LAS-Q008

TTLABS POLICY FOR PARTICIPATION IN EXTERNAL QUALITY ASSURANCE PROGRAMMES

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TTLABS POLICY FOR

PARTICIPATION IN

EXTERNAL QUALITY ASSURANCE PROGRAMMES

[Intended for use with *ISO/IEC 17025* and *ISO 15189*]

0.0 PREAMBLE

Accreditation assesses the competence of a conformity assessment body to perform a specific conformity assessment activity. The assessment of this competence uses criteria and various tools to confirm that the conformity assessment body is performing as expected. The need to ensure the validity of results of laboratories is critical to demonstrate objectively this competence.

Laboratories ensure the validity of results through both an internal quality control programme and an external quality assurance programme. The external quality assurance programme demonstrates the laboratory's performance against other participating laboratories and is reported on and managed by an independent third party entity. This presents an independent assessment of the performance of the specific test or calibration against at least other similar organisations and at most against a sample of known value. This process allows a laboratory to assess any bias that it may have in its measurement system and therefore investigate and take corrective action to ensure that the measuring system is measuring accurately.

The external quality assurance programme is usually defined by either participation in proficiency testing or external quality assessment programmes or interlaboratory comparisons other than proficiency testing. The participation in proficiency testing or external quality assessment programmes are required in *ISO/IEC 17025:2017* Clause 7.7.2 and *ISO 15189:2022* Clause 7.3.7.3, respectively. If an appropriate proficiency testing or external quality assurance programme cannot be accessed, the laboratory is expected to participate in an interlaboratory comparison other than proficiency testing.

This Policy is intended to provide guidance for the laboratories seeking accreditation from TTLABS on the expectation and usage of external quality assurance programme for laboratories within the TTLABS schemes for *ISO/IEC 17025:2017* for testing and calibration laboratories and *ISO 15189:2022* for medical (clinical) laboratories. Laboratories will be assessed against these criteria in addition to that of *ISO/IEC 17025:2017* or *ISO 15189:2022*, as applicable.

This Policy is based on **ILAC-P9:01/2024** – *ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing*. **EA-4/18 G: 2021** – *Guidance on the level and frequency of proficiency testing participation* and **EA-4/21 INF: 2018** – *Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation* were used to inform the usage and expectation of laboratories to participate in an external quality assurance programme. TTLABS acknowledges ILAC and the European Accreditation Cooperation for the content published in these documents and permission to use them to inform this TTLABS Policy.

1.0 INTRODUCTION

1.1 TTLABS requires laboratories to participate in appropriate and available proficiency testing or external quality assessment programmes to provide independent data of the laboratory's competence to perform the specific test or calibration, including medical testing. Ensuring the validity of test and/or calibration results, including medical examination results, is a requirement for accreditation as stated in *ISO/IEC 17025*: *2017* Clause 7.7.2 and *ISO 15189:2022* Clause 7.3.7.3.

1.2 This policy explains how TTLABS uses the information from the participation in the external quality assurance programmes to assess the laboratory's competence.

2.0 SCOPE

2.1 This policy is applicable to all applicant and accredited laboratories, including medical laboratories.

3.0 DEFINITIONS

3.1 External Quality Assurance Programme – the programme established by a laboratory to monitor through external comparison with other laboratories its technical competence to perform a specific test, inclusive of proficiency testing, external quality assessment, and interlaboratory comparison other than proficiency testing.

3.2 Proficiency Testing (PT) – evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

3.3 External Quality Assessment (EQA) – evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

3.4 Interlaboratory Comparison (ILC) – organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

3.5 Reference Material (RM) – material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.

4.0 POLICY

4.1 PARTICIPATION IN EXTERNAL QUALITY ASSURANCE PROGRAMMES

4.1.1 TTLABS requires that all applicant and accredited laboratories shall participate in proficiency testing or external quality assessment schemes where such schemes are available and appropriate. If such schemes do not exist, the laboratory shall participate in interlaboratory comparisons other than proficiency testing.

4.1.2 Applicant laboratories or those wishing to extend their scope of accreditation must have performed satisfactorily in the PT and/or ILC Schemes covering their proposed scope of accreditation before accreditation can be granted.

4.1.3 The laboratory's participation in external quality assurance programmes shall be based on a risk assessment of its technical competence to consistently perform the specific test.

4.1.4 The laboratory shall establish a plan to participate in proficiency testing/interlaboratory comparison other than proficiency testing to monitor and demonstrate its technical competence.

4.1.5 TTLABS assesses the External Quality Assurance Participation Plan that it is representative and satisfactory given the applicant and accredited laboratory's scope of accreditation.

4.1.6 Where the laboratory receives unsatisfactory results in a proficiency testing or interlaboratory comparison other than proficiency testing, the laboratory shall investigate the causes for the poor performance and promptly implement appropriate corrective action(s) to ensure that the technical competence issue is addressed.

4.1.7 The laboratory shall justify and document its decision to not participate in a proficiency testing programme or an interlaboratory comparison other than proficiency testing. The laboratory shall define the alternative approach(es) that will be used to demonstrate the technical competence. This shall be submitted to TTLABS, and is used during the assessment to verify that the laboratory is ensuring the validity of its results.

4.1.8 The laboratory shall have appropriate records to demonstrate the competence of the proficiency testing provider and/or the organization providing interlaboratory comparisons other than proficiency testing.

4.2 USAGE OF EXTERNAL QUALITY ASSURANCE PARTICIPATION PLAN IN THE ASSESSMENT OF TECHNICAL COMPETENCE

4.2.1 TTLABS uses the results from the participation in proficiency testing and interlaboratory comparison programmes other than proficiency testing as a tool to assess technical competence of the laboratory.

