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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 15189:20— (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 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 18113-1:2009, 3.7, modified — The EXAMPLE has been removed. Note 5 to entry 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 referrd 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 18113-1:2009 3.27, modified — Note 1 to entry has 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 values 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 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 18113-1:2009, 3.54, modified — "or other sample associated with the human body" deleted from the definition. 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: 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 a large 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 low.

[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: Validation can be applied to claims to confirm the information declared with the claim regarding an intended future use.

Note 2 to entry: Objective evidence can be obtained through observation, measurement, examination or by other means.

Note 3 to entry: The word "validated" is used to designate the corresponding status.

Note 4 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 17000:2020, 6.5, modified — Notes 2 to 4 to entry have been added.]

3.32
verification
confirmation of truthfulness, through the provision of objective evidence that specified requirements have been fulfilled

EXAMPLE 1 Confirmation that performance specifications of a measuring system are achieved.

EXAMPLE 2 Confirmation that a target measurement uncertainty can be met.

Note 1 to entry: Verification can be applied to claims to confirm the information declared with the claim regarding events that have already occurred or results that have already been obtained.

Note 2 to entry: Verification is the process by which the laboratory confirms that the established performance claims of a measuring system (e.g. trueness, precision, reportable rangecan be replicated in the laboratory before human sample examination is performed.

Note 3 to entry: The objective evidence needed for a verification can be the results of an inspection, or other forms of determination, such as performing alternative calculations or reviewing documents.

Note 4 to entry: Verification may be sufficient to implement a new IVD device under circumstances where the *examination* (3.8) is performed and used in the manner as directed in the package insert.

Note 5 to entry: The word “verified” is used to designate the corresponding status.

[SOURCE: ISO 17000:2020, 6.6 modified — EXAMPLES 1 and 2 have been added. Notes to entry 2 to 5 have been added.]

4 General requirements

4.1 Impartiality

a) Laboratory activities shall be undertaken impartially. The laboratory shall be structured and managed to safeguard impartiality.

b) The laboratory management shall be committed to impartiality.

c) The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

d) The laboratory shall monitor its activities and its relationships to identify threats to its impartiality. This monitoring shall include relationships of its personnel.

NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new laboratory users, etc. Such relationships do not necessarily present the laboratory with a threat to impartiality.

e) If a threat to impartiality is identified, the effect shall be eliminated or minimized so that the impartiality is not compromised. The laboratory shall be able to demonstrate how it mitigates such threat**.**

4.2 Confidentiality

4.2.1 Management of information

The laboratory shall be responsible, through legally enforceable agreements, for the management of all patient information obtained or created during the performance of laboratory activities. Management of patient information shall include privacy and confidentiality. The laboratory shall inform the user and/or the patient in advance, of the information it intends to place in the public domain. Except for

information that the user and/or the patient makes publicly available, or when agreed between the laboratory and the patient (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

4.2.2 Release of information

When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the patient concerned shall be notified of the information released, unless prohibited by law.

Information about the patient from a source other than the patient (e.g. complainant, regulator) shall be kept confidential by the laboratory. The identity of the source shall be kept confidential by the laboratory and shall not be shared with the patient, unless agreed by the source.

4.2.3 Personnel responsibility

Personnel, including any committee members, contractors, personnel of external bodies, or individuals with access to laboratory information acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities.

4.3 Requirements regarding patients

Laboratory management shall ensure that patients' well-being, safety and rights are the primary considerations. The laboratory shall establish and implement the following processes:

a) opportunities for patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the examination results;

b) provision of patients and users with publicly available information about the examination process, including costs when applicable, and when to expect results;

c) periodic review of the examinations offered by the laboratory to ensure they are clinically appropriate and necessary;

d) where appropriate, disclosure to patients, users and any other relevant persons, of incidents that resulted or could have resulted in patient harm, and records of actions taken to mitigate those harms;

e) treatment of patients, samples, or remains, with due care and respect;

f) obtaining informed consent when required;

g) ensuring the ongoing availability and integrity of retained patient samples and records in the event of the closure, acquisition or merger of the laboratory;

h) making relevant information available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf;

i) upholding the rights of patients to care that is free from discrimination.

5 Structural and governance requirements

5.1 Legal entity

The laboratory or the organization of which the laboratory is a part shall be an entity that can be held legally responsible for its activities.

NOTE For the purposes of this document, a government laboratory is deemed to be a legal entity on the basis of its government status

5.2 Laboratory director

5.2.1 Laboratory director competence

The laboratory shall be directed by a person, or persons however named, with the specified qualifications, competence, delegated authority, responsibility, and resources to fulfil the requirements of this document.

5.2.2 Laboratory director responsibilities

The laboratory director is responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed.

The duties and responsibilities of the laboratory director shall be documented.

5.2.3 Delegation of duties

The laboratory director may delegate either selected duties or responsibilities, or both, to qualified and competent personnel and such delegation shall be documented. However, the laboratory director shall maintain the ultimate responsibility for the overall operation of the laboratory.

5.3 Laboratory activities

5.3.1 General

The laboratory shall specify and document the range of laboratory activities, including laboratory activities performed at sites other than the main location (e.g. point-of-care-testing, sample collection) for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

5.3.2 Conformance with requirements

Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the users, regulatory authorities and organizations providing recognition. This applies to the complete range of specified and documented laboratory activities, regardless of where the service is provided.

5.3.3 Advisory activities

Laboratory management shall ensure that appropriate laboratory advice and interpretation are available and meet the needs of patients and users.

The laboratory shall establish arrangements for communicating with laboratory users on the following when applicable:

a) advising on choice and use of examinations, including required type of sample, clinical indications and limitations of examination methods; and the frequency of requesting the examination;

b) providing professional judgments on the interpretation of the results of examinations;

c) promoting the effective utilization of laboratory examinations;

d) advising on scientific and logistical matters such as instances of failure of sample(s) to meet acceptability criteria.

5.4 Structure and authority

5.4.1 General

The laboratory shall:

a) define its organization and management structure, its place in any parent organization, and the relationships between management, technical operations and support services;

b) specify the responsibility, authority, lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;

c) specify its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

5.4.2 Quality management

The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;

b) identification of deviations from the management system or from the procedures for performing laboratory activities;

c) initiation of actions to prevent or minimize such deviations;

d) reporting to laboratory management on the performance of the management system and any need for improvement;

e) ensuring the effectiveness of laboratory activities.

NOTE These responsibilities can be assigned to one or more persons.

5.5 Objectives and policies

a) Laboratory management shall establish and maintain objectives and policies (see 8.2) to:

   1) meet the needs and requirements of its patients and users;

   2) commit to good professional practice;

   3) provide examinations that fulfil their intended use;

   4) conform to this document.

b) Objectives shall be measurable, and consistent with policies. The laboratory shall ensure that the objectives and policies are implemented at all levels of the laboratory organization.

c) Laboratory management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

d) The laboratory shall establish quality indicators to evaluate performance throughout key aspects of pre-examination, examination, and post-examination processes and monitor performance in relation to objectives.

NOTE Types of quality indicators include the number of unacceptable samples relative to the number received, the number of errors at either registration or sample receipt, or both, the number of corrected reports, the rate of achievement of specified turnaround times.

5.6 Risk management

a) Laboratory management shall establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement (see 8.5).

b) The laboratory director shall ensure that these processes are evaluated for effectiveness and modified, when identified as being ineffective.

NOTE 1 ISO 22367 provides details for managing risk in medical laboratories.

NOTE 2 ISO 35001 provides details for laboratory biorisk management.

6 Resource requirements

6.1 General

The laboratory shall have available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities.

6.2 Personnel

6.2.1 General

a) The laboratory shall have access to a sufficient number of competent persons to perform its activities.

b) All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, ethically, be competent and work in accordance with the laboratory's management system.

NOTE ISO/TS 22583 provides Guidance for supervisors and operators of point-of-care testing equipment.

c) The laboratory shall communicate to laboratory personnel the importance of meeting the needs and requirements of users as well as the requirements of this document.

d) The laboratory shall have a programme to introduce personnel to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements, and occupational health services.

6.2.2 Competence requirements

a) The laboratory shall specify the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, re-training, technical knowledge, skills and experience.

b) The laboratory shall ensure all personnel have the competence to perform laboratory activities for which they are responsible.

c) The laboratory shall have a process for managing competence of its personnel, that includes requirements for frequency of competence assessment.

d) The laboratory shall have documented information demonstrating competence of its personnel.

NOTE Examples of competence assessment methods that can be used in any combination include:

— direct observation of an activity,

— monitoring the recording and reporting of examination results,

— review of work records,

— assessment of problem-solving skills,

— examination of specially provided samples, e.g. previously examined samples, interlaboratory comparison materials, or split samples.

6.2.3 Authorization

The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

a) selection, development, modification, validation and verification of methods;

b) review, release, and reporting of results;

c) use of laboratory information systems, in particular: accessing patient data and information, entering patient data and examination results, changing patient data or examination results.

6.2.4 Continuing education and professional development

A continuing education programme shall be available to personnel who participate in managerial and technical processes. All personnel shall participate in continuing education and regular professional development, or other professional liaison activities.

The suitability of the programmes and activities shall be periodically reviewed.

6.2.5 Personnel records

The laboratory shall have procedures and retain records for:

a) determining the competence requirements specified in 6.2.2 a)

b) position descriptions;

c) training and re-training;

d) authorization of personnel;

e) monitoring competence of personnel.

6.3 Facilities and environmental conditions

6.3.1 General

The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results, or the safety of patients, visitors, laboratory users, and personnel. This shall include pre-examination related facilities and sites other than the main laboratory premises where examinations are performed, as well as POCT.

The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be specified, monitored, and recorded.

NOTE 1 ISO 15190 provides details for facility and environmental conditions.

NOTE 2 Environmental conditions that can adversely affect the validity of results include, but are not limited to: adventitious amplified nucleic acid, microbial contamination, dust, electromagnetic disturbances, radiation, lighting conditions (illumination), humidity, electrical supply, temperature, sound and vibration.

6.3.2 Facility controls

Facility controls shall be implemented, recorded, monitored, periodically reviewed, and shall include:

a) control of access, taking into consideration safety, confidentiality, quality, and safeguarding medical information and patient samples;

b) prevention of contamination, interference, or adverse influences on laboratory activities that can arise from energy sources, lighting, ventilation, noise, water and waste disposal;

c) prevention of cross-contamination, where examination procedures pose a risk, or where work can be affected or influenced by lack of separation;

d) provision of safety facilities and devices, where applicable and regularly verifying their functioning;

EXAMPLES The operation of emergency release, intercom and alarm systems for cold rooms and walk-in freezers, accessibility of emergency showers, eyewash and resuscitation equipment.

e) maintenance of laboratory facilities in a functional and reliable condition.

6.3.3 Storage facilities

a) Storage space, with conditions that ensure the continuing integrity of samples, equipment, reagents, consumables, documents and records, shall be provided.

b) Patient samples and materials used in examination processes shall be stored in a manner that prevents cross contamination and deterioration.

c) Storage and disposal facilities for hazardous materials and biological waste shall be appropriate to the classification of the materials in the context of any statutory or regulatory requirements.

6.3.4 Personnel facilities

There shall be adequate access to toilet facilities and a supply of drinking water, as well as facilities for storage of personal protective equipment and clothing.

