



SLOVENSKI STANDARD SIST EN ISO 17034:2017

01-februar-2017

Ugotavljanje skladnosti - Splošne zahteve za usposobljenost proizvajalcev referenčnih materialov (ISO 17034:2016)

Conformity assessment - General requirements for the competence of reference material producers (ISO 17034:2016)

Konformitätsbewertung - Allgemeine Anforderungen an die Kompetenz von Referenzmaterialherstellern (ISO 17034:2016)

Exigences générales pour la compétence des producteurs de matériaux de référence (ISO 17034:2016)

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EUROPEAN STANDARD

EN ISO 17034

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English version

General requirements for the competence of reference material producers (ISO 17034:2016)

Exigences générales pour la compétence des producteurs de matériaux de référence (ISO 17034:2016)

Konformitätsbewertung - Allgemeine Anforderungen an die Kompetenz von Referenzmaterialherstellern (ISO 17034:2016)

This European Standard was approved by CEN on 26 October 2016.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



**CEN-CENELEC Management Centre:
Avenue Marnix 17, B-1000 Brussels**

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European foreword

This document (EN ISO 17034:2016) has been prepared by Technical Committee ISO/CASCO "Committee on conformity assessment" in collaboration with Technical Committee CEN/CLC/TC 1 "Criteria for conformity assessment bodies" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2017, and conflicting national standards shall be withdrawn at the latest by May 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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The text of ISO 17034:2016 has been approved by CEN as EN ISO 17034:2016 without any modification.

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INTERNATIONAL
STANDARD

ISO
17034

First edition
2016-11-01

**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
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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; [SIST EN ISO 17034:2017](https://standards.iteh.ai/catalog/standards/sist/4b22b061-4e66-42f9-b1ac-003d27c635ca/sist-en-iso-17034-2017)
- “should” indicates a recommendation; <https://standards.iteh.ai/catalog/standards/sist/4b22b061-4e66-42f9-b1ac-003d27c635ca/sist-en-iso-17034-2017>
- “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>