4.2.2 TTLABS requires the laboratory to monitor its performance in programmes over time to assess bias and accuracy, as required by *ISO/IEC 17025:2017* Clause 7.7.3 and *ISO 15189:2022* Clause 7.3.7.1. TTLABS shall assess the laboratory's review of its performance and actions taken to address the occurrence of bias and/or poor performance, including the review of its risks identified and actions taken to address them.

4.2.3 If the external quality assurance participation plan is not satisfactory, TTLABS shall require the laboratory to review the plan ensuring that risks are reviewed and the plan updated.

4.2.4 The laboratory shall submit to TTLABS the results of performance in proficiency testing and interlaboratory comparison programmes other than proficiency testing, within two weeks of receipt of them with any investigation and proposed corrective actions to be implemented, if applicable. TTLABS shall review and communicate to the laboratory thereafter.

4.2.5 TTLABS shall use the results from the participation in the external quality assurance plan in planning the next assessment.

4.3 APPROPRIATE PT PROVIDERS OR ORGANIZATIONS PROVIDING INTERLABORATORY COMPARISONS OTHER THAN PROFICIENCY TESTING

4.3.1 Applicant and accredited laboratories are encouraged to use the EPTIS database to identify or source available proficiency testing programmes. It is a worldwide database which can be accessed using the following link, www.eptis.org.

4.3.2 The following list identifies types of organizations that can be used to access proficiency testing programmes or interlaboratory comparisons other than proficiency testing.

a) A proficiency testing provider, accredited to *ISO/IEC 17043:2023* by an accreditation body that is a signatory of the ILAC MRA for proficiency testing providers;

b) A proficiency testing provider, accredited to *ISO/IEC 17043:2023* by an accreditation body that is either an applicant or a non-signatory of the ILAC MRA for proficiency testing providers;

c) Participation in an interlaboratory comparison, which is organised for other purposes than determining a laboratory's competence (*ISO/IEC 17043:2023*);

d) Organisation of, or participation in, interlaboratory comparisons organised, in accordance with the relevant requirements of *ISO/IEC 17043:2023*, to determine the performance of accredited laboratories by comparison with results of other laboratories.

It is noted that in case a), the accredited proficiency testing providers have been subject to relevant assessment through the ILAC MRA. In the other cases, there is no formal recognition of competence of the proficiency testing and/or interlaboratory comparison provider via the ILAC MRA.

NOTE 1 **EA-4/21 INF: 2018** – *Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation* can be used to assess the provider in cases c) and d) above.

NOTE 2 TTLABS facilitates the One World Accuracy Medical Proficiency Testing Programme as an accessible programme based on the medical laboratory needs. Medical laboratories are **NOT** required to participate in this programme to be considered for accreditation.

4.4 DOCUMENTED LABORATORY EXTERNAL QUALITY ASSURANCE PLAN

4.4.1 Laboratories shall formulate and document a plan for the level and frequency of participation in external quality assurance programmes. This plan shall be regularly reviewed by management for continued suitability given changes in risks of the laboratory.

4.4.2 In the development of the plan, the laboratory shall assess the availability and appropriateness of the proficiency testing and/or interlaboratory comparison scheme other than proficiency testing.

NOTE 1 A PT scheme 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 laboratory;

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 laboratory needs formalized in its PT participation plan.

NOTE 2 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.

4.4.3 The laboratory shall justify the level and frequency of the participation identified in the plan. This is determined 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 shall be made dependent on the extent to which other measures have been taken.

NOTE 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.

4.4.4 The laboratory shall also consider the level of risk presented by the laboratory based on the sector within which it is operating and the method it is using. This may be determined by considering the following issues, which is not an exhaustive listing.

- Number and frequency of tests, calibrations, sampling or 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.

4.4.5 TTLABS recognizes different types of interlaboratory comparison schemes, which may be available to accredited laboratories including, but not limited to:

a) ILC organised by a sufficient number of laboratories as a one-off or continual exercise;

b) Organisation of small interlaboratory comparisons (among seven or less participating laboratories);

c) Schemes based on parts of the test or calibration undertaken due to economic or practical feasibility; and

d) Any requirements for frequency and type of PT participation from other sources such as legislation and customers.

4.4.6 The laboratory shall identify groups of areas of technical competence, which may contain more than one test or measurement technique, characteristic or product that have been demonstrated to be equivalent and comparable. This defines the level of participation.

4.4.7 The laboratory is required to establish the minimum requirement for frequency of participation based on an assessment of the level of risk for each area of technical competence.

5.0 REFERENCES

5.1 International Vocabulary Of Metrology – Basic And General Concepts And Associated Terms (VIM)

5.2 ISO/IEC 17043:2023 Conformity Assessment – General Requirements for the Competence of Proficiency Testing Providers

5.3 ISO/IEC 17025:2017 General Requirements for the Competence of Testing And Calibration Laboratories

5.4 ISO 15189:2022 Medical Laboratories – Requirements for Quality and Competence

5.5 ILAC-P9:01/2024 ILAC Policy for Proficiency Testing and/or Interlaboratory Comparisons other than Proficiency Testing

5.6 EA-4/18 G: 2021 – Guidance on the level and frequency of proficiency testing participation (Appendix I)

5.7 EA-4/21 INF: 2018 – Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation (Appendix II)

6.0 APPENDICIES

6.1 Appendix I, EA-4/18 G: 2021 – Guidance on the level and frequency of proficiency testing participation

6.2 Appendix II, EA-4/21 INF: 2018 – Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation

APPENDIX I

EA-4/18 G: 2021 – Guidance on the level and frequency of proficiency testing participation

EUROPEAN ACCREDITATION

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Guidance on the level and frequency of proficiency testing participation

PURPOSE

The aim of this paper is to promote harmonization between accreditation bodies on how the level and frequency of participation in PT is evaluated and to assist laboratories in determining their own levels and frequency of participation.

