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Requirements for participation in proficiency testing (PT) and/or interlaboratory comparisons (ILC)

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NOTE *The present document represents the English version of the document under reference at the specified revision. In case of conflict, the Italian version will prevail. To identify the revised parts reference must be made to the Italian version only.*

PREPARATION

The Directors of the departments of certification and inspection, testing laboratories, and calibration laboratories

APPROVAL

The Directive Council

AUTHORIZATION

The General Director

APPLICATION DATE

01-02-2025

Contents

NOTE: This Regulation entirely repeals and replaces the RT-24 “Proficiency Testing” regulations for testing and medical laboratories and the RT-36 “Requirements for the Accreditation of Calibration Laboratories in Measurement Comparisons” regulations for calibration laboratories.

1. Foreword

This document incorporates the provisions outlined in the ILAC P9:01/2024 document "*Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing*" concerning Interlaboratory Comparisons (ILC) and Proficiency Testing (PT). It thereby establishes ACCREDIA's policy for the participation of all Conformity Assessment Bodies (CABs) conducting testing or calibration activities in Proficiency Testing (PT) and Interlaboratory Comparisons (ILC). For medical laboratories, the term "External Quality Assessment (EQA)" is generally used.

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

It is reminded that, in line with the provisions of the UNI CEI EN ISO/IEC 17011 standard, the review of performance results from interlaboratory proficiency tests and other interlaboratory comparisons is regarded as an assessment technique.

2. Scope and field of application

This Regulation applies to all Conformity Assessment Bodies (CABs), both accredited and in the process of accreditation[1], that perform testing[2] or calibration activities within the scope of their accreditation, as required by the relevant accreditation standards. This includes, for example: testing laboratories, calibration laboratories, medical laboratories, inspection bodies, interlaboratory proficiency testing providers, reference material producers and biobanks.

This document therefore outlines the ACCREDIA policy for participation in PT and ILCs other than PT, which accredited CABs and those in the process of accreditation must adhere to in order to demonstrate the validity of their results, as well as for ACCREDIA in evaluating their competence.

Specifically, the main references to the accreditation standard requirements for the aforementioned CABs are outlined below[3]. For specific details, reference should be made to the mentioned standards.

a. **UNI CEI EN ISO/IEC 17025:2018** §7.7.2, prescribes that laboratories monitor their performance by comparing their results with those of other laboratories, through participation in PT and/or ILCs other than PT, when available and appropriate.
b. **UNI EN ISO 15189:2024** §7.3.7.3, prescribes that laboratories monitor their performance by comparing their results with those of other laboratories, through participation in appropriate EQA programmes for examinations and the interpretation of examination results, including POCT examination methods. When EQA programmes are not available or are considered unsuitable, the laboratory must use

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[1] In the process of accreditation" also includes applications for extensions.

[2] For the purposes of this regulation, the term 'tests' is also applicable to 'examinations' for medical laboratories, unless otherwise specified, and to sampling activities, where applicable.

[3] Non-exhaustive list, in relation to any future accreditation schemes.

alternative methods to monitor the performance of the examination method (including ILCs other than PT) and must justify the reasons for the chosen alternative and provide evidence of its effectiveness.

c. **UNI CEI EN ISO/IEC 17020:2012** does not contain specific requirements for PT and/or ILCs other than PT; however, the requirements of UNI CEI EN ISO/IEC 17025 must be considered for testing or calibration activities. Further information on the need to ensure the validity of results in the field of inspection is available in the ILAC G27 document.
d. **UNI CEI EN ISO/IEC 17043:2024** does not contain specific requirements for PT and/or ILCs other than PT; however, the requirements of UNI CEI EN ISO/IEC 17025 and UNI EN ISO 15189 must be met when performing testing or calibration activities.
e. **UNI CEI EN ISO 17034:2017** does not contain specific requirements for PT and/or ILCs other than PT; however, the requirements of UNI CEI EN ISO/IEC 17025 and UNI EN ISO 15189 must be fulfilled when performing testing or calibration activities.
f. **UNI CEI EN ISO 20387:2024** §7.8.2.9 prescribes that approaches be used to provide objective evidence to demonstrate the comparability of the quality of the biological material (the output of processing or testing), when available and appropriate. These approaches include EQA, PT, and ILC.

