SLOVENSKI STANDARD
oSIST prEN ISO 15189:2021

01-december-2021

Medicinski laboratoriji - Zahteve za kakovost in kompetentnost (ISO/DIS 15189:2021)

Medical laboratories - Requirements for quality and competence (ISO/DIS 15189:2021)

Medizinische Laboratorien - Anforderungen an die Qualität und Kompetenz (ISO/DIS 15189:2021)

Laboratoires de biologie médicale - Exigences concernant la qualité et la compétence (ISO/DIS 15189:2021)

Ta slovenski standard je istoveten z: prEN ISO 15189

ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
11.100.01	Laboratorijska medicina na splošno	Laboratory medicine in general

oSIST prEN ISO 15189:2021 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 15189

ISO/TC **212**

Secretariat: **ANSI**

Voting begins on:
2021-10-19

Voting terminates on:
2022-01-11

Medical laboratories — Requirements for quality and competence

Laboratoires de biologie médicale — Exigences concernant la qualité et la compétence

ICS: 11.100.01; 03.120.10

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 15189:2021(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 fourth edition cancels and replaces the third edition ISO 15189:2012, which has been technically revised.

The fourth edition provides alignment with ISO/IEC 17025:2017

Correlations between this document, ISO 9001:2015 and ISO/IEC 17025:2017 are in Annex A. The comparison of ISO 15189:2012 to ISO 15189:2022 is in Annex B.

Any feedback or questions on this document should be directed through the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is based upon ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. It has been developed with the objective of promoting the welfare of patients through confidence in the quality and competence of medical laboratories.

Because the primary consideration is the welfare of patients and the satisfaction of users, this document contains requirements for the medical laboratory to plan and implement actions to address risks and opportunities. This is the basis for increasing the effectiveness of the management system, achieving improved results, and preventing negative effects which could result in harm to patients, laboratory personnel, the public and the environment.

The requirements for risk management are aligned with the principles of ISO 22367:2020 *Medical laboratories – Application of risk management to medical laboratories.*

The requirements for laboratory safety are aligned with the principles of ISO 15190:2020 *Medical laboratories – Requirements for Safety.*

The requirements for sample collection and transport are aligned with ISO/TS 20658:2017 *Medical laboratories - Requirements for collection and transport of samples.*

This document contains the requirements for point-of-care testing (POCT) and supersedes ISO 22870:2016 *Point-of-care testing (POCT) – Requirements for quality and competence*, which is to be withdrawn.

The medical laboratory is essential to patient care; activities are provided within an ethical and governance framework, that recognizes the obligations of healthcare providers to the patient. These activities are undertaken in a timely manner to meet the needs of all patients and the personnel responsible for the care of those patients. Activities include arrangements for examination requests, patient preparation, patient identification, collection of samples, transportation, processing of clinical samples, selection of examinations that are fit for intended use, examination of samples, sample storage, together with subsequent interpretation, reporting and advice to users. This may also include the provision of results to the patient, arrangements for urgent testing and the notification of critical results. It is recommended that the medical laboratory provide advice on patient cases where indicated.

While this document is intended for use throughout the currently recognized medical laboratory disciplines, it can effectively be applied to other healthcare services, such as diagnostic imaging, respiratory therapy, physiological sciences, blood banks and transfusion services.

The use of this document will facilitate cooperation between medical laboratories and other healthcare services, assist in the exchange of information, and in the harmonization of methods and procedures.

The consistency of results between countries is facilitated when medical laboratories conform to this document. Also, laboratories conforming to this document will contribute to reduction of waste, minimize repeat testing, and sometimes reduce carbon emissions.

When a laboratory seeks accreditation, it should select an accreditation body which operates in accordance with ISO/IEC 17011, and which takes into account the particular requirements of medical laboratories.

The management system requirements in Clause 8 are written in a language relevant to a medical laboratory's operations and meet the principles of ISO 9001:2015 *Quality management systems – Requirements.*

In this document, the following verbal forms are used:

- 'shall' indicates a requirement;
- 'should' indicates a recommendation;
- 'may' indicates a permission;

- ‘can’ indicates a possibility or capability.

Medical laboratories — Requirements for quality and competence

1 Scope

This document specifies requirements for quality and competence in medical laboratories.

This document can be used by medical laboratories in developing their management systems and assessing their competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory users, regulatory authorities and accreditation bodies.

This document includes requirements for Point of Care Testing (POCT).