Authorship

This document has been prepared by the EEE-PT Working Group “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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Further information

For further information about this publication, please contact the Secretariat.

Please check our website for up-to-date information http://www.european-accreditation.org

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CONTENTS

1. INTRODUCTION

The standard ISO/IEC 17025:2017 [1] General requirements for the competence of testing and calibration laboratories (7.7.1) establishes that the laboratory shall have a procedure for monitoring the validity of results and that this monitoring shall be planned and reviewed.
In 7.7.2 it is required 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 [2] contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 [2] are considered to be competent.

b) participation in interlaboratory comparisons other than proficiency testing.

In addition, ILAC [3] has established specific policy regarding participation of laboratories in PT activities. This paper, which has been prepared by the joint stakeholder working group, EEE-PT, on proficiency testing in accreditation is the result of extensive discussions and helps the accreditation bodies in their implementation of this policy. This paper provides guidance to accreditation bodies with the aim to promote harmonization between accreditation bodies on how the level and frequency of participation in PT is evaluated and to assist laboratories in determining their own levels and frequency of participation.

For the purpose of this document, “measurement” covers also testing, calibration, analysis, investigation, examination, determination, assay and other concepts commonly used to describe core laboratory work.
Furthermore, the term laboratory used in this document covers all organizations that provide information on items based on experimental observation, including testing, calibration, examination and sampling. Thus, the principles described in the document are applicable to any accredited organization when performing laboratory activities.

Note: This document is also applicable to medical laboratories and when used in such instances reference to ISO/IEC 17025 [1] should be read as ISO 15189 [4].

2. TERMS AND DEFINITIONS

The definitions below which do not have a specific reference, have been written for the purpose of this document in order to provide clarity for its implementation.

Proficiency testing (PT): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043:2010, definition 3.7) [2].

Proficiency testing (PT) scheme: proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection (ISO/IEC 17043:2010, definition 3.11) [2].

Interlaboratory comparison (ILC): organization, 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 17043:2010, definition 3.4) [2].

Measurement process: The process of measuring the characteristic, including any pre-treatment required to present the sample, as received by the laboratory, to the measuring device.

Characteristic: The parameter being measured.

Product: The item to which the measurement process is being applied.

Area of technical competence: Field of expertise defined by a minimum of one measurement process, characteristic and product, which are related
Example: amount of arsenic in soil by ICP-MS.

Level of participation: The number of specific activities that an organisation identifies within its scope of accreditation, and therefore the number of specific proficiency tests that should be considered for participation.

Frequency of participation: The number of proficiency tests per unit of time, in which a laboratory participates for an activity as specified in their scope of accreditation.

Scope of accreditation: specific conformity assessment activities for which accreditation is sought or has been granted (ISO/IEC 17011 [5], 3.6).

Small interlaboratory comparison (small ILC): An interlaboratory comparison organised by, and among seven or less laboratories (EA-4/21 INF:2018 [6])

3. GENERAL ASPECTS

The following aspects should be taken into consideration by accreditation bodies when determining the suitability of a laboratory's "level" and "frequency" of participation in proficiency testing:

(1) The laboratory should define the level and frequency of its participation after careful analysis of its other quality assurance (QA) measures to ensure the validity of the results (especially those that are able to disclose, quantify and follow the development of bias of a stated magnitude). The level and frequency of participation should be made dependent on the extent to which other measures have been taken into account. QA measures can include, but are not limited to:

- Regular use of certified reference materials and/or reference materials.
- Comparison of analysis by independent techniques.
- Participation in ILCs for method development/validation and/or reference material characterisation studies.
- Use of internal quality control (IQC) measures.

- Other inter/intra – laboratory comparisons e.g. analysis on blind samples within the laboratory.
- Robustness of the metrological traceability chain. (Are instruments calibrated under the same conditions as routinely used versus assumptions on e.g. influence factors or secondary parameters)

Note: Other approaches to ensuring the validity of the results can be found in ISO/IEC 17025:2017 (7.7.1) [1] and ISO 15189:2012 (5.6) [4].

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

- Number of measurements undertaken.
- Frequency of tests at a different concentration level.
- Number of different calibration intervals.
- Turnover of technical staff.
- Experience and knowledge of technical staff.
- Source of metrological traceability (information and availability of reference materials, national measurement standards, etc.).
- Known stability/instability of the methodology.
- Complexity and robustness of the methodology.
- Significance and final use of measurement data (e.g. forensic science represents an area requiring a high level of assurance).
- 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 laboratories, and which should be accepted by accreditation bodies as PTs, include:

- ILC organised by a sufficient number of laboratories as a one-off or continual exercise.
- Organisation of, or participation in, an ILC with a small number of participants.

  Note: Organisations that organise a small ILC among themselves should apply the appropriate requirements of ISO/IEC 17043 [2], and EA-4/21 INF [6] 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 must be recognised that there are sectors where participation in PT may be difficult, due to the technical characteristics of the measurement, the lack of PT schemes, the

low number of existing laboratories in the sector, etc. For innovative fields PTs may not yet exist for some fields. PT may only be possible or economically feasible for parts of the measurement undertaken. In these areas the suitability of other QA/IQC measures is paramount.

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

4. LEVEL AND FREQUENCY OF PARTICIPATION

The first step for a laboratory is to consider their scope of accreditation concerning the measurements for which it is accredited.

Ideally, a laboratory would participate in a specific PT for every measurement process it uses and for every characteristic measured in every product. However, it is acknowledged that this is unlikely to be feasible, both logistically and economically. Therefore, accreditation bodies should expect laboratories to identify areas of technical competence comprising sets of measurement processes, characteristics and products on which the outcome of a PT for one of these sets can be directly correlated to the other sets of measurement processes, characteristics and products contained within their accreditation scope.

