QAI CIA 005

Quality and Accreditation Institute

Centre for International Accreditation

POLICY FOR PARTICIPATION IN PROFICIENCY TESTING & INTER-LABORATORY COMPARISON ACTIVITIES

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CHANGE HISTORY

Sl. No.	Doc No.	Current Issue No.	Revised Issue No.	Date of Issue	Reasons
1	CLA 005	01	02	October 2021 (01 October 2021)	Added Biobank in programme names Replaced Program with programme
2	CLA 005	02	03	January 2023 (27 January 2023)	• Added PT plan • Added ILC procedure • Added Annexure-A- ILC/PT Plan • Added Annexure-B- ILC/PT Evaluation sheet
3	CIA 005	03	04	November 2023 (07 November 2023)	• Centre for Laboratory Accreditation (CLA) changed to Centre for International Accreditation (CIA) • Office address changed from 811 to 709 • Borders and QAI logo added in the header and Mobile number added
4	CIA 005	04	05	February 2025 (12 February 2025)	Updated the reference of latest publication of ILAC P9

CONTENTS

1. Objective:

Proficiency Testing (PT) is one of the important tools to determine the technical competence of the conformity assessment bodies (CABs).

Both the accreditation standards (ISO/IEC 17025 and ISO 15189) require a mechanism to be in place to ensure quality of test results.

This document of QAI is based on the requirements of ILAC-P9- ILAC Policy for Participation in Proficiency Testing activities. In the context of this document, "accredited CAB" implies all CABs performing testing or calibration activities – i.e. testing, sampling, calibration and medical laboratories, inspection bodies, biobanks, PT providers and reference material producers.

The minimum PT activity according to a laboratory's scope is:

- evidence of satisfactory participation prior to gaining accreditation where PT is available and appropriate;
- further and ongoing activity that is appropriate to the scope of accreditation and consistent with the PT participation plan

It is recognised that there are areas of Testing, Calibration and Medical for which suitable PT does not exist or is not practical. In such cases, the laboratory should follow alternative approaches as provided in ISO/IEC 17025 and ISO 15189.

A. According to ISO/IEC 17025:2017, The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

a) use of reference materials or quality control materials;

b) use of alternative instrumentation that has been calibrated to provide traceable results;

c) functional check(s) of measuring and testing equipment;

d) use of check or working standards with control charts, where applicable;

e) intermediate checks on measuring equipment;

f) replicate tests or calibrations using the same or different methods;

g) retesting or recalibration of retained items;

h) correlation of results for different characteristics of an item;

i) review of reported results;

j) intra laboratory comparisons;

k) testing of blind sample(s)

The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:

a) participation in proficiency testing

Note: ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

b) participation in inter-laboratory comparisons other than proficiency testing

B. According to ISO 15189:2022, The laboratory shall participate in an inter-laboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results. The laboratory shall monitor the results of the inter-laboratory comparison programme(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled.

Note: The laboratory should participate in inter-laboratory comparison programmes that substantially fulfil the relevant requirements of ISO/IEC 17043.

The laboratory shall establish a documented procedure for inter-laboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the inter-laboratory comparison programme.

Inter-laboratory comparison programme(s) chosen by the laboratory shall, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible.

Alternative approaches
Whenever an inter-laboratory comparison is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results.
Whenever possible, this mechanism shall utilize appropriate materials.

NOTE Examples of such materials may include:

— certified reference materials;
— samples previously examined;
— material from cell or tissue repositories;
— exchange of samples with other laboratories;
— control materials that are tested daily in inter-laboratory comparison programmes.

2. Scope:

This document stipulates the QAI CIA policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing for Testing, Calibration and Medical laboratories. This document is also applicable to laboratories of Proficiency Testing Provider (PTP), Reference Material Producer (RMP) and Inspection Body (IB).

The conformity assessment standards used for accrediting CABs, listed below, specify the need for participation in PT and/or ILCs other than PT:

ISO/IEC 17025:2017, clause 7.7.2, requires that the laboratory monitors its performance by comparison with results of other laboratories, through participation in PT and/or ILCs other than PT, where available and appropriate;

ISO 15189:2022, clause 7.3.7.3, requires that the laboratory participates in an EQA program appropriate to the examination and interpretation of examination results, including POCT (Point of care testing) examination methods. When an EQA programme is either not available, or not considered suitable, the laboratory shall use alternative methodologies to monitor examination method performance, including ILCs other than PT;

ISO/IEC 17020:2012 does not mention any specific requirements for PT and/or ILCs other than PT, however, the requirements for ISO/IEC 17025:2017 are to be considered for testing or calibration activities. Further information on the need for ensuring the validity of results in the field of inspection can be found in ILAC G27:2019;

ISO 20387:2018, clause 7.8.2.9, requires that 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;

For ISO/IEC 17043:2023, no specific requirements for PT and/or ILCs other than PT are mentioned in the standard, however, the requirements for ISO/IEC 17025:2017 and ISO 15189:2022 are to be met when considering testing or calibration activities;
Note: ISO/IEC 17043: 2010 is also to be considered as it is still valid until May 2026.

