FINAL
DRAFT

INTERNATIONAL
STANDARD

**ISO/FDIS
15189**

ISO/TC **212**

Secretariat: **ANSI**

Voting begins on:
2012-08-09

Voting terminates on:
2012-10-09

Medical laboratories — Requirements for quality and competence

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

Please see the administrative notes on page iii

Reference number
ISO/FDIS 15189:2012(E)

ISO/CEN PARALLEL PROCESSING

This final 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. The final draft was established on the basis of comments received during a parallel enquiry on the draft.

This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

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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 a n 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*.

This third edition cancels and replaces the second edition (ISO 15189:2007), which has been technically revised.

A correlation between the second and third editions of this International Standard is provided as Annex B. The third edition continues the alignment established in ISO/IEC 17025:2005.

Introduction

This International Standard, based upon ISO/IEC 17025 and ISO 9001, specifies 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 requests, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent 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 should also provide suitable educational and scientific opportunities for professional staff working with it.

While this International Standard is intended for use throughout the currently recognized 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 in accordance with 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 this International Standard 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 Clause 4 are written in a language relevant to a medical laboratory's 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 International Standard, with specific references in 5.2.2, 5.2.6, 5.3, 5.4, 5.5.1.4 and 5.7.

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

Medical laboratories — Requirements for quality and competence

1 Scope

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

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.

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

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

ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC Guide 2, *Standardization and related activities — General vocabulary*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC Guide 2 and ISO/IEC Guide 99 and the following apply.

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

3.2
alert interval
critical interval
interval of examination results for an alert (critical) test that indicates an immediate risk to the patient of injury or death

NOTE 1 The interval may be open ended, where only a threshold is defined.

NOTE 2 The laboratory determines the appropriate list of alert tests for its patients and users.

3.3
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

3.4
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 presumed 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.

3.5
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
documented procedure
specified way to carry out an activity or a process that is documented, implemented and maintained

NOTE 1 The requirement for a documented procedure may be addressed in a single document or by more than one document.

NOTE 2 Adapted from ISO 9000:2005, definition 3.4.5.

3.7
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 a value of a property are called quantitative examinations; those that determine the characteristics of a property are called qualitative examinations.

NOTE 3 Laboratory examinations are also often called assays or tests.

3.8
interlaboratory comparison
organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

[ISO/IEC 17043:2010, definition 3.4]

3.9
laboratory director
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.

3.10
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.

3.11
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 microorganisms.

3.12
nonconformity
nonfulfillment of a requirement

[ISO 9000:2005, definition 3.6.2].

NOTE Other terms frequently used include: accident, adverse event, error, event, incident, and occurrence.

3.13
point-of-care testing
POCT
near-patient testing
testing performed near or at the site of a patient, with the result leading to possible change in the care of the patient

[ISO 22870:2006, definition 3.1]

3.14
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

3.15
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 end when the analytical examination begins

3.16
primary sample
specimen
discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for 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.

3.17
process
set of interrelated or interacting activities which transform inputs into outputs

NOTE 1 Inputs to a process are generally outputs of other processes.

NOTE 2 Adapted from ISO 9000:2005, definition 3.4.1.

3.18
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]

3.19
quality indicator
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 organization 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.

3.20
quality management system
management system to direct and control an organization with regard to quality

NOTE 1 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.

NOTE 2 Adapted from ISO 9000:2005, definition 3.2.3.

3.21
quality policy
overall intentions and direction of a laboratory related to quality as formally expressed by laboratory management

NOTE 1 Generally the quality policy is consistent with the overall policy of an organization and provides a framework for setting quality objectives.

NOTE 2 Adapted from ISO 9000:2005, definition 3.2.4

3.22
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 organization.

NOTE 3 Adapted from ISO 9000:2005, definition 3.2.5.

3.23
referral laboratory
external laboratory to which a sample is submitted for examination

NOTE A referral laboratory is one to which laboratory management chooses to submit a sample or sub-sample for examination or when routine examinations cannot be carried out. This differs from a laboratory that may include public health, forensics, tumour registry, or a central (parent) facility to which submission of samples is required by structure or regulation.

