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Requirements for the accreditation of testing laboratories according to the standard UNI CEI EN ISO/IEC 17025:2018

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1. Scope and field of application

1.1. This document defines the general criteria for the accreditation of testing laboratories by the Department of Testing Laboratories of ACCREDIA (the Italian Accreditation Body).
The objective of the application of these criteria is to favour the creation and maintenance of the trust of customers, operators and users in the activities of accredited laboratories, as well as in the impartiality and integrity of the technical and commercial operations associated with them. ACCREDIA accreditation is granted to laboratories that comply with the requirements of the standard UNI CEI EN ISO/IEC 17025 and with the provisions of this document and of the other ACCREDIA, EA and ILAC prescriptive documents.

1.2. Accreditation demonstrates the technical competence of the laboratory to carry out the activities indicated in the scope of accreditation.

1.3. This document refers to the requirements of the standard UNI CEI EN ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories” and contains the information necessary for the application of the requirements. The numbering of the paragraphs is the same as in UNI CEI EN ISO/IEC 17025.
Additional requirements specific to certain testing sectors may be defined by mandatory regulations or at international or national level (EA, ILAC, ISO, EN, UNI, CEI, etc.).

1.4. This document is applicable to all testing laboratories, both those that are organisationally and commercially independent and those that depend on a larger organisation (such as manufacturing companies, public or private organisations, research centres, etc.).

1.5. In order to obtain and maintain accreditation, the laboratory must demonstrate that it complies with all the requirements of the standard, except those declared - with adequate justification - to be inapplicable, for all the activities defined in the scope of application of the accreditation.

1.6. The laboratory must comply with this document, with the ACCREDIA document RG-09 and with the other documents, where applicable (e.g. RT-23, RT-26, RT-39).

2. Standards and reference documents

The list of reference documents (LS-04) is available on the website www.accredia.it.

It is specified that any references to ILAC or IAF documents are also to be understood as applicable to subsequent adoptions by GLOBAL ACI, unless otherwise indicated.

The list contains prescriptive documents and general guidelines. Furthermore, additional specific documents may exist for certain technical sectors.

It is the laboratory's responsibility to ensure the completeness and current validity of the documents applicable to the various sectors.

The guidelines, unless otherwise indicated, do not constitute additional requirements but provide guidance for the consistent application of the requirements; however, if the laboratory decides not to apply what is set out in them, it must demonstrate the validity and adequacy regarding the scope of its activities.

3. Terms and definitions

The definitions of the standard UNI CEI EN ISO/IEC 17025:2018, of the reference standards (UNI EN ISO 9000, UNI CEI EN ISO/IEC 17000, UNI CEI 70099, UNI CEI EN 45020) and of Regulation (EC) No 765/2008, as amended, apply.

Some definitions are given below:

3.1. **Customer/Applicant:** Party for which the laboratory conducts accredited tests.

3.2. **Test:** Determination of one or more characteristics of an object of conformity assessment, according to a procedure.

3.3. **Testing phase:** Every individual part into which a test can be physically divided. E.g. sampling, pre-treatment of the sample, dissolution, extraction, reaction, final measurement and confirmation tests are considered testing phases.

3.4. **Testing technique:** Technique that identifies the principle on which the testing method is based.
Note: a testing method may consist of several phases, each of which may require the use of a specific technique.

3.5. **Testing method:** Specified technical procedure for conducting a test.

3.6. **Official test method:** Test method set out or referred to in mandatory normative documents and/or published in the Italian Official Journal (GU) or the Official Journal of the European Union (GUCE), or in any case referred to or set out in a document issued by a competent authority (e.g. Ministry, Region, Province).

3.7. **Standard testing method:** Method published by a standardization body or by an authoritative technical-scientific body, according to documented and shared procedures aimed at ensuring its technical validity and dissemination.

Examples include UNI, CEI, CEN, ISO, UNICHIM, ASTM, AOAC, USDA, FDA, EPA, NIOSH, IUPAC, APHA, OIV, WOAH, WHO, APAT, CNR, IRSA, ISPRA, NMKL methods)

3.8. Non-standardized testing method: Method issued by national or international technical organizations, or method developed by national or international accredited Laboratories or Reference Centres. One of the distinguishing factors, compared with standard methods, is that the responsibility for the data provided lies not with the issuing organization but with the individual authors.

3.9. Testing method developed by the laboratory (internal): Testing method developed or adopted by a laboratory on the basis of knowledge obtained from the scientific literature and/or practical experience. The internal method may be either a method developed by the laboratory or a standard or non-standardized method that has been substantially modified following the particular needs of the laboratory.

Articles published in journals (e.g. published in the Journal of AOAC International, Bollettino dei Chimici Igienisti) cannot be considered official or standardized methods, since the responsibility for the method lies with the authors and not with the publisher. Methods contained in articles published in journals, as well as the instructions of equipment suppliers, must be managed as methods developed by the laboratory.

3.10. Testing/sampling procedure: Document detailing the working modalities adopted by the laboratory that are not fully described in the testing/sampling method.
This procedure must not constitute a modification of the testing/sampling method.

3.11 Opinions and Interpretations (O&I): Opinions and interpretations are the outcome of a process where one or more results of a test or calibration activity are extended beyond the scope of the result. They are formulated by a technically qualified person/organisation, and further inferences are made on the basis of the result obtained, using the knowledge and professionalism of the person/organisation in the activity being undertaken. Opinions and interpretations may be formulated without stating the measurement uncertainty, the decision rules or the level of risk; however, these elements must in any case be taken into account in their preparation, where appropriate (see EA-4/24).

