Reference materials — Contents of certificates, labels and accompanying documentation

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

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Contents

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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 document 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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 334, *Reference materials*.

This first edition of ISO 33401 cancels and replaces ISO Guide 31:2015, which has been technically revised.

The main changes are as follows:

— ~~Transformation~~transformation from a Guide to an International Standard~~.~~;

— ~~Addition~~addition of requirements for product information sheets and revision of Table 1~~Table 1~~ accordingly~~.~~;

— ~~Editorial~~editorial changes for clarification.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Reference materials (RMs) are essential for quality assurance in various fields of measurement. RMs are used in diverse measurement processes, including calibration, quality control, proficiency testing and method validation.

Users of RMs obtain the information necessary for their proper use through the documentation that accompanies RMs. Therefore, standardization is required for the content and format of RM documentation. In response to growing needs, the ISO Committee on Reference Materials (ISO/REMCO) published the first, second and third editions of ISO Guide 31 in 1981, 2000 and 2015, respectively. The first edition of ISO Guide 31 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 certified reference material (CRM). The third edition introduced the concepts of a "product information sheet" and a "reference material certificate" and described the information that should be included in these RM documents.

Having assumed the responsibilities of ISO/REMCO, ISO/TC 334 publishes this first edition of International Standard, which largely follows the third edition of ISO Guide 31. This document is intended to be complementary to ISO 17034 and provides support for the implementation of ISO 17034 on the requirements for RM documentation.

In this document, the term "certification" refers to the certification of RMs.

Reference materials — Contents of certificates, labels and accompanying documentation

1   Scope

This document is intended to help reference material producers (RMPs) in preparing clear and concise documentation to accompany a reference material (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 document also contains the minimum requirements for a label attached to the container of an individual RM unit.

2   Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 30:2015, *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.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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 can 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 (VIM), 5.13 has an analogous definition but restricts the term "measurement" to apply to quantitative values. However, ISO/IEC Guide 99:2007, 5.13, NOTE 3 specifically includes qualitative properties, called "nominal properties".

[SOURCE: ISO Guide 30:2015, 2.1.1, modified — Note 4 to entry revised.]

3.2
certified reference material
CRM

reference material (3.1(3.1)) characterized by a metrologically valid procedure for one or more specified properties, accompanied by a *reference material certificate* (3.4(3.4)) 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: ISO/IEC Guide 99:2007, 5.14 has an analogous definition.

[SOURCE: ISO Guide 30:2015, 2.1.2, modified — Notes 2 and 3 to entry deleted.]

3.3
product information sheet

document containing all the information that is essential for using a *reference material* (3.1(3.1)) other than a *certified reference material* (3.2(3.2))

[SOURCE: ISO Guide 30:2015, 2.3.4]

3.4
reference material certificate
RM certificate

document containing the essential information for the use of a *certified reference material* (3.2(3.2),), 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 to entry deleted.]

3.5
reference material document
RM document

document containing all the information that is essential for using any *reference material* (3.1(3.1))

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

3.6
reference material producer
RMP

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* (3.4(3.4)) or other statements for the *reference materials* (3.1(3.1)) it produces

[SOURCE: ISO Guide 30:2015, 2.3.5]

3.7
operationally defined measurand

measurand that is defined by reference to a documented and widely accepted measurement procedure to which only results obtained by the same procedure can be compared

EXAMPLES: EXAMPLE Crude fibre in foods, impact toughness, enzyme activities and extractable lead in soils.

[SOURCE: ISO 17034:2016, 3.7, modified — Note 1 to entry changed to EXAMPLES.]

3.8
~~reference material~~ certification report
document giving detailed information in addition to that contained in a *reference material certificate* (3.4~~(3.4),~~), e.g. on the preparation of the material, methods of measurement, factors affecting accuracy, statistical treatment of results or the way in which metrological traceability was established

[SOURCE: ISO Guide 30:2015, 2.3.3, modified — <u>Term revised and </u>Note 1 to entry deleted.]

