ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

TITLE **REQUIREMENTS FOR THE ACCREDITATION OF CALIBRATION LABORATORIES**

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PREPARATION

THE DIRECTOR OF CALIBRATION LABORATORIES DEPARTMENT

APPROVAL

THE DIRECTIVE COUNCIL

AUTHORIZATION

THE GENERAL DIRECTOR

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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 UNI CEI EN ISO/IEC 17025:2018 "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.

The accreditation attests the technical competence of the Laboratory to carry out the calibrations indicated in the scope of accreditation indicated in the annex to the Accreditation Certificate. Calibration Laboratories (LAT) accredited from ACCREDIA operate as Calibration Centres within the framework of the National Calibration System defined by law 273/91 and are considered competent to carry out calibrations to support the activities of testing laboratories, certification and inspection accredited bodies.

2. SCOPE AND APPLICATION FIELD

This document refers to the requirements of the UNI CEI EN ISO/IEC 17025:2018 standard. The numbering of the paragraphs, for chapters 4 to 8, coincides with those of the standard. These chapters, and chapters 9 and 10, contain the information introduced by ACCREDIA that Calibration Laboratories must implement together with the standard and EA and ILAC requirements.

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.

This document is applicable to all laboratories that perform a calibration service, regardless of the number of people working in them. Both organizationally and commercially independent laboratories, and those dependent on a larger organization (such as manufacturing companies, public or private organizations, research centres, etc.) are taken into consideration.

The information given in this document are applicable for any metrological sector; specific requirements defined by the binding legislation or at international level (EA, ILAC, ISO, EN, etc.) are listed in ACCREDIA Department of Calibration Laboratories LS-09 "Reference regulations and documents for accreditation of Calibration Laboratories", in the revision in force, downloadable from the website www.accredia.it.

In order to obtain, extend and maintain accreditation, the Laboratory must demonstrate that it complies with all the requirements of the standard, with the exception of those declared not applicable with a reason, for all the calibration activities defined in the application field of the management system.

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

3. DEFINITIONS AND REFERENCES

3.1. DEFINITIONS

For the purposes of this document the definitions contained in the reference standards UNI EN ISO 9000, UNI CEI EN ISO/IEC 17000, UNI CEI EN ISO/IEC 17011, UNI CEI EN ISO/IEC 17025:2018, UNI CEI EN ISO 17034, UNI CEI EN 45020, UNI CEI 70099 International Metrology Vocabulary (VIM3), in the revision in force on the subject, in the General Accreditation Regulations and in other applicable Regulations/technical documents shall apply.

Some definitions are also shown 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 (UNI CEI EN 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 (UNI CEI EN ISO 17034:2017 - §3.2)

NOTA 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.

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

NOTA 3 ISO Guide 31 gives guidance on the contents of reference material certificates.

NOTA 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:

- does not fall within the scope of accreditation of the LAT (and as such cannot be offered as an accredited calibration service);
- is performed by LAT personnel and instrumentation (or under its direct control), applying technical procedures evaluated positively 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 proportional to the expected effect and probability 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 time validity of the documents reported.

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

4. GENERAL REQUIREMENTS

4.1. IMPARTIALITY

4.1.1.

The standard requirement applies.

4.1.2.

The standard requirement 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 standard requirement applies.

4.1.4.

The standard requirement 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 are:

- relationship with the parent company;
- relations between different functions of the same Organization;
- relations with connected Organizations/Companies;
- relations with the Supervisory Authorities (for example Ministries, Agencies, ARPA ...);
- customer relations;
- staff relations;
- relations with intermediary companies;
- relations with staffing companies.

4.1.5.

The standard requirement 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: with regard to risk management, please see the ISO Guide 31000 "*Risk management — Principles and guidelines*".

4.2. CONFIDENTIALITY

4.2.1.

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

Note: the identification i) of the personnel authorized to access the laboratory premises, ii) of the personnel authorized to access the Customer's data (whether these are managed in paper or electronic format), and iii) of the envisaged control of these accesses to company software and shared areas of corporate networks, is recommended.

