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Medical laboratories — Particular requirements for quality and competence

Laboratoires d'analyses de biologie médicale — Exigences particulières concernant la qualité et la compétence

[Revision of second edition (ISO 15189:2007)]

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ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 15189 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*, Subcommittee SC , .

This second/third/... edition cancels and replaces the first/second/... edition (), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.

This third edition cancels and replaces the second edition (ISO 15189:2007). A correlation between the second and third editions of this Standard is provided as Annex C.

The third edition continues the alignment established with the drafting of the second edition with the second edition of ISO/IEC 17025.

Introduction

This International Standard, based upon ISO/IEC 17025 and ISO 9001, provides requirements for competence and quality that are particular to medical laboratories[1]. It is acknowledged that a country could have its own specific regulations or requirements applicable to some or all its professional personnel and their activities and responsibilities in this domain.

Medical laboratory services are essential to patient care and therefore have to be available to meet the needs of all patients and the clinical personnel responsible for the care of those patients. Such services include arrangements for examination request, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent validation, interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work.

Whenever allowed by national, regional, or local regulations and requirements, it is desirable that medical laboratory services include the examination of patients in consultation cases, and that those services actively participate in the prevention of disease in addition to diagnosis and patient management. Each laboratory ought also to provide suitable educational and scientific opportunities for professional staff working with it.

While this International Standard is intended for use throughout the currently recognised disciplines of medical laboratory services, those working in other services and disciplines such as clinical physiology, medical imaging and medical physics could also find it useful and appropriate. In addition, bodies engaged in the recognition of the competence of medical laboratories will be able to use this International Standard as the basis for their activities. If a laboratory seeks accreditation, it should select an accrediting body which operates to ISO/IEC 17011 and which takes into account the particular requirements of medical laboratories.

This International Standard is not intended to be used for the purposes of certification, however:

A medical laboratory's fulfilment of the requirements of ISO 15189:2007 means the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid results. The management system requirements in ISO 15189 (Section 4) are written in a language relevant to a medical laboratories operations and meet the principles of ISO 9001:2008 Quality management systems- Requirements and are aligned with its pertinent requirements (Joint IAF-ILAC-ISO Communiqué issued in 2009)

The correlation between the clauses and subclauses of this third edition of ISO 15189 and those of ISO 9001:2008 and of ISO/IEC 17025:2005 is detailed in Annex A of this International Standard.

Environmental issues associated with medical laboratory activity are generally addressed throughout this Standard, with specific references in Sections 5.2.6, 5.3, 5.4 and 5.7.

1) In other languages, these laboratories can be designated by the equivalent of the English term "clinical laboratories."

Medical laboratories — Particular requirements for quality and competence

1 Scope

1.1 This International Standard specifies the requirements for quality and competence in medical laboratories.

1.2 This International Standard is for use by medical laboratories in developing their quality management systems and assessing their own competence. Laboratory customers, regulating authorities, and accreditation bodies may also use it for confirming or recognizing the competence of medical laboratories.

This International Standard is not intended to be used as the basis for certification of laboratories.

1.3 International, national, or regional regulations or requirements may apply to specific topics covered in this International Standard and shall be followed when applicable.

2 Normative references

The following referenced documents are indispensable for the application 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/IEC80000 (all parts), *Quantities and units*

ISO 9001:2008, *Quality management systems — Requirements*

ISO/IEC 17025:2005, *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 9000, ISO/IEC Guide 2, ISO 17000, ISO/IEC Guide 99:2007 and the following apply.

3.1
accreditation
procedure by which an authoritative body gives formal recognition that an organisation or person is competent to carry out specific tasks

3.2
automated selection and reporting of results
process by which patient examination results are sent to the laboratory information system and compared with laboratory-defined acceptance criteria, and in which results that fall within the defined criteria are automatically included in patient report formats without any additional intervention

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

EXAMPLE The central 95% biological reference interval for sodium ion concentration values in serum from a population of healthy male and female adults is 135 mmol/l to 145 mmol/l.

NOTE 1 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 A reference interval can depend upon the type of primary samples and the examination procedure used.

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

NOTE 4 Terms such as “normal range”, “normal values”, and “clinical range” are ambiguous and therefore discouraged.

3.4
detection limit
limit of detection
measured quantity value, obtained by a given measurement procedure, for which the probability of falsely claiming the absence of a component in a material is β, given a probability α of falsely claiming its presence

NOTE 1 IUPAC recommends default values for α and β equal to 0.05.

NOTE 2 The abbreviation LOD is sometimes used and is discouraged.

NOTE 3 The term ‘analytical sensitivity’ ” is sometimes used to mean detection limit, but such usage is now discouraged

[ISO/IEC Guide 99:2007, definition 4.18]

3.5
competence
demonstrated ability to apply knowledge and skills

NOTE The concept of competence is defined in a generic sense in this International Standard. The word usage can be more specific in other ISO documents.