Space for personnel activities, such as meetings, quiet study and a rest area, should be provided.

6.3.5 Sample collection facilities

Sample collection facilities shall:

a) enable collection to be undertaken in a manner that does not invalidate results or adversely affect the quality of examinations;

b) consider privacy, comfort and needs (e.g. disabled access, toilet facility) of patients and accommodation of accompanying persons (e.g. guardian or interpreter) during collection;

c) provide separate patient reception and collection areas;

d) maintain first aid materials for both patients and personnel.

NOTE ISO 20658 provides details for sample collection facilities.

6.4 Equipment

6.4.1 General

The laboratory shall have processes for the selection, procurement, installation, acceptance testing (including acceptability criteria), handling, transport, storage, use, maintenance, and decommissioning of equipment, in order to ensure proper functioning and to prevent contamination or deterioration.

NOTE Laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory information systems, or any equipment that influences the results of laboratory activities, including sample transportation systems.

6.4.2 Equipment requirements

a) The laboratory shall have access to equipment required for the correct performance of laboratory activities.

b) Where the equipment is used outside the laboratory's permanent control, or equipment manufacturer's functional specification, laboratory management shall ensure that the requirements of this document are met.

c) Each item of equipment that can influence laboratory activities shall be uniquely labelled, marked or otherwise identified and a register maintained.

d) The laboratory shall maintain and replace equipment as needed to ensure the quality of examination results.

6.4.3 Equipment acceptance procedure

The laboratory shall verify that the equipment conforms to specified acceptability criteria before being placed or returned into service.

Equipment used for measurement shall be capable of achieving either the measurement accuracy or measurement uncertainty,or both, required to provide a valid result (see 7.3.3 and 7.3.4 for details).

NOTE 1 This includes equipment used in the laboratory, equipment on loan, or equipment used in point of care settings, or in associated or mobile facilities, authorized by the laboratory.

NOTE 2 The verification of equipment acceptance testing can be, where relevant, based on the calibration certificate of the returned equipment.

6.4.4 Equipment instructions for use

a) The laboratory shall have appropriate safeguards to prevent unintended adjustments of equipment that can invalidate examination results.

b) Equipment shall be operated by trained, authorized, and competent personnel.

c) Instructions for the use of equipment, including those provided by the manufacturer, shall be readily available.

d) The equipment shall be used as specified by the manufacturer, unless validated by the laboratory (see 7.3.3).

6.4.5 Equipment maintenance and repair

a) The laboratory shall have preventive maintenance programmes, based on manufacturer’s instructions. Deviations from the manufacturer's schedules or instructions shall be recorded.

b) Equipment shall be maintained in a safe working condition and working order. This shall include electrical safety, any emergency stop devices and the safe handling and disposal of hazardous materials by authorized personnel.

c) Equipment that is defective or outside specified requirements, shall be taken out of service. It shall be clearly labelled or marked as being out of service, until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate actions when non-conforming work occurs (see 7.5).

d) When applicable, the laboratory shall decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.

6.4.6 Equipment adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific equipment shall be investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required.

The laboratory shall have procedures for responding to any manufacturer's recall or other notice, and taking actions recommended by the manufacturer .

6.4.7 Equipment records

Records shall be maintained for each item of equipment that influences the results of laboratory activities.

These records shall include the following, where relevant:

a) manufacturer and supplier details, and sufficient information to uniquely identify each item of equipment, including software and firmware;

b) dates of receipt, acceptance testing and entering into service;

c) evidence that equipment conforms with specified acceptability criteria;

d) the current location;

e) condition when received (e.g. new, used or reconditioned);

f) manufacturer's instructions;

g) the programme for preventive maintenance;

h) any maintenance activities performed by the laboratory or approved external service provider;

i) damage to, malfunction, modification, or repair of the equipment;

j) equipment performance records such as reports or either certificates of calibrations or verifications, or both, including dates, times and results;

k) status of the equipment such as active or in-service, out-of-service, quarantined, retired or obsolete.

These records shall be maintained and shall be readily available for the lifespan of the equipment or longer, as specified in 8.4.3.

6.5 Equipment calibration and metrological traceability

6.5.1 General

The laboratory shall specify calibration and traceability requirements that are sufficient to maintain consistent reporting of examination results over time. For quantitative methods of a measured analyte, specifications shall include calibration and metrological traceability requirements. Qualitative methods and quantitative methods that measure characteristics rather than discrete analytes shall specify the characteristic being assessed and such requirements necessary for reproducibility over time.

NOTE Examples of qualitative methods and quantitative methods that may not allow metrological traceability include red cell antibody detection, antibiotic sensitivity assessment, genetic testing, erythrocyte sedimentation rate, flow cytometry marker staining, and tumour HER2 immunohistochemical staining.

6.5.2 Equipment calibration

The laboratory shall have procedures for the calibration of equipment that directly or indirectly affects examination results. The procedures shall specify:

a) conditions of use and manufacturer's instructions for calibration;

b) recording of the metrological traceability;

c) verification of the required measurement accuracy and the functioning of the measuring system at specified intervals;

d) recording the calibration status and date of re-calibration;

e) ensuring that, where correction factors are used, these are updated and recorded when re-calibration occurs;

f) handling of situations when calibration may have been out of control, to minimize risk to service operation and to patients.

6.5.3 Metrological traceability of measurement results

a) The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

   NOTE Information of traceability to a higher order reference material or reference procedure can be provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer's examination system and calibration procedures are used without modification.

b) The laboratory shall ensure that measurement results are traceable to the highest possible order of traceability and as close as possible to the International System of Units (SI) through:

   — calibration provided by a competent laboratory; or

     NOTE 1 Calibration laboratories fulfilling the requirements of ISO/IEC 17025 are considered competent for performing calibrations.

   — certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI;

     NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

     NOTE 3 Certified reference material fulfilling the requirements of ISO 15194 are considered suitable.

c) Where it is not possible to provide traceability according to 6.5.3 a), other means for providing confidence in the results shall be applied, including but not limited to the following:

— results of reference measurement procedures, specified methods or consensus standards, that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison;

— measurement of calibration/calibrator by another procedure.

NOTE ISO 17511 provides further information on how to manage the compromises in the metrological traceability of measurands.

d) For genetic examinations, traceability to genetic reference sequences shall be established.

e) For qualitative methods, traceability may be demonstrated by testing of known material or previous samples sufficient to show consistent identification and, when applicable, intensity of reaction.

6.6 Reagents and consumables

6.6.1 General

The laboratory shall have processes for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables.

NOTE Reagents include substances which are commercially supplied or prepared in-house, reference materials, (calibrators and QC materials); culture media; consumables include pipette tips, glass slides, POCT supplies etc.

6.6.2 Reagents and consumables — Receipt and storage

The laboratory shall store reagents and consumables according to manufacturers' specifications and monitor the environmental conditions where relevant.

When the laboratory is not the receiving facility, it shall verify that the receiving facility has adequate storage and handling capabilities to maintain supplies in a manner that prevents damage and deterioration.

6.6.3 Reagents and consumables — Acceptance testing

Each reagent or new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, shall be verified for performance before placing into use, or before release of results, as appropriate.

Consumables that can affect the quality of examinations shall be verified for performance before placing into use.

NOTE 1 Comparative IQC performance of new reagent lots and that of previous lots can be used as evidence for acceptance (see 7.3.7.2). Patient samples are preferred when comparing different reagent lots to avoid issues with commutability of IQC materials.

NOTE 2 Verification can sometimes be based on the certificate of analysis of the reagent.

6.6.4 Reagents and consumables — Inventory management

The laboratory shall establish an inventory management system for reagents and consumables.

The system for inventory management shall segregate reagents and consumables that have been accepted for use from those that have been neither inspected nor accepted for use.

6.6.5 Reagents and consumables — Instructions for use

Instructions for the use of reagents and consumables, including those provided by the manufacturers, shall be readily available. Reagents and consumables shall be used according to the manufacturer's specifications. If they are intended to be used for other purposes see 7.3.3.

6.6.6 Reagents and consumables — Adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific reagents or consumables shall be investigated and reported to either the manufacturer or supplier, or both, and appropriate authorities, as required.

The laboratory shall have procedures for responding to any manufacturer's recall or other notice and taking actions recommended by the manufacturer.

6.6.7 Reagents and consumables — Records

Records shall be maintained for each reagent and consumable that contributes to the performance of examinations. These records shall include, but not be limited, to the following:

a) identity of the reagent or consumable;

b) manufacturer's information, including instructions, name and batch code or lot number;

c) date of receipt and condition when received, the expiry date, date of first use and, where applicable, the date the reagent or consumable was taken out of service;

d) records that confirm the reagent's or consumable's initial and ongoing acceptance for use.

Where the laboratory uses reagents prepared or completed in-house, the records shall include, in addition to the relevant information above, reference to the person or persons undertaking the preparation, as well as the dates of preparation and expiry.

6.7 Service agreements

6.7.1 Agreements with laboratory users

The laboratory shall have a procedure to establish and periodically review agreements for providing laboratory activities.

The procedure shall ensure:

a) the requirements are adequately specified;

b) the laboratory has the capability and resources to meet the requirements;

c) when applicable, the laboratory advises the user of the specific activities to be performed by referral laboratories and consultants.

Laboratory users shall be informed of any changes to an agreement that can affect examination results.

Records of reviews, including any significant changes, shall be retained.

6.7.2 Agreements with POCT operators

Service agreements between the laboratory and other parts of the organization using laboratory supported POCT, shall ensure that respective responsibilities and authorities are specified and communicated.

NOTE Established multidisciplinary POCT committees can be used to manage such service agreements as described in Annex A.

6.8 Externally provided products and services

6.8.1 General

The laboratory shall ensure that externally provided products and services that affect laboratory activities are suitable when such products and services are:

a) intended for incorporation into the laboratory's own activities;

b) provided, in part or in full, directly to the user by the laboratory, as received from the external provider;

c) used to support the operation of the laboratory.

It can be necessary to collaborate with other organizational departments or functions to fulfil this requirement.

NOTE Services include, e.g. sample collection services, pipette and other calibration services, facility and equipment maintenance services, EQA programmes, referral laboratories and consultants.

6.8.2 Referral laboratories and consultants

The laboratory shall communicate its requirements to referral laboratories and consultants who provide interpretations and advice, for:

a) the procedures, examinations, reports and consulting activities to be provided;

b) management of critical results;

c) any required personnel qualifications and demonstration of competence.

Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) shall be responsible for ensuring that examination results of the referral laboratory are provided to the person making the request.

A list of all referral laboratories and consultants shall be maintained.

6.8.3 Review and approval of externally provided products and services

The laboratory shall have procedures and retain records for:

a) defining, reviewing, and approving the laboratory's requirements for all externally provided products and services;

b) defining the criteria for qualification, selection, evaluation of performance and re-evaluation of the external providers;

c) referral of samples;

d) ensuring that externally provided products and services conform to the laboratory's established requirements, or where applicable to the relevant requirements of this document, before they are used or directly provided to the user;

e) taking any actions arising from evaluations of the performance of the external providers.

7 Process requirements

7.1 General

The laboratory shall identify potential risks to patient care in the pre-examination, examination and post-examination processes. These risks shall be assessed and mitigated to the extent possible. The residual risk shall be communicated to users as appropriate.