4. General requirements

4.1. Impartiality

The requirement of the standard applies.

In identifying risks to impartiality, it is advisable to consider the contents of the "*Recommendations expressed by the Steering and Guarantee Committee of ACCREDIA regarding the definition of consistent criteria for verifying certain requirements of the standard UNI CEI EN ISO/IEC 17025:2018, during the assessment and surveillance of accredited testing laboratories and calibration laboratories*", available on the ACCREDIA website.

It should be remembered that, in applying the requirements, account must be taken of what is stated in the note to § 8.5.2 of the standard.

4.2. Confidentiality

The requirement of the standard applies.

5. Structural 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 laboratory only for those activities that it carries out itself and for which ACCREDIA assesses the competence.

The outsourcing of entire tests and/or testing phases on a continuous basis is therefore excluded from the scope of accreditation. It is specified that the non-continuous outsourcing of accredited activities consists solely of the cases indicated in the first point of NOTE 1 of § 7.1.1 of the standard (unforeseen reasons).

Accreditation cannot be issued for testing phases, since by outsourcing the phases not performed it is not possible to ensure compliance with requirements 5.3 and 5.4 of the reference standard and, in the legal sphere, the analytical validity of the test result would be lost and, in the case of official controls, the legal validity of the sample would be lost, because the right to defence at the two accredited laboratories would not be guaranteed. Sampling[1] is an exception, for which see § 7.3.

.....

[1] It should be remembered that sampling is a laboratory activity (ref. UNI CEI EN ISO/IEC 17025:2018)

The laboratory cannot exclude and/or outsource the confirmation phases, either when they are described in the method (e.g. UNI EN ISO 6579-1) or when they are referred to in the applied method (e.g. AFNOR BIO 12/11-03/04).

The confirmation phases that require tests on laboratory animals, or that, according to provisions, must be performed at national or EU reference laboratories/centres or national reference centres, are an exception.

If a laboratory outsources activities to a laboratory which, in turn, outsources them to another laboratory, it is not possible to consider such activities as accredited.

5.4. The requirement of the standard applies.

5.5. The requirement of the standard applies.

The laboratory must have an organisation chart, managed by the management system, which clearly reflects its organisation and its relations with any other functions that have an influence on the laboratory's operations.

When the laboratory belongs to a larger organisation, there must also be a general organisation chart showing the laboratory's position.

In more complex organisations, some activities (for example the purchase of products and/or services or personnel selection) may be centralised or managed by the parent company or by other functions located outside or inside the laboratory (e.g. a company/office for personnel recruitment). In this case, the laboratory must communicate to the function in charge the provisions of the applicable points of the standard (e.g. § 6.2, § 6.6.3), coordinating with it for compliance with the applicable requirements.

Furthermore, the laboratory must have documents describing the tasks assigned, the authorisations, the education, experience, training and on-the-job training relating to the role and the assignments held by all the personnel who manage, perform or verify work that influences the results of laboratory activities; such documents must be brought to the attention of the personnel, so that they are aware of the extent and the limits of their responsibilities.

5.6. The requirement of the standard applies.

The laboratory must ensure that the personnel in charge of 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. The laboratory's assessments of the commitment required must be available, in particular in the case of external personnel (e.g. consultants) or internal personnel who also hold other functions.

5.7. The requirement of the standard applies.

The laboratory must define the modalities and responsibilities for the management of change (e.g. in a document), in order to maintain the integrity of the management system.

6. Resource requirements

6.1. General requirements

The requirement of the standard applies.

6.2. Personnel

6.2.1. The requirement of the standard applies.

In the case of personnel not directly employed by the laboratory (for example, freelance professionals, or personnel formally employed by another area of the same company or by a different legal entity but operationally assigned to the laboratory, as in cases of secondment or temporary assignment), the laboratory must assess the risks associated with this organisational arrangement and must demonstrate that it has full availability of such personnel for the performance of the relevant laboratory activities.
In these cases, there must be a written agreement between the laboratory and the professional/area/supplying company that provides for specific conditions guaranteeing the full integration of the external personnel into the laboratory's management system, including those relating to competence, impartiality, confidentiality and the modalities for authorisation to carry out the activities.

If personnel carry out activities remotely, the laboratory, within its management system, must define the operating modalities and the tools adopted to ensure the confidentiality of information and compliance with the applicable requirements.

6.2.2 The requirement of the standard applies.

See § 5.5 of this document.

In defining the competence requirements of the personnel, the laboratory must consider any mandatory requirements and/or requirements for registration in professional rolls or registers (for example: professions organised in professional orders or associations, non-destructive tests, acoustic technicians, ATP technicians, asbestos).

6.2.3. The requirement of the standard applies.

6.2.4. The requirement of the standard applies.

6.2.5. The requirement of the standard applies.

6.2.6. The requirement of the standard applies.

An example of a record of authorisations can be a summary table showing the personnel authorised for the performance of individual tests, sampling, internal calibration, validation and statements of conformity, with evidence of acceptance by the personnel themselves.

6.3. Facilities and environmental conditions

6.3.1. The requirement of the standard applies.

The laboratory must demonstrate the full availability of the premises in which laboratory activities take place, which must be for its exclusive use (with the exception of off-site tests).

6.3.2. The requirement of the standard applies.

For defining the requirements relating to environmental conditions, it should be remembered that for some testing sectors there are support guides (e.g. ISO 7218, the Eurachem guide “Accreditation for Microbiological Laboratories” for microbiological analyses, EA-4/09 for sensory analyses, etc.). Furthermore, in addition to the testing/sampling methods, equipment manuals and material storage instructions may also specify particular conditions that must be met.

