ACCREDIA
ENTE ITALIANO DI ACCREDITAMENTO

Calibration Laboratories Department

# Requirements for the Accreditation of Calibration Laboratories

REVISION
**09**

DATE
**03-12-2025**

TITLE **Requirements for the Accreditation of Calibration Laboratories**

REFERENCE **RT-25**

REVISION **09**

DATE **03-12-2025**

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

PREPARATION
**Director of the Calibration Laboratories Department**

APPROVAL
**Directive Council**

AUTHORIZATION
**Director General**

APPLICATION DATE
**01-01-2026**

# Contents

# 1. Introduction

This Technical Regulation defines the general criteria for the accreditation of the Calibration Laboratories by the Department of Calibration Laboratories (DT) of ACCREDIA (the Italian Accreditation Body).

The application of the following criteria has the objective of favouring the creation and maintenance of the trust of the Clients in the calibration activities of the accredited laboratories as well as in the impartiality and integrity of the technical and commercial operations associated with them. ACCREDIA accreditation is granted to calibration laboratories that comply with the requirements of the standard ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories" (hereinafter simply "the standard"), to the EA and ILAC requirements and the ones of this Regulation and of the other ACCREDIA prescriptive documents applicable to calibration laboratories.

Accreditation attests to the Laboratory's technical competence to carry out the activities indicated in the scope of accreditation set out in the annex to the Accreditation Certificate. Calibration Laboratories (LAT) accredited by ACCREDIA operate as Calibration Centres within the framework of the National Calibration System established by Law 273/91.

# 2. Scope and Field of Application

This document refers to the requirements of ISO/IEC 17025:2017. The numbering of the paragraphs, for clauses 4 to 8, corresponds to that of the standard. In these clauses, and in clauses 9 and 10, the requirements and provisions introduced by ACCREDIA are reported, which Calibration Laboratories must implement together with the requirements of the standard and the requirements of EA and ILAC.

This document specifies the management and technical competence requirements for the calibration laboratories on the basis of:

- the metrological sectors covered by the scope of accreditation
- the sites;
- the update of EA and ILAC provisions.

The information contained in this document is applicable to any metrological sector. Specific requirements defined by mandatory regulations or at an international level (EA, ILAC, ISO, EN, etc.) are listed in the ACCREDIA document LS-09 "Standards and reference documents for the accreditation of Calibration Laboratories", in the current revision, which can be downloaded from the website www.accredia.it. In order to obtain, extend and maintain accreditation, the Laboratory shall demonstrate compliance with all the requirements of the standard, with the exception of those declared, with justification, as not applicable, for the range of laboratory activities defined in the management system.

The Laboratory is required to comply with the provisions of the ACCREDIA document RG-09 regarding the use of the ACCREDIA logo and mark and the reference to accreditation.

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# 3. Definitions and references

## 3.1. Definitions

For the purposes of this document, the definitions contained in the following reference standards apply: ISO 9000, ISO/IEC 17000, ISO/IEC 17011, ISO/IEC 17025:2017, ISO 17034, UNI CEI EN 45020, and UNI CEI 70099 International Vocabulary of Metrology (VIM3), as well as those contained in the standards currently in force on the subject, in the General Accreditation Regulations, and in other applicable regulations/technical documents.

Some definitions are also provided below:

### 3.1.1. Reference Measurement Standard (reference standard):

Measurement standard designated for the calibration of other measurement standards for quantities of a given kind, in a given organization or a given location (UNI CEI 70099 – VIM3 - §5.6).

### 3.1.2. Working Measurement Standard (Working Standard):

Measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems (UNI CEI 70099 – VIM3 - §5.7).

### 3.1.3. Travelling Measurement Standard (Travelling Standard):

Measurement standard, sometimes of special construction, intended for transport between different locations (UNI CEI 70099 – VIM3 - §5.8).

**Note:** normally used for external calibrations**.**

### 3.1.4. Transfer Measurement Device (Transfer Device):

Device used as an intermediary to compare measurement standards (UNI CEI 70099 – VIM3 - §5.9).

### 3.1.5. Reference Material (RM):

Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process (ISO 17034:2017 - §3.3).

**Note 1:** RM is a generic term.

**Note 2:** Properties can be quantitative or qualitative, e.g. identity of substance or species.

**Note 3:** Uses can include calibration of a measurement system, assessment of a measurement procedure, assignment of values to other materials and quality control.

**Note 4:** ISO/IEC Guide 99: 2007 (UNI CEI 70099: 2008, 5.13) has an analogous definition, but restricts the term "measurement" to apply to quantitative values. However, note 3 of ISO/IEC Guide 99: 2007 specifically includes qualitative properties, called "nominal properties".

### 3.1.6 Certified Reference Material (CRM):

Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. (ISO 17034:2017 - §3.2).

**Note 1** The concept of the value of a nominal property or qualitative attribute, such as identity or sequence. Uncertainties for such attributes can be expressed as probabilities or confidence levels.

**Note 2** Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guide 35.

**Note 3** ISO 33405 gives guidance on the contents of reference material certificates.

**Note 4** ISO/IEC Guide 99:2007 has an analogous definition (UNI CEI 70099:2008, 5.14).

### 3.1.7 Internal Calibration

Calibration performed to establish the metrological traceability of its activities in relation to the scope of accreditation and that:

- it does not fall within the Laboratory's scope of accreditation (and as such cannot be offered as an accredited calibration service)
- it is carried out by the Laboratory's personnel and instrumentation (or under its direct control), applying technical procedures that have been positively evaluated by ACCREDIA DT.

### 3.1.8 Risk:

Effect on an activity that may arise from certain processes/activities carried out by the Laboratory, including the work of its internal staff and collaborators.

**Note:** It is recommended that the Laboratory identify risk indicators proportionate to the expected impact and the likelihood of occurrence of a given situation.

