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Testing Laboratories Department

Requirements for the accreditation of Proficiency Testing Providers - UNI CEI EN ISO/IEC 17043:2024

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TITLE **Requirements for the accreditation of Proficiency Testing Providers - UNI CEI EN ISO/IEC 17043:2024**

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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 Director of the Department of Testing Labs

APPROVAL
The Directive Council

AUTHORIZATION
The President

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Contents

0. Introduction

The present document defines the general criteria for the accreditation of Proficiency Testing Providers (PTPs) by the ACCREDIA Department of Testing Laboratories (ACCREDIA is the Italian Accreditation Body).

The application of such criteria is intended to foster and maintain the trust of clients in the proficiency testing activities of accredited PTPs, as well to increase trust in the impartiality and integrity of related technical and commercial operations. ACCREDIA's accreditation is granted to PTPs which are in conformity with the requirements of UNI CEI EN ISO/IEC 17043 and with the present document and the other prescriptive ACCREDIA, EA, ILAC documents.

The accreditation demonstrates the PTP's technical competence to perform the activities specified in the scope of accreditation.

1. Scope and field of application

1.1. The present document makes reference to UNI CEI ISO/IEC 17043 "*Conformity assessment – general requirements for proficiency testing*" requirements. The numbering of the paragraphs is the same as the numbering of UNI CEI EN ISO/IEC 17043.

The standard also includes two annexes (Annex A and Annex B), which, although informational rather than prescriptive in nature, provide useful guidance for the application of the standard itself.

Additional specific requirements for certain sectors may be defined by mandatory regulations or at international or national levels (EA, ILAC, ISO, EN, UNI, CEI, etc.)

1.2 The present document is applicable to all PTPs, independent PTPs from an organizational and commercial point of view as well as those which belong to a larger organization (such as manufacturing companies, public or private organizations, research centres etc.).

1.3 In order to obtain and maintain accreditation, the PTP shall demonstrate conformity with all the requirements of the standard (except for those which are declared to be inapplicable, with justifiable motivation) for all testing activities defined in the scope of application of the accreditation.

1.4. The PTP is required to comply with this document, the ACCREDIA RG-09 document, and other applicable documents (e.g., RG-14, RT-26).

2. Standards and reference documents

The complete list of reference documents (LS-04) can be consulted on the ACCREDIA website www.accredia.it.

For certain technical sectors, there are specific documents available for the application of the UNI CEI EN ISO/IEC 17043 standard. These documents, unless explicitly stated as mandatory, serve as guidelines and do not constitute additional requirements but support the consistent application of the existing requirements.

However, if the PTP chooses not to follow the guidance provided, it must demonstrate the validity and adequacy of its operations for the intended purpose.

With reference to §2 of UNI CEI EN ISO/IEC 17043:2024, it is highlighted that the standards ISO/IEC 17025 (ISO 15189 for medical laboratories) and ISO 17034, where referenced, constitute prescriptive requirements (e.g., §6.1.2, §6.1.3, and §7.2.1.1). Where metrological traceability is required, the requirements of ILAC P10 apply.

It is the responsibility of the PTP to ensure the validity of the applicable documents.

3. Terms and definition

The definitions and acronyms from ISO/IEC 17043, the reference standards (UNI EN ISO 9000, UNI CEI EN ISO/IEC 17000, UNI CEI 70099, UNI CEI EN 45020), Regulation (EC) No. 765/2008, and the applicable ACCREDIA regulations (e.g., RG-09, RG-14, RT-26) apply.

4. General requirements

4.1 Impartiality

The requirement of the standard applies.

When interlaboratory proficiency testing is provided by a PTP that is also a laboratory, and there is a single responsible person for both the PTP and the laboratory and/or the same personnel in charge of the management system, the responsibilities of the PTP must be clearly defined and differentiated from those of the laboratory, in order to ensure impartiality and the absence of conflicts of interest. This is particularly important when the laboratory also participates in the proficiency testing organized by the PTP.

It is reminded that, in the application of the requirements, consideration should be given to what is stated in the note to §8.5.2 of the standard.

4.2 Confidentiality

The requirement of the standard applies.

When the PTP assigns a unique code to participants to ensure their anonymity, it is recommended that this code be differentiated for each round, or according to a criterion defined by the PTP, in order to maintain anonymity over time.

With reference to the requirement of §4.2.2, it is reminded that some PTPs must transmit the results to the competent authorities for their evaluations.

5. Structure requirements

5.1 The requirement of the standard applies.

5.2 The requirement of the standard applies.

5.3 The requirement of the standard applies.

Accreditation is granted to a PTP only for the schemes listed in the scope of accreditation attached to the certificate and for which ACCREDIA verifies its competence.

