GUIDE 34

General requirements for the competence of reference material producers

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft Guides adopted by the responsible Committee or Group are circulated to the member bodies for voting. Publication as a Guide requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO Guide 34 was prepared by the ISO *Reference Materials Committee* (REMCO).

This third edition cancels and replaces the second edition (ISO Guide 34:2000), which has been technically revised. It also incorporates the Technical Corrigendum ISO Guide 34:2000/Cor.1:2003.

Introduction

The use of reference materials enables the transfer of the values of measured or assigned properties between testing and measurement laboratories. Such materials are widely used, e.g. for the calibration of measuring equipment and for the evaluation or validation of measurement procedures. In certain cases, they enable properties to be expressed conveniently in arbitrary units.

NOTE The concept “reference material” is included in the concept “measurement standard”, both of which also include physical reference materials used for calibrating instruments in mechanical, non-destructive and construction type-testing facilities.

There are an increasing number of reference material producers, and a demonstration of their scientific and technical competence is nowadays a basic requirement for ensuring the quality of reference materials. The demand for new reference materials of higher quality is increasing as a consequence of both the increased precision of measuring equipment and the requirement for more accurate and reliable data in the scientific and technological disciplines. Some previously acceptable reference materials may not meet these more stringent requirements anymore. It is, therefore, not only necessary for reference material producers to provide information about their materials in the form of reports, certificates and statements, but also to demonstrate their competence in producing reference materials of appropriate quality.

The first edition of ISO Guide 34 set out specific guidelines on the interpretation of ISO/IEC Guide 25 and the International Standards prepared by ISO/TC 176[1)] in the context of reference material production. The more general requirements of these International Standards were omitted. Since the first edition of ISO Guide 34 was published in 1996, the assessment of the competence of reference material producers has gained considerable impetus. The second edition of ISO Guide 34 set out all the general requirements in accordance with which a reference material producer has to demonstrate that it operates. The present edition makes these requirements mandatory and in line with ISO/IEC 17025:2005/Cor.1:2006 in view of its use for the assessment of the competence of reference material producers applying for accreditation. For tests performed in the medical field, ISO 15189 may be used as the reference instead of ISO/IEC 17025.

1) Including ISO 9000, ISO 9001 and ISO 9004.

General requirements for the competence of reference material producers

1 Scope

1.1 This Guide specifies general requirements in accordance with which a reference material producer has to demonstrate that it operates, if it is to be recognized as competent to carry out the production of reference materials.

1.2 This Guide is intended for the use by reference material producers in the development and implementation of their management system for quality, administrative and technical operations. Reference material customers, regulatory authorities and accreditation bodies may also use it in confirming and recognizing the competence of reference material producers.

NOTE This Guide is not intended to be used as the basis for conformity assessment by certification bodies.

1.3 This Guide sets out the management system requirements in accordance with which reference materials shall be produced. It is intended to be used as part of a reference material producer's general quality assurance (QA) procedures.

1.4 This Guide covers the production of certified and non-certified reference materials. For non-certified reference materials, the production requirements are less stringent than for certified reference materials. The minimum requirements for the production of non-certified reference materials are specified throughout the Guide.

2 Normative references

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

ISO Guide 30, *Terms and definitions used in connection with reference materials*

ISO Guide 31, *Reference materials — Contents of certificates and labels*

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

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

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

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

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

ISO 15189, *Medical laboratories — Particular requirements for quality and competence*

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

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/IEC 17025, ISO Guides 30 and 35, ISO 9000, ISO/IEC Guide 99 and the following apply.

NOTE The definition of (certified) reference materials in this Guide is referenced to ISO Guide 30 (not ISO/IEC Guide 99).

Unless explicitly stated otherwise, the term “certification” is used for the certification of reference materials and shall not be confused with product certification or certification of management systems.

3.1
reference material producer
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 issue of the certificate or other statements for the reference materials it produces

3.2
subcontractor
body (organization or company, public or private) that undertakes aspects of the processing, handling, homogeneity and stability assessment, characterization, storage or distribution of the reference material on behalf of the reference material producer, on a contractual basis, either paid or non-paid (see 5.3.1)

NOTE 1 Key tasks/aspects of the reference material production process which cannot be performed by external parties are project planning, assignment and decision on property values and relevant uncertainties, authorization of property values and issuing of certificates or other statements for the reference materials.

NOTE 2 The concept “subcontractor” is equivalent to the concept “collaborator”.

