INTERNATIONAL STANDARD

ISO 17034

First edition
2016-11-01

General requirements for the competence of reference material producers

Exigences générales pour la compétence des producteurs de matériaux de référence

Reference number
ISO 17034:2016(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

ISO 17034 was prepared by the *ISO Committee on Conformity Assessment* (CASCO), in collaboration with the *ISO Committee on Reference Materials* (REMCO).

This first edition of ISO 17034 cancels and replaces ISO Guide 34:2009, which has been technically revised.

The following major changes have been made compared with ISO Guide 34:2009:

— inclusion of requirements for production of all types of reference materials, and additional specified requirements for certified reference materials;

— harmonization with the revisions of ISO Guide 31 and ISO Guide 35;

— inclusion of more details on required reference material documentation;

— inclusion of risks and opportunities;

— restructuring based on the common structure adopted by other International Standards on conformity assessment developed by CASCO;

— incorporation of modifications based on ISO/CASCO PROC 33.

Introduction

Reference materials (RMs) are used in all stages of the measurement process, including for method validation, calibration and quality control. They are also used in interlaboratory comparisons for method validation and for assessing laboratory proficiency.

The demonstration of the scientific and technical competence of reference material producers (RMPs) is a basic requirement for ensuring the quality of RMs. The demand for new RMs of higher quality is increasing as a consequence of both the improved precision of measuring equipment and the requirement for more accurate and reliable data in the scientific and technological disciplines. It is not only necessary for RMPs to provide information about their materials in the form of RM documents, but also to demonstrate their competence in producing RMs of appropriate quality.

This International Standard outlines the general requirements for the producers of RMs, including certified reference materials (CRMs). It supersedes ISO Guide 34:2009 and is aligned with the relevant requirements of ISO/IEC 17025. Further guidance (e.g. concerning the content of certificates and the design of characterization, homogeneity and stability studies) is provided in ISO Guide 31 and ISO Guide 35. While the approaches outlined in ISO Guide 31 and ISO Guide 35 meet the relevant requirements of this International Standard, there might be alternative ways to achieve compliance to this International Standard.

RMPs that comply with this International Standard will also operate generally in accordance with the principles of ISO 9001. For tests performed in the medical field, ISO 15189 can be used as the reference instead of ISO/IEC 17025.

In this International Standard, the term “certification” refers to the certification of RMs.

In this International Standard, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

For the purposes of research, users are encouraged to share their views on this document and their priorities for changes to future editions. Click on the link below to take part in the online survey:

https://www.surveymonkey.com/r/CDZZWYH

General requirements for the competence of reference material producers

1 Scope

This International Standard specifies general requirements for the competence and consistent operation of reference material producers.

This International Standard sets out the requirements in accordance with which reference materials are produced. It is intended to be used as part of the general quality assurance procedures of the reference material producer.

This International Standard covers the production of all reference materials, including certified reference materials.

NOTE Reference material producers, regulatory authorities, organizations and schemes using peer assessment, accreditation bodies and others can also use this International Standard in confirming or recognizing the competence of reference material producers.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO Guide 30, ISO/IEC Guide 99, ISO 9000 and the following apply.[1)]

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
reference material producer
RMP
body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference materials it produces

[SOURCE: ISO Guide 30:2015, 2.3.5]

1) The definitions in ISO Guide 30 take precedence where more than one definition for the same term related to reference materials exist.

3.2
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

Note 1 to entry: 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 to entry: Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guide 35.

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

Note 4 to entry: ISO/IEC Guide 99:2007 has an analogous definition.

[SOURCE: ISO Guide 30:2015, 2.1.2, modified — Reference to ISO Guide 34 has been removed from Note 2 to entry]

3.3
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 to entry: Reference material is a generic term.

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

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

Note 4 to entry: 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”.

[SOURCE: ISO Guide 30:2015, 2.1.1, modified — Second sentence of Note 4 to entry has been modified.]

3.4
certified value
value, assigned to a property of a reference material that is accompanied by an uncertainty statement and a statement of metrological traceability, identified as such in the reference material certificate

[SOURCE: ISO Guide 30:2015, 2.2.3]

3.5
impartiality
presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the reference material producer.

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “independence”, “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — In Note 1 to entry, “certification body” has been replaced by “reference material producer”.]

3.6
reference material document
RM document
document containing all the information that is essential for using any reference material

Note 1 to entry: The reference material document covers both the product information sheet and reference material certificate.

[SOURCE: ISO Guide 31:2015, 3.5, modified — The second preferred term "reference material document" has been added.]

3.7
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 to entry: Examples include crude fibre in foods, impact toughness, enzyme activities and extractable lead in soils.

4 General requirements

4.1 Contractual matters

4.1.1 Any request, tender or contract concerning the production of an RM shall be reviewed, following documented policies and procedures established by the RMP, to ensure that:

a) the requirements for RMs and their production are adequately defined, documented and understood;

b) the RMP has the capability and resources to meet the requirements.

NOTE 1 Capability means that the RMP has access to, for example, the necessary equipment, knowledge and information resources and that its personnel have the skills and expertise necessary for the production of those RMs in question. The review of capability can include an assessment of previous RM production and/or the organization of interlaboratory characterization programmes using samples of similar composition to the RMs to be produced.

NOTE 2 A contract can be any written or verbal agreement.

NOTE 3 A request to prepare a specific RM can originate from the RMP.

4.1.2 The review shall include any work that needs to be subcontracted by the RMP.

4.1.3 The RMP shall maintain records of these reviews, including any changes, records of pertinent discussions with the customer relating to the customer's requirements, and subcontracted work.

4.2 Impartiality

4.2.1 The RMP shall be structured and managed so as to safeguard impartiality.

NOTE Impartiality implies that decisions are based on objective criteria and not on the basis of bias, prejudice, or preferring the benefit of one person over another for improper reasons.

