INTERNATIONAL ACCREDITATION SERVICE®

POLICY ON PARTICIPATION IN PROFICIENCY TESTING AND/OR INTERLABORATORY COMPARISONS

1.0 SCOPE:

1.1 This document defines the International Accreditation Service (IAS) policy on the use of Proficiency Testing (PT) and/or interlaboratory comparison (ILCs) other than PT for accreditation involving, i.e., testing, sampling, calibration, medical examination, inspection, biobanking, PT providers and reference material producers performing measurements/analysis/examinations as part of their activities.

Successful results from PT/ILC are an indication of CAB technical competence and an essential part of IAS accreditation. In the context of this document, CAB implies all organizations performing testing or calibration activities – i.e. testing, sampling, calibration and medical laboratories, inspection bodies, biobanks, PT providers and reference material producers.

Participation in PT and/or ILC 'other than PT,' organized by a competent provider, is a tool used by CABs for monitoring:

(a) validity of testing, calibration and inspection results

(b) effectiveness of the CABs compliance to accreditation criteria.

Participation in ILCs other than PT should only be envisaged when PTs are not available, and/or appropriate.

1.2 This policy incorporates the PTs/ILCs requirements published by the International Laboratory Accreditation Cooperation (ILAC) (refer to Section 2).

1.2 This policy requires all IAS accredited CABs and those seeking accreditation to participate in PT programs organized by providers accredited to the international standard ISO/IEC 17043.

2.0 NORMATIVE AND REFERENCES DOCUMENTS: Publications listed below refer to current editions (unless otherwise stated)

2.1 ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*
2.1 ISO 15189: *Medical laboratories - Requirements for quality and competence*
2.2 ISO/IEC 17020: *Conformity assessment - Requirements for the operation of various types of bodies performing inspection.*

2.3 ISO 13528: *Statistical methods for use in proficiency testing by interlaboratory comparison.*
2.4 ISO/IEC Standard 17043: *Conformity assessment – General requirements for the competence of proficiency testing providers.*

2.5 ISO 17034: *General requirements for the competence of reference material producers*
2.6 ISO 20387: *Biotechnology – Biobanking -General requirements for biobanking*

2.7 ILAC-P9:01/2024, *ILAC Policy for Proficiency Testing and/or Interlaboratory comparison other than Proficiency Testing*

3.0 DEFINITIONS:

3.1 Conformity Assessment Body (CAB): body that performs conformity assessment activities and that can be the object of accreditation (ISO/IEC 17011:2017, 3.4)

Note: Whenever the term "conformity assessment body" is used, it applies to both the applicant and accredited conformity assessment bodies.

3.2 External quality assessment (EQA): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO 15189:2022, 3.10)

Note: In ISO 15189:2022, the term PT is replaced by EQA (external quality assessment).

3.3 Interlaboratory comparison (ILC): design, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions (ISO/IEC 17043:2023, 3.4).

3.4 Proficiency testing (PT): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043:2023, 3.7).

Note: Further information regarding the design of various proficiency testing schemes is provided in Annex A (Informative) of ISO/IEC 17043:2023.

4.0 PT/ILC REQUIREMENTS:

4.1 CABs are required to formally document a PT/ILC Participation plan and provide such 'plan' to IAS.

4.2 This plan should be adequate to ensure the validity of test/calibration results within the accreditation scope, where PTs/ILCs are available and appropriate. The CAB should define its level and frequency of PT/ILC participation taking into account its risk assessment and improvement opportunities, based on the following factors but not limited to:

a) the number, volume and frequency of tests/calibrations/sampling/measurements undertaken
b) turnover of technical staff
c) experience and knowledge of technical staff.
d) source of metrological traceability.
e) known stability/instability of the test or measurement technique.
f) stability of the analyte and matrix.
g) impact of storage and transportation.
h) significance and final use of testing/calibration/sampling data.
i) use of biohazardous PT items.
j) availability of certified reference materials and frequency of testing and strength of internal quality control activities.
k) use of different techniques/examination methods/analyzers for same test parameters.
l) level of professional judgement required for the activities.
m) Other sector specific risks.

4.3 The Plan is reviewed by IAS assessors during the assessments to ensure there is representative and satisfactory participation in PT and/or ILC activities to cover the approved scope of accreditation of the CAB. Where such accredited PT Providers are not available, the laboratory shall provide sufficient justification to IAS.

In case the PT participation plan is considered not suitable in relation to the scope of accreditation a non-conformity shall be raised. Participation in an ILC shall only be accepted where organized PTs are not available, and/or appropriate). CABs are expected to participate in at least one appropriate PT and or ILC for each field of accreditation when these participations are:

a) available
b) appropriate, and,
c) do not cause undue hardship for the laboratory.

Note: Details of available PT providers and the programs they offer are available from the EPTIS database http://www.eptis.org.

4.4 For new CABs seeking accreditation, the PT participation plan shall be assessed prior to granting accreditation to ensure that there is a representative and suitable participation in PT and/or ILCs. In general, a CAB is expected to complete the participation plan covering the scope of accreditation within four years. Each CAB is required to maintain a PT Participation Plan and evidence of its involvement in PT activities. This evidence must include the participation results, including any observations and derived data, and clear identification of the CAB. For initial accreditation, a non-conformity raised during document review related to poor performance will result in an increase of the assessment duration to specifically witness the affected disciplines. 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 medical discipline. This shall be conducted prior to gaining accreditation and including all parameters/ types of tests in the accredited scope for each medical discipline in at least three times a year.

