAC PT Programmes

3.3.1 SLAB shall nominate its accredited/applicant laboratories for participation in APLAC and other international Proficiency Testing programs, 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 program.
- Accredited laboratories not having participated in PT program or any other program recognized by SLAB
- Laboratories having unsatisfactory performance in a past PT program.
- Laboratory with long period of accreditation
- Applicant laboratory

3.3.2 SLAB PT coordinator shall co-ordinate all activities related to PT program with APLAC and the participating laboratories as per AC –PR -16.

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3.4 Calibration Laboratories

3.4.1 In the field of calibration where formal PT Programs are not available, alternatively the applicant / accredited laboratories may participate in suitable inter-laboratory comparisons organized by National Measurement Institute (NMI) or any other accredited calibration laboratory as per SLAB PT Guidelines (AC-GL(P)-08).

Note: For calibration laboratories, measurement audits will be considered to be a complimentary effort to Inter-Laboratory Proficiency Testing. The calibration laboratories will be provided with artifacts with their characterization by National Measurement Institute (MUSSD) or calibration laboratory recognized by SLAB as pilot laboratory for the same objective or any other NMI's who are signatory to BIPM.

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