4.2.2 The RMP shall:

a) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

b) identify risks to its impartiality on an on-going basis, which shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel; however, such relationships do not necessarily present an RMP with a risk to impartiality;

c) be able to demonstrate, if a risk to impartiality is identified, how it eliminates or minimizes such risk;

d) have top management commitment to impartiality.

NOTE A relationship that threatens the impartiality of the RMP can be based on ownership, governance, management, personnel, shared resources, finances or contracts for purposes other than the sale or production of RMs.

4.3 Confidentiality

4.3.1 The RMP shall be responsible for and shall treat in an appropriate manner all information obtained, including confidential information. Where information is received from another individual or body, such information shall be regarded as confidential unless the individual or body concerned places the information in the public domain or agrees to its disclosure to others.

4.3.2 When the RMP is required by law or authorized by contractual arrangements to release confidential information, the individual or the body concerned shall, unless prohibited by law, be notified of the information provided.

5 Structural requirements

5.1 The RMP shall be a legal entity, or a defined part of a legal entity, that can be held responsible for all its activities related to the production of RMs.

5.2 The RMP shall be organized and shall operate in such a way that it meets all the applicable requirements of this International Standard, whether carrying out work at its permanent facilities or at other sites (including associated temporary or mobile facilities).

5.3 The RMP shall:

a) have a description of its legal status, define the organizational and management structure of the RMP, its place in any parent organization and the relations between management, technical operations, support services and subcontractors;

b) define the parts of the organization covered by the management system for the production of RMs;

c) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of RMs produced;

d) have managerial personnel, supported by technical personnel, with the authority and resources needed to discharge their duties and to identify the occurrence of departures from the management system or the procedures for the production of RMs and to initiate actions to prevent or minimize such departures;

e) have technical management with overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of each operation which forms part of the RM production;

f) appoint personnel (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the requirements of this International Standard are implemented and followed at all times – these appointed personnel shall have direct access to the highest level of management at which decisions are taken on RM production policy or resources;

g) have adequate provision (e.g. insurance or reserves) to cover liabilities arising from its activities.

5.4 The RMP management shall ensure that:

a) internal and external communication mechanisms are established;

b) communication takes place regarding the effectiveness of the management system;

c) the importance of meeting customer and other requirements is communicated to the RMP personnel.

6 Resource requirements

6.1 Personnel

6.1.1 The RMP shall ensure that all personnel involved in RM production are supervised and competent and that they work in accordance with the RMP's management system.

6.1.2 Personnel, including subcontractors, personnel of external bodies, or other individuals acting on the RMP's behalf, shall comply with the policies and procedures for management of confidential information that are set by the RMP.

6.1.3 The RMP shall ensure the competence of all personnel, including technical management personnel, operating under its management system who undertake activities relating to the production of each particular type of RM. There shall be sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions.

6.1.4 The RMP shall have procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated tasks of the RMP.

6.1.5 The RMP shall maintain records of job descriptions for its personnel involved in RM production activities.

6.1.6 The RMP shall authorize competent personnel to perform particular activities relating to RM production. The RMP shall maintain records of the authorizations, competence, educational and professional qualifications of those personnel. These records shall provide evidence that individuals have been adequately trained and that their competence to perform particular activities in the RM production has been assessed. This information shall be readily available and shall include the date on which the authorization and/or competence has been confirmed.

6.2 Subcontracting

6.2.1 Where an RMP uses subcontractors to undertake part of the production, including sampling, processing, handling, homogeneity and stability testing, characterization, storage or distribution of an RM, the RMP shall have procedures to ensure that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of this International Standard and other appropriate standards.

NOTE 1 It is possible that an RMP does not have its own laboratory facilities or processing facilities, or it can choose not to use its own facilities.

NOTE 2 Subcontractors can be paid or unpaid.

6.2.2 The RMP shall select subcontractors on the basis of their ability to meet the requirements stipulated by the RMP.

6.2.3 RMPs shall not subcontract the following processes:

— the production planning;

— the selection of subcontractors;

— the assignment of property values and their uncertainties;

— the authorization of property values and their uncertainties;

— the authorization of RM documents.

6.2.4 The RMP shall establish and maintain procedures to assess that all tasks performed by subcontractors comply with the requirements set by the RMP and with any relevant clauses of this International Standard.

6.2.5 Evidence of the subcontractor's competence shall be established and maintained, including records of evaluations and any audits made of their capability to carry out contracted tasks.

NOTE Examples of evidence are assessments of tasks performed for the RMP in the past, evidence of successful participation in relevant proficiency testing, conformity assessment certificates relevant for the task contracted and acceptable results on well-characterized materials of similar or equivalent nature to that of the candidate RM.

6.2.6 Where the competence of subcontractors cannot be ascertained via provision of documentary evidence, the RMP shall evaluate the competence of the subcontractor or supervise the operations carried out by the subcontractor.

6.2.7 The RMP shall ensure that results and the descriptions of procedures used by subcontractors are available to allow the technical evaluation of data.

6.2.8 When working with subcontractors, the RMP shall have personnel operating under its management system having sufficient knowledge of the subcontractor's task to evaluate the subcontractor's activity.

NOTE For testing activities, this includes knowledge of the task involved and familiarity with this International Standard and ISO/IEC 17025 for calibration and testing.

6.3 Provision of equipment, services and supplies

6.3.1 The RMP shall have procedures in place for the selection of equipment, services and supplies that affect the quality of the RMs produced.

6.3.2 The RMP shall use only equipment, services and supplies that comply with specified requirements to ensure the quality of the RMs it produces.