NOTE 3 Advisors, who could be asked for recommendations, but who are not involved in decision making or the execution of any aspects mentioned in the definition above, are not considered as subcontractors.

3.3
production of a reference material
all necessary activities and tasks leading to a reference material (certified or non-certified) supplied to customers

NOTE Production of a reference material includes production planning, production control, material handling and storage, material processing (also referred to as “manufacturing” or “preparation”), assessment of homogeneity and stability, issue of statements and post-distribution service of the reference materials. It can include characterization, assignment of property values and their uncertainties, authorization and issue of certificates for certified reference materials.

3.4
reference material
RM
material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process

NOTE 1 RM 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 A single RM cannot be used for both calibration and validation of results in the same measurement procedure.

NOTE 5 VIM has an analogous definition (ISO/IEC Guide 99:2007, 5.13), but restricts the term “measurement” to apply to quantitative values and not to qualitative properties. However, Note 3 of ISO/IEC Guide 99:2007, 5.13, specifically includes the concept of qualitative attributes, called “nominal properties”.

[ISO Guide 30:1992/Amd.1:2008, definition 2.1]

3.5
certified reference material
CRM
reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a 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 qualitative attributes such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities.

NOTE 2 Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guides 34 and 35.

NOTE 3 ISO Guide 31 gives guidance on the contents of certificates.

NOTE 4 VIM has an analogous definition (ISO/IEC Guide 99:2007, 5.14).

[ISO Guide 30:1992/Amd.1:2008, definition 2.2]

3.6
commutability of a reference material
property of a reference material, demonstrated by the closeness of agreement between the relation among the measurement results for a stated quantity in this material, obtained according to two given measurement procedures, and the relation obtained among the measurement results for other specified materials

NOTE 1 The reference material in question is normally a calibrator and the other specified materials are usually routine samples.

NOTE 2 The measurement procedures referred to in the definition are the one preceding and the one following the reference material (calibrator) in question in a calibration hierarchy.

NOTE 3 The stability of commutable reference materials is monitored regularly.

[ISO/IEC Guide 99:2007, definition 5.15]

3.7
metrological traceability
property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

NOTE 1 For this definition, a “reference” can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.

NOTE 2 Metrological traceability requires an established calibration hierarchy.

NOTE 3 Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.

NOTE 4 For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrologically traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.

NOTE 5 Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

NOTE 6 A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

NOTE 7 The ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (see ILAC-P10:2002[9]).

NOTE 8 The abbreviated term “traceability” is sometimes used to mean “metrological traceability” as well as other concepts, such as “sample traceability” or “document traceability” or “instrument traceability” or “material traceability”, where the history (“trace”) of an item is meant. Therefore, the full term of “metrological traceability” is preferred if there is any risk of confusion.

[ISO/IEC Guide 99:2007, definition 2.41]

3.8
measurement uncertainty
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

NOTE 1 Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for, but, instead, associated measurement uncertainty components are incorporated.

NOTE 2 The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

NOTE 3 Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.

NOTE 4 In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

[ISO/IEC Guide 99:2007, definition 2.26]

4 Organization and management requirements

4.1 Management system requirements

4.1.1 General

The reference material producer shall establish, implement and maintain a documented management system appropriate to the scope of its activities, including the type, range and volume of the reference material production it undertakes.

It shall be recognized that a reference material property needs to be characterized mainly to the level of accuracy required for its intended purpose (i.e. appropriate measurement uncertainty for a property value of a certified reference material). The reference material producer shall describe the procedure for establishing the quality of materials as a component of the management system.

Reference material producers shall define their scope of activities in terms of the types of reference materials (including the sample matrices, if applicable), the properties to be certified and the ranges of assigned values (and their uncertainties) of the reference materials they produce, and their involvement in the performance of testing, calibration and measurements in relation to homogeneity, stability and characterization assessments and their use of subcontractors in these tasks.

4.1.2 Quality policy

The reference material producer shall define and document its policy, objectives and commitment to ensuring and maintaining the quality of all aspects of reference material production, including material quality (e.g. homogeneity and stability with respect to specified properties), characterization (e.g. equipment calibration and measurement method validation), assignment of property values (e.g. use of appropriate statistical procedures for data evaluation) and material handling, storage and transport procedures.

The reference material producer's management system policies related to quality, including a quality policy statement, shall be documented in a quality manual (however named). It shall be issued under the authority of the top management.

