Title	**Requirements for the accreditation of Reference Material Producers**
Reference	**RT-34**
Revision	**01**
Date	**11-04-2019**

NOTE: The present document represents the English version of 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 version in Italian language only.

Preparation	Approval	Authorization	Application date
The Department Director	The Directive Council	The General Director	15-07-2019

CONTENTS

0. INTRODUCTION

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

It was elaborated by a specific working team coordinated by ACCREDIA, composed by representatives of INRIM, ENEA, ISS and representatives of other Individuals competent and involved in the subject, in order to reach the widest level of sharing of provisions contained in the Regulation itself.

0.2. The application of these criteria has the target to help build and keep confidence in the activities of Reference Material Producers, and in the impartiality and integrity of technical and commercial operations related to them. ACCREDIA accreditation is granted to Producers compliant with the requirements of ISO 17034 international standard: "*General requirements for the competence of reference material producers*" or of standards recognized for this scope at international level (below simply "the standard"), with EA and ILAC requirements and requirements of this Technical Regulation and other ACCREDIA prescriptive documents applicable to Reference Material Producers.

0.3. This Technical Regulation refers to the provisions of standard ISO 17034. The paragraph numbers from 4 to 8 coincide with those of the standard. These chapters show the clarifications introduced by ACCREDIA to the requirements of the standard, sometimes coincident with the NOTES of the standard itself.

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

0.5. The implementation of what is provided for in ISO *Guide* 31 *"Reference materials — Contents of certificates, labels and accompanying documentation*" and in ISO *Guide* 35 *"Reference materials — General and statistical principles for certification"* ensures the compliance with the requirements of standard ISO 17034; however, alternative methods are admitted.

0.6. 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 that characterize them (see ILAC P10 *"ILAC Policy on the Traceability of Measurement Results"*).

1. SCOPE AND APPLICATION FIELD

1.1. This Regulation specifies the general, managing and technical competence requirements for the Reference material producers. Standard ISO 17034 and the current Technical Regulation refer to the production of all the reference materials, including the certified ones. ACCREDIA introduces provisions for the accreditation of Reference Material Producers on the basis of:

- if the value of some properties is certified or not;
- the different types of materials and their use;
- the working locations;
- the updating of the provisions of the standard, of EA and ILAC.

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

The RMP obtains accreditation for the production of RMs described in the accreditation table using specific procedures. As a consequence, the accreditation covers all RM batches that belong to the scope of accreditation produced after the granting of the accreditation. However, it may include existing batches if the RMP demonstrates their compliance to the set requirements and ACCREDIA considers them as such.

1.3. In order to get and keep the accreditation, the Reference material producers have to show their compliance to all requirements of applicable standards, for all the activities expected to produce reference material.

1.4. Where the standard prescribes documented procedures, the Reference material producer has to prepare this documentation, which will be evaluated by ACCREDIA, including any subsequent variations.

1.5. The Reference material producer is compelled to respect what provided for in the ACCREDIA Regulation RG-09 concerning the use of the accreditation mark.

1.6. If the Reference material producer operates in the medical field, standard UNI EN ISO 15189 may be used as regulatory reference as an alternative to standard UNI CEI EN ISO/IEC 17025.

2. TERMS AND DEFINITIONS

DEFINITIONS

For the purposes of this document, the definitions given in reference standards UNI EN ISO 9000, UNI CEI EN ISO/IEC 17000, UNI CEI 70099, ISO 17034, and ISO Guide 30 apply.

Note: in the cases where in the documents before mentioned, different definitions are given for specific metrological terms referring to reference materials, the definitions given in ISO Guide 30 shall be preferred.

Below are some definitions.

2.1. REQUIREMENT, PROVISION

A disposition that defines the needs to meet, and is expressed by the modal "shall". The requirements of a regulatory document must be respected in order to comply with the document itself.

2.2. GUIDE, GUIDELINE

Document that contains indications on how to meet the requirements of a regulatory document. It does not contain binding provisions, but an RMP that decides not to follow the indications of a guideline indicated by ACCREDIA takes on the responsibility to show that he meets the requirements equivalently.

2.3. 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: 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 has an analogous definition, but restricts the term "measurement" to apply to quantitative values. However, Note 3 of the definition in ISO/IEC Guide 99:2007 specifically includes qualitative properties, called "nominal properties".