4.2.2.

The standard requirement applies.

4.2.3.

The standard requirement 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 standard requirement applies. ACCREDIA therefore requires that all sites and all activities, including calibration activities, be listed in the chamber of commerce certificate.

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 standard requirement applies.

Note: The identification of the person carrying out the management review is recommended, as evidence of the responsibility and authority required by the standard.

5.3.

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

- a document officially issued by the management declaring the scope and coverage of the activities that the Laboratory performs 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 a Laboratory that in turn outsources them to a third Laboratory, it is not possible to consider this activity as accredited.

5.4.

The standard requirement 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 application DA-05 the list of all the sites where the activities described in the Standard are performed, including calibration operations. A site may be a permanent, temporary or mobile facility of the Laboratory or a site outside the Laboratory's permanent facilities or a Customer's facility (see definition in RG-13).

5.5.

a) The standard requirement 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.

b) The standard requirement 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.

c) The standard requirement applies, with the provision that the **document description** chosen by the Laboratory contains the technical activities that lead to the CMC and those explicitly referred to as procedures by the standard.

5.6.

The standard requirement 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 standard requirement 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 standard requirement applies with the specification that the Laboratory must define in a system document the modalities and responsibilities for change management (e.g., change of Technical Management/Laboratory Manager/Substitute).

6. RESOURCE REQUIREMENTS

6.1. GENERAL

The standard requirement applies.

6.2. PERSONNEL

6.2.1.

The standard requirement applies.

6.2.2.

The standard requirement applies with the prescription that the Laboratory shall document, for each role, the skills necessary to fulfil it.

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 standard requirement applies.

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

6.2.4.

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

6.2.6.

The standard requirement applies.

Note: The authorizations can be registered as part of the job descriptions or can be explained in the job descriptions themselves. An example of registration of authorizations can be a summary table, showing the authorized personnel to perform each accredited calibration, sampling, internal calibration, etc.

6.3. FACILITIES AND ENVIRONMENTAL CONDITIONS

6.3.1.

The standard requirement applies.

Note: It is recommended to establish, in relation to the sites, the limits of acceptability and related assessment methods for the conditions of the environment in which operations relevant to the quality assurance of results are performed. Particular attention must be paid to the conditions of the environment in which calibration operations are performed.

6.3.2.

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

6.3.3.

The standard requirement 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.

Note: If the records of the environmental conditions show that the limits defined by the Laboratory are exceeded, it is recommended that this situation is treated as non-Conformity according to the provisions of the Laboratory Management System.

6.3.4.

The standard requirement 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 standard requirement applies. ACCREDIA evaluates, among other evidences, that the Laboratory has a document of the management system that illustrates how the laboratory adopts the requirement. Where environmental conditions are important, detection systems shall be included in the **documented** metrological confirmation **procedure** of the instrumentation and records of environmental conditions at the time of accreditation calibrations, when necessary, shall be kept for at least ten years.

6.4. EQUIPMENT

6.4.1.

The standard requirement applies.

6.4.2.

The standard requirement applies.

6.4.3.

The standard requirement 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 standard requirement applies.

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

6.4.5.

The standard requirement applies.

6.4.6.

The standard requirement 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 standard requirement 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 standard requirement applies.

6.4.9.

The standard requirement applies.

6.4.10.

The standard requirement 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 of standards and instruments. This process must first be positively evaluated by ACCREDIA. It is also recommended to implement the requirements of the UNI EN ISO 10012 standard.

6.4.11.

The standard requirement 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 standard requirement applies.

6.4.13.

The standard requirement applies.

6.5. METROLOGICAL TRACEABILITY

6.5.1.

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

Note: The Department assesses compliance with ILAC-P10 requirements "ILAC Policy on the Traceability of Measurement Results" and in accordance with them evaluates how the Calibration Laboratories guarantee the metrological traceability to SI System of measurement units, using equipment, instruments, calibrated measurement standards and reference materials certified by competent bodies, as described in chapter 9 of this document.

6.5.2.