NOTE International, national, or regional regulations or requirements may also apply to specific topics covered in this document.

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 17000:2020, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*

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

NOTE ISO/IEC Guide 99 is also known as the Joint Commission for Guides in Metrology (JCGM) 200.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 and ISO/IEC 17000 and the following apply.

ISO and IEC maintain terminological 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
bias
measurement bias
estimate of a systematic measurement error

Note 1 to entry: This definition applies to quantitative measurements only.

[SOURCE: ISO/IEC Guide 99:2007 2.18, Note has been added]

3.2
critical limit
critical decision limit
examination (3.6) result that indicates an immediate risk to the patient of injury or death

3.3
biological reference interval
reference interval
specified interval of the distribution of values taken from a biological reference population.

Note 1 to entry: A reference interval is commonly defined as the central 95 % interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases.

Note 2 to entry: A reference interval can depend upon the type of *primary sample* (3.20) and the *examination method* (3.7) used.

Note 3 to entry: In some cases, only one biological reference limit is important, for example, an upper limit, x, so that the corresponding biological reference interval would be less than or equal to x.

Note 4 to entry: Terms such as 'normal range', 'normal values', and 'clinical range' are ambiguous and therefore discouraged.

[SOURCE: ISO 18113-1]

3.4
commutability of a reference material
commutability
property of a reference material, demonstrated by the closeness of agreement between the relation among the measurement results for a stated quantity in this material, obtained according to two given *measurement procedures* (3.15) and the relation obtained among the measurement results for other specified materials

Note 1 to entry: The reference material in question is usually a calibrator and the other specified materials are usually routine samples.

Note 2 to entry: It is typical that there are more than two measurement procedures available and comparison among all applicable measurement procedures is desirable.

Note 3 to entry: Closeness of agreement of measurement results is defined in terms of fitness for purpose as appropriate for the intended use of the reference material

Note 4 to entry: A commutability statement is restricted to the measurement procedures as specified in a particular comparison

[SOURCE: ISO 17511:2020 3.10]

3.5
complaint
expression of dissatisfaction by any person or organization to a *laboratory* (3.18), relating to the activities or results of that laboratory, where a response is expected

[SOURCE: ISO/IEC 17000:2020, 8.7, modified — The words "other than appeal" have been deleted, and the words "a conformity assessment body or accreditation body, relating to the activities of that body" have been replaced by "a laboratory, relating to the activities or results of that laboratory".]

3.6
examination
set of operations having the objective of determining the value or characteristics of a property

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

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.

Note 3 to entry: Laboratory examinations are also called assays or tests.

3.7
examination method
detailed description of the different steps for processing a sample/specimen including the pre-examination, examination and post-examination. An examination method can include a *measurement procedure* (3.15)

3.8
impartiality
objectivity with regard to the outcome of tasks performed by the medical laboratory

Note 1 to entry: Objectivity can be understood as freedom from bias or freedom from conflicts of interest.

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “independence”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

[SOURCE: ISO/IEC 17000-1:2020 2.2.3 modified — “outcome of a conformity assessment activity” has been changed to “tasks performed by the medical laboratory”]

3.9
interlaboratory comparison
organization, performance and evaluation of measurements or examinations on the same or similar materials by two or more independent laboratories in accordance with pre-determined conditions

[SOURCE: ISO/IEC 17043:2010 3.4]

3.10
external quality assessment
EQA
evaluation of participant performance against pre-established criteria by means of *interlaboratory comparison* (3.9)

Note 1 to entry: This is also known as proficiency testing (PT).

Note 2 to entry: External quality assessment (EQA) is an interlaboratory comparison organized by a provider that distributes EQA materials as blinded samples with no prior knowledge of the results by the participants. According to ISO/IEC 17043:2010 the EQA provider reports the findings to the participants in a way that facilitates the verification of trueness, to establish the corrective actions needed and to assess the success of prior corrective actions.

[SOURCE: ISO/IEC 17043:2010 3.7, modified — Term and definition are used here without the original notes.]

3.11
internal quality control (IQC)
quality control (QC)
internal procedure which monitors the testing process to decide if the system is working correctly and gives confidence that the results are reliable enough to be released

[SOURCE: ISO/TS 22583:2019 3.9]

3.12
in vitro diagnostic medical device
IVD medical device
device, whether used alone or in combination, intended by the manufacturer, for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes and including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

[SOURCE: ISO 18113-1:2009 3.27]

3.13
laboratory management
person(s) with responsibility for, and authority over a *laboratory* (3.18)

Note 1 to entry: Laboratory management has the power to delegate authority and provide resources within the laboratory.

Note 2 to entry: The laboratory management includes the laboratory director(s) and delegates together with individuals specifically assigned to ensure the quality of the activities of the laboratory.

3.14
management system
set of interrelated or interacting elements of an organization to establish objectives and policies, with processes to achieve those objectives

Note 1 to entry: This was formerly referred to and is synonymous with "quality management system".

Note 2 to entry: The management system elements establish the organization's structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives and processes to achieve those objectives.

[SOURCE: ISO 9000:2015 3.5.3 modified – Notes to entry 1, 3 and 4 are omitted and a new Note 1 to entry has been added]

3.15
measurement procedure
detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result

Note 1 to entry: A measurement procedure is usually documented in sufficient detail to enable an operator to perform a measurement.

Note 2 to entry: A measurement procedure can include a statement concerning a target *measurement uncertainty* (3.17).

Note 3 to entry: A measurement procedure is sometimes called a standard operating procedure, abbreviated SOP.

[SOURCE: ISO/IEC Guide 99:2007 2.6]

3.17
measurement uncertainty
MU
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurement based on the information used

Note 1 to entry: MU includes components arising from systematic effects, as in the case of corrections to the assigned quantity values of measurement standards. Sometimes estimated systematic effects are not corrected for, but instead, the associated MU components are incorporated.

Note 2 to entry: The parameter may be, for example, a standard deviation (SD) called standard MU (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

Note 3 to entry: MU comprises, in general, of many components. Some of these may be evaluated by Type A evaluation of MU from the statistical distribution of the quantity values from series of measurements and can be characterized by SD. The other components, which may be evaluated by Type B evaluation of MU, can also be characterized by SD or evaluated from probability density functions based on experience or other information.

Note 4 to entry: In general, for a given set of information, it is understood that the MU is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

Note 5 to entry: All measurements have bias and imprecision. For example, replicate measurements of a sample performed under repeatability conditions generally produce different values for the same *measurand*. Because the different values could all be reasonably attributed to the same amount of *measurand*, there is uncertainty as to which value should be reported as the value of the measurand.

Note 6 to entry: Based on available data about the analytical performance of a given *measurement procedure*, an estimation of MU provides an interval of values that is believed to include the actual value of the *measurand*, with a stated level of confidence.

Note 7 to entry: Available data about the analytical performance of a given *measurement procedure* typically comprise uncertainty of calibrator assigned values and long-term imprecision of IQC materials.

Note 8 to entry: In medical laboratories, most measurements are performed in singleton, and are taken to be an acceptable estimate of the value of the measurand, while the MU interval indicates other results that are also possible.

[SOURCE: ISO/IEC Guide 99:2007 2.26 with Notes 5 and 6 replaced by Notes 5 to 8 from ISO/TS 20914:2019]

3.18
medical laboratory
clinical laboratory
laboratory
an entity for the *examination* (3.6) of materials for the purpose of providing information for the diagnosis, management, prevention and treatment of disease, or assessment of health; the laboratory can also provide advice covering all aspects of *examinations* (3.6) including the interpretation of results and advice on further examinations

3.19
point-of-care testing
POCT
examination (3.6) performed near or at the site of a patient

[SOURCE: ISO22583:2019 3.11]

3.20
primary sample
specimen
discrete portion of material intended for *examination* (3.6), study or analysis of one or more quantities or properties and assumed to apply for the whole

Note 1 to entry: The International Medical Device Regulators Forum (IMDRF) uses the term specimen in its harmonized guidance documents to mean a sample of biological origin intended for examination by a *medical laboratory* (3.18).

Note 2 to entry: In some ISO and CEN documents, a specimen is defined as “a biological sample derived from the human body”.

[SOURCE: ISO 15189:2012 3.16]

3.21
quality indicator
measure of the degree to which a set of inherent characteristics of an object fulfils requirements

Note 1 to entry: Measure can be expressed, for example, as % yield (% within specified requirements), % defects (% outside specified requirements), defects per million occasions (DPMO) or on the Six Sigma scale.

Note 2 to entry: Quality indicators can measure how well an organization meets the needs and requirements of users and the quality of all operational processes.

[SOURCE: ISO 15189:2012 3.19]