3. Normative references

This Regulation refers, where applicable, to the following documents:

- UNI CEI EN ISO/IEC 17025:2018 – “General requirements for the competence of testing and calibration laboratories”;
- UNI EN ISO 15189:2024 – “Medical laboratories — Requirements for quality and competence”;
- UNI CEI EN ISO/IEC 17043:2024 – “Conformity assessment — General requirements for the competence of proficiency testing providers”;
- UNI CEI EN ISO/IEC 17020:2012 – “Conformity assessment — Requirements for the operation of various types of bodies performing inspection”;
- UNI CEI EN ISO 17034:2017 - – “General requirements for the competence of reference material producers”;
- UNI CEI EN ISO 20387:2024 – “Biobanking — General requirements for biobanking”;
- UNI ISO 13528:2022 – “Statistical methods for use in proficiency testing by interlaboratory comparison”.
- ILAC-P9:01/2024 “ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing”;
- ILAC-G27:07/2019 “Guidance on measurements performed as part of an inspection process”
- EA-4/18 G:2021 – “Guidance on the level and frequency of proficiency testing participation”;
- EA-4/21 INF:2018 – “Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation” (re-published in 2019);
- ACCREDIA General and Technical Regulations applicable to individual accreditation schemes.

4. Terms and definition

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 (UNI CEI EN ISO/IEC 17043 §3.4).

Proficiency testing (PT): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (UNI CEI EN ISO/IEC 17043 §3.7).

External Quality Assessment (EQA): evaluation through interlaboratory comparisons of participants' performance based on established criteria (UNI EN ISO 15189 §3.10).
For the purposes of this regulation, what is specified for PTs is to be considered applicable to EQAs.

Interlaboratory comparison other than PT (ILC other than PT): interlaboratory comparison with a purpose other than the evaluation of participants' performance against pre-established criteria. Examples are provided in points h), i), and j) of the introduction of UNI CEI EN ISO/IEC 17043 and in point 7.3.7.3.f) of UNI EN ISO 15189.

Small interlaboratory comparison (small ILC, S_ILC): an ILC organized by and among seven or less laboratories (EA-4/21 INF).
Note: In this document, "small ILC" is to be understood as an ILC (as defined in UNI CEI EN ISO/IEC 17043 §3.4) with a maximum limit of participants and organised spontaneously by one or more laboratories.

Proficiency testing item: sample, product, artefact, reference material, piece of equipment, measurement standard, object, image, data set or other information used for proficiency testing (UNI CEI EN ISO/IEC 17043 §3.8).

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 (ref. EA-4/18).

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 (ref. EA-4/18).

Measurement audit: testing or calibration of an item, sample, or known measuring instrument, carried out by the Laboratory exclusively and entirely in the presence of the appointed technical assessor, during an on-site assessment. The calibration results are compared with the results of the same calibration performed by the reference laboratory.

Experimental on-site assessment (applicable exclusively to calibration activities): on-site assessment in which the Laboratory staff performs one or more calibrations, issuing the Calibration Certificate, in the presence of a Technical Assessor, who verifies the proper application of technical procedures, knowledge of the state of the art, and the Laboratory’s ability to apply correct professional practice. If possible, the calibration results are compared with the results of previous calibrations of the same sample/instrument.

The information collected is used by the assessor to issue a report, which contains the outcome of the assessment.

Measurement comparison (applicable exclusively to calibration activities): it refers to one of the following types of comparison: PT, ILC, *S_ILC*, measurement audit, and experimental on-site assessment.

Accreditation scope or Field of application of accreditation[4]: specific conformity assessment activities for which accreditation is sought or has been granted (see ISO/IEC 17011 §3.6).

Visit: For the purposes of this document, it refers, unless otherwise specified, to on-site assessment, remote assessment, or mixed assessment.

Test: For the purposes of this document, the term 'test' also refers to 'sampling', unless otherwise specified and as applicable (ref. ISO/IEC 17025).

Further definitions are provided in the regulations for the accreditation of testing laboratories, calibration laboratories, medical laboratories, inspection bodies, interlaboratory proficiency test providers, reference material producers, and biobanks.

5. Participation criteria for PT and/or ILC other than PT

5.1. General requirements

One of the ways accredited CABs, or those in the process of accreditation (such as laboratories or other accredited CABs carrying out testing or calibration activities), must demonstrate their technical competence and the validity of their results is through comparison with the results of other CABs, when available and suitable.

This paragraph outlines the general requirements applicable to all CABs, while the following paragraphs provide further details and specific requirements for testing and medical laboratories (§5.2), calibration laboratories (§5.3), and other CABs performing testing and/or calibration, with an impact on their accreditation scope, but not included within it (§5.4).

