



General requirements for the competence of testing and calibration laboratories



AS ISO/IEC 17025:2018

This Australian Standard® was prepared by QR-010, Conformity Assessment. It was approved on behalf of the Council of Standards Australia on 14 March 2018.

This Standard was published on 16 April 2018.

The following are represented on Committee QR-010:

- Association of Accredited Certification Bodies
- Australasian Procurement and Construction Council
- Australian Information Industry Association
- Certification Interests, Australia
- Consumer Electronics Suppliers Association
- Consumers' Federation of Australia
- Joint Accreditation System of Australia and New Zealand
- National Association of Testing Authorities Australia
- Therapeutic Goods Administration

This Standard was issued in draft form for comment as DR AS ISO/IEC 17025:2018.

Keeping Standards up-to-date

Ensure you have the latest versions of our publications and keep up-to-date about Amendments, Rulings, Withdrawals, and new projects by visiting:

www.standards.org.au

www.saiglobal.com (sales and distribution)

ISBN 978 1 76072 043 8



General requirements for the competence of testing and calibration laboratories

Originated as AS ISO/IEC 17025—1999.
Second edition 2005.
Third edition 2018.

COPYRIGHT

© ISO/IEC 2018 — All rights reserved
© Standards Australia Limited 2018

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher, unless otherwise permitted under the Copyright Act 1968 (Cth).

Published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001, Australia.

Preface

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee QR-010, Conformity Assessment, to supersede AS ISO/IEC 17025—2005, *General requirements for the competence of testing and calibration laboratories*.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

The objective of this Standard is to specify the general requirements for the competence, impartiality and consistent operation of laboratories. This Standard is applicable to all organizations performing laboratory activities, regardless of the number of personnel.

This Standard is identical with, and has been reproduced from ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*.

As this document has been reproduced from an International Standard, a full point substitutes for a comma when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

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

Contents

Preface	ii
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements	3
4.1 Impartiality.....	3
4.2 Confidentiality.....	3
5 Structural requirements	4
6 Resource requirements	5
6.1 General.....	5
6.2 Personnel.....	5
6.3 Facilities and environmental conditions.....	6
6.4 Equipment.....	6
6.5 Metrological traceability.....	8
6.6 Externally provided products and services.....	8
7 Process requirements	9
7.1 Review of requests, tenders and contracts.....	9
7.2 Selection, verification and validation of methods.....	10
7.2.1 Selection and verification of methods.....	10
7.2.2 Validation of methods.....	11
7.3 Sampling.....	12
7.4 Handling of test or calibration items.....	12
7.5 Technical records.....	13
7.6 Evaluation of measurement uncertainty.....	13
7.7 Ensuring the validity of results.....	13
7.8 Reporting of results.....	14
7.8.1 General.....	14
7.8.2 Common requirements for reports (test, calibration or sampling).....	14
7.8.3 Specific requirements for test reports.....	15
7.8.4 Specific requirements for calibration certificates.....	16
7.8.5 Reporting sampling – specific requirements.....	16
7.8.6 Reporting statements of conformity.....	16
7.8.7 Reporting opinions and interpretations.....	17
7.8.8 Amendments to reports.....	17
7.9 Complaints.....	17
7.10 Nonconforming work.....	18
7.11 Control of data and information management.....	18
8 Management system requirements	19
8.1 Options.....	19
8.1.1 General.....	19
8.1.2 Option A.....	19
8.1.3 Option B.....	20
8.2 Management system documentation (Option A).....	20
8.3 Control of management system documents (Option A).....	20
8.4 Control of records (Option A).....	21
8.5 Actions to address risks and opportunities (Option A).....	21
8.6 Improvement (Option A).....	21
8.7 Corrective actions (Option A).....	22
8.8 Internal audits (Option A).....	22

8.9 Management reviews (Option A)..... 23

Annex A (informative) **Metrological traceability**..... **24**

Annex B (informative) **Management system options**..... **26**

Bibliography..... **28**

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. In the field of conformity assessment, ISO and the International Electrotechnical Commission (IEC) develop joint ISO/IEC documents under the management of the ISO Committee on Conformity assessment (ISO/CASCO).

