SLOVENSKI STANDARD
SIST EN ISO 15189:2003

01-september-2003

Medicinski laboratoriji – Posebne zahteve za kakovost in usposobljenost (ISO 15189:2003)

Medical laboratories - Particular requirements for quality and competence (ISO 15189:2003)

Medizinische Laboratorien - Besondere Anforderungen an die Qualität und Kompetenz (ISO 15189:2003)

Laboratoires d'analyses de biologie médicale - Exigences particulieres concernant la qualité et la compétence (ISO 15189:2003)

Ta slovenski standard je istoveten z: **EN ISO 15189:2003**

ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
11.100.01	Laboratorijska medicina na splošno	Laboratory medicine in general

SIST EN ISO 15189:2003 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15189

February 2003

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English version

Medical laboratories - Particular requirements for quality and competence (ISO 15189:2003)

Laboratoires d'analyses de biologie médicale - Exigences particulières concernant la qualité et la compétence (ISO 15189:2003)

Medizinische Laboratorien - Besondere Anforderungen an die Qualität und Kompetenz (ISO 15189:2003)

This European Standard was approved by CEN on 17 January 2003.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovak Republic, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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CORRECTED 2003-09-24

Foreword

This document (EN ISO 15189:2003) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2003, and conflicting national standards shall be withdrawn at the latest by August 2003.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 15189:2003 has been approved by CEN as EN ISO 15189:2003 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

Annex ZA
(normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 9000	2000	Quality management systems - Fundamentals and vocabulary	EN ISO 9000	2000
ISO 9001	2000	Quality management systems - Requirements	EN ISO 9001	2000
ISO/IEC 17025	1999	General requirements for the competence of testing and calibration laboratories	EN ISO/IEC 17025	2000

INTERNATIONAL STANDARD

ISO 15189

First edition
2003-02-15

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2003-07-15

Medical laboratories — Particular requirements for quality and competence

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

Reference number
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Contents

Page

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]