## 3.2. Reference Standards and Documents

The list of applicable documents (LS-09) can be consulted on the ACCREDIA website at www.accredia.it. It is the responsibility of the Calibration Laboratory to verify the validity of the documents referenced.

This Regulation also makes reference to the applicable ACCREDIA documents/requirements.

# 4. General Requirements

## 4.1. Impartiality

### 4.1.1.

The requirement of the standard applies.

### 4.1.2.

The requirement of the standard applies. The Laboratory Management shall provide indications that allow the monitoring and minimization of residual risks with regard to impartiality. Personnel at any level shall demonstrate that they know and understand these indications.

### 4.1.3

The requirement of the standard applies.

### 4.1.4.

The requirement of the standard applies taking into account that the impartiality risks must be assessed on the basis of objective, possibly measurable, parameters.

Examples of relationships that could compromise impartiality include:

- relationship with the parent company;
- relationships between different functions within the same Organisation;
- relationships with affiliated Organisations/Companies;
- relationships with Regulatory Authorities (for example, Ministries, Agencies, ARPA…);
- relationships with clients;
- relationships of personnel;
- relationships with intermediary companies;
- relationships with companies providing personnel.

**Note:** Regarding the topic of impartiality, it is recommended to consult the document “Recommendations issued by the Steering and Guarantee Committee for the verification of certain requirements of UNI CEI EN ISO/IEC 17025:2017, during the assessment and surveillance of accredited Testing and Calibration Laboratories.

### 4.1.5

The requirement of the standard applies taking into account that the Laboratory's risk analysis must include the identification of real and/or potential risks and residual risk assessments. In the application of the requirements, it is necessary to take into account the information in the note in 8.5.2 of the standard.

**Note:** Regarding risk management, reference is made to UNI ISO 31000 “Risk Management – Guidelines”.

## 4.2. Confidentiality

### 4.2.1.

The requirement of the standard applies. The implementation of any element that may affect calibration activities must also take into account the requirement of confidentiality.

**Note:** It is recommended to identify i) personnel authorised to access the Laboratory premises, ii) personnel authorised to access Client data (whether managed in paper or electronic format), and iii) the established procedures for controlling such access to company software and shared areas of the corporate networks.

### 4.2.2.

The requirement of the standard applies.

### 4.2.3.

The requirement of the standard applies.

### 4.2.4.

The standard requirement is applied taking into account that any contracts with personnel not employed by the laboratory acting on its behalf must consider the confidentiality aspects of the information. Consultants participating in third party assessments must be required by the laboratory to sign a confidentiality commitment and this must be made available to ACCREDIA upon request.

# 5. Structural Requirements

## 5.1.

The requirement of the standard applies. ACCREDIA requires that the Chamber of Commerce registration extract lists all sites and all activities for which accreditation is requested or has been obtained.

**Note:** ACCREDIA requires the Laboratory to attach the Chamber of Commerce registration to the DA-00 application in order to verify that it is a legal entity or part of it, having full responsibility for the activities covered by the accreditation.

## 5.2.

The requirement of the standard applies.

**Note:** It is recommended to identify the person responsible for conducting the management review as evidence of the responsibility and authority required by the standard.

## 5.3.

The requirement of the standard applies taking into account that there must be:

- an official document issued by the management personnel declaring the scope and coverage of the activities carried out by the Laboratory in accordance with the standard;
- a document from which the CMC described in section 2 of DA-05 is extracted.

If the Laboratory outsources activities to another Laboratory, which in turn outsources them to a third Laboratory, such activities cannot be considered accredited.

## 5.4.

The requirement of the standard applies taking into account that the Laboratory must define and declare all sites where it performs activities in accordance with the standard, including those where it performs calibration operations.

**Note:** ACCREDIA requires the Laboratory to declare in the DA-05 application the list of all sites where the activities described in the standard are carried out, including those other than calibration, such as metrological confirmations, commercial activities, etc. A site may be a permanent, temporary, or mobile facility of the Laboratory, a site outside the Laboratory's permanent facilities, or a client's facility (see the definition provided in RG-13).

## 5.5.

The requirement of the standard applies.

**Note:** ACCREDIA evaluates among other evidence:

- the overall organization chart of which the Laboratory is a part, with its position highlighted;
- the functional organizational chart of the Laboratory, in cases where this does not coincide with the body, containing the relations between management, the technical operations and the support services;
- the organization chart of the Laboratory staff, with the identification of anyone who, although operating within the Laboratory, hold different roles in other areas of the organization to which the Laboratory belongs.

a. The requirement of the standard applies.

**Note:** ACCREDIA evaluates among other evidences, when these have been foreseen: the organization charts, the job descriptions, the letters of appointment, the possible contracts. It is recommended that all staff is aware of the relevance and importance of their operations related to accredited activities.

b. The requirement of the standard applies, with the provision that, in addition to those explicitly referenced as procedures by the standard, the Laboratory shall prepare procedures describing the technical activities that lead to the definition of the CMCs.

## 5.6.

The requirement of the standard applies with the provision that a function is identified, consisting of a single person or a group of people, who has authority and resources (for example, time commitment) to guarantee the functioning of the management system in compliance to the standard.

## 5.7

a. The requirement of the standard applies.

**Note** It is recommended to identify methods for assessing the effectiveness of communications, appropriate to the size and type of the Laboratory.

b. The requirement of the standard applies, with the provision that the Laboratory shall define in a system document the methods and responsibilities for managing changes (for example, changes in Technical Management/Manager/Deputy of the Laboratory, or Laboratory relocation).

# 6. Resource Requirements

## 6.1. General

The requirement of the standard applies.

## 6.2. Personnel

### 6.2.1.

The requirement of the standard applies.

### 6.2.2.

The requirement of the standard applies, with the provision that the Laboratory shall document, for each function, the competences required to fulfil the role.

**Note:** ACCREDIA assesses, among other evidences, that the Laboratory has established the competence requirements (school curriculum, technical knowledge, work experience, enforcement skills) necessary to acquire the role envisaged in the organization chart and that has documented the appropriate rules to achieve and maintain the related qualifications.

