Policy for Participation in External Quality Assurance activities

1. Scope:

This document describes the policies that SLAB has formulated in relation to the participation in External Quality Assurance (EQA) activities such as Proficiency Testing (PT) and Interlaboratory Comparisons (ILC) in order to comply with ILAC-P9 -06: 2014, ILAC Policy for Participation in Proficiency Testing activities and relevant accreditation criteria.

This document stipulates the minimum requirements of EQA participation for accreditation of testing, calibration, medical laboratories, inspection bodies and good laboratory practice (Where relevant).
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This also gives information about evaluation of performance and the measures against poor performance in an EQA program.

2. Reference:

ILAC P9-06 -2014 -	ILAC Policy for Participation in Proficiency Testing activities
ISO/IEC 17025: 2017-	General Requirements for the Competence of Testing and Calibration Laboratories, Sec. 7.7
ISO 15189: 2012-	Medical Laboratories –Requirements for Quality and Competence, Sec. 5.6

3. Responsibility:

All applicant and accredited Conformity Assessment Bodies (CABs)
Authorized Officer
Technical Manager
Team Leaders/ Technical Assessors/ Assessors
Accreditation Committee members

4. Procedure:

EQA is one of the important tools to determine the technical competence of the testing /calibration laboratories, medical laboratories, inspection bodies and good laboratory practice.

According to ISO/IEC 17025:2017, 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 and measurement activities.

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

Generally, the choice of programmes rests with the laboratory/inspection body.

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. However, those lists are not exhaustive and are constantly revised to include new programmes.

Information on accredited PT providers is also available through official websites of Accreditation Bodies under ILAC and APAC MRA partners for PT.

4.1 Participation

4.1.1Testing Laboratories

4.1.1.1 Applicant testing laboratories shall successfully participate in at least one EQA program to cover all parameters prior to gaining accreditation covering each product group applied. All parameters/ types of tests included in the accredited scope of each discipline of testing laboratories shall be covered at least once every three years.

4.1.1.2 Applicant/Accredited laboratories shall prepare a three year EQA plan considering similar nature of testing/common tests for different product groups/risks associated with the relevant parameters.

4.1.1.3 Where available, the laboratories are encouraged to participate in more than one EQA programme and also programmes organized by accredited PT providers as per ISO/IEC 17043.

4.1.1.4 Where no PT programme is available for a particular field of testing, the laboratory shall participate in inter-laboratory comparisons with at least one or more accredited laboratories. The Organizing laboratory shall consider capabilities of other participant laboratories before executing ILC. Laboratories should evaluate the performance statistically as per ISO/IEC 17043 and ISO 13528 or any other guideline/s published by ILAC/APAC MRA Partner.

4.1.1.5 In case for a particular test parameter, when accredited laboratories are not available or not feasible to participate in foreign Inter-laboratory comparison programmes, the laboratories may compare its results with non-accredited laboratories through prior agreement with SLAB. suitability of such laboratories shall be evaluated for 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 requirements.

4.1.2 Calibration Laboratories

4.1.2.1 Applicant calibration laboratories shall successfully participate in at least one EQA program to cover major calibration disciplines (e.g. Mass, Length, Force, Thermal, etc.) prior to gaining accreditation. All calibrations included in the accredited scope of each discipline of calibration laboratories shall be covered at least once every three years.

4.1.2.2 Applicant/Accredited calibration laboratories shall prepare a three year EQA plan considering similar nature of calibrations and measurements/risks associated with the relevant parameters.

4.1.2.3 Where available, the calibration laboratories are encouraged to participate in more than one EQA programme and also programmes organized by accredited PT providers as per ISO/IEC 17043/National Measurement Institute (NMI) or designated body who published their CMCs in BIPM KCDB

(Calibration Measurement Capabilities in International Bureau of Weights and Measures Key Comparison Data Base).

