



**International  
Standard**

**ISO 33401**

**Reference materials — Contents  
of certificates, labels and  
accompanying documentation**

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

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# Contents

Page

|                                                                                        |           |
|----------------------------------------------------------------------------------------|-----------|
| <b>Foreword</b>                                                                        | <b>iv</b> |
| <b>Introduction</b>                                                                    | <b>v</b>  |
| <b>1 Scope</b>                                                                         | <b>1</b>  |
| <b>2 Normative references</b>                                                          | <b>1</b>  |
| <b>3 Terms and definitions</b>                                                         | <b>1</b>  |
| <b>4 General</b>                                                                       | <b>3</b>  |
| <b>5 The contents of a product information sheet or reference material certificate</b> | <b>3</b>  |
| 5.1 General                                                                            | 3         |
| 5.2 Information required in the RM document                                            | 4         |
| 5.2.1 General                                                                          | 4         |
| 5.2.2 Title of the document                                                            | 4         |
| 5.2.3 Unique identifier of the RM                                                      | 5         |
| 5.2.4 Name of the RM                                                                   | 5         |
| 5.2.5 Name and contact details of the RM producer                                      | 5         |
| 5.2.6 Intended use                                                                     | 5         |
| 5.2.7 Minimum sample size                                                              | 6         |
| 5.2.8 Period of validity                                                               | 6         |
| 5.2.9 Commutability                                                                    | 6         |
| 5.2.10 Storage information                                                             | 6         |
| 5.2.11 Instructions for handling and use                                               | 6         |
| 5.2.12 Document components                                                             | 7         |
| 5.2.13 Document version                                                                | 7         |
| 5.2.14 Measurement procedures for operationally defined measurands                     | 7         |
| 5.2.15 Property of interest                                                            | 7         |
| 5.3 The information required in an RM certificate                                      | 7         |
| 5.3.1 General                                                                          | 7         |
| 5.3.2 Description of the material                                                      | 7         |
| 5.3.3 Property value and associated uncertainty                                        | 8         |
| 5.3.4 Metrological traceability                                                        | 8         |
| 5.3.5 Name and function of the RM producer's approving officer                         | 8         |
| 5.4 Other useful information                                                           | 8         |
| 5.4.1 General                                                                          | 8         |
| 5.4.2 Measurement methods for non-operationally defined measurands                     | 8         |
| 5.4.3 Health and safety information                                                    | 8         |
| 5.4.4 Subcontractors                                                                   | 8         |
| 5.4.5 Indicative values                                                                | 9         |
| 5.4.6 Legal notice                                                                     | 9         |
| 5.4.7 Reference to a certification report                                              | 9         |
| <b>6 Labels</b>                                                                        | <b>9</b>  |
| <b>Bibliography</b>                                                                    | <b>10</b> |

## 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](http://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](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

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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](http://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](http://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.]