[ISO 9000:2005, definition 3.1.6]

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

NOTE 1 In some disciplines (e.g., microbiology) an examination is the total activity of a number of tests, observations or measurements.

NOTE 2 Laboratory examinations that determine the value of a property are called quantitative examinations; those that determine the characteristics of a property are called qualitative examinations.

NOTE 3 In clinical chemistry, laboratory examinations are called assays or tests.

3.7
laboratory director
competent person(s) with responsibility for, and authority over, a laboratory

NOTE 1 For the purposes of this International Standard, the person or persons referred to are designated collectively as *laboratory director*.

NOTE 2 National, regional and local regulations may apply with regard to qualifications and training

3.8
laboratory management
person(s) who direct and manage the activities of a laboratory

NOTE The term 'laboratory management' is synonymous with the term 'top management' in ISO 9000:2005.

3.9
measurand
quantity intended to be measured

NOTE 1 The specification of a measurand in laboratory medicine requires knowledge of the kind of quantity (e.g., mass concentration), a description of the matrix carrying the quantity (e.g., blood plasma), and the chemical entities involved (e.g., the analyte).

EXAMPLES In "mass of protein in 24-hour urine", "protein" is the analyte and "mass" is the property. In "concentration of glucose in plasma", "glucose" is the analyte and "concentration" is the property. In both cases, the full phrase designates the measurand

NOTE 2 The measurand can be a biological activity.

NOTE 3 In chemistry, "analyte", or the name of a substance or compound, are terms sometimes used for "measurand". This usage is erroneous because these terms do not refer to quantities.

[ISO/IEC Guide 99:2007, definition 2.3]

3.10
measurement
process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity

NOTE 1 Measurement implies comparison of quantities or counting of entities.

NOTE 2 Measurement presupposes description of the quantity commensurate with the intended use of the measurement result, of a measurement procedure, and of a calibrated measuring system operating according to the specified measurement.

NOTE 3 The operations can be performed automatically.

[ISO/IEC Guide 99:2007, definition 2.1]

3.11
measurement accuracy
accuracy of measurement
accuracy
closeness of the agreement between a measured quantity value, and a true quantity value of the measurand
NOTE 1 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 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 'Measurement accuracy' is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measurand

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

3.12
measurement precision
precision
closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions

NOTE 1 Measurement precision is usually expressed numerically by measures of imprecision, such as standard deviation, variance, or coefficient of variation under the specified conditions of measurement.

NOTE 2 The specified conditions can be, for example, repeatability conditions of measurement, intermediate precision conditions of measurement, or reproducibility conditions of measurement (see ISO 5725-5 [78]).

NOTE 3 Measurement precision is used to define measurement repeatability, intermediate measurement precision and measurement reproducibility.

NOTE 4 Replicate measurements means measurements that are obtained in a manner not influenced by a previous measurement on the same or similar sample.

[ISO/IEC Guide 99:2007, definition 2.15]

3.13
measurement trueness
trueness of measurement
trueness
closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value

NOTE 1 Measurement trueness is not a quantity and cannot be expressed numerically, but measures for closeness of agreement are given in ISO 5725-3.

NOTE 2 Measurement trueness is inversely related to systematic measurement error (measurement bias or bias is an estimate of systematic measurement error), but is not related to random error measurement.

NOTE 3 The term “measurement trueness” should not be used for “measurement accuracy” and vice versa.

[ISO/IEC Guide 99:2007, definition 2.14]

3.14
measurement uncertainty
uncertainty of measurement
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

NOTE 1 Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but instead associated measurement uncertainty components are incorporated.

NOTE 2 The parameter cannot be negative. The parameter might be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

NOTE 3 The standard measurement uncertainty that is obtained from the measurement results of the input quantities in a measurement model is called combined standard measurement uncertainty. The product of a combined standard measurement uncertainty and a coverage factor larger than the number one is called the expanded measurement uncertainty in VIM 3rd edition, 2.35, overall uncertainty by the BIPM Working Group on the Statement of Uncertainties, and simply uncertainty in IEC documents.

NOTE 4 The minimum measurement uncertainty resulting from the finite amount of detail in the definition of a measurand is called “definitional uncertainty” in ISO/IEC Guide 99:2007, 2.27. In the GUM and in IEC 60359[83], the concept is called intrinsic uncertainty.

NOTE 5 Measurement uncertainty comprises, in general, many components. Some of these can be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which can be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information (see ISO/IEC Guide 99:2007, 2.26, Note 3).

NOTE 6 The statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination is called an uncertainty budget. An uncertainty budget typically includes the measurement model, estimates and measurement uncertainties of the quantities in the measurement model, covariances, type of applied probability density functions, degrees of freedom, type of evaluation of measurement uncertainty, and any coverage factor (see ISO/IEC Guide 99:2007, 2.33).