6.3.3 The RMP shall ensure that equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with the specifications or requirements defined for the RM production activities.

6.3.4 The RMP shall maintain records of purchases of equipment, services and supplies, including records of the selection criteria used, confirmation of acceptance, and any commissioning data.

NOTE 6.3 applies to all equipment including material processing and measuring equipment. 7.7 includes more provisions on operation of measuring equipment.

6.4 Facilities and environmental conditions

6.4.1 The RMP shall ensure that all laboratory facilities, calibration and testing areas (if applicable), material handling, storage, processing and packaging areas, energy sources, lighting, humidity, temperature, pressure and ventilation are such as to facilitate proper material handling, storage, processing and packaging, as well as proper performance of calibration and testing activities (if applicable).

6.4.2 When the environmental conditions could have an adverse effect on the RM, the environmental conditions in which the RM production activities are undertaken shall be monitored with appropriately calibrated equipment, and shall be controlled and recorded, such that results and processes are not adversely affected.

6.4.3 All RM processing and calibration and testing areas, in addition to satisfying requirements for humidity and temperature, shall be protected, where appropriate, from other environmental factors such as incompatible activities, vibration, aerosols, airborne dust and microbiological contamination, magnetic fields, light and electromagnetic and/or ionising radiation.

6.4.4 Access to and use of areas shall be controlled as appropriate to maintain the quality of the RMs.

7 Technical and production requirements

7.1 General requirements

The RMP shall address the requirements in this clause for the production of RMs, including CRMs.

NOTE 1 A CRM has at least one certified value.

NOTE 2 7.9 applies only to certified values.

NOTE 3 7.2 to 7.18 contain requirements for certified values and other property values where necessary. Annex A is a summary of production requirements for RMs and CRMs.

7.2 Production planning

7.2.1 The RMP shall identify and plan those processes that directly affect the quality of RM production, and the production plan shall be documented.

NOTE A mechanism (e.g. a management/technical advisory group) can be established to make recommendations on part or all of the production processes, for example, assigning the property values of interest.

7.2.2 Technical input of subcontractors involved shall be specified and the required information documented and regularly reviewed.

7.2.3 The RMP shall address, during the planning stage, the following:

a) material selection (including, where appropriate, sampling);

b) verification of the identity of the material;

c) maintaining suitable environments for all aspects of production (see 6.4);

d) material processing (see 7.5);

e) choice of measurement procedures (see 7.6,);

f) validation of measurement procedures (see 7.6);

g) verification and calibration of measuring equipment (see 7.7);

h) specification of acceptance criteria for, and assessment of, homogeneity, including sampling (see 7.10);

i) specification of acceptance criteria for, and assessment and monitoring of, stability, including sampling (see 7.11);

j) designing and organizing appropriate characterization, including sampling (see 7.12);

k) assessing commutability (where appropriate);

NOTE Guidance on the need for commutability assessment of RMs is given in a REMCO position paper[15].

l) assigning property values (see 7.13);

m) establishing uncertainty budgets and estimating uncertainties of certified value(s) (see 7.13);

n) defining acceptance criteria for measurand levels and their uncertainties;

o) establishing metrological traceability of measurement result(s) and certified value(s) (see 7.9);

p) issuing RM documents (see 7.14);

q) ensuring adequate storage facilities and conditions (see 7.4);

r) ensuring appropriate labelling and packaging of the RMs (see 7.14);

s) ensuring appropriate transport arrangements (see 7.15);

t) ensuring post-production stability monitoring, if applicable (see 7.11);

u) ensuring an adequate post-distribution service for RM users (see 7.15).

7.2.4 Where multiple batches of RMs with equivalent properties are produced by using similar starting materials and by applying the same procedures, verification shall ensure that information obtained from previous batches remains applicable for the new batch (see 7.2.3).

NOTE 1 Multiple batches can be batches of the same material produced at the same time, or can be successive batches of material produced at substantially different times.

NOTE 2 Further guidance for multiple batch productions is given in ISO Guide 35.

NOTE 3 Where multiple batches are produced, some tests can be omitted or simplified for some batches (see 7.10.2 and 7.11.3).

7.3 Production control

The RMP shall verify that the production plan has been implemented as specified, and deviations from the plan shall be documented and approved.

7.4 Material handling and storage

7.4.1 The RMP shall make arrangements to ensure the integrity of its candidate RMs and RMs throughout the production process. Precautions shall be taken against adverse environmental influences (see 6.4) and possible contamination of the candidate RM during its processing.

NOTE For example, the packaging of a cement material requires conditions of low humidity, while the processing and characterization of a material in which the content of traces of lead is to be measured requires clean room conditions to prevent contamination from dust containing lead. Clean room conditions can also be required for other types of trace analysis. Proper choice of container material and adequate cleaning procedures are also important to avoid contamination.

7.4.2 The RMP shall identify, preserve and separate candidate RMs and RMs from chemicals and other samples, from the time of processing through to their distribution to users.

NOTE It can be useful to uniquely identify each unit of a (candidate) RM in order to facilitate subsequent sampling, trend analysis, distribution services or complaints investigation.

7.4.3 The RMP shall ensure adequate packaging of all RMs (e.g. where appropriate, use light-shielding, air-free, moisture-free or inert-gas packaging) and provide secure storage areas/stock rooms which prevent damage or deterioration of any item or material between characterization and distribution.

7.4.4 The condition of all RMs shall be assessed at appropriate intervals throughout the storage period, in order to detect possible deterioration.

7.4.5 The RMP shall control packaging and labelling processes to the extent necessary to ensure conformity with safety and transport requirements. Procedures for transport to the customer shall be defined.

7.4.6 The RMP shall take measures to ensure that the integrity of each individual RM unit is maintained until the seal, if any, has been broken or up to the point when first used.