The identified risks and effectiveness of the mitigation processes shall be monitored and evaluated according to the potential harm to the patient.

The laboratory shall also identify opportunities to improve patient care and develop a framework to manage these opportunities (see 8.5).

7.2 Pre-examination processes

7.2.1 General

The laboratory shall have procedures for all pre-examination activities and make them accessible to relevant personnel.

NOTE 1 The pre-examination processes can influence the outcome of the intended examination.

NOTE 2 ISO 20658 provides detailed information for sample collection and transport.

NOTE 3 ISO 20186-1, ISO 20186-2, ISO 20186-3, ISO 20166 (all parts), ISO 20184 (all parts), ISO 23118 and ISO 4307 provide detailed information for samples from particular sources (e.g. tissue, whole blood, serum and saliva) for specific analytes, e.g. ge, ct, ccf, DNA, RNA, metabolites, staining and proteins).

7.2.2 Laboratory information for patients and users

The laboratory shall have appropriate information available for its users and patients. The information shall be sufficiently detailed to provide laboratory users with a comprehensive understanding of the laboratory's scope of activities and requirements.

The information shall include as appropriate:

a) the location(s) of the laboratory, operating hours and contact information;

b) the procedures for requesting and the collection of samples;

c) the scope of laboratory activities and time for expected availability of results;

d) the availability of advisory services;

e) requirements for patient consent;

f) factors known to significantly impact the performance of the examination or the interpretation of the results; and

g) the laboratory complaint process.

7.2.3 Requests for providing laboratory examinations

7.2.3.1 General

a) Each request accepted by the laboratory for examination(s) shall be considered an agreement.

b) The examination request shall provide sufficient information to ensure:

— unequivocal traceability of the patient to the request and sample;

— identity and contact information of requester;

— examinations requested;

— informed clinical and technical advice and interpretation can be provided.

c) The examination request information may be provided in a format or medium as deemed appropriate by the laboratory and acceptable to the user.

d) Where necessary for patient care, the laboratory shall communicate with users or their representatives, to clarify the user's request.

7.2.3.2 Oral requests

The laboratory shall have a procedure for managing oral requests for examinations, if applicable, that includes the provision of documented confirmation of the examination request to the laboratory, within a given time.

7.2.4 Primary sample collection and handling

7.2.4.1 General

The laboratory shall have procedures for the collection and handling of primary samples. Information shall be available to those responsible for sample collection.

Any deviation from the established collection procedures shall be clearly recorded. The potential risk and impact on the patient outcome of acceptance or rejection of the sample shall be assessed, recorded and shall be communicated to the appropriate personnel.

The laboratory shall periodically review requirements for sample volume, collection device and preservatives for all sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected, and samples are properly collected to preserve the analyte.

7.2.4.2 Information for pre-collection activities

The laboratory shall provide information and instructions for pre-collection activities with sufficient detail to ensure that the integrity of the sample is not compromised.

This shall include:

a) preparation of the patient (e.g. instructions to caregivers, sample collectors and patients);

b) type and amount of the primary sample to be collected with descriptions of the containers and any necessary additives,and when relevant the order of collecting samples;

c) special timing of collection, where relevant;

d) provision of clinical information relevant to, or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs);

e) sample labelling for unequivocal identification of the patient, as well as source and site of sample, and labelling, when several samples from the same patient are to be collected, including multiple pieces of tissue or slides;

f) the laboratory’s criteria for acceptance and rejection of samples specific to the examinations requested.

7.2.4.3 Patient consent

a) The laboratory shall obtain the informed consent of the patient for all procedures carried out on the patient.

NOTE For most routine laboratory procedures, consent can be inferred when the patient willingly submits to the sample collecting procedure, for example, venipuncture.

b) Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, may need a more detailed explanation and, in some cases, recorded consent.

c) If obtaining consent is not possible in emergency situations, the laboratory may carry out necessary procedures, provided they are in the patient's best interest.

7.2.4.4 Instructions for collection activities

To ensure safe, accurate and clinically appropriate sample collection and pre-examination storage, the laboratory shall provide instructions for:

a) verification of the identity of the patient from whom a primary sample is collected;

b) verification and when relevant, recording that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals];

c) collection of primary samples, with descriptions of the primary sample containers and any necessary additives, as well as the order of sample collection, where relevant;

d) labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;

e) recording of the identity of the person collecting the primary sample and the collection date, and, when relevant, recording of the collection time;

f) requirements for separating or dividing the primary sample when necessary;

g) stabilization and proper storage conditions before collected samples are delivered to the laboratory;

h) safe disposal of materials used in the collection process.

7.2.5 Sample transportation

a) To ensure the timely and safe transportation of samples, the laboratory shall provide instructions for:

   1) packaging of samples for transportation;

   2) ensuring the time between collection and receipt in the laboratory is appropriate for the requested examinations;

   3) maintaining the temperature interval specified for sample collection and handling;

   4) any specific requirements to ensure integrity of samples, e.g. use of designated preservatives.

b) When sample integrity is compromised and the safety of the carrier or the general public is placed at risk, the organization responsible for the the transport of the sample shall be notified immediately and measures taken to mitigate the risk and to avoid recurrence.

c) The laboratory shall establish and periodically evaluate adequacy of sample transportation systems.

7.2.6 Sample receipt

7.2.6.1 Sample receipt procedure

The laboratory shall have a procedure for sample receipt that includes:

a) the unequivocal traceability of samples by request and labelling, to a uniquely identified patient and when applicable the anatomical site;

b) criteria for acceptance and rejection of samples;

c) recording the date and time of receipt of the sample when relevant;

d) recording the identity of the person receiving the sample, when relevant;

e) evaluation of received samples, by authorized personnel, to ensure compliance with acceptability criteria relevant for the requested examination(s);

f) instructions for samples specifically marked as urgent, which include details of special labelling, transport, any rapid processing method, turnaround times, and special reporting criteria to be followed;

g) ensuring that all portions of the sample shall be unequivocally traceable to the original sample.

7.2.6.2 Sample acceptance exceptions

a) The laboratory shall have a process that considers the best interests of the patient in receiving care, when a sample has been compromised due to:

   1) incorrect patient or sample identification,

   2) sample instability due to, for example, delay in transport,

   3) incorrect storage or handling temperature,

   4) inappropriate container(s), and

   5) insufficient sample volume.

b) When a compromised clinically critical or irreplaceable sample is accepted, after consideration of the risk to patient safety, the final report shall indicate the nature of the problem and where applicable, advising caution when interpreting results that can be affected.

7.2.7 Pre-examination handling, preparation, and storage

7.2.7.1 Sample protection

The laboratory shall have procedures and appropriate facilities for securing patient samples, ensuring sample integrity and preventing loss or damage during, handling, preparation and storage.

7.2.7.2 Criteria for additional examination requests

Laboratory procedures shall include time limits for requesting additional examinations on the same sample.

7.2.7.3 Sample stability

Considering the stability of the analyte in a primary sample, the time between sample collection and performing the examination shall be specified and monitored where relevant.

7.3 Examination processes

7.3.1 General

a) The laboratory shall select and use examination methods which have been validated for their intended use to assure the clinical accuracy of the examination for patient testing.

NOTE Preferred methods are those specified in the instructions for use of in vitro diagnostic medical devices or those that have been published in established/authoritative textbooks, peer-reviewed texts, or journals, or in international and national consensus standards or guidelines, or national or regional regulations.

b) The performance specifications for each examination method shall relate to the intended use of that examination and its impact on patient care.

c) All procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and be readily available to personnel (see 8.3).

d) Personnel shall follow established procedures and the identity of persons performing significant activities in examination processes be recorded, including POCT operators.

e) Authorized personnel shall periodically evaluate the examination methods provided by the laboratory to ensure they are clinically appropriate for the requests received.

7.3.2 Verification of examination methods

a) The laboratory shall have a procedure to verify that it can properly perform examination methods before introducing into use, by ensuring that the required performance, as specified by the manufacturer or method, can be achieved.

b) The performance specifications for the examination method confirmed during the verification process shall be those relevant to the intended use of the examination results.

c) The laboratory shall ensure the extent of the verification of examination methods is sufficient to ensure the consistent validity of results pertinent to clinical decision making.

d) Personnel with the appropriate authorization and competence shall review the verification results and record that the results meet the specified requirements.

e) If a method is revised by the issuing body, the laboratory shall repeat verification to the extent necessary.

f) The following records of verification shall be retained:

1) performance specifications to be achieved,

2) results obtained, and

3) a statement of whether the performance specifications were achieved and if not, action taken.

7.3.3 Validation of examination methods

a) The laboratory shall validate examination methods derived from the following sources:

1) laboratory designed or developed methods;

2) methods used outside their originally intended scope (i.e. outside of the manufacturer's instructions for use, or original validated measurement range, third party reagents other than on intended instruments and where no validation data is available);

3) validated methods subsequently modified.

b) The validation shall be as extensive as is necessary and confirm, through the provision of objective evidence in the form of performance specifications, that the specific requirements for the intended use of the examination have been fulfilled. The laboratory shall ensure the extent of validation of an examination method is sufficient to ensure the consistent validity of results pertinent to clinical decision making.

c) Personnel with the appropriate authorization and competence shall review the validation results and record that the results meet the specified requirements.

d) When changes are proposed to a validated examination method, the clinical impact shall be reviewed, and a decision made as to whether to implement the modified method.

e) The the following records of validation shall be retained:

1) the validation procedure used,

2) specific requirements for the intended use,

3) determination of the performance specifications of the method,

4) results obtained, and

5) a statement on the validity of the method, detailing its fitness for the intended use.

7.3.4 Evaluation of measurement uncertainty (MU)

a) All measurements have a certain bias and imprecision. The MU of measured quantity values shall be evaluated and maintained for its intended use, where relevant. The MU shall be compared against performance specifications and documented.

NOTE ISO/TS 20914 provides details on these activities together with examples.

b) MU evaluations shall be regularly reviewed.

c) For examination procedures where estimation of MU is not possible or applicable, the rationale for exclusion from MU estimation shall be documented.

d) MU information shall be made available to laboratory users on request.

e) When users have inquiries on MU, the laboratory's response shall take into account other sources of uncertainty, such as, but not limited to biological variation.

f) If the qualitative result of an examination relies on a test which produces quantitative output data and is specified as positive or negative, based on a threshold, MU in the output quantity shall be estimated using representative positive and negative samples.

g) For examinations with qualitative results, MU in intermediate measurement steps or IQC results which produce quantitative data should also be considered for key (high risk) parts of the process.

h) MU should be taken into consideration when performing verification or validation of a method, when relevant.

7.3.5 Biological reference intervals and clinical decision limits

Biological reference intervals and clinical decision limits, when needed for interpretation of examination results, shall be specified and communicated to users.

a) Biological reference intervals and clinical decision limits shall be specified, and their basis recorded, to reflect the patient population served by the laboratory, while considering the risk to patients.

NOTE Biological reference values, provided by the manufacturer can be used by the laboratory, if the population base of these values is verified and deemed acceptable by the laboratory.

b) Biological reference intervals and clinical decision limits shall be periodically reviewed, and any changes communicated to users.

c) When changes are made to an examination or pre-examination method, the laboratory shall review the impact on associated biological reference intervals and clinical decision limits and communicate to the users when applicable.

d) For examinations that identify presence or absence of a characteristic the biological reference interval is the characteristic to be identified, e.g genetic examinations.