3.24
sample
one or more parts taken from a primary sample

EXAMPLE A volume of serum taken from a larger volume of serum.

3.25
turnaround time
elapsed time between two specified points through pre-examination, examination and post-examination processes

3.26
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

NOTE 1 The term "validated" is used to designate the corresponding status.

NOTE 2 Adapted from ISO 9000:2005, definition 3.8.5.

3.27
verification
confirmation, through provision of objective evidence, that specified requirements have been fulfilled

NOTE 1 The term "verified" is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as

— performing alternative calculations,

— comparing a new design specification with a similar proven design specification,

— undertaking tests and demonstrations, and

— reviewing documents prior to issue.

[ISO 9000:2005, definition 3.8.4]

4 Management requirements

4.1 Organization and management responsibility

4.1.1 Organization

4.1.1.1 General

The medical laboratory (hereinafter referred to as 'the laboratory') shall meet the requirements of this International Standard when carrying out work at its permanent facilities, or in associated or mobile facilities.

4.1.1.2 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.

4.1.1.3 Ethical conduct

Laboratory management shall have arrangements in place to ensure the following:

a) there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity;

b) management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work;

c) where potential conflicts in competing interests may exist, they shall be openly and appropriately declared;

d) there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements;

e) confidentiality of information is maintained.

4.1.1.4 Laboratory director

The laboratory shall be directed by a person or persons with the competence and delegated responsibility for the services provided.

The responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory.

The laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory.

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

The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfil the requirements of this International Standard.

The laboratory director (or designate/s) shall:

a) provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities;

b) relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required;

c) ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users;

d) ensure the implementation of the quality policy;

e) implement a safe laboratory environment in compliance with good practice and applicable requirements;

f) serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate;

g) ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;

h) select and monitor laboratory suppliers;

i) select referral laboratories and monitor the quality of their service (see also 4.5);

j) provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;

k) define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;

NOTE This may be done within the context of the various quality improvement committees of the parent organization, as appropriate, where applicable.

l) monitor all work performed in the laboratory to determine that clinically relevant information is being generated;

m) address any complaint, request or suggestion from staff and/or users of laboratory services (see also 4.8, 4.14.3 and 4.14.4);

n) design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable;

NOTE Contingency plans should be periodically tested.

o) plan and direct research and development, where appropriate.

4.1.2 Management responsibility

4.1.2.1 Management commitment

Laboratory management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:

a) communicating to laboratory personnel the importance of meeting the needs and requirements of users (see 4.1.2.2) as well as regulatory and accreditation requirements;

b) establishing the quality policy (see 4.1.2.3);

c) ensuring that quality objectives and planning are established (see 4.1.2.4);

d) defining responsibilities, authorities and interrelationships of all personnel (see 4.1.2.5);

e) establishing communication processes (see 4.1.2.6);

f) appointing a quality manager, however named (see 4.1.2.7);

g) conducting management reviews (see 4.15);

h) ensuring that all personnel are competent to perform their assigned activities (see 5.1.6);

i) ensuring availability of adequate resources (see 5.2 and 5.3) to enable the proper conduct of pre-examination, examination and post-examination activities (see 5.4, 5,5, and 5.7).

4.1.2.2 Needs of users

Laboratory management shall ensure that laboratory services, including appropriate advisory and interpretative services, meet the needs of patients and those using the laboratory services. (see also 4.4 and 4.14.3).

4.1.2.3 Quality policy

Laboratory management shall define the intent of its quality management system in a quality policy. Laboratory management shall ensure that the quality policy:

a) is appropriate to the purpose of the organization;

b) includes a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard, and continual improvement of the quality of laboratory services;

c) provides a framework for establishing and reviewing quality objectives;

d) is communicated and understood within the organization;

e) is reviewed for continuing suitability.

