

SLOVENSKI
PREDSTANDARD

SIST EN ISO
15189:2003/oprA1:2005

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)

ICS

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.

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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.

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

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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:
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Voting terminates on:
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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

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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.

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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.

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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.