



Frequently Asked Questions about ISO / IEC 17025

BACKGROUND

For laboratories and users of laboratory services, occasionally there is misunderstanding and confusion about the objectives and functions of “accreditation” based on ISO/IEC 17025:2005 *General Requirements for the competence of testing and calibration laboratories*, and “certification” of laboratories based on ISO 9001:2000, *Quality Management Systems – Requirements*. This document is based on a communiqué prepared by the IAF-ILAC-ISO/CASCO Joint Working Group on image and integrity of conformity assessment to clarify the key distinctions between the different types of recognition.

1. What does Accreditation to ISO/IEC 17025 mean?

ISO/IEC 17025 is applicable to testing and calibration laboratories and covers the use of standard, non-standard and laboratory-developed methods.

Laboratories that can demonstrate compliance with ISO/IEC 17025 at assessment have demonstrated they operate using sound management practices and are technically competent to perform specific tests, calibrations and/or measurements for which they hold accreditation.

The management requirements of the Standard were written to meet the systems requirements of ISO 9000:1994 series. However, accreditation against ISO/IEC 17025 cannot be interpreted to be the same as certification against the ISO 9000 series Standards.

2. What does Certification to ISO 9001 Mean?

From 15th December 2003, the ISO 9000:1994 series of Quality Management Standards becomes obsolescent and will be superseded by a single Standard known as ISO 9001:2000.

ISO 9001:2000 is a generic standard for quality management systems (QMS) applicable to all organisations including laboratories. Its purpose is to specify a QMS that will allow an organisation to demonstrate its ability to provide products or services that meet customer and applicable regulatory requirements.

The “new” Standard has several differences in terms of requirements for documentation, customer focus, quality objectives, and continual improvement. However the main difference is the change to an outcome driven, process approach, for quality management.

Certification of a laboratory against ISO 9001:2000 cannot be interpreted to mean that it demonstrates the technical competence to produce valid data and results.

3. What are the key differences between accreditation and certification?

Certification:

- Means compliance with a standard or specification (e.g. systems or product standards).
- Is assessed by management systems auditors who are certified by an independent body as meeting internationally agreed criteria.
- Can cover more than the sections or tests that have been accredited through laboratory accreditation.
- May be general in the scope of recognition.
- Considers the total business including strategy and planning.

Accreditation:

- Is the recognition of a specific technical competence?
- The scope of accreditation is normally highly specific.
- Evaluates people skills and knowledge.
- Is formal recognition that the attesting laboratory is competent to carry out specific tests or specific types of tests.
- Uses technical assessors who are recognised experts in their field.
- Also evaluates management systems compliance.

Both accreditation and certification use publicly available criteria and can provide public reassurance because both use independent, qualified assessors and an ongoing surveillance program.

4. Why would a laboratory that is accredited to ISO/IEC 17025 want to take up or keep certification to ISO 9001:2000?

There are several reasons why dual recognition may be important.

- The laboratory's customers may specify that the laboratory gains or retains ISO 9001 certification.
- ISO 9001 certification is seen by an increasing number of businesses as a way of underpinning continuous improvement.
- It depends on where the laboratory fits within an organisation e.g. if the laboratory is only a part of a larger organisation, which has ISO 9001 certification, the laboratory may need to retain it. If the laboratory is a complete business itself, i.e. a testing laboratory, and certification is not required by its clients, then ISO 9001 certification may not be required.
- Many laboratory-based organisations undertake activities additional to the generation of test, measurement and calibration data. Laboratory accreditation does not address these ancillary activities of a laboratory. If an organisation's quality system covers non-testing functions such as production, accounting, marketing, information services, training etc, it may be necessary or desirable to seek to have such activities recognised through ISO 9001 certification.

5. Will the ISO/IEC 17025 laboratory assessment take into account ISO9001 certification and reduce the time of the assessment?

If a laboratory holds current ISO 9001 certification, and the NATA assessment team have access to recent ISO 9001 audit reports and any associated follow-up and corrective action data, then it is possible that the assessment time could be reduced. However, this will depend on the level of confidence derived from the audit reports and a sample of management system processes and records.

6. Can my ISO 9001 auditor conduct the ISO/IEC 17025 assessment?

No. Management systems auditors are usually only qualified to perform assessments against a management system standard. ISO/IEC 17025 is both a technical and management systems standard and requires technical experts in the assessment team who are able to make judgements of the specific technical competence of the laboratory.

7. Can the ISO/IEC 17025 assessment team also audit the ISO 9001 management system to save time and cost?

No. A laboratory accreditation assessment by NATA against ISO/IEC 17025 only includes assessment against the requirements of the ISO 9000:1994 series of quality management standards.

Certification assessments, or periodic surveillance audits, against the ISO 9001:2000 standard can only be performed by an assessor from a certification body meeting the accreditation requirements of JAS-ANZ, such as NCS International Pty Limited. However, it is certainly possible, and in some cases desirable, to conduct the two assessments simultaneously. This can reduce overall time and possibly offer benefits in terms of integrated findings.

8. Which standard is the more appropriate for laboratories?

There are differences between the purpose, criteria and emphasis of the ISO 9001 quality system standard, and those of the accreditation standard ISO/IEC 17025. For laboratories concerned with demonstrating technical competence underpinned by sound quality system elements, ISO/IEC 17025 is the appropriate standard. However, if the laboratory is seeking a more holistic, quality management recognition that demonstrates customer focus and continual improvement, it may decide to *also* maintain a certified ISO 9001 management system.

9. Where can I find out more?

You can:

- Request more information through the website at www.ncsi.com.au
- Call 1800 652 345
- Contact an NCSI staff member at the office in your state, listed on the NCSI Home Page under "NCSI Offices".
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About NCS International

NCS International Pty Ltd (NCSI) assesses how well an organisation goes about its business, and whether its operations meet accepted International and National Standards.

Operating across a wide range of industries and government sectors, NCSI provides diligent and practical audits that cover an enterprise's systems and processes.

NCSI awards its **WorldStar** mark to organisations which meet the relevant standard to which they aim to be certified (see below). The **WorldStar** mark is the public proclamation that an organisation is certified and indicates its commitment to sound management systems and effective customer service.

Customers of organisations that display NCSI's **WorldStar** mark can be confident they're dealing with people committed to excellence and continual improvement in meeting their customers requirements.

NCSI's certification programs offer audit and certification to Standards for Quality Assurance, Environment, OH&S, Food Safety (HACCP), and Disability Employment Services, amongst many other programs.

NCSI was established in its own right in 1997. It is a subsidiary of the National Association of Testing Authorities (NATA), which is Australia's national provider of laboratory accreditation and the world's first and largest association of accredited laboratories. NCSI is JAS-ANZ accredited, and is entitled to use the International Accreditation Forum (IAF) accreditation symbol on its certification.

