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

PURPOSE

This paper provides specific guidance to accreditation bodies for assessing whether interlaboratory comparisons that have been organised by, and among, only a few laboratories, the maximum being seven laboratories, including the organiser(s) can be used in the laboratory accreditation process. This document may also be used as guidance by organisers of and participants in such an ILC. This document is not intended as a substitute to ISO/IEC 17043 for the accreditation of small PT schemes.

Authorship
The publication has been written by the EEE-PT Working Group “Proficiency Testing in Accreditation”.

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

Further information
For further information about this document, contact the EA Secretariat. Please check the EA website for up-to-date information (http://www.european-accreditation.org).

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CONTENTS

1. INTRODUCTION

A regular independent assessment of the technical performance of a laboratory is necessary to monitor the validity of measurements (the term “measurement” is used in this document and covers measurement, tests, calibrations and examinations), and should be part of an overall quality strategy. A common approach to this independent assessment is the participation in Interlaboratory Comparisons.

The standard ISO/IEC 17025:2017 [1] establishes in sub-clause 7.7.2 that “the laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken”. These procedures may include the “participation in interlaboratory comparisons (ILC) or proficiency testing (PT) programmes”.

The standard ISO 15189:2012 [2] establishes in sub-clause 5.6.3 that:

“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 interlaboratory comparisons other than proficiency testing.”

If inspection bodies perform measurements, they should comply with the relevant requirements of ISO/IEC 17025 for these activities; therefore this document is also applicable for these inspection bodies. The term “laboratory” is to be understood in this document as any organisation performing measurements.

PT providers cover a large share of the market's demand for PT schemes. Nonetheless, there may be reasons for laboratories to organise or participate in a small ILC. Reasons may include for example:

- there is no suitable PT scheme available, for example in fields with fast technical developments (e.g. mobile internet), or where such measurements are very advanced or (e.g. full-scale fire testing), or in fields with few laboratories performing very specific measurements (e.g. plant health); or in areas where PT is not practical
- participation in a PT scheme would not be appropriate if it poses an unreasonable burden to the laboratory;
- the low number of existing laboratories in the sector.

In such cases, a laboratory or a small group of laboratories may decide to organise an ILC among themselves, which may include laboratories from the same organisation (e.g. from different sites*), or laboratories from different organisations. However, it must be emphasized that the choice of participation in a small ILC shall be taken only after careful evaluation of the existing PT schemes on the market.
*Note: Assumes that the test items are unknown to each of the sites

For the purpose of this document, whilst the participation in a small ILC involves in the majority cases two to four participant laboratories, the maximum size of this group is set to seven participants, including the organiser(s) of the small ILC.

Laboratories that organise a small ILC among themselves should apply the appropriate requirements of ISO/IEC 17043, "General requirements for proficiency testing", if the results and evaluation of performance are to be used as a tool to monitor and demonstrate the quality of their measurement results. However, the standard has an implicit focus on routine PT schemes and it may not be sensible or necessary to fulfil all of its requirements for a small ILC that is organised within a small group of participants.

This document acknowledges that many activities necessary to organise a small ILC are already covered by regular laboratory quality management systems based on ISO/IEC 17025 and/or ISO 15189. Therefore, this document only lists those additional requirements from ISO/IEC 17043 [3] that are relevant for the assessment of a small ILC. This helps to provide trust to participants of a small ILC. The assessment of the suitability of these small ILCs will be a part of the normal laboratory accreditation audit.

2. SCOPE OF APPLICATION

This document is intended to give guidance to assessors from accreditation bodies on which elements from ISO/IEC 17043 are to be taken into consideration when assessing the results from a small ILC, in the frame of laboratory assessments against ISO/IEC 17025 or ISO 15189, and where relevant of inspection bodies against 17020 (see note)

"Note: Proficiency testing may be used in some types of inspection where available and justified by the inclusion of testing activities that directly affect and determine the inspection result or when required by law or by regulators. It is, however, recognized that proficiency testing is not a usual and expected element in the accreditation of most types of inspections."

