AS ISO 15189—2009
ISO 15189:2007

AS ISO 15189—2009

Australian Standard®

Medical laboratories—Particular requirements for quality and competence

This Australian Standard® was prepared by Committee HE-029, Clinical Laboratory Testing and In Vitro Diagnostic Test Systems. It was approved on behalf of the Council of Standards Australia on 21 July 2009.
This Standard was published on 11 August 2009.

The following are represented on Committee HE-029:

- Australasian Association of Clinical Biochemists
- Australian Association of Pathology Practices
- Australian Institute of Medical Scientists
- Australian Society for Microbiology
- Consumers Federation of Australia
- Human Genetics Society of Australasia
- Medical Technology Association of Australia
- National Association of Testing Authorities Australia
- National Coalition of Public Pathology
- National Pathology Accreditation Advisory Council
- Royal College of Pathologists of Australasia
- Therapeutic Goods Administration

Additional Interests:

- Ausbiotech

This Standard was issued in draft form for comment as DR AS ISO 15189.

Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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Australian Standard®

Medical laboratories—Particular requirements for quality and competence

Originated as AS 4633—2004.
Revised and redesignated as AS ISO 15189—2009.

Published by Standards Australia GPO Box 476, Sydney, NSW 2001, Australia

ISBN 0 7337 9220 0

PREFACE

This Standard was prepared by the Standards Australia Committee HE-029, Clinical Laboratory Testing and In Vitro Diagnostic Test Systems to supersede AS 4633—2004.

This Standard is identical to, and has been reproduced from ISO 15189:2007, *Medical laboratories—Particular requirements for quality and competence*.

The objective of this Standard is to provide requirements for quality and competence 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 page of the text, and its identity is shown only on the cover and title page.

(b) In this reproduced text, 'this International Standard' should be read as 'this Australian Standard'.

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 Standard/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		AS/NZS ISO	
17025	General requirements for the competence of testing and calibration laboratories	17025	General requirements for the competence of testing and calibration laboratories
Guide 43-1	Proficiency testing by interlaboratory comparisons Part 1: Development and operation of proficiency testing schemes	HB 18.43.1	Guidelines for third-party certification and accreditation Guide 43: Proficiency testing by interlaboratory comparisons—Part 1: Development and operation of proficiency testing schemes
International vocabulary of basic and general terms in metrology (VIM). BIPM, CLSI, IEC, IFCC, ISO, IuPAC, IUPAP, OIML		—	

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is for information or guidance only.

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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 recognised 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. If a laboratory seeks accreditation, it should select an accrediting body which operates to appropriate international standards and which takes into account the particular requirements of medical laboratories.

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.

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.

1) In other languages, these laboratories can be designated by the equivalent of the English term “clinical laboratories.”

AUSTRALIAN STANDARD

Medical laboratories—Particular requirements for quality and competence

1 Scope

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

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 recognising the competence of 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 31 (all parts), *Quantities and units*

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

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

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

ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
accreditation
procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks

3.2
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]