

Title	Requirements for the accreditation of Proficiency Testing Providers
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NOTE: The present document represent the English version of 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 version in Italian language only.

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0. INTRODUCTION

0.1. GENERAL

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

0.1.2 The application of such criteria is intended to foster and maintain the trust of clients in the 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 ISO/IEC 17043 and with the present document and the other prescriptive ACCREDIA documents.

0.1.3 The present document makes reference to UNI CEI ISO/IEC 17043 "*Conformity assessment – general requirements for proficiency testing*"

The numbering of the paragraphs for chapters 4 and 5 is the same as the numbering of UNI CEI ISO/IEC 17043. In these chapters, and in chapter 6, the specifications are presented regarding the necessary requirements of the standard for ACCREDIA, which sometimes coincide with the NOTES contained in the standard itself.

0.1.4 Accreditation attests the technical competence of the PTPs to plan, organize and manage the tests set out in the scope of application.

The interlaboratory PTP has the responsibility of ensuring that the technical and management requirements specified in the reference standard are fulfilled, also by collaborators involved in accredited PTs and for subcontracted activities. PTPs accredited by ACCREDIA are deemed competent to carry out testing activities also in support of the testing, calibration, certification and inspection activities of accredited bodies.

1. SCOPE AND FIELD OF APPLICATION

1.1. The present document specifies the general, management and technical competence requirements for PTPs. ACCREDIA can prescribe requirements for PTPs to apply according to the different proficiency testing schemes.

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 centers etc.) are taken into consideration.

1.3. The requirements set out in the present document are applicable to all proficiency testing schemes. Specific additional requirements defined in the mandatory standards or at international level by EA, ILAC, ISO, EN etc. or by ACCREDIA, are listed among the documents referred to as reference documents and/or on the ACCREDIA website www.accredia.it.

1.4. In order to obtain and maintain accreditation, PTPs 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. The technical competence (staff training, the measurement properties to be determined, the validation of the methods used in the proficiency testing schemes, measurement traceability etc.) shall also be verified.

NOTE. In the current edition of UNI CEI EN ISO/IEC 17043 the management requirements are defined in point 5, whilst the technical requirements are set out in point 4.

1.5. Accreditation obtained by PTPs on the basis of the requirements of the present document includes activities related to suggestions for improvement as well as general recommendations or comments.

1.6 PTPs shall respect ACCREDIA document RG-09 for use of the accreditation Mark.

2. TERMS AND DEFINITIONS

2.1. Definitions

For the purpose of the present document the definitions of the reference standards UNI EN ISO 9000, UNI CEI EN ISO/IEC 17000, UNI CEI 70099, UNI CEI EN ISO/IEC 17043 and UNI CEI EN 45020 are applicable. A number of definitions are given below.

2.1.1. Proficiency Testing Provider - PTP: an organization which takes the responsibility for all tasks in the development and operation of an proficiency testing scheme
[UNI CEI EN ISO/IEC 17043 point 3.9].

2.1.2. Proficiency testing scheme: proficiency testing designed and operated in one or more rounds for a specific area of testing, measurement, calibration or inspection.

Note: a proficiency testing scheme might cover a particular type of test, calibration, inspection or a number of tests, calibrations or inspections on proficiency test items.

[UNI CEI EN ISO/IEC 17043, point 3.11]

2.1.3. Coordinator: one or more individuals with responsibility for organizing and managing all of the activities involved in the operation of a proficiency testing scheme.

[UNI CEI EN ISO/IEC 17043, point 3.2]

2.1.4. Subcontractor: organization or individual engaged by proficiency testing provider to perform activities specified in the international standard and that affect the quality of a proficiency testing schemes.

The Note is applicable: the term “subcontractor” includes what many PTPs call “collaborators”.

[UNI CEI EN ISO/IEC 17043, punto 3.14]

2.1.5. Customer: organization or individual for which a proficiency testing scheme is provided through a contractual arrangement.

[UNI CEI EN ISO/IEC 17043, point 3.3]

2.1.6 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 point 3.4].

2.1.7 Participant: laboratory, organization or individual that receives proficiency testing items and submits results for review by the proficiency testing provider.

Note: in some cases the participant can be an inspection body.

