International Standard

ISO 15194

In vitro diagnostic medical devices — Requirements for certified reference materials and the content of supporting documentation

Dispositifs médicaux de diagnostic in vitro — Exigences relatives aux matériaux de référence certifiés et au contenu de la documentation associée

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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).

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This document was prepared by Technical Committee ISO/TC 212, *Medical laboratories and in vitro diagnostic systems,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 15194:2009), which has been technically revised.

The main changes are as follows:

— incorporated requirements, concepts and definitions for consistency with ISO 17511:2020;

— removed Clause 4 of the second edition;

— expanded and clarified the Scope to specify requirements for higher order certified reference materials (CRMs) whose intended use is to underpin routine measurements in laboratory medicine;

— added requirements regarding description of the intended use and commutability of the CRM;

— strengthened the documentation requirements for both the certificate and the certification report accompanying a CRM.

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.

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Introduction

Reference measuring systems are needed to enable the results produced by end user measurement procedures (MPs) to be metrologically traceable to either measurement standards or MPs of the highest metrological level. Such systems exist within a metrological traceability chain/calibration hierarchy as described in ISO 17511. In the context of in vitro diagnostic (IVD) medical devices, metrological traceability to the highest metrological level mitigates the risk of harm to patients by avoiding inconsistent results from different measuring systems.

Reference materials (RMs) are used to establish and maintain metrological traceability of measurement results over time within one location, between different physical locations or with the application of different measurement procedures. Certified reference materials (CRMs) are a category of RMs required at the higher metrological levels of a calibration hierarchy or that underpin the metrological traceability of measurement results.

A given CRM is supported by documentation describing the sources of the material, its processing and production, measurement results, metrological traceability, instructions for use, homogeneity and stability data, commutability data when applicable, and storage conditions, as well as health and safety warnings. When the intended application of the CRM is as a secondary calibrator in the calibration hierarchy of IVD devices, the commutability of the CRM is a critical property to be reported.

This document specifies the quality requirements for such materials and the recommended content of their supporting documentation.

CRMs are used for one of three main purposes:

a) calibration of quantity values indicated by a measuring system or assigned to another RM;

b) assessment of measurement trueness of quantity values obtained in a given laboratory, or in a group of laboratories;

c) assessment of measurement trueness of quantity values obtained using a new MP.

NOTE 1 “Measurement trueness” (ISO 17511:2020, 3.47) is the closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value. It is inversely related to systematic measurement error but is not related to random measurement error.

NOTE 2 “Measurement precision” (ISO 17511:2020, 3.34) is the closeness of agreement between measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions. It is usually expressed numerically by measures of imprecision, such as standard deviation, variance, or coefficient of variation under the conditions of measurement. “Measurement precision” is a measure of random measurement error.

The combined measurement uncertainty of the assigned value of a CRM is the combined measurement uncertainty of the steps above the CRM in the calibration hierarchy and the CRM uncertainties associated with its homogeneity and stability. Suitability of its measurement uncertainty is determined by its intended use in the calibration hierarchy.

Since the proper use of a CRM depends on the provision of detailed information on its production, characterization and intended use, it is important to apply rules for the documentation of CRMs.

Annex A provides information on CRMs for qualitative nominal properties and ordinal quantities, to provide guidance on important quality attributes for such CRMs, whilst recognizing that they are not within the metrological traceability schemes described in ISO 17511:2020.

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In vitro diagnostic medical devices — Requirements for certified reference materials and the content of supporting documentation

1 Scope

This document specifies requirements for certified reference materials (CRMs) of higher metrological order and the content of the supporting documentation and the calibration hierarchies as described in ISO 17511:2020, 5.2.1, 5.3.1, 5.4.1, 5.5.1, 5.6.1, 5.7.1. It is applicable to CRMs intended for use as either primary reference materials (PRMs), secondary calibrators or international conventional calibrators within calibration hierarchies appropriate for measurands used in laboratory medicine, or for applications as trueness controls. It also specifies requirements for determining the certified value of a CRM, including evaluation, and reporting of the assigned uncertainty.

This document is applicable primarily to CRMs with assigned property values where the property has a magnitude that can be expressed as a quantitative scalar number or ratio to a reference or refers to a counting scale as also described in ISO 17511:2020, Clause 1.

When a CRM includes multiple measurands, this document is applied to each of the certified quantity values present in the CRM.

Although intended to be applicable to producers of CRMs, this document is also useful for reference materials (RMs) that are not in conformity with the full metrological requirements of CRMs. For example, this document does not apply to an RM created by an in vitro diagnostic medical device (IVD MD) manufacturer for use as working calibrator or end-user calibrator within a calibration hierarchy traceable to a CRM, although some content can be useful in assessing its performance.

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 17034, *General requirements for the competence of reference material producers*

ISO 17511, *In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples*

ISO/IEC Guide 99, *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 17511 and ISO/IEC Guide 99 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/

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