AS ISO 15189—2013

Australian Standard®

Medical laboratories—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 2 April 2013.
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The following are represented on Committee HE-029:

- AusBiotech
- Australasian Association of Clinical Biochemists
- Australasian College of Medical Sciences and Research
- Australian Association of Pathology Practices
- Australian Institute of Medical Scientists
- Australian Medical Association
- Australian Society for Microbiology
- Consumers Federation of Australia
- Human Genetics Society of Australasia
- IVD Australia
- 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

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Medical laboratories—Requirements for quality and competence

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PREFACE

This Standard was approved by the Standards Australia Committee HE-029, Clinical Laboratory Testing and In Vitro Diagnostic Test Systems, to supersede AS ISO 15189—2009, *Medical laboratories—Particular requirements for quality and competence*.

The objective of this Standard is to specify requirements for quality and competence in medical laboratories.

This Standard is identical with, and has been reproduced from ISO 15189:2012, *Medical laboratories—Requirements for quality and competence*.

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

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

(b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

ISO		AS/NZS ISO	
9001	Quality management systems—Requirements	9001	Quality management systems—Requirements
ISO/IEC		AS ISO/IEC	
17000	Conformity assessment—Vocabulary and general principles	17000	Conformity assessment—Vocabulary and general principles
17025	General requirements for the competence of testing and calibration laboratories	17025	General requirements for the competence of testing and calibration laboratories

Only international references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

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

CONTENTS

INTRODUCTION

This International Standard, based upon ISO/IEC 17025 and ISO 9001, specifies 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 examination requests, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work.

Whenever allowed by national, regional or local regulations and requirements, 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 should also 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 such as clinical physiology, medical imaging and medical physics 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 in accordance with ISO/IEC 17011 and which takes into account the particular requirements of medical laboratories.

This International Standard is not intended to be used for the purposes of certification, however a medical laboratory's fulfilment of the requirements of this International Standard means the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid results. The management system requirements in Clause 4 are written in a language relevant to a medical laboratory's operations and meet the principles of ISO 9001:2008, *Quality management systems — Requirements*, and are aligned with its pertinent requirements (Joint IAF-ILAC-ISO Communiqué issued in 2009).

The correlation between the clauses and subclauses of this third edition of ISO 15189 and those of ISO 9001:2008 and of ISO/IEC 17025:2005 is detailed in Annex A of this International Standard.

Environmental issues associated with medical laboratory activity are generally addressed throughout this International Standard, with specific references in 5.2.2, 5.2.6, 5.3, 5.4, 5.5.1.4 and 5.7.

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

AUSTRALIAN STANDARD

Medical laboratories—Requirements for quality and competence

1 Scope

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

This International Standard can be used by medical laboratories in developing their quality management systems and assessing their own competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies.

NOTE International, national or regional regulations or requirements may also apply to specific topics covered in this International Standard.

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 17000, *Conformity assessment —Vocabulary and general principles*

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

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

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC Guide 2 and ISO/IEC Guide 99 and the following apply.

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

3.2
alert interval
critical interval
interval of examination results for an alert (critical) test that indicates an immediate risk to the patient of injury or death

NOTE 1 The interval may be open ended, where only a threshold is defined.

NOTE 2 The laboratory determines the appropriate list of alert tests for its patients and users.

3.3
automated selection and reporting of results
process by which patient examination results are sent to the laboratory information system and compared with laboratory-defined acceptance criteria, and in which results that fall within the defined criteria are automatically included in patient report formats without any additional intervention

