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GUIDE 34

General requirements for the competence of reference material producers

Third edition 2009

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft Guides adopted by the responsible Committee or Group are circulated to the member bodies for voting. Publication as a Guide requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO Guide 34 was prepared by the ISO *Reference Materials Committee* (REMCO).

This third edition cancels and replaces the second edition (ISO Guide 34:2000), which has been technically revised. It also incorporates the Technical Corrigendum ISO Guide 34:2000/Cor.1:2003.

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Introduction

The use of reference materials enables the transfer of the values of measured or assigned properties between testing and measurement laboratories. Such materials are widely used, e.g. for the calibration of measuring equipment and for the evaluation or validation of measurement procedures. In certain cases, they enable properties to be expressed conveniently in arbitrary units.

NOTE The concept "reference material" is included in the concept "measurement standard", both of which also include physical reference materials used for calibrating instruments in mechanical, non-destructive and construction type-testing facilities.

There are an increasing number of reference material producers, and a demonstration of their scientific and technical competence is nowadays a basic requirement for ensuring the quality of reference materials. The demand for new reference materials of higher quality is increasing as a consequence of both the increased precision of measuring equipment and the requirement for more accurate and reliable data in the scientific and technological disciplines. Some previously acceptable reference materials may not meet these more stringent requirements anymore. It is, therefore, not only necessary for reference material producers to provide information about their materials in the form of reports, certificates and statements, but also to demonstrate their competence in producing reference materials of appropriate quality.

The first edition of ISO Guide 34 set out specific guidelines on the interpretation of ISO/IEC Guide 25 and the International Standards prepared by ISO/TC 176¹⁾ in the context of reference material production. The more general requirements of these International Standards were omitted. Since the first edition of ISO Guide 34 was published in 1996, the assessment of the competence of reference material producers has gained considerable impetus. The second edition of ISO Guide 34 set out all the general requirements in accordance with which a reference material producer has to demonstrate that it operates. The present edition makes these requirements mandatory and in line with ISO/IEC 17025:2005/Cor.1:2006 in view of its use for the assessment of the competence of reference material producers applying for accreditation. For tests performed in the medical field, ISO 15189 may be used as the reference instead of ISO/IEC 17025.

1) Including ISO 9000, ISO 9001 and ISO 9004.