6.3.3. The requirement of the standard applies.

6.3.4. The requirement of the standard applies.

6.3.5. The requirement of the standard applies.

6.4. Equipment

6.4.1. The requirement of the standard applies.

6.4.2. The requirement of the standard applies.

All the equipment necessary for correctly performing laboratory activities and that may affect results, including that for internal calibrations, must be the property of the laboratory.

For equipment used for accredited activities, it is permitted that, although not the property of the laboratory, it is transferred for the laboratory’s exclusive use, which must have full availability of the equipment and of the related documentation. These conditions must be documented in a contract (e.g. leasing, loan for use, tender specifications, service, use and maintenance), signed by the owner of the equipment, with a minimum duration of one year.

6.4.3. The requirement of the standard applies.

6.4.4. The requirement of the standard applies.

6.4.5. The requirement of the standard applies.

6.4.6. The requirement of the standard applies.

The laboratory must define, according to the specifications of the tests/calibrations it will carry out, the requirements and acceptability criteria relating to deviations, uncertainties, etc., both for internal calibrations and for those outsourced to external centres.

Regarding equipment such as incubators, heating cabinets, climate chambers, the thermometer/data logger used for temperature control inside the equipment must be calibrated. Furthermore, it should be remembered

that verifying the homogeneity of the temperature inside the equipment is a preliminary evaluation, to be carried out in order to establish whether the equipment keeps the temperature of interest within the limits indicated by the method.

6.4.7. The requirement of the standard applies.

The calibration programme must be documented and must include the calibration schedule and the related responsibilities.

6.4.8. The requirement of the standard applies.

6.4.9. The requirement of the standard applies.

6.4.10. The requirement of the standard applies.

6.4.11. The requirement of the standard applies.

6.4.12. The requirement of the standard applies.

6.4.13. The requirement of the standard applies.

It should be remembered that the laboratory must define the criteria for establishing the period of validity of materials after opening, where this information is not already specified by the supplier.

6.5. Metrological traceability

The requirements of the standard apply.

Below are clarifications on the metrological traceability policy based on ILAC P10.

a) Calibration of measuring instruments and reference standards

In accordance with the provisions of document ILAC P10, when metrological traceability of results is required, the equipment must be calibrated by:

1 - National metrology institutes and designated institutes (NMI) whose services are suitable and covered by the CIPM-MRA agreement[2] within the limits of the metrological capabilities (CMC) internationally accepted and published in the KCDB by the BIPM[3].
The presence of the CIPM MRA note and/or logo on the calibration certificates demonstrates the coverage of the CMCs; where the note and/or logo are not present, since their inclusion is discretionary, the laboratory must verify the coverage of the CMCs by consulting the BIPM website at: www.bipm.org or kcdb.bipm.org.

2 - Accredited calibration laboratories whose services are suitable and whose accreditation is issued by accreditation bodies (AB) signatory to the EA-MLA or ILAC-MRA agreement for “calibration” scope within the

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[2] **CIPM-MRA**: CIPM Mutual Recognition Arrangement – Mutual recognition among National Metrological Institutes

[3] **KCDB**: BIPM Key Comparison Database: contains information on internationally accepted metrological capabilities (CMCs)

framework and the limits set by the CMC published by the AB.
The use of calibration certificates issued within the framework of these two possibilities is to be deemed of equal validity, without prejudice to the different value of the calibration uncertainties, which must be adequate for the needs of the laboratory.

If it is not possible to obtain metrological traceability from either of the two cases above, the following alternatives are permitted, provided that appropriate evidence is available on the competence of the supplier and particularly on the traceability and the measurement uncertainty of the calibrations supplied:

3a - NMIs whose services are suitable but not covered by the CIPM-MRA agreement. This case should not be chosen on the basis of purely economic or logistical reasons, but should be considered as a last resort when cases 1 and 2 are not available.

3b - Calibration laboratories whose services are suitable but not covered by ILAC agreements or by regional agreements recognised by ILAC. This option must be chosen only in cases in which suppliers of type 1, 2 and 3a are not available. The modalities with which the CAB has assessed the supplier are subject to assessment by ACCREDIA.

In cases 3a and 3b, laboratories must ensure evidence of the declared metrological traceability and measurement uncertainty; such evidence is subject to assessment by ACCREDIA (see the guide set out in ILAC P10 Appendix A).

Calibrations carried out by the equipment manufacturer or by other laboratories not accredited for the specific calibrations are not accepted, except in case 3b indicated above.

b) Use of certified values of certified reference materials

Where metrological traceability is provided by Reference Material Producers (RMP), through certified reference materials (CRM), it is considered, in accordance with ILAC P10, that the certified values assigned to CRMs have valid metrological traceability when:

4 - the CRMs are produced by NMIs through a service included in the BIPM KCDB.
The presence of the CIPM MRA note and/or logo on the reference material certificates demonstrates the coverage of the CMCs; where the note and/or logo are not present, since their inclusion is discretionary, the laboratory must verify the coverage of the CMCs by consulting the BIPM website at: www.bipm.org or kcdb.bipm.org.

5 - the CRMs are produced by an RMP accredited in accordance with ISO 17034 within its field of accreditation, and the relevant accreditation body is a signatory to the ILAC-MRA or to regional agreements recognised by ILAC.

6 - the certified values assigned to the CRMs are supported by entries in the JCTLM database (in www.bipm.org).

If it is not possible to find CRMs falling within the three cases above, the laboratory may have recourse to producers whose competence it must assess (as suppliers, ref. § 6.6), in relation to their use. The extent of

the checks made by the laboratory regarding the producer depends on the information available, as well as on the nature and criticality of the material in relation to its intended use.

