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AS 4633—2004

Australian Standard™

Medical laboratories—Particular requirements for quality and competence

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Australian Diagnostic Manufacturers Association
Australian Institute of Medical Scientists
Australian Medical Association
Australian Society for Microbiology
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Medical laboratories—Particular requirements for quality and competence

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PREFACE

This Standard was prepared by the Standards Australia Committee HE-029, Clinical Laboratory Testing and In Vitro Diagnostic Test Systems.

The Standard has been reproduced from, and is identical to, ISO 15189:2003, *Medical laboratories—Particular requirements for quality and competence*.

The objective of this Standard is to provide requirements for competence and quality that are particular for medical/clinical laboratories.

As this Standard is reproduced from an International Standard, the following modifications apply:

(a) Its number does not appear on each pages of the text, and its identity is shown only on the cover and title page.

(b) In the source text, 'this International Standard' should read 'this Australian Standard'.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the annex or appendix to which they apply. A 'normative' annex or appendix is an integral part of a Standard, whereas an 'informative' one is for information or guidance only.

The reference to International Standards should be replaced by references to the following Australian or Australian/New Zealand Standards:

Reference to International Standard or other publication		*Australian/New Zealand Standard*	
ISO		AS	
31	Quantities and units (all parts)	2900	Quantities and units (all parts)
		AS/NZS ISO	
9000	Quality management systems—Fundamentals and vocabulary	9000	Quality management systems—Fundamentals and vocabulary
9001	Quality management systems—Requirements	9001	Quality management systems—Requirements
ISO/IEC			
17025	General requirements for the competence of testing and calibration laboratories	—	
Guide 2	Standardization and related activities—General vocabulary	—	
Guide 43	Proficiency testing by interlaboratory comparisons	—	
Guide 43-1	Part 1: Development and operation of proficiency testing scheme	—	
International vocabulary of basic and general terms in metrology (VIM). BIPM, IEC, IFCC, ISO, IuPAC, IUPAP, OIML			

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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 requisition, 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 regulations, 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 recognized disciplines of medical laboratory services, those working in other services and disciplines 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. For it is surely preferable that a laboratory seeking accreditation select an accrediting body which operates to appropriate international standards and which takes into account the particular requirements of medical laboratories.

During the preparation of this International Standard, ISO 9001 and ISO/IEC 17025 were under revision, and it was therefore impossible to present this International Standard in a format and style which corresponded precisely to those of either of the aforementioned documents. The correlation that nevertheless does exist between the clauses and subclauses of this first edition of ISO 15189 and those of ISO 9001:2000 and of ISO/IEC 17025:1999 is detailed in Annex A of this International Standard.

A second edition of this International Standard, aimed at more closely aligning it with a second edition of ISO/IEC 17025 and with ISO 9001:2000, is anticipated. Moreover, terminology has changed within the disciplines concerned and this has created differences of expression such that certain terms (e.g. “sensitivity”) now have entirely different meanings between disciplines. Furthermore, it is planned to replace yet another document related to this International Standard, ISO/IEC Guide 58, by ISO/IEC 17011. The second edition of ISO 15189 is to take all this into account.

1) In the French language, these laboratories are termed “laboratoires d’analyses de biologie médicale”, while in other languages they might be referred to using a term equivalent to the English “clinical laboratories”.

AUSTRALIAN STANDARD

Medical laboratories — Particular requirements for quality and competence

1 Scope

This International Standard specifies requirements for quality and competence particular to medical laboratories.

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/IEC Guide 2, *Standardization and related activities — General vocabulary*

ISO 31 (all parts), *Quantities and units*

ISO/IEC Guide 43-1, *Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes*

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 9001:2000, *Quality management systems — Requirements*

ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*

International vocabulary of basic and general terms in metrology (VIM). BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC Guide 2, VIM and the following apply.

3.1
accuracy of measurement
closeness of the agreement between the result of a measurement and a true value of the measurand

[VIM: 1993, definition 3.5]

3.2
biological reference interval
reference interval
central 95 % interval of the distribution of reference values

NOTE 1 This supersedes such incorrectly used terms as “normal range”.

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