2.4. 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.

Note 1: The concept of value includes a nominal property or a qualitative attribute such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities or levels of confidence.

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

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

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

2.5. CANDIDATE REFERENCE MATERIAL

Material, intended to be produced as a reference material (RM).

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 an RM for other properties, and a candidate reference material for the target property (ISO Guide 30).

2.6. 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.

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

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

Note 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).

2.7. 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 3534-2:2006.

Note 4: See also the IUPAC Compendium of Analytical Nomenclature (ISO Guide 30).

2.8. 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 1: Examples include crude fibre in foods, impact toughness, enzyme activities and extractable lead in soils (ISO 17034).

2.9. 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).

2.10. QUALITY CONTROL MATERIAL

Reference material used for quality control of a measurement (ISO Guide 30).

3. REFERENCE STANDARDS AND DOCUMENTATION

The list of applicable documents (LS-09) can be consulted on the ACCREDIA website at www.accredia.it. It is the responsibility of the organization to verify that the documents reported are in force.

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 purpose of accreditation, 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 standard requirement applies. When reviewing the contract, the RMP shall ensure that customer's requests regarding: matrix, property value assignment, relative metrological traceability and measurement uncertainty are included in such contract. There may be cases where stability shall also be included in the contract. If necessary, the RMP shall inform the customer to help him understand the needs.

4.1.2. The standard requirement 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 subcontract);
- 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 customers. A documented review may not include cases of productions carried out on a tacitly renewed contract or on pre-determined periods by agreement with Customer.

4.1.3. The standard requirement applies.

4.2. IMPARTIALITY

4.2.1. The standard requirement applies.

4.2.2.

a) The standard requirement applies.

b) The standard requirement applies taking into account that the risks of impartiality shall be evaluated on the basis of objective, possibly measurable parameters.

Examples of relationships that could influence impartiality are:

- Relations with the parent company;
- Relations between different Departments of the same Organization;

- Relations with Organizations/Companies connected;
- Relations with the Control Authorities (e.g. Ministries, Agencies, ARPA ...);
- Relations with customers;
- Staff relations.

c) The standard requirement applies.

d) The standard requirement applies.

Note: For risk management, please refer to ISO Guide 31000 "Risk management - Principles and guidelines".

4.3. CONFIDENTIALITY

4.3.1. The standard requirement applies. The implementation of any element that may have an effect on accredited production shall also take into account the requirement of confidentiality.

Note: It is recommended to identify (i) the personnel authorized to access RMP premises, (ii) the personnel authorized to access the Customer's data (whether in paper or electronic format), and iii) the procedures for control of such accesses.

4.3.2. The standard requirement applies.

5. STRUCTURAL REQUIREMENTS

5.1. The standard requirement applies.

Note: 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 standard requirement applies.

5.3.

a) The standard requirement applies;

Note: ACCREDIA evaluates among the other evidences:

- the overall organizational chart of the organization of the RMP, which shows the position of the RMP;
- the functional organization chart of the RMP, in cases where this does not coincide with the entity, containing the relations between functions, including support and subcontracting;
- the nominal organization chart of RMP personnel, identifying possible figures that, while operating both within the organization and within the RMP, have different roles in the two areas.

b) The standard requirement 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 standard requirement applies, with the prescription that the organizational chart or document that clearly identifies the organization of the RMP in terms of hierarchical relations includes at least the following functions:

- Direction, see following point d);
- Technical Direction, also see following point e); the technical direction can be composed by a single figure or by a group of people, responsible for a specific area. The responsibility of technical activities for all the accredited activities shall be completely covered by the Technical Direction. The appointment of the Technical Direction shall be evaluated by ACCREDIA and supported by evidences about competence and skills of candidates and possible training actions effectively performed;
- Personnel responsible for the Management System, see also following point f).

