DRAFT AMENDMENT ISO 15189:2003/DAmd 1

ISO/TC **212**

Secretariat: **ANSI**

Voting begins on:
2005-09-08

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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

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.

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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.

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.

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Page iv, Foreword

Replace “This corrected version of ISO 15189:2003 ... minor typographical errors” by:

> “The following version of Draft Amendment 1 to ISO 15189:2003 is now submitted to a new ISO enquiry”

Page v, Introduction

Replace “For it is surely preferable that a laboratory seeking accreditation” by:

> “If a laboratory seeks accreditation, it should”

Replace “During the preparation of this International Standard ... is to take all this into account” by:

> “Demonstrated conformity to this International Standard does not imply conformity of the quality management system within which the laboratory operates to all the requirements of ISO 9001. This International Standard is not intended to be used for the purposes of certification."

In this second edition, minor changes have been made to align this International Standard more closely with the second edition of ISO/IEC 17025.

The correlation between the clauses and subclauses of this second edition of ISO 15189 and those of ISO 9001:2000 and of ISO/IEC 17025:2005 is detailed in Annex A of this International Standard.

Page 1, clause 1, Scope

Preface existing text with subclause numbering “1.1”.

Insert new subclause 1.2 “This International Standard is for use by medical laboratories in developing their quality management systems and assessing their own competence, and for use by accreditation bodies in confirming or recognizing the competence of medical laboratories.”

Page 1, clause 2, Normative references

Delete “ISO/IEC Guide 2 ...”.

Delete “ISO 9000 ...”.

Delete “ISO 9001:2000 ...”.

Replace “ISO/IEC 17025:1999” by “ISO/IEC 17025:2005”.

Clause 3, Terms and definitions:

Insert new subclause 3.1

> "accreditation procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks"

Insert new subclause 3.13

> "quality management system to direct and control an organization with regard to quality [ISO 9000:2000]"

NOTE: For the purposes of this International standard, the "quality" referred to in this definition relates to matters of both management and technical competence.

Pages 1 – 3, subclauses 3.1, 3.11, 3.12, and 3.17

Renumber existing subclauses 3.1 to 3.11 as 3.2 to 3.12, and subclauses 3.12 to 3.17 as 3.14 to 3.19.

Page 2, subclause 3.2

Replace "see [11]" by "see [13]"

Page 4

Insert new subclause 4.1.6:

> "Laboratory management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the quality management system"

Page 7, subclause 4.4.4

Replace "Clients" by "Customers"

Page 10, subclause 4.11.1

Replace "quality system" by "quality management system"

Page 11, subclause 4.14.2

Replace "quality system" by "quality management system"

Page 25, Annex A

Replace "Annex A (normative)" by "Annex A (informative)"

Delete "During the preparation ... those other documents"

Replace "ISO/ IEC 17025:1999" by "ISO/IEC 17025:2005".

Page 28, Table A.2

Replace Table A.2 by the following:

Table A.2 — Correlation between ISO/IEC 17025:2005 and this International Standard

ISO/IEC 17025:2005	ISO 15189:200x
1 Scope	1 Scope
2 Normative references	2 Normative references
3 Terms and definitions	3 Terms and definitions
4 Management requirements	4 Management requirements
4.1 Organisation	4.1 Organisation and management
4.2 Management system	4.2 Quality management system
4.3 Document control	4.3 Document control
4.4 Review of requests, tenders and contracts	4.4 Review of contracts
4.5 Sub-contracting of tests and calibrations	4.5 Examination by referral laboratories
4.6 Purchasing services and supplies	4.6 External services and supplies
4.7 Service to the client	4.7 Advisory services
4.8 Complaints	4.8 Resolution of complaints
4.9 Control of nonconforming testing and/or calibration work	4.9 Identification and control of nonconformities
4.10 Improvement	4.12 Continual improvement
4.11 Corrective action	4.10 Corrective action
4.12 Preventive action	4.11 Preventive action
4.13 Control of records	4.13 Quality and technical records
4.14 Internal audits	4.14 Internal audits
4.15 Management reviews	4.15 Management review
5 Technical requirements	5 Technical requirements
5.1 General	
5.2 Personnel	5.1 Personnel
5.3 Accommodation and environmental conditions	5.2 Accommodation and environmental conditions
5.4 Test and method validation	5.5 Examination procedures