INTERNATIONAL STANDARD

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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

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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*.

This corrected version of ISO 15189:2003 incorporates the following corrections:

- in Clause 2, the normative reference ISO/IEC Guide 2 has been added;
- in 3.2, the bibliographic reference in Note 2 has been changed;
- to the definition of 3.12;
- to 5.4.1 b), 5.4.13 and 5.5.3;
- to 5.8.3, whose note is joined by a second note transposed from 5.8.4, becoming Notes 1 and 2 to 5.8.3, respectively;
- the bibliographic references in C.1 and C.9;
- correction of minor typographical errors.

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 requisition, 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 regulations, 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 recognized disciplines of medical laboratory services, those working in other services and disciplines 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. For it is surely preferable that a laboratory seeking accreditation select an accrediting body which operates to appropriate international standards and which takes into account the particular requirements of medical laboratories.

During the preparation of this International Standard, ISO 9001 and ISO/IEC 17025 were under revision, and it was therefore impossible to present this International Standard in a format and style which corresponded precisely to those of either of the aforementioned documents. The correlation that nevertheless does exist between the clauses and subclauses of this first edition of ISO 15189 and those of ISO 9001:2000 and of ISO/IEC 17025:1999 is detailed in Annex A of this International Standard.

A second edition of this International Standard, aimed at more closely aligning it with a second edition of ISO/IEC 17025 and with ISO 9001:2000, is anticipated. Moreover, terminology has changed within the disciplines concerned and this has created differences of expression such that certain terms (e.g. “sensitivity”) now have entirely different meanings between disciplines. Furthermore, it is planned to replace yet another document related to this International Standard, ISO/IEC Guide 58, by ISO/IEC 17011. The second edition of ISO 15189 is to take all this into account.

1) In the French language, these laboratories are termed “laboratoires d’analyses de biologie médicale”, while in other languages they might be referred to using a term equivalent to the English “clinical laboratories”.

Medical laboratories — Particular requirements for quality and competence

1 Scope

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

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 Guide 2, *Standardization and related activities — General vocabulary*

ISO 31 (all parts), *Quantities and units*

ISO/IEC Guide 43-1, *Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes*

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 9001:2000, *Quality management systems — Requirements*

ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*

International vocabulary of basic and general terms in metrology (VIM). BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC Guide 2, VIM and the following apply.

3.1
accuracy of measurement
closeness of the agreement between the result of a measurement and a true value of the measurand

[VIM: 1993, definition 3.5]

3.2
biological reference interval
reference interval
central 95 % interval of the distribution of reference values

NOTE 1 This supersedes such incorrectly used terms as “normal range”.

NOTE 2 It is an arbitrary but common convention to define the reference interval as the central 95 % interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases. See [11].

3.3
examination
set of operations having the object of determining the value or characteristics of a property

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

3.4
laboratory capability
physical, environmental and information resources, personnel, skills and expertise available for the examinations in question

NOTE A review of laboratory capability could include results of earlier participation in interlaboratory comparisons or external quality assessment schemes or the running of trial examination programmes, or all these, in order to demonstrate uncertainties of measurement, limits of detection, etc.

3.5
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.

3.6
laboratory management
person(s) who manage the activities of a laboratory headed by a laboratory director

3.7
measurement
set of operations having the object of determining a value of a quantity

[VIM:1993, definition 2.1]

3.8
medical laboratory
clinical laboratory
laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, 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 specimens, or act as a mailing or distribution centre, are not considered to be medical or clinical laboratories, although they may be part of a larger laboratory network or system.

3.9
post-examination procedures
postanalytical phase
processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples of the examinations

3.10
pre-examination procedures
preanalytical phase
steps starting, in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins

3.11
primary sample
specimen
set of one or more parts initially taken from a system

NOTE 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.

