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General requirements for the competence of reference material producers

Exigences générales pour la compétence des producteurs de matériaux de référence

**Ta slovenski standard je istoveten z: ISO/DGuide 34**

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# General requirements for the competence of reference material producers

[Revision of the second edition (ISO GUIDE 34:2000)]

*Exigences générales pour la compétence des producteurs de matériaux de référence*

ICS 03.120.10; 71.040.30

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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.

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## 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” also includes 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 standards prepared by ISO/TC 176<sup>1)</sup> in the context of reference materials production. The more general requirements of these 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.

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

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# 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 of 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:1995)*

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*

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

NOTE 2 Unless explicitly stated otherwise, the term “certification” is used for the certification of reference materials and must not be confused with product certification or certification of management systems.

**3.1**  
**reference material producer**  
technically competent body (organization or company, public or private) that is fully responsible for project planning and management, assignment of and decision on property values, authorization of property values and issue of the certificate or other statements for the reference materials it produces

**3.2**  
**collaborator**  
technically competent 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, either on a contractual or voluntary basis

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 non-certified reference materials.

NOTE 2 The concept “collaborator” is equivalent to the concept “sub-contractor” as used in ISO/IEC 17025.

**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 1 Production of a reference material includes production planning, production control, material handling and storage, material processing, 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.

NOTE 2 Production is not restricted to the manufacturing or preparation of the candidate 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 can 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.

### 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.

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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<sup>[9]</sup>).

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.

## 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 collaborators 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 conformity with the requirements of ISO/IEC 17025<sup>2)</sup>;
- 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;
- 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 by the extension of the assigned validity period 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 collaborators. It shall include policies and procedures used by the producer to ensure that all activities conducted by collaborators comply with the relevant clauses of this Guide.

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