The standard requirement and the metrological traceability policy set out in chapter 9 of this document apply. In the event that the Laboratory performs ACCREDIA calibrations internally, it evaluates the metrological traceability and the uncertainty budget in compliance with the requirements set out in chapter 10 of this document.

6.5.3.

The standard requirement applies.

6.6. EXTERNALLY PROVIDED PRODUCTS AND SERVICES

6.6.1.

The standard requirement applies. ACCREDIA does not provide for calibrations in its scope of accreditation or parts thereof to be outsourced on an ongoing basis.

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 CMC. 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 Customer.

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 standard requirement applies.

6.6.3.

The standard requirement applies.

7. PROCESS REQUIREMENTS

7.1. REVIEW OF REQUESTS, TENDERS AND CONTRACTS

7.1.1.

The standard requirement applies with the prescription that the Laboratory must have one or more procedures for the management of requests, offers 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 Customer 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 CMC).

With regards to the use of references to accreditation and, in particular, the use of the ACCREDIA accreditation mark and/or the reference to accreditation, the Laboratory is required to comply with the provisions of this Regulation and the Regulations for the use of the ACCREDIA 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.

Note: It is recommended that the Laboratory provide its Customers with adequate support in interpreting the results of calibration activities and to foresee the actions to be taken should it become impossible to carry out the required calibrations.

7.1.2.

The standard requirement applies.

7.1.3.

The standard requirement applies. The laboratory may not a priori exclude issuing declarations of conformity if requested by the customer, unless prohibited by binding provisions.

Note: For further guidance on declarations of conformity, please refer to the requirements of UNI EN ISO 14253-1:2018, and ILAC document G8 and ACCREDIA document DT-10-DT.

7.1.4.

The standard requirement applies.

7.1.5.

The standard requirement applies.

7.1.8.

The standard requirement applies.

7.2. SELECTION, VERIFICATION AND VALIDATION OF METHODS

7.2.1 SELECTION AND VERIFICATION OF METHODS

7.2.1.1.

The standard requirement 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 estimation of uncertainty, to internal calibrations, shall be previously positively evaluated by ACCREDIA before their use.

7.2.1.2.

The standard requirement 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 standard requirement 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 **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 technically the choice to continue to operate according to a method reported in editions no longer in force as a rule, is appropriate, then the purpose of accreditation will report this method as internal.

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 standard requirement applies.

7.2.1.6.

The standard requirement applies. Regarding calibration methods with a flexible scope, the provisions of the RT-26 Regulation apply. The Laboratory that requires the accreditation of calibrations performed according to internal methods (developed by it) must send ACCREDIA a copy of these methods to be evaluated by ACCREDIA, accompanied by the validation procedure and the declaration of validation and suitability (summary of what described in point 7.2.2.4 of the standard).

7.2.1.7.

The standard requirement 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 standard requirement 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.

The ACCREDIA policy regarding the use of measurement comparisons is contained in the technical regulation RT-36 "Proficiency Tests (PTs) and Interlaboratory Comparisons (ILCs) for the Department of Calibration Laboratory ".

7.2.2.2.

The standard requirement applies.

7.2.2.3.

The standard requirement applies.

7.2.2.4.

The standard requirement applies.

7.3. SAMPLING

7.3.1.

The standard requirement 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 standard requirement 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.

7.3.3.

The standard requirement applies.

7.4. HANDLING OF CALIBRATION ITEMS

7.4.1.

The standard requirement applies.

7.4.2.

The standard requirement applies.

7.4.3.

The standard requirement applies.

7.4.4.

The standard requirement applies. The laboratory must identify areas within its premises 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 customer, 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 standard requirement 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 standard requirement applies. In case of correction of data, where the explanation cannot be deduced from the recordings, the reason for the correction shall be noted.

7.6. EVALUATION OF MEASUREMENT UNCERTAINTY

7.6.1.

The standard requirement applies, adequately documenting all the uncertainties identified as significant by the Laboratory. 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 existing calibratable instrument (reference ILAC P14 §4.3).