7.5 Material processing

7.5.1 The RMP shall establish procedures to ensure that the material has undergone adequate processing for its intended use. Procedures for material processing shall address at least the following:

a) qualitative analysis for verification of material type and/or identity;

b) synthesis, purification (e.g. distillation, extraction), incubation, and transformation into the final form (e.g. machining, grinding, blending, sieving and riffling, extrusion, melting);

c) homogenization;

d) proper handling (e.g. protection from contamination and use of inert equipment) (see 7.4);

e) measurements for control of material processing (e.g. particle size distribution, moisture content);

f) pre-treatment, cleaning or sterilization of processing equipment and sample containers;

g) stabilization of material (e.g. drying, irradiation, sterilization);

h) packaging (e.g. bottling, ampouling) of the material;

i) safety precautions.

7.5.2 Equipment used in material processing shall be operated in accordance with documented procedures.

NOTE Manufacturer's instructions are one form of documented procedure.

7.6 Measurement procedures

The RMP shall ensure that the relevant requirements of ISO/IEC 17025 are met with respect to calibration and testing. These activities shall, where appropriate, be consistent with the required

accuracy of the property values of the RM, and with any standard specifications relevant to the measurement concerned.

7.7 Measuring equipment

The RMP shall ensure that measuring equipment used in RM production is used in compliance with the relevant requirements of ISO/IEC 17025.

NOTE Additional information on the management of measurement systems, including information on equipment that is found to drift outside acceptable limits, can be found in ISO 10012.

7.8 Data integrity and evaluation

7.8.1 The RMP shall ensure that all calculations and data transfers are subject to appropriate checks.

7.8.2 The RMP shall ensure that:

a) computer software developed in-house or off-the-shelf software further developed for specific use is validated and shown to be adequate for use;

   NOTE Examples of software validation can be a computer-based spreadsheet calculation that is checked by manual calculation or using test data sets with known solutions.

b) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but are not limited to, integrity of data entry and capture, data storage, data transmission and data processing;

c) equipment and software are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain data integrity;

d) appropriate procedures are established and implemented for the maintenance of data security, including prevention of unauthorized access and changes to records, including computer records.

7.8.3 Statistical procedures used in monitoring, testing, calibration or value assignment of RMs shall be appropriate for their application.

NOTE 1 Validation of statistical procedures can include evidence of a sound theoretical basis (usually by reference to appropriate literature), known performance under the expected conditions of use and assumptions or conditions which can be shown to apply to the data sufficiently for the purpose at hand.

NOTE 2 Additional information on control of data is provided in ISO/IEC 17025.

7.9 Metrological traceability of certified values

7.9.1 When producing CRMs, the metrological traceability of the certified values shall be established in compliance with the relevant requirements of ISO/IEC 17025. The RMP shall provide evidence of the metrological traceability of the certified value to a stated reference.

NOTE 1 A combination of results obtained by different measurement procedures and/or laboratories all being traceable to the same reference is also traceable to that reference.

NOTE 2 The evidence can be based on evaluation of the measurement process or on confirmation of metrological traceability by comparison of results with independent traceable values.

NOTE 3 Clear identification of the property of interest, traceability of the numerical value and the stated reference contribute to the traceability of results.

NOTE 4 ISO/TR 16476 contains additional information on establishment and expression of metrological traceability of certified values.

7.9.2 The stated reference shall be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit, or a measurement standard.

7.9.3 Where it is technically possible, the RMP shall demonstrate that the stated reference is traceable to the International System of Units (SI).

7.9.4 Where metrological traceability to the SI units is not technically possible, the RMP shall demonstrate metrological traceability to an appropriate reference (see traceability requirements in ISO/IEC 17025).

7.9.5 For studies in which the values need to be traceable to a higher order reference system (e.g. characterization studies with measurements under reproducibility conditions), it shall be ensured that the measurements are calibrated with standards with metrologically traceable values.

7.9.6 Secondary parameters that have a significant influence on the certified value or its uncertainty shall have evidence of metrological traceability.

NOTE Examples of secondary parameters are temperature and humidity.

7.10 Assessment of homogeneity

7.10.1 The RMP shall carry out an assessment of the homogeneity of any candidate RM in its final packaged form to ensure its fitness for purpose.

NOTE 1 Assessment of homogeneity can include the use of prior evidence (including prior experimental evidence), the conduct of an experimental homogeneity study on the candidate RM or both. In most cases, an experimental study is necessary. Guidance on the need for an experimental homogeneity study is provided in ISO Guide 35.

NOTE 2 In most cases, experimental homogeneity tests require measurements of a representative number of randomly chosen units. The units can be chosen for example by random selection, stratified random selection or systematic selection from a random start point.

7.10.2 When the material is produced in multiple batches, the equivalence of the batches shall be demonstrated or the homogeneity of each batch shall be evaluated separately.

7.10.3 Validated measurement procedures shall be selected so that the precision and selectivity are fit for the purpose required.

7.10.4 Where homogeneity needs to be determined experimentally, the RMP shall determine the homogeneity for every property of interest unless it can be shown, using scientific evidence or previous experience, that particular groups of properties are sufficiently closely associated that measurement of one property in such a group furnishes evidence of homogeneity for other properties in the same group.

NOTE Guidance for homogeneity testing and the establishment of minimum sample size is given in ISO Guide 35.

7.10.5 For certified values, homogeneity shall be quantified as an uncertainty contribution to the certified value or shall be shown to be a negligible contribution to the uncertainty of the certified value.

