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IQAS-009

Policy and Guidelines for Proficiency Testing and/or Inter Laboratory Comparison (ILC) other than Proficiency Testing

AMENDMENT SHEET

Sr. No.	Page No.	Clause No.	Date of Amendment	Reasons of amendment	Amendment details	Remarks	Approved by
1.	All	All	01.07.2024	Detailing to align with ILAC Guidelines	ILAC P9 references insert	Replaces previous issue dated 20.11.2023	R.S. Rana
2.	14	Annexure	02.09.2024	Outcome of APAC evaluation	Typographical error corrected	-	R.S.Rana
3.							

1. Objective

Policy and Guidelines for Proficiency Testing and Inter laboratory comparison (ILC) other than Proficiency Testing

2. .Scope

This document applies to all the laboratories/CABs(Conformity Assessment Body) which are accredited by IQAS and applicant laboratories in the field of calibration and testing and medical laboratories as per ISO/IEC 17025:2017 and ISO 15189:2012/22 respectively.

3. Responsibility

IQAS and CABs

4. Reference

ISO/IEC 17011, ILAC P9, ISO/IEC 17025:2017, ISO 15189:2012/22.

Note: In ISO 15189:2012/22 ,PT is External Quality Assessment (EQA).

5. Policy on PT and /or ILC other than PT.

One of the elements by which CABs have to demonstrate the validity of their results is by comparison with results of other CABs, where such activities are available and appropriate. The ILAC policy on PT and/or ILCs other than PT is the following:

1) Taking into consideration the outcome of the CAB's 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 15189:2012/22, participation in PT is considered mandatory when available, appropriate and deemed necessary.

2) Participation is applicable not only to laboratories, but also to CABs accredited to other standards performing testing and/or calibration activities as part of their accredited conformity assessment activities.

3) Applicant and accredited CABs shall develop a participation plan in PT and/or ILC s other than PT (PT participation plan).

4) IQAS assesses the PT participation plan to ensure that there is a representative and satisfactory participation in PT and/or ILCs other than PT activities regarding an applicant scope before granting accreditation.

5) IQAS ensures that the PT participation plan foresees a representative participation in PT and/or ILCs other than PT activities regarding any accreditation scope.

6) Where satisfactory performance is not achieved, IQAS assesses the evidence of the implementation of prompt and appropriate corrective actions.

7) IQAS assesses the justifications of the CAB's alternative approaches when there are no available and appropriate PT and/or ILC's other than PT to cover the applicant or accredited scope. IQAS verifies that the alternative approach implemented by the CAB ensures the validity of the results.

8) The AB shall define its process on the use of PT and/or ILCs other than PT. The process shall include, at least, the following: a) how the AB takes into consideration PT and/or ILCs other than PT participation and performance (in particular when persistent poor performance is identified); Note: This includes PT and/or ILCs other than PT that has been mandated, for example by a regulator, an industry or professional sector. b) how the AB deals with the situation where the CAB's PT participation plan is considered not suitable in relation to the scope of accreditation; c) how the AB takes into account a CAB's PT and/or ILCs other than PT performance, to plan the assessments; d) how the AB ensures that the CABs have appropriate evidence of the competence of the PT provider or the organization providing ILCs other than PT .

6.Guide for PT and /or ILC other than PT.

Annexure A (Informative)

Participation through PT and/or ILCs other than PT to demonstrate the validity of results can be done through:

1. A PT provider, accredited to ISO/IEC 17043:2023 by an AB signatory of the ILAC MRA for PT providers;

2. A PT provider, accredited to ISO/IEC 17043:2023 by an applicant AB or an AB non-signatory of the ILAC MRA for PT providers;

3.Participation in an ILC, which is organised for other purposes than determining a CAB's competence (ISO/IEC 17043:2023);

4. of, or participation in, ILCs organised, in accordance with the relevant requirements of ISO/IEC 17043:2023, to determine the performance of accredited CABs by comparison with results of other laboratories.

Accredited CABs offering PT schemes according to the first bullet point have been subject to relevant assessment through the ILAC MRA. For the other bullet points, there is no formal recognition of competence, in terms of ILAC MRA, of the PT and/or ILC provider.

Note: EA-4/21 INF[11] (Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation) can be used to assess the validity of the two last bullet points in regard to meeting the relevant requirements of ISO/IEC 17043:2023.

Annexure B (Informative)

The following considerations may be taken into account in setting the criteria for availability and appropriateness of PT and/or ILC schemes other than PT:
Availability:
A PT is considered available, if:
1. it is offered by a competent PT provider and the required documents are provided in the national language of the participating body or a language understood by the CAB;
2.if it does not require a development by the PT provider and the results can be provided within a short time in regard to the CAB needs formalized in its PT participation plan.

Note: EPTIS is a worldwide database (https://www.eptis.org) that may be used to find an available PT scheme.