The evaluation of uncertainty must be reviewed both by a periodic programme and in case of changes in 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 standard requirement applies. The requirements foreseen by ACCREDIA for the internal calibration of the measuring devices are reported in the following chapter 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 standard requirement applies with the provision that the Laboratory shall prepare one or more **documented procedures** to monitor the validity of the results through appropriate control plans. The Laboratory must prepare **documented procedures** for the statistical analysis of the data collected from the metrological confirmation, for example control charts or more simply diagrams of the calibration and verification values with respect to the relative pre-established limits.

7.7.2.

The standard requirement applies. The Laboratory shall, where possible, contact organizers of inter-laboratory comparisons that operate in compliance with the UNI CEI EN ISO/IEC 17043 standard (for example, by contacting organizers accredited for this activity or declaring to operate in compliance with the aforementioned standard). The requirements provided by ACCREDIA for the validation of CMCs through Measurement Comparisons are reported in the technical regulation RT-36 " Proficiency Tests (PT) and Interlaboratory Comparisons (ILC) for the Calibration Laboratory Department".

If the laboratory is also the organiser of an S_ILC, the management system must also be extended to cover this activity and records must be kept.

7.7.3.

The standard requirement applies.

7.8. REPORTING OF RESULTS

7.8.1. GENERAL

7.8.1.1.

The standard requirement applies. The calibration certificates must be issued using the ACCREDIA mark, according to the model foreseen by the IO-09-DT Instruction, on which non-accredited calibration results cannot be reported, i.e., measurement points not included in the accreditation table, i.e., covered from the CMC published for the scope of accreditation.

Note: It is recommended that the Laboratory maintains a copy compliant to the original of the Calibration Certificates issued, in paper format (as a reproduction) or in electronic format, provided that they guarantee total correspondence to the original.

Note: It is recommended that the Laboratory uses for calibration reports issued out of accreditation a model different from that of the Certificate (reference IO-09-DT) in order not to induce the customer to erroneously think that it is an accredited service. It is also recommended that the numbering of the non-accreditation reports follow different criteria from those applied for the numbering of the calibration certificates, in particular that an alphanumeric string containing the initials "LAT" is not used.

7.8.1.2.

The standard requirement applies.

7.8.1.3.

The standard requirement 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 standard requirements and the indications given in the document IO-09-DT apply.

In the event that the Laboratory reports on its own Calibration Certificate also the calibration or sampling results outsourced to accredited laboratories for the specific activities, the accreditation number of the external Laboratory shall be indicated and, in the case of non-Italian organization, also the name of the accrediting body.

7.8.2.2.

The standard requirement 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 standard requirement applies. The Certificates shall fully describe the environmental conditions where these are essential for calibration. The measurement uncertainty shall be expressed according to the relevant normative standards (see also document EA-4/02). The contents of the document IO-09-DT also apply.

7.8.4.2.

The standard requirement and what is stated in the document IO-09-DT shall apply.

7.8.4.3.

The standard requirement applies.

The use of labels with the ACCREDIA mark is allowed directly on the instrument/standard subject to calibration, provided that this calibration is included in the scope of accreditation. The ACCREDIA mark shall not be used/glued on the instrument/standard independently of the label that identifies it. This label must include at least the fields listed below:

- the company name and the accreditation number of the LAT;
- identification of the instrument/standard;
- the calibration date;
- the univocal reference to the Certificate associated with the instrument/standard.

The use of the ACCREDIA mark shall comply with the provisions of the RG-09 Regulation. These requirements are necessary to guarantee that the calibration is performed by an organization accredited in compliance with the UNI CEI EN ISO IEC 17025:2018 standard. The presence of the ACCREDIA mark label on an instrument/standard does not imply that this instrument/standard is approved by ACCREDIA.

7.8.5. REPORTING SAMPLING – COMPLIANCE SPECIFIC REQUIREMENTS

The standard requirement applies.

7.8.6. REPORTING STATEMENT OF CONFORMITY

7.8.6.1.

The standard requirement applies.

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

7.8.6.2.

The standard requirement applies.

7.8.7. REPORTING OPINIONS AND INTERPRETATIONS

7.8.7.1.

