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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.*

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Errata corrige due to typographical errors: deletion of § 8.8.4 (not included in UNI CEI EN ISO 17034:2017), correction of the numbering of §§ 8.10, 8.10.1, 8.10.2, 8.10.3 and 8.11 (alignment with the requirements of UNI CEI EN ISO 17034:2017).

1. Introduction

This Technical Regulation specifies the general criteria for accreditation of Reference Material Producers (RMP) performed by the Calibration Laboratories Department (DT) of ACCREDIA, the Italian Accreditation Body.

It was originally developed by a dedicated Working Group coordinated by ACCREDIA, composed of representatives from INRIM, ENEA, ISS, and representatives of numerous other competent and involved bodies, with the aim of achieving the widest possible consensus on the provisions contained in the Regulation itself.

The application of such criteria aims to promote the establishment and maintenance of customers' confidence in the activities of Reference Material Producers, as well as in the impartiality and integrity of the technical and commercial operations associated with them. ACCREDIA accreditation is granted to Producers complying with the requirements of the international standard ISO 17034:2017, *"General requirements for the competence of reference material producers"*, or with standards that may in future be internationally recognised for this purpose (hereinafter also referred to simply as "the standard"), with EA and ILAC requirements, and with the requirements of this Technical Regulation and of the other prescriptive documents issued by ACCREDIA applicable to Reference Material Producers.

This Technical Regulation refers to the requirements of the standard ISO 17034:2017. The numbering of clauses 4 to 8 corresponds to that of the standard. Within these chapters, the clarifications introduced by ACCREDIA to the requirements of the standard are also provided, in some cases corresponding to the Notes contained in the standard itself.

The standard ISO 17034:2017 specifies the general requirements for the reference material production, including certified reference materials.

The implementation of the provisions set out in the standards of the "33400" family issued by the ISO/TC 334 Reference Materials Technical Committee, and in particular ISO 33401:2024 *"Reference materials — Contents of certificates, labels and accompanying documentation"* and ISO 33405:2024 *"Reference materials — Approaches for characterisation and assessment of homogeneity and stability"*, ensures compliance with the requirements of the ISO 17034:2017 standard.

In case the Producer is accredited for the production of certified reference materials (CRM) these are produced so as to guarantee the metrological traceability of the property values (see ILAC P10 *"ILAC Policy on the Traceability of Measurement Results*").

2. Scope and Field of Application

This Technical Regulation refers to the requirements of the ISO 17034:2017 standard. The numbering of clauses 4 to 8 corresponds to that of the standard. Within those chapters, as well as in Chapters 9 and 10, the

clarifications introduced by ACCREDIA to the requirements of the standard are set out; in some cases, these correspond to the Notes contained in the standard itself and to EA and ILAC requirements.

This Technical Regulation specifies the general, management and technical competence requirements for Reference Material Producers. The ISO 17034:2017 standard and this Technical Regulation apply to the production of all reference materials, including certified reference materials. ACCREDIA introduces specific provisions for the accreditation of reference material producers based on:

- whether the value of certain properties is certified or not;
- the different types of materials and their use;
- the operational sites;
- updates to the requirements of the standard, EA and ILAC.

The information set out in this document applies to the production of any reference material; Specific requirements established by mandatory legislation or at international level (EA, ILAC, ISO, EN, etc.) are listed in ACCREDIA document LS-09, *List of reference standards and documents for the accreditation of Calibration Laboratories and RMPs"*, in its current revision, which may be downloaded from the website www.accredia.it.

This Technical Regulation applies to Reference Material Producers (RMP below) and covers the production of all reference materials (RM), including certified reference materials (CRM).

The RMP obtains accreditation for the production of the RMs described in the annex to the accreditation certificate, using specified procedures. Accreditation therefore covers all RM batches falling within the scope of accreditation and produced after accreditation has been granted. However, it may also include existing batches, provided that the RMP demonstrates that they comply with the established criteria and ACCREDIA assesses them as such.

In order to obtain and maintain accreditation, reference material producers must demonstrate compliance with all the requirements of the applicable standards for all activities involved in the production of the reference material.

Where applicable to its production plan, the producer, in demonstrating compliance with the applicable requirements, may refer to the guidance provided in the "33400" family of standards issued by the ISO/TC 334 Reference Materials Technical Committee. If an RMP chooses not to follow the guidance set out in these standards, it assumes the responsibility of demonstrating that the requirements are met in an equivalent manner.

Where the standard requires documented procedures, the Reference Material Producer is obliged to prepare such documentation, which will be assessed by ACCREDIA, including any subsequent amendments.

The Reference Material Producer is required to comply with the provisions of ACCREDIA Regulation RG-09 regarding the use of the ACCREDIA logo and mark.

If the Reference Material Producer operates in the medical field, the ISO 15189 standard may be used as a normative reference as an alternative to ISO/IEC 17025.

3. Terms and Definitions

3.1. Definitions

For the purposes of this document, the definitions set out in the reference standards apply: ISO 9000, ISO/IEC 17000, 70099, ISO/IEC 17011, ISO/IEC 17025:2018, ISO 17034:2017, 45020, ISO Guide 30, the *International Vocabulary of Metrology (VIM3)*, in the current standards on the subject, in the General Accreditation Regulations, and in other applicable technical regulations/documents.

Note: It should be noted that, in cases where the documents cited above provide differing definitions for specific metrological terms related to reference materials, preference shall be given to the definitions set out in ISO Guide 30.

Some definitions are provided below:

3.1.1. 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.

Note 1: RM Reference Material is a generic term.

Note 2: Properties can be quantitative or qualitative (e.g., identity of substances or species).

Note 3: Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

Note 4: ISO/IEC Guide 99:2007 (70099:2008, 5.13) proposes a similar definition but restricts its applicability: it limits the term “measurement” to the application to quantitative values (quantities) and not to qualitative properties. However, note 3 of the definition in ISO/IEC Guide 99 includes the concept of qualitative attributes and qualitative properties, referred to as “nominal properties”.