An area of technical competence, as mentioned above, may contain more than one measurement process, characteristic or product as long as the equivalence between the combined measurement processes, characteristics or products can be justified. 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 measurement process through characteristics to products. This is because it is more likely that there will be several products and/or characteristics associated with one measurement process within a given area of technical competence than vice versa:

(i) With reference to the **measurement process**: It is possible but not common to include different measurement processes in the same area of technical competence.

(ii) With reference to the **characteristic** to be measured 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 measured: It may be possible to include different products in the same area of technical competence provided that the items included are of equivalent nature.

Once the laboratory has defined its areas of technical competence the “level of participation” can be deemed to have been defined. The AB should assess the suitability of the laboratory´s risk based approach for determining its participation frequencies in different technical areas, and how it takes into consideration the extent and character of other quality control initiatives.

Therefore, once the “level” and “frequency” of participation have been established, this will be included in the laboratory’s overall quality control strategy.

It is recommended that the PT participation plan, resulting from the establishment of the various “levels” and “frequencies” of participation, covers, at least, one accreditation cycle (period between full reassessments), and is reviewed with the overall PT strategy by the laboratory for its suitability, usually on an annual basis during the formal management review.

Note: If unsatisfactory results are obtained from the PT participation, this may also influence the ongoing strategy.

5. REFERENCES

1 ISO/IEC 17025:2017: General Requirements for the competence of testing and calibration laboratories.
2 ISO/IEC 17043:2010: Conformity assessment — General requirements for proficiency testing.
3 ILAC-P9 (Current Version): ILAC Policy for Participation in National and International Proficiency Testing Activities.
4 ISO 15189:2012: Medical laboratories. Requirements for quality and competence.
5 ISO/IEC 17011:2017: Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies.
6 EA-4/21: 2018-03: Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation

6. CASE STUDIES

It is for each individual laboratory to consider how many areas of technical competence will adequately cover the scope of their work and thus define their “level” and “frequency” of participation in PT, which should be detailed in their PT strategy. Six studies have been provided to illustrate how a laboratory might review their scope of work and thus derive the number of areas of technical competence. However, these case studies are only examples of how this could be approached and should not be regarded as a benchmark. Specific frequencies are for illustrative purposes only.

Case Study 1 – Environmental Chemistry Testing Laboratory

Accredited measurements performed by the laboratory

- Polychlorinated Biphenyls (PCB) by GC-MS in soils and sewage sludge
- Polyaromatic Hydrocarbons (PAH) by GC-MS in soils and sewage sludge
- Volatile Organic Compounds (VOC) by Purge and Trap GC-MS in waters
- Metals by ICP-MS in soils, sewage sludge and waters
- pH in soils, sewage sludge and waters

Considerations for determinations of areas of technical competence

- For pH the laboratory identifies that it utilises the same ISO method for all three matrices (soils, waters and sewage sludge). This ISO method has been validated against all three matrices and therefore the laboratory identifies this as one area of technical competence.

- For the analysis of metals, the laboratory identifies that it uses the same measurement process (ICP-MS) for all three matrices (soils, waters and sewage sludge). However, the preparation of water samples compared to soils and sewage sludge is significantly different. As such, the laboratory identifies that it cannot declare this as one area of technical competence, but as the methodologies for soils and sewage sludge are demonstrably comparable, they can be. Therefore, the laboratory identifies two more areas of technical competence.

- For PAH and PCB analysis the laboratory identifies that it uses the same measurement process (GC-MS) and the extraction of the matrices (soils and sewage sludge) is identical for both matrices. However, via its initial validation of the methods it is apparent that PCB and PAH are effected in different ways by variations in the methodology and therefore acceptable performance or problematic performance on PCB would not necessarily mean the same for PAH (and vice versa). Therefore, the laboratory identifies two more areas of technical competence.

- For its VOC method, the laboratory only has one matrix (water) to consider. However, the laboratory is aware that the method analyses several different parameters that could potentially react in different ways to problems with the method. Through its method validation data, the laboratory has demonstrated that the differing parameters react in comparable ways to variations in the method. Therefore, the laboratory identifies one more area of technical competence.

Resulting areas of technical competence from this exercise

- Polychlorinated Biphenyls (PCB) by GC-MS in soil and sewage sludge
- Polyaromatic Hydrocarbons (PAH) by GC-MS in soil and sewage sludge
- Volatile Organic Compounds (VOC) by purge and trap GC-MS in water
- Metals by ICP-MS in soil and sewage sludge
- Metals by ICP-MS in water
- pH in soil, sewage sludge and water

Considerations for determining frequency of participation

For the various areas of competence, the laboratory has defined the following frequencies:

- For the analysis of PCB and PAH, the laboratory uses certified reference materials once a year, one at the lower level of the typical concentration range and one at the higher level. It has decided to participate twice a year in PT as it enables the laboratory to cover the rest of the concentration range over a period of three years.

- For VOC analysis, it does not use a certified reference material, and therefore it participates in a PT four times a year even though the PT provider also provides the possibility of participation twice a year. It has selected the higher frequency because the two technicians responsible for this analysis have only just been trained and thus are reasonably inexperienced.

- For measurements made by ICP-MS, the laboratory has four technicians that undertake the analysis, but since there is not enough PT items to do more than one determination, the laboratory participates four times a year, so that each technician can participate once per year. In addition, the level of concentration of the certified reference materials do not correspond to the level of concentrations usually analysed. The level of concentrations proposed by the PT provider cover adequately the levels of concentration analysed by the laboratory, so the emphasis is made on PT participation rather than the use of certified reference materials.

- For the determination of pH, the laboratory participates once a year as it uses a pH meter that it calibrates internally, and the pH measurement is not a critical value.