NOTE 7 In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

[ISO/IEC Guide 99:2007, definition 2.26]

3.15
medical laboratory
clinical laboratory
laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation

NOTE These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or micro-organisms. Facilities which only collect or prepare samples, or act as a mailing or distribution centre, are not considered to be medical or clinical laboratories.

3.16
metrological comparability of measurement results
comparability of measurement results, for quantities of a given kind, that are metrologically traceable to the same reference

EXAMPLE Measurement results from two different commercial clinical chemistry measuring systems are comparable when they are both metrologically traceable to the same primary reference standard, for example, a Certified Reference Material for the mass concentration of glucose.

NOTE 1 For this definition, a reference can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard

NOTE 2 Metrological comparability of measurement results does not necessitate that the measured quantity values and associated measurement uncertainties compared are of the same order of magnitude.

[ISO/IEC Guide 99:2007, definition 2.46]

3.17
metrological traceability
property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

NOTE 1 For this definition, a reference can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.

NOTE 2 Metrological traceability requires an established calibration hierarchy. The sequence of measurement standards and calibrations which is used to relate a measurement result to a reference is called a traceability chain. A metrological traceability chain is used to establish metrological traceability of a measurement result, including calibrator values.

NOTE 3 Specification of the stated reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.

NOTE 4 For measurements with more than one input quantity in the measurement model, each of the quantity values should itself be metrologically traceable and the calibration hierarchy involved can form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity should be commensurate with its relative contribution to the measurement result.

NOTE 5 A comparison between two measurement standards can be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

NOTE 6 The abbreviated term traceability is sometimes used to mean metrological traceability as well as other concepts, such as sample traceability or document traceability or instrument traceability or material traceability, where the history (trace) of an item is meant. Therefore, the full term of metrological traceability is preferred if there is any chance of confusion.

[ISO/IEC Guide 99:2007, definition 2.41]

3.18
nonconformity
nonfulfillment of a requirement. Other terms frequently used include: accident, adverse event, error, event, incident, and occurrence.

[ISO 9000:2005, definition 3.6.2].

3.19
post-examination processes
postanalytical phase
processes following the examination including review of results; retention and storage of clinical material; sample (and waste) disposal; and formatting, releasing, reporting and retention of examination results.

3.20
pre-examination processes
preanalytical phase
processes that start, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s), and transportation to and within the laboratory, and ending when the analytical examination begins

3.21
primary sample
specimen
discrete portion of a body fluid or tissue taken for examination, study or analysis of one or more quantities or properties to determine the character of the whole

NOTE 1 Global Harmonisation Task Force (GHTF) uses the term specimen in its harmonized guidance documents to mean a sample of biological origin intended for examination by a medical laboratory.

NOTE 2 In some ISO and CEN documents, a specimen is defined as "a biological sample derived from the human body."

NOTE 3 In some countries, the term "specimen" is used instead of primary sample (or a subsample of it), which is the sample prepared for sending to, or as received by, the laboratory and which is intended for examination.

3.22
procedure
specified way to carry out an activity or a process

[ISO 9000:2005, definition 3.4.5]

3.23
process
set of interrelated or interacting activities which transform inputs into outputs

NOTE Inputs to a process are generally outputs of other processes.

[ISO 9000:2005, definition 3.4.1]

3.24
quality
degree to which a set of inherent characteristics fulfils requirements

NOTE 1 The term “quality” can be used with adjectives such as poor, good or excellent.

NOTE 2 “Inherent”, as opposed to “assigned”, means existing in something, especially as a permanent characteristic.

[ISO 9000:2005, definition 3.1.1]

3.25
quality indicator
a measure of the degree to which a set of inherent characteristics fulfils requirements

NOTE 1 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 Quality indicators can measure how well an organisation meets the needs and requirements of users and the quality of all operational processes

EXAMPLE If the *requirement* is to receive all urine samples in the laboratory uncontaminated. The number of contaminated urine samples received as a % of all urine samples received (*the inherent characteristic of the process*) is a measure of the quality of the process.

3.26
quality management system
management system to direct and control an organisation with regard to quality

NOTE The term "quality management system" referred to in this definition relates to general management activities, the provision and management of resources, the pre examination, examination and post examination processes and evaluation and continual improvement .

[ISO 9000:2005, definition 3.2.3]

3.27
quality policy
overall intentions and direction of a laboratory related to quality as formally expressed by laboratory management

NOTE Generally the quality policy is consistent with the overall policy of an organisation and provides a framework for setting quality objectives

NOTE Adapted from ISO 9000:2005, definition 3.2.4

3.28
quality objective
something sought, or aimed for, related to quality

NOTE 1 Quality objectives are generally based on the laboratory's quality policy

NOTE 2 Quality objectives are generally specified for relevant functions and levels in the organisation