[UNI CEI EN ISO/IEC 17043, point 3.6]

2.1.8 Proficiency Testing - PT: evaluation of participant performance against pre-established criteria by means of interlaboratory comparison.

NOTE 1: in accordance with UNI CEI EN ISO/IEC 17043, the term "PT" is taken in its widest sense and includes, for example, as follows:

- a) Quantitative scheme – where the objective is to quantify one or more measurands of the proficiency test item;
- b) Qualitative scheme - where the objective is to identify or describe one or more characteristics of the proficiency test item;
- c) Sequential scheme – where one or more proficiency test item are distributed sequentially for testing or measurement and returned to the PTP at intervals;
- d) Simultaneous scheme - where the proficiency test item are distributed sequentially for concurrent testing or measurement within a defined time period;
- e) Single occasion exercise - where proficiency test item are provided on a single occasion;
- f) Continuous scheme - where proficiency test item are provided at regular intervals;
- g) Sampling – where samples are taken for subsequent analysis;
- h) Data transformation and interpretation – where sets of data or other information are furnished, and the information is processed to provide an interpretation (or other outcome).

NOTE 2: Some PTPs in the medical area use the term External Quality Assessment – EQA – for their proficiency testing schemes or for their broader programs or both (see Appendix A). The requirements of UNI CEI EN ISO/IEC 17043 cover only those EQA activities that meet the definition of proficiency testing. [UNI CEI EN ISO/IEC 17043, point 3.7]

2.1.9 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, point 3.8]

2.1.10 Metrological comparability of measurement results: comparability between measurement results for the quantities of the same species, which are characterized by metrological traceability to the same reference. [UNI CEI 70099, point 2.46].

3. STANDARDS AND REFERENCE DOCUMENTS.

The list of reference documents (LS-04) can be consulted on the ACCREDIA website. The requirements given in the ILAC and EA guides and procedures for PTPs, where applicable, shall be fulfilled. The most important reference documents are listed below:

- UNI CEI EN ISO/IEC 17043 Conformity assessment – general requirements for proficiency testing;
- UNI CEI EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories;
- UNI EN ISO 15189: Medical laboratories – requirements for quality and competence;
- UNI CEI EN ISO/IEC 17000: Conformity assessment – vocabulary and general principles;
- UNI CEI 70099: International vocabulary of metrology – basic and general concepts and associated terms (VIM).
- UNI CEI EN 45020: Standardization and related activities – general vocabulary;.
- UNI 4546: Measures and measurements – basic terms and definitions.
- UNI EN ISO 9000 Quality management systems – Fundamentals and vocabulary.
- UNI EN ISO 9001 Quality management systems – requirements;
- UNI EN ISO 10012 Measurement management systems – requirements for measurement processes and measuring equipment;

- ISO 13528 Statistical methods for use in proficiency testing by interlaboratory comparisons;
- ISO 21748 Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation;
- ISO/TS 22117: Microbiology of food and animal feeding stuffs - Specific requirements and guidance for proficiency testing by interlaboratory comparison;
- ISO Guide 34: General Requirements for the competence of reference material producers;
- ISO Guide 35: Reference materials: general and statistical principles, for certification;
- ISO/IEC Guide 98-3:2009: Uncertainty of measurement -- Part 3: Guide to the expression of uncertainty in measurement (GUM);
- ILAC G8: Guidelines on the Reporting of Compliance with Specification;
- ILAC P9: ILAC Policy for Participation in Proficiency Testing Activities;
- ILAC P10:ILAC Policy on Traceability of Measurement Results;
- ILAC P13 Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers;
- EA-2/15: EA Requirements for the Accreditation of Flexible Scopes;
- EA-2/18: EA Guidelines for Accreditation Bodies on the contents of the scope of accreditation for Proficiency Testing Providers;
- EA-4/02: Expression of the uncertainty of measurement in calibration;
- EA-4/16: EA guidelines on the expression of uncertainty in quantitative testing;
- EA 4/18: Guidance on the level and frequency of proficiency testing participation;
- EURACHEM/CITAC Guide: Quantifying Uncertainty in Analytical Measurement;
- EURACHEM/CITAC Guide: Measurement Uncertainty arising from sampling.

