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, 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, Proficiency Testing providers (PTP), Reference Material producers (RMP), Biobanking and Good Laboratory Practice (GLP) (Where relevant).

This also gives information about evaluation of performance and the measures against poor performance in an EQA program.

2. Reference:

ILAC P9	- ILAC Policy for Participation in Proficiency Testing activities
ISO/IEC 17025	- General Requirements for the Competence of Testing and Calibration Laboratories
ISO 15189	- Medical Laboratories - Requirements for Quality and Competence
ISO/ IEC 17020	- Conformity assessment - Requirements for the operation of various types of bodies performing inspection
ISO/ IEC 17043	- Conformity assessment - General requirements for the competence of proficiency testing providers
ISO 17034	- General requirements for the competence of reference material producers
ISO 20387	- Biotechnology - Biobanking - General requirements for biobanking
OECD Guidelines	

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, Proficiency Testing providers, Reference Material producers, Biobanking and good laboratory practice.

Testing/ Calibration/ Medical laboratories and **Biobank** shall participate in Proficiency Testing programs /Inter laboratory comparison as per the stipulated requirements according to ISO/IEC 17025, ISO 15189 and ISO 20387.

Where relevant, **Inspections bodies**, are also required to comply with ISO/IEC 17025 requirements for testing and measurement activities.

Where relevant, **Proficiency testing providers and Reference material producers** are also required to comply with ISO/IEC 17025 or ISO 15189 requirements as applicable for testing and measurement activities.

Generally, the choice of programmes rests with the Laboratory/Inspection Body/ PTP/ RMP/ Biobank/GLP.

Information on accredited PT providers is available through official websites of Accreditation Bodies under ILAC and APAC MRA partners for PT and Annex B of ILAC-P9:01/2024.

Laboratories/Inspection Bodies/ PTP/ RMP/ Biobank/GLP shall conduct risk assessment for participation in PT and/or ILCs other than PT.

Based on the risk assessment, participation in PT and/or ILCs other than PT is considered, by ISO/IEC 17025:2017 as mandatory when available, appropriate and deemed necessary. For ISO 15189:2022, participation in PT is considered mandatory when available, appropriate and deemed necessary.

4.1 Participation

4.1.1 Testing Laboratories

4.1.1.1 Applicant testing laboratories shall successfully participate in at least one PT and/or ILCs other than PT to cover all test methods prior to gaining accreditation. All test methods included in the accredited scope of testing laboratories shall be covered at least once every two years. However, based on the level of risk associated with the test or measurement technique, laboratory shall consider to increase the frequency of participation for PT and/or ILCs other than PT.

4.1.1.2 Applicant/Accredited laboratories shall prepare a two year PT and/or ILCs other than PT plan considering similar nature of test methods/ product groups/ matrixes. Applicant/Accredited laboratories shall justify the technical arguments that have led to the decision on the “defined areas” “level” and “frequency” of participation in PT and/or ILCs other than PT in the risk assessment.

Note: *Please refer EA-4/18 Guidance on the level and frequency of proficiency testing participation*

4.1.1.3 Where available, the laboratories are encouraged to participate in PT and/or ILCs other than PT 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 (ILC) with at least three accredited laboratories. The Organizing laboratory shall consider capabilities of other participant laboratories before executing ILC and the laboratory shall follow requirements of ISO/IEC 17043 when executing ILC. Laboratories shall evaluate the performance statistically as per ISO/IEC 17043 and ISO 13528 or any other guideline/s published.

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. Suitability of such laboratories shall be evaluated 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 PT and/or ILCs other than PT to cover major calibration disciplines prior to gaining accreditation. All calibrations included in the accredited scope of each discipline of calibration laboratories shall be covered at least once every two years. However, based on the level of risk associated with the test or measurement technique, laboratory shall consider to increase the frequency of participation for PT and/or ILCs other than PT.

4.1.2.2 Applicant/Accredited calibration laboratories shall prepare a two year PT and/or ILCs other than PT plan considering similar nature of calibrations/ measurements. Applicant/Accredited laboratories shall justify the technical arguments that have led to the decision on the "defined areas" "level" and "frequency" of participation in PT and/or ILCs other than PT in the risk assessment.

Note: *Please refer EA-4/18 Guidance on the level and frequency of proficiency testing participation*

4.1.2.3 Where available, the calibration laboratories are encouraged to participate in PT and/or ILCs other than PT organized by accredited PT providers as per ISO/IEC 17043/ National Measurement Institute (NMI) or designated body who published their Calibration Measurement Capabilities (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 (ILC) with accredited calibration laboratories having smaller uncertainties or CMCs/ NMI or designated body who published their CMCs in BIPM KCDB. Calibration laboratories shall evaluate the performance statistically as per ISO/IEC 17043 and ISO 13528 or any other guideline/s published.

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. Suitability of such laboratories shall be evaluated as per ISO/IEC 17025 requirements.

4.1.3 Medical Laboratories

4.1.3.1 Applicant medical laboratories shall successfully participate in at least one PT and/or ILCs other than PT to cover all tests prior to gaining accreditation. All test methods included in the accredited scope of medical laboratories shall be covered at least three times per year. However, based on the level of risk associated with the test or measurement technique, laboratory shall consider to increase the frequency of participation for PT and/or ILCs other than PT.

4.1.3.2 Applicant/Accredited laboratories shall prepare a two year PT and/or ILCs other than PT plan considering similar nature of test or measurement technique. Applicant/Accredited laboratories shall justify the technical arguments that have led to the decision on the "defined areas" "level" and "frequency" of participation in PT and/or ILCs other than PT in the risk assessment.

Note: *Please refer EA-4/18 Guidance on the level and frequency of proficiency testing participation*

4.1.3.3 Where available, the laboratories are encouraged to participate in PT and/or ILCs other than PT 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 (ILC) with at least three accredited laboratories. The Organizing laboratory shall consider capabilities of other participant laboratories before executing ILC and the laboratory shall follow requirements of ISO/IEC 17043 when executing ILC. Laboratories shall evaluate the performance statistically as per ISO/IEC 17043 and ISO 13528 or any other guideline/s published.

4.1.3.5 In case for a particular test, 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. Suitability of such laboratories shall be evaluated as per ISO 15189 requirements.

4.1.4 Inspection Bodies

In inspection, applicant inspection bodies shall participate in at least one PT and/or ILCs other than PT (where relevant and applicable) prior to applying for accreditation and accredited inspection bodies shall cover all inspections under the scope at least once every two years. The measurements and testing activities covered during inspections/ obtained from outsourced services shall comply with Sec. 4.1.1 and 4.1.2, where applicable.

4.1.5 Biobanking

Biobanks shall require approaches to provide objective evidence to demonstrate the comparability of biological material quality (the processing or testing output) are used, where such approaches are available and appropriate. Such approaches include EQA schemes, PT schemes and/or ILCs other than PT as per Sec. 4.1.1 and 4.1.3, where applicable.