

**TITLE REQUIREMENTS FOR THE ACCREDITATION OF
CALIBRATION LABORATORIES RELATED TO PT/ILC**

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1. INTRODUCTION

With reference to the UNI CEI EN ISO/IEC 17025: 2018, paragraph 7.7.2, whenever possible and appropriate, the Laboratory must monitor its performance by comparing it with the results of other Laboratories.

ACCREDIA DT therefore considers it necessary to participate in Measurement Comparisons, in order to demonstrate competence, in relation to each metrological sector, accredited or in accreditation, and the assurance of the validity of the results.

2. SCOPE AND FIELD OF APPLICATION

This Regulation identifies the different types of Measurement Comparisons and describes how the results are managed and used by ACCREDIA DT for the purpose of assessing the technical skills of the Calibration Laboratories (hereafter Laboratories) accredited and in the process of being accredited.

3. NORMATIVE REFERENCES

The present Regulation refers to, when applicable, the following normative documents:

- UNI CEI EN ISO/IEC 17025:2018 - "General requirements for the competence of test and Calibration Laboratories";
- UNI CEI EN ISO/IEC 17043:2010 - "Conformity assessment - General requirements for proficiency testing";
- ILAC-P9:06/2014 - "ILAC Policy for Participation in Proficiency Testing Activities";
- EA-4/21 INF:2018 - "Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation";
- ISO 13528:2015 - "Statistical methods for use in proficiency testing by interlaboratory comparisons".

4. TERMS AND DEFINITIONS

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).

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

Small interlaboratory comparison (small ILC, S_ILC): an ILC organized by and among seven or less laboratories (EA-4/21 INF: 2018).

Note: In this document the small ILC is to be understood as ILC (defined in UNI CEI EN ISO/IEC 17043 §3.4) but having a maximum limit of participants and spontaneously organized by one or more Laboratories.

Measurement audits: calibration of a known measurement standard or measurement instrument by a Laboratory exclusively and entirely in the presence of the technical Assessor during the on-site assessment.

Experimental on-site assessment: an on-site assessment in which Laboratory personnel are asked to perform one or more calibrations in the presence of a Technical Assessor who verifies the correct application of technical procedures, knowledge of the state of the art and the Laboratory's ability to apply good professional practice. If possible, calibration results are compared with the results of previous calibrations of the same sample/instrument.

Measurement comparison: one of the following comparison types is meant: PT, ILC, S_ILC, measurement audits and experimental on-site assessment.

Further definitions are contained in Regulation RG-13 'REGULATION FOR THE ACCREDITATION OF CALIBRATION LABORATORIES' and RT-25 'REQUIREMENTS FOR THE ACCREDITATION OF CALIBRATION LABORATORIES'.

For the purposes of this document, visit means, unless otherwise specified, on-site assessment, remote assessment or mixed assessment.

5. TYPES OF MEASUREMENT COMPARISONS

Measurement comparisons can be identified in some main types:

5.1. PT AND/OR ILC PROPOSED BY INDEPENDENT ORGANIZERS

ACCREDIA DT accepts the following organisations operating in accordance with UNI CEI EN ISO/IEC 17043 as PT and/or ILC providers.

- Proficiency Testing Providers (PTP) accredited by ABs signatory to the EA or ILAC agreements of mutual recognition for calibration and testing scopes;
- National Metrological Institutes and Designated Institutes signatory of CIPM MRA multilateral agreements in (for example INRIM and ENEA-INMRI in Italy).

ACCREDIA DT also accepts as PT and/or ILC providers, but following qualification by the Laboratory, organisations that are present:

- On the EPTIS site at the address <https://www.eptis.bam.de/en/index.htm>

5.2. SMALL INTERLABORATORY COMPARISON (S_ILC) ORGANIZED BY LAT ACCREDITED LABORATORIES

The participation of Laboratories belonging to the same organisation and different locations of the same Laboratory is allowed.

ACCREDIA DT, applying document EA-4/21 INF accepts participation in S_ILCs in the case where no PT and/or ILC providers are available for certain metrological sectors, subject to assessment of the organiser's qualification, except for scenario 3 in that document. Laboratories must in any case keep records of research done to prove the unavailability of PT and/or ILC providers.

5.3. MEASUREMENT AUDIT

In cases where no PT and/or ILC providers are available and no S_ILC for certain metrological sectors has been participated in, Laboratories must still maintain records of research done to prove the unavailability of PT and/or ILC.

Under these conditions, ACCREDIA DT accepts the request for a measurement audit.

5.4. EXPERIMENTAL ON-SITE ASSESSMENT

In cases where the way in which a calibration is carried out is the most important aspect of the calibration itself, and in cases where measuring instruments or systems have a calibration uncertainty essentially due to the instrument or system itself (e.g., bench-top instrumentation), ACCREDIA DT accepts the request for an experimental on-site assessment.