7.3.6 Documentation of examination procedures

a) The laboratory shall document its examination procedures to the extent necessary to ensure the consistent application of its activities and the validity of its results.

b) Procedures shall be written in a language understood by laboratory personnel and be available in appropriate locations.

c) Any abbreviated document content shall correspond to the procedure.

NOTE Working instructions, flow process diagrams or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a full procedure is available for reference and that the summarized information is updated as needed, concurrently with the full procedure update.

d) Information from product instructions for use, that contain sufficient information, can be incorporated into procedures by reference.

e) When the laboratory intends to make a validated change to an examination procedure which could affect interpretation of results, the implications of this shall be explained to users.

f) All documents associated with the performance of examinations, shall be subject to document control (see 8.3).

7.3.7 Ensuring the validity of examination results

7.3.7.1 General

The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends and shifts are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed.

7.3.7.2 Internal quality control (IQC)

a) The laboratory shall have an IQC procedure for monitoring the ongoing validity of examination results, according to specified criteria, that verifies the attainment of the intended quality and ensures consistent validity pertinent to clinical decision making.

1) The intended clinical application of the examination should be considered, as the performance specifications for the same measurand can differ in different clinical settings;

2) The procedure should also allow for the detection of either lot-to-lot reagent or calibrator variation, or both, of the examination method. To enable this, the laboratory procedure should avoid lot change in IQC material on the same day/run as either lot-to-lot reagent or calibrator change, or both;

3) The use of third-party IQC material should be considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer.

NOTE Monitoring of interpretations and opinions can be achieved through regular peer review of examination results.

b) The laboratory shall select IQC material that is fit for its intended purpose. When selecting IQC material factors to be considered shall include:

1) stability with regard to the properties of interest;

2) the matrix is as close as possible to that of patient samples;

3) the IQC material reacts to the examination method in a manner as close as possible to patient samples;

4) the IQC material provides a clinically relevant challenge to the examination method, has concentrations levels at or near clinical decision limits and when possible, covers the measurement range of the examination method.

c) If appropriate IQC material is not available, the laboratory shall consider the use of other methods for IQC. Examples of such other methods may include:

1) trend analysis of patient results, e.g. with moving average of patient results, or percentage of samples with results below or above certain values or associated with a diagnosis;

2) comparison of results for patient samples on a specified schedule to results for patient samples examined by an alternative procedure validated to have its calibration metrologically traceable to the same or higher order references as specified in ISO 17511;

3) retesting of retained patient samples.

d) IQC shall be performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the patient from an erroneous result.

e) The resulting data shall be recorded in such a way that trends and shifts are detectable and, where applicable, statistical techniques shall be applied to review the results.

f) IQC data shall be reviewed with specified acceptability criteria, at regular intervals and in a time frame, which allows a meaningful indication of current performance.

g) The laboratory shall prevent the release of patient results in the event that IQC fails the defined acceptability criteria.

1) When IQC defined acceptability criteria are not fulfilled and indicate results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error has been corrected (see 7.5);

2) The results from patient samples that were examined after the last successful IQC event shall be evaluated.

7.3.7.3 External quality assessment (EQA)

a) The laboratory shall monitor its performance of examination methods, by comparison with results of other laboratories. This includes participation in EQA programmes appropriate to the examinations and interpretation of examination results, including POCT examination methods.

b) The laboratory shall establish a procedure for EQA enrollment, participation and performance for examination methods used, where such programmes are available.

c) EQA samples shall be processed by personnel who routinely perform pre-examination, examination, and post-examination procedures.

d) The EQA programme(s) selected by the laboratory shall, to the extent possible:

1) have the effect of checking pre-examination, examination, and post-examination processes,

2) provide samples that mimic patient samples for clinically relevant challenges,

3) fulfill ISO/IEC 17043 requirements.

e) When selecting EQA programme(s), the laboratory should consider the type of target value offered.

Target values are:

1) independently set by a reference method, or

2) set by overall consensus data, and/or

3) set by method peer group consensus data, or

4) set by a panel of experts.

NOTE 1 When method-independent target values are not available, consensus values can be used to determine whether deviations are laboratory- or method-specific.

NOTE 2 Where commutability of EQA materials can hamper comparison between some methods, it can still be useful for comparisons to be made between methods for which it is commutable, rather than relying only on within-method comparisons.

f) When an EQA programme is either not available, or not considered suitable, the laboratory shall use alternative methodologies to monitor examination method performance. The laboratory shall justify the rationale for the chosen alternative and provide evidence of its effectiveness.

NOTE Acceptable alternatives include:

— participation in sample exchanges with other laboratories;

— interlaboratory comparisons of the results of the examination of identical IQC materials, which evaluates individual laboratory IQC results against pooled results from participants using the same IQC material;

— analysis of a different lot number of the manufacturer's end-user calibrator or the manufacturer's trueness control material;

— analysis of microbiological organisms using split/ blind testing of the same clinical sample by at least two persons, or on at least two analyzers, or by at least two methods;

— analysis of reference materials considered to be commutable with patient samples;

— clinical correlation studies;

— materials from cell and tissue repositories.

g) EQA data shall be reviewed at regular intervals with pre-defined acceptability criteria, in a time frame which allows for a meaningful indication of current performance.

h) Where EQA results fall outside specified acceptability criteria, appropriate action shall be taken (see 8.7), including an assessment of whether the non-conformance is clinically significant as it relates to patient samples.

i) Where it is determined that the impact is clinically significant, a review of patient results that could have been affected and the need for amendment shall be considered and users advised as appropriate.

7.3.7.4 Comparability of examination results

a) When either different methods or equipment, or both, are used for an examination, and/or the examination is performed at a different site, a procedure for establishing the comparability of results for patient samples throughout the clinically significant intervals shall be specified.

NOTE The use of patient samples when comparing different examination methods can avoid the difficulties linked to the limited commutability of IQC materials. When patient samples are either not available or impractical, see all options described for IQC and EQA.

b) The laboratory shall record the results of comparability performed and its acceptability.

c) The laboratory shall periodically review the comparability of results.

d) Where differences are identified, the impact of those differences on biological reference intervals and clinical decision limits shall be evaluated and acted upon.

e) The laboratory shall advise users of any clinically significant differences in comparability of results.

7.4 Post-examination processes

7.4.1 Result reporting

7.4.1.1 General

a) Examination results shall be reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedure. The report shall include all available information necessary for the interpretation of the results.

b) The laboratory shall have a procedure to notify users when examination results are delayed, based on the impact of the delay on the patient.

c) All information associated with issued reports shall be retained in accordance with management system requirements (see 8.4).

NOTE For the purposes of this document, reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.

7.4.1.2 Result review and release

Results shall be reviewed and authorized prior to release.

The laboratory shall ensure that authorized personnel review the results of examinations and evaluate them against IQC and, as appropriate, available clinical information and previous examination results.

Responsibilities and procedures for how examination results are released for reporting, including by whom and to whom, shall be specified.

7.4.1.3 Critical result reports

When examination results fall within established critical decision limits:

a) the user or other authorized person is notified as soon as relevant, based on clinical information available;

b) actions taken are documented, including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication, and any difficulties encountered in notification;

c) the laboratory shall have an escalation procedure for laboratory personnel when a responsible person cannot be contacted.

7.4.1.4 Special considerations for results

a) When agreed with the user, the results may be reported in a simplified way. Any information listed in 7.4.1.6 and 7.4.1.7 that is not reported to the user shall be readily available.

b) When results are transmitted as a preliminary report, the final report shall always be forwarded to the user.

c) Records shall be kept of all results which are provided orally, including details of verification of accuracy of communication, as in 7.4.1.3 b). Such results shall always be followed by a report.

d) Special counselling may be needed for examination results with serious implications for the patient (e.g. for genetic or certain infectious diseases). Laboratory management should ensure that these results are not communicated to the patient without the opportunity for adequate counselling.

e) Results of laboratory examinations that have been anonymized may be used for such purposes as epidemiology, demography, or other statistical analyses, provided that all risks to patient privacy and confidentiality are mitigated and in accordance with any either legal or regulatory requirements, or both.

7.4.1.5 Automated selection, review, release and reporting of results

When the laboratory implements a system for automated selection, review, release and reporting of results, it shall establish a procedure to ensure that:

a) the criteria for automated selection, review and release are specified, approved, readily available and understood by personnel responsible for authorizing the release of results;

b) the criteria are validated and approved before use, regularly reviewed and verified after changes to the reporting system that can affect their proper functioning and place patient care at risk;

c) results selected by an automated reporting system for manual review are identifiable; and as appropriate, date and time of selection and review, as well as identity of the reviewer are retrievable;

d) when necessary, rapid suspension of automated selection, review, release and reporting is applied.

7.4.1.6 Requirements for reports

Each report shall include the following information, unless the laboratory has documented reasons for omitting any items:

a) unique patient identification, the date of primary sample collection and the date of the issue of the report, on each page of the report;

b) identification of the laboratory issuing the report;

c) name or other unique identifier of the user;

d) type of primary sample and any specific information necessary to describe the sample (e.g. source, site of specimen, macroscopic description);

e) clear, unambiguous identification of the examinations performed;

f) identification of the examination method used, where relevant, including, where possible and necessary, harmonized (electronic) identification of the measurand and measurement principle;

NOTE Logical Observation Identifiers Names and Codes (LOINC) and Nomenclature for Properties and Units (NPU, NGC) and SNOMED CT are examples of electronic identification.

g) examination results with, where appropriate, the units of measurement, reported in SI units, units traceable to SI units, or other applicable units;

h) biological reference intervals, clinical decision limits, likelihood ratios or diagrams/nomograms supporting clinical decision limits as necessary;

NOTE Lists or tables of biological reference intervals can be distributed to users of the laboratory.

i) identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;

j) identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed);

k) identification of any results that need to be considered as preliminary;

l) indications of any critical results;

m) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end (e.g. page number to total number of pages).

7.4.1.7 Additional information for reports

a) when necessary for patient care, the time of primary sample collection shall be included;

b) time of report release, if not contained in the report, shall be readily available when needed;

c) reports of results of examinations or parts of examinations performed by a referral laboratory, shall include any information provided by consultants, as well as the name of the laboratory performing the examinations;

d) when applicable, a report shall include interpretation of results and comments on:

   1) sample quality and suitability that can compromise the clinical value of examination results;

   2) discrepancies when examinations are performed by different procedures (e.g. POCT) or in different locations;

   3) possible risk of misinterpretation when different units of measurement are in use regionally or nationally;

   4) result trends or significant changes over time.

7.4.1.8 Amendments to reported results

Procedures for the issue of amended or revised results shall ensure that:

a) the reason for the change is recorded and included in the revised report, when relevant;

b) revised results shall be delivered only in the form of an additional document or data transfer, and clearly identified as having been revised, and the date and patient's identity in the original report shall be indicated;

c) the user is made aware of the revision;

d) when it is necessary to issue a completely new report, this shall be uniquely identified and shall contain a reference and traceability to the original report that it replaces;

e) when the reporting system cannot capture revisions, a record of such shall be kept.