5.1.1. Plan for participation in PT and/or ILCs other than PTP

Accredited CABs and those in the process of accreditation must develop a plan for participation in PT and/or ILCs other than PT, ensuring the representativeness of the testing and calibration activities related to their accreditation scope.

In defining the level and frequency of participation in PT and/or ILCs other than PT, accredited CABs and those in the process of accreditation must:

a. consider their accreditation scope;

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[4] In everyday language, the abbreviation ‘accreditation scope’ can be used.

b. consider that participation in ILCs other than PT should be planned only when PTs are not available or suitable.
c. subject to the previous point, also consider other measures to ensure the validity of results, such as those outlined in §7.7.1 of ISO/IEC 17025 and §7.3.7.3 of ISO 15189.
d. adopt a risk-based approach, considering, for example, the following factors:
    - area of activity;
    - number and frequency of tests/examinations/calibrations/sampling/measurements performed;
    - staff turnover;
    - experience and knowledge of the staff;
    - source of metrological traceability (e.g., availability of reference materials, primary standards, etc.);
    - known stability/instability of the test or testing technique;
    - stability of the analyte and matrix, and the impact of storage and transportation;
    - significance and final use of test/examination/calibration/sampling data (for example, forensic science, food safety, and medical laboratories are areas that require a high level of assurance);
    - level of risk posed by the PT items with biological hazards and the necessary containment precautions;
    - calibration intervals, in relation to the instrument's measurement range;
    - complexity and robustness of the method;
    - issuing of declarations of conformity;
    - risks and opportunities associated with laboratory activities;
    - extension of the validation and/or verification of methods;
    - potential health interest/impact of the activity.
e. consider any mandatory requirements (e.g., laws, regulations, regional provisions), or those arising from other sources (e.g., customers).
f. consider the availability and suitability of the same PT and/or ILCs other than PT (see §5.1.3).

5.1.2. Approved providers of PT and ILCs other than PT

ACCREDIA accepts the following competent and independent organizations, operating in accordance with UNI CEI EN ISO/IEC 17043, as suppliers of PT and/or ILCs other than PT:

- Providers of interlaboratory proficiency testing (PTP) accredited by Accreditation Bodies that are signatories of mutual recognition agreements at the EA or ILAC level for the ISO/IEC 17043 scheme;
- National Metrology Institutes and Designated Institutes that are signatories of the multilateral agreements under the CIPM MRA (e.g., INRIM and ENEA-INMRI in Italy);
- Providers of interlaboratory proficiency testing (PTP) accredited by Accreditation Bodies that have not yet signed mutual recognition agreements at the EA or ILAC level for the ISO/IEC 17043 scheme;
- Providers listed on the EPTIS website at the following address: https://www.eptis.bam.de/en/index.htm.

Provider accreditation, in accordance with the UNI CEI EN ISO/IEC 17043 standard for the specific activity, is sufficient to demonstrate their competence.

However, it is the responsibility of the CAB to assess the competence of its providers, based on the suitability of the requested services, necessary to ensure compliance with the requirements for ensuring the validity of the results.

5.1.3. Availability and suitability of PT and/or ILCs other than PT

As outlined in § 5.1.1, when determining the level and frequency of participation in PT and/or ILCs other than PT, CABs must consider their availability and suitability, as detailed in the following ILAC P9 guidelines.

For practical examples and case studies, please refer to the document EA-4/18.

5.1.3.1. Availability

A PT is considered available if:

- it is offered by a competent PT provider[5] and the required documents are provided in the national language of the participating organization or in a language understood by the CAB;
- it does not require development by the PT provider, and the results can be provided within a short time in accordance with the CAB's participation plan for the PT.

5.1.3.2. Suitability:

A PT and/or an ILC other than PT can be considered technically suitable if the scope of the activity provided is similar to the activity of the accredited CAB. In the case of specific testing or measurement techniques for which PT and/or ILCs other than PT are not available, it may be appropriate to choose a PT and/or ILC other than PT that is similar to the scope of application or covers an important partial aspect of the activity. For operational aspects, refer to §5.1.5.

5.1.4. Evaluation of participation in PT or ILCs other than PT

The participation plan for PT and ILCs other than PT must be verified by ACCREDIA in terms of the representativeness of the requested scope of accreditation and satisfactory participation (understood in terms of acceptability criteria defined by the provider, or by the CAB, if more stringent) before the granting of accreditation, extension, or renewal.

Where satisfactory performance is not attained, ACCREDIA will assess the evidence of the implementation of timely and appropriate corrective actions.

