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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
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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.

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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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