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L'ENTE ITALIANO DI ACCREDITAMENTO

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

PREPARATION

THE DEPARTMENT OF TESTING LABORATORIES

APPROVAL

THE DIRECTIVE COUNCIL

AUTHORIZATION

THE PRESIDENT

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Errata corrige due to a mistake on pag. 4, pag. 11 and pag. 15.

0. INTRODUCTION

0.1 GENERAL

This document defines the general criteria for the accreditation of testing laboratories by the ACCREDIA Department of Testing Laboratories.

The objective of the application of these criteria is to favour the creation and maintenance of the trust and confidence of clients, operators and users in the activities of accredited testing laboratories as well as in the impartiality and integrity of the technical and commercial operations associated with them. ACCREDIA accreditation is granted to laboratories operating in compliance with UNI CEI EN ISO/IEC 17025 and with the provisions of this document and other ACCREDIA, EA and ILAC regulatory documents.

Accreditation attests the technical competence of the laboratory to perform the tests in the scope of accreditation.

1. SCOPE AND FIELD OF APPLICATION

1.1. 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 it 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 for certain testing sectors may be defined in the mandatory standards, both national and International (EA, ILAC, ISO, EN, UNI, CEI, etc.).

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

1.3. In order to obtain and maintain accreditation, the laboratory must demonstrate that it is in full compliance with the requirements of the standard, other than those which it declares to be inapplicable, giving reasons, for all the activities defined in the scope of application of the accreditation.

1.4. The laboratory must comply with this document, with ACCREDIA regulation RG-09 with regard to use of the accreditation mark and with any other applicable document (e.g. RT-23, RT-24, RT-26).

2. NORMATIVE REFERENCE DOCUMENTS

The complete list of reference documents (LS-04) is available on ACCREDIA's website – www.acccredia.it.

For some technical sectors there are specific documents for the application of UNI CEI EN ISO/IEC 17025. These documents, unless specified as being mandatory, are guidelines and do not constitute additional requirements but they help in the consistent application/interpretation of existing requirements. However, if the lab decides not to apply them it must be able to demonstrate the validity and adequacy regarding the scope of its activities.

It is the lab's responsibility to check that the documents referred to are in their current version.

3. TERMS AND DEFINITIONS

The definitions contained in ISO IEC 17025 are applicable as well as the reference standards UNI EN ISO 9000, UNI CEI EN ISO/IEC 17000, UNI CEI 70099, UNI CEI EN 45020) and Reg.(CE) n. 765/2008.

Some definitions are given below:

3.1. Client/applicant: Party for which the laboratory conducts accredited tests.

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

3.3. Testing phase: Every individual part into which a test can be physically divided. For example, in a chemical test the following are considered as sampling phases: sampling, pre-treatment of sample, dissolution, extraction, reaction, final measurement, confirmation tests.

3.4. Testing technique: Technique to identify the basic principle of the testing method.

Note: a testing method may be indicated by a number of techniques.

3.5. Testing method: Specific technical procedure for conducting a test.

3.6. Official test method: Test method referred to in the mandatory normative documents and/or published by the Italian (GU) or the European (GUCE) Official Journal, or in any case contained or mentioned in a document issued by a competent authority (e.g. ministry, regional or provincial authority etc.).

3.7. Standard testing method: method approved by national or international standardization bodies (e.g. UNI, CEI, CEN, ISO, UNICHIM, ASTM, AOAC, etc.) or by public authority entities (e.g. USDA, FDA, EPA, NIOSH, IUPAC, APHA, OIV, OIE, WHO, APAT, CNR, IRSA, ISPRA, NMKL etc.).

3.8. Non-standardized testing method: method issued by national or international technical organizations and developed by national or EU reference labs or cantres, or by accredited national centres. The basic distinguishing factor is that the responsibility of the data produced does not belong to the issuing organization but to the individual author.

3.9. Testing method developed internally by the lab: 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 a method developed by the lab or a standard or non-standard method which has been substantially modified in accordance with the special needs of the lab in question.

Articles published in journals are not considered official methods, or standardized because this is the responsibility of the authors and not of the editor.

Methods contained in journals or the instructions of suppliers of equipment must be considered as methods developed by the lab.

3.10. Testing/sampling procedure: Document containing the details and working modalities adopted by a laboratory not fully described in the standard testing/sampling method.

NOTE: this procedure does not constitute a modification of the testing/sampling method.

4. GENERAL REQUIREMENTS

4.1. IMPARTIALITY

The requirement of the standard is applied

In the application of the requirement it is necessary to take into consideration the contents of the note to § 8.5.2 of the standard.

4.2. CONFIDENTIALITY

The requirement of the standard is applied.

5. STRUCTURAL REQUIREMENTS

5.1. The requirement of the standard is applied

5.2. The requirement of the standard is applied

5.3. The requirement of the standard is applied

Accreditation is granted to a lab only for the activities it carries out itself and for which ACCREDIA assesses the competence.

The outsourcing of entire tests on a continuous basis is excluded from the field of accreditation. The non-continuous outsourcing of accredited activities is done only as in the cases specified in the first point of NOTE 1 of § 7.1.1. of the standard (unexpected reasons).

Accreditation cannot be issued for test phases which have not yet been performed: it is not possible to ensure fulfilment of the requirements 5.3 and 5.4 of the reference standard and, from a legal point of view, it would reduce the validity of the test result, and in case of an official check there would be a reduction to the legal validity of the sampling because it would not be possible to guarantee the right to defence on the part of the two accredited labs. Exception is made for sampling[1] as defined in § 7.3.

The lab cannot exclude and/or outsource the confirmation phases either as they are described in the method (e.g. UNI EN ISO 6579-1) or if they are referred to in the applied method (e.g. AFNOR BIO 12/04-02/95). Exception is made for the confirmation phases which require testing on laboratory animals or if they have to be performed at national or EU labs/centers or national reference centers.