### 6.2.3.

The requirement of the standard applies.

**Note:** ACCREDIA evaluates, among other evidences, the records of the supervision of the activities.

### 6.2.4.

The requirement of the standard applies, specifying that the Management must clearly define the role, the commitment, the responsibilities and the limits in relation to the activities carried out by all the personnel, including any contracted one, and that the personnel has understood them.

### 6.2.5.

The requirement of the standard applies, with the provision that the Laboratory shall document, by means of a procedure, the application of the requirements.

### 6.2.6.

The requirement of the standard applies.

**Note:** Authorisations may be recorded as a supplement to job descriptions or may be explicitly stated within the job descriptions themselves. An example of recording authorisations may be a summary table listing the personnel authorised to perform each accredited calibration, sampling activity, internal calibration, etc.

## 6.3. Facilities and Environmental Conditions

### 6.3.1.

The requirement of the standard applies.

**Note:** It is recommended to establish, in relation to the sites, the acceptability limits and the corresponding assessment methods for the conditions of the environment in which operations relevant to ensuring the validity of the results are carried out. Particular attention should be given to the environmental conditions in which calibration operations are performed.

### 6.3.2.

The requirement of the standard applies. Where environmental conditions are important to ensure metrological traceability, the monitoring systems must be included in the documented procedure for the metrological confirmation of measuring equipment.

### 6.3.3.

The requirement of the standard applies. The records of the environmental conditions of the premises where the laboratory performs the calibrations, when necessary, must be kept for at least ten years.

### 6.3.4.

The requirement of the standard applies.

**Note:** If the maintenance activities are entrusted to external staff (for example, cleaning the premises where the accredited activities are carried out), it is recommended that the Laboratory establishes adequate and precise operating instructions for external personnel, including any operating restrictions for specific areas of the premises or for specific instrumentation.

### 6.3.5.

The requirement of the standard applies. ACCREDIA assesses, among other evidence, that the Laboratory has a management system document showing how the Laboratory implements the requirement. Where environmental conditions are important, the monitoring systems must be included in the documented procedure for the metrological confirmation of the equipment, and records of the environmental conditions during the execution of calibrations must be retained for at least ten years.

## 6.4. Equipment

### 6.4.1.

The requirement of the standard applies.

### 6.4.2.

The requirement of the standard applies. Where the equipment is outside the permanent control of the Laboratory, it is recommended to consider this aspect among the factors to be evaluated in the risk analysis and to document, in a specific technical procedure, the metrological confirmation activities to be carried out before each use of the equipment.

### 6.4.3.

The requirement of the standard applies.

**Note:** In cases where special measures are envisaged by the manufacturers, it is recommended that the Laboratory adequately trains the personnel in charge.

### 6.4.4.

The requirement of the standard applies.

**Note:** It is recommended to include these activities in the process of metrological confirmation of standards and instruments.

### 6.4.5.

The requirement of the standard applies.

### 6.4.6.

The requirement of the standard applies.

**Note:** ACCREDIA evaluates, among other evidences, the calibrations of the instruments, the standards and the characterization of the property values of the certified reference materials used to verify the measurement conditions (which, if satisfied, legitimize the measurement models, the respective uncertainty budget and therefore lead to valid results) and those used to transfer the metrological traceability to the results.

### 6.4.7.

The requirement of the standard applies. The periodicity of the calibrations must be inserted in the **documented procedure of metrological confirmation**, positively evaluated by ACCREDIA previously. Subsequent changes must be documented (and evaluated positively).

### 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, with the provision that the verification activities are described in documented procedures that must be positively evaluated by ACCREDIA previously.

**Note:** It is recommended to include the intermediate checks programme in the metrological confirmation process for standards and instruments. This process must be positively evaluated by ACCREDIA in advance. It is also recommended to incorporate the requirements of ISO 10012 and to use the ILAC G24:2022 guide, "Guidelines for the Determination of Recalibration Intervals of Measuring Equipment".

### 6.4.11.

The requirement of the standard applies with the provision that the Laboratory shall keep records of the corrections applied for the same retention period of the Certificates that are affected.

**Note:** It is recommended to include these activities in the process of metrological confirmation of standards, instruments and materials.

### 6.4.12.

The requirement of the standard applies.

### 6.4.13.

The requirement of the standard applies.

## 6.5. Metrological Traceability

### 6.5.1.

The requirement of the standard applies. The laboratories shall implement the metrological traceability according to the definition provided in UNI CEI 70099.

**Note:** ACCREDIA assesses compliance with the requirements of ILAC-P10 “ILAC Policy on Metrological Traceability of Measurement Results” and, in accordance with them, evaluates how Calibration Laboratories ensure metrological traceability to the International System of Units (SI), using equipment, instruments, calibrated measurement standards, and certified reference materials from competent Bodies, as described in §9 of this document.

### 6.5.2.

The requirement of the standard and the metrological traceability policy described in §9 of this document apply. In cases where the Laboratory performs internal calibrations, as defined in §3.1.7, it shall assess metrological traceability and the uncertainty budget in accordance with the requirements set out in §10 of this document.

### 6.5.3.

The requirement of the standard applies.

## 6.6. Externally Provided Products and Services

### 6.6.1.

The requirement of the standard applies. ACCREDIA does not allow the continuous outsourcing of calibrations included within the Laboratory’s scope of accreditation, or any part thereof.

a. Services purchased externally and falling within the Laboratory's activities, provided for by the management system, are configured as activities deriving from external suppliers. The Laboratory may include the results of subcontracted activities in its Calibration Certificate only if they are part of its CMCs. In this case it must indicate in the Certificate that the calibration/sampling was

performed by subcontractors (for further details on the information to be included in the Certificate, refer to point 7.8.2.1 of this document).

b. In the case of requests for calibration that cannot be performed by the Laboratory through its accreditation, these can be entrusted by it to another accredited Laboratory, with the prior consent of the Client.