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 the 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 include those mentioned in ISO 17034.

An RM document shall contain information essential for the use of any RM, ~~e.g.~~<u>for example</u> 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. An RM certificate shall contain additional information, including a statement of metrological traceability and measurement uncertainty. In conclusion, producers of RMs should pay careful attention to the preparation of RM documents.

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.

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 in <u>5.2</u>~~5.2.~~. 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. These can include those certified for quantity values of physical properties, chemical composition or isotope ratios expressed according to the International System of Units (SI), for conventional or biological property values expressed in other international units or for properties specifying the identity of chemical or biological species.

A summary of the information that is essential in an RM document is given in order to assist those organizations ~~which~~<u>that</u> wish to include some parts of this document in their requirements. Other details are optional and can be provided if they would enhance the usefulness of the RM, ~~e.g.~~<u>for example</u> 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 <u>5.2</u>~~5.2~~ and the essential information that is required only for an RM certificate is stated in <u>5.3</u>~~5.3.~~. Finally, useful information to include in the RM document is given in <u>5.4</u>~~5.4.~~. A summary of the requirements is given in <u>Table 1</u>~~Table 1.~~.

Table 1 — Contents of the product information sheet or the RM certificate

Content	Product information sheet	RM certificate	Subclause
Title of the document	Mandatory	Mandatory	<u>5.2.2</u>~~5.2.2~~
Unique identifier of the RM	Mandatory	Mandatory	<u>5.2.3</u>~~5.2.3~~

Content	Product information sheet	RM certificate	Subclause
Name of the RM	Mandatory	Mandatory	5.2.4~~5.2.4~~
Name and contact details of the RM producer	Mandatory	Mandatory	5.2.5~~5.2.5~~
Intended use	Mandatory	Mandatory	5.2.6~~5.2.6~~
Minimum sample size	Mandatory whenever applicable	Mandatory whenever applicable	5.2.7~~5.2.7~~
Period of validity	Mandatory	Mandatory	5.2.8~~5.2.8~~
Commutability	Mandatory whenever applicable	Mandatory whenever applicable	5.2.9~~5.2.9~~
Storage information	Mandatory	Mandatory	5.2.10~~5.2.10~~
Instructions for handling and use	Mandatory	Mandatory	5.2.11~~5.2.11~~
Document components	Mandatory	Mandatory	5.2.12~~5.2.12~~
Document version	Mandatory	Mandatory	5.2.13~~5.2.13~~
Measurement procedures for operationally defined measurands	Mandatory whenever applicable	Mandatory whenever applicable	5.2.14~~5.2.14~~
Property of interest	Mandatory	Mandatory	5.2.15~~5.2.15~~
Description of the material	Recommended	Mandatory	5.3.2~~5.3.2~~
Property value and associated uncertainty	Optional	Mandatory	5.3.3~~5.3.3~~
Metrological traceability	Optional	Mandatory	5.3.4~~5.3.4~~
Name and function of the RM producer's approving officer	Optional	Mandatory	5.3.5~~5.3.5~~
Measurement procedures for non-operationally defined measurands	Recommended	Recommended	5.4.2~~5.4.2~~
Health and safety information	Recommended	Recommended	5.4.3~~5.4.3~~
Subcontractors	Optional	Optional	5.4.4~~5.4.4~~
Indicative values	Optional	Optional	5.4.5~~5.4.5~~
Legal notice	Optional	Optional	5.4.6~~5.4.6~~
Reference to a certification report	Optional	Optional	5.4.7~~5.4.7~~

5.2 Information required in the RM document

5.2.1 General

The RM document shall include the following information.

5.2.2 Title of the document

The title of the document shall be stated. There should be a distinct title, such as "Product information sheet" or "Reference material certificate".

NOTE 1 "Certificate" or "Certificate of ~~Analysis~~analysis" has often been used for the title of a document. It is good practice that the user of a CRM checks, even if the title of the document includes the word "certificate", whether the mandatory information from this document is present in the document, thus fulfilling the requirement of a CRM.