3.1.2. 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.

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

Note 2: ISO/IEC Guide 99 proposes a similar definition (70099:2008, 5.14).

3.1.3. Candidate Reference Material

Material, intended to be produced as a reference material.

Note 1: A candidate material has yet to be characterized and tested to ensure that it is fit for use in a measurement process. To become an RM, a candidate material needs to be investigated to determine if it is sufficiently homogeneous and stable with respect to one or more specified properties, and is fit for its intended use in the development of measurement and test methods that target those properties.

Note 2: a candidate reference material may be a RM for other properties and a candidate reference material for the target property.

(ISO Guide 30, 2.1.3)

3.1.4. Matrix reference material

Reference material that is characteristic of a real sample.

Examples: Soil, drinking water, metal alloys, blood.

Note 1: Matrix reference materials may be obtained directly from biological, environmental or industrial sources.

Nota 2: Matrix reference materials may also be prepared by spiking the component(s) of interest into an existing material.

Nota 3: A chemical substance dissolved in a pure solvent is not a matrix material.

Nota 4: Matrix materials are intended to be used in conjunction with the analysis of real samples of the same or a similar matrix. (ISO Guide 30, 2.1.4)

3.1.5. Production Batch (Lot)

Definite amount of material produced during a single manufacturing cycle, and intended to have uniform character and quality.

Note 1: The uniform conditions of manufacture or production of the batch or lot must be such as to ensure a homogeneous product.

Note 2: In statistics, an entire batch may be considered a finite population (totality of items under consideration).

Note 3: See also “lot” in ISO 3534-2:2014.

Note 4: See also the IUPAC Compendium of Analytical Nomenclature”.

(ISO Guide 30, 2.1.9)

3.1.6. Operationally Defined Measurand

Measurand that is defined by reference to a documented and widely accepted measurement procedure to which only results obtained by the same procedure can be compared.

Note: Examples include crude fibre in foods, impact toughness, enzyme activities and extractable lead in soils (ISO 17034 3.7)

3.1.7. Reference Measurement Procedure

Measurement procedure accepted as providing measurement results fit for their intended use in assessing measurement trueness of measured quantity values obtained from other measurement procedures for quantities of the same kind, in calibration, or in characterizing reference materials (UNI CEI 70099: 2008 2.7).

4. General Requirements

4.1. Contractual Matters

The RMP must inform the customer about the significance of the accreditation and the accreditation of the activities covered by the offer (extension and limits of the accreditation scope, as published).

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 RMP is required to comply with the provisions of this Regulation and the Regulations for the use of the ACCREDIA mark RG-09.

4.1.1.

The requirement of the standard applies.

All activities covered by accreditation shall be contractually managed as accredited, unless the client explicitly requests otherwise. In such cases, the client’s request shall be clearly stated in the contractual agreements (ref. EA 3/01).

During the review process, the RMP shall ensure that the client contract includes, at a minimum and where applicable, requirements concerning: the matrix, the value assigned to the properties, the related metrological traceability, and the measurement uncertainty.

ACCREDIA excludes the possibility of producing reference materials using methods proposed by the client that do not fall within the scope of accreditation. The RMP shall apply exclusively the production plan and the related procedures that have been positively evaluated by ACCREDIA.

4.1.2.

The requirement of the standard applies. Since accreditation is granted to the RMP and does not concern its potential subcontractors, a written agreement with the same is required, including the following points:

- The subcontractor's prohibition of any use of RMP assessments as an attestation of accreditation or certification. Failure to comply with this requirement may impose sanctions against the RMP;
- Consent for the presence of ACCREDIA personnel as an observer for any second-party audits;
- Commitment by subcontractor not to subcontract itself (serial subcontracting);
- Commitment to carry out activities in compliance with the requirements of applicable standards.

Note: In cases where the exchange of information takes place by e-mail, it is sufficient to keep the archive of contacts with clients. A documented review may not include cases of productions carried out on a tacitly renewed contract or on pre-determined periods by agreement with Client.

4.1.3.

The requirement of the standard applies.

4.2. Impartiality

4.2.1.

The requirement of the standard applies.

4.2.2.

The requirement of the standard applies.

The standard requirement applies taking into account that the risks of impartiality shall be evaluated on the basis of objective, possibly measurable parameters. The risk analysis shall include the identification of actual and/or potential risks and the assessment of residual risks.

Examples of relationships that could compromise impartiality include those:

- with the parent company;

- between different functions within the same organisation;
- with affiliated organisations/companies;
- with regulatory authorities (e.g., ministries, agencies, ARPA…);
- with clients;
- involving personnel;
- with intermediary companies;
- with distributors;
- with companies with which personnel and equipment are shared.

The requirement of the standard applies, with the stipulation that Management shall provide guidance enabling the monitoring and minimisation of residual risks related to impartiality. Personnel at all levels must demonstrate that they understand and are familiar with this guidance.

Note: regarding risk management, reference is made to ISO Guide 31000 – Risk management: Principles and guidelines**.**

4.3. Confidentiality

4.3.1.

The requirement of the standard applies. The implementation of any element that may affect accredited production must also take into account the requirement for confidentiality. Any consultants invited to attend third-party assessments must be required by the RMP to sign a confidentiality agreement, which shall be made available to ACCREDIA upon request.

Note 1: It is recommended to identify (i) personnel authorised to access the RMP's premises, (ii) personnel authorised to access the Client's data (whether in paper or electronic format), and (iii) the established methods for controlling such access**.**

Note 2: It is recommended that the RMP consider the confidentiality aspects of information in contracts with non-employee personnel acting on its behalf.

4.3.2.

The requirement of the standard applies.

5. Structural Requirements

5.1.

The requirement of the standard applies.

Note 1: ACCREDIA requires that the Chamber of Commerce company registration lists all locations and all activities within the scope of accreditation, including those related to the production of Reference Materials.