4. TECHNICAL REQUIREMENTS (UNI CEI EN ISO/IEC 17043)

4.1. GENERAL

The requirement of the standard is applicable.

If the PTP also has an internal lab which carries out activities for the PT schemes (e.g. tests for the preparation of materials, homogeneity and stability tests, determination of assigned values), the technical assessor shall assess the conformity of testing activities against the requirements of ISO/IEC 17025, ISO 15189).

The accreditation of the testing lab against ISO/IEC 17025 for the specific tests is sufficient to guarantee conformity. If this is not done, ACCREDIA shall verify such requirements during the assessment visit.

NOTE 1: the conformity to ISO/IEC 17025 – ISO 15189 for tests carried out by the PTP does not necessarily involve accreditation.

NOTE 2: accreditation of a test regarding a specific activity of the PTP (e.g. evaluation of homogeneity) does not attest conformity to all the applicable requirements of ISO/IEC 17043 (regarding, e.g., statistical evaluations).

4.2 PERSONNEL

4.2.1. The requirement of the standard is applicable.

4.2.2. The requirement of the standard is applicable.

4.2.3. The requirement of the standard is applicable.

4.2.4. The requirement of the standard is applicable.

4.2.5. The requirement of the standard is applicable.

Records shall be kept with regard to personnel, including subcontractors, giving evidence of their competence (e.g. a list of tests with indication of the names of persons qualified to perform them, attestations of attendance at courses, training reports, details of assessment methods used, results of audits done to subcontractors by the PTP, accreditations of subcontractors etc.).

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

4.2.6. The requirement of the standard is applicable.

4.2.7. The requirement of the standard is applicable.

4.3. EQUIPMENT, ACCOMODATION AND ENVIRONMENT

4.3.1. The requirement of the standard is applicable.

4.3.2. The requirement of the standard is applicable.

4.3.3. The requirement of the standard is applicable.

4.3.4. The requirement of the standard is applicable.

4.3.5. The requirement of the standard is applicable.

4.3.6. The requirement of the standard is applicable.

4.4. DESIGN OF PROFICIENCY TESTING SCHEMES

4.4.1. Planning

4.4.1.1. The requirement of the standard is applicable.
The planning of the PT processes shall describe in details the operations which shall be conducted.

4.4.1.2. The requirement of the standard is applicable.

4.4.1.3. The requirement of the standard is applicable.
The PTP shall not disclose the results of the PT until it has received all the results of the participants, i.e. it has not excluded those which have not yet sent their results.
The PTP shall define its policies and procedures for the acceptance of modifications of data subsequent to the preliminary report and establish a timeframe between the sending of the provisional results and the sending of the final report.
The provisional results shall be validated before issue; they shall have the same criteria of performance assessment as those set out in the final report. The content of the provisional report (see § 4.8.2.e) shall be approved by the authorized and competent personnel, and shall state that it is a provisional presentation of the results and that the final report will follow.

4.4.1.4. The requirement of the standard is applicable.
If consultancy is used, the PTP shall maintain a record of the members of the consultancy group, of their appointment letters and of their competencies (these may be contained in their CVs). A record shall be kept of their activities and meetings, including the agendas for the day, the minutes and the participants' names.

4.4.1.5. The requirement of the standard is applicable.

4.4.2. Preparation of proficiency testing items

4.4.2.1. The requirement of the standard is applicable.
The PTP (coordinator and subcontractors) shall be competent in the testing sector offered to the client and in the mandatory requirements relevant to the scheme in question (e.g. EC regulation on the limits to food pollutants).
The PTP shall prepare adequate instructions to establish the quantity and modalities of preparation, the retention and sending of items.

4.4.2.2. The requirement of the standard is applicable.
The PTP shall keep part of the items used for the ILC for the amount of time agreed with the participant at the PT or as laid down by the law.
If such agreement does not exist, the PTP shall define the timeframe for the retention of the items and communicate it to the participants.

4.4.2.3. The requirement of the standard is applicable.

4.4.2.4. The requirement of the standard is applicable.
The instructions sent by the PTP shall be sufficiently detailed to ensure metrological compatibility (*UNI CEI 70099, point 2.46*) of the testing results. Participants shall be asked to communicate any deviations from the instructions in order to include them, if necessary, in the statistical evaluation.