**Note:** see also note 1 in §7.1.1 of the standard.

c. Externally purchased products and services that are part of the Laboratory's normal activities are activities derived from external suppliers (examples of such activities may be internal audits and/or interlaboratory proficiency testing).

**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 with the provision that the Laboratory must have one or more procedures for the management of requests, tenders and contracts. All activities covered by accreditation must be contractually managed as accredited, unless the customer explicitly requests otherwise. In that case, the customer's request must be clearly stated in the contractual agreements (ref. EA 3/01).

ACCREDIA excludes the possibility of performing calibrations using methods proposed by the Client that do not fall within the scope of accreditation. The Laboratory shall exclusively apply methods that have been positively assessed by ACCREDIA.

The Laboratory shall inform the client about the meaning of accreditation and about the accreditation of the activities covered by the tender (extension and limits of accreditation in terms of published CMCs).

With regard to the use of accreditation references, and in particular the use of the ACCREDIA mark and/or reference to accreditation, the Laboratory is required to comply with the provisions of this Regulation and the Regulation on the Use of the ACCREDIA Logo and Mark RG-09.

For requests for opinions and interpretations, in the process of reviewing requests, tenders and contracts the Laboratory shall:

- verify that the Laboratory activities used to express opinions and interpretations are accredited;
- clarify that opinions and interpretations are based exclusively on the results reported in the Certificate and should not be used, alone, as a product certification of the instrument being calibrated.

**7.1.2.**

The requirement of the standard applies.

**7.1.3.**

The requirement of the standard applies. The Laboratory cannot a priori refuse to issue statements of conformity when requested by the client, unless prohibited by mandatory regulations.

Note: For further guidance on statements of conformity, reference is made to the requirements of ILAC G8 and ACCREDIA DT-10-DT.

**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.

## 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, with the provision that the method shall be described in one or more documented procedures. These procedures (and their subsequent revisions) relating to the calibration methods including evauation of uncertainty, shall be previously positively evaluated by ACCREDIA before their use.

**7.2.1.2.**

The requirement of the standard applies, with the provision that the documented procedures are re-examined after the metrological confirmation activities in order to be kept constantly updated. The updating of these procedures must be positively evaluated by ACCREDIA before their use.

**Note**: With regard to calibration methods with a flexible scope, the provisions of the RT-26 Regulation apply.

**7.2.1.3.**

The requirement of the standard applies. The uncertainty budget must always be documented (see §7.6.1 of this document).

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 updated methods according to the new versions within **3 (three) months** of the issue.

It is allowed to maintain calibrations accredited in accordance with editions no longer in force of regulations when these are referred to by mandatory provisions, by Public Administration specifications, or by regulations for product certification, in force, or requested by notified bodies.

If the Laboratory demonstrates that the decision to continue operating in accordance with a method contained in editions of a standard that are no longer in force is technically appropriate, the scope of accreditation shall report that method as an internal method (in cases not covered in the previous paragraph).

**Note:** if the method is sufficiently detailed in the referenced technical standard, it is recommended that the laboratory maintain records of the review performed to demonstrate that it did not deem it appropriate to rewrite the method (it is not necessary to rewrite the text of the standard in the documented procedure if the method is sufficiently detailed).

**7.2.1.4.**

The Laboratory must exclusively apply methods that have been previously positively evaluated by ACCREDIA.

**Note:** ACCREDIA recommends describing any deviations from the published method so that it is possible to insert an indication in the annex to the accreditation certificate.

**7.2.1.5.**

The requirement of the standard applies.

**7.2.1.6.**

The requirement of the standard applies. A Laboratory seeking accreditation for calibrations performed using internal methods (developed by the Laboratory) must submit copies of these methods to ACCREDIA for evaluation together with the validation procedure and the declaration of validation and suitability (a summary of what is described in clause 7.2.2.4 of the standard). With regard to calibration methods with flexible scope, the requirements of Regulation RT-26 apply.

**7.2.1.7.**

The requirement of the standard applies. The Laboratory, for accredited calibrations, shall always follow its CMC. Where it fails to satisfy the customer, he must give it written notice. With regard to calibration methods with a flexible scope, the provisions of the RT-26 Regulation apply.

### 7.2.2. Validation of Methods

**7.2.2.1.**

The requirement of the standard applies. ACCREDIA considers the content of note 2 to be prescriptive. In particular, ACCREDIA considers the use of interlaboratory comparisons for the validation of CMC to be an important tool for the validation and confirmation of methods.

ACCREDIA's policy regarding the use of measurement comparisons is contained in Technical Regulation RT-39 "Requirements for Participation in Proficiency Testing (PT) and/or Interlaboratory Comparisons (ILC)".

**7.2.2.2.**

The requirement of the standard applies.

**7.2.2.3.**

The requirement of the standard applies.

**7.2.2.4.**

The requirement of the standard applies.

## 7.3. Sampling

### 7.3.1.

The requirement of the standard applies with the provision that the sampling method shall be reported in a procedure documented in advance and positively evaluated by ACCREDIA before its use.

### 7.3.2.

The requirement of the standard applies with the provision that any deviation from the sampling procedure shall be recorded and reported as a note on the Certificate, whether this is imposed by the Client, or whether it has become somehow necessary.

## 7.4. Handling of Items to Be Calibrated

### 7.4.1.

The requirement of the standard applies.

### 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 identify areas within its sites in which to safely store and handle instruments and samples during their stay. These areas shall be clearly recognizable and possibly accompanied by appropriate indications (e.g., waiting area for calibration, waiting area for information from the client, waiting area for shipping). If instruments and standards destined for non-accredited activities are stationed in the laboratory, the Laboratory shall ensure appropriate procedures that avoid confusion with those related to accredited calibrations.