7.4.2 Post-examination handling of samples

The laboratory shall specify the length of time samples are to be retained following examination and the conditions under which samples are to be stored.

The laboratory shall ensure that after the examination, the:

a) patient and source identification of the sample are maintained,

b) suitability of the sample for additional examination is known,

c) sample is stored in a manner that optimally preserves suitability for additional examination,

d) sample can be located and retrieved, and

e) sample is discarded appropriately.

7.5 Nonconforming work

The laboratory shall have a process for when any aspect of its laboratory activities or examination results do not conform to its own procedures, quality specifications, or the user requirements (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The process shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work are specified;

b) immediate and long-term actions are specified and based upon the risk analysis process established by the laboratory;

c) examinations are halted, and reports withheld when there is a risk of harm to patients;

d) an evaluation is made of the clinical significance of the nonconforming work, including an impact analysis on examination results which were or could have been released prior to identification of the nonconformance;

e) a decision is made on the acceptability of the nonconforming work;

f) when necessary, examination results are revised, and the user is notified;

g) the responsibility for authorizing the resumption of work is specified.

The laboratory shall implement corrective action commensurate with the risk of recurrence of the nonconforming work (see 8.7).

The laboratory shall retain records of nonconforming work and actions as specified in 7.5 a) to g).

7.6 Control of data and information management

7.6.1 General

The laboratory shall have access to the data and information needed to perform laboratory activities.

NOTE 1 In this document, "laboratory information systems" includes the management of data and information contained in both computer and non-computerized systems. Some of the requirements can be more applicable to computer systems than to non-computerized systems.

NOTE 2 Risks associated with computerized laboratory information systems are discussed in ISO 22367:2020, A.13.

NOTE 3 The information security controls, strategies and best practices to ensure the preservation of confidentiality, integrity and availability of information, are listed in ISO/IEC 27001:2013, Annex A Reference control objectives and controls.

7.6.2 Authorities and responsibilities for information management

The laboratory shall ensure that the authorities and responsibilities for the management of the information systems are specified, including the maintenance and modification to the information systems that can affect patient care. The laboratory is ultimately responsible for the laboratory information systems.

7.6.3 Information systems management

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:

a) validated by the supplier and verified for functionality by the laboratory before introduction. Any changes to the system, including laboratory software configuration or modifications to commercial off-the shelf software, shall be authorized, documented and validated before implementation;

NOTE 1 Validation and verification include, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as laboratory equipment, hospital patient administration systems and systems in primary care.

NOTE 2 Commercial off-the-shelf software used within its designed application range can be considered sufficiently validated (e.g. word processing and spreadsheet software, and quality management software programs).

b) documented, and the documentation readily available to authorized users , including that for day to day functioning of the system;

c) implemented taking cybersecurity into account, to protect the system from unauthorized access and safeguarded data against tampering or loss;

d) operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

e) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions; and

f) calculations and data transfers shall be checked in an appropriate and systematic manner.

7.6.4 Downtime plans

The laboratory shall have planned processes to maintain operations in the event of failure or during downtime in information systems that affects the laboratory's activities. This includes automated selection and reporting of results.

7.6.5 Off site management

When the laboratory information system(s) are managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

7.7 Complaints

7.7.1 Process

The laboratory shall have a process for handling complaints that shall include at least the following:

a) a description of the process for receiving, substantiating and investigating the complaint, and deciding what actions shall be taken in response;

NOTE The resolution of complaints can lead to implementation of corrective actions (see 8.7) or be used as input into the improvement process (see 8.6).

b) tracking and recording the complaint, including the actions undertaken to resolve it;

c) ensuring appropriate action is taken.

A description of the process for handling complaints shall be publicly available.

7.7.2 Receipt of complaint

a) Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that the laboratory is responsible for and, if so, shall resolve the complaint. (see 8.7.1).

b) The laboratory receiving the complaint shall be responsible for gathering all necessary information to determine whether the complaint is substantiated.

c) Whenever possible the laboratory shall acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports.

7.7.3 Resolution of complaint

Investigation and resolution of complaints shall not result in any discriminatory actions.

The resolution of complaints shall be made by, or reviewed and approved by, persons not involved in the subject of the complaint in question. Where resources do not permit this, any alternative approach shall not compromise impartiality.

7.8 Continuity and emergency preparedness planning

The laboratory shall ensure that risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, have been identified, and a coordinated strategy exists that involves plans, procedures, and technical measures to enable continued operations after a disruption.

Plans shall be periodically tested and the planned response capability exercised, where practicable.

The laboratory shall:

a) establish a planned response to emergency situations, taking into account the needs and capabilities of all relevant laboratory personnel;

b) provide information and training as appropriate to relevant laboratory personnel;

c) respond to actual emergency situations;

d) take action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential impact.

NOTE CLSI GP36-A [35] provides more details.

8 Management system requirements

8.1 General requirements

8.1.1 General

The laboratory shall establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of this document.

As a minimum, the management system of the laboratory shall include the following:

— responsibilities (8.1)

— objectives and policies (8.2)

— documented information (8.2, 8.3 and 8.4)

— actions to address risks and opportunities for improvement (8.5)

— continual improvement (8.6)

— corrective actions (8.7)

— evaluations and internal audits (8.8)

— management reviews (8.9)

8.1.2 Fulfilment of management system requirements

The laboratory may meet 8.1.1 by establishing, implementing, and maintaining a quality management system (e.g. in accordance with the requirements of ISO 9001) (see Annex B.1). This quality management system shall support and demonstrate the consistent fulfilment of the requirements of Clauses 4 to 7 and the requirements specified in 8.2 to 8.9.

8.1.3 Management system awareness

The laboratory shall ensure that persons doing work under the laboratory's control are aware of:

a) relevant objectives and policies;

b) their contribution to the effectiveness of the management system, including the benefits of improved performance;

c) the implications of not conforming with the management system requirements.

8.2 Management system documentation

8.2.1 General

Laboratory management shall establish, document, and maintain objectives and policies for the fulfilment of the purposes of this document and shall ensure that the objectives and policies are acknowledged and implemented at all levels of the laboratory organization.

NOTE The management system documents can, but are not required to, be contained in a quality manual.

8.2.2 Competence and quality

The objectives and policies shall address the competence, quality and consistent operation of the laboratory.

8.2.3 Evidence of commitment

Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

8.2.4 Documentation

All documentation, processes, systems, and records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.

8.2.5 Personnel access

All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 Control of management system documents

8.3.1 General

The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.

NOTE In this context, "document" can be policy statements, procedures and related job aids, flow charts, instructions for use, specifications, manufacturer's instructions, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software documentation, drawings, plans, agreements, and documents of external origin such as laws, regulations, standards and textbooks from which examination methods are taken, documents describing personnel qualifications (such as job descriptions), etc. These can be in any form or type of medium, such as hard copy or digital.

8.3.2 Control of documents

The laboratory shall ensure that:

a) documents are uniquely identified;

b) documents are approved for adequacy before issue by authorized personnel who have the expertise and competence to determine adequacy;

c) documents are periodically reviewed and updated as necessary;

d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

e) changes and the current revision status of documents are identified;

f) documents are protected from unauthorized changes and any deletion or removal;

g) documents are protected from unauthorized access;

h) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose;

i) at least one paper or electronic copy of each obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements.

8.4 Control of records

8.4.1 Creation of records

The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements of this document.

Records shall be created at the time each activity that affects the quality of an examination is performed.

NOTE Records can be in any form or type of medium.

8.4.2 Amendment of records

The laboratory shall ensure that amendments to records can be traced to previous versions or to original observations. Both the original and amended data and files shall be kept, including the date and where relevant, the time, of alteration, an indication of the altered aspects and the personnel making the alterations.

8.4.3 Retention of records

a) The laboratory shall implement the procedures needed for the identification, storage, protection from unauthorized access and changes, back-up, archive, retrieval, retention time, and disposal of its records.

b) The retention times for records shall be specified.

NOTE 1 In addition to requirements, retention times can be chosen based on identified risks.

c) Reported examination results shall be retrievable for as long as necessary or as required.

d) All records shall be accessible throughout the entire retention period, legible in whichever medium the laboratory keeps records, and available for laboratory management review (see 8.9).

NOTE 2 Legal liability concerns regarding certain types of procedures (e.g. histology examinations, genetic examinations, pediatric examinations) can require the retention of certain records for much longer times than for other records.

8.5 Actions to address risks and opportunities for improvement

8.5.1 Identification of risks and opportunities for improvement

The laboratory shall identify risks and opportunities for improvement associated with the laboratory activities to:

a) prevent or reduce, undesired impacts and potential failures in the laboratory activities;

b) achieve improvement, by acting on opportunities;

c) assure that the management system achieves its intended results;

d) mitigate risks to patient care;

e) help achieve the purpose and objectives of the laboratory.

8.5.2 Acting on risks and opportunities for improvement

The laboratory shall prioritize and act on identified risks. Actions taken to address risks shall be proportional to the potential impact on laboratory examination results, as well as patient and personnel safety.

The laboratory shall record decisions made and actions taken on risks and opportunities.

The laboratory shall integrate and implement actions on identified risks and improvement opportunities into its management system and evaluate their effectiveness.

NOTE 1 Options to address risks can include identifying and avoiding threats, eliminating a risk source, reducing the likelihood or consequences of a risk, transferring a risk, taking a risk in order to pursue an opportunity for improvement, or retaining risk by informed decision.

NOTE 2 Although this document requires that the laboratory identifies and addresses risks, there is no requirement for any particular risk management method. Laboratories can use ISO 22367 and ISO 35001 for guidance.

NOTE 3 Opportunities for improvement can lead to expanding the scope of the laboratory activities, applying new technology, or creating other possibilities to fulfil patient and user needs.

8.6 Improvement

8.6.1 Continual improvement

a) The laboratory shall continually improve the effectiveness of the management system, including the pre-examination, examination and post-examination processes as stated in the objectives and policies.

b) The laboratory shall identify and select opportunities for improvement and develop, document, and implement any necessary actions. Improvement activities shall be directed at areas of highest priority based on risk assessments and the opportunities identified (see 8.5).

NOTE Opportunities for improvement can be identified through risk assessment, use of the policies, review of the operational procedures, overall objectives, external evaluation reports, internal audit findings, complaints, corrective actions, management reviews, suggestions from personnel, suggestions or feedback from patients and users, analysis of data and EQA results.

c) The laboratory shall evaluate the effectiveness of the actions taken.

d) Laboratory management shall ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care.

e) Laboratory management shall communicate to personnel its improvement plans and related goals.

8.6.2 Laboratory patients, user, and personnel feedback

The laboratory shall seek feedback from its patients, users, and personnel. The feedback shall be analyzed and used to improve the management system, laboratory activities and services to users.

Records of feedback shall be maintained including the actions taken. Communication shall be provided to personnel on actions taken arising from their feedback.