4.1.2.4 Where no PT programme is available for a particular field of calibration, the laboratory shall participate in inter-laboratory comparisons with at least one or more accredited calibration laboratories having smaller uncertainties or CMCs/ NMI or designated body who published their CMCs in BIPM KCDB. Calibration laboratories should evaluate the performance statistically as per ISO/IEC 17043 and ISO 13528 or any other guideline/s published by ILAC/APAC MRA Partner.

4.1.2.5 In case for a particular calibration parameter, when accredited laboratories are not available or not feasible to participate in foreign Inter-laboratory comparison programmes, the laboratories may compare its results with non-accredited laboratories/NMI or designated body through prior agreement with SLAB. suitability of such laboratories shall be evaluated for 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 requirements.

4.1.3 Medical Laboratories

4.1.3.1 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.

4.1.3.2 Applicant/Accredited laboratories shall prepare a three year EQA plan considering field of testing/risks associated with the relevant parameters.

4.1.3.3 Where available, the laboratories are encouraged to participate in more than one EQA programme and also programmes organized by accredited PT providers as per ISO/IEC 17043.

4.1.3.4 Where no PT programme is available for a particular field of testing, the laboratory shall participate in inter-laboratory comparisons with at least one or more accredited laboratories. The Organizing laboratory shall consider capabilities of other participant laboratories before executing ILC. Laboratories should evaluate the performance statistically as per ISO/IEC 17043 and ISO 13528 or any other guideline/s published by ILAC/APAC MRA Partner, where applicable.

4.1.3.5 In case for a particular test parameter, when accredited laboratories are not available or not feasible to participate in foreign Inter-laboratory comparison programmes, the laboratories may compare its results with non-accredited laboratories through prior agreement with SLAB. suitability of such laboratories shall be evaluated for 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 15189 requirements.

4.1.4 Inspection Bodies

4.1.4.1 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. The measurements and testing activities covered during inspections/obtained from outsourced services shall comply with Sec. 4.1.1 to 4.1.3, where applicable.

4.1.4.2 Applicant/Accredited inspection bodies, if applicable shall prepare a three year EQA plan considering similar nature of inspection/type of inspection /risks associated with the relevant inspections.

4.1.4.3 Where available, the inspection bodies are encouraged to participate in more than one EQA programme and also programmes organized by accredited PT providers as per ISO/IEC 17043.

4.1.4.4 Where no PT programme is available for a particular field of inspection, the inspection body shall participate in inter-comparisons with at least one or more accredited inspection bodies. The Organizing inspection body shall consider capabilities of other participant inspection bodies before executing the programme. Inspection bodies should evaluate the performance statistically as per ISO/IEC 17043 and ISO 13528 or any other guideline/s published by ILAC/APAC MRA Partner.

4.2 Evaluation of Performance

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

4.2.2 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.

4.2.3 At the time of on-site assessment, assessment team shall verify whether the laboratories/inspection bodies have participated in recognized EQA as per the EQA plans and whether the necessary corrective actions were taken after root cause analysis. Any failure to implement satisfactory corrective actions shall result in suspension/withdrawal/reduction of accreditation. Use of SLAB accreditation symbol/ILAC MRA combined mark/any claim on accreditation for a particular parameter related to an outlier is not allowed until the effective implementation of corrective actions (e.g. participation in another EQA). SLAB assessment team specifically verify compliance to this requirement.

4.2.4 For testing programmes, the criteria for performance is typically z-score ($|Z| \leq 3$) and En ratio ($|En| < 1$) for calibration programme or criteria defined by the EQA provider.

4.3 APAC/any other EQA Programmes

4.3.1 When EQA programmes are organized by APAC or any other organization, SLAB shall nominate its accredited/applicant laboratories/inspection bodies for participation in such programs. Following sequential preference shall be given to the laboratories/inspection bodies.

- Accredited laboratories/inspection bodes not having participated in any other APAC PT program.
- Accredited laboratories/ inspection bodes not having participated in EQA program.
- Laboratories/ inspection bodes having unsatisfactory performance in a past EQA program.
- Laboratory /inspection body with long period of accreditation
- Applicant laboratory/ inspection body