PD ISO Guide 31:2015

BSI Standards Publication

Reference materials — Contents of certificates, labels and accompanying documentation

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National foreword

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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).

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.

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.

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.

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

Content	Product information sheet	RM certificate	Subclause in this Guide
Title of the document	Mandatory	Mandatory	5.2.1
Unique identifier of the RM	Mandatory	Mandatory	5.2.2
Name of the RM	Mandatory	Mandatory	5.2.3
Name and contact details of the RM producer	Mandatory	Mandatory	5.2.4
Intended use	Mandatory	Mandatory	5.2.5
Minimum sample size	Mandatory whenever applicable	Mandatory whenever applicable	5.2.6
Period of validity	Mandatory	Mandatory	5.2.7
Commutability	Mandatory whenever applicable	Mandatory whenever applicable	5.2.8
Storage information	Mandatory	Mandatory	5.2.9
Instructions for handling and use	Mandatory	Mandatory	5.2.10
Page number and the total number of pages	Mandatory	Mandatory	5.2.11
Document version	Mandatory	Mandatory	5.2.12
Description of the material	Recommended	Mandatory	5.3.1
Property of interest, property value and associated uncertainty	Optional	Mandatory	5.3.2
Metrological traceability	Optional	Mandatory	5.3.3
Measurement methods for method dependent measurands	Recommended	Mandatory whenever applicable	5.3.4
Name and function of the RM producer's approving officer	Optional	Mandatory	5.3.5
Measurement methods for method-independent measurands	Recommended	Recommended	5.4.1
Health and safety information	Recommended	Recommended	5.4.2
Subcontractors	Optional	Optional	5.4.3
Indicative values	Optional	Optional	5.4.4
Legal notice	Optional	Optional	5.4.5
Reference to a certification report	Optional	Optional	5.4.6

5.2 The information required in the RM document

The RM document shall include the following information.

5.2.1 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 Guide is present in the document thus fulfilling the requirement of a CRM.

NOTE 2 Examples of other terms used for the product information sheet are material information sheet, analysis report, statement to users, information leaflet, etc.; and those for the reference material certificate are certificate of analysis, certificate, etc.

5.2.2 Unique identifier of the RM

Every RM and its related RM document shall carry a unique identifier by which it is uniquely distinguishable from the document of any other RM issued by the same or any other producer.

A unique combination of a product code and a batch number is one example. The 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 will help prevent confusion that may 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.

5.2.3 Name of the RM

The name of the RM shall be stated.

As far as possible, 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; e.g. "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, e.g. "Aflatoxin M1 in whole milk powder (medium level)". For metallurgical samples, it is appropriate to indicate the composition of the important elements, e.g. "6Al-4V titanium alloy".

5.2.4 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, e-mail address and website.

5.2.5 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 shall provide sufficient information to the users so that they are able to decide whether or not the respective RM meets their requirements (e.g. matrix type, measurand, quantity level, etc.).

Because there may 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), where the materials are inherently stable;

— 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.

5.2.6 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, characterisation, and interlaboratory characterisation 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.

5.2.7 Period of validity

A period of validity (or expiry date) shall be stated. The fitness for purpose of the material cannot be guaranteed beyond the period of validity (or expiry date).

5.2.8 Commutability

Where commutability information is required the RM producer shall provide sufficient information 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 commutability assessment of RMs is given in the ISO/REMCO position paper (2014)[5].

5.2.9 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.

5.2.10 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 prepare a 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.

5.2.11 Page number

An RM document shall include the page number and the total number of pages.

5.2.12 Document version

The version of the RM document shall be clearly stated by, e.g. a unique version number or the approval date of the documentation.

5.3 The information required in an RM certificate

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

5.3.1 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 composition, the main characteristics of the matrix, especially the presence or absence of interfering substances, may 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;

— whether the analytes have been spiked in or are naturally present.