These guidelines are applicable to small ILCs comprising quantitative measurements; similar considerations (but outside the scope of this guidance document) hold for other (e.g. a qualitative) types of small ILCs.

This document does not cover small ILCs that are organised by PT providers.

3. TERMS AND DEFINITIONS

- **Interlaboratory comparison (ILC)**
  The organisation, 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: 3.4)

- **Small interlaboratory comparison (small ILC)**
  An interlaboratory comparison organised by, and among seven or less laboratories

- **Proficiency testing (PT)**
  Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043: 3.7)

- **ILC test item [ILC test item]**
  Sample, product, artefact, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing (Adapted from ISO/IEC 17043: 3.8).
  Note: For the purpose of this document, the ILC test item can be regarded equivalent to the proficiency test item.

ILC organiser
The laboratory which takes responsibility for the development and operation of the ILC. adapted from ISO/IEC 17043: 3.9)

- **Assigned value**
  Value attributed to a particular property of a proficiency test item (ISO/IEC 17043: 3.1)
  Note: for the purpose of this document, this is the property value of the ILC test item.

- **Standard deviation for proficiency assessment (SDPA, σ_{PT})**
  Measure of dispersion used in the evaluation of results of proficiency testing, based on the available information (ISO/IEC 17043: 3.13)

- **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 Guide 30: 2.1.2)

- **Certified reference material (CRM)**
  Reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by a RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability (ISO Guide 30: 2.1.2)

4. EVALUATION OF PERFORMANCE

The statistical evaluation of participant results for a small ILC is often less straightforward than for a large ILC. With a decreasing number of participants, it gets increasingly difficult to identify the distribution of the results, to detect outliers reliably, or to apply robust statistical analysis. It is generally not recommended to derive the assigned value and SDPA from the results obtained by the participants, or at least this should be done with great care and expertise. Similar considerations (but outside the scope of this document) hold for other evaluations, e.g. in case of a qualitative small ILC.

Accreditation body assessors should give due care to these peculiarities when reviewing the technical relevance and the outcome of a small ILC. To aid this review, the three scenarios below provide examples for a sound evaluation of a small ILC. Which scenario applies in practice depends on the presence and reliability of an externally assigned value, the quality of the dataset, the experience of the participants and the competence and experience of the small ILC organiser.

From a metrological point of view, and in the frame of a small ILC, the use of an assigned value based on an external reference (see Scenario 1 below) should be preferred over an assigned value based on participants results (see Scenario 2 below), which in turn should be preferred over not using any assigned value (see Scenario 3 below). However, elements from Scenario 3 may also be relevant to the other scenarios, because of their educative character.

In order to establish an evaluation of performance, the ILC organiser should define, pre-assessment criteria, where relevant, before the round is organised

Scenario 1: The organiser has used an assigned value based on an external reference

The evaluation of results from a small ILC, and performance scoring of participants, are straightforward in this scenario. The organiser may use z scores in which both the assigned value

and SDPA are independent of the reported results or use an En number if the assigned value and reported values have stated uncertainties. The assigned value may stem from a suitable reference standard e.g. the certificate of a CRM or of a measurement standard or instrument in the field of calibration, measurements performed by expert laboratories, or an earlier ILC on the same or a similar material. Similarly, the SDPA could be an external target value that is in line with the results of an earlier ILC or meets specific legislation for which the test has been undertaken. Zeta scores may also be used, preferably in combination with z scores.

Scenario 2: The organiser has used an assigned value based on participants' results

If an external reference value is not available, quantitative analysis and performance scoring on the basis of the reported results only is generally not recommended. However, there may be exceptions, e.g.:

a) The participants are experienced laboratories that have gathered competence to harmonise their accuracies (trueness and precision) for this particular type of measurement, e.g. through earlier rounds of the same or a similar ILC. This is likely to keep the uncertainty of the assigned value small;

b) One of the participants is considered to operate at a higher metrological level (i.e. lower measurement uncertainty), due to the use of reference methodology and more advanced equipment. Its measurement result could be used as the assigned value.