4.4.3. Homogeneity and stability

4.4.3.1. The requirement of the standard is applicable.

4.4.3.2. The requirement of the standard is applicable.

4.4.3.3. The requirement of the standard is applicable.
If it is not possible to assess the homogeneity on the sample ready for sending, the PTP shall justify and record the cause.

4.4.3.4. The requirement of the standard is applicable.

4.4.3.5. The requirement of the standard is applicable.

4.4.3.5. The requirement of the standard is applicable.

4.4.4. Statistical design

4.4.4.1. The requirement of the standard is applicable.

4.4.4.2. The requirement of the standard is applicable.

4.4.4.3. The requirement of the standard is applicable.

4.4.5. Assigned values

4.4.5.1. The requirement of the standard is applicable.
The participants shall not acquire knowledge of the assigned value until the issue of the report by the PTP.

4.4.5.2. The requirement of the standard is applicable.
Documents and guides are listed in point 2 of the present document and on ACCREDIA's website.

4.4.5.3. The requirement of the standard is applicable.

4.4.5.4. The requirement of the standard is applicable.

4.4.5.5. The requirement of the standard is applicable.

4.5 CHOICE OF METHOD OR PROCEDURE

4.5.5.1. The requirement of the standard is applicable.

4.5.5.2. The requirement of the standard is applicable.

4.6 OPERATION OF PROFICIENCY TESTING SCHEMES

4.6.1. Instruction for participants

4.6.1.1. The requirement of the standard is applicable.

4.6.1.2. The requirement of the standard is applicable.
The PTP shall indicate to the participants the number of significant figures or decimal digits necessary for recording results.

4.6.2. Proficiency testing items handling and storage

4.6.2.1. The requirement of the standard is applicable.

4.6.2.2. The requirement of the standard is applicable.

4.6.2.3. The requirement of the standard is applicable.

4.6.2.4. The requirement of the standard is applicable.

4.6.3. Packaging, labeling and distribution of proficiency testing items

4.6.3.1. The requirement of the standard is applicable.
The PTP shall identify the set of mandatory requirements and regulations regulating the transport of goods, especially if there are participants from foreign countries, and it shall maintain adequate records which shall be part of the management systems documents.

4.6.3.2. The requirement of the standard is applicable.
The PTP shall request that participants provide information regarding the condition of material upon arrival in cases where conditions of transport could affect them.

4.6.3.3. The requirement of the standard is applicable.

4.6.3.4. The requirement of the standard is applicable.

4.6.3.5. The requirement of the standard is applicable.

4.7. DATA ANALYSIS AND EVALUATION OF PROFICIENCY TESTING SCHEME RESULTS

4.7.1. Data analysis and records

4.7.1.1. The requirement of the standard is applicable.
With regard to the use of electronic sheets and other commercial calculation programs, the applications developed by the PTP (e.g. formulae, macro etc.) shall be documented and validated.
A record of the validation shall be kept. Systematic controls shall be conducted to ensure that the calculation program used is suitable for the specific PT.

4.7.1.2. The requirement of the standard is applicable.

4.7.1.3. The requirement of the standard is applicable.

4.7.1.4. The requirement of the standard is applicable.

4.7.1.5. The requirement of the standard is applicable.

4.7.1.6. The requirement of the standard is applicable.

4.7.2. Evaluation of performance

4.7.2.1. The requirement of the standard is applicable.

4.7.2.2. The requirement of the standard is applicable.

4.8 REPORTS

4.8.1. The requirement of the standard is applicable.

4.8.2. The requirement of the standard is applicable.

In the case of simplified reports (which do not give all the information required by the standard such as for PTs managed systematically or for internal use by the PTP or for contractual agreements with clients) they shall indicate that the complete information is given in another document (e.g. the periodical summary report) which shall be available.

With regard to the evaluation of the homogeneity and stability of proficiency testing items, where the report does not state each single test result, it shall nevertheless be indicated that such information is available on request from the PTP.