Note 2: ACCREDIA requires the RMP to attach the Chamber of Commerce company registration to the DA-00 application, in order to verify that the RMP is a legal entity or part of it that has full responsibility for the activities covered by the accreditation.

5.2.

The requirement of the standard applies, taking into account that the RMP must define and declare all locations where it carries out activities in conformity with the standard, including those where production operations are performed. A location may be a permanent, temporary, or mobile RMP facility, or a site outside the RMP's permanent facilities (see definition provided in RG-18).

Note: ACCREDIA requires the Laboratory to declare, in application form DA-09, the list of all locations where activities described in the standard are performed, including production operations.

5.3.

a. The requirement of the standard applies.

Note: Among other evidence, ACCREDIA evaluates:

- the overall organisational chart of the organisation to which the RMP belongs, highlighting the position of the RMP;
- the functional organisational chart of the RMP, in cases where this does not coincide with the parent organisation, showing the relationships between functions, including support and subcontracted functions;
- the nominative organisational chart of the RMP personnel, identifying any individuals who, while working both in the parent organisation and within the RMP, hold different roles in the two contexts.

b. The requirement of the standard applies.

Note: If the management system also extends to activities other than those relating to the manufacturer's accreditation field, it is recommended that the latter be clearly defined and identified.

c. The requirement of the standard applies, with the stipulation that the organisational chart or the document enabling clear identification of the RMP's organisation in terms of hierarchical relationships shall include at least the following functions:

- Management (see also the following point d);

- Technical Management (see also the following point e); Technical Management may consist of a single individual or a group of people responsible for a specific area. Responsibility for technical activities across all accredited operations must be fully covered by Technical Management;
- Personnel responsible for the Management System (see also the following point f).

Note: Among other evidence, ACCREDIA evaluates—when these have been provided—the organisational charts, job descriptions, letters of appointment, and any relevant contracts. It is recommended that evidence be provided showing that all personnel are aware of the relevance and importance of their own activities in relation to the accredited operations.

d. The requirement of the standard applies.

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

e. The requirement of the standard applies.

Note: It is recommended that appointments for these functions be formalised and include a precise specification of authorisations, particularly regarding the signing of documents accompanying the reference material.

f. The requirement of the standard applies. If this role of responsibility is held by personnel external to the Producer (e.g., an external consultant), the precise definition of the role and the temporal terms of the appointment must be formalised in the contract.
g. The requirement of the standard applies. In particular, the RMP must hold third-party liability insurance for risks arising from the performance of its activities, with a coverage limit commensurate with a credible assessment of the risks associated with its operations. The RMP must identify these risks through an appropriate risk analysis and make this information available to ACCREDIA. The insurance coverage must include activities carried out by all personnel, whether internal or external, acting on behalf of and in the name of the RMP.

5.4.

The requirement of the standard applies, taking into account that the RMP shall define, in a management system document, the procedures and responsibilities for change management (e.g., changes in Technical Management / Responsible Person / Deputy of the RMP).

Note: It is recommended to identify methods for evaluating the effectiveness of communications, appropriate to the size and type of the Producer**.**

6. Resource Requirements

6.1. Personnel

6.1.1.

The requirement of the standard applies.

6.1.2.

The requirement of the standard applies.

6.1.3.

The requirement of the standard applies, taking into account that, for each function, the competences necessary to fulfil the role are appropriately documented.

Note: ACCREDIA assesses, among other evidence, that the RMP has defined the competence requirements (educational background, professional experience, and operational skills) necessary to assume the functions set out in the organisational chart and has documented the appropriate procedures for obtaining and maintaining the relevant qualifications.

6.1.4.

The requirement of the standard applies.

Note: ACCREDIA also assesses, among other evidence, the evaluation of the effectiveness of training and instruction activities (for example, questionnaires, interviews, quizzes, open-ended questions, and measurement comparisons between operators).

6.1.5.

The requirement of the standard applies.

6.1.6.

The requirement of the standard applies. The RMP shall identify the authorised person(s) authorised by Management to approve documents associated with a reference material (for example, by signature). Authorisations must be dated, signed by Management, and countersigned by the relevant personnel.

Note: Authorisations may be recorded as an attachment to the job descriptions or explicitly stated within the job descriptions themselves, provided that they comply with the requirements of the standard. An example of recording such authorisations may be a summary table listing the personnel authorised to carry out each accredited activity (production, sampling, internal calibration, issuance of documents accompanying the materials, etc.).

6.2. Subcontracting

6.2.1.

The requirement of the standard applies. The RMP is an organisation that shall be responsible, as a minimum, for the following activities: planning and management of the production plan; assignment of and decision on property values and the uncertainties associated with them; authorisation of the property values; and issuance of the documents associated with the reference materials. Consequently, the entity to be accredited will be the legal entity, or a clearly defined part of it, responsible for all activities related to the production of RMs.

RMP may subcontract part of production to a competent subcontractor whose choice cannot be subcontracted. The RMP shall set up procedures and impose requirements to ensure that the subcontractors' experience and technical expertise is sufficient for the tasks assigned and that the subcontracted activities are carried out in compliance with the relevant points of ISO 17034:2017 and other international standards when applicable.

6.2.2.

The requirement of the standard applies, taking into account that the RMP shall maintain records of periodic requalifications and consider, in the risk analysis, any selection or change of subcontractor. The list of subcontractors must be specified in the accreditation application (DA-09), attaching documentation demonstrating the supplier’s qualification (competence assessment as required in § 6.2.1). Any changes to the contract with subcontractors or to the subcontractors themselves must be subject to ACCREDIA’s review, even immediately following the assignment of the activities. The assessment of these aspects falls within the activities carried out by ACCREDIA DT during the first available assessment.

The requirement of the standard applies. Serial subcontracting is not permitted (the subcontractor may not further subcontract).

6.2.3.

The requirement of the standard applies. In case the RMP subcontract tests or calibrations, the requirements required for subcontractors shall comply with those of standard ISO/IEC 17025. The accreditation of the subcontractor for the subcontracted activity, s specified in its scope, is sufficient to demonstrate its competence.

