GUIDE 30

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Reference materials — Selected terms and definitions

Matériaux de référence — Termes et définitions choisis

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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).

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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 the ISO Committee on Reference Materials (REMCO), which is concerned with guidelines for the preparation, certification and use of reference materials (RMs) and certified reference materials (CRMs). The first edition of this Guide (1981) was the outcome of collaboration between REMCO and the organizations EEC, IAEA, OIML, IUPAC, IFCC and WHO, and was produced largely by Dr D. A. Lowe of WHO and Prof. Dr R. Neider of BAM. The revision leading to the second edition was undertaken because it had become apparent that some confusion existed as to what types of measurement standards or etalons should legitimately be included within the definition of an RM. Moreover, the recognition that CRMs are measurement standards made it desirable to examine the vocabulary of standards in metrology, as detailed in the International vocabulary of basic and general terms in metrology (VIM), currently published as ISO/IEC Guide 99:2007 and as JCGM 200:2012, with particular reference to CRMs.

This third edition of ISO Guide 30 cancels and replaces ISO Guide 30:1992. It was revised principally for introducing new definitions for RMs and CRMs as well as to update other terms and definitions. The definitions for RM and CRM were developed by REMCO to incorporate the concepts of both quantitative and qualitative analysis. There exist different definitions for these terms in other sources, notably ISO/IEC Guide 99:2007 and JCGM 200:2008. It remains as a future goal to harmonize these definitions in subsequent editions of these terminology guides. The terms included in this version are limited to those required to support the principles and concepts set forth in other REMCO Guides. Existing definitions in referenced publications are used wherever possible. In other cases, some definitions are specifically tailored to enhance the understanding of RMs and their uses.

Where definitions from other references are used, the source is given. References to similar terms defined in other sources are indicated in a note after the prompt "See also".

Introduction

Reference materials (RMs) and certified reference materials (CRMs) (defined in 2.1 and 2.2) are widely used for the calibration of measuring apparatus, for the evaluation of measurement procedures and for the internal or external quality control of measurements and laboratories. They may enable the expression of functional properties, for instance in certain cases relevant for biology or material sciences, in arbitrary units. RMs and CRMs play an increasingly important role in national and international standardizing activities and in the accreditation of laboratories.

This document is intended to serve as a guide to terms and definitions used in connection with the production and use of RMs as described in the respective ISO guides. It should prove useful in helping to ensure a greater degree of uniformity in the terminology used by different organizations concerned with the production and use of RMs throughout the world.

In some cases, admitted alternate terms are listed below the bold typeface defined term.

Reference materials — Selected terms and definitions

1 Scope

This Guide recommends terms and definitions that should be used in connection with reference materials, with a particular emphasis on terms that are used in reference material product information sheets, certificates and corresponding certification reports.

2 Terms and definitions

2.1 Terms related to materials

2.1.1
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[1] 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".

2.1.2
certified reference material
CRM
reference material (RM) 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 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 RMs are given in, among others, ISO Guides 34[2] and 35[3].

Note 3 to entry: ISO Guide 31[4] gives guidance on the contents of RM certificates.

Note 4 to entry: ISO/IEC Guide 99:2007[1] has an analogous definition (5.14).

2.1.3
candidate reference material
material, intended to be produced as a reference material (RM)

Note 1 to entry: A candidate material has yet to be characterized and tested to ensure that it is fit for use in a measurement process. To become an RM, a candidate material needs to be investigated to determine if it is sufficiently homogeneous and stable with respect to one or more specified properties, and is fit for its intended use in the development of measurement and test methods that target those properties.

Note 2 to entry: A candidate reference material may be an RM for other properties, and a candidate reference material for the target property.

2.1.4
matrix reference material
reference material that is characteristic of a real sample

EXAMPLE Soil, drinking water, metal alloys, blood.

Note 1 to entry: Matrix reference materials may be obtained directly from biological, environmental or industrial sources.

Note 2 to entry: Matrix reference materials may also be prepared by spiking the component(s) of interest into an existing material.

Note 3 to entry: A chemical substance dissolved in a pure solvent is not a matrix material.

Note 4 to entry: Matrix materials are intended to be used in conjunction with the analysis of real samples of the same or a similar matrix.

2.1.5
primary measurement standard
measurement standard that is designated or widely acknowledged as having the highest metrological qualities and whose property value is accepted without reference to other standards of the same property or quantity, within a specified context

Note 1 to entry: See also ISO/IEC Guide 99:2007.[1]

2.1.6
secondary measurement standard
measurement standard whose property value is assigned by comparison with a primary measurement standard of the same property or quantity

Note 1 to entry: See also ISO/IEC Guide 99:2007.[1]

2.1.7
sample
portion (amount) of material taken from a batch

Note 1 to entry: The sample should be representative of the batch with respect to the property or properties being investigated.

Note 2 to entry: The term may be used to cover either a unit of supply or a portion for analysis.

Note 3 to entry: The portion taken may consist of one or more sampling units (such as subsamples or units) and the batch may be considered to be the population from which the sample is taken.

Note 4 to entry: See also the IUPAC Compendium of Analytical Nomenclature.[5]

2.1.8
minimum sample size
minimum sample intake
lower limit of the amount of an RM, usually expressed as a mass quantity, that can be used in a measurement process such that the values or attributes expressed in the corresponding RM documentation are valid

2.1.9
production batch
lot
definite amount of material produced during a single manufacturing cycle, and intended to have uniform character and quality

Note 1 to entry: The uniform conditions of manufacture or production of the batch or lot must be such as to ensure a homogeneous product.

Note 2 to entry: In statistics, an entire batch may be considered a finite population (totality of items under consideration).

Note 3 to entry: See also “lot” in ISO 3534-2:2006.[6]

Note 4 to entry: See also the IUPAC Compendium of Analytical Nomenclature.[5]

2.1.10
characterization
<of a reference material> determination of the property values or attributes of a reference material, as part of the production process

Note 1 to entry: See also the IUPAC Compendium of Analytical Nomenclature.[5]

2.1.11
value assignment
process by which reference material (RM) property values or attributes obtained by characterization are combined and expressed in accompanying RM documentation

2.1.12
homogeneity
uniformity of a specified property value throughout a defined portion of a reference material (RM)

Note 1 to entry: Tests for homogeneity are described in ISO Guide 35.

Note 2 to entry: The ‘defined portion’ may be, for example, an RM batch or a single unit within the batch.

Note 3 to entry: See also IUPAC Compendium of Analytical Nomenclature.[5]

2.1.13
between-unit homogeneity
uniformity of a specified property value among units of a reference material

Note 1 to entry: It is understood that the term “between-unit homogeneity” applies to any type of package (e.g. vial) and other physical shapes and test pieces.

2.1.14
within-unit homogeneity
uniformity of a specified property value within each unit of a reference material

2.1.15
stability
characteristic of a reference material, when stored under specified conditions, to maintain a specified property value within specified limits for a specified period of time

Note 1 to entry: See also the IUPAC Compendium of Analytical Nomenclature.[5]

2.1.16
transportation stability
stability of a reference material (RM) property for the time period and conditions encountered in transportation to the user of the RM.

Note 1 to entry: Transportation stability has often been referred to as “short term stability”.

2.1.17
long-term stability
stability of a reference material property over an extended period of time.

2.1.18
lifetime
<of a reference material (RM)> time interval during which RM properties retain their assigned values within their associated uncertainties

Note 1 to entry: The lifetime is often determined retrospectively, i.e. after RM properties no longer retain assigned values or attributes.