If it is not technically possible to document metrological traceability to the SI system by using a CRM, as described above, what is described in ILAC P10 applies at the following points:

7a - use certified values of certified reference materials, supplied by a competent producer;

7b - provide evidence of adequate comparison with reference measurement procedures, specified methods or consensus references clearly described and accepted as suitable for the intended use.

With reference to note 5 of ILAC P10, it should be remembered that: excess proficiency test (PT) materials are often available from the providers (PTPs). The laboratory should verify whether the PT provider can supply additional information on stability, in order to demonstrate the continued stability of the property value and of the matrix of the test material. If this cannot be provided, these test materials should not be considered as an alternative way to ensure the validity of results.
It should be noted that if the assigned value of the PT is determined on the basis of the consensus value of the participants, and the PT participants have used different measurement procedures, and the result is operationally defined, this assigned value cannot be used to establish the metrological traceability of the results (see also ISO Guide 35).

c) Internal calibrations

If the laboratory performs internal calibrations:

- the reference standards/materials must have metrological traceability in accordance with the indications given above, for the quantities of interest, for appropriate measurement ranges and uncertainties;
- the reference standards must be used only for calibrations and for intermediate checks of the calibration status;
- it must operate according to suitable calibration procedures and make use of competent personnel.

An internal calibration is also one performed by personnel external to the laboratory, provided that the laboratory possesses the reference standards/materials and has incorporated into its management system the calibration procedures used.

The calibration procedures, in addition to the instructions relating to calibration operations, must, where applicable, provide indications (or contain references to other documents) for:

- the protection of any adjustments that could be tampered with, where applicable;
- the completion of calibration reports (ref. § 7.8.2 and § 7.8.4);
- the instructions for affixing labels or other identification of the calibration status;
- the evaluation of results (acceptability criteria) and the actions to be taken in the event of results that do not comply with the specifications.

It should be remembered that the calibration procedures developed by the laboratory must be validated according to an appropriate documented validation procedure, and the laboratory must keep the related records (ref. § 7.2.2.1 of this document).

For calibration reports see § 7.8.4.

6.6. Externally provided products and services

6.6.1. The requirement of the standard applies.

6.6.2. The requirement of the standard applies.

6.6.3. The requirement of the standard applies

7. Process requirements

7.1. Review of requests, tenders and contracts

7.1.1. The requirement of the standard applies.

In the sub-paragraphs below, clarifications are provided regarding certain specific aspects.

7.1.1.1. Meaning of accreditation and principle of transparency

The laboratory must inform the customer of the meaning of accreditation and of the accreditation of the activities that are the subject of the tender/contract.

All activities covered by accreditation must be contractually managed as accredited (see § 7.8.3, DT-09-DL and RG-09), unless the customer explicitly requests otherwise. In this case, the customer's request must be clearly indicated in the contractual agreements (ref. EA 3/01).

Where the laboratory also has a certified management system, the requirements for users of accredited certification services, set out in § 7 of Regulation RG-09, apply.

In the event of **suspension** (partial/total, including self-suspension), or other sanctioning measures, the laboratory is required to review the existing contracts and to inform the customers involved of the measure taken against it.

7.1.1.2. Identification of the customer/any intermediaries

Where the testing services subject to accreditation are offered and/or contracted through an intermediary, the contractual documents must clearly indicate, without prejudice to all the other applicable requirements of UNI

CEI EN ISO/IEC 17025, both the identity of the customer (intermediary) and that of the recipient of the RdP[4].

Customer/intermediary means the party that requests the tests from the laboratory; recipient means the party to whom the RdP must be addressed (e.g. the operator of the business at which food samples are taken; the manufacturer, importer or purchaser of a machine under test; the owner of the site at which noise measurements are carried out).

7.1.1.3. Definition of the modalities for reporting results

At the stage of review of requests, tenders and contracts, the laboratory must define with the customer the modalities for reporting results:

- any modalities for reporting results adopted, if different from the issue of complete RdPs (see § 7.8 and DT-09-DL);
- any need for immediate communication of any out-of-limit results (non-conforming with specifications) and the related modalities;
- situations in which the laboratory must interrupt the testing activity before providing the final results[5]. In this case, whether or not to continue must be provided for contractually or be the subject of subsequent reviews of the contract, and, in the case of non-completion, the modalities for reporting results must also be clarified.

7.1.1.4. Definition of retention times

The laboratory must define contractually, where there are no normative provisions in this regard, the retention times of the samples, of any counter-samples and of the technical records relating to the tests that are the subject of the contract. Where the information is provided by public communication (e.g. website), it must be referred to in the contractual agreements.

7.1.1.5. Requests for opinions and interpretations

For **requests for opinions and interpretations**, at the stage of review of requests, tenders and contracts the laboratory must:

- verify that the laboratory activities used to express the opinions and interpretations are accredited;
- clarify that the opinions and interpretations will be released by the laboratory on the basis of the results of the tested sample and that they cannot be used as the sole input for product certification. Product certification, in fact, also requires other information.

.....

[4] The terms indicated in the text (customer, recipient, intermediary) are to be considered preferable. Other uses/terminologies by the laboratory must be such as to avoid misunderstandings.

[5] E.g. for product standards that provide for the execution of several tests in series and preliminary to one another, and in the case of failure of one test, it may not be necessary to continue with the execution of the others.