Other methods for assessing the competence of the subcontractor may consist of: audits, quality control of materials, measurement comparisons (PT/ILC), copies of Certificates (calibration and reference materials) attesting metrological traceability in compliance with ILAC P10 (§ 9). It is not considered acceptable to demonstrate the competence of the subcontractor through its self-assessment through questionnaire.

6.2.4.

The requirement of the standard applies. The RMP shall keep records of the subcontractor's competence about the subcontracted activities. The evidence may be, for example, results obtained in the past on reference materials well characterized with similar matrix, results obtained by participating in interlaboratory tests, etc.

In the case of subcontracting tests and/or calibrations, the minimum evidence that the RMP must retain is as follows:

a. requested measurands;
b. test/calibration methods used;
c. required measurement uncertainty;
d. metrological traceability (see ILAC P10, § 9);
e. test reports/calibration certificates;
f. performance in measurement comparisons (PT/ILC).

6.2.5.

The standard requirement applies. The supplier assessment by the RMP must be carried out through a second-party audit, according to its own documented procedures, for those activities considered critical by the producer, as referred to in § 7.2.1. For activities considered critical, ACCREDIA expects to be present at such audits in order to evaluate the procedures and competence with which the RMP qualifies the subcontractor on-site.

6.2.6.

The requirement of the standard applies.

6.2.7.

The requirement of the standard applies.

6.3. Procurement of Equipment, Services, and Supplies

6.3.1.

The requirement of the standard applies.

Note: If the Producer is part of a larger organisation, reference may be made to higher-level general procedures; however, the requirements of the standard—particularly those relating to technical aspects—must still be met to obtain and maintain accreditation.

6.3.2.

The requirement of the standard applies.

6.3.3.

The requirement of the standard applies.

6.3.4.

The requirement of the standard applies.

6.4. Facilities and Environmental Conditions

6.4.1.

The requirement of the standard applies.

6.4.2.

The requirement of the standard applies. Any records of environmental conditions and of the facilities involved in accredited activities shall be retained for at least **10 (ten) years**. If the records of environmental conditions indicate that the limits defined by the RMP have been exceeded, it is recommended that this situation be treated as a non-conformity in accordance with the RMP's management system.

Where applicable, the requirements related to facilities and environmental conditions necessary for carrying out the RMP's activities shall be documented and periodically reviewed.

6.4.3.

The requirement of the standard applies.

6.4.4.

The requirement of the standard applies.

7. Technical and production Requirements

7.1. General Requirements

The requirement of the standard applies. This chapter sets out the requirements for RMs, including the additional requirements for CRMs: only the certified values of the latter enable the correct dissemination of metrological traceability in accordance with the requirements of ILAC P10 (§ 9).

Where the certified values are based on data obtained during the production processes described in points 7.2 to 7.18, the procedures of such processes shall, where applicable, address the requirements relating to the assignment of property values and their relative uncertainties.

The application of the methods described in ISO 33405:2024 for homogeneity and stability studies and for characterisation ensures compliance with the requirements of ISO 17034:2017; however, alternative methods are permitted if they are technically valid and suitable for the type of RM produced, and if the RMP can demonstrate that they allow compliance with the standard's requirements. If the RMP uses a method different from those specified in ISO 33405:2024 and the method is assessed as unsuitable, this deficiency shall be considered a non-conformity to ISO 17034:2017. Where international standards exist for the production of specific reference materials, it is recommended that the RMP use these standards (for example, ISO 6142-1 "Gas analysis -- Preparation of calibration gas mixtures -- Part 1: Gravimetric method for Class I mixtures").

7.2. Production Planning

7.2.1.

The requirement of the standard applies. The production plan is part of the documents evaluated by ACCREDIA, and any changes must therefore also be communicated to ACCREDIA for assessment. Only after formal positive evaluation by ACCREDIA may the plan be included among the activities under accreditation. If the production of a specific RM requires a pilot study, this must be identified at this stage.

7.2.2.

The requirement of the standard applies.

7.2.3.

The requirement of the standard applies.

Note 1: ACCREDIA recommends evaluating, documenting, and including product variability in the production plan.

Note 2: ACCREDIA recommends defining rejection criteria for RMs and CRMs.

7.2.4.

The requirement of the standard applies. Experimental studies for certain characteristics, such as homogeneity, stability, and commutability, may be reduced in the case of multiple batches composed of the same material with the same chemical-physical composition, the same biological composition, and the same qualitative and/or quantitative properties, etc. The batches may be produced simultaneously and/or at different times. In this case, the RMP shall verify that the information derived from previous experimental studies is applicable to the new batch. ISO 33405 provides further information on the characteristics of replacement batches.

7.3. Production Control

The requirement of the standard applies.

7.4. Movement, Handling, and Storage of Materials

7.4.1.

The requirement of the standard applies. This requirement applies to all phases of the production process. If the material is transferred to a subcontractor, the RMP shall provide the necessary instructions for proper storage and correct handling to the person in charge of the areas where the material is transferred. Environmental storage conditions shall be documented and recorded where necessary. Materials storage and handling areas shall allow the avoidance of any contamination or confusion between materials in the different production steps.

7.4.2.

The requirement of the standard applies.

7.4.3.

The requirement of the standard applies. Particular attention shall be paid to packaging security issues to avoid any damage or deterioration between characterization and distribution. It is the responsibility of the RMP to

ensure that packaging and labelling of materials are carried out in compliance with the legal requirements. Please note that compliance with legal requirements does not qualify for accreditation.

7.4.4.

The requirement of the standard applies. Assessments carried out during the storage period must be recorded.

7.4.5.

The requirement of the standard applies.

7.4.6.

The requirement of the standard applies.

7.5. Material Processing

7.5.1.

The requirement of the standard applies.

7.5.2.

The requirement of the standard applies. When the same equipment is used for different materials, the RMP shall check, if applicable, that no contamination occurs.

