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General requirements for the competence of reference material producers

Exigences générales pour la compétence des producteurs de matériaux de référence

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 General requirements **3**
4.1 Contractual matters 3
4.2 Impartiality 3
4.3 Confidentiality 4

5 Structural requirements **4**

6 Resource requirements **5**
6.1 Personnel 5
6.2 Subcontracting 5
6.3 Provision of equipment, services and supplies 6
6.4 Facilities and environmental conditions 7

7 Technical and production requirements **7**
7.1 General requirements 7
7.2 Production planning 7
7.3 Production control 8
7.4 Material handling and storage 8
7.5 Material processing 9
7.6 Measurement procedures 9
7.7 Measuring equipment 10
7.8 Data integrity and evaluation 10
7.9 Metrological traceability of certified values 10
7.10 Assessment of homogeneity 11
7.11 Assessment and monitoring of stability 11
7.12 Characterization 12
7.13 Assignment of property values and their uncertainties 13
7.14 RM documents and labels 14
7.15 Distribution service 15
7.16 Control of quality and technical records 16
7.17 Management of non-conforming work 16
7.18 Complaints 17

8 Management system requirements **18**
8.1 Options 18
8.1.1 General 18
8.1.2 Option A 18
8.1.3 Option B 18
8.2 Quality policy (Option A) 18
8.3 General management system documentation (Option A) 19
8.4 Control of management system documents (Option A) 19
8.5 Control of records (Option A) 19
8.6 Management review (Option A) 20
8.7 Internal audit (Option A) 20
8.8 Actions to address risks and opportunities (Option A) 21
8.9 Corrective actions (Option A) 21
8.9.1 General 21
8.9.2 Cause analysis 21
8.9.3 Selection and implementation of corrective actions 21
8.9.4 Monitoring of corrective actions 22

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8.9.5 Additional audits 22
8.10 Improvement (Option A) 22
8.11 Feedback from customers (Option A) 22
Annex A (informative) **Summary of production requirements for RMs and CRMs** **23**
Bibliography **24**

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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 any 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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

ISO 17034 was prepared by the *ISO Committee on Conformity Assessment* (CASCO), in collaboration with the *ISO Committee on Reference Materials* (REMCO).

This first edition of ISO 17034 cancels and replaces ISO Guide 34:2009, which has been technically revised.

The following major changes have been made compared with ISO Guide 34:2009:

— inclusion of requirements for production of all types of reference materials, and additional specified requirements for certified reference materials;

— harmonization with the revisions of ISO Guide 31 and ISO Guide 35;

— inclusion of more details on required reference material documentation;

— inclusion of risks and opportunities;

— restructuring based on the common structure adopted by other International Standards on conformity assessment developed by CASCO;

— incorporation of modifications based on ISO/CASCO PROC 33.

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Introduction

Reference materials (RMs) are used in all stages of the measurement process, including for method validation, calibration and quality control. They are also used in interlaboratory comparisons for method validation and for assessing laboratory proficiency.

The demonstration of the scientific and technical competence of reference material producers (RMPs) is a basic requirement for ensuring the quality of RMs. The demand for new RMs of higher quality is increasing as a consequence of both the improved precision of measuring equipment and the requirement for more accurate and reliable data in the scientific and technological disciplines. It is not only necessary for RMPs to provide information about their materials in the form of RM documents, but also to demonstrate their competence in producing RMs of appropriate quality.

This International Standard outlines the general requirements for the producers of RMs, including certified reference materials (CRMs). It supersedes ISO Guide 34:2009 and is aligned with the relevant requirements of ISO/IEC 17025. Further guidance (e.g. concerning the content of certificates and the design of characterization, homogeneity and stability studies) is provided in ISO Guide 31 and ISO Guide 35. While the approaches outlined in ISO Guide 31 and ISO Guide 35 meet the relevant requirements of this International Standard, there might be alternative ways to achieve compliance to this International Standard.

RMPs that comply with this International Standard will also operate generally in accordance with the principles of ISO 9001. For tests performed in the medical field, ISO 15189 can be used as the reference instead of ISO/IEC 17025.

In this International Standard, the term “certification” refers to the certification of RMs.

In this International Standard, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

For the purposes of research, users are encouraged to share their views on this document and their priorities for changes to future editions. Click on the link below to take part in the online survey:

https://www.surveymonkey.com/r/CDZZWYH

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General requirements for the competence of reference material producers

1 Scope

This International Standard specifies general requirements for the competence and consistent operation of reference material producers.

This International Standard sets out the requirements in accordance with which reference materials are produced. It is intended to be used as part of the general quality assurance procedures of the reference material producer.

This International Standard covers the production of all reference materials, including certified reference materials.

NOTE Reference material producers, regulatory authorities, organizations and schemes using peer assessment, accreditation bodies and others can also use this International Standard in confirming or recognizing the competence of reference material producers.

2 Normative references

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/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO Guide 30, ISO/IEC Guide 99, ISO 9000 and the following apply.[1)]

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

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

3.1
reference material producer
RMP
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]

1) The definitions in ISO Guide 30 take precedence where more than one definition for the same term related to reference materials exist.

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