Note: ACCREDIA evaluates among the other evidences, when provided for: the organizational charts, job descriptions, assignment letters, and the possible contracts. It is recommended that evidence be made of the awareness of all personnel regarding the relevance and importance of their operations related to accredited activities.

d) The standard requirement applies;

Note: It is recommended to identify the figure that conducts the management review as evidence of liability and the authority required by the standard.

e) The standard requirement applies;

Note: It is recommended that the tasks for these functions be formalized and contain the exact indication of the delegated powers, in particular as regards the signature of the reference material documents.

f) The standard requirement applies. If this role of responsibility is covered by external staff outside the Producer (e.g. external consultant), the exact definition of the role that this task entails and the terms of the assignment shall be formalized in the contract;

g) The standard requirement applies. In particular, the RMP must have insurance coverage for damage to third parties for risks deriving from the performance of the activities for which it is responsible, with a ceiling commensurate with a reliable risk of its activities, which the RMP must identify through appropriate risk analysis and make available to ACCREDIA. The insurance coverage must include the activities carried out by all personnel, both internal and external, who work on behalf of and in the name of the RMP.

5.4. The standard requirement applies.

Note: It is recommended to find ways of assessing the effectiveness of communications, appropriate to the size and type of the Producer.

6. RESOURCE REQUIREMENTS

6.1. PERSONNEL

6.1.1. The standard requirement applies.

6.1.2. The standard requirement applies.

6.1.3. The standard requirement applies.

Note: ACCREDIA evaluates, among other things that the RMP has set the competence requirements (school curriculum, work experience, executive skills) needed to assume the functions provided in the organizational chart.

6.1.4. The standard requirement applies.

Note: ACCREDIA also evaluates other evidence to assess the effectiveness of training and training activities (e.g. questionnaires, interviews, quizzes, open questions, measurement comparisons between operators).

6.1.5. The standard requirement applies.

6.1.6. The standard requirement applies. The RMP shall identify the Manager authorized by the Direction for the approval of documents associated with a reference material (e.g. by signing). Authorizations shall be dated, signed by the Director and countersigned by the staff concerned.

Note: Authorizations can be registered with the job descriptions or may be explicitly stated in the job descriptions themselves, provided that they meet the standard requirements.

6.2. SUBCONTRACTING

6.2.1. The standard requirement applies. The RMP is an organization that shall be responsible for at least the following activities: project planning and management, assignment and decision on property values and uncertainties associated with these, authorization of property values, and issuance of documents associated to reference materials. The accreditation will therefore be granted to the legal entity, or a well-defined part of it, responsible for all the activities related to the production of RM.

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 and other international standards when applicable.

6.2.2. The standard requirement applies. The list of subcontractors shall be specified in the application for accreditation (DA-09); any changes in the contract with the subcontractors and subcontractors themselves shall be communicated to ACCREDIA before the assignment of the activities, enclosing the documentation attesting to the supplier's qualification (assessment of the competence provided in section 6.2.1). Such subcontracting may become effective even if there is no specific positive assessment by ACCREDIA, after fifteen working days from their transmission to the Technical Officer.

6.2.3. The standard requirement applies. Serial subcontracting is not permitted (the subcontractor cannot subcontract itself).

6.2.4. The standard requirement applies. In case the RMP subcontract tests or calibrations, the requirements required for subcontractors shall comply with those of standard UN CEI EN ISO/IEC

17025. The accreditation of the subcontractor for the subcontracted activity, as reported for its purpose, is sufficient to prove 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 (see chapter 9). It is not considered acceptable to demonstrate the competence of the subcontractor through its self-assessment through questionnaire.

6.2.5. The standard requirement 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 of testing and/or calibration, the minimum evidence that the RMP has to keep is as follows:

a) measurands required;

b) testing/calibration methods used;

c) measurement uncertainties required;

d) metrological traceability (see ILAC P10, see chapter 9);

e) test reports/calibration certificates;

f) performance in measurement comparisons (PT/ILC).

6.2.6. The standard requirement applies. The supplier's assessment by the RMP shall be carried out through second-party audits, according to their own documented procedures, for those activities evaluated critically by the producer, as referred to in Section 7.2.1. ACCREDIA, for critically evaluated activities, expects to attend this audit in order to assess the modalities and competences with which the RMP qualifies the subcontractor.

6.2.7. The standard requirement applies.

6.2.8. The standard requirement applies.

6.3. PROVISION OF EQUIPMENT, SERVICES AND SUPPLIES

6.3.1. The standard requirement applies.

Note: If the Producer is part of a larger organization, you can refer to general procedures at higher level, but you will still have to meet the requirements of the standard (especially technical aspects) for obtaining and maintaining accreditation.

