



GUIDE 31

Reference materials — Contents of certificates and labels

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ISO Guide 31:2000

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Second edition 2000

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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.

Guides are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft Guides adopted by the responsible Committee or Group are circulated to national bodies for voting. Publication as a Guide requires approval by at least 75 % of the national bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this Guide may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO Guide 31 was drawn up by the ISO Committee on reference materials (REMCO) and was approved by ISO member bodies.

This second edition cancels and replaces the first edition (ISO Guide 31:1981), which has been technically revised.

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Introduction

The certificate which accompanies a certified reference material (CRM) should contain all the information which is essential to its use. Without the certificate, the material, however costly its production, is valueless. It follows, therefore, that producers of CRMs should pay very careful attention to the preparation of certificates. The ISO Committee on Reference Materials (ISO/REMCO) published the first edition of this Guide in 1981. During the past sixteen years there has been considerable growth in the number and variety of reference materials produced, and in their use. The increasing demand for reliability in the results obtained by analytical and metrological techniques, which has arisen especially from growing concern about pollution of the environment, has led to the demand for a widening range of CRMs of increasingly high quality for use in validation of measurement methods and as calibrants.

The definition of a CRM in ISO Guide 30 (see clause 2) requires all certified property values to be accompanied by an uncertainty at a stated level of confidence and for traceability to "an accurate realization of the unit in which the property value is expressed" to be demonstrated. These additional requirements must therefore be met in the certificate.

The *Guide to the expression of uncertainty in measurement*, published by ISO (see Bibliography), summarizes more recent international consideration of the subject of uncertainty in measurement and will require some modification of the definition of a CRM quoted above. Uncertainty should now be expressed as combined (type A + type B) standard uncertainty or as expanded uncertainty (with a coverage factor to be applied to the combined standard uncertainty). The concept of probability or level of confidence is now no longer central.

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 past sixteen years, however, have seen a general decline in the issuing of certification reports and an increase in the information provided in certificates. This decline in the publication of certification reports is not necessarily to be condemned, provided all the information appropriate to a full certification report can always be obtained on application to the producers of the CRM. Production of certification reports is expensive and it is clearly unnecessary for one to be supplied to the same user every time a fresh sample from the same batch of material is purchased. At the same time, the information required from a certificate is usually more than the certified property value. Details concerning the way in which the container should be opened, the minimum sample size that should be taken for a measurement, the stability of the material, the way in which it should be stored, and, in the case of CRMs where the certified value is method-dependent, the method used to determine the certified value are all essential information for the user.

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Reference materials — Contents of certificates and labels

1 Scope

This Guide is intended to help producers to prepare clear and concise certificates to accompany certified reference materials. Such certificates, while maintaining their essential character, should help to provide, in summary form, all the information needed by the user of the reference material.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this Guide. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Guide are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO Guide 30:1992, *Terms and definitions used in connection with reference materials*.

3 Terms and definitions

[ISO Guide 31:2000](https://standards.iteh.ai/catalog/standards/sist/e617af66-0494-4f07-9e11-1a3f09a36d08/iso-guide-31-2000)

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For the purposes of this Guide, the terms and definitions given in ISO Guide 30:1992 and the following apply.

3.1

certificate

document containing all the information which is essential to the use of a certified reference material

NOTE A CRM and its certificate should never be parted.

3.2

intended use

the use of a product, process or service in accordance with information provided by the supplier

[ISO/IEC Guide 51:1999, definition 3.13.]

3.3

hazardous situation

circumstance in which people, property or the environment are exposed to a hazard(s)

[ISO/IEC Guide 51:1999, definition 3.3.]

4 General

The amount of information which should be included in a certificate depends on the ready availability of a certification report. When a report is always supplied with the certificate, the amount of detail in the certificate can be limited, provided appropriate reference to the report is made. The details given in a certificate and certification report may permit the user to make a judgement of the quality and integrity of the CRM.

Information provided on the label or marked on the material should serve only to identify the CRM and should be confined to the name of the producer, the name of the material, the producer's code for the material, the batch number, and relevant health and safety warnings. It is recommended that the certified property value(s) **not** be included, in order to prevent use of the material without the information in the certificate having been studied.