The physical description of the material may also be given, where appropriate, e.g. sample size, particle size, dimensions of metal cylinders or discs, and the nature of the container in which it is supplied. The presence of preservatives, such as mercury (II) chloride added to aqueous solutions of ethanol, shall also be stated. Where the same material is also available in alternative forms and sample sizes, this information may also be included.

5.3.2 Property of interest, property value and associated uncertainty

An RM certificate shall contain a clear statement of the property(ies) of interest, its (their) property value(s) and associated uncertainty(ies). Certified values shall be clearly indicated as certified values and distinguished from any other values that may be provided in the RM certificate.

The associated uncertainty(ies) of the property value(s) should be reported according to the *Guide to the expression of uncertainty in measurement* (ISO/IEC Guide 98-3)[6].

NOTE In some cases that are covered by specific legislation (e.g. most pharmacopoeia assay standards), the uncertainties of the assigned 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.

5.3.3 Metrological traceability

An RM certificate shall contain a statement of metrological traceability. It shall include information about the measurement scale to which the certified value is traceable and should list the principle(s) of the measurement procedure(s) used for characterizing the material.

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

— a clear specification of the measurand;

— the measurement scale to which the property value is made traceable.

5.3.4 Measurement methods for method dependent measurands

When the definition of a measurand depends on the measurement method, information about the method used is essential. In such cases, the certificate shall give full details of the method used or a reference to a publication in which the method is fully described.

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

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

Other useful information which may be added to the RM document.

5.4.1 Measurement methods for method-independent measurands

When the measurand is not defined by the measurement method used, it may still be useful to include the following details:

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

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

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

5.4.2 Health and safety information

Whenever appropriate, the RM document should include health and safety information. A reference to the existence of a safety data sheet[7] should also be stated because the safety data sheet is often taken away during the exporting and/or importing process.

5.4.3 Subcontractors

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

Where several laboratories or independent analysts have contributed to the characterization of an RM, their names may be listed, together with the methods they have used.

5.4.4 Indicative values

The RM producer may include indicative values.

EXAMPLE Examples of indicative values that might be included in the RM document are:

— the approximate concentration of an analyte in a complex matrix that does not fulfil the criteria for a certified property value;

— individual results from each laboratory or analyst, where results from several laboratories or analysts were used to assign the property value(s).

5.4.5 Legal notice

A legal notice may be included.

5.4.6 Reference to a certification report

Many users of an RM will not require any information in addition to that contained in the RM document. However, additional information may be made available with an RM in the form of a production or certification report, obtainable on request or otherwise accessible to interested parties.

6 Labels

The label of an RM shall be securely attached to the product container of an individual RM unit. The label shall be designed to remain legible and intact under the defined storage and handling conditions within the period of validity. The information supplied on the label of a unit of an RM shall be clear and concise. The label and/or the container marking shall allow identification of the appropriate RM document, usually by the use of a unique product identifier. Where space allows, it is advisable to include the name of the RM and the producer.

It is advisable that neither (certified) property values nor indicative values are included on the label to prevent the use of the material without the information in the RM document having been studied.

The labels shall, where appropriate, comply with requirements related to health, safety and environmental regulations, e.g. show toxicity symbols, hazard and precautionary phrases.[7] If the material is classified as dangerous for transport or hazardous for use, the label shall contain mandatory information in accordance with the applicable regulations. The Safety Data Sheet contains more information than the label and forms the reference source for the management of hazardous chemicals in the workplace.

Bibliography

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

[2] ISO Guide 30:2015, *Reference materials — Selected terms and definitions*

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

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

[5] ISO/REMCO position paper, *Information on Commutability of Reference Materials, ISO Committee on Reference Material*, July 2014. Available from: http://isotc.iso.org/livelink/livelink/fetch/%E2%80%908854933/8854951/8854960/279217/Commutability_document_final.pdf?nodeid=16787892&

[6] ISO/IEC Guide 98-3:2008, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

[7] The Globally Harmonized System of Classification and Labelling of Chemicals (GHS), United Nations

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