4.8.3. The requirement of the standard is applicable.

4.8.4. The requirement of the standard is applicable.

4.8.5. The requirement of the standard is applicable.

4.9. COMMUNICATION WITH PARTICIPANTS

4.9.1. The requirement of the standard is applicable

The PTP shall inform the participants with respect to the frequency of the distribution of items, the statistical methods to be used for processing results and making available to the participants suitable means of communication such as internet, email, phone etc.

4.9.2. The requirement of the standard is applicable.

If the variations to the interlaboratory testing scheme are programmed, the PTP may communicate to the participants at meetings with regard to the start of the testing programs. If, however, they are not, and they could affect the test, they shall be communicated to the participants before being implemented.

4.9.3. The requirement of the standard is applicable.

4.9.4. The requirement of the standard is applicable.

In order to encourage the exchange of information with the participants, the PTP may use questionnaires or it may organize specific meetings.

4.9.5. The requirement of the standard is applicable.

Declarations regarding performances or regarding participation shall not be misleading, the performance evaluation criteria shall be clear, the identification of the scheme and the participant shall be clarified, the reference to the final report shall be given and it shall be indicated whether the performances refer to just one round.

4.10 CONFIDENTIALITY

4.10.1. The requirement of the standard is applicable.

4.10.2. The requirement of the standard is applicable.

4.10.3. The requirement of the standard is applicable.

Note: an interested party is, for example, a competent authority which requests the preparation of a PT from a PTP with the aim of monitoring the performance of official control labs.

4.10.4. The requirement of the standard is applicable.

5. MANAGEMENT REQUIREMENTS (UNI CEI EN ISO/IEC 17043)

5.1. ORGANIZATION

5.1.1. The requirement of the standard is applicable.

5.1.2. The requirement of the standard is applicable.

5.1.3. The requirement of the standard is applicable.

5.1.4. The requirement of the standard is applicable.

When PTs are provided by a provider which is also a testing/medical lab and there is only one head of the PTP and of the lab and/or only one quality manager, his or her responsibilities shall be clearly defined and differentiated with respect to those concerning the testing lab so as to ensure the impartiality and the absence of conflicts of interests. This is especially important if the testing lab also participates in the PT which is provided.

5.1.5. The requirement of the standard is applicable.

The PTP shall have available an organization chart under the management of the quality system which clearly reflects its organization and the relations with other staff who have an influence on the PTP's operations.

If the PTP belongs to a larger organization there shall also be a general organization chart in which the PTP's position is clearly stated.

The PTP shall have documents available describing the assigned tasks, the qualifications, experience and training concerning the roles covered by all the personnel. Such documents shall:

- be made known to staff so that they are aware of the extent of their responsibilities;
- be available to ACCREDIA.

In accordance with the note, if the PTP has a limited number of personnel, the personnel in question may fulfill more than one position and it may prove to be impractical to appoint substitutes for all the main roles.

5.1.6. The requirement of the standard is applicable.

The communications processes shall be documented.

5.2. MANAGEMENT SYSTEM

5.2.1. The requirement of the standard is applicable.

5.2.2. The requirement of the standard is applicable.

5.2.3. The requirement of the standard is applicable.

5.2.4. The requirement of the standard is applicable.

5.2.5. The requirement of the standard is applicable.

The quality manual shall include sufficient information to enable comprehension regarding how the PTP operates to reach and maintain conformity with the requirements of UNI CEI EN ISO/IEC 17043 and with those of ACCREDIA.

The responsibilities shall be specified with regard to the definition of policies and procedures, their implementation and the preparation and retention of the records in question.

The quality manual shall include a brief description of the operative modalities adopted and the reference to procedures shall be used only for the details.

The quality manual shall specify, where applicable, the location used for the activities it describes.

If the PTP does not perform such activities or if some of the requirements are not applicable, such exclusions shall be declared, with the reasons, in the manual.

The quality manual shall contain a table showing the correspondence between the paragraphs it contains and those of the present document.

5.2.6. The requirement of the standard is applicable.

5.2.7. The requirement of the standard is applicable.

5.2.8. The requirement of the standard is applicable.

5.3. DOCUMENT CONTROL

5.3.1. General

The requirement of the standard is applicable.

In the case of updates of documents with external origin (e.g. standards, methods, laws, regulations), where not indicated otherwise, the PTP shall apply the new versions within 3 months of issue (or publication of information in the case of withdrawal of a document).