7.11 Assessment and monitoring of stability

7.11.1 The RMP shall:

a) assess, by experimentation if necessary, the stability of all relevant properties of an RM under proposed storage conditions and choose pre-treatment, packaging and storage conditions in accordance with the results of the assessment;

b) assess, by experimentation if necessary, the stability of all relevant properties of an RM under proposed conditions of transport, and choose transport conditions to maintain stability during transport;

c) establish any necessary advice on storage and use of the material to maintain stability at the user's premises;

d) select a scheme for monitoring the stability of materials held in long term storage that permits prompt detection of change, taking into account the possible rate of change;

e) where the stability of a certified value cannot be ensured, make due allowance in the stated uncertainty for possible change in the value prior to use or, where the change with time can be predicted, provide a means of correcting the certified value and its uncertainty for the expected change over time;

f) where repeated sampling from an RM unit or repeated use of an entire RM unit is permitted by the instructions for use, assess the possible effects on the stability of the material and take appropriate action.

NOTE 1 Where repeated sampling is permitted [see bullet f) above], appropriate actions can be, for example, provision of detailed instructions for handling and use after opening of the RM unit.

NOTE 2 ISO Guide 35 provides detailed guidance on procedures in bullets a) to f) above.

NOTE 3 The results of stability assessments can contribute to uncertainty evaluation (see 7.13.6).

7.11.2 The RMP shall conduct an experimental assessment of stability before release unless the RMP has evidence of stability or prior experience of stability from closely similar materials held for an extended period under the same planned storage conditions.

NOTE "Closely similar" materials are materials characterized for the same properties, which share the same matrix composition, processing conditions, similar or less effective packaging, etc.

7.11.3 Where an RM is produced in multiple batches that are not individually tested for stability, the RMP shall verify the stability of a sufficient number of different batches experimentally to provide confidence in the stability of all batches.

NOTE 1 Verification can be a simple test to confirm that different batches behave similarly or, for successive batches, do not change over their lifetime, while the experimental assessment of stability typically involves an extended study aimed at determining rates of change.

NOTE 2 Further guidance for multiple batch productions is given in ISO Guide 35.

7.12 Characterization

7.12.1 Where the RMP assigns property values, characterization of the RM is required.

7.12.2 The RMP shall clearly define whether a quantitative or a qualitative property will be characterized and, if quantitative, whether the measurand is operationally defined or is defined independently of any specific procedure.

7.12.3 The RMP shall select a characterization strategy appropriate for the intended use of the RM.

NOTE 1 Such characterization can include, but is not limited to, the following approaches:

a) using a single reference measurement procedure (as defined in ISO/IEC Guide 99) in a single laboratory;

b) characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories;

c) characterization of an operationally-defined measurand using a network of competent laboratories;

d) value transfer from an RM to a closely matched candidate RM performed using a single measurement procedure performed by one laboratory;

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

NOTE 2 ISO Guide 35 provides guidance on characterization.

7.12.4 The RMP shall specify the characterization study so that the properties of interest are each characterized with appropriate traceability and sufficient reliability whether or not traceability and measurement uncertainty are reported on the RM documentation. To this end, the RMP shall:

a) document a measurement plan that clearly describes the tasks to be performed and communicate this to all personnel responsible for measurements used in characterization;

b) for certified values, demonstrate the competence of each involved laboratory by using data from each laboratory that was not obtained on the material to be characterized.

7.12.5 When evaluating the characterization data, the RMP shall perform a technical evaluation of the data and documents involved in characterization to confirm adherence to the measurement plan as defined in 7.12.4, bullet a), and, in the case of deviations from the plan, assess whether the deviation necessitates exclusion of the data from characterization.

7.13 Assignment of property values and their uncertainties

7.13.1 The RMP shall use documented procedures for the assignment of property values.

7.13.2 These procedures shall include, as appropriate:

a) details of the experimental designs and statistical techniques used;

b) policies on treatment and investigation of anomalous results, including outliers;

c) whether weighting techniques are used for contributions to assigned property values derived from different procedures or laboratories with different measurement uncertainties;

d) the approach used to assign uncertainties to the property values;

e) any other significant factors that may affect the assignment of property values.

7.13.3 The RMP shall take due account of technical information on test methods and equipment, including reported uncertainty information, and of any evidence of laboratory performance when assigning the property values of interest.

NOTE ISO Guide 35 provides guidance on valid approaches for value assignment.

7.13.4 Outliers shall not be excluded solely on statistical evidence until they have been investigated and, where possible, the reasons for the discrepancies identified. Robust statistical methods may be applied where appropriate.

NOTE 1 An apparent outlier can be the only technically valid result in the data set.

NOTE 2 ISO Guide 35 provides guidance on the use of robust statistical methods.

7.13.5 For certified values, the RMP shall identify the uncertainty contributions to be included in the assigned uncertainty.

NOTE Further guidance on the estimation of uncertainties is given in ISO Guide 35 and ISO/IEC Guide 98-3.

7.13.6 For certified values, the RMP shall consider, at a minimum, uncertainty contributions of each of the following:

a) characterization, including any difference between multiple procedures used for characterization;

b) between-unit and within-unit inhomogeneity;

c) changes of property values during storage;

d) changes of property values during transport.

NOTE 1 Other uncertainty contributions can be important such as changes of property values in use or on repeated sampling.

NOTE 2 Where values other than certified values are assigned to RMs (e.g. "indicative values" or "information values"), a statement of uncertainties can be appropriate to improve the use of the material.

7.14 RM documents and labels

7.14.1 The RMP shall issue and make available an RM certificate for CRMs and product information sheet for other RMs.

7.14.2 The contents of RM certificates and product information sheets shall include the following:

a) title of the document;

b) unique identifier of the RM;

c) the name of the RM;

d) name and contact details of the RMP;

e) intended use;

f) minimum sample size (whenever applicable);

g) period of validity;

h) storage information;

i) instructions for handling and use that are sufficient to ensure the integrity of the material;

j) page number and the total number of pages;

k) document version;

l) information on commutability of the material (where appropriate).