4.5 The PT Plan and key information in the PT report should be preferably in English.

4.6 If non-representative and/or persistent deficient performance is identified, (repeated non-conformity), an on-site follow-up assessment can be scheduled to evaluate the laboratory's technical competence specifically for the affected disciplines.

5.0 PARTICIPATION IN ILC

5.1 Generally participation in ILCs is accepted when PTs are not available and/or appropriate.

5.1.1 Examples of ILCs other than PT are:

- Evaluation of the performance characteristics of a measurement or test method (often described as collaborative trials).
- Assignment of values to reference materials.
- Support for statements of the equivalence of measurements of National Metrology Institutes (NMIs), or their Designated Institutes (DIs) through "key and supplementary comparisons", conducted on behalf of the International Bureau of Weights and Measures (BIPM) and associated Regional Metrology Organizations (RMOs).

- Comparison of test/calibration/examination results with one or more accredited laboratories

5.1.2 In fields that contain multiple significant disciplines, at least one PT and/or ILC other than PT is expected for each significant discipline, within four years as outlined above.

Note: An example is the field of calibration, which has significant disciplines such as dimensional, mechanical, electrical, and RF/microwave.

5.1.3 There may be circumstances in which PT participation has been mandated for the purposes of accreditation through regulatory bodies, industry or professional sector requirements or an ILAC Regional Cooperation Body.

Note: PT is not a tool for determining calibration and measurement capability (CMC) but a tool that is used to monitor laboratory performance and validity of its results with respect to other laboratories and could be used by the laboratory to validate measurement uncertainty and/or identify appropriate improvements to laboratory processes.

6.0 ARTIFACTS:

6.1 Artifacts or items for testing or calibration generally are one of two types. They are either characterized or non-characterized.

6.1.1 Characterized artifacts are typically easily definable item (e.g., set of gauge blocks). Characterized artifacts are sent to a laboratory by a PT provider or ILC organization that will function as a reference laboratory. The values provided by the reference laboratory become the reference value(s) for the artifact. Additional laboratories participating in the PT programs or ILCs perform tests or calibrations, and their results are calculated relative to the reference value.

Note: Other more established PT providers are National Measurement Institute (NMI).

6.1.2 Non-characterized artifacts are not easily defined. An example would be concrete. The actual strength value of the artifact will depend on such variables as the water, sand, and exact mix ratios that are used. There is no reference laboratory for non-characterized artifacts, and therefore no specific reference value for the artifact. Results from the test or calibration are calculated relative to the results for other laboratories participating in the PT.

6.2 Organization of ILC/EQA programs shall be based on ISO/IEC 17043 and determination of assigned values and evaluation of performance of participants shall be based on appropriate statistical methods as explained in ISO 13528 or any other recognized methodology.

Note: The EQA programs selected/organized by the medical laboratotires are required to considered the effect of checking pre-examination, examination and post-examination proceses.

7.0 LEVEL OF PARTICIPATION:

7.1 Both calibration and testing laboratories are expected to participate in PT and/or ILCs other than PT that demonstrate their claimed/accredited capabilities. For calibration laboratories, it is important that the PT results submitted reflect the level of capabilities claimed in the CMC, i.e., the uncertainties reported with PT results should be similar to those claimed in the scope of accreditation, since validation of measurement uncertainty claims is one of the purposes for interlaboratory comparisons. Any significant differences in uncertainties should be due to the artifact alone.

7.2 When a laboratory's results are classified as "outliers," the laboratory is expected to:

a) Internally document the outlier status using its own internal mechanism, such as an internal audit discrepancy report. Investigate to determine the cause and likely effect(s) of the outlier.
b) Investigate to determine if the cause of the outlier may have affected any tests or calibrations for customers, the extent of any effect, and whether the effects are acceptable or if a recall is necessary.
c) Develop and implement a plan as appropriate for corrective action, to address any noted discrepancies, or for preventive action to improve laboratory processes.
d) Specifically document these steps, for each outlier result.
e) Review each outlier and the subsequent investigation: the review must be documented (e.g, minutes of the management review meeting, etc.)
f) Relate any plan for corrective or preventive action to business support processes (e.g., training, purchase of equipment, procedure review/improvement)

7.3 A non-conformity will be raised in case, for non-satisfactory performance, the laboratory has not implemented prompt and appropriate corrective actions.

7.4 For an accredited Laboratory, a repeated non-conformity related to poor performance in PT and/or ILC other than PT, will result in an assessment.

7.5 Where a PT (1) is not available, (2) is not appropriate, or (3) would place an undue hardship on a laboratory, other forms of interlaboratory comparisons must be performed and results analyzed. The laboratory shall provide justifications of the alternative approaches implemented and evidence of the

competence of the PT provider or the ILC organization providing PT. This evidence must include the participation results, including any observations and derived data, and clear identification of the laboratory.

Note: Annex A of ILAC P9 provides additional information on how to ensure the competence of PT.

7.6 Any outliers must be treated by the laboratory in the same fashion as those arising from a PT.

7.7 In the event of interlaboratory comparisons (ILCs), the laboratory shall be required to demonstrate how planning and designing of ILC, sample preparation, and assessment of homogeneity and stability and assigned values are determined independently by competent persons. Homogeneity & stability testing, determination of assigned values and performance evaluation shall be based on ISO 13528 or any other recognized methodology.

8. APAC PT Programs

When APAC or APAC Member ABs organize PT/ILC programs, where relevant, IAS randomly selects CABs to participate. The selected CABs shall submit the final report to IAS for review and verification, in accordance with this policy.