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[5] A PT provider is considered competent if operating in accordance with the UNI CEI EN ISO/IEC 17043 standard.

For the assessments of the different types of CABs, refer to the following paragraphs.

5.1.5. Alternative approaches in case of unavailability of PT and/or ILCs other than PT

In the case of unavailability or unsuitability of PT and/or ILCs other than PT, accredited or in the process of accreditation CABs may use the following alternatives:

- ILC organized by a sufficient number of laboratories as a one-off or continuous exercise;
- Organization of small ILCs (S_ILC).

Note: CABs that organize an ILC among themselves should apply the relevant requirements of the UNI CEI EN ISO/IEC 17043:2024 standard and, in the case of small ILCs, also those of the EA-4/21 INF document.

ACCREDIA evaluates the reasons that led the CAB to use alternative approaches and verifies that such approaches ensure the validity of the results. In this regard, refer to the following §5.1.3 regarding the availability and suitability of PT and ILCs other than PT (see ILAC P9, Appendix B).

5.2. Criteria for the accreditation of testing laboratories (including sampling) and medical laboratories

This paragraph is specific to testing laboratories and medical laboratories, both accredited and in the process of accreditation, to demonstrate their technical competence and compliance with §7.7.2 of the UNI CEI EN ISO/IEC 17025 standard or §7.3.7.3 of the UNI EN ISO 15189 standard.

These aspects are subject to specific evaluation by the ACCREDIA testing laboratories department (DL).

It is clarified that the information provided in this paragraph details and supplements what is stated in §5.1.

For testing and medical laboratories performing internal calibrations, refer to §5.4.

5.2.1. Types of PT, ILCs other than PT, and alternative approaches

Testing or medical laboratories shall, where possible, turn to PT or ILC providers other than PT that operate in accordance with the UNI CEI EN ISO/IEC 17043 standard (for example, by contacting accredited organizers for this activity or those that declare compliance with the aforementioned standard). However, this is not always possible; therefore, the following outlines the different cases that may arise.

The PTs, ILCs other than PT, and alternative approaches accepted by ACCREDIA DL for the accreditation of testing laboratories and medical laboratories are those outlined in §5.1.2 and §5.1.5.

Additionally, measurement audits may be carried out by ACCREDIA technical assessors during assessments, when certified reference materials are available, in order to verify the technical competence of an individual laboratory.

5.2.2. Participation in PT or ILCs other than PT

To demonstrate their technical competence and compliance with the requirements of §7.7.2 of the UNI CEI EN ISO/IEC 17025 standard (for testing and calibration laboratories) and §7.3.7.3 of the UNI EN ISO 15189 standard (for medical laboratories), laboratories must monitor their performance by comparing their results with those of other laboratories.

ACCREDIA must evaluate the planning and outcomes of participation in PT and ILCs other than PT and take them into account both in the initial assessment and for the maintenance of accreditation.

Laboratories must inform ACCREDIA of their participation in interlaboratory comparisons at the time of the application for accreditation, extension, renewal, and whenever there are updates or changes to the scope of accreditation that result in a modification of the planning itself. At this stage, the following must be specified: the matrix, the parameter, the testing method, any groupings by areas of competence (see next §5.2.3), the year of participation, and the identifying details of the PT/ILC other than PT.

As stated in §5.1.1, the frequency of participation in interlaboratory comparisons, as with other activities related to ensuring the validity of results, shall be established by the laboratory based on a risk-based approach and justifying the choices made, unless otherwise required by mandatory requirements.

The planning must cover the entire accreditation cycle and must be reviewed when necessary, based on changes in the scope of accreditation, any unsatisfactory results, any situation deemed relevant for the impact on test results, and, in any case, during the review of the laboratory's management system.

A laboratory should participate in a specific PT (or ILCs other than PT) for each testing technique used and for each type of test (identified by materials/matrices/products and parameters/characteristics/quantities to be determined).

However, this is not always feasible, both from a logistical and economic standpoint. Therefore, it is acceptable for laboratories to classify testing activities based on the testing techniques used and the different types of tests (identified by materials/matrices/products and parameters/characteristics/quantities to be determined and test category) (see next §5.2.3).

Participation cannot be limited to more frequent tests/examinations and must always ensure coverage of all the testing techniques accredited to the laboratory, both quantitative and qualitative, including on-site activities (e.g., sampling) where applicable.