7.1.1.6. Activities outsourced to external laboratories

When the laboratory intends **to outsource to external laboratories**:

- activities for which it is accredited, for unforeseen and exceptional reasons (e.g. sudden failure of equipment),
- activities for which it is not accredited, but which are outsourced to accredited external laboratories, and it reports on the test report the reference to the accreditation of the external laboratory[6] (cf. § 7.8.2.1 and DT-09-DL),

it must comply with the following conditions:

a. inform the customer in advance, and obtain written consent;
b. verify the competence of the external laboratory to perform the test/sampling (the accreditation of the subcontractor by an accreditation body signatory to the EA MLA or ILAC MRA mutual recognition agreements, for the subcontracted activity, demonstrates its competence);
c. state on the test report that the test/sampling has been outsourced to an external laboratory (performed by subcontract).

The modalities for indicating externally outsourced activities on the RdPs are set out in § 7.8 (see also DT-09-DL).

7.1.2. The requirement of the standard applies.

7.1.3. The requirement of the standard applies.

The laboratory cannot exclude a priori issuing statements of conformity if requested by the customer, unless it is prohibited by mandatory provisions.

Where decision rules can be chosen, the laboratory must discuss with the customer the levels of risk regarding the probability of false acceptance and false rejection associated with the available decision rules.

The decision rule must therefore be technically and statistically consistent with the type of testing sector to which it refers; it must be (like the test method) appropriate for the purpose of the test, technically justified, not compromise the impartiality of the laboratory's operations, take account of any legislative requirements and not have a negative impact on the market. Where it is not, the laboratory must discuss it with the customer, may refuse it and propose a more suitable one.

7.1.4. The requirement of the standard applies.

7.1.5. The requirement of the standard applies.

7.1.6. The requirement of the standard applies.
During the review of the contract with the customer, the timeframes established may also be redefined.

7.1.7. The requirement of the standard applies.

.....

[6] In this case the external laboratory must be accredited for the specific activity entrusted to it.

7.1.8. The requirement of the standard applies.

7.2. Selection, verification and validation of methods

7.2.1. Selection and verification of methods

7.2.1.1. The requirement of the standard applies.

Where a legislative requirement provides for a particular method for a given purpose, the laboratory is required to use it.

It should be remembered that the laboratories in charge of official control (e.g. of food products) are required to verify that all the test methods comply with what is established in the specific Directives/Regulations in force.

It is possible to apply for accreditation while maintaining **the references to the official/standard/non-standardized method** in the following cases:

- modifications such as to improve its performance without distorting its principle/technique (e.g. use of equipment with better resolution and stability, reference materials and reagents of higher purity), duly verified;
- use outside the measurement range (e.g. increasing the upper limit), provided that this modification is subject to validation;
- use outside the indicated field of application, if comparable (matrix), provided that this modification is subject to validation;

It should be remembered that some methods indicate the possibility of extending their use to the determination of additional unforeseen parameters; the laboratory may add them after validating them.

The following types of changes to official/standard/non-standardized methods result in their **management as a method developed by the laboratory**:

- modifications involving equipment based on a different technique (e.g. replacement of atomic absorption with ICP, change of detector from FID to MS);
- other substantial modifications, such as: elimination of testing phases, use of equipment with lower performance than expected, replacement of reagents/materials with others not included in the method.

Occasional deviations from the test method, related to the particular nature of a sample, must be reported on the test report.

7.2.1.2. The requirement of the standard applies.

7.2.1.3. The requirement of the standard applies.

Editions no longer in force of standards or official test methods, and drafts of standards (including final drafts and “final draft” documents submitted to the “formal vote”), must be converted into test methods developed by the laboratory. An exception is made for superseded editions of standards when they are referred to by mandatory provisions, by tender specifications of the Public Administration, or by product certification standards in force, or are required by notified bodies.

On the other hand, if the customer, even in the absence of mandatory provisions, requests that a superseded test method be performed under accreditation, the laboratory may apply for its accreditation, provided that the current method is also accredited.[7]

Any additions, updates, modifications or errata - of a substantial nature - of standards are an integral part of them, both for the purposes of the application for accreditation and for the reporting of results.

It is not permitted to refer only to mandatory regulations when these contain incomplete indications which, for example, refer only to the test technique and do not give full details of the execution modalities; in such cases the laboratory will indicate, in the application for accreditation and on the test reports, the reference to the mandatory regulations and to a standard, non-standardized or laboratory-developed method that contains all the necessary information (see § 7.2.1.1).

7.2.1.4. The requirement of the standard applies.

7.2.1.5. The requirement of the standard applies.

If the performance characteristics of the methods have not been defined, the laboratory must determine them.

The laboratory must verify that it maintains the required performance over time (see § 7.7 of the standard).

It should be remembered that for certain applications the performance characteristics may be contained in mandatory requirements.

7.2.1.6. The requirement of the standard applies.

The laboratory that requests accreditation for tests performed according to laboratory-developed test methods must send ACCREDIA a copy of those methods, accompanied by the statement of validation and suitability (a summary of what is described in point 7.2.2.4 of the standard). Each revision must be sent to ACCREDIA; if the laboratory does not send this documentation to ACCREDIA, the relevant tests will be excluded from accreditation.

Laboratory-developed methods must contain, where applicable, all the information necessary for carrying out the test:

a. appropriate identification (see RT-23);
b. scope and field of application;
c. description of the type of object to be tested or calibrated;
d. parameters or quantities and measurement ranges to be determined;
e. facilities and equipment, including technical performance requirements;
f. required reference standards and reference materials;
g. environmental conditions and any required stabilisation period;
h. description of the procedure, including:

- affixing identification marks, handling, transport, storage and preparation of the objects to be tested,

.....

[7] Exceptional situations, linked for example to product standards, must be expressly authorised by ACCREDIA.

- checks to be carried out before starting activities,
- checks on the proper functioning of the equipment and, if required, on its calibration and adjustment before use,
- methods for recording observations and results,
- all the safety measures to be observed;

i. criteria and/or requirements for approval/rejection;
j. data to be recorded and methods of analysis and reporting;
k. uncertainty or uncertainty estimation procedures.

It should be noted that, for some sectors, technical standards are available that provide guidance for drafting laboratory-developed methods (e.g. ISO 78-2).

7.2.1.7. The requirement of the standard applies.

7.2.2. Validation of methods

7.2.2.1. The requirement of the standard applies.

a) **Standard methods** and **official methods** are considered validated by the body that issued them, unless the responsibility for the data provided lies not with the organisation that issued them but with the individual authors.

Where the method does not report the performance characteristics, the laboratory is required to determine them and to verify that they are adequate to meet the mandatory requirements and/or those of the customer.

b) **Non-standardized methods** must be validated by the laboratory.

Where the non-standardized method has been validated by an independent third-party organisation or by accredited product certification bodies (e.g. AFNOR), the laboratory must verify that it falls within the values of the performance parameters of the validation.

Methods validated by accredited national or EU reference / laboratories centres recognised by the central authority, may be used by other laboratories without further validation provided that:

- those methods fall within the scope of accreditation of the laboratory that validated them;
- they contain at least the repeatability and reproducibility limits (or intermediate repeatability);
- they are made available by the reference laboratory, in the version in force, accompanied by the statement of validation;
- the statement of validation of the reference laboratory is up to date (date of issue not more than 3 years);
- the laboratory applying them has verified that it is able to perform them in its own laboratory, obtaining results within the limits defined by the method (precision data);
- the laboratory applying them has verified that the performance characteristics that depend on the laboratory and not on the method (such as those depending on the type and condition of the equipment the laboratory uses, the ability of the personnel authorised to perform the test, the environmental conditions of the laboratory, the quality of the reagents and materials the laboratory uses, the test

procedure defined by the laboratory) are compatible with those obtained during the validation of the method.

c) **Laboratory-developed methods** must be validated by the laboratory, in accordance with the indications of note 2 to point 7.2.2.1 of the standard.

If the method includes sampling, handling, transport, the validation must also include these phases.

The statement of validation of the method must contain a summary of the data indicated in point 7.2.2.4 of the standard.

If the calibration procedures used by the laboratory are of external origin (provided by calibration centres accredited by bodies signatory to the EA or ILAC mutual recognition agreements, by the equipment manufacturer, standards, guides), their validation is not necessary. Calibration procedures developed autonomously by the laboratory must be validated.

7.2.2.2. The requirement of the standard applies.

The laboratory must define the criteria for the periodic review of the validation of methods (e.g. positive results from proficiency tests, confirmations from tests on reference materials), both in terms of frequency and of the compatibility of the results obtained.

7.2.2.3. The requirement of the standard applies.

Guidance documents for the validation of methods have been published, for example, by EURACHEM and by other organisations.

In addition, for laboratories operating in the field of official control of food products there are specific EU provisions such as, for example, Commission Decision 2002/657/EC, SANTE documents.

7.2.2.4. The requirement of the standard applies.

7.3. Sampling

7.3.1. The requirement of the standard applies.

Sampling can be accredited only if associated with a subsequent accredited test.

The following situations may occur:

1. The sampling modalities are specified in a standard or official method that is different from the one for the determination (e.g. ISO 18593, UNI EN 1948-1).

   In this case, the following conditions must be met:

   - the subsequent test associated with the sampling must be carried out under UNI CEI EN ISO/IEC 17025 accreditation, either because it is accredited by the laboratory itself or because it is carried out by another testing laboratory accredited for the specific test;
   - the method used for the subsequent associated test must be chosen in compliance with the indications of the sampling method, where applicable, and in any case with what is provided for by Regulation RT-23 regarding the combination of methods;

- the laboratory undertakes to agree with the customer, at the contractual stage, the subsequent tests associated with the sampling and to comply with what is indicated in § 7.1.1, with the clarification that, for point b) of § 7.1.1, the external laboratory must be accredited according to the standard UNI CEI EN ISO/IEC 17025 for the specific test.

2. A method includes, within itself, both the sampling and the determination.
   In this case the laboratory may:

   - request accreditation of the entire method (sampling + determination);
   - request accreditation of the analytical determination only, explicitly excluding the section relating to sampling.

It is advisable that the laboratory provide the customer, where the customer carries out the sampling, with suitable assistance (sampling instructions and related records, containers, etc.).

7.3.2. The requirement of the standard applies.

7.3.3. The requirement of the standard applies.

7.4. Handling of test or calibration items

7.4.1. The requirement of the standard applies.

The laboratory must retain the samples on which it has performed the test and/or any counter-samples and the technical records relating to the tests carried out, for the time agreed with the applicant, or established by the relevant laws or ordered by the Judicial Authority (cf.7.1.1.).

7.4.2. The requirement of the standard applies.

7.4.3. The requirement of the standard applies.

7.4.4. The requirement of the standard applies.

The laboratory must have adequate segregation areas to store unsuitable samples.

7.5. Technical records

7.5.1. The requirement of the standard applies.

For the retention times of technical records see § 8.4 of this document.

7.5.2. The requirement of the standard applies.

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

7.6. Evaluation of measurement uncertainty

7.6.1. The requirement of the standard applies.

If the laboratory requests accreditation for sampling activity only (see § 7.3) it must make available the information necessary for the subsequent calculation of the measurement uncertainty associated with the result.

