International Standard

ISO 33401

First edition
2024-01

Reference materials — Contents of certificates, labels and accompanying documentation

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

Reference number
ISO 33401:2024(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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 from a Guide to an International Standard;

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

— 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 ISO 33401, 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) characterized by a metrologically valid procedure for one or more specified properties, accompanied by a *reference material certificate* (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) other than a *certified reference material* (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), 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)

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) or other statements for the *reference materials* (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

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 EXAMPLE.]

3.8
certification report
document giving detailed information in addition to that contained in a *reference material certificate* (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 — Term revised and 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, for example 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 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 that 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, for example 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 and the essential information that is required only for an RM certificate is stated in 5.3. Finally, useful information to include in the RM document is given in 5.4. A summary of the requirements is given in 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	5.2.2
Unique identifier of the RM	Mandatory	Mandatory	5.2.3
Name of the RM	Mandatory	Mandatory	5.2.4
Name and contact details of the RM producer	Mandatory	Mandatory	5.2.5
Intended use	Mandatory	Mandatory	5.2.6
Minimum sample size	Mandatory whenever applicable	Mandatory whenever applicable	5.2.7
Period of validity	Mandatory	Mandatory	5.2.8
Commutability	Mandatory whenever applicable	Mandatory whenever applicable	5.2.9
Storage information	Mandatory	Mandatory	5.2.10
Instructions for handling and use	Mandatory	Mandatory	5.2.11
Document components	Mandatory	Mandatory	5.2.12
Document version	Mandatory	Mandatory	5.2.13
Measurement procedures for operationally defined measurands	Mandatory whenever applicable	Mandatory whenever applicable	5.2.14
Property of interest	Mandatory	Mandatory	5.2.15
Description of the material	Recommended	Mandatory	5.3.2
Property value and associated uncertainty	Optional	Mandatory	5.3.3
Metrological traceability	Optional	Mandatory	5.3.4
Name and function of the RM producer's approving officer	Optional	Mandatory	5.3.5
Measurement procedures for non-operationally defined measurands	Recommended	Recommended	5.4.2
Health and safety information	Recommended	Recommended	5.4.3
Subcontractors	Optional	Optional	5.4.4
Indicative values	Optional	Optional	5.4.5
Legal notice	Optional	Optional	5.4.6
Reference to a certification report	Optional	Optional	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" 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 RM document, thus fulfilling the requirement of a CRM.

NOTE 2 Examples of other terms used for the product information sheet include material information sheet, statement to users and information leaflet. Other terms for the RM certificate include certificate of analysis and certificate.

5.2.3 Unique identifier of the RM

The RM document shall carry the unique identifier for the RM. The unique identifier should be stated on every separable portion (e.g. page) of the document.

The unique identifier should be distinguishable from those of any other RMs issued by the same producer. RMs for which each unit is individually characterized should have an additional identifier, such as a serial number, that corresponds to the individually characterized RM unit.

EXAMPLE An example of a unique identifier can be a combination of a product code and a batch number. The product code number makes it easy to distinguish an RM from any other RM, e.g. NMIJ CRM 7305, ERM-AC110, NIST SRM 41. In addition, the batch number helps prevent confusion that could arise when a laboratory has material from more than one batch in use at the same time. Some producers incorporate the batch number in the alphanumeric code for the material, e.g. NMIJ CRM 7305-a.

5.2.4 Name of the RM

The name of the RM shall be stated.

The name should describe the type of RM in sufficient detail to distinguish it from other similar materials. Thus, the name of the rock or ore, followed by its origin or a compositional characteristic, gives more individuality to geological materials, for example “Syenite (Phalaborwa)” or “Nepheline syenite”.

For trace analysis of pollutants in natural matrices, it is important to state the nature of the matrix. If several similar RMs are available, the level of contamination could be stated, for example “Aflatoxin M1 in whole milk powder (medium level)”. For metallurgical samples, it is appropriate to indicate the composition of the important elements, for example “6Al-4V titanium alloy”.

5.2.5 Name and contact details of the RM producer

The name and contact details of the RM producer shall be stated. Examples of the contact details are full postal address, telephone number, fax number, email address and website.

5.2.6 Intended use

The main intended use of an RM shall be stated. When the properties provided are independent of a particular analytical or measurement procedure, this statement is not intended to restrict the use for other purposes. The RM document should provide sufficient information to users so that they are able to decide whether or not the respective RM meets their requirements (e.g. matrix type, measurand, quantity level).

Because there could be uses for which the material is not appropriate or has not been sufficiently characterized, the RM document may include a statement explaining restrictions.

EXAMPLE 1 Examples of intended use of an RM other than a CRM are:

— to demonstrate control of a measurement process within a laboratory over a period of time;

— to check instrument performance;

— repeatability and reproducibility studies: repeated use over an extended period of time, instruments, operators, etc. to estimate long-term reproducibility or robustness of a measurement process or laboratory;

— to confirm the degree of equivalence of measurement results from two or more laboratories (e.g. provider and user);

— to check operator variability;

— to investigate the impact of any changes to the environmental conditions (e.g. temperature, humidity).

EXAMPLE 2 Examples of intended uses for a CRM are:

— the realization of a fixed point of an (international) measurement scale;

— the calibration of instruments or measurement systems;

— the transfer of property values among different materials;

— the validation of analytical methods, in particular regarding trueness;

— the determination of the recovery factor of matrix separation operations such as extraction.

5.2.7 Minimum sample size

Whenever applicable, the minimum sample size of the RM to be used shall be stated based on the degree of the RM homogeneity or other methods, such as stability, characterization and interlaboratory characterization studies. This should be accompanied by a statement that the property value and its associated uncertainty are only guaranteed if the minimum sample size is respected.