3.12
quantity
attribute of a phenomenon, body or substance that may be distinguished qualitatively and determined quantitatively

[VIM:1993, definition 1.1]

3.13
referral laboratory
external laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure and report

3.14
sample
one or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or its production

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

3.15
traceability
property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties

[VIM:1993, definition 6.10]

3.16
trueness of measurement
closeness of agreement between the average value obtained from a large series of results of measurements and a true value

NOTE Adapted from ISO 3534-1:1993, definition 3.12

3.17
uncertainty of measurement
parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

[VIM:1993, definition 3.9]

4 Management requirements

4.1 Organization and management

4.1.1 The medical laboratory or the organization of which the laboratory is a part shall be legally identifiable.

4.1.2 Medical laboratory services, including appropriate interpretation and advisory services, shall be designed to meet the needs of patients and all clinical personnel responsible for patient care.

4.1.3 The medical laboratory (hereafter referred to as "the laboratory") shall meet the relevant requirements of this International Standard when carrying out work in its permanent facilities, or at sites other than the permanent facilities for which it is responsible.

4.1.4 The responsibilities of personnel in the laboratory with an involvement or influence on the examination of primary samples shall be defined in order to identify conflicts of interest. Financial or political considerations (e.g. inducements) should not influence testing.

4.1.5 Laboratory management shall have responsibility for the design, implementation, maintenance and improvement of the quality management system. This shall include the following:

a) management support of all laboratory personnel by providing them with the appropriate authority and resources to carry out their duties;

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

c) policies and procedures for ensuring the protection of confidential information (see Annex C);

d) policies and procedures for avoiding involvement in any activities that would diminish confidence in its competence, impartiality, judgement, or operational integrity;

e) the organizational and management structure of the laboratory and its relationship to any other organization with which it may be associated;

f) specified responsibilities, authority, and interrelationships of all personnel;

g) adequate training of all staff and supervision appropriate to their experience and level of responsibility by competent persons conversant with the purpose, procedures and assessment of results of the relevant examination procedures;

h) technical management which has overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory procedures;

i) appointment of a quality manager (however named) with delegated responsibility and authority to oversee compliance with the requirements of the quality management system, who shall report directly to the level of laboratory management at which decisions are made on laboratory policy and resources;

j) appointment of deputies for all key functions, while recognizing that in smaller laboratories individuals can have more than one function and that it could be impractical to appoint deputies for every function.

4.2 Quality management system

4.2.1 Policies, processes, programmes, procedures and instructions shall be documented and communicated to all relevant personnel. The management shall ensure that the documents are understood and implemented.

4.2.2 The quality management system shall include, but not be limited to, internal quality control and participation in organized interlaboratory comparisons such as external quality assessment schemes.

4.2.3 Policies and objectives of the quality management system shall be defined in a quality policy statement under the authority of the laboratory director and documented in a quality manual. This policy shall be readily available to appropriate personnel, shall be concise and shall include the following:

a) the scope of service the laboratory intends to provide;

b) the laboratory management's statement of the laboratory's standard of service;

c) the objectives of the quality management system;

d) a requirement that all personnel concerned with examination activities familiarize themselves with the quality documentation and implement the policies and procedures at all times;

e) the laboratory's commitment to good professional practice, the quality of its examinations, and compliance with the quality management system;

f) the laboratory management's commitment to compliance with this International Standard.

4.2.4 A quality manual shall describe the quality management system and the structure of the documentation used in the quality management system. The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation in the quality management system. The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.

All personnel shall be instructed on the use and application of the quality manual and all referenced documents, and of the requirements for their implementation. The quality manual shall be kept up to date under the authority and responsibility of [see 4.1.5 i)] an individual appointed to be responsible for quality by the laboratory management.

