PD ISO GUIDE 30:2015

BSI Standards Publication

Reference materials — Selected terms and definitions

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National foreword

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Foreword

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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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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.

2.1.19
period of validity
<of a reference material (RM)> time interval during which the producer of the RM warrants its stability

Note 1 to entry: The period of validity may be expressed as a specific date or an otherwise defined period of time.

Note 2 to entry: The period of validity is designed to be within the lifetime of an RM.

2.1.20
commutability
property of a reference material (RM), demonstrated by the equivalence of the mathematical relationships among the results of different measurement procedures for an RM and for representative samples of the type intended to be measured

Note 1 to entry: See also ISO/IEC Guide 99:2007,[1] ISO 17511:2003.[7]

[SOURCE: CLSI document EP30-A[8]]

2.1.21
calibrant
Note 1 to entry: reference material used for calibration of equipment or a measurement procedure

2.1.22
quality control material
Note 1 to entry: reference material used for quality control of a measurement

2.2 Terms related to measurement and testing

2.2.1
property value
<of a reference material (RM)> value corresponding to a quantity representing a physical, chemical or biological property of an RM

2.2.2
property attribute
<of a reference material (RM)> value or non-numerical descriptor corresponding to a qualitative characteristic representing a physical, chemical or biological property of an RM

2.2.3
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

2.2.4
indicative value
information value
informative value
value of a quantity or property, of a reference material, which is provided for information only

Note 1 to entry: An indicative value cannot be used as a reference in a metrological traceability chain

2.2.5
interlaboratory comparison
interlaboratory study
interlaboratory test
collaborative study
organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

Note 1 to entry: See also “interlaboratory test” in the IUPAC Compendium of Analytical Nomenclature[5].

Note 2 to entry: See also the Codex Alimentarius Commission Procedural Manual.[9]

[SOURCE: ISO/IEC 17043:2010,[10] 3.4, modified — The admitted terms ("interlaboratory study", "interlaboratory test" and "collaborative study") and the notes to entry have been added.]

2.2.6
reference method
reference procedure
measurement method, that has been shown to have the appropriate trueness and precision for its intended use and has been officially defined as reference method by a competent body

Note 1 to entry: See also "reference measure procedure" in ISO/IEC Guide 99:2007.[1]

2.3 Terms related to certification and issuance of reference materials

2.3.1
reference material certification
action of a reference material (RM) producer that formally establishes the certified values of a CRM and states them in an RM certificate

Note 1 to entry: RM certification is a first-party attestation in accordance with the definition of the term "declaration" (ISO/IEC 17000:2004, 5.4[11]) whereas certification is a third-party attestation in accordance with the definition of the term "certification" (ISO/IEC 17000:2004, 5.5[11]).

2.3.2
reference material certificate
document containing the essential information for the use of a CRM, confirming that the necessary procedures have been carried out to ensure the validity and metrological traceability of the stated property values

Note 1 to entry: The required and recommended content of a reference material certificate is described in ISO Guide 31.[4]

2.3.3
reference material certification report
document giving detailed information, in addition to that contained in a reference material certificate, e.g. the preparation of the material, methods of measurement, factors affecting accuracy, statistical treatment of results, and the way in which metrological traceability was established

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

2.3.4
product information sheet
document containing all the information that is essential for using an RM other than a CRM

2.3.5
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 issuance of a reference material certificate or other statements for the reference materials it produces

2.3.6
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 under its own management system on behalf of the reference material producer

Note 1 to entry: According to ISO Guide 34,[2] key tasks/aspects of the RM 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 reference material certificates or other statements for the RMs.

Note 2 to entry: The concept "subcontractor" is equivalent to the concept "collaborator".

Note 3 to entry: 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.

2.3.7
production
<of a reference material (RM)> all necessary activities and tasks leading to the release and maintenance of an RM (certified or non-certified)

Note 1 to entry: Activities include, e.g. planning, control, material handling and storage, material processing, assessment of homogeneity and stability, characterization, assignment of property values and their uncertainties, authorization and issue of RM certificates or other statements..

2.4 Statistical terms used in the characterization of reference materials

2.4.1
simple random sampling
sampling where a sample of *n* sampling units is taken from a batch in such a way that all the possible combinations of *n* sampling units have the same probability of being taken

Note 1 to entry: In bulk sampling, if the sampling unit is an increment, the positioning, delimitation and extraction of increments is such that all sampling units have an equal probability of being selected.

[SOURCE: ISO 3534-2:2006,[6] 1.3.4, modified — In the definition, "batch" is used instead of "population".]

2.4.2
stratified sampling
sampling such that portions of the sample are drawn from the different strata and each stratum is sampled with at least one sampling unit

Note 1 to entry: In some cases, the portions are specified proportions determined in advance. If the stratification is done after the sampling, the specified proportions would not be known in advance.

Note 2 to entry: Items from each stratum are often selected by random sampling.

[SOURCE: ISO 3534-2:2006,[6] 1.3.6]

2.4.3
stratified simple random sampling
simple random sampling from each stratum

Note 1 to entry: If the proportions of items drawn from the differing strata are equal to the proportions of population items in the strata, it is called proportional stratified simple random sampling.

[SOURCE: ISO 3534-2:2006,[6] 1.3.7]

2.4.4
target value
property value of an RM specified on the basis of its intended use

Note 1 to entry: The target value of an RM property is usually specified in the design phase of RM production.

Note 2 to entry: See also ISO 3534-2:2006.[6]

2.4.5
target measurement uncertainty
target uncertainty
measurement uncertainty specified as an upper limit and decided on the basis of the intended use of measurement results

Note 1 to entry: For the production of RMs, the term target uncertainty may be used to describe the intended uncertainty for the assigned property value

[SOURCE: ISO/IEC Guide 99:2007[1], 2.34, modified — Note 1 has been added.]

Bibliography

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

[2] ISO Guide 34:2009, *General requirements for the competence of reference material producers*

[3] ISO Guide 35:2006, *Reference materials — General and statistical principles for certification*

[4] ISO Guide 31, *Reference materials — Contents of certificates, labels and accompanying documentation materials*

[5] *IUPAC Compendium of Analytical Nomenclature* ("Orange Book"), 3rd edition. J. Inczedy, T. Lengyel, and A.M. Ure, Blackwell Science, Oxford, UK, 1998, ISBN 0-632-05127-2

[6] ISO 3534-2:2006, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

[7] ISO 17511:2003, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials*

[8] Clinical and Laboratory Standards Institute (CLSI). *Characterization and Qualification of Commutable Reference Materials for Laboratory Medicine, Approved Guideline*. CLSI document EP30-A (ISBN 1-56238-726-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2010

[9] Codex Alimentarius Commission Procedural Manual. Rome, Eighteenth Edition, 2008

[10] ISO/IEC 17043:2010, *Conformity assessment — General requirements for proficiency testing*

[11] ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

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