The quality policy shall include but shall not be limited to the following commitments:

a) to produce reference materials which conform to the requirements of this Guide and to the definitions given in ISO Guide 30;

b) to produce, where applicable, certified reference materials according to the requirements of ISO Guide 35 and accompanied by certificates meeting the requirements of ISO Guide 31;

c) to conduct all testing and calibration in support of the production of reference materials in compliance with the requirements of ISO/IEC 17025[2)];

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

e) 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 reference materials.

The overall objectives shall be reviewed during the management review.

4.1.3 Management system

The reference material producer shall document all of its policies, systems, programmes, procedures, instructions, findings, etc., to the extent necessary to enable the producer to ensure the quality of the reference materials produced. Documentation used in this management system shall be communicated to, understood by, available to and implemented by all personnel concerned. In particular, the producer shall have a management system that covers the following:

a) arrangements for ensuring the suitable choice (e.g. type of material, concentration range, etc.) of the candidate reference materials;

b) processing procedures;

c) assessment of the required degree of homogeneity of the reference material;

d) assessment of the stability of the reference material and determination of the period of validity of the certificate or statement;

2) For tests performed in the medical field, ISO 15189 may be used as a reference instead of ISO/IEC 17025.

e) procedures for undertaking characterization (if applicable);

f) assessment of commutability (where appropriate);

g) practical realization of metrological traceability of measurement results to a stated reference;

h) assignment of property values, including preparation of certificates or statements in accordance with ISO Guide 31 when appropriate;

i) arrangements for ensuring adequate storage facilities;

j) arrangements for suitable identification, labelling and packaging facilities, packing and delivery procedures in compliance with international safety regulations, and customer service;

k) assessment of post-certification stability monitoring as required for the extension of the assigned period of validity of the reference material certificate (if applicable);

l) compliance with ISO Guide 30 and with appropriate sections of ISO Guides 31 and 35.

The documented management system shall specify which activities are undertaken by the reference material producer and, where relevant, which activities are undertaken by subcontractors. It shall include policies and procedures used by the producer to ensure that all activities conducted by subcontractors comply with the relevant clauses of this Guide.

The documented management system shall define the roles and responsibilities of the technical management and the quality manager (however named), including their responsibilities for ensuring compliance with this Guide.

4.2 Organization and management

4.2.1 The reference material producer, or the organization of which it is part, shall be an entity that can be held legally responsible.

4.2.2 The reference material producer shall be organized and shall operate in such a way that it meets all the applicable requirements of this Guide, whether carrying out work at its permanent facilities or at sites (including associated temporary or mobile facilities) away from its permanent facilities.

4.2.3 The reference material producer shall

a) 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 reference materials and to initiate actions to prevent or minimize such departures;

b) 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;

c) have policies and procedures to ensure the protection of its customer's confidential information and proprietary rights;

d) have policies and procedures to avoid involvement in any activities that might diminish confidence in its competence, impartiality, judgement or operational integrity;

e) define, with the aid of organizational charts, the organization and management structure of the reference material producer, its place in any parent organization, and the relations between management, technical operations, support services, subcontractors and the quality management system;

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

g) have technical management, including a technical manager, who has 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 reference material production;

h) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the requirements of this Guide are implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are taken on production policy or resources;

i) appoint deputies for key managerial personnel such as the technical and quality managers.

4.3 Document and information control

4.3.1 General

The reference material producer shall establish and maintain procedures to control all documents (both internally generated and from external sources) and other information that form part of its management system. These may include documents of external origin, such as standards, guides, test and/or calibration methods, as well as specifications, instructions and manuals related to the reference material under production.

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

4.3.2 Document approval and issue

4.3.2.1 All documents issued to personnel as part of the management system shall be suitably controlled. This shall include review and approval for use by authorized personnel prior to issue. A master list or equivalent, identifying the current revision status of documents in the management system, shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

4.3.2.2 The procedures adopted shall also ensure that

a) authorized editions of appropriate documents are available at all locations where operations essential to the effective production of reference materials are performed;

b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

d) obsolete documents retained for either legal or information preservation purposes are suitably marked.

4.3.2.3 Management system documents generated by the reference material producer shall be uniquely identified. Such identification shall include the date of issue and/or revision number, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

4.3.3 Document changes

4.3.3.1 Changes to documents shall be reviewed and approved by designated personnel performing the same function as that conducted for the original review and approval unless specifically decided otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.