The laboratory must establish and document a minimum level of participation for each grouping by area of competence, taking into account **the minimum participation requirements** outlined below:

- coverage of all groupings of testing techniques and matrices before the granting of accreditation (or extension, or renewal).
- coverage of all groupings of the entire scope of accreditation in terms of material/matrix/product, measured measurand/property, and testing method/technique in each accreditation cycle.

Additionally, with reference to §5.1.1e) (mandatory requirements), it is reminded that national reference laboratories must participate in PTs organized by European reference laboratories.

If it is found that PTs or ILCs other than PT are not available for the relevant area of competence, the laboratory must provide evidence of the investigation conducted and other activities undertaken to ensure the validity of results (e.g., internal quality control, also see UNI CEI EN ISO/IEC 17025 §7.7, and UNI EN ISO 15189 §5.7.3.3).

5.2.3. Groupings by areas of competence (level and frequency of participation)

The laboratory, when defining the participation plan for PT or ILCs other than PT, must first consider its scope of accreditation.

Where it is not possible to participate in a specific PT (or in ILCs other than PT) for each testing technique used and for each type of test (identified by materials/matrices/products and parameters/characteristics/quantities to be determined), the laboratory may group activities within its scope of accreditation according to competence criteria, whereby the result of a PT (or ILC other than PT) can be considered directly applicable to all tests within the same grouping.

Each laboratory, therefore, is responsible for establishing its own classification, which it must document and justify.

With reference to document EA-4/18, groupings for different technical competencies can usually be identified by the need for qualifications, training, and the use of different equipment, knowledge, or experience.

When defining a technical competence area, it can be helpful to consider a gradual approach that goes from the measurement process through parameters/characteristics/quantities to be determined, up to materials/matrices/products. This is because it is more likely that there are multiple products and/or characteristics associated with a measurement process within a given technical competence area, rather than the other way around:

- With reference to the measurement process: it is possible, but not common, to include different measurement processes within the same technical competence area.
- With reference to parameters/characteristics/quantities to be determined: it may be possible to include more than one characteristic within the same technical competence area.
- With reference to materials/matrices/products: it may be possible to include different products within the same technical competence area, provided that the included elements are of an equivalent nature.

Once the laboratory has defined its technical competence areas, the 'level of participation' can be considered established, on which the frequency of participation (according to the criteria outlined in the previous sections) can be determined, and thus the planning of the accreditation cycle can be defined.

For practical examples of grouping and case studies, refer to section 6 of document EA-4/18.

5.2.4. Evaluation of participation in PT or ILCs other than PT

Laboratories must review the results of participation in PT (or ILCs other than PT) at least during the laboratory's management review. Furthermore, they must make available to the ACCREDIA audit team a summary of the results (date of execution, type of test, method applied, evaluation by the organising body) and any actions taken in response to non-conforming results.

The criteria for the acceptability of results are generally those proposed by the organising body; the laboratory may define different criteria, provided they are aligned with the requirements of UNI CEI EN ISO/IEC 17043 and any relevant sector-specific requirements, justifying this choice.

It is also advisable that laboratories and assessors, during the verification process, consider not only the Z-score results (or other criteria used) but also other assessments that may arise from specific statistical analyses of the data resulting from the interlaboratory comparison.

In the case of non-conforming (unsatisfactory) results with respect to the acceptability criteria defined by the PT provider (or ILCs other than PT), or by the laboratory itself, the laboratory must:

- provide evidence of having reviewed the entire analytical process to identify the causes of the non-conformity and of having implemented appropriate corrections and corrective actions.
- in order to verify the effectiveness of the corrective action taken, immediately request the organising body (or another provider) – where technically possible – to re-perform the test related to the non-conformity on a remaining sample from the same PT/ILC other than PT, or to participate in a new PT (or ILC other than PT).
- review its participation planning for PT/ILCs other than PT and assess any need for updates. In this regard, it is reminded that repeating a test on a remaining sample from a PT/ILC other than PT does not constitute the execution of a second PT/ILC other than PT, and therefore the laboratory must take this into account when reviewing its planning.

In the case of participation in PT (or ILCs other than PT) with two consecutive unsatisfactory results, the laboratory must notify ACCREDIA of the self-suspension of the specific test and all those related, in terms of representativeness, to the same grouping, unless a written justification is provided by the CAB.

In the event of failure to communicate by ACCREDIA, either during an audit or following a specific request made by ACCREDIA to the organising body, ACCREDIA reserves the right to suspend the laboratory's accreditation.

5.3. Criteria for the accreditation of calibration laboratories

This paragraph is specific to calibration laboratories, both accredited and in the process of accreditation, to demonstrate their technical competence and compliance with paragraph 7.7.2 of the UNI CEI EN ISO/IEC 17025 standard.