6.3.2. The standard requirement applies.

6.3.3. The standard requirement applies.

6.3.4. The standard requirement applies.

6.4. FACILITIES AND ENVIRONMENTAL CONDITIONS

6.4.1. The standard requirement applies.

6.4.2. The standard requirement applies. Any records of environmental conditions and facilities involved in accredited activities shall be kept for at least ten years.

6.4.3. The standard requirement applies.

6.4.4. The standard requirement applies.

Note: If maintenance activities are entrusted to external personnel (e.g., cleaning the premises where accredited activities are performed), it is recommended that the Producer establish appropriate and accurate operational instructions for external personnel, including any operational limitations for specific areas of the Producer or for specific instrumentation.

7. TECHNICAL AND PRODUCTION REQUIREMENTS

7.1. GENERAL REQUIREMENTS

The standard requirement applies. This chapter includes the requirements for RMs, including the additional ones for CRMs: only the certified values of the latter allow the correct dissemination of metrological traceability in compliance with the requirements of the ILAC P10 document (see Chapter 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 in ISO Guide 35 for homogeneity and stability studies and for characterization ensures compliance with the requirements of standard ISO 17034; however, alternative methods are acceptable if technically valid and appropriate for the RM type product and if the RMP demonstrates that they are able to obtain compliance with the standard requirements. If the RMP uses a method other than those provided for in ISO Guide 35 and if this method is considered unsuitable, this shortage would be a Non-conformity to standard ISO 17034. In case there are international standards for the production of specific reference materials the RMP is recommended to use these standards (e.g. 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 standard requirement applies. The production planning is part of the documents evaluated by ACCREDIA and therefore any variations shall also be communicated to ACCREDIA for evaluation. Only after formal positive evaluation by ACCREDIA will this plan become effective. If the production of a particular RM requires a pilot study, the latter shall be identified at this stage.

7.2.2. The standard requirement applies.

7.2.3. The standard requirement applies.

7.2.4. The standard requirement applies. Experimental studies for some characteristics such as homogeneity, stability and commutability can be reduced in the case of multiple lots made up of the same material with the same chemical-physical composition. Lots can be produced at the same time and/or at different times. The RMP in this case will have to check that the information from previous experimental studies is applicable to the new lot. ISO Guide 35 provides more information on the characteristics of replacement lots.

7.3. PRODUCTION CONTROL

The standard requirement applies.

7.4. MATERIAL HANDLING AND STORAGE

7.4.1. The standard requirement 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 standard requirement applies.

7.4.3. The standard requirement 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 standard requirement applies. The checks carried out during the storage period shall be recorded.

7.4.5. The standard requirement applies.

7.4.6. The standard requirement applies.

7.5. MATERIAL PROCESSING

7.5.1. The standard requirement applies.

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

7.6. MEASUREMENT PROCEDURE

The standard requirement applies. If the measurement, test or calibration process is used under accreditation, in compliance with UNI CEI EN ISO/IEC 17025 standard, this attestation is enough to demonstrate the fulfilment of 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 three months of the issue.

7.7. MEASUREMENT EQUIPMENT

The standard requirement applies. ACCREDIA considers in the relevant requirements to be met also the one in relation to the metrological traceability provided by UN CEI EN ISO/IEC 17025 standard. The use of equipment also used for activities other than those accredited shall not in any way affect the metrological characteristics and reliability. The RMP shall prepare a metrological confirmation programme (including calibration and intermediate checks) of the instrumentation used in the production. It is necessary to indicate in the procedures the acceptability criteria of the instrumentation, equipment and reference standards in relation to the requirements of the production process.

For equipment also used under accreditation in compliance with UNI CEI EN 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 Chapter 9.

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

7.8. DATA INTEGRITY AND EVALUATION

7.8.1. The standard requirement applies.

7.8.2. The standard requirement applies.

7.8.3. The standard requirement applies**.** The assessment of homogeneity, stability, characterization, assignment of property values and 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 standard requirement applies. The RMPs that produce CRMs shall ensure the metrological traceability of certified values, as defined in standard UNI CEI 70099, in compliance with the applicable requirements of UNI CEI EN ISO/IEC 17025 standard, either when the characterization is performed internally or in the case of subcontracting.

