SLOVENSKI STANDARD
oSIST prEN ISO 15193:2024

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Diagnostični medicinski pripomočki in vitro - Zahteve za predstavitev referenčnih merilnih postopkov (ISO/DIS 15193:2023)

In vitro diagnostic medical devices - Requirements for reference measurement procedures (ISO/DIS 15193:2023)

In□vitro-Diagnostika - Anforderungen an Referenzmessverfahren (ISO/DIS 15193:2023)

Dispositifs médicaux de diagnostic in vitro - Mesurage des grandeurs dans des échantillons d'origine biologique - Exigences relatives au contenu et à la présentation des procédures de mesure de référence (ISO/DIS 15193:2023)

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In vitro diagnostic medical devices — Requirements for reference measurement procedures

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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, *Clinical laboratory testing and in vitro diagnostic test systems*.

This third edition cancels and replaces the second edition (ISO 15193:2009), which has been technically revised.

The main changes are as follows:

— title and chapter headings have been changed to better reflect the objective of the document;

— requirements, concepts and definitions have been incorporated for consistency with ISO 17511:2020, ISO 15194:XXXX, and ISO 15195:2018;

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

— the subchapters of Chapter 4 "Requirements for a reference measurement procedure" have been revised and specified in order to present the requirements more transparently;

— subclause 4.1 has been added to emphasize quality requirements for a reference measurement procedure; and

— aspects of validation have been updated and summarized in Chapter 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.

Introduction

Reference measurement systems are needed to enable the results produced by end user measurement procedures to be metrologically traceable to measurement standards and/or measurement procedures of the highest metrological level. Such systems exist within a traceability chain/calibration hierarchy as described in ISO 17511:2020. In the context of in vitro diagnostic (IVD) medical devices, they mitigate 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 end user 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 vitally important to both patient care and health screening that the measurement results reported by different end user 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. It is advisable that a reference measurement procedure 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.

The advantages of having a standard for reference measurement procedures are listed in the ISO/IEC Directives, Part 1, 2021, (Annex SM).

In this document, defined concepts are indicated by *italicized text*.

In vitro diagnostic medical devices — Requirements for reference measurement procedures

1 Scope

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

This document applies to

a) reference measurement procedures providing values of differential or rational quantities. Annex A provides information on nominal properties and ordinal quantities.

b) any person, body or institution developing reference measurement procedures 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 98-3:2008, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

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 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 *quantity* (3.29)

EXAMPLE In the type of *quantity* (3.29) "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]

3.2
analytical interference
systematic effect on a measurement caused by an *influence quantity* (3.14) which does not by itself produce an indication, but which causes an enhancement or depression of the indication

3.3
analytical portion
portion of material taken from the *analytical sample* (3.4) and on which the measurement is actually carried out, either directly or following dissolution

Note 1 to entry: The analytical portion is taken directly from the *primary sample* (3.28) or *laboratory sample* (3.16) if no preparation of these is required. The *analytical portion* is sometimes dissolved to give an *analytical solution* (3.7) before being exposed to the measuring device.

3.4
analytical sample
sample prepared from the *laboratory sample* (3.16) and from which *analytical portions* (3.3) can be taken

Note 1 to entry: The analytical sample can be subjected to various treatments before an *analytical portion* (3.3) is taken.

3.5
analytical selectivity
selectivity of a measuring system
selectivity
property of a *measuring system* (3.24), used with a specified *measurement procedure* (3.21), whereby it provides measured *quantity* (3.29) values for one or more *measurands* (3.18) such that the values of each *measurand* (3.18) are independent of other *measurands* (3.18) or other quantities in the phenomenon, body, or substance being investigated

Note 1 to entry: Adapted from ISO 17511:2020 and ISO/IEC Guide 99:2007.

3.6
analytical sensitivity
quotient of the change in an indication of a *measuring system* (3.24) and the corresponding change in the value of a *quantity* (3.29) being measured

Note 1 to entry: The term analytical sensitivity is not intended to be used as a synonym for *detection limit* (3.12).

Note 2 to entry: ISO/IEC Guide 99:2007, 4.12 uses the term “sensitivity of a measuring system”.

3.7
analytical solution
solution prepared prior to measurement by dissolving an *analytical portion* (3.3) in a liquid material or dispersing it in a solid material, with or without reaction

3.8
blank
lack of the *analyte* (3.1) or another component necessary to produce an indication of a *measuring system* (3.24) that is specific to the *analyte* (3.1)

3.9
calibrator
measurement standard (3.22) used in calibration of a *measuring system* (3.24) according to a specified *measurement procedure* (3.21)

Note 1 to entry: Adapted from ISO/IEC Guide 99:2007, 5.12 and ISO 17511:2020.

Note 2 to entry: The *measurement standard* (3.22) should be a *certified reference material* (3.10), if available.

3.10
certified reference material
CRM
reference material (3.31), accompanied by documentation issued by an authoritative body, that provides one or more specified property values with associated *uncertainty* (3.41) and traceability using valid procedures

Note 1 to entry: Documentation is given in the form of a *reference material* (3.31) certificate and a certification report.

Note 2 to entry: Requirements for the production and characterization of CRMs are given in ISO 17034 and ISO 15194 ; guidance on characterization and value assignment is provided in ISO Guide 35.

Note 3 to entry: In this definition, "uncertainty" covers both *measurement uncertainty* (3.41) and uncertainty associated with the value of a nominal property, such as for identity or sequence. Traceability covers both *metrological traceability* (3.25) of a *quantity* (3.29) and traceability of a nominal property.

Note 4 to entry: Specified *quantity* (3.29) values of CRMs require *metrological traceability* (3.25) with associated *measurement uncertainty* (3.41).

Note 5 to entry: ISO 17034 has an analogous definition.

Note 6 to entry: For a specified material, a calibration certificate provided by an accredited calibration laboratory is not by itself sufficient to confer the status of CRM on these types of materials.

EXAMPLE Human serum with an assigned *quantity* (3.29) value and associated *measurement uncertainty* (3.41) for concentration (amount of substance per unit volume) of cholesterol inherently present in the serum and used as a *calibrator* (3.9) or as a trueness *control material* (3.11) is an example of a CRM.

[SOURCE: ISO 17511: 2020, 3.9]

3.11
control material
substance, material or artefact intended by its producer to be used to verify the performance of a *measurement procedure* (3.21)

Note 1 to entry: The control material should be a *reference material* (3.31), if available.

3.12
detection limit
limit of detection
measured *quantity* (3.29) value, obtained by a given *measurement procedure* (3.21), for which the probability of falsely claiming the absence of a component in a material is β, given a probability α of falsely claiming its presence

Note 1 to entry: IUPAC recommends default values for α and β equal to 0.05.

Note 2 to entry: The abbreviation LOD is sometimes used.

Note 3 to entry: The term "sensitivity" is discouraged for this concept.

Note 4 to entry: Adapted from ISO/IEC Guide 99:2007, 4.18.

3.13
examination
set of operations having the objective of determining the numerical value, text value or characteristics of a property

Note 1 to entry: An examination may be the total of a number of activities, observations or measurements required to determine a value or characteristic.

Note 2 to entry: Laboratory examinations that determine a numerical value of a property are called "quantitative examinations"; those that determine the characteristics of a property are called "qualitative examinations".