Where appropriate, the degree of homogeneity should be stated. An assessment of homogeneity is required for an RM to establish the degree of homogeneity of the RM with respect to the property of interest and ensure that it is fit for purpose. The RM document may specify a procedure to ensure that a representative subsample of the RM is used.

5.2.8 Period of validity

A period of validity (or expiry date) shall be stated. It cannot be guaranteed that the material is fit for purpose beyond the period of validity (or expiry date).

NOTE The period of validity does not need to have specific dates if the RM is inherently stable. A pure metal certified for its isotope ratios can be an example.

5.2.9 Commutability

Where appropriate, the RM producer shall provide information on commutability. The commutability information provided should be sufficient for the user to judge whether the material is appropriate for its particular use without further qualification or whether additional qualification by the user is required before use.

NOTE Detailed guidance on the requirements for the commutability assessment of RMs is given in the ISO/REMCO position paper (2020).[5]

5.2.10 Storage information

The conditions for storage (e.g. temperature, exposure to light) of the RM in order to maintain the validity of the RM document shall be stated.

5.2.11 Instructions for handling and use

Instructions for the handling and use of the RM shall be stated.

EXAMPLE Examples of instructions for handling and use of an RM are:

— appropriate instructions to ensure homogenization of the container contents before use;

— prescribed instructions for the opening of the container;

— the exact conditions for the drying of the material and/or the dry mass correction;

— where necessary, instructions for further particle size reduction;

— appropriate instructions for the reconstitution of a solid RM to a suitable form for use (e.g. solution);

— appropriate mathematical expression for the calculation of the value of the property at the time of use, e.g. in the case of materials which are inherently unstable, such as radioactive substances.

Where repeated use of an RM is permitted, appropriate conditions and/or instructions for use shall be stated.

5.2.12 Document components

An RM document shall be arranged so that all its components are recognized as being part of the whole document and the end is clearly marked.

EXAMPLE The identification can be page number and total number of pages.

5.2.13 Document version

The version of the RM document shall be clearly stated by, for example, a unique version number or the approval date of the documentation. The version should be stated on every separable portion (e.g. page) of the document.

NOTE The version number can be accompanied by a revision history.

5.2.14 Measurement procedures for operationally defined measurands

In the case of operationally defined measurands, information about the procedure(s) used is essential. In such cases, the RM document shall give full details of the procedure(s) used or reference(s) to publication(s) in which the procedure(s) are fully described.

NOTE 1 See also ISO Guide 35:2017, 9.2.3 for a discussion of the concept of operationally defined measurand.

NOTE 2 The same principle applies in the case of qualitative properties.

5.2.15 Property of interest

The property or properties of interest for the intended use of the RM shall be stated.

5.3 The information required in an RM certificate

5.3.1 General

An RM certificate shall include the following information in addition to the mandatory information listed in 5.2.

5.3.2 Description of the material

A general description of the material shall be stated in an RM certificate that provides a more detailed explanation of the name.

For materials certified for their chemical or biological composition, the main characteristics of the matrix, especially the presence or absence of interfering substances, could be of considerable importance in the selection of appropriate analytical methods.

EXAMPLE Examples of when matrix information should be included are:

— alloys prepared from individual constituents;

— rocks or waters obtained from natural sources;

— products of animal or vegetable origin;

— preservatives added to improve the stability;

— when confirming whether the analytes have been added to the material by spiking or are naturally present.

The physical description of the material may also be given, where appropriate, for example sample size, particle size, dimensions of metal cylinders or discs or the nature of the container in which the material is supplied. Where the same material is also available in alternative forms and sample sizes, this information may also be included.

5.3.3 Property value and associated uncertainty

An RM certificate shall contain a clear statement of property values and associated uncertainties of properties of interest. Certified values shall be clearly indicated as certified values and distinguished from any other values that are provided in the RM certificate.

The associated uncertainties of the property values should be reported according to ISO/IEC Guide 98-3.

NOTE In some cases that are covered by specific legislation (e.g. most pharmacopoeia assay standards), the uncertainties of the assigned property values are not stated since they are considered to be negligible in relation to the defined limits of the method-specific assays for which they are used.

5.3.4 Metrological traceability

An RM certificate shall contain a statement of metrological traceability for each certified value. It shall include information about the reference to which the certified value is traceable and should list the measurement method used for each certified value.

To summarize, the information on metrological traceability that shall be stated in the RM certificate is, therefore:

— a clear specification of the measurand;

— the reference to which the property value is made traceable.

5.3.5 Name and function of the RM producer's approving officer

The name and function of an officer representing the RM producer and accepting responsibility for the contents of the certificate shall be stated in an RM certificate.

NOTE The name of the officer can be the name of the responsible organization.

5.4 Other useful information

5.4.1 General

An RM document may include the following information in addition to the mandatory information listed in 5.2 and 5.3.

5.4.2 Measurement methods for non-operationally defined measurands

When the measurand is defined without reference to a particular procedure for measurement (non-operationally defined measurands), it can still be useful to include the following details:

— the measurement method(s) or technique(s) of characterization;

— the approach for characterization (e.g. single method, multiple methods);

— whenever applicable, the method used for sample handling or transformation.

5.4.3 Health and safety information

The RM document should include a statement on the existence of the safety data sheet. For RMs that consist of or contain hazardous substances or mixtures, the RM document should also include appropriate warnings in addition to a reference to a safety data sheet.

5.4.4 Subcontractors

When an RM is produced under a subcontract, the name and contribution of the subcontractor may be listed.