5.4 The requirement of the standard applies.

5.5 The requirement of the standard applies.

The PTP must have an organizational chart managed by the management system that clearly reflects its structure and the relationships with any other functions that influence the PTP's operations.

When the PTP is part of a larger organization (e.g., a company that carries out activities other than PT), there must also be a general organizational chart that shows the position of the PTP within the organization.

In complex organizations, certain activities (such as the purchase of products and/or services or personnel selection) may be centralized or managed by the parent company or by other functions located either outside or within the laboratory (e.g., personnel recruitment company/office). In such cases, the PTP must communicate the applicable requirements (e.g., §6.2, §6.4, etc.) to the relevant function, coordinating with it to ensure compliance with the applicable requirements.

If the organization includes a laboratory that performs activities supporting the PT's operations (e.g., preparation, characterization of proficiency testing items, and/or testing for homogeneity and stability assessment), the PTP must specify in its management system the responsibilities and whether or not the laboratory is dependent on the PTP itself (e.g., the positioning of the laboratory and the PTP within the legal identity and their interrelationships).

Furthermore, the PTP must have documents that describe the assigned tasks, authorizations, qualifications, experience, training, and instruction related to the roles and responsibilities of all personnel who manage, perform, or verify work that impacts the results of the PTP's activities. These documents must be made available to the personnel so that they are aware of the extent and limits of their responsibilities.

5.6 The requirement of the standard applies.

The PTP must ensure that the personnel responsible for implementing and maintaining the management system are able to oversee it adequately in terms of logistics and time, in order to ensure that it is implemented and followed at all times.

5.7 The requirement of the standard applies.

The PTP must define the methods and responsibilities for managing change (e.g., in a document) to maintain the integrity of the management system.

6. Resource requirements

6.1 General requirements

6.1.1. The requirement of the standard applies.

6.1.2. The requirement of the standard applies.

If a PTP also has an internal testing laboratory that performs testing or measurement activities for interlaboratory proficiency testing under the responsibility of the PTP itself (e.g., testing for item characterization, homogeneity and/or stability assessment, or assigned value determination), the laboratory must operate in accordance with the relevant requirements of the ISO/IEC 17025 standard (or ISO 15189 for medical laboratories).

The laboratory's accreditation according to the ISO/IEC 17025 standard (or ISO 15189 for medical laboratories) for specific tests is sufficient to demonstrate its conformity. Otherwise, the relevant requirements are verified by ACCREDIA during assessments visits (e.g., technical competence of personnel, measurement of properties to be determined, validation of methods used in the interlaboratory proficiency testing scheme, management of equipment, traceability of measurements, etc.).

Compliance with the ISO/IEC 17025 - ISO 15189 standard for tests performed by the PTP's internal laboratory does not imply its accreditation.

6.1.3. The requirement of the standard applies.

In the case outlined by requirement 6.1.3, when producing proficiency testing items, the PTP must operate in accordance with ISO 17034 for the applicable requirements.

Accreditation according to ISO 17034 for the specific material is sufficient to demonstrate its conformity. Otherwise, the relevant requirements are verified by ACCREDIA during assessments (e.g., preparation of mixtures, handling, storage, etc.).

Compliance with the ISO 17034 standard for activities performed by the PTP does not imply its accreditation.

6.2 Personnel

6.2.1. The requirement of the standard applies.

6.2.2. The requirement of the standard applies.

Refer to §5.5 of this document.

6.2.3. The requirement of the standard applies.

In defining the competencies of personnel, the PTP must also take into account the specific characteristics of the sector of the organized proficiency testing and any relevant mandatory requirements associated with the proposed schemes (e.g., EU regulations on maximum limits for food contaminants).

6.2.4. The requirement of the standard applies.

6.2.5. The requirement of the standard applies.

Records shall be kept with regard to personnel (both internal and external), giving evidence of competence for the performance of assigned tasks (for example, a list of activities with the individuals authorized to carry them out, certificates of participation in courses, training-education records, details of the assessment methods used, etc.).

The PTP shall define the criteria and frequency of the assessments for the maintenance of the qualifications of personnel.

Where an advisory group is used, the PTP must maintain a register of the group members, appointment letters, and evidence of their competence (e.g., curricula). Additionally, a record of the group's activities and meetings must be kept, including agendas, meeting minutes, and a list of participants.

6.2.6. The requirement of the standard applies.

An example for recording authorisations could be a summary table, detailing the personnel authorised to perform specific activities, accompanied by documented acknowledgment from the personnel concerned.

