SLOVENSKI STANDARD
oSIST prEN ISO 15189:2011

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Medicinski laboratoriji - Posebne zahteve za kakovost in usposobljenost (ISO/DIS 15189:2011)

Medical laboratories - Requirements for quality and competence (ISO/DIS 15189:2011)

Medizinische Laboratorien - Besondere Anforderungen an die Qualität und Kompetenz (ISO/DIS 15189:2011)

Laboratoires d'analyses de biologie médicale - Exigences concernant la qualité et la compétence (ISO/DIS 15189:2011)

Ta slovenski standard je istoveten z: **prEN ISO 15189**

ICS:

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

oSIST prEN ISO 15189:2011 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
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ICS 03.120.10; 11.100.01

Will supersede EN ISO 15189:2007

English Version

Medical laboratories - Requirements for quality and competence (ISO/DIS 15189:2011)

Laboratoires d'analyses de biologie médicale - Exigences concernant la qualité et la compétence (ISO/DIS 15189:2011)

Medizinische Laboratorien - Besondere Anforderungen an die Qualität und Kompetenz (ISO/DIS 15189:2011)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 140.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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 CEN-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

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Foreword

This document (prEN ISO 15189:2011) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 15189:2007.

Endorsement notice

The text of ISO/DIS 15189:2011 has been approved by CEN as a prEN ISO 15189:2011 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 15189

ISO/TC **212** Secretariat: **ANSI**

Voting begins on **2011-01-06** Voting terminates on **2011-06-06**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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)]

ICS 03.120.10; 11.100.01

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*.