
Reference materials — Contents of certificates, labels and accompanying documentation

Matériaux de référence — Contenu des certificats, des étiquettes et de la documentation d'accompagnement

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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 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 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). <https://standards.iteh.ai/catalog/standards/sist/bd144ef4-7d9c-4e97-bc4f-241512158437/iso-guide-31-2015>

This third edition cancels and replaces the second edition (ISO Guide 31:2000), which has been technically revised.

Introduction

The ISO Committee on Reference Materials (ISO/REMCO) published the first and second editions of this Guide in 1981 and 2000, respectively. Since the second edition was published, there has been considerable growth in the number and variety of reference materials (RMs) produced, and in their use. The demand for reliability in the results obtained by analytical techniques has risen, especially due to growing concern about legal requirements, environment, and clinical applications. This has led to a need for a wide range of RMs used for quality control purposes, as well as certified reference materials (CRMs) used in the validation of measurement methods, evaluation of the performance of new measurement procedures or laboratories, and calibration of instruments.

According to the definition of an RM in ISO Guide 30, information on the homogeneity and stability of the material is required. Moreover, it is mandatory for a CRM that all certified values are accompanied by an associated uncertainty at a stated level of confidence and a statement on the metrological traceability of these values. Therefore, guidance is required on the content and the format of the information that accompanies a reference material, whether it is certified or not.

The first edition of this Guide discussed the difference between the information provided on the label, the certificate, and the certification report, and stressed the brief synoptic nature of the certificate. The second edition focused on the required content of the certificate of a CRM. This present edition introduces the concepts of a 'product information sheet' and a 'reference material certificate' and describes the information that should be included in these RM documents. For the purpose of this Guide, the RM document is either the 'product information sheet' or 'RM certificate' which accompanies the RM.

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Reference materials — Contents of certificates, labels and accompanying documentation

1 Scope

This Guide is intended to help reference material (RM) producers in preparing clear and concise documentation to accompany an RM. It lists and explains mandatory, recommended and other categories of information to be considered in the preparation of product information sheets and RM certificates. This information can be used by RM users and other stakeholders in confirming the suitability of an RM or certified reference material (CRM).

This Guide also contains the minimum requirements for a label attached to the RM container.

2 Normative reference

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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, *Reference materials — Selected terms and definitions*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO Guide 30 and the following apply.

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^[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”.

[SOURCE: ISO Guide 30:2015, 2.1.1^[2]

3.2 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.

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Note 2 to entry: Metrologically valid procedures for the production and certification of RMs are given in, among others, ISO Guides 34[3] and 35[4].

Note 3 to entry: ISO/IEC Guide 99:2007 has an analogous definition (5.14).

[SOURCE: ISO Guide 30:2015, 2.1.2, modified – Note 3 has been deleted]

3.3 product information sheet

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

[SOURCE: ISO Guide 30:2015, 2.3.4]

3.4 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

[SOURCE: ISO Guide 30:2015, 2.3.2, modified – Note 1 has been deleted]

3.5 RM document

document containing all the information that is essential for using any RM

Note 1 to entry: The RM document covers both the product information sheet and the RM certificate.

3.6 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

[SOURCE: ISO Guide 30:2015, 2.3.5]

4 General

In this document, the term 'reference material certificate' is used for a document accompanying a CRM and the term 'product information sheet' is used for a document accompanying any other type of RM. RM document covers concepts of both the reference material certificate and the product information sheet.

The specifications for product information sheets, RM certificates and labels given in the following clauses of this Guide include those mentioned in technical clauses of ISO Guide 34.

An RM document shall contain information essential for the proper use of any RM, e.g. detailed information about the way the container should be opened, the minimum sample size, if applicable, that shall be taken for a measurement, period of validity based on the stability of the material and the way in which it should be stored. Additional information is required for an RM certificate. The RM certificate shall contain all the information that is essential for the correct use of a CRM. Issuing an RM certificate is mandatory for the production of a CRM, while an RM producer may issue a product information sheet for an RM other than a CRM.

In conclusion, producers of RMs should pay careful attention to the preparation of a product information sheet or RM certificate. Additional information may be provided in a separate report or other document.

The information provided on a label of an individual unit of an RM shall serve to uniquely identify the material and allow the identification of the appropriate product information sheet or RM certificate. Whenever applicable, health and safety information shall be included in compliance with relevant legislation or directives.

5 The contents of a product information sheet or reference material certificate

5.1 General

The categories of information to be considered in the preparation of an RM document, i.e. a product information sheet or an RM certificate, are indicated below. An explanation is given under each category, together with examples where clarification is considered necessary. The categories are intended to cover the required information over a wide range of RMs that may include those certified for quantity values of physical properties, chemical composition or isotope ratios expressed in International System of Units (SI), for conventional or biological property values expressed in other international units, for properties specifying the identity of chemical or biological species, etc.

A summary of the information that is essential to be included in an RM document is given, in order to assist those organizations which may wish to include some parts of this Guide in their requirements. Other details are optional and may be provided if they would enhance the usefulness of the RM, e.g. the origin of a material prepared from natural sources.

This clause concerns the information contained in the RM document; the order or titles of the categories may be changed to suit the preference of the RM producer. The information required for any RM document is listed in [5.2](#); then the essential information that is required only for an RM certificate is stated in [5.3](#). Finally, useful information to add in the RM document is given in [5.4](#). A summary of the requirements is given in [Table 1](#).

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