7.14.3 In addition to the minimum requirements given in 7.14.2, RM certificates shall contain the following additional information:

a) description of the CRM;

b) property of interest, property value and associated uncertainty;

c) measurement procedure for operationally defined measurands;

d) metrological traceability of the certified values;

e) name and function of RMP's approving officer.

NOTE 1 Further information on the content of certificates and accompanying documentation is given in ISO Guide 31.

NOTE 2 Sector-specific requirements for RM certificates and product information sheets can exist and can be considered (e.g. ISO 15194 for *in vitro* diagnostic medical devices).

7.14.4 The RM label shall be securely attached to the product container of an individual RM unit, and shall be designed to remain legible and intact under the defined storage and handling conditions within the lifetime of the RM, i.e. the period during which the RM is available from the RMP extended by the period of validity of its certificate. The label shall identify the material, the RMP, its batch, and any other information necessary to enable the material to be uniquely distinguished and referenced (such as the individual sample number), where appropriate, to its product information sheet or RM certificate.

7.14.5 Where the physical size of the RM unit limits the amount of information that can be contained on the label, the information shall be included elsewhere (e.g. in an RM document). A unique identifier shall be given [see 7.14.2, bullet b)].

NOTE Further guidance concerning the contents of RM certificates, labels and accompanying documentation can be found in ISO Guide 31.

7.15 Distribution service

7.15.1 The distribution process shall be specified including precautions needed to avoid deterioration of the RM (see 7.11.1). The RMP shall determine the conditions of shipment and ensure that appropriate documentation is provided to allow customs clearance.

NOTE 1 The conditions of shipment can include for example shipping temperature, packaging, duration of transport and other precautions necessary for integrity of the material.

NOTE 2 For some RMs, additional documentation related to, for example, origin and, conformity of the material to safety requirements, might be required for customs clearance.

7.15.2 The RMP shall maintain up-to-date records of all RM sales and distribution.

7.15.3 The RMP shall offer to users reasonable guidance and technical support related to the RMs it produces.

7.15.4 The RMP shall employ best efforts to notify users of any change to the property value or uncertainty for any RM within the validity period of the RM certificate or product information sheet.

7.15.5 Where RMs are subject to resale through a distributor with whom the RMP has a contractual relationship, the RMP shall pass on to the authorized distributor all necessary information to ensure that an effective post-distribution service is maintained and make arrangements with the distributor to ensure that its activities are executed in accordance with the relevant clauses of this International Standard.

NOTE Where RMs are subject to resale by other organizations, the RMP has no control over these organizations' activities after the RMs have been purchased. The requirements regarding distribution service to such resellers are limited to the first reseller.

7.16 Control of quality and technical records

7.16.1 The RMP shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records.

NOTE 1 Quality records are records providing objective evidence of the extent of the fulfilment of the requirements for quality or the effectiveness of the operation of the management system. They include reports from internal audits and management reviews, and corrective action and improvement records.

NOTE 2 Technical records are accumulations of data and information which result from carrying out RM production, measurement, testing and calibration procedures and which indicate whether specified quality or process parameters are achieved. They include forms, contracts, work sheets, work books, check sheets, control charts/graphs, calibration reports/certificates, reports, certificates and other statements to users.

7.16.2 The RMP shall ensure that it has recorded such information that might be needed in a future dispute situation.

7.16.3 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable and in facilities that provide a suitable environment to prevent damage, deterioration or loss. Retention time of records shall be established in accordance with customer or other relevant requirements, and shall be documented.

NOTE Records can be in the form of any type of media, such as hard copy or electronic media.

7.16.4 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct information entered alongside. All such alterations to records shall be signed or initialled, and dated by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid the loss or change of original information.

7.16.5 All records shall be held securely and, where appropriate, in confidence.

7.16.6 The RMP shall have procedures to protect electronically held data at all times and to prevent unauthorized access to, or amendment of, such data.

7.16.7 The RMP shall arrange for all individual measurement observations, appropriate calculations and derived data (e.g. statistical treatments and uncertainty budgets), calibration records and preparation reports to be retained for a defined period beyond which it is no longer probable that they will be referred to, taking into account the period for which the RM remains valid.

7.16.8 The results of each calibration or measurement (or series of either) carried out by the RMP or by a subcontractor shall be reported in accordance with ISO/IEC 17025.

7.17 Management of non-conforming work

7.17.1 The RMP shall have procedures that shall be implemented when it establishes that any aspect of its production activities does not conform to its own specified production procedures or the agreed requirements of the customer.

7.17.2 The procedures shall ensure that:

a) responsibilities and authorities for the management of non-conforming work are designated;

b) the actions to be taken when any non-conforming work and/or RMs are identified including root-cause analysis and a system that ensures that they are effectively implemented;

c) an evaluation of the significance of the non-conforming work is made and identification and implementation of correction and corrective action;

d) where necessary, work is halted and, if appropriate, issue of the affected RM and its certificates and other appropriate documentation is withheld;

e) remedial actions such as customer notifications are taken within a defined time-frame;

f) where necessary, best efforts are employed to notify the users of the possible effects, within an appropriate period and, where necessary, non-conforming RMs and/or their certificates and other appropriate documentation already distributed, are recalled;

g) the responsibility for authorization of the resumption of work is defined;

h) where necessary, an internal audit is conducted to verify the closure and effectiveness of the corrective actions taken.

7.17.3 The decision on recall of RMs shall be taken in a timely manner to limit the use of non-conforming RMs.

NOTE The identification of non-conforming RMs or problems with the management system or with production activities can occur at various places within the management system, such as complaints, quality control, checking of consumable materials, staff observations or supervision, certificate and other appropriate documentation checking, management reviews and internal or external audits.