6.2.7. The requirement of the standard applies.

6.3. Facilities and environmental conditions

The requirement of the standard applies.

6.4. Externally provided products and services

6.4.1. The requirement of the standard applies.

6.4.2. The requirement of the standard applies.

6.4.3. The requirement of the standard applies.

6.4.4. The requirement of the standard applies.

If the PTP uses external providers for certain activities, it must ensure the provider's competence for the specific activities.

Where testing/calibration activities are outsourced (e.g., tests for the characterisation of items, for the assessment of homogeneity and/or stability, or for the determination of the assigned value), the provider must operate in compliance with the relevant requirements of the ISO/IEC 17025 standard (or ISO 15189 for medical laboratories).

Where material preparation activities are outsourced, the provider must operate in compliance with the relevant requirements of the ISO 17034 standard.

The provider's accreditation for the specific activity is sufficient to demonstrate their competence.

The evidence of the PTP's evaluation of the provider is assessed by ACCREDIA, which may also arrange to accompany the PTP during audits at the provider's premises.

It is recommended to include in the documentation related to the provision of products and services any materials/products that have an expiration date or require specific storage conditions (e.g., low-temperature storage, storage in the dark, etc.).

6.4.5. The requirement of the standard applies.

Where testing activities are outsourced, it is recommended to define requirements for the repeatability value of the external laboratory to ensure compliance with the conditions specified in ISO 13528 for the assessment of sufficient homogeneity and stability.

6.4.6. The requirement of the standard applies.

7. Process requirements

7.1 Establishing, contracting and communicating the PT scheme objectives

7.1.1. Review of requests, tenders and contracts

The requirement of the standard applies.

The PTP must inform the client about the meaning of accreditation and the accreditation of the activities covered by the tender/contract.

All activities covered by accreditation must be contractually managed as accredited (see §7.4.3), unless explicitly requested otherwise by the client (not applicable in cases where accreditation is mandatory). In such cases, the client's request must be clearly stated in the contractual agreements (ref. EA 3/01 and RG-09).

It is reminded that, according to §4.2 of ISO/IEC 17043, confidentiality commitments must be included in the contractual agreements.

7.1.2. PT scheme communication

The requirement of the standard applies.

With reference to the communication of the criteria for determining the assigned value and performance evaluation, and in accordance with §7.2.2.3 of the reference standard, it is recommended to consider, where required by the statistical design, cases involving a small number of participants or few results returned. In

such cases, preliminary information should be provided regarding the minimum number of results required for assessment purposes.

It is reminded that, in the case of sanctions or self-suspension measures, the PTP is required to inform the involved clients (see RG-14).

7.2 Design and planning of a PT scheme

7.2.1 General Requirements

The requirement of the standard applies.

It is reminded that 'significant changes' must be managed within the scope of extensions or the application of the flexible accreditation scope, where granted.

It is also reminded that the method of assigning the assigned value is a characteristic of the scheme, and any changes cannot fall within the flexible scope; they can only be managed through an extension.

Regarding preliminary reports, please refer to §7.4.3.

7.2.2 Statistical Design

The requirement of the standard applies.

Regarding the minimum number of participants, it is recommended to take into account the provisions of the applicable regulations (e.g., ISO 13528).

7.2.3 Determination of the assigned value

The requirement of the standard applies.

It is reminded that participants must not be informed of the assigned value until the report is issued by the PTP.

7.3 Production and distribution of PT items

7.3.1 Production of PT items

The requirement of the standard applies.

7.3.2 Homogeneity and stability assessment of PT items

The requirement of the standard applies.

With reference to requirement 7.3.2.6 of the standard, it is reminded of the provisions of document ILAC P10 §2, note 5, regarding items from previous rounds.

7.3.3 Handling and storage of PT items

The requirement of the standard applies.

7.3.4 Packaging, labelling and distribution of PT items

The requirement of the standard applies.

7.3.5 Instructions for participants

7.3.5.1. The requirement of the standard applies.

7.3.5.2. The requirement of the standard applies.

In the case of PTs for residue/trace determinations, where the pretreatment procedure (e.g., concentration/ purification/extraction) may affect the retrieval, the instructions to participants must specify whether the retrieval should be used in the calculations to provide the result.

It is recommended to include in the instructions to participants guidance for any potential reporting, such as the integrity of the received sample.

7.4 Evaluation and reporting of PT scheme results

7.4.1 Data analysis

The requirement of the standard applies.

7.4.2 Evaluation of performance

The requirement of the standard applies.

7.4.3 PT reports

7.4.3.1. The requirement of the standard applies.

In the case of reports issued in languages other than Italian or English, the PTP is required to issue a bilingual report (Italian-foreign language or English-foreign language).

