GUIDE 33

Third edition
2015-02-01

Reference materials — Good practice in using reference materials

Matériaux de référence — Bonne pratique d'utilisation des matériaux de référence

Reference number
ISO GUIDE 33:2015(E)

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Published in Switzerland

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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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/REMCO, *Committee on reference materials*.

This third edition cancels and replaces the second edition (ISO Guide 33:2000), and ISO Guide 32:1997 which have been technically revised.

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Introduction

The aim of this Guide is to provide general recommendations on the use of RMs. These recommendations are exemplified by real-world examples, which to some degree also reflect the level of complexity associated with RMs. This level of detail is deemed to be useful for anyone who has a responsibility in the quality management in laboratories, such as drafters, reviewers, managers, and assessors of procedures, working instructions, standard operating procedures and the like.

The main applications of reference materials are calibration, establishing traceability, method validation, assigning values to other materials, and quality control.

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Reference materials — Good practice in using reference materials

1 Scope

1.1 This Guide describes good practice in using reference materials (RMs), and certified reference materials (CRMs) in particular, in measurement processes. These uses include the assessment of precision and trueness of measurement methods, quality control, assigning values to materials, calibration, and the establishment of conventional scales. This Guide also relates key characteristics of various types of RMs to the different applications.

1.2 For CRMs, the metrological traceability of the property values to international scales or other measurement standards has been established. For RMs not being CRMs, this kind of traceability of property values has often not been established. Nevertheless, these RMs can still be used for assessing parts of measurement procedures, including evaluating various levels of precision

1.3 Mainstream applications of RM include precision control (Clause 8), bias assessment (Clause 9), calibration (Clause 10), preparation of calibration RMs (Clause 11) and maintaining conventional scales (Clause 12).

NOTE Not all types of RMs can be used for all indicated purposes.

1.4 The preparation of RMs for calibration is also part of the scope of ISO Guides 34[1] and 35[2]. The treatment in this Guide is limited to the fundamentals of small-scale preparation of RMs and the value assignment, as used by laboratories to calibrate their equipment. Larger scale production of such RMs, with the possible aim of distribution is beyond the scope of this Guide. This type of activity is covered in ISO Guides 34[1] and 35[2].

1.5 The development of working standards, as used in, e.g. natural gas analysis, clinical chemistry, and the pharmaceutical industry is not covered in this Guide. This type of activity is covered in ISO Guides 34[1] and 35[2].

2 Normative references

ISO 3534-1, *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

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

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

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

NOTE The “Guide to the expression of uncertainty in measurement” is referred to as “GUM”, whereas the “International vocabulary of basic and general terms in metrology” is referred to as “VIM”.

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3 Terms and definitions

For the purposes of this document, the terms and definitions in ISO/IEC Guide 98-3, ISO/IEC Guide 99 and ISO Guide 30 and the following apply.

NOTE Further definitions can be found in the ISO online browsing platform, accessible through https://www.iso.org/OBP/ui/

3.1
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: RM 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 (5.13), but restricts the term "measurement" to apply to quantitative values. However, Note 3 of ISO/IEC Guide 99:2007, 5.13 (VIM), specifically includes qualitative properties, called "nominal properties".

[SOURCE: ISO Guide 30]

3.2
certified reference material
CRM
reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM 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 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 RMs are given in, among others, ISO Guides 34 and 35.

Note 3 to entry: ISO Guide 31[17] gives guidance on the contents of RM certificates.

Note 4 to entry: ISO/IEC Guide 99:2007 has an analogous definition (5.14).

[SOURCE: ISO Guide 30]

3.3
property value
<of a reference material> value corresponding to a quantity representing a physical, chemical or biological property of a reference material

[SOURCE: ISO Guide 30]

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

[SOURCE: ISO Guide 30]

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