SLOVENSKI

SIST EN ISO 15189:2003/oprA1:2005

PREDSTANDARD

november 2005

Medicinski laboratoriji – Posebne zahteve za kakovost in usposobljenost – Dopolnilo 1 (ISO 15189:2003/DAM 1:2005)

Medical laboratories - Particular requirements for quality and competence - Amendment 1 (ISO 15189:2003/DAM 1:2005)

ICS 03.120.10; 11.100.01

Referenčna številka
SIST EN ISO
15189:2003/oprA1:2005(en)

EUROPEAN STANDARD

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English Version

Medical laboratories - Particular requirements for quality and competence - Amendment 1 (ISO 15189:2003/DAM 1:2005)

Laboratoires d'analyses de biologie médicale - Exigences particulières concernant la qualité et la compétence (ISO 15189:2003/DAM 1:2005)

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

This draft amendment A1, if approved, will modify the European Standard EN ISO 15189:2003. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment 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 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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 15189:2003/prA1:2005:2005: E

Foreword

This document (EN ISO 15189:2003/prA1:2005) 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.

Endorsement notice

The text of ISO 15189:2003 has been approved by CEN as EN ISO 15189:2003/prA1:2005 without any modifications.

DRAFT AMENDMENT ISO 15189:2003/DAmd 1

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

Voting begins on: **2005-09-08**

Voting terminates on: **2006-02-08**

Medical laboratories — Particular requirements for quality and competence

AMENDMENT 1

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

AMENDEMENT 1

ICS 03.120.10; 11.100.01

ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS 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.

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.

Amendment 1 to ISO 15189:2005 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Introduction

In the longer term, ISO 15189 needs substantial revision. However, in the meantime TC 212 has undertaken the task of making the changes necessary to preserve alignment with ISO/IEC 17025, taking into account the changes made in the second edition of 17025, with a clear understanding that this should be done quickly. The Final Draft Amendment (FDAM) to ISO/IEC 17025:1999 was approved in February 2005 by both ISO and IEC. It is expected that the new edition of ISO/IEC 17025 will be published in June 2005.

In preparing the amendment to ISO/IEC 17025, CASCO/WG 25 decided not to undertake a full and comprehensive alignment of 17025 with ISO 9001:2000, but rather to make only the minimum of changes that were necessary to ensure that 17025 and ISO 9001:2000 were compatible. This included decoupling the linkage between the two standards by removing the statement in the Scope that laboratories fulfilling the requirements of 17025 also automatically fulfilled the requirements of ISO 9001:2000. Other changes are: the word “client” has been replaced throughout 17025 by “customer”, “non-conformance” by “nonconformity” and “quality system” by “management system”, and new subclauses have been added, of which 4.1.6 concerning communication within the laboratory and 4.10 “Improvement” are the most relevant to the realignment of 15189.

Since the changes to 17025 are minimal, the changes necessary to realign 15189 are also minimal. 15189 already uses “nonconformity” rather than “non-conformance” and already includes a subclause “Continual improvement”. 15189 uses the term “quality management system” rather than “quality system” or “management system” and it is proposed that this term should be retained. This is in keeping with the principle adopted in the development of 15189 that it should use language and terms familiar to medical laboratory professionals.