The standard requirement applies. The standard requirement and the provisions of the document IO-09-DT apply. As clarified in the Note, opinions and interpretations shall not be formulated in such a way as to be confused with product certifications (ISO/IEC 17065), inspection reports (ISO/IEC 17020) and statements of conformity as per 7.8.6.

7.8.7.2.

The standard requirement applies.

7.8.7.3.

The standard requirement applies.

7.8.8. AMENDMENTS TO REPORTS

7.8.8.1.

The standard requirement applies. When a calibration certificate is identified containing this type of shortcomings, the Laboratory, in the context of the management of the non-compliant activity, shall review all the calibration certificates issued, trace, correct and re-issue all those affected by the same shortcomings.

7.8.8.2.

The standard requirement applies. When, for any reason, a correction is necessary, the issuing of the same shall include the words "Amendment to Certificate, serial number... ".

7.8.8.3.

The standard requirement 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 standard requirement 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 standard requirement applies.

7.9.3.

The standard requirement applies.

7.9.4.

The standard requirement applies.

7.9.5.

The standard requirement applies.

7.9.6.

The standard requirement 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 standard requirement applies.

7.10. NON-CONFORMING WORK

7.10.1.

The standard requirement applies.

7.10.2.

The standard requirement applies.

7.10.3.

The standard requirement applies.

7.11. CONTROL OF DATA AND INFORMATION MANAGEMENT

7.11.1.

The standard requirement applies.

7.11.2.

The standard requirement applies.

7.11.3.

The standard requirement applies.

7.11.4.

The standard requirement applies.

7.11.5.

The standard requirement applies.

7.11.6.

The standard requirement applies.

Note: It is recommended to validate, check and protect also electronic processing sheets (e.g., spreadsheets designed in the laboratory) developed within the Laboratory.

8. MANAGEMENT SYSTEM REQUIREMENTS

8.1. OPTIONS

8.1.1. GENERAL

The standard requirement applies.

Modifications to the quality management system which do not affect the fulfilment of the technical requirements must be communicated to ACCREDIA DT, even immediately after their application, and their assessment falls within the activities performed by ACCREDIA DT during the first suitable surveillance visit. The assessment of updates to the technical documentation does not fall within the maintenance activities and, if they require assessment by Assessors and/or Technical Experts, they are the subject of a specific quotation. The Laboratory may apply the revised technical procedures only after positive assessment by ACCREDIA DT; the only exception allowed is for accreditation with flexible scope (see RT 26).

In the case of updates of documents of external origin (e.g., standards, methods, laws, regulations), unless otherwise indicated, the Laboratory is required to apply the new versions within three months of the issue.

Note: ACCREDIA requires the Laboratory to operate as described in RG-13 §2.2.1.

8.1.2. OPTION A

The standard requirement applies.

Note: ACCREDIA assesses the compliance of the management system as documented by the laboratory.

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 UNI CEI EN ISO/IEC 17025:2018. 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 UNI CEI EN ISO/IEC 17025:2018, which means that the management system contains the necessary references to describe completely how the calibration activities comply with all the paragraphs of UNI CEI EN ISO/IEC 17025:2018. 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 standard requirement 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 standard requirement applies.

8.2.3.

The standard requirement applies.

8.2.4.

The standard requirement applies.

8.2.5.

The standard requirement 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 DOCUMENT (OPTION A)

8.3.1.

The standard requirement applies.

Note: In applying the standard requirement, 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 standard requirement applies.

8.4. CONTROL OF RECORDS (OPTION A)

8.4.1.

The standard requirement applies.

8.4.2.

The standard requirement 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 standard requirement applies.

8.5.2.

The standard requirement applies.

8.5.3.

The standard requirement applies.

8.6. IMPROVEMENT (OPTION A)

8.6.1.

The standard requirement applies.

Note: The following elements may be considered by the laboratory as an example:

- staff training programmes;
- improvement of calibration methods and increase of their efficiency, in order to better respond to the requirements and requests of customers;
- automation of activities and data recording;

- updating of the equipment and its maintenance at the best possible level.

