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## **GUIDE 34**

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### **General requirements for the competence of reference material producers**

Third edition 2009

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Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

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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<sup>1)</sup> 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.

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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 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.