5.3.2. Approval and dissemination of documents

5.3.2.1. The requirement of the standard is applicable.

Together with the application for accreditation, duly completed, it is necessary to send to ACCREDIA the documents as per point 4 of DA-06.

If there are any acronyms or abbreviated forms in the QM or in other documents sent by the PTP to ACCREDIA, the PTP shall provide written indications as to their full meaning.

The PTP shall send to ACCREDIA the revisions of the QM. Other documents shall be sent only if so requested by ACCREDIA.

5.3.2.2. The requirement of the standard is applicable.

5.3.2.3. The requirement of the standard is applicable.

5.3.3. Documents changes

5.3.3.1. The requirement of the standard is applicable.

5.3.3.2. The requirement of the standard is applicable.

5.3.3.3. The requirement of the standard is applicable.

Corrections by hand are allowed on operative instructions and on quality records for internal use if they are urgent. Modified instructions shall be updated promptly.

5.3.3.4. The requirement of the standard is applicable.

If the PTP uses IT procedures (software programs) in order to fulfill conformity requirements of the standard, it shall make available a brief description of the flows of information concerning the configuration status of such software programs with reference to their modifications and retentions.

5.4. REVIEW OF REQUESTS, TENDERS AND CONTRACTS

5.4.1. The requirement of the standard is applicable.

The PTP shall inform the client regarding the significance of accreditation and accredited tests.

5.4.2. The requirement of the standard is applicable.

The records of reviews shall be kept for a period of time as indicated in point 5.13.2.1.

5.5. SUBCONTRACTING OF SERVICES

5.5.1. The requirement of the standard is applicable.

The subcontracting of phases of the PT scheme activities shall be given to a competent subcontractor.

The head of the PTP shall ensure the competence of the subcontractor.

If testing activities are subcontracted (e.g. tests for the preparation of items, the evaluation of homogeneity and/or stability, for determining an assigned value), the subcontractor shall operate in conformity with the requirements of ISO/IEC 17025 o ISO 15189. Accreditation of the subcontractor for subcontracted activities is sufficient for the demonstration of competence.

ACCREDIA may carry out on-site visits to verify the performance of assigned tasks.

NOTE: the accreditation of a test used for a specific activity of the PTP (e.g. chemical tests for the evaluation of homogeneity) does not guarantee conformity with all the requirements of ISO/IEC 17043 (regarding, for example, statistical evaluations).

5.5.2. The requirement of the standard is applicable.

NOTE: the possibility of using consultants, experts or policy groups is not precluded for PTPs.

5.5.3. The requirement of the standard is applicable.

5.5.4. The requirement of the standard is applicable.

5.5.5. The requirement of the standard is applicable.

The list of subcontractors shall be specified in the application for accreditation (DA-06 section 8). Any variations made by the subcontractor shall be communicated to ACCREDIA before activities are started, attaching the documentation attesting the qualified ability of the supplier (appraisal of competence, as set out in point 5.5.5 of the standard).

5.6. PURCHASING OF SERVICES AND SUPPLIES

5.6.1. The requirement of the standard is applicable.

There shall be procedures and records for verification upon receipt and subsequently during use regarding the materials/products which have an expiry date or which require particular conditions of retention (e.g. storage at a low temperature, in the dark etc.).

5.6.2. The requirement of the standard is applicable.

5.6.3. The requirement of the standard is applicable.

5.6.4. The requirement of the standard is applicable.

5.7. CLIENT SERVICES

5.7.1. The requirement of the standard is applicable.

5.7.2. The requirement of the standard is applicable.

5.8. COMPLAINTS AND APPEALS

The requirement of the standard is applicable

5.9. CONTROL OF NONCONFORMING WORK

5.9.1. The requirement of the standard is applicable.

NOTE: in cases of non-conform testing and/or calibration activities such as to cause the suspension of testing activities, the PTP shall communicate as such to ACCREDIA.

5.9.2. The requirement of the standard is applicable.

In cases of NCs which could cast doubt on the validity of the results of the evaluations of the PTP, the PTP shall suspend the issuance of reports bearing the ACCREDIA Mark and any other reference to accreditation regarding such tests until a positive verification has been performed of the effective implementation of CAs.