8.6.2.

The standard requirement applies.

8.7. CORRECTIVE ACTIONS (OPTION A)

8.7.1.

The standard requirement 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 standard requirement applies

8.7.3.

The standard requirement applies.

8.8. INTERNAL AUDITS (OPTION A)

8.8.1.

The standard requirement applies. The second- and third-part assessment cannot replace the internal technical and/or system audits.

Note: in the planning of the internal audits the assessment of effectiveness of the corrective actions related to the findings of the previous audits should be included, both of the first part (and second) and of the third part.

8.8.2.

The standard requirement applies.

8.9. MANAGEMENT REVIEW (OPTION A)

8.9.1.

The standard requirement applies.

Note: In relation to the size of the Laboratory and the possible organization of which it is a part, it is possible to envisage reviews at different levels, for example: one at a local level where the Laboratory problems are discussed and a more general, corporate one, to which the results of the local reviews come as input.

8.9.2.

The standard requirement applies.

8.9.3.

The standard requirement applies.

9. PROVISIONS RELATING TO THE APPLICATION OF THE REQUIREMENT ON THE METROLOGICAL TRACEABILITY OF THE MEASUREMENTS 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 CMC 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 CMC published by the AB.

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.

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

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

Case 3a should not be chosen on the basis of purely economic or logistical reasons, but should be considered as a last resort if cases 1 and 2 were not available.

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.

4 - Point 6.5.3 of UNI CEI EN ISO/IEC 17025:2018 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:

5 - NMIs or DIs producing certified reference materials whose properties are included in the KCDB of the BIPM.

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.

6 - Accredited reference material producers (RMPs) producing certified reference materials (CRM) whose certified values are reported in the scope of accreditation.

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

8 - 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 checks depends on the information available as well as on the nature of the material. The assessment of conformity to UNI CEI EN 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.

9 - 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.

ACCREDIA Traceability policy - implementation of points 3a, 3b, 4, 8 and 9 (reference Annex A ILAC - P10)

It should be noted that the choice of cases described in points 3a, 3b, 4, 8 and 9 implies the use of services that have not been subject to peer assessment or accreditation. The Laboratory shall therefore ensure that appropriate evidence is available on the competence of the supplier and particularly on the traceability and 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 estimating 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 CALIBRATION

The technical aspects related to the execution of internal calibrations shall comply with UNI CEI EN ISO/IEC 17025:2018. In particular, internal calibrations shall be performed:

- by competent personnel of the LAT or the organization to which the LAT belongs, adequately educated, and trained and qualified/licensed;
- with instruments or standards under the control of the LAT or of the organization to which the LAT belongs, calibrated so as to guarantee the dissemination of the metrological traceability;
- in an environment suitable for the type of calibration;
- implementing process requirements compliant with the contents of chapter 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 UNI CEI EN ISO/IEC 17025:2018.

11. ACCREDIA REQUIREMENTS CONTAINED IN OTHER ACCREDIA DOCUMENTS

The following table shows the ACCREDIA documents and the subject to which the Laboratory shall guarantee conformity. In cases where the document contains some or all of the topics related to the Standard, the relative paragraph is inserted.

Document	**Subject**	**Standard paragraph (UNI CEI EN ISO/IEC 17025:2018)**
IO-09-DT: Operational instruction on the compilation of a calibration certificate for the calibration centres accredited by ACCREDIA DT	Requirements concerning the form and content of calibration certificates; compliance with these requirements contributes to ensuring the uniformity of all calibration certificates, with a view to their recognition in particular between the signatories of the EA and ILAC multilateral agreements.	§7.8.1.1, §7.8.2.1, §7.8.4.1, §7.8.4.2, §7.8.7.1
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: Requirements for accreditation with a flexible accreditation field	Requirements regarding accreditation with a flexible accreditation field	§7.2.1.2, §7.2.1.6, §7.2.1.7
RT-36: Proficiency Tests (PT) and Interlaboratory Comparisons (ILC) for the Calibration Laboratory Department	Quality assurance of test and calibration results	§7.2.2.1, §7.7.2.