POLICY FOR PROFICIENCY TESTING AND/OR INTERLABORATORY COMPARISONS OTHER THAN PROFICIENCY TESTING

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FURTHER INFORMATION

For further information on this document or other Global Accreditation Cooperation Incorporated (Global ACI) documents, contact the Global ACI Secretariat.

Email: secretariat@global-aci.org

Phone: +1 (571) 569-2614

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1. INTRODUCTION

1.1 Preamble

This document is based upon the ILAC (International Laboratory Accreditation Cooperation) document ILAC_P9_01_2024 *ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing*. On the transfer of the role of ILAC to the Global Accreditation Cooperation Incorporated (Global ACI), the text has been reformatted to be a Global ACI document without any substantive change to the text.

The revision of ILAC-P9 was prepared to align with the current versions of ISO/IEC 17025[1], ISO 15189[2] and ISO/IEC 17011[3]. Within ISO/IEC 17025:2017 and ISO 15189:2022, specific clauses are included on proficiency testing (PT) and/or interlaboratory comparisons (ILC) other than PT (clauses 7.7.2 and 7.3.7.3 respectively). Within ISO/IEC 17011:2017 the review of performance in PT and ILCs is considered as an assessment technique.

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

This Policy includes any applicant or accredited conformity assessment body (CAB) that performs testing and calibration.

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.

Participation in PT and/or ILCs other than PT, organised by competent providers is, for an accredited CAB, an integral part of the monitoring of the validity of its results.

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

Examples of ILCs other than PT are given in:

1) ISO/IEC 17043:2023[4] (Introduction points h), i), j), three types of ILCs are considered as ILCs other than PT as they consider in advance that the laboratories are competent and the purpose of the ILCs is not to assess the performance of the laboratory.

2) ISO 15189:2022 (clause 7.3.7.3, point f)), ILCs other than PT are for example “participation in sample exchanges with other laboratories” or “ILCs of the results of the examination of identical IQC (internal quality control) materials, which evaluates individual laboratory IQC results against pooled results from participants using the same IQC material”

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[5] 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 Global ACI-TECH-2-002[6];

- ISO 20387:2018[7], 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[8], 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. This includes an evaluation of the level and frequency of participation in PT and/or ILCs other than PT. Some guidance for the applicant or accredited CAB on this can be found in the EA-4/18 G:2021[9] document *Guidance on the level and frequency of proficiency testing participation*. In Annex C of this document, the main principles of EA-4/18 G:2021 have been considered.

Other regional documents may also be available in evaluating the level and frequency of participation in PT and/or ILCs other than PT.

In this document, the following verbal forms are used:

- “shall”: indicates a requirement;
- “should”: indicates a recommendation;
- “may”: indicates a permission;
- “can”: indicates a possibility or capability.

Further details can be found in the ISO/IEC Directives, Part 2.

1.2 Purpose

1.2.1 This policy sets out the requirements for, and gives guidance to, accreditation bodies (ABs) on the use and assessment of PT and/or ILCs other than PT in the accreditation process for all CABs performing testing or calibration activities – i.e. testing, sampling, calibration and medical laboratories, inspection bodies, biobanks, PT providers and reference material producers.

1.2.2 It also aims to assist ABs to consistently define and apply relevant PT policies, thereby providing a tool for harmonisation in the process of establishing multilateral and bilateral agreements according to Global ACI-MRA-004 [10].

1.3 Scope

This document is applicable to all Global ACI accreditation bodies accrediting CABs performing testing or calibration activities – i.e. testing, sampling, calibration and medical laboratories, inspection bodies, biobanks, PT providers and reference material producers.

2. TERMINOLOGY

2.1 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).

2.2 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.

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

3. GLOBAL ACI POLICY ON PROFICIENCY TESTING AND/OR INTERLABORATORY COMPARISONS OTHER THAN PROFICIENCY TESTING

3.1 ABs seeking to sign or to maintain their status as a signatory to the Global ACI Arrangement (MRA) shall demonstrate the technical competence of their accredited CABs (i.e. laboratories or other accredited CABs performing testing or calibration activities). 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 Global ACI 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 15189:2022, 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) The AB shall request their applicant and accredited CABs to develop a participation plan in PT and/or ILCs other than PT (PT participation plan).

4) The AB shall assess 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) The AB shall ensure 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, the AB shall assess the evidence of the implementation of prompt and appropriate corrective actions.

7) The AB shall assess 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. The AB shall verify 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);
   (b) Note: This includes PT and/or ILCs other than PT that has been mandated, for example by a regulator, an industry or professional sector.
   (c) 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;
   (d) how the AB takes into account a CAB's PT and/or ILCs other than PT performance, to plan the assessments;
   (e) how the AB ensures that the CABs have appropriate evidence of the competence of the PT provider or the organisation providing ILCs other than PT (see Annex A).

4. REFERENCES

1.	ISO/IEC 17025:2017	General requirements for the competence of testing and calibration laboratories
2.	ISO 15189:2022	Medical laboratories - Requirements for quality and competence
3.	ISO/IEC 17011:2017	Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies

4.	ISO/IEC 17043:2023	Conformity assessment - General requirements for the competence of proficiency testing providers.
5.	ISO/IEC 17020:2012	Conformity assessment - Requirements for the operation of various types of bodies performing inspection
6.	Global ACI-TECH-2-002	Guidance on measurements performed as part of an inspection process
7.	ISO 20387:2018	Biotechnology - Biobanking - General requirements for biobanking
8.	ISO 17034:2016	General requirements for the competence of reference material producers
9.	EA-4/18 G:2021	Guidance on the level and frequency of proficiency testing participation
10.	Global ACI-MRA-004	Requirements and Procedures for Evaluation of a Single Accreditation Body
11.	EA-4/21 INF:2018	Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation

5. AMENDMENT TABLE

Section	Previous Version	Summary Of Changes
All	ILAC_P9_01_2024	Initial issue of Global Accreditation Cooperation Incorporated (Global ACI) document

ANNEX A (INFORMATIVE)

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

- A PT provider, accredited to ISO/IEC 17043:2023 by an AB signatory of the Global ACI MRA for PT providers;
- A PT provider, accredited to ISO/IEC 17043:2023 by an applicant AB or an AB non-signatory of the Global ACI MRA for PT providers;
- Participation in an ILC, which is organised for other purposes than determining a CAB's competence (ISO/IEC 17043:2023);
- Organisation 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 Global ACI MRA. For the other bullet points, there is no formal recognition of competence, in terms of Global ACI 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.

ANNEX 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:

a) 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;

b) 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 formalised 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.

ANNEX C (INFORMATIVE)

This Annex 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 should be taken into consideration by the AB when determining 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 AB 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, the AB should expect 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 AB should evaluate 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, ABs should expect 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.