If a lab outsources activities to a lab which then outsources them to another lab it is not possible to consider the activities performed as being under accreditation.

5.4. The requirement of the standard is applied

5.5. The requirement of the standard is applied

[1] Kindly note that sampling is a laboratory activity ((rif. ISO/IEC 17025:2017)

The lab must have available an organization chart managed by the management system which clearly reflects its organization and the relations with other personnel who have influence on the lab's operations.

If the lab belongs to a larger organization there must also be a general organization chart which shows the laboratory's position.

In more complex organizations, some activities (for example the purchase of products and/or services or personnel selection) can be centralized or managed by the parent company or by other structures located outside or inside the laboratory (e.g. company/staff recruitment office). In this case, the laboratory must communicate to the staff in question the provisions of the applicable points of the standard (e.g. § 6.2, § 6.6.3, etc.), coordinating with them for compliance with the applicable requirements.

The lab must have available documents describing the tasks given, the authorizations, training and experience and other tasks covered by all members of the lab's staff who manage, carry out or verify work which influences the results of the lab's activities. Such documents must be submitted to the attention of personnel so that they are aware of the extent and the limits of their responsibilities;

5.6. The requirement of the standard is applied

The lab must ensure that the staff involved in the implementation and maintenance of the MS can adequately supervise – in terms both of logistics and of timelines – the MS so as to ensure that it is implemented and respected at all times.

5.7. The requirement of the standard is applied

The lab must define the modalities and responsibilities for the management of changes (e.g. to a document) in order to maintain the integrity of the MS.

6. REQUIREMENTS REGARDING RESOURCES

6.1. GENERAL REQUIREMENTS

The requirement of the standard is applied

6.2 PERSONNEL

6.2.1. The requirement of the standard is applied

6.2.2. The requirement of the standard is applied
See § 5.5 of this document.

In defining the competence requirements of the personnel, the laboratory must consider any mandatory requirements and/or registration in professional registers or (e.g. professions organized in orders or guilds, non-destructive tests, acoustic technicians, ATP technicians, asbestos).

6.2.3. The requirement of the standard is applied

6.2.4. The requirement of the standard is applied

6.2.5. The requirement of the standard is applied

6.2.6. The requirement of the standard is applied

An example of registration of authorizations can be a summary table, showing the authorized personnel for the performance of individual tests, sampling, internal calibration, validation, declarations of conformity, etc., with evidence of the assignment of tasks by the personnel in question.

6.3. FACILITIES AND ENVIRONMENTAL CONDITIONS

6.3.1. The requirement of the standard is applied

The laboratory must demonstrate the full availability of the premises in which its 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 is applied

For the definition of the environmental conditions, for some testing sectors, there are support guides (e.g. ISO 7218, Eurachem guide "Accreditation for Microbiological Laboratories" for microbiological analyses, EA-4/09 for sensory analyses etc.). As well as the testing/sampling methods, there are manuals for equipment and maintenance instructions of materials which can provide for certain conditions which have to be fulfilled.

6.3.3. The requirement of the standard is applied

6.3.4. The requirement of the standard is applied

6.3.5. The requirement of the standard is applied

6.4 EQUIPMENT

6.4.1. The requirement of the standard is applied

6.4.2. The requirement of the standard is applied

All equipment necessary for performing the lab's activities and which may affect results, including equipment for internal calibrations, must be the property of the lab.
For equipment used for accredited activities it is acceptable that, although not the property of the lab, the lab has exclusive use and the lab must have it available as well as the related documents. This must be formalized in a contract (e.g. leasing, renting etc.) signed by the owner of the equipment with validity of at least one year.

6.4.3. The requirement of the standard is applied

6.4.4. The requirement of the standard is applied

6.4.5. The requirement of the standard is applied

6.4.6. The requirement of the standard is applied

The lab must define, in line with the specifics of the testing/sampling to be performed, the acceptable requirements relating to deviations, uncertainties etc. both for internal calibrations and calibrations outsourced to external centers.
Regarding such equipment as incubators, heaters, climate chambers, the thermometer/logger data in the equipment must be calibrated. The control of consistent temperatures in the equipment is a preliminary evaluation for establishing whether the instrument keeps the temperature within the limits of the method.
For complex equipment such as spectrometry, GC, HPLC mass spectrometry, the calibration is done using suitable reference materials (see also § 6.5). For spectrometry, the verification of the wavelength and photometric accuracy are required by the methods.

6.4.7. The requirement of the standard is applied

The calibration program must be documented and must include the expiry dates for calibrations and the relative responsibilities.

6.4.8. The requirement of the standard is applied

6.4.9. The requirement of the standard is applied

6.4.10. The requirement of the standard is applied

6.4.11. The requirement of the standard is applied

6.4.12. The requirement of the standard is applied

6.4.13. The requirement of the standard is applied

The lab must define the criteria for establishing the period of validity of the materials after opening. In accordance with the scientific literature, it may define the revalidation criteria of materials after expiry.

6.5 METROLOGICAL TRACEABILITY

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

CALIBRATION OF MEASURING INSTRUMENTS AND REFERENCE SAMPLES

In accordance with ILAC P-10, when metrological traceability of results is required, the equipment must be calibrated by:

1 – National metrological institutes (NMI) whose services are suitable and covered by the CIPM MRA[2] agreement within the limits of the internationally accepted CMCs and published in the KCDB of 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 optional, the laboratory must verify the coverage of the CMCs by consulting the BIPM website at: www.bipm.org or kcdb.bipm.org.

[2] **CPM-MRA**: CIPM Mutual Recognition Arrangement – Mutual recognition among National Metrological Institutes
[3] **KCDB**: BIPM Key Comparison DataBase: contains information on internationally accepted metrological capabilities (CMC)

2 – Accredited calibration laboratories whose services are suitable and whose accreditation is issued by accreditation bodies (ABs) signatory to the EA-MLA or ILAC-MRA agreement for the purpose of calibration within the framework and the limits set by the CMC published by the ABs.

The use of calibration certificates issued within the framework of these two possibilities is to be deemed of equal validity granted the different value of the calibration uncertainties which must be adequate for the needs of the lab.

If it is not possible to obtain metrological traceability from neither of the two above possibilities, the following alternatives are acceptable as long as there is appropriate evidence available of the competence of the supplier especially with regard to the measurement traceability and uncertainty of the calibrations in question:

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 it should be considered as a last resort when cases 1 and 2 are not available.

3b – Calibration labs whose services are suitable but not covered by the ILAC agreement or regional agreements with ILAC recognition. 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 audited the supplier are subject to evaluation by ACCREDIA.

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

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

Use of certified values of certified reference materials

If metrological traceability is provided by Producers of Reference Materials (RMPs), through certified reference materials (CRMs), it is considered, in accordance with ILAC P10, that the certified values assigned to CRMs have valid metrological traceability when produced by:

4 - NMIs producing CRMs whose properties are included in the BIPM's KCDB.

The presence of the CIPM MRA note and/or logo on the certificates of reference materials demonstrates the coverage of the CMCs; where the note and/or logo are not present, since their inclusion is optional, the laboratory must verify the coverage of the CMCs by consulting the BIPM website at: www.bipm.org or kcdb.bipm.org. The values assigned to CRMs listed in the JCTLM database (at www.bipm.org) provide valid evidence of traceability.

5 - Reference material producers accredited in accordance with ISO/IEC 17034 who produce CRMs whose certified values are reported in the scope of accreditation.

6 - Organizations listed in the JCTLM database (at www.bipm.org).

If it is not possible to find CRMs that fall within the previous three cases, the laboratory may resort to producers whose competence it must assess (such as suppliers, ref. § 6.6), regarding their use. The range of the evaluations made by the laboratory regarding the manufacturer depends on the information available as well as on the nature of the material.

If it is not technically possible to document the metrological traceability to the SI System by using a CRM, as described above, the following points set out in ILAC P10 are applicable:

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

7b - provide evidence of adequacy with respect to 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, note that: often the excess proficiency testing materials are available from the Providers (PTPs). The laboratory should verify whether the PTP can provide additional information regarding stability, to demonstrate the continued stability of the ownership value and 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 the 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 participants in the PT have used different measurement procedures and the result is operatively defined, this assigned value cannot be used to establish the metrological traceability of the results (see also ISO Guide 35).

INTERNAL CALIBRATIONS

If the lab performs internal calibrations:

- the reference samples/materials must be have metrological traceability according to the indications given above for the quantities, measurement fields and appropriate uncertainties;
- the reference samples must be used only for calibrations and interim controls of the status of calibration;
- it must operate using suitable calibration procedures and competent staff.

An internal calibration is also one performed by the lab's external staff as long as the lab possesses the reference samples/reference materials and has implemented in its MS the calibration procedures it uses.

The calibration procedures as well as giving indications regarding calibration activities must also provide indications (or contain references to other documents) with regard to:

- the protection of adjustments which could be tampered with, where necessary;
- the completion of the calibration reports (see § 7.8.2 and § 7.8.4);
- instructions for affixing labels or similar identification regarding the status of calibration;
- the evaluation of results (acceptability criteria) and actions to undertake in cases of non-conform results.

Calibration procedures developed by the laboratory must be validated according to an appropriate documented validation procedure, and the laboratory must keep the relative records (ref. § 7.2.2.1 of this document).

For calibration reports see § 7.8.4.

6.5.1. The requirement of the standard requirement is applied.

6.5.2. The requirement of the standard requirement is applied.

6.5.3. The requirement of the standard requirement is applied.

6.6 PRODUCTS AND SERVICES PROVIDED EXTERNALLY

6.6.1. The requirement of the standard is applied

6.6.2. The requirement of the standard is applied

6.6.3. The requirement of the standard is applied

7. PROCESS REQUIREMENTS

7.1 REVIEW OF APPLICATIONS, QUOTATIONS AND CONTRACTS

7.1.1. The requirement of the standard is applied

The laboratory must inform the client of the significance of accreditation and of the accreditation of the activities which are the objects of the quotation/contract.

The laboratory must contractually define, in cases not covered by normative regulations, the timeframes of retention of the samples and any counter-samples and technical records of tests in accordance with the contract. If the information is provided by public communication (e.g. website), this must be referred to in the contractual agreements.

All activities covered by accreditation must be contractually managed as accredited (see § 7.8.3), unless explicitly requested by the client to the contrary. In this case, the client's request must be clearly indicated in the contractual agreements (ref. EA 3/01).

Note that in cases where accreditation is mandatory or when RdP must be provided to a third party, it is not possible to agree with the client the performance of activities as non-accredited (ref. EA 3/01).

If the laboratory does not know a priori the destination or use of the RdP by its clients, it is recommended to clarify in the contract that, in the event of non-use of the ACCREDIA mark, the RdP are not covered by accreditation and cannot be provided to third parties.

During the contract review with the client, the time limits established may also be redefined.

For requests for opinions/interpretations, the review of the applications, quotations and contracts the lab must:

- verify that the activities of the lab used for expressing opinions/interpretations are accredited;
- clarify that the opinions/interpretations are disclosed by the lab based on the results of the tested sample and cannot be used as sole input for product certification which also requires other information.

When the Laboratory intends to entrust 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 entrusted to accredited external laboratories and the RdP shows the reference to the accreditation of the external laboratory (see § 7.8.2.1)

it must comply with the following conditions:

a) inform the client in advance and obtain written agreement;
b) verify the competence of the external lab to perform the test/sampling (accreditation of the subcontracted lab by an AB signatory to the EA MLA or ILAC MRA agreements, with competence to perform the activities in question);
c) state on the test report that the test/sampling was performed by sub-contract.

7.1.2. The requirement of the standard is applied

7.1.3. The requirement of the standard is applied

The laboratory cannot exclude a priori issuing declarations of conformity if requested by the client, unless it is forbidden by mandatory provisions/regulations.

Where decision rules can be chosen, the laboratory should discuss with the client the risk levels regarding the likelihood of false acceptance and false rejections associated with the available decision rules.

7.1.4. The requirement of the standard is applied

7.1.5. The requirement of the standard is applied

7.1.6. The requirement of the standard is applied

7.1.7. The requirement of the standard is applied

7.1.8. The requirement of the standard is applied

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 is applied

If, for a certain purpose, the law envisages a specific method, the lab must implement it.

Labs undertaking official controls (e.g. of food products) must verify that all the testing methods comply with the directives and regulations in question.

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

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

- use outside the field of application indicated, if comparable (matrix), provided that this modification is subject to validation;

Note that some methods indicate the possibility of expanding their use for the determination of additional unforeseen parameters; the laboratory can add them after validating them.

The following types of changes to official/standardized/non-standardized methods result in the transformation into a method developed by the lab:

- 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 test phases, use of equipment with lower performance than expected, replacement of reagents/materials not included in the method.

Occasional deviations of the test method related to the particular nature of a sample must be reported in the RdP.

7.2.1.2. The requirement of the standard is applied

7.2.1.3. The requirement of the standard is applied

Superseded editions of standards or official test methods, together with designs of standards which have yet to be approved, must be changed into test methods developed by the laboratory. Exception is made in the case of superseded editions of standards and designs for standards when they are subject to mandatory regulations from the public administration authorities or standards for product certification, in force, or requested by notified bodies.

If the client, despite the absence of mandatory provisions, requests that a superseded test method be performed under accreditation, the laboratory can request accreditation, provided that the current method is also accredited.

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

It is not permitted to refer only to the mandatory normative document if it contains incomplete indications which, for example, refer only to the testing technique without providing full details of the performance modalities. In such cases the lab must indicate, in the application for accreditation and in the test report, the reference to the mandatory normative document and to a standardized or non-standardized method or one developed by the lab which contains all the necessary information (see § 7.2.1.1).

7.2.1.4. The requirement of the standard is applied

7.2.1.5. The requirement of the standard is applied

If the performance characteristics of the method have not been defined the lab must determine them.

The lab must verify maintenance over time of the required performances.

For certain applications the performance characteristics may be contained in the mandatory requirements.

7.2.1.6. The requirement of the standard is applied

A lab seeking accreditation for tests carried out against methods developed by the lab must send to ACCREDIA a copy of the methods accompanied by a validation and suitability declaration (a brief summary of which is given in point 7.2.2.4 of the standard). If ACCREDIA does not receive these documents from the lab, the tests in question will be excluded from the accreditation.

The methods developed must contain, where applicable, all the information necessary for conducting the test, as follows:

a) appropriate identification;
b) scope and field of application;
c) description of the type of object to be tested or calibrated;
d) parameters or quantities and measurement fields to be determined;
e) equipment, including performance technical requirements;
f) required reference samples and materials;
g) environmental conditions and any required stabilization period;
h) description of the procedure, including:

- affixing the marks for identification, handling, transport, storage and preparation of objects for testing;
- verifications to be conducted before the start of activities;
- verification of the good functioning of the equipment, if required, of the calibration and preparation for use,
- recording methods of observations and results,
- all the safety/security measures to be respected;

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

For some sectors there are technical standards providing indications for the creation of methods developed by labs (e.g. ISO 78-2).

7.2.1.7. The requirement of the standard is applied

7.2.2. Validation of methods

7.2.2.1. The requirement of the standard is applied

a) **Standardized methods** and **official methods** are considered valid by the body which issued them, unless the responsibility for the data provided does not refer to the organization that issued them but to the individual authors.

if the method does not report the performance characteristics the lab must determine them and verify that they are adequate and meet the mandatory requirements and/or those of the client.

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

If the non-standard method has been validated by a third party organization which is independent of the accredited product CBs (e.g. AFNOR) the lab must verify that it falls within the performance parameters of the validation.

Methods which have been validated by accredited labs/centres of national or EU reference centres and recognized by the central authority, may be used by other labs without undergoing further validation as long as:

- these methods come within the scope of accreditation of the lab which validated them;
- they contain the limits of repeatability or reproducibility (or intermediate repeatability);
- they are made available by the reference lab, in the version in force, together with the declaration of validation;
- the declaration of validation of the reference lab is updated (date of issue not more than 3 years);
- the lab applying them has verified that it is able to perform them in its own lab, obtaining results within the limits as defined by the method (precision data);
- the lab applying them has verified that the performance characteristics which depend on the lab and not on the method (such as those depending on the type and condition of the equipment used, the ability of authorized staff to do the test, the ambient conditions of the lab, the quality of reactive agents and materials used, the testing procedure defined by the lab) are all compatible with those obtained during the validation of the method.

c) **Methods developed by the laboratory** must be validated by the lab following the indications of Note 2 of point 7.2.2.1 of the standard.

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

The declaration of validation of the method must contain a summary of the data set out 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 which are signatory to the MLA ILAC agreements of mutual recognition, by the manufacturer of the equipment), it is not necessary to validate them. Calibration procedures autonomously developed by the laboratory must be validated.

7.2.2.2. The requirement of the standard is applied

The lab must define the criteria for the periodical review of the validation of the methods (e.g. positive results of PTs, confirmation of tests on reference materials) in terms both of frequencies and of the compatibility of results obtained.

7.2.2.3. The requirement of the standard is applied

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

For labs operating in the area of official controls of food products there are specific rules in the EU such as, for example, the Decision of the Commission n.2002/657/CE, SANTE documents.

7.2.2.4. The requirement of the standard is applied

7.3. SAMPLING

7.3.1. The requirement of the standard is applied

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 standardized or official method which is different from the one for determination (e.g. **ISO 18593, UNI EN 1948-1**).

   In these cases the following conditions must be respected:

   - the next due test related to the sampling must be carried out under ISO/IEC 17025 accreditation, either because it is accredited by the lab itself or because it is carried out by another lab accredited for the specific test;
   - the method used for the next due test must be chosen respecting the indications of the sampling method, if applicable, and the requirements of RT-23 regarding the combination of methods;
   - the lab must agree with the client during the contract agreement stage, regarding the subsequent tests related to the sampling and must comply with § 7.1.1 with the specification that, for point b) of 7.1.1, the external lab must be accredited against ISO/IEC 17025 for the specific test.

2) A method includes both the sampling and the determination,

   in these cases the lab may:

   - request accreditation of the entire method (sampling and determination);
   - request accreditation only of the analytical determination, excluding the section regarding the sampling.

If the client performs the sampling, the lab should provide adequate assistance (sampling instructions and relative records, containers etc.).

7.3.2. The requirement of the standard is applied

7.3.3. The requirement of the standard is applied

7.4. HANDLING OF TEST AND CALIBRATION ITEMS

7.4.1. The requirement of the standard is applied

The lab must keep the tested samples and/or any counter-samples and the relative technical records of the tests for a period of time agreed with the client or established by the law or legal authorities (see § 7.1.1).

7.4.2. The requirement of the standard is applied

7.4.3. The requirement of the standard is applied

7.4.4. The requirement of the standard is applied

The lab must have available adequate areas of separation for the storage of unsuitable samples.

7.5. TECHNICAL RECORDS

7.5.1. The requirement of the standard is applied

For the storage time of records see § 8.4 of this document.

7.5.2. The requirement of the standard is applied

In cases of the correction of data, if it is not possible to deduce the explanation from the records, the justification for the correction must be noted.

7.6. EVALUATION OF MEASUREMENT UNCERTAINTY

7.6.1. The requirement of the standard is applied

If the lab requests accreditation only for the sampling activities (see § 7.3) it must make available information for the subsequent calculation of measurement uncertainties relating to the result.

7.6.2. The requirement of the standard is applied

If the laboratory performs internal calibration, the uncertainty must be determined in accordance with the JCGM 100 Guide, EA-4/02 or in accordance with technical sector procedures.

7.6.3. The requirement of the standard is applied

When a standardized/non-standardized/official method not developed by the lab has the statistical parameters of the validation (standard deviation of repeatability) and the lab 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, accuracy).

For chemical tests it is important to verify that the level of concentration for which the reproducibility is given is similar to the test result, in that the uncertainty (and the reproducibility which provides the estimation) could be a non-linear function of the concentration (e.g. Horwitz law). It is therefore not always correct to express uncertainties in terms relating to all the field of application of a method when this has been determined only for one concentration value.

The lab must check that the uncertainty to be associated with the result has been estimated to be at significant levels for the client (e.g. legal limits); and it must also check the repeatability limit of the lab's method or calculated by the lab with the measurement uncertainty value (2U>r).

It is also important to check that the uncertainty estimation is consistent with the performance data available in the literature if they exist (e.g. incorporated in the method, taken from the participation at appropriate ILCs etc.).

Some reference documents for the evaluation of measurement uncertainties are listed in Note 3 of the standard. For specific sectors there are specific documents and guidelines.

7.7. ENSURING THE VALIDITY OF RESULTS

7.7.1. The requirement of the standard is applied

7.7.2. The requirement of the standard is applied

The lab must, where possible, have recourse to an organization of interlaboratory proficiency tests (proficiency testing – PT) operating in conformity with UNI CEI EN ISO/IEC 17043 (e.g. an organization accredited for these activities or which declares that it operates in conformity with the standard).

For the policy of participation in PTs see ACCREDIA Reg. RT-24.

Such participation in PT comparisons may be requested by ACCREDIA for applicant or accredited labs as an instrument of assessment for granting or maintaining accreditation.

The laboratory must plan its participation in PTs using a risk-based approach, also taking into account internal calibrations. This approach will also depend on the context and on the specific activities carried out and on the criticalities of the internal calibration (for example when the internal calibration has the greatest influence on the validity of the result).

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

7.7.3. The requirement of the standard is applied

7.8. PRESENTATION OF THE RESULTS

This paragraph contains the indications for test reports relating also to sampling, where applicable and are indicated by the acronym RdP.

In the case of presentation of results in foreign languages (other than English), the laboratory is still required to issue a bilingual RdP (Italian-foreign language or English-foreign language).

If a translation is requested by the client after the issuance of a RdP, the laboratory must report a clear reference to the RdP issued in Italian in the translated report.

In the management of documents, the laboratory must provide for the management of attachments to the RdP, establishing rules and modalities of issuance. However, it must be provided for that the documents are referred to in the RdP that generated them, and vice versa.

Where the RdP contains attachments, the presence of the ACCREDIA mark or references to accreditation on the RdP does not require that the mark or reference to accreditation be present on all attachments. In particular, the laboratory must assess when the presence of the mark on the attachment of a RdP (also with a mark) is compatible with the content of the attachment itself, with regard to the requirements of Regulation RG-09 and, in this case, must comply with the relevant requirements applicable to the RdP (for example distinction of accredited/non-accredited activities, identification of information provided by the client, etc.).

The presence or, on the contrary, the absence of the mark on the attachments of the RdP must meet criteria consistently applied by the laboratory.

The laboratory has the right to produce separate documents, not attached to the RdP, such as expert appraisals or reports. It should be noted that documents such as reports, technical documents and appraisals, although they contain the results of accredited activities, cannot be considered as RdP and therefore cannot carry the mark or reference to the accreditation.

7.8.1. General

7.8.1.1. The requirement of the standard is applied

7.8.1.2. The requirement of the standard is applied

7.8.1.3. The requirement of the standard is applied

In the case of a simplified presentation of the results the lab must give a clear identification of the person/s who approved them.

7.8.2. Common requirements for reports (testing, sampling or calibration)

7.8.2.1. The requirement of the standard is applied

The RdP must not include titles or subtitles relating to the possible use or destination, which generate confusion with other activities not covered by accreditation.

The authorization for issuing the RdPsmust be clearly indicated by means of a signature or equivalent form of identification. If there are mandatory requirements for the signing the lab must respect them.

With reference to requirement 7.8.2.1.d) it is specified that the end of the RdP does not necessarily have to be made explicit by means of a specific sentence or wording. Other ways to define the end of the document are therefore acceptable, such as, for example, the page numbering (page n ... of ...), or the digital signature of the entire document.

If the lab reports in its own RdP also the results of tests conducted externally by an accredited lab it is not necessary to state them as being accredited, on the condition that the accreditation number of the lab is specified and if it is not an Italian lab, also the name of the relevant AB.

Regarding use of the ACCREDIA mark (and/or reference to accreditation) on the RdP, this is permitted only if the RdP contains the result of at least one accredited activity (test/sampling) performed by the lab.

It is also specified that the activities can be indicated on the RdP as accredited only if they are accredited at the time of their performance and not at the time of issuing the test report.

If the lab only states the results of outsourced activities on the RdP it is not possible to use the ACCREDIA mark or reference to accreditation of the external lab.

If a laboratory does not report the results provided by the external laboratory on its own RdP, but directly provides the external laboratory's RdP, it is in any case required to comply with the requirements regarding information to the client and verification of competence of the external laboratory (see § 7.1.1).

The RdPs must include preferably the starting and ending date of each test.

The RdPs must indicate the properties measured and the methods must be in keeping with the list of accredited tests; it is also possible to state the measurands in a different manner from the list of tests, if required by the sector standards, either mandatory or by the client (contractually agreed), providing for the use, for example, of technical synonyms.

It is possible to add other information to the report, apart from matrix, measurand and method, e.g. temperature, equipment, re-agent purity or intervals of the measurement of methods.

Test procedures may be indicated in brackets after the reference of the standardised method. If the lab's own methods are used, it is possible to indicate the origin in brackets (bibliographical reference, modified standard, superseded standard, clearly identified).

The results can be given with a unit of measurement which is different from the one indicated in the method if this is necessary under the mandatory standard and the agreements with the client.

The RdP must also contain a declaration according to which it cannot be reproduced except fully, unless approved in writing by the laboratory.

7.8.2.2. The requirement of the standard is applied

All information provided by the client must be clearly identified and distinguished from the information, which is the laboratory's responsibility.

If the laboratory carries out sampling, but it is excluded from accreditation, the RdP must report this exclusion and the sampling must be indicated as not subject to accreditation.

When the sampling involves the performance of measurements (e.g. volume, flow rate, surface, etc.) the laboratory must express the results using a traceable measurement unit.

Therefore, if the sampling is not accredited or carried out by the client, the lab must express the result without taking into consideration the measures performed during the sampling phase (e.g. mg and not mg/m^3, UFC and not UFC/m^2, etc.) and identify correctly the sample accepted (e.g. vial, filter, etc. and not the work area).

It is acceptable to express the test results even in the prescribed measurement units taking into consideration the measurements made in the sampling phase, provided that:

the laboratory provides for, during the sample acceptance phase, the acquisition of a declaration, duly signed, that it has performed the sampling of the measurements made in the sampling phase (e.g. surfaces it has sampled),

the must RdP clearly specify that:

if the sampling was done by the lab the sampling is not accredited;

if the sampling was not done by the lab, the entity which performed it must be specified (e.g. client);

the result, as expressed in a unit of measurement (e.g. surfaces), has been obtained by means of a preparation of the data (e.g. area measured) expressly declared by the person/s who performed the sampling.

7.8.3. Specific requirements for test reports

7.8.3.1. The requirement of the standard is applied

Unless otherwise established by mandatory requirements or by needs related to the use of the results, the numerical values of the results and associated uncertainties must not be given with an ex-

cessive number of digits. It is usually sufficient to report the measurement uncertainty with a maximum of two significant digits and the rounded result with a number of digits consistent with the associated uncertainty, although in some cases it may be necessary to keep a number of additional digits to avoid errors of rounding if the results are used for subsequent calculations.

When an uncertainty of measurement is reported, this must be expressed as a distributed uncertainty (U) it must also contain a declaration relating to the trust level and the cover factor used. K=2 is generally accepted as a coverage factor, with a 95% reliability level.

In certain cases, uncertainty can be expressed as a trust range – upper and lower limits – as, for example, in the identification of the toxicity in water against standard UNI EN ISO 6341for the identification of micro-organisms in water according to ISO 8199 and in the identification of asbestos in accordance with Annex 2 of Ministerial Decree 06/09/94.

In cases in which labs performing the determination of residues/traces, when the pre-treatment procedure (e.g. concentration/purification/extraction) may influence retrieval, the retrieval must be indicated in the report and whether this has been used in the calculations (some mandatory dispositions require the correction for retrieval of results and it is therefore recommended to apply the mandatory dispositions in question).

If one or more significant components of the measurement uncertainty cannot be evaluated, or the requirement for their inclusion in the uncertainty balance is not applicable, it should be clarified on the RdP (ref. ILAC G-17).

For accredited activities, the lab must issue the RdP with the ACCREDIA mark and/or the reference to accreditation. Exception is made in cases in which the client explicitly requests a RdP not covered by accreditation and therefore without a mark and/or reference to accreditation: in this case, the request must be provided for in the contract (see §7.1.1 and RG-09) and the assets will be considered as non-accredited.

If the RdP does not carry the ACCREDIA mark or other reference to accreditation, it is not necessary to highlight non-accredited tests or any reference to the accreditation of the external lab.

For the performance of surveillance/extension/renewal assessments, the lab must make available the number of RdP issued in the previous calendar year with or without the ACCREDIA mark or other reference to accreditation. All RdP issued (both with and without brand/reference) must be made available, so that ACCREDIA can verify compliance with Reg. RG-09 for the use of the mark and the accreditation requirements.

7.8.3.2. The requirement of the standard is applied

7.8.4. Specific requirements for calibration certificates

7.8.4.1. The requirement of the standard is applied, for both internal and external calibrations.

7.8.4.2. The requirement of the standard is applied

7.8.4.3. The requirement of the standard is applied

7.8.5. Presentation of information relative to sampling - specific requirements

The requirement of the standard is applied

If the lab is accredited for the sampling activity referred to in § 7.3.1. point 1), and issues a document relating only to sampling (e.g. sampling report), it must specify in this document that the entire analytical process is considered accredited only if both the sampling and the subsequent test/s are accredited according to CEI EN ISO/IEC 17025.

If the lab carries out the sampling it is recommended to state in the RdP the reference to the sampling report, when applicable.

When relevant for the use of the results, as well as the date, the time of sampling must be recorded.

7.8.6. Formulation of the declaration of conformity

7.8.6.1. The requirement of the standard is applied

If the lab formulates a declaration of conformity to the requirements, specifications, or if it indicates reference limits, it must ensure that it refers to documents which are in force (the reference may be to mandatory or contractual requirements): the references to documents containing limits/specifics must be stated in the RdP.

Note: for declarations of conformity see, for example, the documents ILAC-G8 and EURACHEM/CITAC.

A lab which issues declarations of conformity must define in its documents the criteria for their issuance, taking into consideration, where necessary, the measurement uncertainties.

The accreditation/non-accreditation status of the declaration of conformity must not be indicated in the RdP, as the accreditation status is clearly indicated by the tests to which it refers.

7.8.6.2. The requirement of the standard is applied. The declarations of conformity must be reported on the RdP (or any attachment uniquely related to it and forming part of it).

7.8.7. Presentation of opinions and interpretations

The present section is applicable only for labs whose scope of accreditation includes opinions and interpretations.

In all cases opinions and interpretations given in the RdP must indicate clearly: "Opinions and interpretations – not the object of ACCREDIA accreditation".

7.8.7.1. The requirement of the standard is applied

As stated in the Note of the standard, opinions and interpretations must not be formulated in a such a way as to be confused with product certifications (ISO/IEC 17065) inspection reports (ISO/IEC 17020) or declarations of conformity as defined in paragraph 7.8.6.

For the purposes of accreditation the following items are examples of elements which are not considered to be acceptable opinions and interpretations: the attribution of the European Refuse Code (CER), the classification of waste dangers, professional opinions issued under personal responsibility

by those who formulated them and not by labs (e.g. by an expert appointed by a judge or by the counter-party), opinions formulated for risk assessment, the risk exposure estimation or risk nature.

Specific competence is required for the issuance of opinions and interpretations and these may be expressed only by authorized personnel (see § 6.2).

In cases of the formulation of opinions and interpretations the lab must provide evidence of traceability of data relating to tested samples (see § 7.5).

If information of the client is used in the formulation of opinions and interpretations, the lab must keep the relative records and the RdP must clearly state that the opinions and interpretations are based on information received from the client.

Opinions and interpretations must not lead to the supposition of approval by ACCREDIA either of them or of the test results.

7.8.7.2. The requirement of the standard is applied

Opinions and interpretations must be an integral part of the RdP and stated in a section entitled "Opinions and interpretations". They must not appear in any document other than the RdP or any attachment (see § 7.8 for the management of this).

Opinions and interpretations must be based only on results obtained by tested sampling, but other information may also be necessary deriving from calculations, from the literature or from bibliographies.

Accreditation of opinions and interpretations is granted only on the basis of results obtained from accredited tests.

If results which were obtained also from external labs are used for the formulation of opinions and interpretations, they must be accredited results for the specific tests in question.

It is not possible to express accredited opinions and interpretations only using results obtained from external labs.

7.8.7.3. The requirement of the standard is applied

Opinions and interpretations issued verbally, even if they were recorded, cannot be accredited.

7.8.8. Corrections to reports

7.8.8.1. The requirement of the standard is applied

RdP must be corrected and re-issued in cases of:

incorrect or misleading use of the ACCREDIA mark or references to accreditation;

mistakes in the test results;

any other failure or mistake which may result in improper use of the RdP by the client or by a third party, or might prejudice the correct understanding of the results by the client, by a third party or by the authorities in question.

When a RdP is identified with this type of issue, the lab must perform, as a part of the management of non-conform activities, a review of all issued reports; it must trace, correct and re-issue all the relevant reports.

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

In exceptional cases in which it is necessary to make a purely formal (editorial) correction to a RdP already issued without changing its validity, the issuance of a general correction document may be acceptable, provided that the information required by the standard in § 7.8.8 is guaranteed (e.g. clear identification of the RdP affected by the same error, correct information, reasons for the correction).

7.8.8.2. The requirement of the standard is applied

7.8.8.3. The requirement of the standard is applied

When a new RdP is issued in place of the one previously given to the client, the RdP must clearly indicate that the new RdP replaces the previous one. The laboratory is not obliged to ask for the incorrect one to be returned, but it is better to ask the client for written evidence of receipt of the replacement report.

7.9. COMPLAINTS

7.9.1. The requirement of the standard is applied

7.9.2. The requirement of the standard is applied

7.9.3. The requirement of the standard is applied

7.9.4. The requirement of the standard is applied

7.9.5. The requirement of the standard is applied

7.9.6. The requirement of the standard is applied

7.9.7. The requirement of the standard is applied

7.10 NON-CONFORM ACTIVITIES

7.10.1. The requirement of the standard is applied

7.10.2. The requirement of the standard is applied

7.10.3. The requirement of the standard is applied

If nonconformities are found which could lead to the suspension of testing/sampling activities or raise doubts concerning the validity of the results of accredited tests (for example a negative evaluation of participation at ILCs, unavailability or deterioration of resources etc.) the lab must communicate to ACCREDIA its self-suspension of accreditation for these tests, until positive evaluation of the corrective actions by ACCREDIA has been performed.

Where NCs are raised regarding RdPs which have already been issued which could prejudice the use of results by clients (e.g. a technical NC, or one concerning references to accreditation) the lab must identify the reports in question and inform the client by issuing a replacement RdP.

7.11. CONTROL OF DATA AND MANAGEMENT OF INFORMATION

7.11.1. The requirement of the standard is applied

7.11.2. The requirement of the standard is applied

The extension and range of the validations to be performed on an externally provided system must be commensurate with the evidence supplied by the producer with regard to the conformity of the system.

7.11.3. The requirement of the standard is applied

7.11.4. The requirement of the standard is applied

The lab must communicate to the external supplier or operator of the system – in cases of systems managed by the organization of which the lab is a part – the applicable requirements, including those related to confidentiality, integrity and accessibility to information stored off-site.

7.11.5. The requirement of the standard is applied

7.11.6. The requirement of the standard is applied

With reference to the use of electronic sheets or other programs of commercial calculation, the applications developed by the lab (formulas, macro) must be documented, validated and protected to prevent involuntary alteration.

8. MANAGEMENT SYSTEM REQUIREMENTS

8.1. OPTIONS

8.1.1. General

The requirement of the standard is applied

During the phases of first accreditation and renewal, the lab must provide to ACCREDIA sufficient information to be able to understand how the lab operates to achieve and maintain compliance with UNI CEI EN ISO/IEC 17025 and with ACCREDIA's regulations.

In order to do this the lab may prepare a MS manual or a self-assessment using the relevant ACCREDIA self-assessment modules, containing at least:

the responsibilities concerning the definition of policies and procedures, their implementation and the preparation and retention of the relative records;

a brief description of the operative modalities used by the lab without excessive recourse to procedures and annexes;

the activities carried out at secondary locations or temporary sites, in cases of multisite laboratories;

any exclusions or non-applicability of requirements together with the relative justifications.

In cases of modifications regarding the lab's organization and/or policies and procedures adopted, ACCREDIA may request an update of the MS manual/self-assessment.

Self-assessment consists of a module prepared by ACCREDIA and completed by the laboratory, for the purpose of submitting the application for accreditation and, as such, it is not a document of the laboratory's management system.

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

8.1.2. Option A

The requirement of the standard is applied

8.1.3. Option B

§ B.3 of Annex B of the standard is applicable

8.2. MANAGEMENT SYSTEM DOCUMENTATION (OPTION A)

8.2.1. The requirement of the standard is applied

8.2.2. The requirement of the standard is applied

8.2.3. The requirement of the standard is applied

8.2.4. The requirement of the standard is applied

8.2.5. The requirement of the standard is applied

8.3. CONTROL OF MANAGEMENT SYSTEM DOCUMENTATION (OPTION A)

8.3.1. The requirement of the standard is applied

In cases of updates of external origin documents, such as standards, methods, laws or regulations, unless otherwise indicated, the lab must apply the new version within three months of its issuance.

8.3.2. The requirement of the standard is applied

Corrections made by hand are permitted only in documents for internal use if they are urgent. Such documents must be updated promptly following modification.

8.4. CONTROL OF RECORDS (OPTION A)

8.4.1. The requirement of the standard is applied

8.4.2. The requirement of the standard is applied

All records must be kept for a minimum of 48 months as long as there are no mandatory or contractual obligations requiring a longer period, including external records (e.g. calibration certificates, reference material certificates, ILC reports).

Data regarding calibrations should be kept for the entire life-cycle of the measurement equipment because based on these data the frequencies of the calibrations can be established or modified.

8.5. ACTIONS FOR ADDRESSING RISKS AND OPPORTUNITES (OPTION A)

8.5.1. The requirement of the standard is applied

Reference must be made to the introduction of the standard with regard to risk identification.

8.5.2. The requirement of the standard is applied

8.5.3. The requirement of the standard is applied

8.6. IMPROVEMENTS (OPTION A)

8.6.1. The requirement of the standard is applied

8.6.2. The requirement of the standard is applied

8.7. CORRECTIVE ACTIONS (OPTION A)

8.7.1. The requirement of the standard is applied

It should be remembered that assessment of the effectiveness of CAs is different from the assessment of their implementation.

The CAs planned and communicated following second and third party assessments (e.g. ACCREDIA) must be managed as a part of the lab's management system.

8.7.2. The requirement of the standard is applied

8.7.3. The requirement of the standard is applied

8.8. INTERNAL AUDITS (OPTION A)

8.8.1. The requirement of the standard is applied

8.8.2. The requirement of the standard is applied

The choice of auditors and the conduct of audits must ensure objectivity and impartiality of the internal audit process. It is therefore advisable – if resources permit –that the internal audits are performed by staff members who are independent of the object area of the audit.

It is necessary to provide evidence (CVs and attestations) regarding training and audit experience with respect to UNI CEI EN ISO/IEC 17025 and the requirements for accreditation.

Second and third party audits cannot substitute the internal audits of labs.

8.9. MANAGEMENT REVIEW (OPTION A)

8.9.1. The requirement of the standard is applied

Extraordinary reviews may become necessary following findings whose CAs require special investments (e.g. purchase of equipment, staff hiring) or structural organizational changes (e.g. lab layout, staff reorganization).

8.9.2. The requirement of the standard is applied

8.9.3. The requirement of the standard is applied