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO) and circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This third edition cancels and replaces the second edition (ISO/IEC 17025:2005), which has been technically revised.

The main changes compared to the previous edition are as follows:

- the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;
- there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities;
- a definition of “laboratory” has been added (see [3.6](#)).

Introduction

This document has been developed with the objective of promoting confidence in the operation of laboratories. This document contains requirements for laboratories to enable them to demonstrate they operate competently, and are able to generate valid results. Laboratories that conform to this document will also operate generally in accordance with the principles of ISO 9001.

This document requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.

The use of this document 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. The acceptance of results between countries is facilitated if laboratories conform to this document.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

For the purposes of research, users are encouraged to share their views on this document and their priorities for changes to future editions. Click on the link below to take part in the online survey:

[17025_ed3_usersurvey](#)

Australian Standard®

General requirements for the competence of testing and calibration laboratories

1 Scope

This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories.

This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel.

Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*¹⁾

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

impartiality

presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the *laboratory* (3.6).

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — The words “the certification body” have been replaced by “the laboratory” in Note 1 to entry, and the word “independence” has been deleted from the list in Note 2 to entry.]

1) Also known as JCGM 200.

3.2

complaint

expression of dissatisfaction by any person or organization to a *laboratory* (3.6), relating to the activities or results of that laboratory, where a response is expected

[SOURCE: ISO/IEC 17000:2004, 6.5, modified — The words “other than appeal” have been deleted, and the words “a conformity assessment body or accreditation body, relating to the activities of that body” have been replaced by “a laboratory, relating to the activities or results of that laboratory”.]

3.3

interlaboratory comparison

organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

[SOURCE: ISO/IEC 17043:2010, 3.4]

3.4

intralaboratory comparison

organization, performance and evaluation of measurements or tests on the same or similar items within the same *laboratory* (3.6) in accordance with predetermined conditions

3.5

proficiency testing

evaluation of participant performance against pre-established criteria by means of *interlaboratory comparisons* (3.3)

[SOURCE: ISO/IEC 17043:2010, 3.7, modified — Notes to entry have been deleted.]

3.6

laboratory

body that performs one or more of the following activities:

- testing;
- calibration;
- sampling, associated with subsequent testing or calibration

Note 1 to entry: In the context of this document, “laboratory activities” refer to the three above-mentioned activities.

3.7

decision rule

rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

3.8

verification

provision of objective evidence that a given item fulfils specified requirements

EXAMPLE 1 Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.

EXAMPLE 2 Confirmation that performance properties or legal requirements of a measuring system are achieved.

EXAMPLE 3 Confirmation that a target measurement uncertainty can be met.

Note 1 to entry: When applicable, measurement uncertainty should be taken into consideration.

Note 2 to entry: The item may be, for example, a process, measurement procedure, material, compound, or measuring system.

Note 3 to entry: The specified requirements may be, for example, that a manufacturer's specifications are met.

Note 4 to entry: Verification in legal metrology, as defined in VIML, and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system.

Note 5 to entry: Verification should not be confused with calibration. Not every verification is a *validation* (3.9).

Note 6 to entry: In chemistry, verification of the identity of the entity involved, or of activity, requires a description of the structure or properties of that entity or activity.

[SOURCE: ISO/IEC Guide 99:2007, 2.44]

3.9

validation

verification (3.8), where the specified requirements are adequate for an intended use

EXAMPLE A measurement procedure, ordinarily used for the measurement of mass concentration of nitrogen in water, may be validated also for measurement of mass concentration of nitrogen in human serum.

[SOURCE: ISO/IEC Guide 99:2007, 2.45]

4 General requirements

4.1 Impartiality

4.1.1 Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

4.1.2 The laboratory management shall be committed to impartiality.

4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

4.2 Confidentiality

4.2.1 The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the

laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

4.2.2 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

5 Structural requirements

5.1 The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.

NOTE For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

5.2 The laboratory shall identify management that has overall responsibility for the laboratory.

5.3 The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

5.4 Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

5.5 The laboratory shall:

- a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;
- b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;
- c) document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

5.6 The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

- a) implementation, maintenance and improvement of the management system;
- b) identification of deviations from the management system or from the procedures for performing laboratory activities;
- c) initiation of actions to prevent or minimize such deviations;