If the assignment of the certified value occurs through a measurement process, performed under accreditation, and therefore in compliance with UNI CEI EN 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 UNI CEI EN ISO/IEC 17025 and the traceability policy described in Chapter 9.

ACCREDIA considers the application of the methods in note of standard ISO 17034 as evidence of the traceability of the certified value.

Standard ISO/TR 16476 contains more information on how to determine and how to express the metrological traceability of certified values.

7.9.2. The standard requirement applies.

7.9.3. The standard requirement applies.

7.9.4. The standard requirement applies. If a CRM is used to ensure the metrological traceability of the certified value, the uncertainty associated with the CRM certificate value used shall be smaller than that of the CRM 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 Chapter 9.

7.9.5. The standard requirement applies.

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

7.10. ASSESSMENT OF HOMOGENEITY

The assessment of homogeneity applies to all RMs.

7.10.1. The standard requirement applies.

7.10.2. The standard requirement applies.

7.10.3. The standard requirement applies.

7.10.4. The standard requirement applies.

7.10.5. The standard requirement applies.

Note: ISO Guide 35 provides some methods for performing the homogeneity study.

7.11. ASSESSMENT AND MONITORING OF STABILITY

The assessment of stability applies to all RMs.

7.11.1. The standard requirement 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.

7.11.2. The standard requirement applies

7.11.3. The standard requirement applies.

Note: The ISO Guide 35 provides some methods for carrying out the stability study.

7.12. CHARACTERIZATION

7.12.1. The standard requirement applies.

7.12.2. The standard requirement applies.

7.12.3. The standard requirement applies. ACCREDIA considers as competent laboratories the UNI CEI EN ISO/IEC 17025 accredited laboratories and considers a network of competent laboratories the circuit organized 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 single 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 value assigned to a given property from a RM to a candidate RM with the same physico-chemical characteristics of the matrix (e.g. characterization of a substitution batch against a batch of RM being depleted);

e) Characterization based on mass or volume of ingredients used in the preparation of the RM.

Note: ISO Guide 35 provides guidance on some methods to perform RM characterization.

7.12.4. The standard requirement applies.

7.12.5. The standard requirement applies.

7.13. ASSIGNMENT OF PROPERTY VALUES AND THEIR UNCERTAINTIES

7.13.1. The standard requirement applies.

7.13.2. The standard requirement applies.

7.13.3. The standard requirement applies.

7.13.4. The standard requirement applies.

7.13.5. The standard requirement 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 classification property (DNA sequence, colour, etc.).

Note: The RMP in calculating uncertainty shall also consider contributions associated with negligible corrections in the assignment of property value to ensure metrological traceability.

7.13.6. The standard requirement applies.

Note: Other contributions to uncertainty can be important as variations in properties induced by use or sampling repeated from a single RM unit. Where applicable, to minimize such contributions to uncertainty, the RMP shall report how to use CRMs in the Certificate (e.g. homogenise the material before sampling).

7.14. REFERENCE MATERIAL DOCUMENTS AND LABELS

7.14.1. The standard requirement applies.

7.14.2. The standard requirement applies. Documents associated with a reference material shall be issued using headed paper with ACCREDIA mark, according to a template provided by IO-09-DT. It is not permitted to include information on reference materials that are not included in the scope of the accreditation on such documents. It is permissible to include in the Certificates of Reference Materials non-certified values, provided that they are clearly identified by an asterisk and accompanied by the statement that such data cannot and shall not be used for the dissemination of metrological traceability (e.g. they can not be used for the purposes of calibration of an instrument).

The use of the ACCREDIA mark is carried out in compliance with the RG-09 requirements.

7.14.3. The standard requirement applies.

Note: it is recommended that you do not use simplified statements of the type "referable to NIST/INRIM" as the measurement traceability is not to a National Metrology Institute but to the SI measurement units standards or to other internationally recognized standards, through the use of CRMs, according to the application of ILA P10 and Chapter 9.