Appropriateness:

A PT and/or ILC other than PT can be regarded as technically appropriate, if the scope of activity being provided is similar to the current practice of the accredited CAB. In the case of specific test or measurement techniques, for which no regular PT and/or ILCs other than PT is available, it may be adequate to choose a PT and/or ILCs other than PT, which is similar to the scope or which covers an

important partial aspect of the activity.

Annexure C (Informative)

This appendix is not a literal copy of EA-4/18 but highlights the general principles included in the guide.
The guidance document EA-4/18 (Guidance on the level and frequency of proficiency testing participation) aims to promote harmonisation between ABs on how the level and frequency of participation in PT is assessed during the accreditation process and to assist CABs in determining their own levels and frequency of participation.

A: General aspects
The following aspects are taken into consideration when IQAS determines the suitability of an accredited CAB's PT participation plan. That is, its "level" and "frequency" of participation in PT in relation to the activities, performed under its accreditation scope:

(1) The accredited CAB should define its level and frequency of participation after careful analysis of its other measures for ensuring the validity of results (especially those that are able to disclose, quantify and follow the development of bias of a stated magnitude). The level of participation should be made dependent on the extent to which other measures have been taken.
Other types of measures for ensuring validity of results include, but are not limited to those listed in ISO/IEC 17025:2017, clause 7.7.1 and ISO 15189:2022 clause 7.3.7.3:

(2) The level of risk presented by the accredited CAB, the sector in which it operates or the methodology it is using. This can be determined, for example, by considering:

- Number and frequency of tests/calibrations/sampling/measurements undertaken;
- Turnover of technical staff;
- Experience and knowledge of technical staff;
- Source of metrological traceability (e.g. availability of reference materials, national measurement standards, etc.);
- Known stability/instability of the test or measurement technique;
- Stability of the analyte and matrix, and the impact of storage and transportation;
- Significance and final use of testing/calibration/sampling data (e.g. forensic science, food safety and medical laboratories represent areas requiring a high level of assurance);
- Level of risk posed by Biohazardous PT items used and the containment precautions required;

Number of different calibration intervals;
- Complexity and robustness of the methodology;
- When statements of conformity are required and changes in related specifications are made;
- Risks and opportunities associated with the laboratory activities, in particular those that will prevent, or reduce, undesired impacts and potential failures in the laboratory activities and achieve improvement;
- Extent of validation and/or verification.

(3) Different types of ILCs that can be used by accredited CABs and that should be accepted by the IQAS as alternatives to PTs, include:
- ILC organised by a sufficient number of laboratories as a one off or continual exercise;
- Organisation of small interlaboratory comparisons.
Note: CABs that organise a small ILC among themselves should apply the relevant requirements of ISO/IEC 17043:2023, and EA-4/21 INF if the results and evaluation of performance are to be used as a tool to monitor and demonstrate the validity of their results.

(4) It should be recognised that there are sectors where participation in PT may be difficult, due to the technical characteristics of the test or measurement, the lack of PT schemes, the low number of existing CABs in the sector, etc. For some fields PT may only be possible or economically feasible for parts of the test/calibration undertaken (i.e. EMC (Electromagnetic compatibility) tests on simple objects for a limited number of quantities to be measured). In these areas the suitability of other measures is paramount.

(5) Any requirements for frequency and type of PT participation from other sources, e.g. legislation, customers, etc.

B: Level and frequency of participation

The first step for the CABs is to consider the scope of accreditation and the tests/calibrations/sampling for which they are accredited.

Ideally, an accredited CAB would participate in a specific PT for every test or measurement technique it uses and for every characteristic (component, parameter) measured in every product. However, it is acknowledged that this is not always feasible, both logistically and economically. Therefore, IQAS accepts CABs to identify groups of areas of technical competence (defined by a minimum of one test or measurement technique, characteristic and product which are related). The performance obtained in the PT for one combination within a defined area can be directly correlated to the other

combinations of test or measurement techniques, characteristics and products contained within the same area of technical competence.

An area of technical competence, as mentioned above, may contain more than one test or measurement technique, characteristic or product as long as equivalence and comparability can be demonstrated. The first consideration for an accredited CAB, when determining an area of technical competence, is that it should generally not contain different technical competences. Different technical competences can usually be identified by the need for different qualifications, training, and use of different equipment, knowledge or experience.

When determining an area of technical competence, it may be helpful to consider a stepwise approach working up from the test or measurement technique through characteristics to products. This is because it is more likely that there will be several products and/or characteristics associated with one test or measurement technique within a given area than vice versa:

(i) With reference to the test or measurement technique: It is possible but not common to include different test or measurement techniques in the same area of technical competence;

(ii) With reference to the characteristic to be measured, determined or identified: It may be possible to include more than one characteristic in the same area of technical competence;

(iii) With reference to products to be tested: It may be possible to include different products in the same area of technical competence provided that the matrices, objects or materials included, are of equivalent nature.