## 7.5. Technical Records

### 7.5.1.

The requirement of the standard applies, with the provision to set a minimum period of ten years for the conservation of all documentation relating to accredited calibrations, unless otherwise provided by law, in which case the latter shall prevail.

### 7.5.2.

The requirement of the standard applies. In the event of data correction, where the reason cannot be inferred from the records, the reason for the correction must be documented.

## 7.6. Evaluation of Measurement Uncertainty

### 7.6.1.

The requirement of the standard applies, with all uncertainty contributions identified as significant by the Laboratory appropriately documented. For any contributions considered negligible, it is required to document the reasons for this justification. The documents above shall be previously assessed positively by ACCREDIA before their use.

The uncertainty evaluation must be summarised in a table or more tables (also known as the uncertainty budget). One or more tables detailing the uncertainty budget used in the determination of CMC and the numerical values used in their determination must also be prepared. Particular attention must be paid to the description and quantification of the uncertainty components resulting from the choice of the best available instrument capable of being calibrated (reference ILAC P14 §4.3).

The uncertainty evaluation must be reviewed both according to a periodic schedule and in the event of changes to its components.

**Note:** the calibration of the reference standard is configured as one of the possible variations that determine a review of the evaluation of the uncertainty.

### 7.6.2.

The requirement of the standard applies. The requirements foreseen by ACCREDIA for the internal calibration of the measuring equipment are reported in the following § 10 of the present document.

**7.6.3.**

This point of the standard is not applicable to Calibration Laboratories.

## 7.7. Ensuring the Validity of Results

**7.7.1.**

The requirement of the standard applies, with the provision that the Laboratory shall prepare one or more documented procedures to monitor the validity of results through appropriate control plans. The Laboratory shall also prepare documented procedures for the statistical analysis of data collected from metrological confirmation, for example control charts or, more simply, graphs of calibration and verification values against their respective predetermined limits.

**7.7.2.**

The requirement of the standard applies. The requirements established by ACCREDIA for the validation of CMCs through measurement comparisons are set out in Technical Regulation RT-39 “Requirements for Participation in Proficiency Testing (PT) and/or Interlaboratory Comparisons (ILC)”.

If the Laboratory also acts as the organiser of an S_ILC, the management system must be extended to cover this activity, and the records must be retained.

**7.7.3.**

The requirement of the standard applies.

## 7.8. Reporting of Results

### 7.8.1. General

**7.8.1.1.**

The requirement of the standard applies. Calibration Certificates must be issued using the ACCREDIA mark, according to the template provided in document DT-11-DT. Calibration Certificates must not include results of non-accredited calibrations, that is, measurement points not covered by the accreditation table, meaning they are outside the CMC published in the scope of accreditation.

**Note:** It is recommended that the Laboratory retain a true copy of the issued calibration certificates, either in paper form (as a reproduction) or in electronic format, provided that they ensure full correspondence with the original.

**Note:** It is recommended that the Laboratory use a different template for calibration reports issued outside the scope of accreditation, distinct from the Certificate template (reference DT-11-DT), so as not to mislead the client into incorrectly assuming that the service is accredited. It is also recommended that the numbering of non-accredited reports follow a system different from that used for Calibration Certificates, in particular avoiding the use of an alphanumeric string containing the acronym “LAT”.

**7.8.1.2.**

The requirement of the standard applies.

**7.8.1.3.**

The requirement of the standard applies. In the case of a simplified presentation of the results, the Laboratory is required to report a clear identification of the person(s) who approved the result.

### 7.8.2. Common Requirements for Reports (test, calibration or sampling)

**7.8.2.1.**

The requirement of the standard applies. The Laboratory is required to use the DT-11-DT template for the issuance of the Calibration Certificate.

If the Laboratory includes on its own Calibration Certificate the results of calibrations or sampling outsourced to accredited Laboratories for specific activities, the accreditation number of the external Laboratory must be indicated and, in the case of a non-Italian Laboratory, the name of the accrediting Body must also be provided.

**7.8.2.2.**

The requirement of the standard applies.

### 7.8.3. Specific Requirements for Test Reports

This point of the standard is not applicable to Calibration Laboratories.

### 7.8.4. Specific Requirements for Calibration Certificates

**7.8.4.1.**

The requirement of the standard applies. Measurement uncertainty must be expressed in accordance with the relevant standards (see also the GUM document, EA-4/02, and ILAC P14).

The requirement of the standard applies.

**7.8.4.2.**

The requirement of the standard applies.

The use of labels bearing the ACCREDIA mark directly on the instrument or standard being calibrated is permitted, provided that the calibration is included within the scope of accreditation.

The use of the ACCREDIA mark must comply with the provisions of Regulation RG-09. These provisions are necessary to ensure that the calibration is performed by an accredited organization in accordance with ISO/IEC 17025:2017.

### 7.8.5. Reporting Sampling – Specific Requirements

The requirement of the standard applies.

### 7.8.6. Reporting Statements of Conformity

**7.8.6.1.**

The requirement of the standard applies.

**Note:** For statements of conformity, see, by way of example, the ILAC G8 document, the EURACHEM/CITAC Guide, and the DT-10-DT document.

**Note:** As guidance for the correct formulation of statements, the contents of the following documents can be used as examples: ILAC G8, the EURACHEM/CITAC Guide, and the DT-10-DT document.

**7.8.6.2.**

The requirement of the standard applies.

The statement of conformity is an integral part of the Calibration Certificate and must therefore be included before the wording “End of Certificate” rather than as an annex to it.

### 7.8.7. Reporting Opinions and Interpretations

**7.8.7.1.**

The requirement of the standard applies.

**7.8.7.2.**

The requirement of the standard applies.

**7.8.7.3.**

The requirement of the standard applies.

### 7.8.8. Amendments to Reports

**7.8.8.1.**

The requirement of the standard applies.

**7.8.8.2.**

The requirement of the standard applies.

**7.8.8.3.**

The requirement of the standard applies. When, for any reason, a correction of what is reported on a calibration certificate with consequent re-issue is necessary, the new certificate shall be issued with a new number and with the words "replaces the Certificate no. ..."