7.14.4. The standard requirement applies. Acceptance of ACCREDIA labels is permitted directly on the reference material, provided that such labels are only affixed on the batches of materials for the purpose of accreditation. The ACCREDIA mark shall not be used/pasted on the material independently of the label identifying it. Such label shall bear at least the following fields:

- Business name and Accreditation Number of the RMP;
- Identification of RM;
- The production date and the information necessary to make the material univocally identifiable (e.g. serial number/lot number);
- The univocal reference to the document associated with the reference material.

Use of the ACCREDIA mark shall comply with the requirements of the RG-09. These requirements are necessary to ensure that the production and characterization of the specific material are carried out by an accredited organization in compliance with ISO 17034. The presence of the ACCREDIA label on a material does not imply that such material is approved by ACCREDIA.

7.14.5. The standard requirement applies.

7.15. DISTRIBUTION SERVICE

The standard requirement applies.

7.16. CONTROL OF QUALITY AND TECHNICAL RECORDS

7.16.1. The standard requirement applies. The RMP shall also deal with the data for the statistical study of the properties of the materials produced and the instruments used in the production in compliance with the requirement.

7.16.2. The standard requirement applies.

7.16.3. The standard requirement applies.

7.16.4. The standard requirement applies.

7.16.5. The standard requirement applies.

7.16.6. The standard requirement applies.

7.16.7. The standard requirement applies.

7.16.8. The standard requirement applies. If calibration and/or measurements are part of the accreditation issued in compliance with UNI CEI EN ISO/IEC 17025 standard or performed by an NMI, this attestation is sufficient to demonstrate compliance with the requirement. Conversely, the RMP shall either apply or ensure that its subcontractor meets the applicable requirements of Chapter 9.

7.17. MANAGEMENT OF NON-CONFORMING WORK

The standard requirement applies. In the event that non-conforming activities are identified that could affect the execution of accredited production, the RMP, in addition to what provided for by its quality management system to comply with the requirements of the standard, shall promptly inform ACCREDIA and, if necessary, proceed to the request for self-suspension in compliance with the provisions of the RG-18 Regulation.

7.18. COMPLAINTS

7.18.1 The standard requirement applies.

7.18.2 The standard requirement applies.

7.18.3 The standard requirement applies.

7.18.4 The standard requirement applies.

7.18.5 The standard requirement applies.

7.18.6 The standard requirement applies.

7.18.7 The standard requirement applies.

7.18.8 The standard requirement applies. In the event that the organization of the RMP includes a single person, the involvement of an external resource is required.

7.18.9 The standard requirement applies.

7.18.10 The standard requirement applies.

8. MANAGEMENT SYSTEM REQUIREMENTS

8.1. OPTIONS

8.1.1. The standard requirement applies.

The documentation that the RMP may consider convenient or necessary to update, for various reasons, such as for example: the documentation of the management system and/or the technical procedures must be sent in advance for evaluation to ACCREDIA DT. Changes to the quality management system that do not affect the fulfillment of the requirements by the RMP can also be communicated immediately after their application and their assessment falls within the activities carried out by ACCREDIA DT for maintenance. On the other hand, any updates of the technical documentation that require evaluation also by Technical Assessors and/or Technical Experts, do not fall within the maintenance activities and are the subject of a specific estimate.

The revised management system documentation, unlike the technical documentation, can be used by the RMP, even in the absence of a specific positive assessment, after fifteen calendar days from their transmission to the Technical Officer.

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 **three months** of the issue.

8.1.2. OPTION A

The standard requirement 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. 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 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. As evidence of the coverage of the purpose of activity ACCREDIA evaluates the presence of references to the RMP in all records provided by the management system.

8.2. QUALITY POLICY (OPTION A)

8.2.1. The standard requirement applies.

8.2.2. The standard requirement applies.

8.2.3. The standard requirement 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 organization, quality policy is included in any similar higher-level documents.

8.2.4. The standard requirement applies.

8.3. GENERAL MANAGEMENT SYSTEM DOCUMENTATION (OPTION A)

The standard requirement 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 DOCUMENTATION (OPTION A)

8.4.1. The standard requirement applies.

8.4.2. The standard requirement applies.

8.5. CONTROL OF RECORDS (OPTION A)

8.5.1. The standard requirement applies.

8.5.2. The standard requirement applies.

Note: ACCREDIA provides for ten years as a minimum period for the retention of all documents relating to accredited productions, unless there are different legal provisions, in which case the latter shall prevail.