Following any NC raised, the PTP shall verify the consequences on results already provided and inform the client and the participants, issuing, if necessary, a substitute report.

If there is a NC on a previously issued report which could impact negatively on the use of the results by clients or by participants (e.g. a NC of a technical nature or related to the reference to accreditation) the PTP shall identify the reports of previous tests affected by such NC and advise the client by issuing a substitute report.

5.10. IMPROVEMENT

The requirement of the standard is applicable.

5.11. CORRECTIVE ACTIONS

5.11.1. General

The requirement of the standard is applicable.

Also planned and communicated CAs following a second or third party assessment (e.g. ACCREDIA) shall be managed within the PTP's management system.

5.11.2. Cause analysis

The requirement of the standard is applicable.

5.11.3. Selection and implementation of corrective actions

The requirement of the standard is applicable.

5.11.4. Monitoring of corrective actions

The requirement of the standard is applicable.

The verification of the effectiveness of CAs (and PAs – see point 5.12 below) is different from the verification of their implementation.

NOTE: it is recommended to prepare a plan of the CAs and PAs in order to facilitate the verification of their implementation and effectiveness within the set timeframe. It is also recommended to establish (when a CA or PA is opened) both the date of the verification of implementation and the date of the verification of effectiveness,

5.11.5. Additional audits

The requirement of the standard is applicable.

5.12. PREVENTIVE ACTIONS

5.12.1. The requirement of the standard is applicable.

5.12.2. The requirement of the standard is applicable.

5.13. CONTROL OF RECORDS

5.13.1. General

5.13.1.1. The requirement of the standard is applicable.

5.13.1.2. The requirement of the standard is applicable.

5.13.1.3. The requirement of the standard is applicable.

All the records shall be kept for a period of time at least equal to the period defined in the applicable national and International legislation for ILC testing activities.

If there is no retention time limit ACCREDIA recommends retention of all documents related to the activities for at least 10 years, in line with EC conformity assessment Directives (see also Decision 768//2008/CE of the European Parliament regarding a common framework for the Marketing of products [official gazette L218 of 13.08.2008]). It is also recommended to consider the applicability of D. Lgs. 206/2006 (Consumption Code).

5.13.1.4 The requirement of the standard is applicable.

With regard to the extension of activities managed with the IT system aimed at ensuring conformity with the requirements of the standard, the PTP shall have in place adequate procedures for providing guarantees regarding the secure management of matters concerning confidentiality, integrity and the accessibility of reports kept in IT systems. Back-up alone of data is not sufficient to guarantee respect for this requirement.

5.13.2. Technical records

5.13.2.1. The requirement of the standard is applicable.

ACCREDIA has set minimum retention times of records for the sole purpose of ACCREDIA assessments, where there are not more demanding mandatory or contractual obligations.

	Type of document	Retention times
1.	Internal audit reports	Last 48 months
2.	Management reviews	Last 48 months
3.	Instructions for participants	Last 48 months
4.	Results sent to participants in original form	Last 48 months
5.	Data for statistical analysis	Last 48 months

	Type of document	Retention times
6.	Results of homogeneity and stability tests	Last 48 months
7.	Information regarding the preparation of items	Last 48 months
8.	Information for the definition of assigned values	Last 48 months
9.	Information for the preparation of reports	Last 48 months
10.	Final reports	Last 48 months
11.	Conformity reports	Last 48 months
12.	Contracts for activities and review of such	For the period of validity of the contract and 12 months after expiry
13.	Instrumental records, where present	Last 48 months

Where two different time intervals are given, the longer one should be taken.

5.13.2.2. The requirement of the standard is applicable

5.13.2.3. The requirement of the standard is applicable

In the case of correction of data, the reason for correction shall be given.

5.14 INTERNAL AUDITS

5.14.1. The requirement of the standard is applicable.

The choice of assessors and the performance of the audit shall ensure objectivity and impartiality of the internal audit

Evidence shall be provided, (CVs and references) regarding the training and qualification of the assessors, with regard to UNI CEI EN ISO/IEC 17043 and the requirements for accreditation.

Internal audits can be performed, in the absence of internal resources, by qualified assessors from outside the PTP.

Second and third party audits cannot substitute internal PTP audits.