## 7.9. Complaints

**7.9.1.**

The requirement of the standard applies with the provision that the entire process of handling complaints, from receipt, evaluation and treatment, must be described in advance in a procedure documented and positively evaluated by ACCREDIA before its use.

**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. In the event that the organization of the Laboratory includes a single person, the involvement of an external resource is required.

**7.9.7.**

The requirement of the standard applies.

## 7.10. Nonconforming Work

**7.10.1.**

The requirement of the standard applies. If nonconforming activities have an impact on the Calibration Certificate, the Laboratory shall review all issued Calibration Certificates, trace, correct, and reissue all those affected by the same deficiencies.

**7.10.2.**

The requirement of the standard applies.

## 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.

**7.11.3.**

The requirement of the standard applies.

#### 7.11.4.

The requirement of the standard applies.

#### 7.11.5.

The requirement of the standard applies.

#### 7.11.6.

The requirement of the standard applies.

# 8. Management System Requirements

## 8.1. Options

### 8.1.1. General

The requirement of the standard applies.

For the assessment of updates to technical documentation, reference should be made to the current RG-13 regulation. In the case of updates to externally sourced documents (e.g., standards, methods, laws, regulations), unless otherwise specified, the Laboratory is required to implement the new versions within three (3) months of their entry into force.

**Note:** ACCREDIA requires the Laboratory to operate as described in RG-13 § 4.2.

### 8.1.2. Option A

The requirement of the standard applies.

### 8.1.3. Option B

ACCREDIA in assessing the management system of a laboratory applies the resolution number 22 of the EA of May 2015 (reference EA Resolution 2015 (35) 22 published at http://www.european-accreditation.org), recognizing that a Laboratory operating with a management system compliant to ISO 9001 is able to obtain the same results that would have had directly implementing the requirements set out in paragraphs from 8.2 to 8.9 of the ISO/IEC 17025:2017. ACCREDIA's assessment therefore extends to this correspondence.

ACCREDIA does not evaluate the certified system in accordance with the requirements of ISO 9001 but assesses its coverage with respect to all requirements of ISO/IEC 17025:2017, which means that the

management system contains the necessary references to describe completely how the calibration activities comply with all the paragraphs of ISO/IEC 17025:2017. As evidence of coverage of the field of activity ACCREDIA assesses the presence of the references to the Laboratory in all the records provided by the management system.

## 8.2. Management System Documentation (Option A)

### 8.2.1.

The requirement of the standard applies.

**Note:** ACCREDIA assesses that the Quality Policy contains specific declarations regarding the fulfilment of the requirements of the standard and those deriving from ACCREDIA, EA and ILAC mandatory documents, as indicated in this regulation, aimed at obtaining and maintaining accreditation. ACCREDIA checks that this happens even if, being the Laboratory part of a larger organization, the quality policy is included in any similar documents of a higher level.

### 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.

**Note:** As regards the provision of system documentation to personnel, if the Laboratory uses company information systems to support the management system, it is recommended that the relevant access methods are identified (such as authorizations, limitations, access control).

## 8.3. Control of management system documents (Option A)

### 8.3.1.

The requirement of the standard applies.

**Note:** In applying the requirement of the standard, the attention of the Laboratory is drawn to the need to identify ways of adapting technical procedures to regulatory developments in the sector.

### 8.3.2.

The requirement of the standard applies.

## 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.

**Note:** ACCREDIA envisages ten years as a minimum period for the conservation of all documentation related to accredited productions, unless otherwise provided by law, in which case the latter shall prevail.

## 8.5. Actions to Address Risks and Opportunities (Option A)

### 8.5.1.

The requirement of the standard applies.

### 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.

**Note:** By way of example, the laboratory may consider the following elements:

- Personnel training and development programmes;
- Improvement of calibration methods and enhancement of their efficiency to better meet requirements and client requests;
- Automation of activities and data recording;
- Upgrading equipment and maintaining it at the best possible level.

### 8.6.2.

The requirement of the standard applies.

## 8.7. Corrective Actions (Option A)

### 8.7.1.

The requirement of the standard applies. If non-compliant activities are identified that could compromise the implementation of accredited calibrations, the Laboratory - in addition to the provisions of its quality management system in application of the standard requirements - shall promptly inform ACCREDIA and, if necessary, request the self-suspension according to the provisions of the RG-13 Regulation.

### 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. The second- and third-part assessments cannot replace the internal technical and/or system audits.

**Note:** It is recommended that the planning of internal audits include the evaluation of the effectiveness of corrective actions relating to the findings of previous audits, both first- (and second-) party and third-party audits.

### 8.8.2.

The requirement of the standard applies.

## 8.9. Management Review (Option A)

### 8.9.1.

The requirement of the standard applies.

**Note:** Depending on the size of the Laboratory and of the organisation, if any, of which it is part, reviews may be carried out at different levels, for example: one at a local level, where the Laboratory's issues are discussed, and another of a more general, corporate nature, to which the results of the local reviews are provided as input.

### 8.9.2.

The requirement of the standard applies.

# 9. Provisions relating to the Application of the Requirement on the Metrological Traceability of the Measurement Results for Calibration Laboratories

The Calibration Laboratories shall guarantee the metrological traceability as required by the standard. ACCREDIA recognizes, according to the ILAC - P10, that there are different ways to guarantee traceability, shown below.

The traceability of the measurement results is ensured through calibrations performed by:

1. National Metrological Institutes (NMI) and Designated Institutes (DI) whose services (CMC) are suitable and covered by the International Mutual Recognition Agreement (CIPM MRA) and included in the BIPM KCDB database. The presence of the note and/or the CIPM MRA logo on the Calibration Certificates demonstrates the coverage of the CMC; where the note and/or logo are not present, being their insertion discretionary, the Laboratory shall 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) signatories of the EA-MLA or ILAC-MRA agreement for the scope of "calibration" within the framework and within the limits set by the CMCs published by the ABs.