Summary Table

	Characteristic	**Measurement process**	**Product**	**Frequency**
1	PCB	GC-MS	soil/sewage	1 CRM; 2 PTs
2	PAM	GC-MS	soil/sewage	1 CRM; 2 PTs
3	VOC	GC-MS	water	4 PTs, all technicians
4	Metal	ICP-MS	soil/sewage	4PTs, 1 technician/PTs
5	Metal	ICP-MS	water	4 PTs
6	pH		soil/sewage/water	1 PT

Case Study 2 – Microbiology Testing Laboratory

Accredited measurements performed by the laboratory

- Enumeration of *Escherichia coli* in meat
- Detection of *Salmonella* in meat
- Enumeration of *Escherichia coli* in vegetables
- Detection of *Salmonella* in vegetables
- Enumeration of *Escherichia coli* in dairy products
- Enumeration of *Escherichia coli* in drinking water
- Enumeration of *Escherichia coli* in swimming pool water

Considerations for determining areas of technical competence

- For the enumeration of Escherichia coli, the laboratory identifies that it uses the same method for the analysis of both meat and vegetable samples. This method has been validated for these two sample matrix types and therefore the laboratory identifies this as one area of technical competence. Since this method has not been validated for the analysis of dairy products, the laboratory uses a different method for such sample matrices. Thus, this is identified as an additional area of technical competence.

- The method used by the laboratory for the detection of Salmonella has been validated for both meat and vegetable matrices, and thus the laboratory identifies this as one additional area of technical competence.

- For the enumeration of Escherichia coli in water, although different sampling and pre-treatment techniques are used for the collection of the samples, the method used (which is different to that used for the food products) has been validated for both drinking water and swimming pool water, so this has been identified as one additional area of technical competence.

Resulting areas of technical competence from this exercise

- Enumeration of *Escherichia coli* in meat and vegetables
- Enumeration of *Escherichia coli* in dairy products
- Detection of *Salmonella* in meat and vegetables
- Enumeration of *Escherichia coli* in drinking water and swimming pool water

Considerations for determining frequency of participation

For the various areas of competence, the laboratory has defined the following frequencies:

- The laboratory carries out the analysis of a high volume of meat and vegetable samples every week for both the enumeration of Escherichia coli and the detection of Salmonella. There are no certified reference materials available for use, so the laboratory is very reliant on PT participation to monitor its performance. Therefore, the laboratory decides to participate at the maximum frequency offered by the PT provider which is once a month. Furthermore, since there are four different microbiologists, that undertake the analysis and

there is sufficient test material provided, each microbiologist participates in the PT each month.

- For the enumeration of Escherichia coli in dairy products, the laboratory only receives a small number of samples to test each month. Therefore, it has decided to participate in the PT four times a year. However, again since there are four microbiologists that undertake the analysis, they all participate each quarter.

- A different department than that for food undertakes the enumeration of Escherichia coli in drinking water and swimming pool water. The monthly volume of samples received for testing is not that high and two microbiologists undertake the work. Whilst based on the volume of samples tested it would be sufficient to participate four times a year, there is a high turnover of staff in this team, so the laboratory has selected to participate every month with both microbiologists participating in the PT.

- For the different areas of technical competence, the laboratory has chosen PT programs that cover a high variety of different matrices to ensure that over an accreditation cycle all the parameters and matrices are considered.

Summary Table

	Characterisitic □□- organism)	**Measurement process**	**Product**	**Frequency**	**Comment**
1	Salmonella	Detection	Meat/ vegetables	Once/month every microbiologist	High number of samples
2	E coli	Enumeration	Meat /vegetables	Once/month every microbiologist	High number of samples
3	E coli	Enumeration	Dairy	4 PTs every microbiologist	Low number of samples
4	E coli	Enumeration	Water	Once/month every microbiologist	High turnover of staff

Case Study 3 – Medical Laboratory

Accredited measurements performed by the laboratory

- Screening for drugs of abuse in blood by ELISA (Enzyme-Linked Immunosorbent Assay) and Liquid EIA (Enzyme Immunoassay)
- Screening for drugs of abuse in urine by ELISA and Liquid EIA
- Confirmation of Amphetamine in blood and urine by GC-MS (Gas Chromatography-Mass Spectrometry)
- Confirmation of Amphetamine in urine by GC-MS
- Confirmation of Codeine in blood by GC-MS
- Confirmation of Codeine in urine by GC-MS
- Confirmation of Diazepam in blood by LC-MS/MS (Liquide Chromatography – Mass Spectrometry
- Confirmation of Diazepam in urine by LC-MS/MS
- Confirmation of Cocaine in blood by LC-MS/MS
- Confirmation of Cocaine in urine by LC-MS/MS
- Confirmation of EDDP (2-ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine) in blood by LC-MS/MS
- Confirmation of EDDP in urine by LC-MS/MS
- Confirmation of Buprenorphine in blood by GC-MS/MS
- Confirmation of Buprenorphine in urine by GC-MS/MS
- Confirmation of Tetrahydrocannabinol in blood by GC-MS/MS
- Confirmation of Tetrahydrocannabinol in urine by GC-MS/MS

Considerations for determining of areas of technical competence

- The two methods used for the screening for drugs of abuse are different, however both have been verified for use with both blood and urine samples. Thus, the laboratory identifies these as two areas of technical competence.

- Even though the three techniques used for the confirmation of various drugs of abuse are very different, each has been validated for both blood and urine matrices. Furthermore, each different detection system is considered to belong to a separate group of areas of technical competence. The drugs, although coming from different families of products, are considered as equivalent from a competence point of view. Thus, the laboratory identifies that their confirmation tests consist of three additional areas of technical competence.

Resulting areas of technical competence from this exercise

- Screening for drugs of abuse in blood and urine by ELISA
- Screening for drugs of abuse in blood and urine by Liquid EIA
- Confirmation of Amphetamine and Codeine in blood and urine by GC-MS*
- Confirmation of Diazepam, Cocaine and EDDP in blood and urine by LC-MS/MS*
- Confirmation of Buprenorphine and Tetrahydrocannabinol in blood and urine by GC-MS/MS*

*Note: although the different drugs have been combined into one area of technical competence for each detection system in terms of being equivalent from a competency point

of view, this does not suggest that they are equivalent in terms of method and laboratory performance. Therefore, the laboratory would be expected to undertake such PTs specifically covering all the drugs in their scope on a periodic basis. This would be expected to be clearly detailed in their proficiency testing strategy.

Considerations for determining frequency of participation

For the various areas of competence, the laboratory has defined the following frequencies:

- For the screening of drugs of abuse, the laboratory recognises that whilst their methods are different, they are applicable to both blood and urine. The PT scheme available covers both ELISA and Liquid EIA methods and covers both matrices on a monthly basis. Therefore, the laboratory has decided to participate monthly for both methods but to alternate the matrix being used i.e. participates six times a year for blood and six times a year for urine.

- For the confirmation tests, the volume of samples that are tested are much lower than the screening tests. However, it is recognised that whilst the groups of drugs can form one area of technical competence for a particular technique, it is important to ensure that PT participation does encompass all the drugs over an agreed period. Furthermore, the results of these tests inform critical decisions. Therefore, the laboratory decides to participate on a monthly basis for both blood and urine for each of the techniques, in a PT scheme that provides sufficient coverage of all the drugs requiring confirmation on an annual basis.

Summary Table

	Characteristic	**Product**	**Measurement process**	**Frequency**
1	Drugs	Blood, urine	ELISA (screening)	6 PTs for blood 6 PTs for urine
2	Drugs	Blood, urine	Liquid EIA (screening)	6PTs for blood 6 PTs for urine
3	Amphetamine, Codeine	Blood, urine	GC-MS (Confirmation)	monthly, for each matrix, for each technician
4	Diazepam, Cocain,EDDP	Blood, urine	LC-MS/MS (Confirmation)	monthly, for each matrix, for each technician
5	Buprenorphine, Tetrahydrocannabinole	Blood, urine	GC-MS/MS (Confirmation)	monthly, for each matrix, for each technician

Case Study 4 – Mechanical Testing Laboratory

Accredited measurements performed by the laboratory

- Fracture toughness and fatigue crack growth of metals and metal alloys (ASTM E 399)
- Tensile and compression testing of metals and metal alloys (example: ISO EN 6892-1)
- Tensile and compression testing of plastics (ISO 527-1)
- Hardness test according to Brinell (ISO 6506), Vickers (ISO 6507), and Rockwell (ISO 6508)
- Charpy impact test according to ISO 148-1
- Determination of grain size (ISO 643)
- Optical emission spectrometry (Quantification of chemical elements in steel matrix, in house procedure)

Considerations for determining areas of technical competence

Many accredited laboratories perform these named activities in the field of mechanical testing. ISO, EN or ASTM standards describe the test methods. The standards usually define the required equipment and other test related parameters. The named test activities are performed using the same or different types of equipment requiring a specific calibration status and specific knowledge of the staff performing these tests.

- The same measurement process is used for examining fatigue crack growth and fracture toughness and the method (ASTM E 399 [1]) has been validated for metals and metal alloys. Therefore, the laboratory identifies this as one area of technical competence.

- Tensile testing and compression testing for metals and metal alloys are based on the same measurement process [2]. However, the testing of fatigue crack growth encompasses the measurement capability of tensile/compression testing and so the laboratory has identified no need to undertake additional PTs for metals and alloys. (Note: participation in a PT for tensile and compression testing would not be sufficient to cover the testing of fatigue crack growth).

- For tensile test on plastics, a similar test system can be used, but usually a lower load capacity is necessary. The supplementary equipment is different because of the high ductility of plastics. Additionally, the definitions of the characteristics that are determined are different in ISO 527 [3]. The equipment must be calibrated once a year and the use of reference material is limited to a small number of laboratories. Therefore, the laboratory identifies this as an additional area of technical competence since this uses a different method.

- In the hardness tests according to Brinell (ISO 6506 [4]), Vickers (ISO 6507 [5]), a ball or a pyramid is used to make an indentation in a surface of a steel material. After this step, the diagonals of the indentation are measured and the hardness of the material is calculated. In the related ISO 6506-1 [4] and 6507-1 [5] series, the requirements on the direct calibration status of the equipment (load, indenter, length measurement device) are defined. They must be repeated once a year, and the use of certified reference material

prior to a test is mandatory. Thus, the laboratory identifies an additional area of technical competence for these two methods.

- The Rockwell (ISO 6508-1 [6]) hardness test uses a different measurement procedure compared to Brinell and Vickers. According to ISO 6508 [6] different types of indenters can be used to make an indentation on a metal's surface under pre- defined loading conditions. In this test, the depth of the indentation is measured using the specific test procedure. The ISO standard requires calibration and the use of certified reference material. Therefore, this is identified as an additional area of technical competence by the laboratory.

- The Charpy impact test standard, ISO 148-1 [6], defines the specimen dimensions. The test equipment is calibrated once a year, and the Standard requires additionally specific reference material for indirect calibration of the whole test setup. The impact energy is measured. Thus, another area of technical competence is identified by the laboratory.

- For the determination of grain size (ISO 643 [8]), the surface of a steel is prepared in a specific way, grinding, polishing, etching to mark the grain boundaries of the material. After this preparation step, a microscope with calibrated magnification is used to measure the size of the grains and calculate the relevant parameters according to the standard. The laboratory identified this as another area of technical competence.

- Optical emission spectrometry is used by many laboratories to identify steel alloys. Certified reference materials and secondary in-house standards are used to calibrate the equipment. This is identified by the laboratory as an additional area of technical competence.