7.6. Measurement Procedures

The requirement of the standard applies. If the measurement, testing, or calibration process is performed under accreditation in accordance with ISO/IEC 17025, such accreditation is sufficient to demonstrate compliance with the requirement.

In the case of updates to documents of external origin (e.g. standards, methods, laws, regulations), unless otherwise indicated, the RMP is required to apply the new versions within **3 (three) months** of the issue.

7.7. Measurement Equipment

The requirement of the standard applies. ACCREDIA considers in the relevant requirements to be met also the one in relation to the metrological traceability provided by ISO/IEC 17025 standard. The use of equipment also employed for activities other than those accredited must not, in any way, compromise its metrological

characteristics or reliability. The RMP shall prepare a metrological confirmation programme (including calibration and intermediate checks) for the instrumentation used in the production. he procedures must specify the acceptance criteria for the instrumentation, equipment, and reference samples in relation to the requirements of the production process.

For equipment also used under accreditation in compliance with ISO/IEC 17025 standard, this attestation is sufficient to demonstrate the fulfilment of the requirement. Conversely, the RMP shall apply, or ensure that its subcontractor applies the policy of traceability described in § 9.

Note: For metrological confirmation, please refer to standard ISO 10012 "Measurement Management Systems – Requirements for Process and Measurement Equipment".

7.8. Data Integrity and Evaluation

7.8.1.

The requirement of the standard applies.

7.8.2.

The requirement of the standard applies.

7.8.3.

The requirement of the standard applies. The assessment of homogeneity, stability, characterization, assignment of property values and their uncertainties require data evaluation. For these assessments the RMP shall use appropriate and scientifically-based statistical techniques.

7.9. Metrological Traceability of Certified Values

7.9.1.

The requirement of the standard applies. RMPs producing CRMs must ensure the metrological traceability of the certified values, as defined in UNI CEI 70099, in accordance with the applicable requirements of ISO/IEC 17025, whether the characterisation is carried out internally or in the case of subcontracting certain processes.

If the assignment of the certified value occurs through a measurement process, performed under accreditation, and therefore in compliance with ISO/IEC 17025 standard, this attestation is sufficient to demonstrate compliance with the requirement. Conversely, the RMP shall conform or ensure that its subcontractor is compliant with the applicable requirements of ISO/IEC 17025 and the traceability policy described in § 9.

ACCREDIA considers the application of the methods reported in the Notes of ISO 17034:2017 as evidence of the traceability of the certified value.

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. If a CRM is used to ensure the metrological traceability of the certified value, the uncertainty associated with the certified value of the CRM used must be smaller than that of the CRM being produced.
The RMP shall determine the expertise of the producer of CRMs producer that he uses as evidence of metrological traceability. The policy implemented by ACCREDIA in this respect is given in § 9.

7.9.5.

The requirement of the standard applies.

7.9.6.

The requirement of the standard and the metrological traceability policy set out in § 9 apply. If the RMP performs the calibration internally, ACCREDIA evaluates metrological traceability and uncertainty in compliance with the requirements in § 10.

7.10. Assessment of Homogeneity

The assessment of homogeneity applies to all RMs.

7.10.1.

The requirement of the standard applies.

7.10.2.

The requirement of the standard applies.

7.10.3.

The requirement of the standard applies.

7.10.4.

The requirement of the standard applies.

7.10.5.

The requirement of the standard applies.

Note: The ISO 33405:2024 standard provides some methods for conducting the homogeneity study.

7.11. Stability Assessment and Monitoring

The homogeneity assessment applies to all RMs.

7.11.1.

The requirement of the standard applies. In assessing the stability of RM, particular attention must be paid to long-term storage conditions and transport conditions. Moreover, in the case where multiple RM use is envisaged, the RMP must assess the possible effects of storage and handling by the user on the stability of the RM.

Note: The ISO 33405:2024 standard provides some methods for conducting the stability study.

7.11.2.

The requirement of the standard applies.

7.11.3.

The requirement of the standard applies.

7.12. Characterization

7.12.1.

The requirement of the standard applies.

7.12.2.

The requirement of the standard applies.

7.12.3.

The requirement of the standard applies. ACCREDIA considers laboratories accredited to ISO/IEC 17025 as competent laboratories, and considers a network of competent laboratories to be the system organised by an accredited PT provider.

Note: The standard contains some approaches that can be used to characterize RM:

a) The use, in a single Laboratory, of a reference measurement procedure (reference UNI CEI 70099). An example of this approach is the characterization of a gas reference material using the procedure in ISO 6142-1;
b) The characterization, in one or more competent laboratories, of a non-operationally defined measurand using two or more methods of demonstrable accuracy;
c) The characterization of an operationally-defined measurand using a network of competent laboratories (example, extractable mass fraction of lead in different soils);
d) The transfer of the assigned value for a given property from an RM to a candidate RM with the same chemical–physical matrix characteristics (e.g., characterisation of a replacement batch when the RM batch is depleted);
e) Characterization based on mass or volume of ingredients used in the preparation of the RM.

Note: The ISO 33405 standard provides some methods for conducting the characterisation of RMs.

If the RMP follows the approach described in point a) with its own internal, non-accredited laboratory, this laboratory must operate in accordance with ISO/IEC 17025:2018 and apply the provisions set out in regulation RT-39 “Requirements for participation in proficiency testing (PT) and/or interlaboratory comparisons (ILC)”.

7.12.4.

The requirement of the standard applies.

7.12.5.

The requirement of the standard applies.

7.13. Assignment of Property Values and their Uncertainties

7.13.1.

The requirement of the standard applies.

7.13.2.

The requirement of the standard applies.

7.13.3.

The requirement of the standard applies.

7.13.4.

The requirement of the standard applies.

7.13.5.

The requirement of the standard applies. Since certified values assigned to a property of a CRM ensure metrological traceability, their uncertainty shall be calculated, taking into account, among other things, the characterization contributions, the homogeneity and stability in the short and long term. Where the RMP considers these contributions negligible, it shall demonstrate it.