7.6.2. The requirement of the standard applies.

If the laboratory performs internal calibrations, the uncertainty must be determined in accordance with the JCGM 100 guide, or the EA-4/02 guide, or according to the provisions of the technical sector standards.

7.6.3. The requirement of the standard applies.

When a standard/non-standardized/official method reports the statistical parameters of the validation (repeatability standard deviation and reproducibility standard deviation) and the laboratory decides to use them for the calculation of measurement uncertainty, it must at least verify that its performance is compatible with those indicated (e.g. repeatability, trueness).

For chemical tests, it is important to verify that the concentration level for which the reproducibility is reported is close to the test result, since the uncertainty (and the reproducibility, which provides an estimate of it) may be a non-linear function of the concentration (e.g. Horwitz law); it is therefore not always correct to express uncertainty in relative terms over the entire field of application of a method, when it has been determined only at one concentration value.

The laboratory must check that the uncertainty to be associated with the result has been evaluated at levels that are significant for the customer (e.g. legal limits) and must also compare the repeatability limit, of the method or calculated by the laboratory, with the value of the measurement uncertainty (2U>r).

It is also important to verify that the evaluated uncertainty is consistent with the performance data available in the literature, where existing (e.g. reported in the method, obtained from participation in appropriate interlaboratory comparisons, etc.).

Some reference documents for the evaluation of measurement uncertainty are listed in note 3 of the standard. For specific sectors, dedicated documents and guidelines are available.

7.7. Ensuring the validity of results

7.7.1. The requirement of the standard applies.

7.7.2. The requirement of the standard applies.

The laboratory must, where possible, have recourse to providers of interlaboratory proficiency tests (proficiency testing – PT) that operate in compliance with the standard UNI CEI EN ISO/IEC 17043 (for example by using providers accredited for this activity or that declare that they operate in compliance with the above-mentioned standard).

For the policy on participation in PT see ACCREDIA Regulation RT-39. It should be remembered that, for the purposes of the granting or extension of accreditation, results of comparisons with other laboratories must be available (in relation to the groupings defined by the laboratory and, where applicable, as provided for by RT-

39). Recourse to proficiency tests with a single participant (e.g. so-called rapid PTs or similar denominations) is permitted only where traditional PTs are not available.

Participation in PT may be requested by ACCREDIA from laboratories undergoing accreditation or already accredited, as an element of assessment for the granting or maintenance of accreditation.

The laboratory must plan its participation in PT by means of a risk-based approach.

If the laboratory performs **internal calibrations**, this activity must be considered within the risk analysis, in relation to the potential impact on the validity of test results.
By way of example, the following cases may be considered:

a. **the internal calibration directly affects the test result** (e.g. mechanical tests in which the test set-up and the calibration of the instrumentation are an integral part of the test itself). In this case, the laboratory should evaluate participation in PT/ILC relating to calibration, depending on availability, suitability and feasibility. If such participation is not carried out, the laboratory should document the reasons in its risk analysis.
b. **the internal calibration is not an integral part of the test, but represents a critical element** of the test process because it contributes to ensuring the metrological traceability of the measurements used, while not constituting a significant contribution to the measurement uncertainty of the result (e.g. calibration of the balances used for tests in which the result depends on weighing, such as the determination of dry residue or of the skeleton). In this case, the laboratory should define the frequency of participation in PTs relating to the tests for which the instrumentation subject to the internal calibration is used, on the basis of the associated risk and, where deemed appropriate, also evaluate participation in PTs or ILCs relating to calibration.
c. **the internal calibration has a negligible impact** on the validity of the test results. In this case, the risk deriving from non-participation in PTs or ILCs for the calibration may be considered low and, where adequately justified by the laboratory, does not require further mitigation measures.

For the use of material derived from previous PTs, see § 6.5 of this document (ref. ILAC P10 note 5).

7.7.3. The requirement of the standard applies.

7.8. Reporting of results

The requirements of the standard apply.

Specific indications for the application of the individual requirements of the standard relating to the reporting of results are given in document DT-09-DL.

It is specified that, in this document and in DT-09-DL, test reports are referred to by the acronym RdP, and the indications given for test reports are also to be understood as relating to sampling reports, as far as applicable.

7.9. Complaints

7.9.1. The requirement of the standard applies.

7.9.2. The requirement of the standard applies.

7.9.3. The requirement of the standard applies.

7.9.4. The requirement of the standard applies.

7.9.5. The requirement of the standard applies.

7.9.6. The requirement of the standard applies.

7.9.7. The requirement of the standard applies.

7.10. Nonconforming work

7.10.1. The requirement of the standard applies.

7.10.2. The requirement of the standard applies.

7.10.3. The requirement of the standard applies.

Where **nonconformities occur that could lead to the suspension of testing/sampling activity or cast doubt on the validity of the results of accredited tests** (e.g. negative evaluations of participation in interlaboratory comparison programmes, unavailability or deterioration of resources), the laboratory must notify ACCREDIA of the self-suspension of accreditation for those tests, until ACCREDIA has positively verified the corrective actions taken, using form MD-09-53-DL available on the ACCREDIA website.

In the case of nonconformities found in test reports already issued, which could prejudice the use of the results by customers (e.g. nonconformities of a technical nature, or relating to the reference to accreditation), the laboratory must identify the test reports affected by the same nonconformity and notify the customers by issuing replacement test reports (see also § 7.8 and DT-09-DL).

7.11. Control of data and information management

7.11.1. The requirement of the standard applies.

7.11.2. The requirement of the standard applies.

The extent and depth of the validations to be performed on an externally provided system are commensurate with the evidence that the producer is able to provide regarding the conformity of the system.