Resulting areas of technical competence from this exercise

- Fracture toughness and fatigue crack growth of metals and metal alloys
- Tensile test on plastics
- Hardness test by Brinell or Vickers
- Hardness test by Rockwell
- Charpy impact test
- Determination of grain size
- Optical emission spectrometry

Considerations for determining frequency of participation

For the various areas of competence, the laboratory has defined the following frequencies:

- The laboratory does not have a high throughput of samples for the majority of the tests, with even less samples tested by optical emission spectrometry. The laboratory has experienced technicians who have been undertaking the tests for many years. Given that some customers for this test come from, for example, the nuclear industry, which is a critical area, the laboratory feels that participating in a PT scheme four times a year enables them to guarantee towards their customers the validity of their performance. If the

customers did not come from critical areas, then participation in a PT scheme once or twice a year would be sufficient.

- The laboratory recognises the particular criticality of the fracture toughness and fatigue crack growth about decisions made on health and safety, and so has decided to increase the frequency for these tests to six times a year, otherwise a frequency of once a year could be considered sufficient. It is also important to ensure the comparability in testing of the different staff members performing these tests.

- Given the much lower number of samples for testing by optical emission spectrometry, the laboratory decides it is sufficient to participate twice a year for this area of technical competence.

References

1 ASTM E399-20a: Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness of Metallic Materials

2 EN ISO 6892-1:2019 - Metallic materials. Tensile testing. Method of test at room temperature

3 ISO 527-1:2019: Plastics — Determination of tensile properties – Part 1: General principles

4 ISO 6506 series: Metallic materials — Brinell hardness test

5 ISO 6507 series: Metallic materials — Vickers hardness test

6 ISO 6508 series: Metallic materials — Rockwell hardness test

7 ISO 148-1: 2016: Metallic materials — Charpy pendulum impact test — Part 1: Test method

8 ISO 643: 2019: Steels — Micrographic determination of the apparent grain size

Case Study 5 – Medical Laboratory (Matrix Approach)

Accredited measurements performed by the laboratory

- FSH (Follicle-stimulating Hormone) by Chemiluminescence in blood
- LH (Luteinizing Hormone) by Chemiluminescence in blood
- Folic acid by Chemiluminescence in blood
- Calcium by Electrochemistry in blood and urine
- Potassium by Electrochemistry in blood and urine
- Cryoglobulins by Electrophoresis in blood
- Carbamazepine by Immunoassay in blood
- Ciclosporin by Immunoassay in blood
- Transferrin by Nephelometry in blood and urine
- □2 Macroglobulin by Nephelometry in blood and urine
- ALAT (Alanine Aminotransferase) by UV-Visible spectroscopy in blood
- ASAT (Aspartate Aminotransferase) by UV-Visible spectroscopy in blood
- Magnesium by UV-Visible spectroscopy in blood and urine

Considerations for determining areas of technical competence

In order to determine its areas of technical competence, the laboratory lists all the measurement processes it uses within its scope, all the characteristics, which can be individual characteristics or areas of technical competence of equivalent characteristics.

From the defined measurement processes, characteristics and products, the laboratory, for each individual characteristic, links it to one measurement process, one group of characteristics and one product.

Resulting areas of technical competence from this exercise

- Hormones by Chemiluminescence in blood
- Vitamins by Chemiluminescence in blood
- Electrolytes by Electrochemistry in blood and urine
- Specific proteins by Electrophoresis in blood
- Drugs by Immunoassay in blood
- Specific proteins by Nephelometry in blood and urine
- Electrolytes by UV-Visible spectroscopy in blood and urine
- Enzymes by UV-Visible spectroscopy in blood

The laboratory takes into account the decision threshold (example: for therapeutic decision) because it can be different according to the product. For example, if the blood and urine tests are correlated, they can only be considered as belonging to the same group if, among the test items proposed by the PT, there are concentrations close to each threshold. The test items have to cover measuring ranges of the two products.

Note: Although the different products have been combined into one area of technical competence for each detection system in terms of being equivalent from a competency point of view, this does not suggest that they are equivalent in terms of method and laboratory

performance. Therefore, the laboratory would be expected to undertake such PTs specifically covering all the products in their scope on a periodic basis. This would be expected to be clearly detailed in their proficiency testing strategy.

Considerations for determining frequency of participation

The medical laboratory is regulated by national government legislation in that it needs to participate in PT at least twelve times a year i.e. a monthly participation. Since the PT provider selected offers both blood and urine test materials on a monthly basis, and the sample volume throughput is very high at the laboratory coupled with the criticality of the measurements, the laboratory decides to take test materials for both blood and urine on a monthly basis. Since there is a large team of analysts and a range of different instruments that are used, the laboratory utilises the multi analyst/instrument reporting offered by the PT provider within the limitations of the sample size. Thus, although not all analysts/instruments participate in every round, the laboratory has developed a strategy where every analyst/instrument participates at least four times a year.

Summary table

	Characteristic	**Measurement process**	**Product**	**Frequency**
1	Drugs: Carbamazepine, Ciclosporin	Immunoassay	Blood	Monthly
2	Electrolytes: Calcium, Potassium	Electrochemistry	Blood	Monthly
3	Electrolytes: Calcium, Potassium	Electrochemistry	Urine	Monthly
4	Electrolytes: Magnesium	UV-Vis	Blood	Monthly
5	Electrolytes: Magnesium	UV-Vis	Urine	Monthly
6	Enzymes: ALAT, ASAT	UV-Vis	Blood	Monthly
7	Hormones: FSH, LH	Chemiluminesence	Blood	Monthly
8	Specific proteins: Cryoglobuline	Electrophoresis	Blood	Monthly
9	Specific proteins: Transferrine, □2 Macroglobulin	Nephelometry	Blood	Monthly
10	Specific proteins: Transferrine, □2 Macroglobulin	Nephelometry	Urine	Monthly
11	Vitamins: Folic acid	Chemiluminescence	Blood	Monthly

Case Study 6 – Calibration Laboratory

Accredited calibration activities performed by the laboratory:

- Geometric measurement equipment (from gauge blocks to handheld tools)
- DC and LF electrical measurement equipment (from calibrators to handheld DMMs)
- Temperature (measurement systems and sensors in liquid baths and in air)

Considerations for determining areas of technical competence:

Many accredited calibration laboratories have a scope covering several areas of competence, and unless these share traceability, e.g. through internal calibrations, they should be handled separately with regards to PT/ILC programmes.