In combination with an external (target) SDPA, the cases a) and b) may be suitable for quantitative analysis and performance scoring.

Scenario 3: The organiser has not used any assigned value

If no external assigned value is available and an assigned value cannot be reliably calculated from the dataset, then the ILC organiser should not calculate a performance score, however an individual performance may be established. The reported results may for example be graphically displayed and discussed among the small ILC participants. The reproducibility of the results (variation among participants), the repeatability (variation between replicate measurements in the single laboratory under repeatability conditions), the type of distribution, the information contained in extreme values (outliers or not) and the reported measurement uncertainty are examples of information that may be used to establish any individual performance.

5. ASSESSING PARTICIPANT RESULTS IN SMALL ILC

The appropriateness of the participation in a small ILC is to be evaluated when assessing the ILC strategy of the laboratory [4] [5].

When PT results stem from a PT provider, who operates in accordance with ISO/IEC 17043 are assessed, the focus is mainly on the performance obtained by the laboratory and the criteria used by the PT provider to establish the evaluation of performance. But when assessing the results from a small ILC, the operation of the small ILC is to be assessed in order to check that they have been organised in agreement with the relevant requirements of ISO/IEC 17043. The assessment depends on which of the following two situations are encountered when assessing a laboratory in relation to a small ILC:

- The laboratory assessed has organised and participated in the small ILC.
- The laboratory assessed has only participated in the small ILC.

In the first situation, the assessor will evaluate the plan (in accordance to 6.2.3) and report (in accordance to 6.2.7) along with the organisation of the small ILC to conclude upon its relevancy, according to Section 6 of this document.

In the second situation, the laboratory should be able to provide details to the assessor on how they have evaluated and decided on the fitness for purpose of the small ILC. The assessor should evaluate these details, taking into account section 6 of this document, in order to conclude upon the relevancy of the small ILC.

In addition, it is expected that any unsatisfactory results that are obtained from participation in a small ILC are to be treated by the laboratory, like all the other unsatisfactory ILC results, as non-conforming work (see ISO/IEC 17025 and ISO 15189) and the actions taken are to be specifically assessed.

The criteria used for the evaluation of performance should be fit for purpose.

6. ASSESSING THE ORGANIZATION OF SMALL ILC

This section is applicable during the accreditation assessment process if the laboratory being assessed has been involved in the organisation and has participated in the small ILC itself. The standard ISO/IEC 17043 provides the general requirements for the competence of PT providers of and for the development and operation of PT schemes. PT providers that fulfil these requirements safeguard that the participants' performance can be used to monitor the validity of their measurements.

Those requirements of the standard ISO/IEC 17043 that are considered relevant for the organisation of a small ILC (see Section 3 of these guidelines) are listed below. These should be taken specifically into consideration when assessing the organisation of a small ILC in the frame of a routine (ISO/IEC 17025 and/or ISO 15189) laboratory accreditation assessment. Please note that the term 'PT' where stated in the requirement with ISO/IEC 17043 has been changed to 'small ILC' and 'PT test item' changed to 'ILC test item' in this document.

6.1. Management requirements

6.1.1. Organisation / Management system / Document control / Review of requests, tenders and contracts / Subcontracting services

It is expected that the organisation of the small ILC is included in the management system of the accredited (or in the process of being accredited) laboratory.

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

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 organised solely by the laboratory, the arrangements with the other laboratories are to be evaluated.

6.1.2. Purchasing services and supplies

If for the organisation of the small ILC an additional supplier is to be considered, then this should be assessed. If not, the assessment of services and supplies will be covered by the routine assessment of the laboratory.

6.1.3. Service to the customer / Complaints and appeals / Control of non-conforming work / Improvement / Corrective actions / Preventive actions

No specific assessment would be expected for these aspects as they would be assessed during the regular assessment of the laboratory.