The use of Calibration Certificates issued in the framework of these two possibilities is to be considered of equal validity, without prejudice to the different value of the calibration uncertainties which must be adapted to the Laboratory's needs.

There may be situations in which metrological traceability cannot be obtained from either of the two cases mentioned above. The alternatives below are acceptable only if supported by evidence, as described below regarding the implementation of 3a, 3b, 4, 8 and 9.

3. a NMIs or DIs whose services are suitable but not covered by the CIPM-MRA agreement.

3.b Calibration laboratories whose services are suitable, but not covered by ILAC agreements or regional agreements recognized by ILAC.

Case 3b should only be chosen if the suppliers of type 1, 2 and 3a are not available. In this case the assessment of the supplier by the Laboratory shall also take place through a second-part audit in the presence of an ACCREDIA assessment team, including a Technical Officer. The assessment of the supplier by the Laboratory is in turn subject to evaluation by ACCREDIA.

Point 6.5.3 of ISO/IEC 17025:2017 indicates how to operate when the metrological traceability of the calibration to SI units is not technically possible. It is the responsibility of the Laboratory in these cases to provide evidence that meets the standard requirements. These evidences are subject to ACCREDIA's assessments.

The traceability of the results of the measurements through the use of reference materials is ensured through the assignment of the certified value by:

1. NMIs or DIs producing certified reference materials whose properties are included in the KCDB of the BIPM.
2. The presence of the note and/or the CIPM MRA logo on the Certificates of reference material demonstrates the coverage of the CMCs; where the note and/or logo are not present, being their insertion discretionary, the Laboratory shall verify the coverage of the CMCs by consulting the BIPM website at: www.bipm.org or kcdb.bipm.org. The values assigned to CRM listed in the JCTLM database (in www.bipm.org) provide valid evidence of traceability.
3. Accredited reference material producers (RMPs) producing certified reference materials (CRM) whose certified values are reported in the scope of accreditation.
4. Organizations listed in the JCTLM database (at www.bipm.org).
5. If it is not possible to find CRMs that fall within the previous three cases, the Laboratory will be able to resort to producers whose competence they shall evaluate in order to qualify them, in relation to their use. The extent of the assessments depends on the information available as well as on the nature of the material. The assessment of conformity to ISO 17034, ISO Guide 35, other regulations on the subject, the ILAC, EA and ACCREDIA prescriptive documents is carried out according to what is indicated in the following point on the implementation of 3a, 3b, 4, 8 and 9.
6. When points 5, 6, 7 and 8 cannot be applied (i.e., there are no CRMs available), it is recommended, when possible, to use reference materials produced by at least two independent producers. The laboratory must check materials from different producers against each other and ascertain their conformity to the intended use.

It should be noted that the choice of the cases described in points 3a, 3b, 4, 8 and 9 implies the use of services that have not been subject to peer evaluation or accreditation. The Laboratory shall therefore ensure that

appropriate evidence of the supplier's competence is available, particularly regarding the traceability and the measurement uncertainty of the calibrations or materials supplied.

ACCREDIA will assess both these evidences and the laboratory's ability to evaluate them in turn.

Adequate evidence of the supplier's technical expertise and metrological traceability could include, but not necessarily be limited to:

- For NMIs or DIs, records of the outcomes of the participations in interlaboratory comparisons, key and supplementary, within CIPM MRA or organized at regional level (e.g., EURAMET);
- For NMI or DI, records of the results of participation in inter-laboratory comparisons made with other NMIs and/or DIs;
- Recordings on validation of the calibration method (scientific publications, technical reports, etc.) and/or characterizations of RMs;
- Procedures for evaluating uncertainty and copying of Metrological Capabilities (CMC);
- Documentation on the traceability of the measurement results;
- Documentation on the assurance of the quality results of the calibration and/or characterization of RM;
- Evidence of the competence of the personnel in charge of calibration and/or production of RM;
- Documentation on the premises used for laboratory and/or production of RM and on the environmental conditions in which the calibrations and/or the RM characterizations have been carried out;
- Records of internal audits;
- Second-part audit records.

The certification of the management system of a company does not constitute certification of competence of the company Laboratories and of the corporate Producers.

The evidence of metrological traceability accepted by ACCREDIA is limited only to specific procedures and to the quantities and properties of reference materials subject to assessment and does not imply any evaluation of competence for other measures or for other services offered by the organization (in the cases 3a and 3b and the like for RM).

# 10. Provisions relating to Internal Calibrations

The technical aspects related to the execution of internal calibrations shall comply with ISO/IEC 17025:2017. In particular, internal calibrations shall be performed:

- by competent personnel of the Laboratory or of the organisation to which the Laboratory belongs, who are appropriately trained and qualified/authorised;
- using instruments or reference standards under the control of the LAT or of the organisation to which the LAT belongs, calibrated so as to ensure metrological traceability;
- in an environment suitable for the type of calibration;
- implementing process requirements compliant with the contents of §7 of RT-25 and positively evaluated by ACCREDIA.

The results of internal calibrations shall:

- be accompanied by measurement uncertainty;
- be registered in a calibration report in accordance with §7.8 of the ISO/IEC 17025:2017.

# 11. Requirements contained in other ACCREDIA documents

The following table lists the ACCREDIA documents and the topics for which the Laboratory must ensure compliance. In cases where the document partly or fully covers subjects related to the Standard, the relevant paragraph is included.

| **Document** | **Subject** | **Paragraph of the Standard (EN ISO/IEC 17025:2017)** |
|---|---|---|
| RG-09: Regulation for the use of the ACCREDIA mark | Requirements regarding the permitted use of the ACCREDIA mark. | §7.8.4.3 |
| RT-26:<br>Requirements for the accreditation of flexible scope | Requirements regarding accreditation with a flexible accreditation scope | §7.2.1.2, |
| RT 39:<br>Requirements for participation in proficiency testing (PT) and/or interlaboratory comparisons (ILC). | Ensuring the validity of test and calibration results | §7.2.2.1,<br>§7.7.2 |

# 12. Requirements for laboratories performing periodic verification activities in accordance with Legislative Decree No. 93 of 21 April 2017.