When an accredited CAB determines that more than one test or measurement technique, characteristic or product is classified within the same area of technical competence, the IQAS evaluates whether an accredited CAB can justify and demonstrate equivalence. This can usually be done by, for example:

- The method validation data, or;
- Use of the same test method

Once the accredited CAB has defined its areas of technical competence the “level of participation” can be deemed to have been defined. The AB will also need to evaluate the suitability of the “frequency” of participation of the CAB, based on the level of risk, and should expect a minimum frequency of participation for each area of technical competence to be set by the CAB.

It should also be considered that according to ISO/IEC 17025:2017 (7.7.1 and 7.7.2) or ISO 15189:2022 (7.3.7.1) the accredited CAB shall have a procedure for monitoring the validity of results and that these are to be planned. Therefore, once the “level” and “frequency” of participation is established, accredited CABs will be able to establish their PT plan. The extent and content of this plan will depend upon the circumstances and scope of the individual CAB. This should form part of the CAB’s overall quality control (QC) strategy.

The establishment of areas of technical competence may be different for every accredited CAB. For this reason, IQAS accepts accredited CABs to be able to justify the technical arguments that have led to the accredited CAB's decision on the "defined areas" "level" and "frequency" of participation in PT. It is recommended that accredited CAB's document this justification.

6.1 The laboratories accredited in the field of calibration as per ISO/IEC 17025:2017 and ISO 15189:2012 need to conduct Inter Laboratory Comparison (ILC) for the accredited scope to assure the quality of measurement results produced by the laboratory.

6.2 The accredited laboratory is required to have participated in one round of PT for each parameter in 4 years.

IQAS may accept the ILC for all the parameters at the time of application for accreditation and subsequently, need to cover the complete scope within 4 years after accreditation.

6.3 IQAS accepts ILC when desired PT is not available.

6.4The critical parameters need to be covered under ILC. The critical parameters can be decided based on the nature of the measuring instrument and the calibration measurement capability (CMC). For a specific parameter, the range of better CMC should be considered for the ILC, based on facilities available in the country.

6.5The participating laboratory may itself initiate ILC with another laboratory having better CMC than the participating laboratory. Participating laboratory is the laboratory which is initiating the ILC and the laboratory having better CMC is considered as the reference laboratory.

6.6The artifact having range for calibration shall cover at least three points, namely minimum (other than zero), middle and maximum of the range.

6.7 In case the reported uncertainty in the measurement of reference laboratory is more than the participating laboratory after final calibration, then the conducted ILC shall be pronounced invalid and participating laboratory need to conduct ILC again.

6.8 The ILC shall be considered satisfactory only for En ratio lying between ±1. In case En ratio exceeds more than ±1, participating laboratory need to do a root cause analysis and appropriate corrective action is required to be taken.

6.9The results of the ILC shall be verified during the assessment of the laboratory

6.10 Applicant laboratory is required to have successful participation in PT in atleast one parameter for the test or calibration.

7. Record of ILC

The record of the ILC shall be maintained in the following format:

Name of Instrument	
Range/Denomination	
Least Count	
Make/Model of instrument	
Sr. No./ID of instrument	
Date of measurement/ calibration	
Name and address of reference lab	
Date of measurement /calibration by ref. lab	
Results	

Sr. No.	Lab Value	Uncertainty in measurement by the Lab	Reference value	Uncertainly in measurement evaluated by the reference Lab	En ratio	Remarks

Signature of Lab representative : _____

Name and Designation : _____

Date : _____

8. For Calibration

Formula for En ratio calculation

$$\mathbf{E_n} = \frac{\mathbf{x - X}}{\sqrt{(\mathbf{U^2 lab} + \mathbf{U^2 ref.})}}$$

Where,

x-Results of participating laboratory

X-Results of reference laboratory

U lab-Uncertainty of participating laboratory

U ref-Uncertainty of reference laboratory

9. For Testing

Formula for Z score calculation

z = (x – μ) / σ

Where x- test value or test score

μ- Mean value of the test score

σ- standard deviation

The testing laboratories may initiate ILC with more than one laboratory and calculate Z score (mean across various laboratory scores). The Z score within ±2 will be termed satisfactory. In case Z score is more than ±2 then results are doubtful and laboratory need to undertake root cause analysis to find out the reason for deviation in the results.

Annexure-I

PT/ILC Plan for four years to cover the scope of accreditation

CAB Name						
CAB ID						
Field			Testing/Calibration/Medical Testing			
Duration			From: to			
Sr. No.	Field	Parameter	Year 1	Year 2	Year 3	Year 4

Note: CAB should ensure that PT/ILC plan covers the major parameters in each group under the relevant discipline

Approved by IQAS: