A015

Proficiency Testing by Inter-laboratory Comparisons

Modifications : complete revision

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1. Introduction

The purpose of accreditation is to attest to the proficiency of laboratories and other organizations to carry out specific activities involving conformity assessment.

Interlaboratory comparisons are a reliable and effective means of attesting to this competence.

The present document applies to all CABs carrying out testing, medical analysis or calibration activities.

It applies not only to laboratories, but also to inspection bodies if they carry out testing or calibration activities as part of their activities.

2. References

- ILAC P9:01/2024 ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing
- ILAC G27:07/2019 Guidance on measurements performed as part of an inspection process
- EA 4/18 Guidance on the level and frequency of proficiency testing participation
- EA-4/21 INF Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation
- ISO/IEC 17025 :2017 Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais
- ISO 15189:2022 Laboratoires médicaux -- Exigences concernant la qualité et la compétence
- ISO/IEC 17020:2012 Évaluation de la conformité -- Exigences pour le fonctionnement de différents types d'organismes procédant à l'inspection
- ISO/IEC 17043:2023 Évaluation de la conformité -- Exigences générales concernant les essais d'aptitude

3. Definitions

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.

Note: the 3 possible objectives of an interlaboratory comparison are the evaluation of:

- the performance of laboratories (ISO / IEC 17043 standard),
- the characteristics of a material (ISO/IEC 17034 standard),
- the accuracy of a method (ISO 5725 standard).

Proficiency testing (PT)

Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

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

ILCs other than PT

Examples of ILCs other than PT are given in:

- 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.
- ISO/IEC 17043:2023 (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.

4. Scope

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 have specific requirements for PT and/or ILCs other than PT. However, document ILAC P9 :01/2024 sets out requirements applicable to all CABs carrying out testing or calibration as part of their accredited activities, including inspection bodies. Further information on the need for ensuring the validity of results in the field of inspection can be found in ILAC G27:2019.

5. Frequency of participation in PT and/or ILCs other than PT

5.1 PT participation plan

Laboratories and inspection bodies (if applicable) shall plan and monitor their participation in proficiency tests or other ILCs. The drafting of a PT participation plan is thus required.

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 on this can be found in the EA-document *EA-4/18 G:2021 Guidance on the level and frequency of proficiency testing participation*.

Participation in ILCs other than PT should only be envisaged when PTs are not available, and/or appropriate. In such cases, it is up to accredited CABs to find other means of demonstrating their competence, such as the use of reference materials, the correlation of results with other laboratories, or the repetition of their tests or calibrations using equivalent methods.

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) 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 (http://www.eptis.bam.de/) lists hundreds of interlaboratory comparisons in the fields of testing, calibration and medical biology.

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.

When a CAB chooses alternative approaches in the absence of available and appropriate proficiency tests or other ILCs, the OLAS assessors will assess the CAB's justifications for this choice. The assessors will also verify that the alternative approach implemented by the CAB ensures the validity of the results.

Initial assessment or extension to a new general domain

Prior to any initial accreditation or for extension to a new general domain, the CAB shall provide evidence of a representative[1] and satisfactory[2] participation in PT and/or ILCs other than PT activities regarding the applicant scope.

The CAB has to send the form *F023 - Interlaboratory comparison program*, setting out the strategy for participation in PTs or other ILCs and a summary of the latest results obtained to OLAS.

Surveillance and/or extension assessment

Before each assessment, the concerned laboratories and inspection bodies (if applicable) send to OLAS the form *F023*.

During the assessments, OLAS examines the results obtained from PTs or other ILCs and also verifies the implementation of any corrective actions that may have been necessary.

5.2 Assessment of the PT participation plan

The relevance of the PT participation plan is systematically examined during accreditation assessments.

The PT participation plan shall foresee a representative participation in PT and/or ILCs other than PT activities regarding the accreditation scope.

If the PT participation plan is considered not suitable in relation to the scope of accreditation, the OLAS assessors may issue a finding. The rating of the finding (critical or non-critical) will depend on the importance of the deficiencies observed and the risk associated with the finding.

[1] Representative participation is assessed with regard to the level and frequency of CAB participation in PT and/or other ILCs.
[2] Satisfactory participation is assessed with regard to the choice of interlaboratory comparison programmes (see Chapter 6) and CAB results (see Chapter 7).

In case of a critical finding, a proof of satisfactory registration or participation in a PT or other ILC will be required by OLAS before continuing with the decision-making process.

6. Choice of interlaboratory comparison programmes

The quality of interlaboratory comparison programmes will be checked during assessments.

CABs shall have appropriate evidence of the competence of the PT provider or the organization providing ILCs other than PT.

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 by an AB signatory of the EA or ILAC mutual recognition arrangement.
- A PT provider, accredited to ISO/IEC 17043 by an applicant AB or an AB non-signatory of the EA or ILAC MRA.
- Participation in an ILC, which is organized for other purposes than determining a CAB's competence (ISO/IEC 17043) [3];
- Organisation of, or participation in, ILCs organized, in accordance with the relevant requirements of ISO/IEC 17043, to determine the performance of accredited CABs by comparison with results of other laboratories [1].

OLAS recognizes the interlaboratory comparison programmes organized by the medical laboratories by the Direction de la Santé – Bureau de Contrôle de la Qualité. These interlaboratory comparisons are organized based on the articles 12 and 13 of the law of the 16th of July 1984 concerning medical laboratories.

7. Assessment of results of participation in proficiency tests

CAB performance and corrective actions in case of unsatisfactory results are systematically checked during accreditation assessments.

PT results shall be used by the CAB to maintain its competence. Where satisfactory performance is not achieved, the CAB shall implement appropriate corrective actions to ensure that its competence is maintained and that the results are reliable.

When poor performance is persistently identified, OLAS assessors may issue a finding. The rating of the finding (critical or non-critical) will depend on the extent of the finding and the associated risk.

[3] The document *EA-4/21 INF Guidelines for the assessment of the appropriateness of small interlaboratory comparisons 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.