7.18 Complaints

7.18.1 The RMP shall have a documented process to receive, evaluate and make decisions on complaints.

7.18.2 A description of the handling process for complaints shall be available to any interested party on request.

7.18.3 Upon receipt of a complaint, the RMP shall confirm whether the complaint relates to conformity assessment activities that it is responsible for and, if so, shall deal with it.

7.18.4 The RMP shall be responsible for all decisions at all levels of the handling process for complaints.

7.18.5 Investigation and decision on complaints shall not result in any discriminatory actions.

7.18.6 The process for handling complaints shall include at least the following elements and methods:

a) a description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

b) tracking and recording complaints, including actions undertaken to resolve them;

c) ensuring that any appropriate action is taken.

7.18.7 The RMP receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.18.8 Whenever possible, the RMP shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.18.9 The decision to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original RM activities in question.

7.18.10 Whenever possible, the RMP shall give formal notice of the end of the complaint handling process to the complainant.

8 Management system requirements

8.1 Options

8.1.1 General

The RMP shall establish and maintain a management system that is capable of achieving the consistent fulfilment of the requirements of this International Standard in accordance with either Option A or Option B.

8.1.2 Option A

8.1.2.1 The RMP shall establish, implement and maintain a documented management system that addresses the scope of its RM production activities, which covers the type, range and scale of the RM production it undertakes.

8.1.2.2 The RMP shall define and document its scope of activities.

8.1.2.3 The management system of the RMP shall address the following:

— quality policy (see 8.2);

— general management system documentation (see 8.3);

— control of management system documents (see 8.4);

— control of records (see 8.5);

— management review (see 8.6);

— internal audit (see 8.7);

— actions to address risks and opportunities (see 8.8);

— corrective actions (see 8.9);

— improvement (see 8.10) ;

— feedback from customers (see 8.11).

8.1.3 Option B

An RMP that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7 of this International Standard (ISO 17034), fulfils the management system clause requirements in 8.2 to 8.11.

8.2 Quality policy (Option A)

8.2.1 The RMP shall define and document its policy, objectives and commitment to ensure and maintain the quality of all aspects of RM production, storage and distribution procedures.

8.2.2 The RMP's management system policies related to quality, including a quality policy statement, shall be documented under the authority of the top management.

8.2.3 The quality policy shall include the following commitments:

a) to produce RMs which conform to the requirements of this International Standard;

b) to conduct all testing and calibration in support of the production of RMs in compliance with the requirements of ISO/IEC 17025;

c) to require that all personnel concerned with the quality of any aspect of RM production activities familiarize themselves with the quality documentation and implement the policies and procedures in their work;

d) for the management to continually improve the effectiveness of the management system and to be committed to good professional practice and to the quality of its RMs.

8.2.4 The overall objectives shall be reviewed during the management review.

8.3 General management system documentation (Option A)

The RMP shall document all of its systems, programmes, procedures, instructions, findings, etc., to the extent necessary to enable the RMP to ensure the quality of the RMs produced. Documentation used in this management system shall be communicated to, understood by, available to and implemented by all personnel concerned.

8.4 Control of management system documents (Option A)

8.4.1 The RMP shall control the documents (internal and external) that relate to the fulfilment of this International Standard.

8.4.2 The RMP shall ensure that:

a) documents are approved for adequacy prior to issue by authorized personnel;

b) documents are periodically reviewed and updated (as necessary);

c) changes and the current revision status of documents are identified;

d) relevant versions of applicable documents are available at points of use;

e) documents are uniquely identified and where necessary their distribution controlled;

f) the unintended use of obsolete documents is prevented, and suitable identification applied to them if they are retained for any purpose.

NOTE 1 These can include documents of external origin, such as standards, guides, test and/or calibration procedures, as well as specifications, instructions and manuals related to the RM under production.

NOTE 2 In this context, "document" means any information or instruction including policy statements, text books, procedures, specifications, calibration tables, charts, software, etc. These can be on various media, whether in hard copy or electronic, and they can be in digital, analogue, photographic or written form.

8.5 Control of records (Option A)

8.5.1 The RMP shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this International Standard.

8.5.2 The RMP shall establish procedures for retaining records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.

8.6 Management review (Option A)

8.6.1 In accordance with a predetermined schedule and procedure, the RMP's top management shall periodically conduct a review of its management system and production processes to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements. The review shall take account of, but not be limited to:

a) the suitability of policies and procedures;

b) reports from managerial and supervisory personnel;

c) the outcome of internal audits;

d) corrective actions;

e) result of risk identification;

f) assessments by external bodies;

g) changes in scale and type of work;

h) feedback from customers;

i) recommendations for improvement including complaints;

j) other relevant factors such as resources, staff training and, where required, technical issues relating to the competence of the subcontractor and distributor of the RMs;

k) the quality objectives (see 8.2).

NOTE 1 Results can feed into the corporate planning programme, can include the goals, objectives and action plans for the coming year and can be communicated to the staff.

NOTE 2 A typical period for conducting a management review is once every year.

8.6.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that these actions are discharged within an appropriate and agreed timescale.

8.7 Internal audit (Option A)

8.7.1 The RMP shall, periodically and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and the requirements of this International Standard. The internal audit programme shall address all elements of the management system, including the technical and production activities leading to the finished product (RM). It is the responsibility of the RMP to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities.

8.7.2 When audit findings cast doubt on the effectiveness of the operations, or on the integrity of the RMs, or on the correctness of their documentation, the RMP shall take timely corrective actions and shall notify, in writing, its customers whose activities may have been adversely affected.

8.7.3 All audit findings and corrective actions that arise from them shall be recorded. The RMP's management shall ensure that these actions are discharged within an appropriate and agreed timescale.