8.7 Nonconformities and corrective actions

8.7.1 Actions when nonconformity occurs

When a nonconformity occurs, the laboratory shall:

a) react to the nonconformity and, as applicable:

   1) take immediate action to control and correct the nonconformity;

   2) address the consequences, with a particular focus on patient safety including escalation to the appropriate person;

b) determine the cause(s) of the nonconformity;

c) evaluate the need for corrective action to eliminate the cause(s) of the nonconformity, in order to reduce the likelihood of recurrence or occurrence elsewhere, by:

   1) reviewing and analyzing the nonconformity;

   2) determining whether similar nonconformities exist, or could potentially occur;

   3) assessing the potential risk(s) and effect(s) if the nonconformity recurs;

d) implement any action needed;

e) review and evaluate the effectiveness of any corrective action taken;

f) update risks and opportunities for improvement, as needed;

g) make changes to the management system, if necessary.

8.7.2 Corrective action effectiveness

Corrective actions shall be appropriate to the effects of the nonconformities encountered and shall mitigate the identified cause(s).

8.7.3 Records of nonconformities and corrective actions

The laboratory shall retain records as evidence of the:

a) nature of the nonconformities, cause(s) and any subsequent actions taken, and

b) evaluation of the effectiveness of any corrective action.

8.8 Evaluations

8.8.1 General

The laboratory shall conduct evaluations at planned intervals to demonstrate that the management, support, and pre-examination, examination, and post-examination processes meet the needs and requirements of patients and laboratory users, and to ensure conformity to the requirements of this document.

8.8.2 Quality indicators

The process of monitoring quality indicators [see 5.5 d)] shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of monitoring. The indicators shall be periodically reviewed, to ensure continued appropriateness.

8.8.3 Internal audits

8.8.3.1 The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:

a) conforms to the laboratory's own requirements for its management system, including the laboratory activities,

b) conforms to the requirements of this document, and

c) is effectively implemented and maintained.

8.8.3.2 The laboratory shall plan, establish, implement and maintain an internal audit programme that includes:

a) priority given to risk to patients from laboratory activities;

b) a schedule which takes into consideration identified risks; the outcomes of both external evaluations and previous internal audits; the occurrence of nonconformities, incidents, and complaints; and changes affecting the laboratory activities;

c) specified audit objectives, criteria and scope for each audit;

d) selection of auditors who are trained, qualified and authorized to assess the performance of the laboratory's management system, and, whenever resources permit, are independent of the activity to be audited;

e) ensuring objectivity and impartiality of the audit process;

f) ensuring that the results of the audits are reported to relevant personnel;

g) implementation of appropriate correction and corrective actions without undue delay;

h) retention of records as evidence of the implementation of the audit programme and audit results.

NOTE ISO 19011 provides guidance for auditing management systems.

8.9 Management reviews

8.9.1 General

Laboratory management shall review its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

8.9.2 Review input

The inputs to management review shall be recorded and shall include evaluations of at least the following:

a) status of actions from previous management reviews, internal and external changes to the management system, changes in the volume and type of laboratory activities and adequacy of resources;

b) fulfilment of objectives and suitability of policies and procedures;

c) outcomes of recent evaluations, process monitoring using quality indicators, internal audits, analysis of non-conformities, corrective actions, assessments by external bodies;

d) patient, user and personnel feedback and complaints;

e) quality assurance of result validity;

f) effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement;

g) performance of external providers;

h) results of participation in interlaboratory comparison programmes;

i) evaluation of POCT activities;

j) other relevant factors, such as monitoring activities and training.

8.9.3 Review output

The output from the management review shall be a record of decisions and actions related to at least:

a) the effectiveness of the management system and its processes;

b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;

c) provision of required resources;

d) improvement of services to patients and users;

e) any need for change.

Laboratory management shall ensure that actions arising from management review are completed within a specified time frame.

Conclusions and actions arising from management reviews shall be communicated to laboratory personnel.

Annex A
(normative)

Additional requirements for Point-of-Care Testing (POCT)

A.1 General

This annex describes the additional requirements for the laboratory with regard to POCT that are distinct from, or in addition to, those outlined in the main text. These requirements specify the laboratory's responsibilities towards organizations, departments and their personnel with regards to selection of devices, training of personnel, quality assurance, and the management review of the complete POCT process.

Patient self-testing is excluded, but elements of this document may be applicable.

NOTE 1 ISO/TS 22583 provides guidance for non-laboratory supported services.

NOTE 2 ISO 15190 and ISO 22367 provide guidance on safety and risk aspects of POCT.

A.2 Governance of POCT

The governing body of the organization shall be ultimately responsible for ensuring that appropriate processes are in place to monitor the accuracy and quality of POCT conducted within the healthcare organization.

Service agreements between the laboratory and all locations using laboratory supported POCT shall ensure that respective responsibilities and authorities are defined and communicated within the organization.

These agreements shall have clinical approval, and where applicable, financial approval.

These service agreements shall be with individual POCT areas and may be managed via a health professional grouping (e.g. medical advisory committee).

A.3 Quality assurance programme

The laboratory shall appoint a person with appropriate training and experience to be responsible for POCT quality, which includes review of and conformity with the requirements of this document as related to POCT.

A.4 Training programme

A person with appropriate training and experience shall be appointed to manage training and competency assessment of personnel performing POCT.

The trainer shall develop, implement, and maintain an appropriate theoretical and practical training programme for all POCT personnel.

Annex B
(informative)

Comparison between ISO 9001:2015 and ISO 15189:20—

ISO 9001 is part of the ISO 9000 family of quality management standards and specifies requirements for a quality management system. Table B.1 illustrates the conceptual relationship between this document and ISO 9001:2015.

The format of this edition of this document more closely resembles that of ISO/IEC 17025:2017, which is used as the model for the structure of this document with specific adjustment for medical laboratories. Table B.2 shows the comparison between these two documents.

Table B.1 — Comparison between ISO 9001: 2015 and this document

ISO 9001:2015	**ISO 15189:20—** (this document)
1 Scope	1 Scope
2. Normative references	2 Normative references
3 Terms and definitions	3 Terms and definitions
4 Context of the organization	4 General requirements
4.1 Understanding the organization and its context	4.1 Impartiality
4.2 Understanding the needs and expectations of interested parties	4.2 Confidentiality
	4.2.1 Management of information
4.3 Determining the scope of the quality management system	4.2.2 Release of information
	4.2.3 Personnel responsibility
4.4 Quality management system and its processes	4.3 Requirements regarding patients
	5.1 Legal entity
	8 Management system requirements
	8.1 General requirements
	8.1.1 General
5 Leadership	5 Structural and governance requirements
5.1 Leadership and commitment	5.2 Laboratory director
5.1.1 General	5.2.1 Laboratory director competence
5.1.2 Customer focus	5.2.2 Laboratory director responsibilities
5.2 Policy	5.2.3 Delegation of duties
5.2.1 Establishing the quality policy	5.3 Laboratory activities
5.2.2 Communicating the quality policy	5.3.1 General
5.3 Organizational roles, responsibilities and authorities	5.3.2 Conformance with requirements
	5.3.3 Advisory activities
	5.4 Structure and authority
	5.4.1 General
	5.4.2 Quality management

Table B.1 *(continued)*

ISO 9001:2015	ISO 15189:20— (this document)
6 Planning 6.1 Actions to address risks and opportunities 6.2 Quality objectives and planning to achieve them 6.3 Planning of changes	8.5 Actions to address risks and opportunities for improvement 8.5.1 Identification of risks and opportunities for improvement 8.5.2 Acting on risks and opportunities for improvement 5.5 Objectives and policies 5.6 Risk management 7.8 Continuity and emergency preparedness planning
7 Support 7.1 Resources 7.1.1 General 7.1.2 People 7.1.3 Infrastructure 7.1.4 Environment for the operation of processes 7.1.5 Monitoring and measuring resources 7.1.6 Organizational knowledge	6 Resource requirements 6.1 General 6.2 Personnel 6.2.1 General 6.2.2 Competence requirements 6.2.3 Authorization 6.2.4 Continuing education and professional development 6.2.5 Personnel records 6.3 Facilities and environmental conditions 6.3.1 General 6.3.2 Facility controls 6.3.3 Storage facilities 6.3.4 Personnel facilities 6.3.5 Sample collection facilities
7.2 Competence	6.2.2 Competence requirements
7.3 Awareness	8.1.3 Management system awareness
7.4 Communication	7.6 Control of data and information management 7.6.1 General 7.6.2 Authorities and responsibilities for information management 7.6.3 Information systems management 7.6.4 Downtime plans 7.6.5 Off site management

Table B.1 *(continued)*

ISO 9001:2015	ISO 15189:20— (this document)
7.5 Documented information	8.2 Management system documentation
7.5.1 General	8.2.1 General
7.5.2 Creating and updating	8.2.2 Competence and quality
7.5.3 Control of documented information	8.2.3 Evidence of commitment
	8.2.4 Documentation
	8.2.5 Personnel access
	8.3 Control of management system documents
	8.3.1 General
	8.3.2 Control of documents
	8.4 Control of records
	8.4.1 Creation of records
	8.4.2 Amendment of records
	8.4.3 Retention of records
8 Operation	6.4 Equipment
8.1 Operational planning and control	6.4.1 General
	6.4.2 Equipment requirements
	6.4.3 Equipment acceptance procedure
	6.4.4 Equipment instructions for use
	6.4.5 Equipment maintenance and repair
	6.4.6 Equipment adverse incident reporting
	6.4.7 Equipment records
	6.5 Equipment calibration and metrological traceability
	6.5.1 General
	6.5.2 Equipment calibration
	6.5.3 Metrological traceability of measurement results
8.2 Requirements for products and services	6.6 Reagents and Consumables
8.2.1 Customer communication	6.6.1 Reagents and consumables – General
8.2.2 Determining the requirements for products and services	6.6.2 Reagents and consumables – Receipt and storage
	6.6.3 Reagents and consumables – Acceptance testing
8.2.3 Review of the requirements for products and services	6.6.4 Reagents and consumables – Inventory management
8.2.4 Changes to requirements for products and services	6.6.5 Reagents and consumables – Instructions for use
	6.6.6 Reagents and consumables – Adverse incident reporting
	6.6.7 Reagents and consumables – Records
	6.8 Externally provided products and services
	6.8.1 General
	6.8.2 Referral laboratories and consultants
	6.8.3 Review and approval of externally provided products and services

Table B.1 *(continued)*

ISO 9001:2015	ISO 15189:20— (this document)
8.3 Design and development of products and services	7 Process requirements
8.3.1 General	7.1 General
8.3.2 Design and development planning	7.2 Pre-examination processes
8.3.3 Design and development inputs	7.2.1 General
8.3.4 Design and development controls	7.2.2 Laboratory information for patients and users
8.3.5 Design and development outputs	7.2.3 Requests for providing laboratory examinations
8.3.6 Design and development changes	7.2.3.1 General
	7.2.3.2 Oral requests
	7.2.4 Primary sample collection and handling
	7.2.4.1 General
	7.2.4.2 Information for pre-collection activities
	7.2.4.3 Patient consent
	7.2.4.4 Instructions for collection activities
	7.2.5 Sample transportation
	7.2.6 Sample receipt
	7.2.6.1 Sample receipt procedure
	7.2.6.2 Sample receipt exceptions
	7.2.7 Pre-examination handling, preparation and storage
	7.2.7.1 Sample protection
	7.2.7.2 Criteria for additional examination requests
	7.2.7.3 Sample stability
8.4 Control of externally provided processes, products and services	6.7 Service agreements
	6.8 Externally provided products and services
8.4.1 General	6.8.1 General
8.4.2 Type and extent of control	6.8.2 Referral laboratories and consultants
8.4.3 Information for external providers	6.8.3 Review and approval of externally provided products and services
8.5 Production and service provision	7.3 Examination processes
8.5.1 Control of production and service provision	7.3.1 General
8.5.2 Identification and traceability	7.3.2 Verification of examination methods
8.5.3 Property belonging to customers or external providers	7.3.3 Validation of examination methods
	7.3.5 Biological reference intervals and clinical decision limits
8.5.4 Preservation	
8.5.5 Post-delivery activities	7.3.6 Documentation of examination procedures
8.5.6 Control of changes	7.3.2 Post-examination handling of samples