For ISO 17034:2016, no specific requirements for PT are mentioned in the standard, however, the requirements for ISO/IEC 17025:2017 and ISO 15189:2022 are to be met when considering testing or calibration activities.

An applicant or accredited CAB is therefore required to plan and monitor its participation in PT and/or ILCs other than PT. Based on ISO/IEC 17025:2017, clause 8.5 and ISO 15189:2022, clauses 8.5 and 7.3.7.3, the planning is to take into account the risks and opportunities of the laboratory activity.

References

- ILAC-P9:01/2024- ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing
- ISO/IEC 17025: 2017- General requirements for the competence of testing and calibration laboratories
- ISO 15189: 2022- Medical laboratories — Requirements for quality and competence
- ISO/IEC 17043: 2023- Conformity assessment — General requirements for proficiency testing
- ISO/IEC 17020:2012: Conformity assessment - Requirements for the operation of various types of bodies performing inspection
- ISO 20387:2018: Biotechnology - Biobanking - General requirements for biobanking
- ISO 17034:2016: General requirements for the competence of reference material producers
- ILAC G27:07/2019: Guidance on measurements performed as part of an inspection process

3. Policy:

3.1 Applicant laboratory shall satisfactorily participate in at least one PT programme/ EQA prior to gaining accreditation in each discipline applied.

Note 1: Refer to the concerned information brochures for more details about disciplines:
Note 2: *It is expected from the laboratory that at least all major analytes/ parameters of the applied scope are covered/ planned under PT participation.*
(Analytes/ parameters whose testing significantly demonstrates the capability and competence of the laboratory and involves the application of critical instrumentation/ equipment may be considered as major analyte/ parameter).
Note 3: *Participation in PT programme with Z score less than 2 or En value less than 1 will be considered as satisfactory participation.*
Participation in PT programme with Z score ≥2 or ≥1 (questionable/ outliers results) will also be acceptable, if the laboratory has taken necessary corrective actions based on root cause analysis.

PT provider should preferably be accredited by an Accreditation Body covered by the APAC/ ILAC Arrangement whose service is suitable for the intended need (i.e. the scope of accreditation specifically covers the appropriate PT items/ parameters). Laboratory shall participate in APAC PT programme when requested.

Accredited laboratory shall have 2-year plan for Proficiency Testing participation which shall cover all the accredited groups as practicable under each discipline of accreditation. In

Medical testing, accredited laboratories shall participate in at least one Proficiency Testing/ EQA in a year per discipline, as appropriate.

PT Plan:

a) Accredited laboratory shall submit 2-year PT plan as per Annexure A which will be reviewed by QAI for its suitability in relation to the scope of accreditation.
b) Continued compliance to PT plan submitted by the laboratory will be verified during the assessment. Appropriateness of root cause analysis and corrective actions undertaken by the laboratory for poor performance will also be verified during the assessment.

3.2 However, where above formal PT Programs are not available/ scheduled or not appropriate, alternatively Testing/ Calibration/ Medical laboratory shall participate in suitable inter-laboratory comparisons with sufficient number of accredited laboratories.

The laboratory shall take appropriate corrective actions based on root cause analysis in case of poor performance in PT programs within one-month period. In two consecutive events of poor performance in PT participation/ unsatisfactory corrective actions may lead to appropriate action including the scope reduction.

Annexure A- ILC/PT Plan

CAB ID				
Name of CAB				
Field of Accreditation	**Testing**	**Calibration**	**Medical**	
Period of Participation				

Accredited Discipline(s)	**Group(s) / Sub groups under Discipline**	**Proficiency Testing Activities Plan (Year wise)**		**Status and Result of Proficiency Testing Activities (Year wise)**		**Remarks (for QAI use only)**
		1st Year	**2nd Year**	**1st Year**	**2nd Year**	

Note: Laboratory should ensure that PT plan covers the groups/ sub-groups, analyte/ parameter and materials/ matrices under each discipline

For QAI use only	
Reviewed and approved by:	

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