In this point we refer to the uncertainties of a quantity and uncertainty associated with a nominal property (DNA sequence, colour, etc.).

Note: When calculating the uncertainty, the RMP must also take into account contributions associated with negligible corrections in the assignment of the property value to ensure metrological traceability.

7.13.6.

The requirement of the standard applies.

The measurement uncertainty reported in the scope of accreditation is the minimum characterisation uncertainty of the specific property, obtained using the method indicated in the scope itself and under the best conditions of homogeneity and stability ensured by the RMP. This value is to be understood as the expanded uncertainty, obtained by multiplying the standard uncertainty by the coverage factor k corresponding to a confidence level of approximately 95%. Any deviations must be explicitly indicated in the table attached to the accreditation certificate.

Within the production plan, which must be positively evaluated by Accredia DT before its implementation, the RMP must identify a range of uncertainty values considered acceptable and the criteria for material rejection. However, the certificate (or information sheet where applicable) must report the representative uncertainty as

stated in the annex to the certificate, or, if agreed in writing with the client, higher values that still fall within the range identified in the production plan.

Note: Other contributions to the uncertainty can be significant, such as property variations induced by use or by repeated sampling from a single RM unit. Where applicable, to minimise such contributions to the uncertainty, the RMP must indicate the recommended use of the CRMs in the Certificate (e.g., homogenise the material before sampling).

7.14. RM Documentation and Labelling

7.14.1.

The requirement of the standard applies.

Note: Please refer to ISO 33401

7.14.2.

The requirement of the standard applies. Documents associated with a reference material shall be issued using headed paper bearing the ACCREDIA mark, in accordance with the template set out in document DT-14-DT. It is not permitted to include in such documents any information relating to reference materials not covered by the scope of accreditation. It is permissible to include in Reference Material Certificates values that are not certified, provided that they are clearly identified with an asterisk and accompanied by a statement that such data cannot and must not be used for the dissemination of metrological traceability (for example, they may not be used for the calibration of an instrument).

The use of the ACCREDIA mark shall be carried out in accordance with the requirements set out in RG-09.

Where, during production, part of the activities are performed by subcontracting them to competent bodies, the name of the subcontractor and the activity subcontracted may be included in the documents associated with the reference material.

7.14.3.

The requirement of the standard applies.

Note: It is recommended not to use simplified statements such as “traceable to NIST/INRIM” since the traceability of measurements is not to a National Metrology Institute, but to the SI system of units, or to other internationally recognised standards, through the use of CRMs, in accordance with the application of ILAC P10 and § 9.

7.14.4.

The requirement of the standard applies. The use of labels bearing the ACCREDIA mark directly on the reference material is permitted, provided that such labels are affixed only to production batches of materials included within the scope of accreditation. The ACCREDIA mark shall not be used or affixed to the material independently of the label identifying it. Such label shall include at least the fields listed below:

- The registered name and accreditation number of the RMP;
- The identification of the RM;
- The date of production and the information necessary to make the material uniquely identifiable (for example, serial number / batch number);
- The unique reference to the document associated with the reference material.

The use of the ACCREDIA mark shall comply with the requirements of Regulation RG-09. These requirements are necessary to ensure that the production and characterisation of the specific material are carried out by an organisation accredited in accordance with the standard ISO 17034:2017. The presence of a label bearing the ACCREDIA mark on a material does not imply that the material has been approved by ACCREDIA.

7.14.5.

The requirement of the standard applies.

7.15. Distribution Service

7.15.1.

The requirement of the standard applies.

7.15.2.

The requirement of the standard applies.

7.15.3.

The requirement of the standard applies.

7.15.4.

The requirement of the standard applies.

7.15.5.

The requirement of the standard applies.

7.16. Control of Quality and Technical Records

7.16.1.

The requirement of the standard applies. The RMP shall also manage, in accordance with the requirement, the data for the statistical study of the properties of the materials produced and of the instruments used in their production.

7.16.2.

The requirement of the standard applies.

7.16.3.

The requirement of the standard applies.

7.16.4.

The requirement of the standard applies.

7.16.5.

The requirement of the standard applies.

7.16.6.

The requirement of the standard applies.

7.16.7.

The requirement of the standard applies.

Note: It is recommended to define the maximum retention period for records within the management system. In the case of a management system implemented under Option A, it is recommended to refer to ISO 17034:2017, 8.5.2.

7.16.8.

The requirement of the standard applies. Where the calibration and/or measurement activity is part of the accreditation granted in accordance with standard ISO/IEC 17025 or is carried out by an NMI, such certification is sufficient to demonstrate compliance with the requirement. Conversely, the RMP shall apply, or ensure that its subcontractor applies, the applicable requirements of § 9.

7.17. Management of Non-conforming Work

The requirements of the standard apply. In the event that non-conforming activities are identified that could affect the execution of accredited productions, the RMP, in addition to the actions required by its quality management system in accordance with the requirements of the standard, shall promptly inform ACCREDIA and, if necessary, initiate a request for self-suspension as provided for in Regulation RG-18.

In the management of non-conformities, it is recommended to also assess the impact on the entire management system.

7.17.1.

The requirement of the standard applies.

7.17.2.

The requirement of the standard applies.

7.17.3.

The requirement of the standard applies.

7.18. Complaints

7.18.1.

The requirement of the standard applies, with the provision that the entire complaints management process, from receipt, through evaluation, to handling, must be described in a documented procedure that has been prepared in advance and positively assessed by ACCREDIA prior to its use.

7.18.2.

The requirement of the standard applies.

7.18.3.

The requirement of the standard applies.

7.18.4.

The requirement of the standard applies.

7.18.5.

The requirement of the standard applies.

7.18.6.

The requirement of the standard applies.

7.18.7.

The requirement of the standard applies.

7.18.8.

The requirement of the standard applies.

7.18.9.

The requirement of the standard applies. Where the organisation of the RMP consists of a single person, the involvement of an external resource is required.