5 Certificate headings

5.1 General

The various categories of information to be considered in the preparation of a certificate are indicated below. An explanation is given under each heading, together with examples where clarification is considered necessary. The headings are intended to cover the required information on the widest possible range of CRMs which may include reference materials certified for physical properties, amount concentrations of chemical species, isotopic composition (expressed in SI units); and for conventional and biological properties (defined in internationally agreed measurement scales based on internationally agreed measurement procedures, if not defineable in terms of the SI). Some information is considered obligatory and shall always be provided, even though it may not be important in every case, e.g. the stability of a metal alloy or of the isotopic composition of natural compounds will rarely be questioned.

A summary of the information which it is essential to include in a certificate is given in order to assist those organizations, e.g. accreditation bodies, which may wish to include some parts of this Guide in their requirements documents. Other details are optional and may be provided if they would enhance the usefulness of the CRM, e.g. the origin of materials prepared from natural sources.

The headings are given in a logical order for presentation of the information, which may be summarized as:

- the general particulars of the certifying body and the reference material (5.2 to 5.5),
- a description of the material and its intended use (5.6 to 5.10), the certified values,
- their traceability and the period of validity of the certificate (5.11 to 5.16),
- other information (5.17 and 5.18), and a summary of the essential contents of a certificate (clause 6).

This Guide, however, is concerned only with the information contained in certificates, and the order or titles of the headings may be changed to suit the preference of the producer.

5.2 Name and address of the certifying body

The name (usually given in prominent type at the head of the certificate) should be that of the body or organization that accepts responsibility for the information in the certificate, i.e. the certifying body. The name should always be accompanied by the full postal address, telephone and fax numbers, and, where available, e-mail address.

5.3 Title of the document

There should be a distinct title, such as *Certificate of Analysis* or *Certificate of Measurement*. The occasional practice of issuing provisional certificates can lead to confusion, with the existence of more than one certificate for the same batch of material, and is to be discouraged.

5.4 Name of material

As far as possible, the name should describe the type of reference material in sufficient detail to distinguish it from other similar materials. Thus the name of the rock or ore, followed by its locality 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 and, if several similar reference materials are available, the level of contamination, for example, "Aflatoxin M1 in whole milk powder".

(medium level)". (It may, however, be advisable to avoid a detailed description on documentation supplied to carriers and customs authorities where the naming of toxic pollutants may introduce unnecessary problems with dispatch). For metallurgical samples, it is appropriate to indicate the concentration of the important elements, for example "6Al-4V titanium alloy".

5.5 Reference material code and batch number

Every CRM should have a unique alphanumeric code by which it is distinguishable from any other CRM issued by the same or any other producer, e.g. BCR CRM 186, LGC 7016, NIST SRM 41. In addition, the batch number should be stated, even when it is the first batch of a particular CRM. This is to avoid confusion which may arise when a user 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, for example NIST SRM 41c.

5.6 Description of the CRM

The general description of the material should, in effect, amount to a more detailed explanation of the name. The source of the material will be largely irrelevant to its use in most cases but for substances certified for their chemical composition, whether they be prepared from individual constituents, such as alloys, or obtained from natural sources, such as rocks, waters, or products of animal or vegetable origin, the composition of the matrix, especially the presence or absence of substances which may interfere with analytical procedures, may be of considerable importance in the selection of appropriate analytical methods. Even if the source is not disclosed, the approximate composition of the material should always be stated. Certifying bodies should always avoid the situation where failure to disclose relevant information about the source may result in the CRM being used to validate an analytical method applied to the same batch of material as the CRM.

The physical description of the material should also be given, where appropriate, for example, 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.

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5.7 Intended use

The primary purpose for which a CRM is issued by the producer should, as far as possible, be stated but, provided the certified properties do not relate only to a particular analytical or measurement procedure (for example, elemental analysis of a mineral after a prescribed leaching procedure or measurement of flash point by a carefully defined method), this statement is not intended to restrict the use for other purposes. The certificate, or additional information provided in the certification report or otherwise supplied, must, however, provide sufficient information for the user to be able to decide whether the proposed application of the CRM is justified.

Examples of intended use are:

- for the realization of a fixed-point temperature on the international temperature scale (ITS-90) and, therefore, for the calibration of temperature-measuring equipment;
- for the calibration of instruments for determining the amount concentration of precious metals in ore sample;
- for the validation of analytical methods used to determine the amount concentration of pollutants in natural matrices;
- as an arbitration sample for commercial transactions;
- for the preparation of "working reference samples" for use in routine laboratory analyses.