These aspects are subject to specific evaluation by ACCREDIA's Calibration Laboratories (DT).

What is outlined in this paragraph details and complements what is stated in §5.1.

It is specified that, as described in the Technical Regulation RT 25, the technical aspects related to the implementation of internal calibrations must comply with UNI CEI EN ISO/IEC 17025:2018; therefore, the laboratory must assess them within its risk and opportunity analysis, considering, where necessary, participation in PT or ILCs other than PT as a tool for monitoring the validity of the results and ensuring the reliability of internal calibration.

5.3.1. Types of measurement comparisons

Measurement comparisons (as defined in §4) that can be used by the calibration laboratory to meet the requirement of §7.7.2 of UNI CEI EN ISO/IEC 17025:2018 can be identified in some main types:

5.3.1.1. PT and/or ILCs proposed by independent organisers

ACCREDIA DT accepts the following organisations, operating in compliance with UNI CEI EN ISO/IEC 17043, as providers of PT and/or ILCs, according to the following hierarchy:

1. Providers of interlaboratory proficiency testing (PTP) accredited by Accreditation Bodies signatories of mutual recognition agreements at the EA or ILAC level for the ISO/IEC 17043 scheme;
2. National Metrology Institutes and Designated Institutes signatories of the multilateral agreements under the CIPM MRA (for example, INRIM and ENEA-INMRI in Italy);
3. Providers of interlaboratory proficiency testing (PTP) accredited by Accreditation Bodies that have not yet signed mutual recognition agreements at the EA or ILAC level for the ISO/IEC 17043 scheme;
4. Providers listed on the EPTIS website at the address https://www.eptis.bam.de/en/index.htm.

It is the responsibility of the CAB to qualify its providers based on the suitability of the services required to monitor its performance.

5.3.1.2. Small interlaboratory comparisons (S_ILC) organised by laboratories accredited by ACCREDIA

The participation of laboratories belonging to the same organisation and different sites of the same laboratory is allowed.

ACCREDIA DT, applying the EA-4/21 INF document, accepts participation in S_ILC in cases where appropriate PT and/or ILC are not available for specific metrological sectors, subject to the evaluation of the organiser's qualifications, excluding scenario 3 as outlined in this document. Laboratories must nevertheless maintain records of the searches conducted to demonstrate the unavailability of PT and/or ILC providers.

5.3.1.3. Measurement audit

In cases where PT and/or ILC providers are not available and there has been no participation in an S_ILC for specific metrological sectors, ACCREDIA DT accepts the request for a measurement audit. Laboratories must nonetheless retain records of the searches conducted to demonstrate the unavailability of PT and/or ILC.

5.3.1.4. Experimental on-site assessment

In cases where the methods used to perform a calibration are the most relevant aspects for the calibration itself, and in cases where the instruments or measurement systems have a calibration uncertainty primarily due to the instrument or system itself, ACCREDIA DT accepts the request for an experimental on-site assessment.

5.3.2. Participation in measurement comparisons

To demonstrate their technical competence and compliance with §7.7.2 of the UNI CEI EN ISO/IEC 17025 standard, laboratories must participate in the measurement comparisons referred to in §5.3.1 (even through a combination of these) to ensure adequate coverage of the accreditation scope for each accredited metrological sector or for which accreditation is requested.

ACCREDIA DT uses the positive results of participation in measurement comparisons to confirm the Calibration and Measurement Capabilities (CMC) of the laboratories.

Therefore, when providing results, the laboratory must not declare an uncertainty greater than that stated in the accredited and/or requested CMCs, whenever the item being calibrated allows for it.

5.3.2.1. Participation Obligations

Participation in measurement comparisons is required for each metrological sector in the following cases:

- during the first accreditation phase;
- during the accreditation extension phase;
- at least once during the validity period of the accreditation;–
- upon request by ACCREDIA DT during the resumption of activities following self-suspension, as described in the applicable RG-13 Regulation.

5.3.2.2. Planning and Assessment by ACCREDIA DT

The laboratory must develop an appropriate programme for participation in measurement comparisons, review it periodically, update it, and monitor its implementation in order to maintain control over its performance and ensure sufficient coverage of its accreditation scope throughout the entire validity period of the accreditation (accreditation cycle). At this stage, it is recommended that Laboratories conduct a risk analysis to adequately cover the scope of accreditation and to take into account past performance (e.g., previous presence of measurement points with normalized errors in absolute value close to unit, presence of corrective actions, presence of recommendations for improvement and/or comments).