In document management, the PTP must ensure the handling of report attachments by establishing rules and procedures for their issuance. It must also be ensured that the attachments are referenced in the report that generated them, and vice versa.

Where the report includes attachments, the presence of the ACCREDIA Mark or references to accreditation[1] on the report does not require that the mark or accreditation reference also appear on all attachments.

In particular, the PTP must assess when the presence of the mark on an attachment to a report (also bearing the mark) is compatible with the content of the attachment itself, in relation to the provisions of Regulation RG-09. In this case, the relevant requirements for reports must be adhered to (for example, distinguishing between accredited and non-accredited activities, etc.).

The presence or, conversely, the absence of the mark on the attachments to reports must follow criteria consistently applied by the PTP.

It is also specified that schemes can only be listed as accredited on the reports if they were accredited at the time of their initiation, not at the time of the report's issuance.

For accredited activities, the PTP must issue reports with the ACCREDIA Mark and/or the reference to accreditation. The exception is in cases where the client explicitly requests a report not covered by accreditation and therefore without the mark and/or reference to accreditation. In such cases, this request must be specified contractually (see §7.1.1 and RG-09), and the activities will be considered as non-accredited.

During surveillance, extension, and/or renewal assessment visits, the PTP must make available the reports issued in the previous calendar year, both with and without the ACCREDIA Mark (and/or reference to accreditation), where applicable, so that ACCREDIA can verify compliance with Regulation RG-09 regarding the use of the mark and the accreditation requirements.

7.4.3.2. The requirement of the standard applies.

With reference to point h), where the individual results of homogeneity and stability tests are not included in the reports, it must still be stated that such information is available upon request from the organisation.

In the case of simplified reports (which do not include all the information required by the standard, such as for interlaboratory proficiency tests managed systematically, for internal use within the organisation, or for contractual agreements with clients), it must be indicated on the report that the complete information is provided in another document (e.g., periodic summary reports), which must be made available.

7.4.3.3. The requirement of the standard applies.

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[1] In accordance with the provisions of Regulation RG-09, the requirements for the accreditation mark are to be considered equally applicable to the reference to accreditation.

The PTP cannot issue a preliminary report (or disclose the results) until it has received all the results from the participants, or has excluded those who have not submitted their results.

The PTP must define policies and procedures for the acceptance of data changes after the preliminary report, and establish a time period between the submission of provisional results and the submission of the final report.

It is reminded that data control is the responsibility of the PTP and therefore cannot be delegated to the participants through the preliminary report.

Preliminary results must be approved before issuance, and they must use the same performance evaluation criteria as those reported in the final report. The content of the provisional report (ref. 7.4.3.2) must be approved by an authorized and competent person and must clearly indicate that it is a provisional presentation of the results, followed by the final report.

7.4.3.4. The requirement of the standard applies.

7.4.3.5. The requirement of the standard applies.

Reports must be corrected and reissued in the event of:

- incorrect or misleading use of the ACCREDIA Mark or the reference to accreditation;
- errors in the results;
- any other deficiency or error that could lead to the improper use of the report or compromise the correct understanding of the results by the participants, clients, or a third party.

When a report containing such deficiencies is identified, the PTP must ensure, as part of the nonconforming work management process, to review all issued reports, trace, correct, and reissue all those affected by the same deficiencies.

In the case of modifications, corrections, or additions, the new document issued by the PTP must clearly indicate whether the original report remains valid or is cancelled and replaced.

In exceptional cases where only purely formal (editorial) aspects of already issued reports need to be corrected without affecting their validity, the issuance of a general correction document may be acceptable, provided that the information required by the standard in §7.4.3 is ensured (e.g., clear identification of the reports affected by the same deficiency, correct information, reasons for the correction).

7.4.3.6. The requirement of the standard applies.

7.4.3.7. The requirement of the standard applies.

Any performance statements or statements regarding participation must not be misleading: they must clarify the performance evaluation criteria, include the identification of the scheme and the participant, reference the final report, and specify whether the performance relates to a single round.

7.5 Control of the pt scheme process

7.5.1 Technical records

For the retention periods of technical records, refer to §8.4 of this document.

In the case of data correction, if the explanation cannot be inferred from the records, the reason for the correction must be noted.

7.5.2 Control of data and information management

7.5.2.1. The requirement of the standard applies.

7.5.2.2. The requirement of the standard applies.

The extent and depth of the validations to be carried out on a system provided from an external source are commensurate with the evidence that the manufacturer can provide regarding the system's compliance.

