AS ISO/IEC 17025—2005
ISO/IEC 17025:2005
(Incorporating Amendment No. 1)

Australian Standard®

General requirements for the competence of testing and calibration laboratories

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- Association of Accredited Certification Bodies
- Australian Information Industry Association
- Certification Interests (Australia)
- Consumers Federation of Australia
- International Accreditation Forum
- Joint Accreditation System of Australia and New Zealand
- National Association of Testing Authorities Australia

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General requirements for the competence of testing and calibration laboratories

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PREFACE

This Standard was prepared by the Standards Australia Committee QR-010, Conformity Assessment to supersede AS ISO/IEC 17025—1999.

Amendment No. 1 (December 2006) is identical to ISO/IEC 17025:2005/Technical Corrigendum 1:2006 and has been added after the source text. The corrigendum applies to Annex A.

The objective of this Standard is to specify the general requirements for the competence to carry out test and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

If testing and calibration laboratories comply with the requirements of this Australian adoption of the international Standard, they will operate a quality management system for their testing and calibration activities that also meets the principles of AS/NZS ISO 9001.

This Standard covers technical competence requirements that are not covered by AS/NZS ISO 9001.

Annex A provides nominal cross-references between ISO/IEC 17025 and ISO 9001. The cross-references also apply to this Standard and AS/NZS ISO 9001, as each is an identical adoption.

This Standard is identical with, and has been reproduced from ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories* which was prepared by the ISO Committee on Conformity Assessment (CASCO) to replace ISO/IEC 17025:1999.

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

Its number appears on the cover and title page while the international standard number appears only on the cover.

In the source text ‘this International Standard’ should read ‘AS ISO/IEC 17025’.

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:

Reference to International Standard		*Australian Standard*	
ISO/IEC		AS ISO/IEC	
17000	Conformity assessment—Vocabulary and general principles	17000	Conformity assessment—Vocabulary and general principles

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

CONTENTS

Page

Page

INTRODUCTION

The first edition (1999) of this International Standard was produced as the result of extensive experience in the implementation of ISO/IEC Guide 25 and EN 45001, both of which it replaced. It contained all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system, are technically competent, and are able to generate technically valid results.

The first edition referred to ISO 9001:1994 and ISO 9002:1994. These standards have been superseded by ISO 9001:2000, which made an alignment of ISO/IEC 17025 necessary. In this second edition, clauses have been amended or added only when considered necessary in the light of ISO 9001:2000.

Accreditation bodies that recognize the competence of testing and calibration laboratories should use this International Standard as the basis for their accreditation. Clause 4 specifies the requirements for sound management. Clause 5 specifies the requirements for technical competence for the type of tests and/or calibrations the laboratory undertakes.

Growth in the use of management systems generally has increased the need to ensure that laboratories which form part of larger organizations or offer other services can operate to a quality management system that is seen as compliant with ISO 9001 as well as with this International Standard. Care has been taken, therefore, to incorporate all those requirements of ISO 9001 that are relevant to the scope of testing and calibration services that are covered by the laboratory's management system.

Testing and calibration laboratories that comply with this International Standard will therefore also operate in accordance with ISO 9001.

Conformity of the quality management system within which the laboratory operates to the requirements of ISO 9001 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results. Nor does demonstrated conformity to this International Standard imply conformity of the quality management system within which the laboratory operates to all the requirements of ISO 9001.

The acceptance of testing and calibration results between countries should be facilitated if laboratories comply with this International Standard and if they obtain accreditation from bodies which have entered into mutual recognition agreements with equivalent bodies in other countries using this International Standard.

The use of this International Standard will facilitate cooperation between laboratories and other bodies, and assist in the exchange of information and experience, and in the harmonization of standards and procedures.

NOTES

AUSTRALIAN STANDARD

General requirements for the competence of testing and calibration laboratories

1 Scope

1.1 This International Standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

1.2 This International Standard is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.

This International Standard is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by this International Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

1.3 The notes given provide clarification of the text, examples and guidance. They do not contain requirements and do not form an integral part of this International Standard.

1.4 This International Standard is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. This International Standard is not intended to be used as the basis for certification of laboratories.

NOTE 1 The term 'management system' in this International Standard means the quality, administrative and technical systems that govern the operations of a laboratory.

NOTE 2 Certification of a management system is sometimes also called registration.

1.5 Compliance with regulatory and safety requirements on the operation of laboratories is not covered by this International Standard.

1.6 If testing and calibration laboratories comply with the requirements of this International Standard, they will operate a quality management system for their testing and calibration activities that also meets the principles of ISO 9001. Annex A provides nominal cross-references between this International Standard and ISO 9001. This International Standard covers technical competence requirements that are not covered by ISO 9001.

NOTE 1 It might be necessary to explain or interpret certain requirements in this International Standard to ensure that the requirements are applied in a consistent manner. Guidance for establishing applications for specific fields, especially for accreditation bodies (see ISO/IEC 17011) is given in Annex B.

NOTE 2 If a laboratory wishes accreditation for part or all of its testing and calibration activities, it should select an accreditation body that operates in accordance with ISO/IEC 17011.