8.7.4 Follow-up activities shall verify and record the implementation and effectiveness of the corrective actions taken.

8.8 Actions to address risks and opportunities (Option A)

8.8.1 The RMP shall consider the risks and opportunities to:

a) give assurance that the management system can achieve its intended result(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) achieve improvement.

8.8.2 The organization shall take actions to:

a) address these risks and opportunities;

b) integrate and implement the actions into its management system processes;

c) evaluate the effectiveness of these actions.

8.8.3 Actions taken to address risks and opportunities shall be proportionate to the potential impact on the quality of the RM production and service.

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

8.9 Corrective actions (Option A)

8.9.1 General

The RMP shall establish a policy and procedure(s) and shall designate appropriate authorities for implementing corrective actions when non-conforming RMs, non-conforming work on the production of RMs, or departures from the policies and procedures in the management system have been identified.

NOTE A problem with the management system or with technical operations can be identified through a variety of activities within the management system, such as control of non-conforming RMs, internal or external audits, management reviews and feedback from customers or staff observations.

8.9.2 Cause analysis

Corrective action procedures shall start with an investigation to identify the root causes of the problem. The investigation shall be conducted for both in-house production and, where required, any work performed by subcontractors.

NOTE The root cause is often not obvious and a careful analysis of all potential causes of the problem is required. Potential causes could include the nature of the RM and its specifications, general procedures and procedures used for characterization, staff skills and training, and the materials and equipment (and/or its calibration) used in the production processes.

8.9.3 Selection and implementation of corrective actions

8.9.3.1 Where corrective actions are needed, the RMP shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

8.9.3.2 Any corrective action taken to eliminate the causes of non-conformities or other departures shall be appropriate to the magnitude of the problem and commensurate with the risks encountered.

8.9.3.3 The RMP shall document and implement any required changes to the operational procedures resulting from corrective action investigations.

8.9.4 Monitoring of corrective actions

After having implemented the corrective actions, the RMP shall monitor the results to ensure that the corrective actions taken have been effective in eliminating the root causes of the problems.

8.9.5 Additional audits

Where the identification of non-conformities or departures casts doubt on the RMP's compliance with its own policies and procedures, or on its compliance with this International Standard, the RMP shall ensure that the appropriate areas of activity are audited in accordance with 7.17, as soon as possible.

8.10 Improvement (Option A)

8.10.1 The RMP shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.10.2 Required improvements and potential sources of non-conformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if improvement is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such non-conformities and to take advantage of the opportunities for improvement.

8.10.3 After the implementation of the improvement, the RMP shall monitor the results to establish any reduction in deficiencies or other improvements in this operational area, thereby establishing the effectiveness of the preventive action.

8.11 Feedback from customers (Option A)

The RMP shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analysed to improve the management system, RM production activities and customer service.

Annex A
(informative)

Summary of production requirements for RMs and CRMs

Table A.1 gives guidance on the application of the requirements of Clause 7 related to the production of RMs, including specific requirements for CRMs.

Table A.1 — Production requirements for RMs and CRMs

General requirements	All RMs	CRMs	Applicable subclause
Production planning	Required	Required	7.2
Production control	Required	Required	7.3
Material handling and storage	Required	Required	7.4
Material processing	Required	Required	7.5
Measurement procedures	Required	Required	7.6
Measuring equipment	Required	Required	7.7
Data integrity and evaluation	Required	Required	7.8
Metrological traceability of certified values	Not required	Required	7.9
Assessment of homogeneity	Required	Required	7.10
Assessment and monitoring of stability	Required	Required	7.11
Characterization	Required, where values are to be assigned	Required	7.12
Assignment of property values	Required, where values are to be assigned	Required	7.13
Assignment of the uncertainties of the property values	Not required	Required for certified values	7.13
RM documents and labels	Required	Required	7.14
Distribution service	Required	Required	7.15
Control of quality and technical records	Required	Required	7.16
Management of non-conforming work	Required	Required	7.17
Handling of complaints	Required	Required	7.18

Bibliography

[1] ISO 9000, *Quality management systems — Fundamentals and vocabulary*

[2] ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

[3] ISO 15189, *Medical laboratories — Requirements for quality and competence*

[4] ISO 15194, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation*

[5] ISO 15195, *Laboratory medicine — Requirements for reference measurement laboratories*

[6] ISO/TR 16476, *Reference materials — Establishing and expressing metrological traceability of quantity values assigned to reference materials*

[7] ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

[8] ISO/IEC 17011, *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*

[9] ISO Guide 30:2015, *Reference materials — Selected terms and definitions*

[10] ISO Guide 31:2015, *Reference materials — Contents of certificates, labels and accompanying documentation*

[11] ISO Guide 35, *Reference materials — General and statistical principles for certification*

[12] ISO/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

[13] ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

[14] ISO/CASCO PROC 33, *Common elements of ISO/CASCO standards*

[15] ISO REMCO. *Information on Commutability of Reference Materials* (2014) http://isotc.iso.org/livelink/livelink/fetch/-8854933/8854951/8854960/279217/Commutability_document_final.pdf?nodeid=16787892&vernum=-2

[16] EUROLAB Technical Report No. 2/2006, *Guidance for the management of computers and software in laboratories with reference to ISO/IEC 17025/2005*. Available from http://www.eurolab.org

[17] Ellison S.L.R., & Williams A. eds. *Eurachem/CITAC guide: Quantifying Uncertainty in Analytical Measurement*, Third edition (2012) ISBN 978-0-948926-30-3. Available from www.eurachem.org

[18] ILAC P-10/01:2013, *ILAC Policy on Traceability of Measurement Results*

ICS 03.120.20

Price based on 24 pages