In this programme, requests for measurement audits and experimental on-site assessments must be planned to take place during the renewal assessment. Regular participation in PT and/or ILC cannot be systematically replaced by the execution of S_ILC and/or measurement audits.

It is further recommended that participation in PT and/or ILC programmes be avoided in the fourth year of the accreditation cycle to prevent any potential delays in the delivery of results from impacting the acceptance of the renewal application.

The laboratory must submit a four-year programme of participation in interlaboratory comparisons:

- when submitting the application for accreditation/renewal/extension;
- upon explicit request from ACCREDIA DT.

This programme is considered an integral part of the technical documentation supporting the application for accreditation/renewal/extension and is therefore evaluated by ACCREDIA DT during the document review process.

For the purpose of programme assessment, the Laboratory must provide ACCREDIA DT with the elements listed in the specific sections of the DA-05 document.

In case of a request for a measurement audit and/or experimental on-site assessment upon submission of the accreditation/extension/renewal application, the Laboratory submits to ACCREDIA DT the information and attachments reported in the specific sections of the DA-05.

The assessment of the required documents may be completed:

- with a negative outcome, in which case the process is repeated;
- with a positive outcome, in this case ACCREDIA DT will organize an on-site assessment.

Any modifications to the programme following the ACCREDIA DT assessment, its implementation, and the performance review conducted by the Laboratory will be subject to verification during the surveillance assessment by the assessment team.

5.3.3. Evaluation of PT participation in PT or ILC other than PT

5.3.3.1. Assessment of PT/ILC results by the laboratory

In the event that the performance of PT and/or ILC and/or S_ILC in its programme is unsatisfactory (i.e. if $|En| \geq 1$ at one or more measurement points), the Laboratory must take action in accordance with its non-conformity management procedure and, if necessary and/or applicable, self-suspend part or all of the specific metrological sector.

In preparing the treatment and the subsequent corrective actions, the Laboratory must also assess the impact of the non-conformities on activities already performed. Corrective actions must be implemented within 3 (three) months from the receipt of the results, unless a request for self-suspension is made. The evidence of the treatment and the verification of its effectiveness must be recorded and made available to the assessment team during visits, during the assessments for the cancellation of the self-suspension, or upon request by ACCREDIA DT.

ACCREDIA DT recommends, for the purpose of verifying the effectiveness of the corrective actions taken, participation in the first available PT and/or ILC and/or S_ILC. ACCREDIA DT reserves the right to require the

Laboratory's participation if the evidence provided is not satisfactory and/or if the planned method for verifying effectiveness is deemed inadequate. In such cases, the Sectoral Accreditation Committee for the Calibration Laboratories Department (CSA DT) may decide to maintain the accreditation with a variation of the surveillance plan and, in more serious cases, may implement a sanctioning measure.

5.3.3.2. Assessments of the results by ACCREDIA DT

In the case of participation in PT/ILC and S_ILC, during the document review phase, the technical assessor prepares a Technical Report (TR) in which they provide an evaluation of the laboratory's participation in the measurement comparison. The evaluation criteria include the adequacy of the PT/ILC provider, the instrument/standard used, the measurement range, the analysis of the results, the adequacy of the expanded uncertainties of the reference values compared to those declared by the CAB, and the consistency of the uncertainties declared by the CAB in relation to the requested CMCs.

If all assessments are positive, the outcome of the Technical Report (TR) will also be positive. Conversely, if one or more assessment are negative, the technical assessor will identify one or more non-conformities, and the outcome of the TR will be negative. In this case, the laboratory must analyse the causes and extent of the non-conformities and propose the corresponding corrections and/or corrective actions within 10 working days from the receipt of the notification. Evidence of implementation must be provided prior to the on-site assessment.

In the case of a request for a Measurement Audit, the technical assessor prepares an Experimental Assessment Report containing the calculation of the normalized error based on the comparison between the on-site calibration and the previous calibration results of the same instrument or measurement system carried out by the reference laboratory (UNI CEI EN ISO/IEC 17043, §B6), as well as the evaluation of the calibration certificate issued by the laboratory.

In the case of a request for an Experimental on-site Assessment, the evaluation conducted by the technical assessor is based on verifying the correct execution of the calibration, including the consistent and compliant preparation of the calibration certificate. The outcomes of this assessment are documented in an Experimental Assessment Report, which may also include, if applicable, the normalized error calculated based on comparisons between the on-site calibration and previous calibration results of the same instrument or measurement system (UNI CEI EN ISO/IEC 17043, §B6).

