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In vitro diagnostic medical devices — Requirements for reference measurement procedures

Dispositifs médicaux de diagnostic in vitro — Exigences relatives aux procédures de mesure de référence

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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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For an explanation of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

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 15193:2009), which has been technically revised.

The main changes are as follows:

— incorporated requirements, concepts and definitions for consistency with ISO 17511, ISO 15194, and ISO 15195;

— adapted content to make the document applicable to all types of measurands;

— revised Clause 4 to present requirements more transparently;

— added 4.1 added to emphasize quality requirements for a reference measurement procedure (MP);

— updated and summarized aspects of validation in 4.15.

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 measurement systems are needed to enable the results produced by end user measurement procedures (MPs) to be metrologically traceable to either measurement standards, or measurement procedures, or both 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, traceability to the highest metrological level reduces the risk of harm to patients by avoiding inconsistent results from different measuring systems.

Reference measurement procedures play a crucial role in this metrological traceability system, because they can be used for the following:

a) assessing performance properties of measuring systems – comprising measuring instruments, auxiliary equipment as well as reagents,

b) assessing whether there is a functional interchangeability of different end user measurement procedures purporting to measure the same quantity,

c) assigning quantity values to reference materials that are then used for purposes of calibration or measurement trueness control of measurement procedures, and

d) detecting analytical influence quantities in biological samples measured using end user measurement procedures.

For medical laboratory measurements, in particular, it is important to both patient care and health screening that the measurement results reported by different end user measuring systems be equivalent, comparable over time, reproducible and accurate. Establishing metrological traceability of an end user measuring system to a reference measurement procedure enables equivalent results to be reported. A reference measurement procedure should be specified, especially when

— it is required by e.g. standards, technical specifications, or technical regulations,

— quantity values are to be stated by the manufacturer, and

— technical requirements have a direct relationship to the performance of a product or process.

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In vitro diagnostic medical devices — Requirements for reference measurement procedures

1 Scope

This document specifies requirements for reference measurement procedures (RMP) for measurands used in laboratory medicine.

This document applies to:

a) RMPs providing values of differential or rational quantities where each quantity value is a numerical value multiplied by a measurement unit. Annex A provides information on ordinal quantities and nominal properties;

b) any person, body or institution developing RMPs for measurands used in laboratory medicine.

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/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

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

ISO 15194, *In vitro diagnostic medical devices — Requirements for certified reference materials and the content of supporting documentation*

ISO 17511:2020, *In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99, ISO 15194, and ISO 17511 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/

3.1
analyte
component represented in the name of a measurable *quantity* (3.31)

EXAMPLE In the type of quantity “mass of protein in 24-hour urine”, “protein” is the analyte. In “amount of substance of glucose in plasma”, “glucose” is the analyte. In both cases the full phrase describes the *measurand* (3.18).

[SOURCE: ISO 17511:2020, 3.1]

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