The audit cycle shall be completed within a year.

NOTE: it is advisable to plan internal audits taking into consideration the failures signaled in previous audits.

5.15 MANAGEMENT REVIEW

5.15.1. The requirement of the standard is applicable.

The quality manager shall make a regular written report to the management, at least annually, regarding the quality situation of the PTP.

The review shall take place at least once a year. The PTP shall undertake a review also after the second and third party audits (e.g. ACCREDIA assessments) in cases in which findings have been raised and the PTP must plan CAs, PAs and improvements, investments etc.

If the PTP belongs to a larger organization it is better to perform a review by the management which is separate from the one regarding the lab and is specific for interlaboratory activities.

5.15.2. The requirement of the standard is applicable.

6. FURTHER ACCREDIA REQUIREMENTS

6.1. The PTP applying for accreditation from ACCREDIA shall demonstrate compliance with the requirements of standard UNI CEI EN ISO/IEC 17043 and those specified in this document.

6.2. The accredited PTP shall offer to its clients, for all accredited tests, a uniform service complying with standard UNI CEI EN ISO/IEC 17043, with this document and with ACCREDIA regulation RG-14. Such requirements shall be complied with throughout the period of validity of the accreditation.

6.3. The PTP shall publicise its accreditation solely referring to tests for which such recognition has been granted.

6.4. The laboratory shall use the ACCREDIA Mark and/or references to accreditation in accordance with the contents of the ACCREDIA document RG-09.

If a report is issued without the ACCREDIA Mark and/or references to accreditation, but containing accredited PTs, the PTP shall ensure that the tests are undertaken in conformity with UNI CEI EN ISO/IEC 17043, with the present document and with ACCREDIA Reg. RG-14.

6.5. The PTP shall promptly inform ACCREDIA with regard to any changes in its structure which might affect the maintenance of conformity with ACCREDIA's requirements.

When such changes take place ACCREDIA reserves the right to carry out a supplementary assessment of the PTP and, if necessary, to reduce or suspend accreditation.

6.6. The PTP shall possess the guidance documents for the application of UNI CEI EN ISO/IEC 17043 (see point 2 of the present document) relevant to its activities. Unless explicitly stated, these documents do not constitute additional requirements, but they provide support for the consistent application/interpretation of what is requested. If the PTP decides not to apply them it shall demonstrate the validity and adequacy with regard to the scope of its operations.

6.7. The PTP shall ensure that its management and technical procedures are applied and verified also for the tests carried out by subcontractors outside the permanent location.

6.8. The PTP seeking accreditation is responsible for the correct definition of its scope of accreditation. Such definition shall be in accordance with the document EA-2/18. In the description of its scope of accreditation the PTP may adopt a fixed or flexible field (for the definitions see ACCREDIA Reg. RT-26).

For fixed scope accreditation the test items and the quantities/property to be determined shall be accurately indicated – unambiguously and not generically. **For flexible scope accreditation** the management requirements and modalities are set out in ACCREDIA Reg. RT-26.

During the accreditation procedure ACCREDIA may request the revision of the list of PTs which are part of the application for accreditation.

6.9 The application for accreditation shall contain the fully defined scope of accreditation for a PT when – at least – the following information is present:

- Identification of the scheme (e.g. reference defined by the PTP), if present;
- The PT sector (e.g. microbiology, environment, food, medical);
- Material / Product / Matrices/Items to be tested;
- Measurand / property / quantities to determine;
- Typology of scheme.

6.10. The applicant PTP shall include in its application the lists of subcontractors and their activities and shall communicate to ACCREDIA any changes (see point 5.5). The PTP shall maintain traceability of the sites where parts of the scheme of such tests were performed.

6.11. In the case of inapplicability of a standard requirement, such cases shall be clearly defined in the documentation sent to ACCRDIA for accreditation, along with the explanations, and ACCREDIA maintains the right to assess them during the examination of such documents, requesting, where necessary, further information and requesting ACCREDIA assessors to verify feasibility during the assessment visit.

6.12. On the occasion of the assessment for surveillance, extension and/or renewal, the PTP shall make available the number of reports issued in the preceding calendar year, both with and without the ACCREDIA Mark (and/or references to accreditation).