Laboratories performing periodic verification activities must integrate within their Management System, compliant with ISO 17025, the requirements set out in Legislative Decree 93/2017, the Regulation for accredited bodies performing periodic verification of measuring instruments pursuant to Legislative Decree No. 93 of 21 April 2017, and the relevant ACCREDIA Circulars.

These aspects are subject to assessment by ACCREDIA DT.

| ISO 17025 :2017 | Additional Requirements DM 93/2027 |
|---|---|
| 4.139 si fa riferimento alla 17025:2017 anche in Italiano? | In cases where the organisation also performs repair activities, the periodic verification function must be carried out in a manner that is distinct and independent from that of repair;<br><br>The person responsible for periodic verification, when simultaneously performing repair functions, must record all operations carried out in the metrological log.<br><br>The Laboratory must ensure adequate measures (policies and procedures) to prevent personnel from being involved in activities that could undermine confidence in the laboratory's impartiality, competence, and integrity.<br><br>Examples of potential risks:<br><br>▪ Laboratory employees, collaborators, or partners who carry out periodic verifications and also own measuring instruments;<br>▪ The laboratory's corporate structure;<br>▪ Interests of laboratory personnel in other companies that own measuring instruments;<br>▪ Contracts entered into by the laboratory with external personnel performing periodic verifications.<br><br>Examples of countermeasures to mitigate the risk to impartiality:<br><br>▪ Preparation of engagement letters specifying the type of activity the operator is required to perform;<br>▪ Procedures/checklists that document in detail the operations to be carried out in cases of periodic verification and repair;<br>▪ Declarations of impartiality by laboratory personnel. |
| 5.3 | The Laboratory must have a document officially issued by the management personnel, declaring the scope and coverage of the activities carried out by the Laboratory in accordance with DM 93/2017 and the UNIONCAMERE Regulation for accredited bodies performing periodic |

| ISO 17025 :2017 | Additional Requirements DM 93/2027 |
|---|---|
| | verification of measuring instruments pursuant to Decree No. 93 of 21 April 2017. |
| 5.4 | Among the reference documents for accreditation, the Laboratory must include the following:<br>▪ DM 93/2017;<br>▪ UNIONCAMERE Regulation for accredited bodies performing periodic verification, No. 71 of 30 October 2017;<br>▪ Accredia circulars. |
| 5.5 | The person responsible for periodic verification must report directly to the legal representative of the company to which the Laboratory belongs.<br>Accredia assesses the company's organisational chart and the structure of hierarchical reporting lines.<br>The Laboratory must appoint (qualify and assign) the person responsible for periodic verification and, if applicable, a deputy, and must provide within its management system for the appointment, the recording of authorisations for specific activities, and the assignment of specific delegations. |
| 6.2 | The Laboratory must document the competence, training, authorisation, and competency monitoring requirements for all personnel involved in periodic verification activities. |
| 6.6 | If the Laboratory uses external personnel to carry out periodic verification activities, specific contracts must be formalised and any potential conflicts of interest must be assessed. |
| 7.1 | The Laboratory must maintain a log in which periodic verification requests are recorded in chronological order, along with their execution date and the corresponding outcome, whether positive or negative.<br>The Laboratory must document within its management system the responsibilities and procedures for handling and technically reviewing requests, tenders, and contracts for carrying out verification activities, in particular ensuring that periodic verification is performed |

| ISO 17025 :2017 | Additional Requirements DM 93/2027 |
|---|---|
| | within **45 (forty-five) days** from the date of the client's formal request.<br><br>It should be noted that the Laboratory is required to submit electronically, within **10 (ten) working days** of the verification, to the Chamber of Commerce of each province where periodic verification operations were carried out, and to Unioncamere, a summary document of the instruments verified (art. 13.1). |
| 7.1.5 | A Laboratory subject to measures prohibiting the continuation of activities or to self-protective actions by Unioncamere must inform the owners of the instruments scheduled for periodic verification of the inability to carry out such verifications. |
| 7.5 | The Laboratory must retain, for at least 5 years, copies of the documentation, including in electronic form, demonstrating the periodic verification operations carried out, together with the records of positive or negative results.<br>It should be noted that, where the manufacturer has not already done so, the Laboratory performing the first periodic verification must provide the measuring instrument, at no cost to its owner, with a metrological log containing the information specified in Annex V of DM 93/2017. |
| 7.8.1.3 | A Laboratory that decides to issue a periodic verification report to the client must describe its content in its technical documentation. |
| 7.10 | The Laboratory must handle any reports from the Chamber of Commerce as non-conformities and make them available to ACCREDIA DT. |
| 8.2 - 8.9 | The Quality Policy must include specific statements regarding compliance with the requirements of DM 93/2017 (and those arising from Unioncamere prescriptive documents) aimed at obtaining and maintaining accreditation.<br>The internal audit programme must include periodic |

| ISO 17025 :2017 | Additional Requirements DM 93/2027 |
|---|---|
| | verification activities.<br>The auditor must possess adequate technical competence. |
| Labels and Seals | The Laboratory must prepare labels and seals in accordance with the provisions of the “Regulation for accredited bodies performing periodic verification of measuring instruments pursuant to Decree No. 93 of 21 April 2017.” |
| Use of the ACCREDIA Mark | The Laboratory must use the ACCREDIA mark in accordance with ACCREDIA Regulation RG-09.<br>The use of the ACCREDIA mark is permitted in the metrological log in the section where the Laboratory records the results of the periodic verification performed.<br>Where the Laboratory issues a periodic verification report to the client, the ACCREDIA mark must be included in the report. |

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