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General requirements for the competence of reference material producers

Exigences générales pour la compétence des producteurs de matériaux de référence

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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.