6. PARTICIPATION IN MEASUREMENT COMPARISONS

In order to demonstrate its technical competence and compliance with paragraph 7.7.2 of the UNI CEI EN ISO/IEC 17025: 2018 standard, Laboratories must participate in the measurement comparisons referred to in paragraph 5 of this document with regard to each metrological sector, accredited or in accreditation.

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

Therefore, the Laboratory in providing results, whenever the calibration object allows it, must not declare an uncertainty greater than the accredited and/or required CMCs.

Participation in measurement comparisons is necessary for each metrological sector, according to the following periodicity:

- at first accreditation and at extension;
- at least once during the period of validity of the accreditation; specifically for Laboratories it is required, where appropriate, that the measuring ranges are fully covered by participation in measurement comparisons
- at the request of ACCREDIA DT when resuming activities since self-suspension, as described in Regulation RG-13 in force.

Performance is considered satisfactory if, where E_n can be calculated, the results show $|E_n| \leq 1$ for all measurement points and/or appropriate and effective corrective actions for those with $|E_n| > 1$.

In the case of experimental on-site assessments without a comparison, the correct implementation of the calibration is considered satisfactory, including the consistent and compliant drafting of the calibration certificate.

In case of presentation of the results of participation in an S_ILC, assessment **for all participants (including the organizers)** will take place in the same way as for the assessment

of participation in a PT/ILC. **The organizer/s of the S_ILC** will be assessed BY ACCREDIA DT on the basis of the relevant requirements of ISO 17043, defined in §6 of document EA-4/21.

In case of a request for measurement audit and/or on-site assessment (sections 5.3 e 5.4) when submitting the application for accreditation/extension/renewal, the Laboratory shall submit for assessment by ACCREDIA DT, the elements and annexes listed in the appropriate sections of the DA-05.

The assessment of the required elements can end:

- with negative outcome, in which case the process is repeated;
- with a positive outcome, in which case ACCREDIA DT organises on-site assessment, in any case subject to receipt and positive assessment of the Calibration Certificate of the instrument/sample, where applicable.

After carrying out the on-site assessment, the Technical Assessor appointed by ACCREDIA DT, draws up an Experimental Assessment Report containing, when applicable, the normalised error calculated on the basis of comparisons of the calibration performed on site with the results of previous calibrations of the same instrument or measuring system (UNI CEI EN ISO/IEC 17043, §B3).

The Laboratory must also prepare a suitable programme of participation in measurement comparisons, review it periodically, update it and monitor its implementation in order to demonstrate the coverage of its scope of accreditation during the whole period of validity of the accreditation (accreditation cycle). At this stage, a risk analysis is recommended to the Laboratories to adequately cover the scope of accreditation and to take into account previous performance (e.g., previous presence of measurement points with normalised errors in absolute value close to unity, presence of Corrective Actions, presence of recommendations for improvement and/or Comments).

In such a programme, requests for measurement audits and experimental on-site assessments must be scheduled to take place during the renewal assessment. Regular participation in PTs and/or ILCs cannot be systematically replaced by the performance of S_ILCs and/or measurement audits.

It is also recommended in the planning to avoid participation in PTP and/or ILC in the fourth year to prevent any delays in the delivery of results from affecting the acceptance of the renewal application.

The Laboratory must send the four-year participation programme to comparisons:

- during the phase of application for accreditation/renewal/extension;
- upon specific request by ACCREDIA DT.

The programme is considered an integral part of the technical documentation annexed to the application for accreditation/renewal/ extension and it is therefore evaluated by ACCREDIA DT as an additional part of the document review.

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

Any changes to the programme following ACCREDIA DT's assessment, its implementation and the performance review carried out by the laboratory will be verified during the surveillance assessment by the assessment team.

7. PT, ILC AND S_ILC INDICATING AN UNSATISFACTORY PERFORMANCE

In the event that the PT and/or ILC and/or S_ILC performance of its programme is not satisfactory (i.e., if $|E_n| >$ at one or more measurement points), the Laboratory shall act in accordance with its non-Conformity management procedure and, if necessary and/or applicable, self-suspend part or all of the specific metrology sector

In the preparation of the treatment and consequent Corrective Actions, the Laboratory must also evaluate the impact of the non-Conformities on the activities already performed. Corrective Actions must be implemented within **3 (three) months** from receipt of results unless self-suspension is requested. Evidence of the treatment and verification of effectiveness must be recorded and made available to the assessment team at the time of assessment visits, self-suspension cancellation assessments or at the request of ACCREDIA DT.

ACCREDIA DT recommends as verification of effectiveness of corrective actions, the participation in the first available PT and/or ILC and/or S_ILC. ACCREDIA DT and reserves the right to impose such participation on the Laboratory in the event that the evidence provided is not satisfactory and/or the planned mode of effectiveness verification is not considered adequate. In such a case, the ACCREDIA Sectorial Accreditation Committee for the Calibration Laboratories Department (CSA DT) will decide for the maintenance with a possible proposal to modify the periodicity of surveillance and, in the most serious cases, a sanctioning measure.