The table of contents of a quality manual for a medical laboratory might be as follows.

a) Introduction.

b) Description of the medical laboratory, its legal identity, resources, and main duties.

c) Quality policy.

d) Staff education and training.

e) Quality assurance.

f) Document control.

g) Records, maintenance and archiving.

h) Accommodation and environment.

i) Instruments, reagents and/or relevant consumables management.

j) Validation of examination procedures.

k) Safety.

l) Environmental aspects. [For example, transportation, consumables and waste disposal, in addition to, and different from, h) and i).]

m) Research and development. (If appropriate.)

n) List of examination procedures.

o) Request protocols, primary sample, collection and handling of laboratory samples.

p) Validation of results.

q) Quality control (including interlaboratory comparisons).

r) Laboratory information system. (See Annex B.)

s) Reporting of results.

t) Remedial actions and handling of complaints.

u) Communications and other interactions with patients, health professionals, referral laboratories and suppliers.

v) Internal audits.

w) Ethics. (See Annex C.)

4.2.5 Laboratory management shall establish and implement a programme which regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical systems. It shall also have a documented and recorded programme of preventive maintenance and calibration (see 5.3.2), which, at a minimum, follows manufacturer's recommendations.

4.3 Document control

4.3.1 The laboratory shall define, document and maintain procedures to control all documents and information (from internal and external sources) that form its quality documentation. A copy of each of these controlled documents shall be archived for later reference and the laboratory director shall define the retention period. These controlled documents may be maintained on any appropriate medium — including, or not, paper. National, regional and local regulations concerning document retention could apply.

NOTE In this context, "document" is any information or instructions, including policy statements, text books, procedures, specifications, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software, drawings, plans, and documents of external origin such as regulations, standards or examination procedures.

4.3.2 Procedures shall be adopted to ensure that

a) all documents issued to laboratory personnel as part of the quality management system are reviewed and approved by authorized personnel prior to issue,

b) a list, also referred to as a document control log, identifying the current valid revisions and their distribution is maintained,

c) only currently authorized versions of appropriate documents are available for active use at relevant locations,

d) documents are periodically reviewed, revised when necessary, and approved by authorized personnel,

e) invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use,

f) retained or archived superseded documents are appropriately identified to prevent their inadvertent use,

g) if the laboratory's documentation control system allows for the amendment of documents by hand pending the re-issue of documents, the procedures and authorities for such amendments are defined,

while amendments are clearly marked, initialled and dated, and a revised document is formally re-issued as soon as practicable, and

h) procedures are established to describe how changes to documents maintained in computerized systems are to be made and controlled.

4.3.3 All documents relevant to the quality management system shall be uniquely identified, to include

a) title,

b) edition or current revision date, or revision number, or all these,

c) number of pages (where applicable),

d) authority for issue, and

e) source identification.

4.4 Review of contracts

4.4.1 Where a laboratory enters into a contract to provide medical laboratory services, it shall establish and maintain procedures for review of contracts. The policies and procedures for these reviews leading to a change in the arrangements for examinations or contracts shall ensure that

a) requirements, including the methods to be used, are adequately defined, documented and understood (see 5.5);

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

c) appropriate procedures selected are able to meet the contract requirements and clinical needs (see 5.5).

In reference to b), the review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary, for the performance of the examinations in question. The review may also encompass results of earlier participation in external quality assurance schemes using samples of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

4.4.2 Records of reviews, including any significant changes and pertinent discussions, shall be maintained (see 4.13.3).

4.4.3 The review shall also cover any work referred by the laboratory (see 4.5).

4.4.4 Clients (e.g. clinicians, health care bodies, health insurance companies, pharmaceutical companies) shall be informed of any deviation from the contract.

4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected parties.

4.5 Examination by referral laboratories

4.5.1 The laboratory shall have an effective documented procedure for evaluating and selecting referral laboratories as well as consultants who are to provide second opinions for histopathology, cytology and related disciplines. Laboratory management, with the advice of users of laboratory services where appropriate, shall be responsible for selecting and monitoring the quality of referral laboratories and consultants and shall ensure that the referral laboratory or referral consultant is competent to perform the requested examinations.