7.11.3. The requirement of the standard applies.

7.11.4. The requirement of the standard applies.

The laboratory must communicate to the external provider or to the operator of the system, in the case of systems managed by the organisation of which the laboratory is a part, the applicable requirements, including those relating to confidentiality, integrity and accessibility of information maintained off-site.

7.11.5. The requirement of the standard applies.

7.11.6. The requirement of the standard applies.

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

8. Management system requirements

8.1. Options

8.1.1. General

The requirement of the standard applies.

During the phases of first accreditation and renewal, the laboratory must provide ACCREDIA with sufficient information to allow an understanding of how the laboratory operates to achieve and maintain compliance with the requirements of UNI CEI EN ISO/IEC 17025 and of ACCREDIA.

To this end, the laboratory may prepare a Management System Manual or a self-assessment on the relevant ACCREDIA forms (self-assessment), which, with reference to the individual requirements for accreditation, contains at least:

- the roles/functions responsible for carrying out the activities necessary to achieve and maintain compliance with the requirements for accreditation;
- a concise description of the activities carried out by the laboratory, without excessive reference to procedures and annexes;
- which records are established in the management system, to give evidence of compliance with the requirements for accreditation;
- the activities carried out at secondary sites, or at temporary sites, in the case of a multisite laboratory;
- any exclusions or non-applicability of certain requirements, together with the relevant justifications.

Where abbreviations or acronyms appear in the Management System Manual or in the self-assessment, the laboratory must provide ACCREDIA with an explicit written indication of them.

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

It is specified that the self-assessment is a form prepared by ACCREDIA and completed by the laboratory for the purpose of submitting the application for accreditation and, as such, is not a document of the laboratory's management system. Therefore, if the laboratory decides to remove the Manual from its management system, it must review its documentation, in order to ensure the organised and consistent structure of the system itself.

The clarifications given in the following paragraphs must also be applied by laboratories that adopt Option B.

8.1.2. Option A

The requirement of the standard applies.

8.1.3. Option B

Attention is drawn to what is provided for in § B.3 of Annex B of the standard.

8.2. Management system documentation (Option A)

8.2.1. The requirement of the standard applies.

8.2.2. The requirement of the standard applies.

8.2.3. The requirement of the standard applies.

8.2.4. The requirement of the standard applies.

8.2.5. The requirement of the standard applies.

8.3. Control of management system documents (Option A)

8.3.1. The requirement of the standard applies.

In the case of updates of documents of external origin (e.g. standards, methods, laws, regulations), unless otherwise indicated, the laboratory is required to apply the new versions within three months of their issue. For ACCREDIA documents, the laboratory is required to apply the new versions by the date of entry into force, explicitly indicated on the document itself and/or in the notice of issue.

8.3.2. The requirement of the standard applies.
Handwritten corrections are permitted on documents for internal use only, where their urgency is recognised. Such amended documents must be promptly updated.

8.4. Control of records (Option A)

8.4.1. The requirement of the standard applies.

8.4.2. The requirement of the standard applies.

All records must be retained for a minimum period of 48 months, where there are no more onerous mandatory or contractual obligations, including external records (e.g. calibration certificates, reference material certificates, proficiency testing reports).

The retention times of technical records must ensure the traceability of information relating to accredited activities and must therefore be consistent with the retention timeframes of the test reports and with any legal requirements.

Data relating to the validations and performance verifications of methods must be retained for the whole period of use/validity of the methods themselves. In the case of revisions of the methods, the reviews of the validations/verifications and all the records that ensure the traceability of the activities carried out must be retained.

Data relating to calibrations should be retained for the life of the measuring equipment, since on the basis of these data the calibration frequencies can be established or modified.

8.5. Actions to address risks and opportunities (Option A)

8.5.1. The requirement of the standard applies.

Reference should be made to what is provided for in the introduction of the standard regarding the identification of risks and opportunities.

8.5.2. The requirement of the standard applies.

8.5.3. The requirement of the standard applies.

8.6. Improvement (Option A)

8.6.1. The requirement of the standard applies.

8.6.2. The requirement of the standard applies.

8.7. Corrective actions (Option A)

8.7.1. The requirement of the standard applies.

It should be remembered that the verification of the effectiveness of corrective actions is different from the verification of their implementation.

It should be remembered that the corrective actions planned and communicated following second- and third-party assessments (e.g. ACCREDIA) must also be managed within the laboratory's management system.

8.7.2. The requirement of the standard applies.

8.7.3. The requirement of the standard applies.

8.8. Internal Audits (Option A)

8.8.1. The requirement of the standard applies.

8.8.2. The requirement of the standard applies.

The choice of auditors and the conduct of audits must ensure the objectivity and impartiality of the internal audit process. It is therefore advisable, where resources permit, that internal audits be conducted by personnel who are independent of the area being audited.

Evidence (CVs and attestations) must be provided of the auditors' education, training and experience with respect to the standard UNI CEI EN ISO/IEC 17025 and the requirements for accreditation.

Second- and third-party audits cannot replace the laboratory's internal audits. In any case, the outcomes of external audits must also be taken into account for the planning, with a risk-based approach, of internal audits.

8.9. Management review (Option A)

8.9.1. The requirement of the standard applies.

Extraordinary reviews may become necessary following findings whose corrective actions entail special investments (e.g. purchase of new equipment, hiring of staff) or structural organisational changes (e.g. laboratory layout, reorganisation of personnel).

8.9.2. The requirement of the standard applies.

8.9.3. The requirement of the standard applies.

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