

DRAFT AMENDMENT ISO 15189:2003/DAmd 1

ISO/TC 212 Secretariat: ANSI

Voting begins on: Voting terminates on:

2005-09-08 2006-02-08

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • MEЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО CTAHДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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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Foreword

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

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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. ISO 15189:2003/DAmd I

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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".

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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: iTeh STANDARD PREVIEW

"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"

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Page 7, subclause 4.4.4 https://standards.iteh.ai/catalog/standards/sist/f98a1085-12a6-4efc-8796-0a48eddeaf0e/iso-15189-2003-damd-1

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
	ISO/IEC 17025.2005	130	13169.200X
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 DAR	4.5	Examination by referral laboratories
4.6	Purchasing services and supplies and ards.	4.6	External services and supplies
4.7	Service to the client ISO 15189:2003/I	4.7)Am	Advisory services
4.8	Complaints https://standards.iteh.ai/catalog/standards/s	4!/8 ⁹	Resolution of complaints 3-damd-1
4.9 worl	Control of nonconforming testing and/or calibration	4.9	Identification and control of nonconformities
4.10) Improvement	4.12	2 Continual improvement
4.11	Corrective action	4.10	Corrective action
4.12	2 Preventive action	4.11	Preventive action
4.13	3 Control of records	4.13	B 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