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GB/T 21919-2022

Replacing GB/T 21919-2008

Laboratory medicine - Requirements for the competence of calibration laboratories using reference measurement procedures

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foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1.Structure and Drafting Rules of Standardization Documents"

drafted.

This document replaces GB/T 21919-2008 "Requirements for Laboratory Medicine Reference Measurement Laboratories", which is consistent with GB/T 21919-2008

The main technical changes are as follows.

a) The terms "measurement accuracy", "certified reference material", "measurable", "measurement precision", "reference material", "reference measurement experiment" were deleted

laboratory, "traceability", "true value of quantity", "measurement accuracy", "validation", "verification" and their definitions (see 3.1~3.6 of the.2008 edition,

3.8~3.10, 3.12, 3.13);

b) Added GB/T 27025-2019 as a normative reference document, deleted the duplicate clauses with GB/T 27025-2019

Content (see Chapters 4 to 8);

c) Changed "Management System Requirements" and "Technical Requirements" to "General Requirements", "Structure Requirements", "Resource Requirements" and "Process Requirements"

requirements" and "management requirements" (see Chapters 4-8, Chapters 4-5 of the.2008 edition).

This document is equivalent to ISO 15195.2018 "Competence requirements for calibration laboratories operating reference measurement procedures in laboratory medicine".

Please note that some content of this document may be patented. The issuing agency of this document assumes no responsibility for identifying patents.

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Introduction

See GB/T 27025-2019 for general requirements for the competence of calibration laboratories. This document is a reference to the competence of calibration laboratories in the field of laboratory medicine.

Additional requirements, these calibration laboratories are also commonly referred to as "reference measurement laboratories".

Results from medical laboratories should be traceable to higher-level reference materials and/or reference measurement procedures (as long as they are available), which are essential for achieving patient outcomes.

The comparability of the measurement results of the patient sample at different measurement locations and measurement times is necessary.

The level of measurement of results provided by the calibration laboratory should be appropriate to support the medical laboratory in meeting medical requirements. Specific requirements for medical laboratories see

ISO 15189.

Calibration laboratories should implement reference measurement procedures and issue reports that are accurate and traceable to existing national or international primary reference materials (where applicable).

measurement results. Wherever possible, traceability to a reference material that reproduces International System of Units (SI) units should be established (ISO 17511).

The calibration laboratory should issue a reference measurement procedure or reference material traceable to the highest level available for the reference material provided by the customer

value of.

In most cases, the molecular structure of the analyte is unclear and its form in the reference material may be different from that of human origin.

For the original sample (such as the glycation state of a certain protein), the properties of the biologically derived material cannot be expressed in SI units.

Even if the value of a property of a biologically derived material is not traceable to SI units, refer to each step of the measurement procedure (e.g. gravimetric determination,

Capacity determination, temperature measurement, potentiometric measurement) should all have values traceable to the corresponding SI units.

The concept of traceability, including its applicability and limitations, is detailed in ISO 17511.

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The requirements described in this document and in GB/T 27025-2019 are prerequisites for calibration laboratories to perform their tasks adequately.

If a calibration laboratory applies for accreditation of the ability to perform a reference measurement procedure, this document may serve as the basis for accreditation.

Laboratory Medicine Running Reference Measurement Procedures

Competency requirements for calibration laboratories

1 Scope

This document specifies requirements for the competence of medical calibration laboratories to run reference measurement procedures. This document is based on the requirements of GB/T 27025-2019

This is a normative reference listing additional requirements for calibration laboratories to adequately perform their tasks.

The relationship between this document and the provisions of GB/T 27025-2019 is summarized in Appendix A.

This document does not include measurements of properties that report results on a nominal or ordinal scale.

This document is not intended for use in medical laboratories.

NOTE. ISO 15189 specifies the requirements for medical laboratories.

2 Normative references

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, dated citations

documents, only the version corresponding to that date applies to this document; for undated references, the latest edition (including all amendments) applies to

this document.

GB/T 27025-2019 General requirements for the competence of testing and calibration laboratories (ISO /IEC 17025.2017, IDT)

ISO /IEC Guide 98-3 Measurement Uncertainty Part 3.Guidelines for the Expression of Measurement Uncertainty [Uncertaintyofmea-

Note. GB/T 27418-2017 Evaluation and representation of measurement uncertainty (ISO /IEC Guide98-3.2008, MOD)

ISO 15193 Requirements for the presentation and content of reference measurement procedures for the measurement of quantities in samples of biological origin for in vitro

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diagnostic medical devices

Note. GB/T 19702-2021 Requirements for the expression and content of reference measurement procedures for the measurement of quantities in biologically derived samples of in vitro diagnostic medical devices

(ISO 15193.2009, IDT)

ISO 15194 Measurement of quantities in biologically derived samples of in vitro diagnostic medical devices Certified reference materials and requirements for the content of supporting documents

Note. GB/T 19703-2020 Requirements for the content of certified reference materials and supporting documents for the measurement of quantities in biologically derived samples of in vitro diagnostic medical devices

(ISO 15194.2009, IDT)

ISO 17511 Requirements for in vitro diagnostic medical devices to establish traceability of calibrators, correctness control substances and human sample assignments

Note. GB/T 21415-2008 Metrological traceability of measurement calibrators and control substance assignments in biological samples of in vitro diagnostic medical devices

(ISO 17511.2003, IDT)

ISO 18153 Enzyme-catalyzed concentration of calibrators and control substances for the measurement of quantities in biologically derived samples of in vitro diagnostic medical devices

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