Table B.1 *(continued)*

ISO 9001:2015	ISO 15189:20— (this document)
8.6 Release of products and services	7.4 Post-examination processes
	7.4.1 Result reporting
	7.4.1.1 General
	7.4.1.2 Result review and release
	7.4.1.3 Critical result reports
	7.4.1.4 Special considerations for result reporting
	7.4.1.5 Automated selection, review, release and reporting of results
	7.4.1.6 Requirements for reports
	7.4.1.7 Additonal information for reports
	7.4.1.8 Amendments to reported results
8.7 Control of nonconforming outputs	7.5 Nonconforming work
9 Performance evaluation	7.3.4 Evaluation of measurement uncertainty
9.1 Monitoring, measurement, analysis and evaluation	7.3.7 Ensuring the validity of examination results
9.1.1 General	7.3.7.1 General
9.1.2 Customer satisfaction	7.3.7.2 Internal quality control (IQC)
9.1.3 Analysis and evaluation	7.3.7.3 External quality assessment (EQA)
	7.3.7.4 Comparability of examination results
9.2 Internal audit	8.8 Evaluations
	8.8.1 General
	8.8.2 Quality indicators
	8.8.3 Internal audits
9.3 Management review	8.9 Management reviews
9.3.1 General	8.9.1 General
9.3.2 Management review inputs	8.9.2 Review input
9.3.3 Management review outputs	8.9.3 Review output
10 Improvement	8.6 Improvement
10.1 General	8.6.2 Laboratory patients, user and personnel feedback
10.2 Nonconformity and corrective action	7.5 Nonconforming work
	7.7 Complaints
	7.7.1 Process
	7.7.2 Receipt of complaint
	7.7.3 Resolution of complaint
	8.7 Nonconformities and corrective actions
	8.7.1 Actions when nonconformity occurs
	8.7.2 Corrective action effectiveness
	8.7.3 Records of nonconformities and corrective actions
10.3 Continual improvement	8.6.1 Continual improvement

Table B.2 — Comparison between ISO/IEC 17025:2017 and this document

ISO/IEC 17025:2017	ISO 15189:20— (this document)
1. Scope	1 Scope
2. Normative references	2 Normative references
3. Terms and definitions	3 Terms and definitions
4. General requirements	4 General requirements
4.1 Impartiality	4.1 Impartiality
4.2 Confidentiality	4.2 Confidentiality 4.2.1 Management of information 4.2.2 Release of information 4.2.3 Personnel responsibility 4.3 Requirements regarding patients
5. Structural requirements	5 Structural and governance requirements 5.1 Legal Entity 5.2 Laboratory director 5.2.1 Laboratory director competence 5.2.2 Laboratory director responsibilities 5.2.3 Delegation of duties 5.3 Laboratory activities 5.3.1 Scope of laboratory activities 5.3.2 Conformance with requirements 5.3.3 Advisory activities 5.4 Structure and authority 5.4.1 General 5.4.2 Quality management 5.5 Objectives and policies 5.6 Risk management
6. Resource requirements 6.1 General	6 Resource requirements 6.1 General
6.2 Personnel	6.2 Personnel 6.2.1 General 6.2.2 Competence requirements 6.2.3 Authorization 6.2.4 Continuing education and professional development 6.2.5 Personnel records
6.3 Facilities and environmental conditions	6.3 Facilities and environmental conditions 6.3.1 General 6.3.2 Facility controls 6.3.3 Storage facilities 6.3.4 Personnel facilities 6.3.5 Sample collection facilities

Table B.2 *(continued)*

ISO/IEC 17025:2017	ISO 15189:20— (this document)
6.4 Equipment	6.4 Equipment 6.4.1 General 6.4.2 Equipment requirements 6.4.3 Equipment acceptance procedure 6.4.4 Equipment instructions for use 6.4.5 Equipment maintenance and repair 6.4.6 Equipment adverse incident reporting 6.4.7 Equipment records
6.5 Metrological traceability	6.5 Equipment calibration and metrological traceability 6.5.1 General 6.5.2 Equipment calibration 6.5.3 Metrological traceability of measurement results
6.6 Externally provided products and services	6.6 Reagents and Consumables 6.6.1 General 6.6.2 Reagents and consumables – Receipt and storage 6.6.3 Reagents and consumables – Acceptance testing 6.6.4 Reagents and consumables – Inventory management 6.6.5 Reagents and consumables – Instructions for use 6.6.6 Reagents and consumables – Adverse incident reporting 6.6.7 Reagents and consumables – Records 6.7 Service agreements 6.7.1 Agreements with laboratory users 6.7.2 Agreements with POCT users 6.8 Externally provided products and services 6.8.1 General 6.8.2 Referral laboratories and consultants 6.8.3 Review and approval of externally provided products and services
7. Process requirements	7 Process requirements

Table B.2 *(continued)*

ISO/IEC 17025:2017	ISO 15189:20— (this document)
7.1 Review of requests, tenders and contracts	7.1 General 7.2 Pre-examination processes 7.2.1 General 7.2.2 Laboratory information for patients and users 7.2.3 Requests for providing laboratory examinations 7.2.3.1 General 7.2.3.2 Oral requests 7.2.4 Primary sample collection and handling 7.2.4.1 General 7.2.4.2 Information for pre-collection activities 7.2.4.3 Patient consent 7.2.4.4 Instructions for collection activities 7.2.5 Sample transportation 7.2.6 Sample receipt 7.2.6.1 Sample receipt procedure 7.2.6.2 Sample receipt exceptions 7.2.7 Pre-examination handling, preparation and storage 7.2.7.1 Sample protection 7.2.7.2 Criteria for additional examination requests 7.2.7.3 Sample stability
7.2 Selection, verification and validation of methods	7.3 Examination processes
7.2.1 Selection and verification of methods	7.3.1 General 7.3.2 Verification of examination methods
7.2.2 Validation of methods	7.3.3 Validation of examination methods
	7.3.5 Biological reference intervals and clinical decision limits
7.3 Sampling	See 7.2
7.4 Handling of test or calibration items	7.4.2 Post-examination handling of samples
7.5 Technical records	7.2.4.4 e) Instructions for collection activities 7.3.1.d) Examination processes - General 7.4.1.8 Amendments to reported results
7.6 Evaluation of measurement uncertainty	7.3.4 Evaluation of measurement uncertainty
7.7 Ensuring the validity of results	7.3.7 Ensuring the validity of examination results 7.3.7.1 General 7.3.7.2 Internal quality control (IQC) 7.3.7.3 External quality assessment (EQA) 7.3.7.4 Comparability of examination results

Table B.2 *(continued)*

ISO/IEC 17025:2017	ISO 15189:20— (this document)
7.8 Reporting of results	7.4 Post-examination processes 7.4.1 Result reporting 7.4.1.1 General 7.4.1.2 Result review and release 7.4.1.5 Automated selection, review, release and reporting of results
7.8.1 General	7.4.1.1 General
7.8.2 Common requirements for reports (test, calibration or sampling) 7.8.3 Specific requirements for test reports 7.8.4 Specific requirements for calibration certificates 7.8.5 Reporting sampling – specific requirements 7.8.6 Reporting statements of conformity 7.8.7 Reporting opinions and interpretations 7.8.8 Amendments to reports	7.4.1.6 Requirements for reports 7.4.1.7 Additonal information for reports 7.4.1.3 Critical result reports 7.4.1.4 Special considerations for result reporting 7.4.1.8 Amendments to reported results
7.9 Complaints	7.7 Complaints 7.7.1 Process 7.7.2 Receipt of complaint 7.7.3 Resolution of complaint
7.10 Nonconforming work	7.5 Nonconforming work
7.11 Control of data and information management	7.6 Control of data and information management 7.6.1 General 7.6.2 Authorities and responsibilities for information management 7.6.3 Information systems management 7.6.4 Downtime plans 7.6.5 Off site management 7.8 Continuity and emergency preparedness planning
8. Management system requirements	8 Management system requirements
8.1 Options	8.1 General requirements
8.1.1 General	8.1.1 General
8.1.2 Option A	8.1.2 Fulfilment of management system requirements
8.1.3 Option B	8.1.3 Management system awareness
8.2 Management system documentation (Option A)	8.2 Management system documentation 8.2.1 General 8.2.2 Competence and quality 8.2.3 Evidence of commitment 8.2.4 Documentation 8.2.5 Personnel access
8.3 Control of management system documents (Option A)	8.3 Control of management system documents 8.3.1 General 8.3.2 Control of documents

Table B.2 *(continued)*

ISO/IEC 17025:2017	ISO 15189:20— (this document)
8.4 Control of records (Option A)	8.4 Control of records 8.4.1 Creation of records 8.4.2 Amendment of records 8.4.3 Retention of records
8.5 Actions to address risks and opportunities (Option A)	8.5 Actions to address risks and opportunities for improvement 8.5.1 Identification of risks and opportunities for improvement 8.5.2 Acting on risks and opportunities for improvement
8.6 Improvement (Option A)	8.6 Improvement 8.6.1 Continual improvement 8.6.2 Laboratory patients, user and personnel feedback
8.7 Corrective actions (Option A)	8.7 Nonconformities and corrective action 8.7.1 Actions when nonconformity occurs 8.7.2 Corrective action effectiveness 8.7.3 Records of nonconformities and corrective actions
8.8 Internal audits (Option A)	8.8 Evaluations 8.8.1 General 8.8.2 Quality indicators 8.8.3 Internal audits
8.9 Management reviews (Option A)	8.9 Management reviews 8.9.1 General 8.9.2 Review input 8.9.3 Review output

Annex C
(informative)

Comparison between ISO 15189:2012 and ISO 15189:20— (this document)

Table C.1 — Comparison between ISO 15189:2012 and ISO 15189:20— (this document)

ISO 15189:2012	ISO 15189:20— (this document)
Foreword	Foreword
Introduction	Introduction
1 Scope	1 Scope
2 Normative references	2 Normative references
3 Terms and definitions	3 Terms and definitions
4 Management requirements 4.1 Organization and management responsibility 4.1.1 Organization 4.1.1.1 General 4.1.1.3 Ethical conduct [includes confidentiality in (e)]	4 General requirements 4.1 Impartiality 4.2 Confidentiality 4.2.1 Management of information 4.2.2 Release of information 4.2.3 Personnel responsibility
4.1.1.2 Legal entity 4.1.1.4 Laboratory director 4.1.2 Management responsibility 4.1.2.1 Management commitment	5 Structural and governance requirements 5.1 Legal Entity 5.2 Laboratory director 5.2.1 Laboratory director competence 5.2.2 Laboratory director responsibilities 5.2.3 Delegation of duties 5.3 Laboratory activities 5.3.1 General 5.3.2 Conformance with requirements 5.4.1 General 5.4.2 Quality management 8.2.3 Evidence of commitment
4.1.2.2 Needs of users	4.3 Requirements regarding patients 5.3.3 Advisory activities
4.1.2.3 Quality policy	5.5 Objectives and policies
4.1.2.4 Quality objectives and planning	5.5 Objectives and policies
4.1.2.5 Responsibility, authority, and interrelationships	5.4 Structure and authority
4.1.2.6 Communication	5.4.1 General b)
4.1.2.7 Quality manager	5.4.2 Quality management
4.2 Quality management system	8 Management system requirements

Table C.1 *(continued)*

ISO 15189:2012	ISO 15189:20— (this document)
4.2.1 General requirements	8.1 General requirements and options
	8.1.1 General
	8.1.2 Fulfilment of management requirements
	8.1.3 Management system awareness
4.2.2 Documentation requirements	8.2 Management system documentation
4.2.2.1General	8.2.1 General
4.2.2.2 Quality manual	*[optional, no longer a requirement, see 8.2.1 NOTE]*
4.3 Document control	8.3 Control of management system documents
	8.3.1 General
	8.3.2 Management of documents
4.4 Service agreements	6.7 Service agreements
4.4.1 Establishment of service agreements	
4.4.2 Review of service agreements	
4.5 Examination by referral laboratories	6.8.2 Referral laboratories and consultants
4.5.1 Selecting and evaluating referral laboratories and consultants	
4.5.2 Provision of examination results	
4.6 External services and supplies	6.8 Externally provided products and services
	6.8.3 Review and approval of externally provided products and services
4.7 Advisory services	5.3.3 Advisory activities
4.8 Resolution of complaints	7.7 Complaints
	7.7.1 Process
	7.7.2 Receipt of complaint
	7.7.3 Resolution of complaint
4.9 Identification and control of nonconformities	7.5 Nonconforming work
4.10 Corrective action	8.7 Corrective action
	8.7.1 Actions when nonconformity occurs
	8.7.2 Corrective action effectiveness
	8.7.3 Records of nonconformities
4.11 Preventive action	8.5 Actions to address risks and opportunities for improvement
	8.5.1 Identification of risks and opportunities for improvement
	8.5.2 Acting on risks and opportunities for improvement
4.12 Continual improvement	8.6 Improvement
	8.6.1 Continual improvement
	8.6.2 Laboratory patients, user and personnel feedback

Table C.1 *(continued)*

ISO 15189:2012	ISO 15189:20— (this document)
4.13 Control of records	8.4 Control of records 8.4.1 Creation of records 8.4.2 Amendment of records 8.4.3 Retention of records
4.14 Evaluation and audits 4.14.1 General	8.8 Evaluations 8.8.1 General 8.8.2 Quality indicators 8.8.3 Internal audits
4.14.2 Periodic review of requests, and suitability of procedures, and sample requirements	7.2.3 Requests for providing laboratory examinations 7.2.3.1 General 7.3 Examination processes 7.3.1 General e)
4.14.3 Assessment of user feedback 4.14.4 Staff suggestions	8.6.2 Laboratory user and personnel feedback
4.14.5 Internal audit	8.8.3 Internal audits
4.14.6 Risk management	5.6 Risk management 8.5 Actions to address risks and opportunities for improvement 8.5.1 Identifications of risks and actions taken 8.5.2 Acting on risks and opportunities for improvement
4.14.7 Quality indicators	5.5 Objectives and policies d) 8.8.2 Quality indicators
4.14.8 Reviews by external organizations	8.7 Nonconformities and corrective action
4.15 Management review	8.9 Management review
4.15.1 General	8.9.1 General
4.15.2 Review input	8.9.2 Review input
4.15.3 Review activities	[*not specified*]
4.15.4 Review output	8.9.3 Review output
5 Technical requirements	6 Resource requirements

Table C.1 *(continued)*

ISO 15189:2012	**ISO 15189:20—** (this document)
5.1 Personnel	6.2 Personnel
5.1.1 General	6.2.1 General
5.1.2 Personnel qualifications	6.2.2 Competence requirements
5.1.3 Job descriptions	6.2.3 Authorization
5.1.4 Personnel introduction to the organizational environment	6.2.4 Continuing education and professional development
5.1.5 Training	6.2.5 Personnel records
5.1.6 Competence assessment	
5.1.7 Review of staff performance	
5.1.8 Continuing education and professional development	
5.1.9 Personnel records	
5.2 Accommodation and environmental conditions	6.3 Facilities and environmental conditions
5.2.1 General	6.3.1 General
5.2.2 Laboratory and office facilities	6.3.3 Storage facilities
5.2.3 Storage facilities	6.3.4 Personnel facilities
5.2.4 Staff facilities	6.3.5 Sample collection facilities
5.2.5 Patient sample collection facilities	6.3.2 Facility controls
5.2.6 Facility maintenance and environmental conditions	

Table C.1 *(continued)*

ISO 15189:2012	ISO 15189:20— (this document)
5.3 Laboratory equipment, reagents, and consumables	6.4 Equipment and 6.6 Reagents and consumables
5.3.1 Equipment	6.4 Equipment
5.3.1.1 General	6.4.1 General
5.3.1.2 Equipment acceptance testing	6.4.2 Equipment requirements
5.3.1.3 Equipment instructions for use	6.4.3 Equipment acceptance procedure
5.3.1.4 Equipment calibration and metrological traceability	6.4.4 Equipment instructions for use
5.3.1.5 Equipment maintenance and repair	6.4.5 Equipment maintenance and repair
5.3.1.6 Equipment adverse incident reporting	6.4.6 Equipment adverse incident reporting
5.3.1.7 Equipment records	6.4.7 Equipment records
	6.5 Equipment calibration and metrological traceability
	6.5.1 General
	6.5.2 Equipment calibration
	6.5.3 Metrological traceability of measurement results
5.3.2 Reagents and consumables	6.6 Reagents and consumables
5.3.2.1 General	6.6.1 Reagents and consumables – General
5.3.2.2 Reagents and consumables – reception and storage	6.6.2 Reagents and consumables – Receipt and storage
5.3.2.3 Reagents and consumables – acceptance testing	6.6.3 Reagents and consumables – Acceptance testing
5.3.2.4 Reagents and consumables – inventory management	6.6.4 Reagents and consumables – Inventory management
5.3.2.5 Reagents and consumables – instructions for use	6.6.5 Reagents and consumables – Instructions for use
5.3.2.6 Reagents and consumables – adverse incident reporting	6.6.6 Reagents and consumables – Adverse incident reporting
5.3.2.7 Reagents and consumables – records	6.6.7 Reagents and consumables – Records

Table C.1 *(continued)*

ISO 15189:2012	ISO 15189:20— (this document)
5.4 Pre-examination processes	7.2 Pre-examination processes
5.4.1 General	7.2.1 General
5.4.2 Information for patients and users	7.2.2 Laboratory information for patients and users
5.4.3 Request form information	7.2.3 Requests for providing laboratory examinations
5.4.4 Primary sample collection and handling	7.2.3.1 General
5.4.4.1 General	7.2.3.2 Oral requests
5.4.4.2 Instructions for pre-collection activities	7.2.4 Primary sample collection and handling
5.4.4.3 Instructions for collection activities	7.2.4.1 General
5.4.5 Sample transportation	7.2.4.2 Information for pre-collection activities
5.4.6 Sample reception	7.2.4.3 Patient consent
5.4.7 Pre-examination handling, preparation, and storage	7.2.4.4 Instructions for collection activities
	7.2.5 Sample transportation
	7.2.6 Sample receipt
	7.2.6.1 Sample receipt procedure
	7.2.6.2 Sample receipt exceptions
	7.2.7 Pre-examination handling, preparation and storage
	7.2.7.1 Sample protection
	7.2.7.2 Criteria for additional examination requests
	7.2.7.3 Sample stability
5.5 Examination processes	7.3 Examination processes
5.5.1 Selection, verification, and validation of examination procedures	7.3.1 General
5.5.1.2 Verification of examination procedures	7.3.2 Verification of examination procedures
5.5.1.3 Validation of examination procedures	7.3.3 Validation of examination methods
5.5.1.4 Measurement uncertainty of measured quantity values	7.3.4 Evaluation of measurement uncertainty
5.5.2 Biological reference intervals or clinical decision values	7.3.5 Biological reference intervals and clinical decision limits
5.5.3 Documentation of examination procedures	7.3.6 Documentation of examination procedures
5.6 Ensuring quality of examination results	7.3.7 Ensuring the validity of examination results
5.6.1 General	7.3.7.1 General
5.6.2 Quality control	7.3.7.2 Internal quality control (IQC)
5.6.2.1 General	
5.6.2.2 Quality control materials	
5.6.2.3 Quality control data	

Table C.1 *(continued)*

ISO 15189:2012	**ISO 15189:20—** (this document)
5.6.3 Interlaboratory comparisons 5.6.3.1 Participation 5.6.3.2 Alternative approaches 5.6.3.3 Analysis of interlaboratory comparison samples 5.6.3.4 Evaluation of laboratory performance	7.3.7.3 External quality assessment (EQA)
5.6.4 Comparability of examination results	7.3.7.4 Comparability of examination results

Table C.1 *(continued)*

ISO 15189:2012	ISO 15189:20— (this document)
5.7 Post-examination processes	7.4 Post-examination processes
5.7.1 Review of results	7.4.1.2 Result review and release 7.4.1.3 Critical result reports
5.7.2 Storage, retention, and disposal of clinical samples	7.4.2 Post-examination handling of samples
5.8 Reporting of results 5.8.1 General 5.8.2 Report attributes 5.8.3 Report content	7.4.1 Result reporting 7.4.1.1 General 7.4.1.4 Special considerationsn for result reports 7.4.1.6 Requirements for reports 7.4.1.7 Additional information for reports
5.9 Release of results	7.4.1.3 Result review and release
5.9.1 General	7.4.1.1 General
5.9.2 Automated selection and reporting of results	7.4.1.5 Automated selection, review, release and reporting of results
5.9.3 Revised reports	7.4.1.8 Amendments to results reported
5.10 Laboratory information management 5.10.1 General 5.10.2 Authorities and responsibilities 5.10.3 Information system management	7.6 Control of data and information management 7.6.1 General 7.6.2 Authorities and responsibilities for information management 7.6.3 Information systems management 7.6.4 Downtime plans 7.6.5 Off site management 7.8 Continuity and emergency preparedness planning
Not specified	Annex A Additional requirements for Point-of-Care Testing
Annex A Table A.1 Correlation between ISO 9001:2008 and this document	Annex B Table B.1 Comparison between ISO 9001:2015 and this document
Annex A Table A.2 Correlation between and ISO/IEC 17025:2005 and this document	Annex B Table B.2 Comparison between ISO/IEC 17025:2017 and this document
Annex B Table B.1 Comparison of ISO 15189:2007 to ISO 15189:2012	Annex C Table C.1 Comparison between ISO 15189:2012 and ISO 15189:20—

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[2] ISO 9001:2015, *Quality management systems — Requirements*

[3] ISO 15190, *Medical laboratories — Requirements for safety*

[4] ISO 15194, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation*

[5] ISO 15198:2004, *Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer*

[6] ISO/IEC 17011, *Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies*

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