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Guidance for the use of referenceReference materials — Requirements and recommendations for use

Guide pour l'utilisation des matériauxMatériaux de référence — Exigences et recommandations pour l'utilisation

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Foreword

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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).

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This document was prepared by Technical Committee ISO/TC 334, *Reference materials*.

This first edition cancels and replaces ISO Guide 33:2015, which has been technically revised.

The main changes are as follows:

— ~~—~~title modified;

— ~~—~~1.5 removed;

— ~~—~~5.3 and 5.4 removed;

— ~~—~~ ~~Figure 1~~Figure 1 revised and explanation inserted;

— ~~—~~ ~~6.1.4:~~6.1.4: former ~~Annex A~~Annex A Table A.1 inserted as ~~Table 1~~;Table 1;

— ~~—~~ ~~9.1.3~~9.1.3 removed;

— ~~—~~ ~~9.2.1~~9.2.1 revised;

— ~~Clauses 9.3.1~~9.3.1 and ~~9.3.2~~9.3.2 revised and merged ~~in 9.3.1~~into 9.3.1

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— ~~— Clause 10.2.1~~10.2.1 moved to ~~10.1.1~~10.1.1 and former ~~10.1.1.~~10.1.1. added as ~~10.1.2;~~10.1.2;

— ~~— 12.2~~12.2 and ~~12.3~~12.3 moved into the new ~~Annex C;~~Annex C;

~~— — former Annex B now Annex A;~~

~~— — former Annex C now Annex B;~~

— — former Annex B now Annex A;

— former Annex C now Annex B;

— Bibliography revised.

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~~www.iso.org/members.html.

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Introduction

~~The aim of this~~This document ~~is to provide~~provides general recommendations on the use of reference materials (RMs). These recommendations are exemplified by real-world examples, which to some degree also reflect the level of complexity associated with RMs. This level of detail is deemed to be useful for users of ~~reference materials~~RMs and anyone who has a responsibility in the quality management in laboratories, ~~such as~~e.g. drafters, reviewers, managers and assessors of procedures, working instructions~~,~~ and standard operating procedures ~~and the like~~.

For certified reference materials (CRMs~~,~~), the metrological traceability of the property values to international scales or other measurement standards has been established. For RMs ~~which~~that are not CRMs, this kind of traceability of property values has often not been established. Nevertheless, these RMs can still be used for assessing parts of measurement procedures, including evaluating various levels of precision.

Mainstream applications of ~~RM~~RMs are listed in ~~6.1.1.~~6.1.1. Not all types of RMs can be used for all indicated purposes.

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Reference materials — Requirements and recommendations for use

1 Scope

This document describes good practice in using reference materials (RMs), and certified reference materials (CRMs) in particular, in measurement processes. These uses include:

— the assessment of precision and trueness of measurement methods;

— quality control;

— assigning values to materials;

— calibration and the establishment of;

— establishing conventional scales.

This document also relates key characteristics of various types of RMs to the different applications.

The preparation of RMs for calibration is also part of the scope of ISO 17034 and ISO Guide 35. The treatment in this document is limited to the fundamentals of small-scale preparation of RMs and the value assignment, as used by laboratories to calibrate their equipment. Larger scale production of such RMs, with the possible aim of distribution, is beyond the scope of this document. This type of activity is covered in ISO 17034 and ISO Guide 35.

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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, *Reference materials — Selected terms and definitions*

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

ISO/IEC Guide 99:200799, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO Guide 30 and ISO/IEC Guide 99 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/obphttps://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/https://www.electropedia.org/

4 Symbols

α risk of error of the first type (type I error)

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β	risk of error of the second type (type II error)
χ^2	chi-squared
d	measurement bias
k	coverage factor
s_w	standard deviation computed from repeat observations
σ_w	intralaboratory standard deviation
σ_{wo}	required intralaboratory standard deviation
$u()$	standard uncertainty of the parameter in parenthesis
$U()$	expanded uncertainty of the parameter in parenthesis
u_{CRM}	standard uncertainty associated with property value of the CRM
u_{meas}	standard uncertainty associated with value obtained by measuring the CRM
u_{prep}	uncertainty associated with the value obtained from preparation of a calibrant
x_{CRM}	value of a specified property of the CRM
x_{meas}	value obtained by measuring the CRM
x_{prep}	value obtained from preparation of a calibrant
~~$\bar{\bar{x}}$~~ $\bar{x}$	average of repeat observations

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5 Conventions

In this document, the following conventions are used~~:~~.

A measurand is specified in such a way that there exists a unique, but unknowable, 'true value'.

All statistical methods used in this document are based on the following assumptions:

a) ~~a)~~ The certified value is the best estimate of the true value of the property of the CRM.

b) ~~b)~~ All variation, be it associated with the material (i.e. homogeneity) or the measurement process, is random and follows a normal probability distribution. The values of probabilities stated in this document assume normality. The probability may be different if there is deviation from normality.

Property values that are not certified values are considered to be unfit for use in metrological applications requiring a value assigned to the measurand, such as calibration, or the assignment of values to other materials.

Throughout this document, the law of propagation of uncertainty is used. Other methods of propagating uncertainties can be applied as well, and in some cases such alternative methods are required by the circumstances of the application. Further guidance on these matters is given in ~~the GUM~~ISO/IEC Guide 98-3:2008 and its supplements.

6 RMs and their role in measurement

6.1 Common applications of RMs

6.1.1 RMs, and CRMs in particular, are widely used for the following purposes:

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