In the present example, a relatively small scope is considered.

For a calibration laboratory, regular calibration of reference equipment is essential and a strict requirement to ensure documented traceability. The accredited scope is defined through a specification of a "calibration and measurement capability (CMC)" specifying measurand, measurement range (including any secondary parameters), measurement uncertainty, method (typically locally defined) and type of instruments[1].

It should be noted, that in the field of calibration very few regularly organised PT schemes exist. Most PTs (in the form of ILCs) are organised in a semi-regular fashion by a number of national metrology institutes or laboratory collaborations as a side business, some of which are accredited against ISO/IEC 17043. Because ILCs in calibration most often are based on the circulation of a single or a very limited number of test items, which need to be monitored over the time period of the ILC, only a limited number of participants is possible, reducing further the availability.

Hence, most calibration laboratories must devise more extensive internal quality assurance measures and engage in collaborations with other laboratories to organise e.g. bi- or tri- lateral comparisons. An important aspect is to seek comparisons of measurements using a different traceability route than that used by the laboratory, and to take into consideration the need for adequacy for the best uncertainties and over the widest possible range (including low and high limits, if possible.

When organised PTs do not exist, assessment by the accreditation body will focus on the relevance of the comparison protocol defined by the participants and the laboratory's own analysis of results of comparisons, including criteria and actions taken when results fall outside these criteria.

[1] ISO/IEC 17011:2017, 7.8.3.c

A constructed example of considerations:

Geometry: Metrological traceability is established through reference gauge blocks calibrated at the National Metrology Institute (NMI) which participates in the CIPM MRA. The laboratory maintains two sets which are calibrated in turn every fourth year. Each set is only used for internal calibrations of working sets. Further standards include internal and external diameter (ring gauges), step-gauges, tapers, glass scales, roughness standards and more. They are calibrated by an accredited calibration laboratory.

Because a large number and brands of geometric measurement tools are covered, the areas of technical competence are broken down to five areas:

- Length standards and tolerance tools (gauge blocks, step gauges, tapers, …)
- Manual length measuring devices (calipers, micrometers, etc.)
- Length measuring apparatus (tape measures, laser length indicators, …)
- Surface measurement (roughness, optical flats, …)
- Other geometric equipment (profile projectors, ring gauges, …)

Electricity: Traceability is established via a reference high-end transfer multimeter, which is calibrated twice a year and used for internal calibrations of calibrators and digital multimeters (DMMs).

A set of discrete reference and working resistors are maintained mainly to support temperature.

Because the main tasks handled by the laboratory are DMMs, calibrators and simulators to support temperature measurements, the technical competence is focused on the areas:

- Precision DMMs (6+ digits)
- Resistance measurement

Temperature: Traceability is established by two SPRTs calibrated in turn annually. Two fixed points are maintained at WTP (0,01 °C) and Ga (~ 39 °C). Calibrations are not performed using these, only internal monitoring of two reference SPRTs. Calibrations are performed in liquid baths as comparison to SPRT and temperature sensors can also be calibrated in air using an air bath and comparison with reference thermometer.

- Temperature measured in liquid bath in the range 0 °C to 40 °C
- Calibration of temperature sensors in air

Considerations for determining frequency of participation:

Geometry: The laboratory has set up internal gauge block comparisons and maintains data on measured differences between blocks in the two sets of references. In this manner, an indirect comparison with the NMI is performed every two years, and the possibility of checks exists for secondary measurement equipment.

The laboratory seeks to participate in ILC on geometric measurement tools every second year, rotating the type of equipment among the five main groups, mainly based on the comparisons available. As an alternative, if a suitable ILC is not available, an agreement with a similar laboratory has been established to swap and calibrate internal standards or equipment and compare results.

The group of calibration technicians can compare their competences in the instances when an ILC is available.

Electricity: The laboratory participates in an organised ILC on calibration of multimeters once every 4-5 years, as these are offered from various sources, and otherwise engages with laboratories with a similar scope and level in bi-lateral comparisons every 2-3 years (exchange of test units - e.g. reference multimeter and high end resistors - and subsequent exchange of calibration certificates). Because organised ILC's in the field seek a "low common denominator", e.g. 4 ½ digit DMM, the laboratory must seek other collaborations to tests its better measurement capabilities.

Temperature: The laboratory compares its SPRTs internally after each calibration and compares final calibration results of standard PRTs performed by different technicians. SPRTs are regularly tested in the two fixed points and the results monitored over time.

As an external comparison activity, the laboratory requests a SPRT from another laboratory, determines SPRT parameters (R_0 and W_{Ga}) for the main usage range (0 °C – 40 °C) and compares to the assigned values.

APPENDIX II

EA-4/21 INF: 2018 – Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation

EUROPEAN ACCREDITATION

Publication Reference

EA-4/21 INF: 2018

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).

Category	**:**	Application document with an informative status
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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 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.".

The standard ISO 15189:2012 [2] establishes in sub-clause 5.6.3.1 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 [3] 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 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 ISO/IEC 17020 [4] (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 [5] [6].

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

Planning

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] ISO/IEC 17020: 2012 General criteria for the operation of various types of bodies performing inspection
[5] EA-4/18 INF:2010 Guidance on the level and frequency of proficiency testing participation.
[6] ILAC-P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities.