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Medical laboratories — Requirements for quality and competence

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

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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).

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,* 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 fourth edition cancels and replaces the third edition (ISO 15189:2012), which has been technically revised. It also replaces ISO 22870:2016.

The main changes are as follows:

— Alignment with ISO/IEC 17025:2017 resulted in the management requirements now appearing at the end of the document;

— Requirements for point-of-care testing (POCT), previously in ISO 22870, have been incorporated;

— Increased emphasis on risk management.

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

The objective of this document is to promote the welfare of patients and satisfaction of laboratory users through confidence in the quality and competence of medical laboratories.

This document contains requirements for the medical laboratory to plan and implement actions to address risks and opportunities for improvement. Benefits of this approach include: increasing the effectiveness of the management system, decreasing probability of invalid results, and reducing potential harm to patients, laboratory personnel, the public and the environment.

The requirements for risk management are aligned with the principles of ISO 22367.

The requirements for laboratory safety are aligned with the principles of ISO 15190.

The requirements for sample collection and transport are aligned with ISO 20658.[1)]

This document contains the requirements for point-of-care testing (POCT) and supersedes ISO 22870, which will be withdrawn upon publication of this document.

The format of this document is based on ISO/IEC 17025:2017.

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 patient samples, selection of examinations that are fit for intended use, examination of samples, sample storage, as well as subsequent interpretation, result reporting and advice to laboratory users. This may also include the provision of results to the patient, arrangements for urgent testing and the notification of critical results.

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 facilitates cooperation between medical laboratories and other healthcare services, assists in the exchange of information, and in the harmonization of methods and procedures.

The comparability of patient examination results between medical laboratories, regardless of city or country, is facilitated when medical laboratories conform to this document.

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.

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

1) First edition under preparation (previous edition was a Technical Specification). Stage at the time of publication: ISO/DIS 20658:2022.

Medical laboratories — Requirements for quality and competence

1 Scope

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

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

This document is also applicable to point-of-care testing (POCT).

NOTE International, national, or regional regulations or requirements can 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 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 Committee for Guides in Metrology (JCGM) 200.

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

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

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 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
bias
measurement bias
estimate of a systematic measurement error

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

[SOURCE: ISO/IEC Guide 99:2007, 2.18, modified — Note 1 to entry has been added.]

3.2
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* (3.25) and the *examination procedure* (3.9) used.

Note 3 to entry: In some cases, only one biological reference limit is important, usually 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 18113-1:2022, 3.1.9, modified — The EXAMPLE has been removed.]

3.3
clinical decision limit
examination (3.8) result that indicates a higher risk of adverse clinical outcomes, or is diagnostic for the presence of a specifc disease

Note 1 to entry: Clinical decision limits for therapeutic drugs are called "therapeutic range".

Note 2 to entry: It is used to determine risk of disease, to diagnose or to treat.

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 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, modified — Note 2 to entry has been replaced by a new Note 2 to entry.]

3.5
competence
demonstrated ability to apply knowledge and skills to achieve intended results

[SOURCE: ISO/IEC 17021-1:2015, 3.7, modified — "demonstrated" added to the beginning of the definition.]

3.6
complaint
expression of dissatisfaction by any person or organization to a *laboratory* (3.20), 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”.]

3.7
consultant
person who provides expert advice professionally

3.8
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".

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

3.9
examination procedure
specifically described set of operations used in the performance of an *examination* (3.8) according to a given method

Note 1 to entry: In the IVD medical device industry and in many laboratories that use IVD medical devices, an examination procedure for an analyte in a biological sample is commonly referred to as an analytical method, analytical procedure or test procedure.

[SOURCE: ISO 15198:2004, 3.7, modified — “set of operations described specifically” changed to “specifically described set of operations”.]

3.10
external quality assessment
EQA
evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

Note 1 to entry: Also known as proficiency testing (PT)

[SOURCE: ISO/IEC 17043:2010, 3.7 modified — The term “external quality assessment”, which was given in Note 2 to entry, is used as the main term. Notes to entry 1 and 2 have been omitted and a new Note 1 to entry added.]

3.11
impartiality
objectivity with regard to the outcome of tasks performed by the *medical laboratory* (3.20)

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 17000:2020 5.3 modified — “outcome of a conformity assessment activity” has been changed to “tasks performed by the medical laboratory”. Note 2 to entry has been added.]

3.12
interlaboratory comparison
organization, performance and evaluation of measurements or *examinations* (3.8) 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, modified — "tests" has been replaced by "examinations". "items" has been replaced by "materials". "laboratories" has been replaced by "independent laboratories".]

3.13
internal quality control
IQC
quality control
QC
internal procedure which monitors the testing process to verify the system is working correctly and gives confidence that the results are reliable enough to be released

[SOURCE: ISO/TS 22583:2019 3.9, modified — “decide” has been replaced by “verify”. Note 1 to entry has been removed.]

3.14
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 18113-1:2022, 3.1.33, modified — "medical" has been removed from the beginning of the definition. "and including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles" has been added to the end of the definition. Notes 1 and 2 to entry have been removed.]

3.15
laboratory management
person(s) with responsibility for, and authority over a *laboratory* (3.20)

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.

3.16
laboratory user
individual or entity requesting services of the *medical laboratory* (3.20)

Note 1 to entry: Users can include patients, clinicians, and, other laboratories or institutions that send samples for examination.

3.17
management system
set of interrelated or interacting elements of an organization to establish policies and objectives, and 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 have been removed and a new Note 1 to entry has been added.]

3.18
measurement accuracy
accuracy of measurement
accuracy
closeness of agreement between a measured quantity value and a true quantity value of a measurand

Note 1 to entry: The concept 'measurement accuracy' is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.

Note 2 to entry: The term "measurement accuracy" should not be used for measurement trueness and the term measurement precision should not be used for 'measurement accuracy', which, however, is related to both these concepts.

Note 3 to entry: 'Measurement accuracy' is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measurand.

[SOURCE: ISO/IEC Guide 99:2007, 2.13]

3.19
measurement uncertainty
MU
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, 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 may result in a modification of the associated uncertainty.

Note 5 to entry: All measurements have *bias* (3.1) 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, modified — Notes to entry 5 to 8 have been added from ISO/TS 20914:2019 3.26.]

3.20
medical laboratory
laboratory
entity for the *examination* (3.8) of materials derived from the human body for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health

Note 1 to entry: The laboratory can also provide advice covering all aspects of examinations including appropriate selection, the interpretation of results and advice on further examinations.

Note 2 to entry: Laboratory activities include *pre-examination* (3.24), *examination* (3.8) and *post-examination processes* (3.23).

Note 3 to entry: Materials for *examination* (3.8) include but are not limited to, microbiological, immunological, biochemical, immunohaematological, haematological, biophysical, cytological, tissue and cells, and genetic material.

3.21
patient
person who is the source of material for an *examination* (3.8)

3.22
point-of-care testing
POCT
examination (3.8) performed near or at the site of a *patient* (3.21)

[SOURCE: ISO/TS 22583:2019, 3.11]

3.23
post-examination processes
processes following the *examination* (3.8) including review of results, formatting, releasing, reporting and retention of examination results, retention and storage of clinical material, *sample* (3.28) and waste disposal

3.24
pre-examination processes
processes that start, in chronological order, from the user's request and include the *examination* (3.8) request, preparation and identification of the *patient* (3.21), collection of the *primary sample(s)* (3.25), transportation to and within the *laboratory* (3.20), ending when the *examination* (3.8) begins

3.25
primary sample
specimen
discrete portion of a body fluid or tissue or other sample associated with the human body taken for *examination* (3.8), study or analysis of one or more quantities or characteristics to determine the character of 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* (3.20).

[SOURCE: ISO 18113-1:2022, 3.1.65, modified — Note 1 to entry has been modified. Note 2 to entry has been deleted.]

3.26
quality indicator
measure of the degree to which a large number of 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.

3.27
referral laboratory
external *laboratory* (3.20) to which a sample or data is submitted for *examination* (3.8)

Note 1 to entry: A referral laboratory is one to which laboratory management chooses to submit a sample or sub-sample for examination, data for analysis or interpretation, or when routine examinations cannot be carried out.

Note 2 to entry: This differs from a laboratory to which submission of samples is required by regulation, or a so called reference laboratory, e.g. public health, forensic, tumour registry, or a central (parent) facility to which submission of samples is required by structure.

3.28
sample
one or more parts taken from a *primary sample* (3.25)

3.29
trueness
measurement trueness
closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value

Note 1 to entry: Measurement trueness is not a quantity and thus cannot be expressed numerically, but measures for closeness of agreement are given in ISO 5725-1.

Note 2 to entry: Measurement trueness is inversely related to systematic measurement error, but is not related to random measurement error.

Note 3 to entry: ‘Measurement accuracy” should not be used for ‘measurement trueness’.

Note 4 to entry: For qualitative examinations, trueness of measurement (closeness of agreement) can be expressed in terms of concordance (i.e. percent agreement with a reference examination).

Note 5 to entry: Trueness is a property of the *examination procedure* (3.9) that reflects the *bias* (3.1) of the measurements from the expected or target value. It is described qualitatively as good or bad. An *examination procedure* (3.9) has good trueness if the *bias* (3.1) of the measurements is acceptable.

[SOURCE: ISO/IEC Guide 99:2007, 2.14, modified — Notes to entry 4 and 5 have been added.]

3.30
turnaround time
elapsed time between two specified points through *pre-examination* (3.24), *examination* (3.8), and *post-examination processes* (3.23)

3.31
validation
confirmation of plausibility for a specific intended use or application through the provision of objective evidence that specified requirements have been fulfilled

Note 1 to entry: Objective evidence can be obtained through observation, measurement, examination or by other means.

Note 2 to entry: The word “validated” is used to designate the corresponding status.

Note 3 to entry: Specified requirements of an examination method may include the following performance specifications: measurement trueness, measurement precision including measurement repeatability, and measurement intermediate precision, analytical specificity, including interfering substances, detection limit and quantitation limit, measuring interval, clinical relevance, diagnostic specificity and diagnostic sensitivity.

[SOURCE: ISO/IEC 17000:2020, 6.5, modified — Notes 1 to 3 to entry have been added.]