It is to be noted that the organisation of, or participation in a small ILC is to be considered as a co-operation between laboratories and not as a service to a customer. Therefore the requirements related to service to the customer, and complaints and appeals will not normally be applicable.

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

6.1.4. Control of records

The records of the data concerning the organisation of the small ILC should be retained. The evaluation of the technical data should be a central point of the assessment.

6.1.5. Internal audits / Management reviews

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

6.2. Technical requirements

6.2.1. Personnel

The records and competence of the personnel involved in the organisation of the small ILC should be assessed. The laboratory should have personnel authorised for the specific tasks within the organisation of the small ILC. Method related competence of the personnel would normally be included in the routine laboratory assessment

If the organiser is also participating in the small ILC the personnel performing the measurements should if possible not be the same personnel which organises the small ILC. The organiser should take precautions to avoid that the personnel that performs the measurement is informed about the levels to be determined in advance.

6.2.2. Equipment, accommodation and environment

If the facilities and equipment used for the organization of the small ILC differ from those used for routine measurements within the scope of accreditation, then they should be specifically assessed to determine whether they are appropriate for the small ILC. If deemed to be critical to the organisation of the small ILC they should be assessed against ISO/IEC 17025 or ISO 15189.

6.2.3. Design of the small ILC

<u>Planning</u>

The planning of the small ILC is the main focus point of the assessment of the small ILCs. A plan, which includes a detailed description of the operation of the small ILC is to be available.

As a minimum, the following points should be included or elaborated in the plan:

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

Preparation of ILC test items

If the organiser prepares the ILC test item itself, then this should be assessed. If not, then all the information relating to the ILC test item e.g. certificates should be checked.

Homogeneity and Stability

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

Statistical design

The appropriateness of the statistical design should be assessed.

Assigned value

The assessment should ensure that an appropriate assigned value where relevant and its associated measurement uncertainty is established and treated as “confidential” as possible.

SDPA

The assessment should ensure that a fit for purpose SDPA has been established.

6.2.4. Choice of method or procedure

The methods or procedures used by the participants should be documented and if different methods or procedures are allowed, this information should be used in the evaluation of performance.

6.2.5. Operation of a small ILC

Instructions for participants

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

ILC test items handling and storage

If the ILC test items differ from items being routinely measured by laboratories, the storage areas and the handling should be assessed.

Packaging, labelling and distribution of ILC test items

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

6.2.6. Data analysis and evaluation of small ILC results

Data analysis and records

The appropriateness of the data analysis should be assessed.

Evaluation of performance

The evaluation of performance and any other comparisons made and lessons learnt from the participants' results (see e.g. Scenario 3 in Section 4) should be reviewed, including measurement uncertainties of the results, if any.

6.2.7. Reports

A report should be established by the ILC organiser. As a minimum, the following points should be included in the report:

- Date of small ILC
- Contact person
- Persons or laboratories involved in the organisation of the small ILC
- Identification of the small ILC scheme
- Description of the small ILC item
- The participants results
- Method for the evaluation of the comparability of the results (assigned value and its associated measurement uncertainty, establishment of the SDPA, range of results, graphical displays)
- Comparability of the participants results and/or participants performance
- Comments and recommendations based on the outcome of the small ILC scheme

If some of the points are clearly included in the plan and the latter is provided to all the participants, then these issues do not need to be included again in the report.

6.2.8. Communication with participants / Confidentiality

It would not be expected to assess this specifically.

7. REFERENCES

[1] ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories.
[2] ISO 15189: 2012 Medical laboratories – Requirements for quality and competence.
[3] ISO/IEC 17043:2010 Conformity assessment – General requirements for proficiency testing.
[4] EA-4/18 INF:2010 Guidance on the level and frequency of proficiency testing participation.
[5] ILAC-P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities.
[6] ILAC-P13:10/2010 Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers.