QAI CIA 005

Quality and Accreditation Institute

Centre for International Accreditation

Change Adapt Improve

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

Issue No.: 04 **Issue Date: November 2023**

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

CONTENTS

1. Objective:

Proficiency Testing (PT) is one of the important tools to determine the technical competence of the Testing, Calibration and Medical laboratories.

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.

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.

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: 2012/2022, 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 PT Participation in Proficiency Testing Activities for Testing, Calibration and Medical laboratories.

References

- ILAC-P9:06- ILAC Policy for Participation in Proficiency Testing activities.
- ISO/IEC 17025: 2017- General requirements for the competence of testing and calibration laboratories
- ISO 15189: 2012/2022- Medical laboratories — Requirements for quality and competence
- ISO/IEC 17043: 2010/2023- Conformity assessment — General requirements for proficiency testing

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 following documents for more details about disciplines:

a. CIA 101: Information brochure for medical laboratories

b. CIA 201: Information brochure for testing laboratories

c. CIA 401: Information Brochure for Calibration Laboratories

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 will be considered as satisfactory participation.*
Participation in PT programme with Z score ≥2 (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.

Satisfactory participation in PT is necessary for significant enhancement of scope such as addition of discipline (including groups).

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 as per following procedure:

a) The participating laboratory must prepare and communicate to QAI a program outline containing details of the artifact / parameters to be calibrated and reference laboratory selected in the reporting format Annexure B. The laboratory shall select the artifact and calibration points in a manner to cover the entire range of the accredited scope.

b) The participating laboratory has to select a reference laboratory which should be either NPL-India or another accredited laboratory having better CMC than the participating laboratory in that particular parameter. The laboratory shall ensure that the reference laboratory is preferably not under the same top management.

c) The artifacts used shall have excellent repeatability and stability to hold their calibration for the period of the activity. Further the artifacts shall have range as per scope, sufficient resolution, to allow the laboratory to report an uncertainty equal to their CMC as defined in their scope of accreditation/ application. The laboratory shall not report uncertainty better than their accredited / claimed CMC. The reported uncertainty for participating and reference laboratory shall be close to or equal to their CMCs.

d) The participating laboratory shall communicate the calibration results to QAI in Format Annexure B along with the calibration certificate for approval of the program before sending the artifact to Reference Laboratory.

e) After QAI approves the plan for programme, participating laboratory should get the artifact calibrated from reference laboratory, analyze the results and calculate E_n ratio as per the following and submit the results to QAI

$$E_n = \frac{x - X}{\sqrt{U_{lab}^2 + U_{ref}^2}}$$

Where,
x is the participating laboratory's result
X is the Reference Laboratory's result
U_{lab} is the expanded uncertainty of the participant's result
U_{ref} is the expanded uncertainty of the reference laboratory's assigned value.

|En| ≤1 indicates the satisfactory performance of the laboratory
|En|>1 indicates the unsatisfactory performance of the laboratory and requires root cause analysis followed by corrective actions.

Note:

a) The formulae in equations are correct only if x and X are independent.
b) Measurement results and reported uncertainty shall be in same unit.
c) In cases where the reference laboratory has reported uncertainty coarser than the participating laboratory the purpose of ILC is defeated. Hence, it shall not be considered as a valid inter-laboratory comparison.

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:	

Annexure B- ILC/PT Evaluation sheet

Note: Laboratory 2-year PT and ILC plan to be submitted along with this format.

1.Results of Participant

Details of artifact (name, least count and range):	
Standard used for calibration:	
Parameter(s) selected:	

Participating Laboratory (Name & Address)	Reference Laboratory (Name & Address)

Calibration Points (at least five points)	Result	Uncertainty Reported	Accredited/ Claimed CMC	Accredited CMC
	Name & Signature of CAB Representative			
	Date:			

2. Approval from QAI

Proceed further: Yes / No	
Remarks (if any)	
Name & Signature of CAB Representative	
Date:	

3. Reference Laboratory Results

Calibration Points	Result	Uncertainty Reported	

4. Performance Evaluation

Parameter(s)	En ratio	

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