8.6. MANAGEMENT REVIEW (OPTION A)

8.6.1. The standard requirement applies.

Note: Regarding the size of the RMP and any organization it is part of, the review can be performed at different levels, for example: one review at a local level where RMP issues are discussed and a more general one, company-related, to which the results of local reviews come as input.

8.6.2. The standard requirement applies.

8.7. INTERNAL AUDITS (OPTION A)

8.7.1. The standard requirement 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 of first and third party.

8.7.2. The standard requirement applies.

8.7.3. The standard requirement applies.

8.7.4. The standard requirement applies.

8.8. ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES (OPTION A)

8.8.1. The standard requirement applies.

8.8.2. The standard requirement applies.

8.8.3. The standard requirement applies.

8.9. CORRECTIVE ACTIONS (OPTION A)

8.9.1. **General:** The standard requirement applies.

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

8.9.2. **Cause analysis:** The standard requirement applies.

8.9.3. **Selection and implementation of corrective actions:** The standard requirement applies.

8.9.4. **Monitoring of corrective actions:** The standard requirement applies.

8.9.5. **Additional audits:** The standard requirement applies.

8.10. IMPROVEMENT (OPTION A)

8.10.1. The standard requirement applies.

Note: As an example, the RMP may consider the following:

- *Staff update programs;*
- *Improving production methods and increasing their efficiency to better meet customer requirements and demands;*
- *Upgrading equipment and maintaining them at the best possible level.*

8.10.2. The standard requirement applies.

8.10.3. The standard requirement applies.

8.11. FEEDBACK FROM CUSTOMERS (OPTION A)

The standard requirement applies.

9. PROVISIONS CONCERNING THE APPLICATION OF THE METROLOGICAL TRACEABILITY REQUIREMENT

Reference materials producers shall guarantee the metrological traceability as required by standards UNI CEI EN ISO/IEC 17025 AND ISO 17034. 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 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.

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

3b - 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 suppliers are unavailable. In this case also the evaluation of the supplier by the RMP shall take place through second-party audit with the presence of an inspection team of ACCREDIA, where a Technical Officer is present. The evaluation to qualify the supplier by the RMP is in turn subject to assessment by ACCREDIA.

4 - Clause 5.6.2.1.2 of standard UNI CEI EN 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 supplier, 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 - Organizations listed in the JCTLM database (www.bipm.org).

8 - In the event that CRMs cannot be found in the previous three cases, the RMP may refer to producers whose expertise has to be evaluated in order to qualify them in relation to their use. The extent of the checks depends on the information available as well as the nature of the material. The verification of compliance with standard ISO 17034, ISO Guide 35, other regulations on the subject, the ILAC, EA and ACCREDIA prescriptive documents, is carried out as indicated in the next step on the implementation of 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 policy of traceability – implementation of points 3a, 3b, 4, 8 e 9 (reference Annex A ILAC P10)

It should be noted that the choice of the cases described in points 3a, 3b, 4, 8 and 9 implies the use of services that have not been subject to peer evaluation or accreditation. The RMP shall therefore ensure that adequate evidence is available on the supplier's competence and in particular on the traceability and uncertainty of the calibration or supplying materials.

ACCREDIA will assess both such evidence and the ability of the RMP to evaluate them itself.

Appropriate evidence of the technical competence of the supplier 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 laboratory premises and/or production of RM and environmental conditions in which calibrations and/or characterizations of RM have been carried out;
- Record of internal audits;
- Record of Second Party Audits.

Certification of a company's management system does not constitute a certificate of competence of Company Laboratories and Company Producers.

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

10. PROVISIONS CONCERNING INTERNAL CALIBRATIONS AND INTERNALLY PRODUCED MATERIALS

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 UNI CEI EN ISO/IEC 17025. Internal calibrations shall be performed:

- by competent RMP staff or the organization to which RMP belongs, suitably trained and qualified;
- with instruments or samples under the direct and exclusive control of the RMP or of the organization 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:

- be accompanied by measurement uncertainty;
- be recorded in a calibration report compliant with point 5.10 of standard UNI CEI EN 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).