7.18.10.

The requirement of the standard applies.

8. Management System Requirements

8.1. Options

8.1.1. General

The requirement of the standard applies.

In the case of updates to externally sourced documents (e.g., standards, methods, laws, regulations), unless otherwise specified, the RMP is required to implement the new versions within **3 (three) months** of their entry into force.

8.1.2. Option A

The requirement of the standard applies.

Note: ACCREDIA evaluates the compliance of the management system as documented (e.g. in a Management System Manual, in management and technical procedures) by the RMP.

8.1.3. Option B

ACCREDIA in evaluating the management system of a RMP applies Resolution No. 22 of the EA of May 2015 (EA Resolution 2015 (35) 22 published at http://www.european-accreditation.org), recognizing that a RMP operating with a management system compliant to standard ISO 9001 is able to obtain the same results that it would have had implementing directly the requirements in paragraphs 8.2 to 8.11 of standard ISO 17034:2017. ACCREDIA's assessment therefore extends to this correspondence.

ACCREDIA does not evaluate the certified system in compliance with the requirements of the ISO 9001 standard but evaluates its coverage to all ISO 17034:2017 requirements, i.e. it evaluates that the management system contains the references required to fully describe how the production of reference materials comply with all paragraphs of standard ISO 17034:2017. As evidence of coverage of the scope of activities, ACCREDIA evaluates the presence of references to the RMP in all records required by the management system.

8.2. Quality Policy (Option A)

8.2.1.

The requirement of the standard applies.

8.2.2.

The requirement of the standard applies.

8.2.3.

The requirement of the standard applies.

Note: ACCREDIA estimates that the Quality Policy contains specific declarations of compliance with the requirements of the standard and those resulting from ACCREDIA, EA and ILAC prescriptive documents as set out in this Regulation for the purpose of obtaining and maintaining accreditation; ACCREDIA also considers this to be the case if, being the RMP part of a wider organisation, quality policy is included in any similar higher-level documents.

8.2.4.

The requirement of the standard applies.

8.3. General Management System Documentation (Option A)

The requirement of the standard applies.

Note: If the management system documentation also deals with activities other than those relating to the RMP's scope of accreditation, it is recommended that the latter be clearly identified and meet the requirements of the standard and this regulation as a whole. For this purpose, it is also recommended that the quality manual follow the numbering of the chapters of the standard (also reproduced in this document) or contain a suitable correlation matrix.

8.4. Control of Management System Documents (Option A)

8.4.1.

The requirement of the standard applies.

8.4.2.

The requirement of the standard applies.

8.5. Control of Records (Option A)

8.5.1.

The requirement of the standard applies.

8.5.2.

The requirement of the standard applies.

Note: ACCREDIA stipulates a minimum retention period of **10 (ten) years** for all documentation relating to accredited productions, unless otherwise required by law, in which case the latter shall prevail.

8.6. Management Review (Option A)

8.6.1.

The requirement of the standard applies.

Note: Depending on the size of the RMP and any organisation of which it is part, reviews may be conducted at different levels, for example: one at a local level, where the RMP's specific issues are discussed, and a more general, organisational-level review, which takes the results of the local reviews as input.

8.6.2.

The requirement of the standard applies.

8.7. Internal Audit (Option A)

8.7.1.

The requirement of the standard applies.

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

8.7.2.

The requirement of the standard applies.

8.7.3.

The requirement of the standard applies.

8.7.4.

The requirement of the standard applies.

8.8. Actions to Address Risks and Opportunities (Option A)

8.8.1.

The requirement of the standard applies.

8.8.2.

The requirement of the standard applies.

8.8.3.

The requirement of the standard applies.

8.9. Corrective Actions (Option A)

8.9.1. General

The requirement of the standard applies.

In the event that non-conforming activities are identified that could affect the execution of accredited productions, the RMP, in addition to what provided for by its quality management system in accordance with the requirements of the standard, shall promptly inform ACCREDIA and, if necessary, submit a request for self-suspension as provided for in Regulation RG-18.

8.9.2. Root Cause Analysis

The requirement of the standard applies.

8.9.3. Selection and Implementation of Corrective Actions

The requirement of the standard applies.

8.9.4. Monitoring of Corrective Actions

The requirement of the standard applies.

8.9.5. Supplementary Audits

The requirement of the standard applies.

8.10. Improvement (Option A)

8.10.1.

The requirement of the standard applies.

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

- Staff refresher training programmes;
- Improvement of production methods and enhancement of their efficiency, in order to better meet the requirements and requests of clients;
- Upgrading of equipment and maintaining it at the highest possible level.

8.10.2.

The requirement of the standard applies.

8.10.3.

The requirement of the standard applies.

8.11. Feedback from Customers (Option A)

The requirement of the standard applies.

9. Provisions Relating to the Application of the Requirement on Metrological Traceability

Reference materials producers shall guarantee the metrological traceability as required by standards ISO /IEC 17025:2018 and ISO 17034:2017. ACCREDIA recognizes, in compliance with ILAC P10, that there are several ways to ensure the traceability, listed below.

The traceability of the equipment is ensured through calibrations carried out by:

1. National Metrology Institutes (NMIs) and Designated Institutes (DIs) whose services (CMCs) are eligible and covered by the International Mutual Recognition Agreement (CIPM MRA) and included in the KCDB database of the BIPM. The presence of the note and/or the CIPM MRA logo on Calibration Certificates demonstrates the coverage of CMCs; if the note and/or logo are not present,

being their entry discretionary, the Laboratory shall verify the coverage of the CMCs by consulting the BIPM website at: http://www.bipm.org or kcdb.bipm.org.

2. Accredited calibration laboratories whose services are eligible and whose accreditation is issued by Accreditation Bodies (AB) signatories to the EA-MLA or ILAC-MRA agreement for the purpose of calibration within the framework and within the limits set by the CMCs published by the AB.