The Experimental Assessment Report will be negative if the normalized error |En| is greater than or equal to 1 at one or more measurement points, or if the calibration certificate is non-compliant. In such cases, the technical assessor will issue one or more non-conformities. The laboratory must then analyse the causes and extent of the non-conformities and propose corrections and/or corrective actions within 10 working days from the receipt of the notification. Evidence of implementation must be provided within 3 (three) months.

In case of:

- Participation in PT/ILC
- Participation in S_ILC

- Measurement Audit

During the document review phase, the technical assessor reports the outcomes of the laboratory's participation in PT/ILC within a Technical Report (TR). The aspects to be evaluated include, for example: adequacy of the PT/ILC provider, assessment of the results, adequacy of the extended uncertainties, and performance.

Performance is considered satisfactory if, when En can be calculated, the results show |En| < 1 for all measurement points; appropriate and effective corrective actions must be taken in the case of |En| ≥ 1.

In the case of a negative outcome, the technical assessor issues one or more non-conformities. The laboratory must analyse the causes and extent of the non-conformities and propose corrective actions (corrections and/or corrective actions) within 10 working days from the receipt of the notification. Evidence of implementation must be provided before the on-site assessment.

In the case of an experimental on-site assessment without a comparison, a satisfactory performance is considered to be the correct execution of the calibration, including the consistent and compliant preparation of the calibration certificate.

Following the execution of the experimental on-site assessment the technical assessor assigned by ACCREDIA DT prepares an Experimental Assessment Report containing, when applicable, the normalized error calculated based on comparisons between the on-site calibration and previous calibration results of the same instrument or measurement system (UNI CEI EN ISO/IEC 17043, §B6).

Following the execution of the measurement audit, the technical assessor assigned by ACCREDIA DT prepares an Experimental Assessment Report containing the normalized error calculated based on comparisons between the on-site calibration and the previous calibration results of the same instrument or measurement system carried out by the reference laboratory (UNI CEI EN ISO/IEC 17043, §B6).

In the case of a negative outcome, the technical assessor issues one or more non-conformities. The laboratory must analyse the causes and extent of the non-conformities and propose corrective actions (corrections and/or corrective actions) within 10 working days from the receipt of the notification. Evidence of implementation must be provided within 3 (three) months.

5.4. CRITERIA FOR THE ACCREDITATION OF CABs CARRYING OUT TESTING OR CALIBRATION ACTIVITIES OUTSIDE THEIR SCOPE OF ACCREDITATION

This section applies to CABs that carry out testing or calibration activities that impact their scope of accreditation, but are not included within it.

These aspects are subject to evaluation by the various departments of ACCREDIA that manage the specific accreditation schemes.

In defining the level and frequency of participation in PT, in accordance with what is stated in §5.1, the first step for CABs is to consider the impact of testing/calibration/sampling on activities within their scope of accreditation and provide evidence of the assessments carried out.

5.4.1. In the case of tests

If a CAB performs tests that impact its scope of accreditation but are not included within it, the CAB should participate in a specific PT (or ILCs other than PT) for each testing technique used and for each type of test (identified by materials/matrices/products and parameters/characteristics/quantities to be determined).

However, this is not always feasible, both from a logistical and economic standpoint. Therefore, it is acceptable for CABs to classify testing activities based on the testing techniques used and the different types of tests (identified by materials/matrices/products and parameters/characteristics/quantities to be determined).

The CAB must establish and document a minimum level of participation for each area of competence, determining a frequency based on the risk level (see also §5.1) and justifying the choices made.

5.4.2. In the case of calibrations

If a CAB performs calibrations that impact its scope of accreditation but are not included within it, the CAB should participate in a specific PT (or ILCs other than PT) for each metrological area of competence.

However, this is not always feasible, both from a logistical and economic standpoint. Therefore, it is acceptable for CABs to classify calibration activities based on metrological area, calibration method, and metrological sectors, planning participation according to criteria of technical competence representativeness.

The CAB must establish and document a minimum level of participation for each area of competence, determining a frequency based on the risk level (see also §5.1) and justifying the choices made.

5.4.3. Evaluation of participation in PT or ILCs other than PT

When a CAB obtains unsatisfactory results from participation in PT, ILC, or S_ILC, it must promptly implement appropriate corrections and corrective actions, which will be subject to evaluation by ACCREDIA.

For the assessment of results, in the case of testing or calibration, refer to §5.2.4 and §5.3.3 respectively.

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