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Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of accreditation

PURPOSE

This paper provides specific guidance to accreditation bodies for assessing whether interlaboratory comparisons (ILCs) that have been organised by, and among, only a few laboratories, including the organiser(s) can be used in the laboratory accreditation process such as according to EN ISO/IEC 17025 or EN ISO 15189. This document may also be used as guidance by organisers of and participants in such an ILC. This document is not a substitute for the accreditation according to EN ISO/IEC 17043 of a Proficiency Test Provider (PTP) for their PT schemes with few participants.

Authorship

The publication has been written by the “EA/Eurolab/Eurachem Working Group on Proficiency Testing in Accreditation".

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

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CONTENTS

1 INTRODUCTION

1.1 Why do CABs use small ILCs

Conformity Assessment Bodies (CABs) use Proficiency Testing (PT) to safeguard the validity of their measurements.

Note 1: Conformity Assessment Body: Body that performs conformity assessment activities and that can be the object of accreditation (3.1) (Definition 3.4 from EN ISO/IEC 17011: 2017).

Note 2: In the frame of this document, "CABs" include all CABs performing activities, such as testing, sampling, calibration, and medical laboratories, inspection bodies, biobanks, PT providers and reference material producers. The term "measurement" covers all related measurements, tests, calibrations and examinations.

However, when only a few CABs are performing a specific type of measurement, particularly if it is in an advanced or rapidly evolving field, PT schemes may not be *available*. Additionally, participation in a PT may be considered by the CAB as in*appropriate*. Considerations on appropriateness can be found in ILAC P9 [1]. In such cases, other types of Interlaboratory Comparisons (ILCs) may be considered as an option. These ILCs are explicitly referenced to in EN ISO/IEC 17025:2017 [2] and EN ISO 15189:2022 [3] as follows:

EN ISO/IEC 17025, clause 7.7.2

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 EN ISO/IEC 17043 [4] contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of EN ISO/IEC 17043 are considered to be competent.

b) participation in interlaboratory comparisons other than proficiency testing.

ISO 15189, clause 7.3.7.3

a) The laboratory shall monitor its performance of examination methods, by comparison with results of other laboratories. This includes participation in EQA (External Quality Assessment) programmes appropriate to the examinations and interpretation of examination results, including POCT (Point of Care Testing) examination methods. (…)

f) When an EQA programme is either not available, or not considered suitable, the laboratory shall use alternative methodologies to monitor examination method performance. The laboratory shall justify the rationale for the chosen alternative and provide evidence of its effectiveness.

NOTE Acceptable “alternatives” include *participation in sample exchanges with other laboratories;* (…).

This guidance document focuses on the case in which a small group of CABs decide to organise an ILC among themselves. This group may consist of CABs from the same organisation (e.g. from different sites), or CABs from different organisations. A small ILC may be organised by one of the CABs or together with others, and the organising CAB(s) usually participate in the ILC as well. For the purpose of this document, a “small ILC” is defined as having a maximum of seven (7) participants, including the organiser(s).

1.2 Small ILCs are different

Assessors from accreditation bodies who come across results from a participation in a small ILC during their regular assessment (usually conducted in the frame of assessments against EN ISO/IEC 17025 or EN ISO 15189) face the following challenges:

- Organising and participating in small ILCs with a limited number of participants can be statistically challenging. Organisers and participants must ensure that the statistical evaluation yields relevant and valid results. Basic guidance for accreditation assessors on this topic is provided in chapter 4;
- Small ILCs are usually organised by CABs with limited or no experience in organising ILCs. Consequently, fundamental requirements for their competent operation may or may not always be met. Guidance for accreditation assessors on this matter is provided in chapter 5.

2 SCOPE

This document provides guidance to assessors from accreditation bodies on the statistical evaluation of small ILCs and the relevant elements from EN ISO/IEC 17043 to be considered when reviewing the results of participation in a small ILC in the frame of the regular assessment against EN ISO/IEC 17025 or EN ISO 15189, or other relevant standards.

This guideline mainly focuses on small ILCs for quantitative measurements, although similar considerations apply to other types of small ILCs, such as qualitative ones. This guideline does not cover the assessment of PT providers.

3 TERMS AND 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 (EN ISO/IEC 17043, Clause 3.4).

- **Small interlaboratory comparison (small ILC)**

  An Interlaboratory Comparison (ILC) having a maximum of seven participants, including the organiser(s).

- **Proficiency testing (PT)**

  Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (EN ISO/IEC 17043, clause 3.7).

- **Small ILC item**

  Sample, product, artefact, reference material, piece of equipment, measurement standard, object, image, data set or other information used for proficiency testing (adapted from the definition of *PT item* in EN ISO/IEC 17043, clause 3.8).

- **ILC organiser**
  The CAB(s) which take(s) responsibility for all activities in the development and operation of the small ILC (adapted from the definition of *PT* provider in EN ISO/IEC 17043, clause 3.9)

- **Assigned value**

  Value attributed to a particular property or characteristic of testing an ILC item (EN ISO/IEC 17043, clause 3.1).

- **Standard deviation for proficiency assessment (SDPA)**

  Measure of dispersion used in the evaluation of results of the ILC, based on the available information (adapted from ISO/IEC 17043, clause 3.12).

- **Reference Material (RM)**

  Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process (ISO 17034, clause 3.3 [5]).

- **Certified reference material (CRM)**

  Reference material (RM) characterised by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability (ISO 17034, clause 3.2).

4 SMALL ILCS AND THEIR STATISTICAL EVALUATION

The evaluation of participant results in a small ILC is challenging and requires careful consideration during the accreditation assessment.

4.1 Key issues

The limited number of participants in a small ILC means that the statistical foundation for evaluations may not be sufficiently robust for performance scoring. A decreasing number of independent participant results leads to an increasing uncertainty of both the mean and the standard deviation. This is a purely statistical effect, independent of the uncertainties reported by the participants. In addition, a small dataset makes it challenging to accurately identify the distribution of the data and to reliably detect outliers.

For this reason, ISO 13528 [6] recommends that organisers of small ILCs do not evaluate their ILCs or provide scores based on statistical parameters derived from the participants' results, e.g. the mean and standard deviation. This recommendation originates from an IUPAC Technical Report [7], initially intended for ILCs with $N < 20$ participants, but even more applicable to those with $N < 8$ participants.

4.2 Risk assessment

The evaluation of results can be straightforward if a sound metrological approach is used and the recommendation from ISO 13528 is followed. However, a wide variety of scenarios may require an assessment of the risk that the ILC does not provide a reliable evaluation (and usually performance scoring) of participants' results. Performing the risk assessment is the responsibility of the ILC organiser who may consider questions such as:

- Is there a traceable reference value independent of the dataset, such as a certified value from a reference material or a measurement result provided by expert laboratories that can be used as the assigned value?
- Are there any alternatives for an assigned value if no independent and traceable reference value exist?
- Is there a suitable (fit for purpose) evaluation criterion independent of the dataset, such as a target value based on experience or derived from legislation, which can be used to set a suitable SDPA for calculating a z score or z' score?
- Does the organiser have experience with the type of measurement performed, which can help them to properly identify the distribution of reported results and detect outliers?
- Do the participants have experience with the type of measurement performed, which can help them report values with minimal spread in the dataset, thereby keeping the uncertainty of the mean small? Even if the mean is not used as the assigned value, it should be compared with the assigned value, and any differences should be examined.

Note: Explanation of the various scoring systems, e.g. z, z', zeta (ζ) or E_n can be found in ISO 13528.

4.3 Three scenarios

The following three scenarios provide examples of good practices that may help accreditation body assessors in reviewing the validity of a small ILC. They reflect various situations an assessor might come across. In Scenario 1, a metrological approach leads to a sound evaluation and performance scoring. This approach is ideal and provides comprehensive insights into participant performance. When a full metrological approach is not feasible, a risk assessment identifies viable options (Scenario 2). This scenario still offers valuable information through a structured risk assessment. In Scenario 3, a risk assessment indicates that only a more qualitative approach is possible. While less quantitative, this scenario can still yield useful educational insights into participant performance.

Scenario 1: Assigned value with metrological traceability available

In this scenario, the assigned value is a metrologically traceable reference value that is independent of the dataset, such as a value from a certified reference material (CRM) certificate, or a measurement result provided by a reference laboratory, or a measurement result obtained by a reference (standard) method. Additionally, the organiser could provide zeta (ζ) or E_n scores if the assigned value and reported participant results are accompanied by an uncertainty statement, while z scores can be used if a suitable SDPA can be established that is equally independent of the dataset, such as a target value based on experience or derived from legislation. This scenario offers the most robust assessment due to its reliance on traceable reference values.

Scenario 2: Other assigned value available

In this scenario, no independent traceable reference value is available, but additional information may improve the usability of the data at hand. This occurs when a reference material (RM) is used, and the corresponding information sheet provides only “informative” reference value(s) with the associated uncertainties, but without evidence of metrological traceability. In this context, the mean of the dataset may be comparable with the results of an earlier small ILC on the same ILC item or may be confirmed by participants operating at a higher metrological level (e.g. a split-sample design as per EN ISO/IEC 17043 A.2.5). However, such approaches require the organiser to carefully assess the suitability of combining different sources of information and the potential risk that may impact the reliability of the small ILC evaluation.

Based on this assessment and in combination with an external target SDPA, the organiser may decide to provide a z (or another suitable) score to the participants. If no target SDPA is available, the organiser may still decide to provide a zeta (ζ) or E_n score if the participants reported their measurement uncertainties, and the uncertainty of the assigned value is given. Thus, in this scenario, the evaluation and performance scoring of the reported results can be a reasonable option. The organiser may also decide not to issue any performance scores if the risk assessment does not lead to convincing results. This scenario provides a balanced approach, combining some metrological elements with practical risk management.

Scenario 3: No assigned value available

In this scenario, there is no reliable assigned value, and any performance scores should be issued for informational purpose only. Although the risk assessment indicates that only a qualitative approach is feasible, this scenario can still yield valuable educational insights into participant performance. The reported results can provide valuable insight such as repeatability, reproducibility, potential outliers, and reported uncertainties. The ILC organiser should consider these aspects in their report.

5 RELEVANT REQUIREMENTS FROM EN ISO/IEC 17043

The standard EN ISO/IEC 17043 provides the general requirements for the competence of PT providers and the development and operation of PT schemes. PT providers fulfil these requirements to safeguard that the performance evaluation of their participants can be used to monitor the validity

of their results. However, the standard implicitly focuses on routine PT schemes, and it is neither sensible nor necessary to fulfil all its requirements for a small ILC. Many activities required to organise a small ILC are already covered by regular laboratory management systems based on EN ISO/IEC 17025, EN ISO 15189 or other relevant standards.

The requirements of the standard EN ISO/IEC 17043:2023 relevant to the organisation of a small ILC are listed below. These should specially be considered when assessing the organisation of a small ILC in the frame of a routine accreditation assessment.

Where the participant is not the organiser of the small ILC, the participant is responsible to ensure that the organiser of the small ILC fulfils the relevant requirements of EN ISO/IEC 17043.

Note: In this document the term ‘PT’ from the EN ISO/IEC 17043 standard has been replaced by ‘small ILC’.

The order of the clauses below follows that of EN ISO/IEC 17043:2023. The specific chapters are mentioned in brackets.

5.1 General requirements and structural requirements (EN ISO/IEC 17043, clauses 4 and 5)

It is usually unnecessary to assess the requirements outlined in these chapters. However, any small ILC should adhere to the principles of impartiality and confidentiality to ensure its suitability for the laboratory process.

5.2 Resource requirements (ISO/IEC 17043, clause 6)

5.2.1 Personnel (ISO/IEC 17043, clause 6.2)

The records and competence of the personnel involved in the organisation of the small ILC should be assessed. The ILC organiser should have personnel authorised for the specific tasks within the organisation of the small ILC. Method related competence of the personnel is usually addressed in the routine CAB assessment.

Given that the ILC organiser also participates in the small ILC, it is preferable for the personnel performing the measurements not to overlap with those organising the ILC. To prevent collusion, the ILC organiser should ensure that personnel performing measurement are not informed in advance of relevant details, such as assigned values.

5.2.2 Facilities and environmental conditions (ISO/IEC 17043, clause 6.3)

If the facilities and equipment used for the organisation of the small ILC differ from those used for routine measurements within the scope of accreditation, they should be specifically assessed to establish their suitability for the small ILC. If deemed critical to the organisation of the small ILC, the relevant requirements ISO/IEC 17025 or ISO 15189 should be considered.

5.2.3 Externally provided products and services (ISO/IEC 17043, clause 6.4)

When external service providers are involved in the organisation of the small ILC, a comprehensive assessment is required. Otherwise, the evaluation of externally provided products and services is usually covered by the routine assessment of the CAB.

5.3 Process requirements (ISO/IEC 17043, clause 7)

5.3.1 Establishing, contracting, and communicating the small ILC scheme objectives EN (ISO/IEC 17043, clause 7.1, 7.6, 7.7)

The organisation and participation in a small ILC are considered as a collaboration between CABs rather than as a service provided to a customer. Therefore, the requirements related to service to the customer, complaints, and appeals do not apply.

5.3.2 Design and planning of a small ILC (EN ISO/IEC 17043, clause 7.2)

Planning

The planning of the small ILC is a key focus of the assessment. A detailed plan, including a detailed description of the operation of the small ILC should be available. At minimum, the plan should include or elaborate on the following topics:

- Main contact person
- If organised jointly, the list of persons or CABs involved
- List of participants
- The measurand or characteristic to be determined
- Requirements (production, homogeneity, stability) for the ILC item
- Information on the use and preparation of the ILC item (including description of preparation, if applicable)
- Timeframe of the small ILC
- Information on the method(s) or procedures to be used by the participants
- Description of the method for evaluating the comparability of the results, including statistical analysis and the criteria used for performance evaluation; and
- Description of the reporting format for participants and from the ILC organiser.

Statistical design, assigned value, and SDPA

The appropriateness of the statistical design, particularly the validity of any assigned value and SDPA should be assessed, considering the challenges and common pitfalls associated with small ILCs, as described in chapter 4.

Assigned values should be treated as confidential, to prevent participants from gaining an unfair advantage.

5.3.3 Choice of method or procedure (EN ISO/IEC 17043, linked to clause 7.2)

The methods or procedures used by the participants should be documented. If different methods or procedures are allowed, this information should be considered when evaluating performance.

5.3.4 Production and distribution of ILC items (EN ISO/IEC 17043, clause 7.3)

Production of ILC items

Documented evidence of the acquisition and production of the ILC items should be assessed for the evaluation of the small ILC results. If the ILC organiser produces the ILC item itself, this should be assessed. Otherwise, information regarding the ILC item should be checked, such as the CRM providing the value of the specified property, its associated uncertainty, and a statement of metrological traceability, or equivalent information sheets of reference materials (RMs).

Homogeneity and Stability

Documented evidence of the homogeneity and stability of the ILC items should be assessed for the evaluation of the small ILC results.

ILC items handling and storage

The storage areas and the handling should be assessed if the ILC items differ from items being routinely measured by the CAB.

Packaging, labelling and distribution of ILC items

The packaging, the labelling and the transport conditions of the ILC items should be assessed.