   The use of calibration certificates issued under these two possibilities is considered to be of equal validity, without prejudice to the different value of the calibration uncertainties that shall be adapted to the needs of the RMP.

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

3. **a.** NMI or DI whose services are eligible but not covered by the CIPM-MRA Agreement.

3. **b.** Calibration laboratories whose services are eligible 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 the last option if cases 1 and 2 were unavailable.

   Case 3b shall only be chosen if type 1, 2 and 3a providers are unavailable. In this case also the evaluation of the provider by the RMP shall take place through second-party audit with the presence of an assessment team of ACCREDIA, where a Technical Officer is present. The evaluation to qualify the provider by the RMP is in turn subject to assessment by ACCREDIA.

4. Clause 5.6.2.1.2 of standard ISO/IEC 17025 specifies how to operate when calibrations cannot be strictly performed with reference to SI units. It is the responsibility of the RMP in these cases to provide evidence that meets the standard requirements. Such evidence, such as the RMP's assessment of the provider, as described below with regard to the implementation of 3a, 3b, 4, 8 and 9, is being evaluated by ACCREDIA.

The traceability of reference materials is ensured by the assignment of the certified value by:

5. NMIs or DIs that produce 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 Reference Material Certificates demonstrates the coverage of CMCs; if the note and/or logo are not present, being their entry discretionary, the RMP shall check the coverage of CMCs by consulting the BIPM website at www.bipm.org or kcdb.bipm.org. The values assigned to CRMs listed in the JCTLM database (at www.bipm.org) provide valid evidence of traceability.

6. Accredited RMPs that produce CRM whose certified values are set out in the scope of accreditation.

7. Organisations listed in the JCTLM database (www.bipm.org).

8. In cases where it is not possible to obtain CRMs falling under the previous three categories, the RMP may turn to producers whose competence must be evaluated in order to qualify them for the intended use. The extent of the assessments depends on the information available as well as the

nature of the material. Verification of compliance with ISO 17034:2017, ISO 33405, other relevant standards, and prescriptive documents from ILAC, EA, and ACCREDIA is carried out as indicated in the following section on the implementation of points 3a, 3b, 4, 8, and 9.

9. When paragraphs 5, 6, 7 and 8 cannot be applied (i.e. there are no CRMs available), it is recommended, whenever possible, to use reference materials produced by at least two independent producers. The RMP will need to verify the materials of different production and to ensure their compliance with the intended use.

ACCREDIA Traceability Policy – Implementation of Points 3a, 3b, 4, 8, and 9 (Reference: ILAC P10 Annex A)

It should be noted that the selection of the cases described in points 3a, 3b, 4, 8, and 9 involves the use of services that have not been subject to peer evaluation or accreditation. The RMP must therefore ensure that appropriate evidence is available regarding the provider's competence, and in particular concerning the traceability and measurement uncertainty of the calibrations or materials provided.

ACCREDIA will assess both such evidence and the RMP's ability to evaluate it in turn.

Appropriate evidence of the technical competence of the provider and metrological traceability could include, but not necessarily be limited to:

- For NMIs or DIs, records of the results of interlaboratory, key and supplementary participations in CIPM MRA or regionally organized (e.g. EURAMET);
- For NMIs or DIs, records of the results of the participation in interlaboratory comparisons made with other NMIs and/or DIs;
- Records on validation of the calibration method (scientific publications, technical reports, etc.) and/or characterizations of RM;
- Procedures for estimating uncertainty and copy of Metrological Capacities;
- Documentation on the traceability of measurement results;
- Documentation on the guarantee of the quality of calibration and/or characterizations of RM results;
- Evidence on the competence of the personnel in charge of RM calibrations/productions;
- Documentation on the premises used as laboratories and/or for the production of RMs, and on the environmental conditions in which the calibrations and/or characterisations of RMs were carried out;
- Record of internal audits;
- Record of second-party Audits.

The certification of a company's management system does not constitute evidence of the competence of the company's Laboratories or company's Producers.

The evidence of metrological traceability accepted by ACCREDIA is limited exclusively to the specific procedures and to the quantities and properties of reference materials under evaluation, and does not imply any assessment of competence for other measurements or for other services offered by the organisation (in cases 3a, 3b, and similar for RMs).

10. Provisions Relating to Internal Calibrations

If the Reference Materials Producer makes internal calibration of equipment used in production, it shall meet the same requirements as the Calibration Laboratories; in particular the technical aspects of internal calibration shall comply with ISO/IEC 17025. Internal calibrations shall be performed:

- by competent RMP staff or the organisation to which RMP belongs, suitably trained and qualified;
- with instruments or samples under the direct and exclusive control of the RMP or of the organisation to which the RMP belongs, calibrated to ensure the dissemination of metrological traceability;
- in an environment suitable to the kind of calibration;
- applying technical procedures managed by the RMP in compliance with the requirements specified in par. 4.3.2.1 of Technical Regulation RT-25 and evaluated positively by ACCREDIA-DT.
- The results of internal calibrations shall:
    - include the measurement uncertainty;
    - be recorded in a calibration report compliant with point 5.10 of standard ISO/IEC 17025.

Note: For RMs internally produced for quality control, it is recommended to apply the ISO Guide 80: 2014 Guidance for the in-house preparation of quality control materials (QCMs).

In the context of internal calibrations, where these are not used for the assignment of CRM properties, the RMP is required to comply with the provisions of § 5.1 and § 5.4 of Regulation RT-39, “Requirements for Participation in Proficiency Testing (PT) and/or Interlaboratory Comparisons (ILC)”.

11. Provisions Relating to Participation in PT/ILC

Where the RMP internally assigns the values of CRM properties, in order to ensure metrological traceability, the relevant requirements of ISO/IEC 17025 must be met. Accordingly, the RMP must apply the provisions set out in paragraphs § 5.1, § 5.2, and § 5.3 of Regulation RT-39, “Requirements for Participation in Proficiency Testing (PT) and/or Interlaboratory Comparisons (ILC)”.

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