7.5.2.3. The requirement of the standard applies.

7.5.2.4. The requirement of the standard applies.

The PTP must communicate the applicable requirements to the external provider or to the system operator, in the case of systems managed by the organisation to which the PTP belongs, including the requirements related to confidentiality, integrity, and accessibility of information stored off-site.

7.5.2.5. The requirement of the standard applies.

7.5.2.6. The requirement of the standard applies.

With reference to the use of spreadsheets or other commercial calculation programs, applications developed by the PTP (formulas, macros) must be documented, validated, and protected to prevent accidental alteration.

7.5.3 Surveillance of the processes

The requirement of the standard applies.

7.5.4 Nonconforming work

The requirement of the standard applies.

In the event of non-conformities that could lead to the suspension of the PTP's activities, even partially, or cast doubt on the validity of the PT results, the PTP must notify ACCREDIA of the self-suspension of accreditation for those schemes, until ACCREDIA has positively verified the corrective actions taken.

In the case of non-conformities found in reports that have already been issued, which may jeopardize the use of the results by clients (e.g., technical non-conformities or issues related to the reference to accreditation),

the PTP must identify the reports affected by the same non-conformity and notify the clients by issuing replacement reports.

7.6 Handling of complaints

The requirement of the standard applies.

7.7 Handling of appeals

The requirement of the standard applies.

8. Management system requirements

8.1 General requirements

The requirement of the standard applies.

During the first accreditation and renewal process, the PTP must provide ACCREDIA with sufficient information to allow an understanding of how the PTP operates to achieve and maintain compliance with the requirements of UNI CEI EN ISO/IEC 17043 and ACCREDIA.

To this end, the PTP may prepare a Management System Manual or a self-assessment using the appropriate ACCREDIA forms (self-assessment), which must contain at least:

- the responsibilities related to the definition of policies and procedures, their implementation, and the preparation and retention of the related records.
- a concise description of the operational methods adopted by the PTP, without excessive references to procedures and attachments.
- the activities carried out at secondary locations or temporary stations, in the case of a multi-site PTP.
- any exclusions or inapplicability of certain requirements, accompanied by the relevant justifications.

If abbreviations or acronyms appear in the Management System Manual or the self-assessment, the PTP must provide ACCREDIA with a clear written explanation of them.

In the case of significant changes to the PTP's organisation and/or the policies and procedures adopted, ACCREDIA may request an update to the Management System Manual/Self-assessment (e.g., revision of the reference standard, corporate reorganisations, etc.).

It is specified that the Self-assessment is a form provided by ACCREDIA and completed by the PTP for the purpose of submitting the accreditation application and, as such, is not a document of the PTP's management system. Therefore, if the PTP decides to remove the Manual from its management system, it must review its documentation to ensure the organizational structure and coherence of the system itself.

8.2 Management system documentation

The requirement of the standard applies.

8.3 Control of management system documents

The requirement of the standard applies.

In the case of updates to externally sourced documents (e.g., standards, methods, laws, regulations), unless otherwise specified, the PTP is required to apply the new versions within three months of their issuance.

8.4 Control of records

The requirement of the standard applies.

All records must be kept for a minimum period of 48 months, unless there are more stringent legal or contractual obligations, including external record documents (e.g., calibration certificates, reference material certificates, test reports).

If the PTP also has equipment subject to calibration, the calibration data should be retained for the lifetime of the measuring equipment, as these data may be used to establish or modify the calibration frequencies.

8.5 Actions to address risks and opportunities

The requirement of the standard applies.

It is reminded of what is stated in the introduction of the standard regarding the identification of risks.

8.6 Improvement

The requirement of the standard applies.

8.7 Corrective actions

The requirement of the standard applies.

It is reminded that the verification of the effectiveness of corrective actions is different from the verification of their implementation.

It is reminded that corrective actions planned and communicated following second and third-party audits (e.g., ACCREDIA) must also be managed within the PTP's management system.

8.8 Internal audits

The requirement of the standard applies.

The selection of assessors and the conduct of audits must ensure the objectivity and impartiality of the internal audit process. Therefore, it is advisable, where resources permit, that internal audits be conducted by personnel independent of the area being audited.

Evidence (curricula and certificates) of the training, education, and experience of the assessors must be provided, specifically regarding the UNI CEI EN ISO/IEC 17043 standard and the accreditation requirements.

Second-party and third-party audits cannot replace the PTP's internal audits. In any case, the results of external audits must also be considered when planning internal audits, with a risk-based approach.

8.9 Management review

Extraordinary reviews may be necessary following findings whose corrective actions involve significant investments (e.g., purchase of new equipment, hiring of staff) or organizational-structural changes (e.g., PTP layout, reorganization of personnel).

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