Instructions for participants

Instructions for the small ILC should be documented and made available to the participants; their appropriateness should be assessed against the objectives of the small ILC.

5.3.5 Evaluation and reporting of small ILC results (EN ISO/IEC 17043, clause 7.4)

Data analysis and evaluation of performance

Taking into account the challenges and common pitfalls of small ILCs, the appropriateness of the data analysis should be assessed, as well as the evaluation of performance and / or lessons learnt from the participants' results (see, e.g., scenario 3 in chapter 4).

5.3.6 Reports (EN ISO/IEC 17043, clause 7.4.3)

A report should be established by the ILC organiser, including, at minimum, the following points:

- Date of the small ILC
- Contact person
- Persons or CABs involved in the organisation of the small ILC
- Identification of the small ILC scheme or round
- Description of the ILC item, including how the homogeneity and stability of the ILC item were determined.

- Participants' results
- Method for evaluating the comparability of the results (e.g., any assigned values and their associated uncertainties, establishment of an SDPA, range of results, graphical displays)
- Comparability of the participants' results and/or participants' performance; and
- Comments and recommendations based on the outcome of the small ILC.

The participants' results and performance evaluation should be anonymised in the report to ensure confidentiality, unless the participants waive confidentiality.

If any of these topics are clearly included in the plan and the latter is provided to the participants, then they do not need to be included again in the report.

5.3.7 Control of the small ILC process (EN ISO/IEC 17043, clause 7.5)

The records of the data concerning the organisation of the small ILC should be retained and assessed.

If any non-conforming work occurs during the organisation of the small ILC, the records and the subsequent actions taken should be assessed.

5.4 Management system requirements (EN ISO/IEC 17043, clause 8)

The organisation of the small ILC is to be executed within and supported by the management system of the CAB (or CABs).

The documents related to the organisation of the small ILC should follow the document control procedures of the CAB. In principle there is no subcontracting of the organisation, with a small ILC, but the organisation could be performed jointly by two or more of the CABs participating.

The assessor should verify that the documents and recordings relating to the organisation of the small ILC are managed in conformity with the management system.

If the organisation of the small ILC is not solely organised by the CAB, the arrangements with other CABs are to be evaluated.

The organisation of the small ILC should be included in the internal audit and the management review processes. It is expected that the effectiveness of the small ILC is considered during the management review.

6 FURTHER CONSIDERATIONS

Existing PT schemes available on the market offer many advantages over small ILCs. Consequently, participants in a small ILC are expected to have thoroughly evaluated the availability of existing PT schemes and made well-considered decisions concerning their appropriateness. These considerations should be detailed in the CAB's PT strategy [1] and assessed accordingly. Furthermore, small ILCs should be included in the CAB's PT participation plan in accordance with ILAC P9 [1].

Any unsatisfactory results obtained from participation in a small ILC must be treated by the CAB as non-conforming work, consistent with the treatment of other unsatisfactory PT or ILC results. Actions taken in response to these results should be assessed in accordance with ISO/IEC 17025 and ISO 15189 standards.

7 REFERENCES

[1] ILAC-P9:01/2024. ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing. https://ilac.org/?ddownload=3259

[2] EN ISO/IEC 17025:2017. General requirements for the competence of testing and calibration laboratories.

[3] EN ISO 15189:2022. Medical laboratories – Requirements for quality and competence.

[4] EN ISO/IEC 17043:2023. Conformity assessment – General requirements for the competence of proficiency testing providers.

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[6] EN ISO 13528: 2022. Statistical methods for use in proficiency testing by interlaboratory comparison

[7] IUPAC Technical Report. Selection and use of proficiency testing schemes for a limited number of participants—chemical analytical laboratories. Pure Appl. Chem., 2010, Vol. 82, No. 5, pp. 1099–1135. http://dx.doi.org/10.1351/PAC-REP-09-08-15.