

From a Series of e-Books published by deGRANDSON Global

THE FAQs ABOUT ISO 17025

The ISO Standard for Quality Management System



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The ISO 17025 Standard

What is ISO?

The International Organization for Standardization (ISO for short) is the world's largest developer of voluntary International Standards. Their 21,000+ standards offer solutions and best practice guidance for all types of technology and businesses, helping companies and organizations increase performance while protecting consumers and the planet.

While most are product and technical standards, the ISO has developed 40+ management system standards.

The best known of these include [ISO 9001 \(quality\)](#), [ISO 14001 \(environment\)](#), [ISO 45001 \(health & safety\)](#) and ISO 27001 (information security management). The feature they all have in common is that they are auditable. They are written to facilitate auditing by an independent third party (e.g., CAB) to confirm compliance with the standards' requirements.

ISO 13485 is a quality management system standard based on ISO 9001, considered the parent of all the other standards.

For more, visit [ISO 9001 on the ISO website](#).

Enjoy!

What is ISO 17025?

ISO 17025 (or, to give it its full title, [ISO 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories](#)) is an internationally recognized standard that sets out **the requirements for a Testing and Calibration Laboratory Management System (TCLMS)**. This Standard is the revision of the previous ISO/IEC 17025:2005 version.

The ISO 17025 standard lays out the general requirements for proving the competence, impartiality, and consistent operations of laboratories that perform testing, sampling, and calibration.

Its guidelines apply to all types of laboratories- private and public- and include a wide range of organizations from academic institutions to research centers and government regulators.



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What is the purpose of ISO 17025?

The purpose of the Standard is to specify the general requirements for the competence, impartiality, and consistent operation of laboratories. It enables laboratories to demonstrate that they operate competently and **generate valid results**, thereby promoting confidence in their work nationally and worldwide.

Test reports and certificates can be accepted from one country to another without the need for further testing, which, in turn, reduces costly duplication of effort and improves international trade.

For more, see the ISO publication [ISO/IEC 17025 Testing and Calibration Laboratories](#).



What is ISO 17025 Accreditation and the Scope of that accreditation?

Certification to ISO 17025 by a Certification Body is not possible as the assessment of laboratory management systems is exclusively in the hands of national accreditation bodies. From such national accreditation bodies, like UKAS, INAB, RvA, and ANAB, one receives accreditation and not certification. Different titles but essentially the same thing - proof through independent third-party auditing of compliance with requirements.

The Scope of Accreditation is a critical consideration. Only those tests listed in the scope statement given on the accreditation body website page for the accredited organization are included in the accreditation. These often are defined as types of tests rather than specific, individual tests, and so are not too restrictive. Unless the test in question is included in their accreditation scope, a test laboratory report or a calibration laboratory certificate cannot carry an accreditation body logo.

Certification to ISO 17025

Do You Need ISO 17025 Certification?

Yes. A claim of compliance with the Standard is meaningless and of no commercial value without accreditation. You receive test laboratory reports or [calibration laboratory certificates that do not have accreditation body logos](#) in addition to the Laboratory's logo, you should always ask why.

The use of ISO 17025 is so widespread globally nowadays that you should expect to see accreditation body logos on all test laboratory reports or calibration laboratory certificates.



How much does ISO 17025 Certification Cost?

The cost of ISO 17025 accreditation varies hugely based on the number of tests included in the scope of accreditation. Whether standard methods are in use or not, the size of the organization, and geographical location.

Let's take the example of an SME with ten employees. And let's assume that the SME is using standard test methods and is already Certified to ISO 9001, which would reduce the work required. Here are some typical prices from the UK for 2023, where we consider three scenarios ...

Scenario (1)	Do-it-yourself (2)	Minimum Consultancy Support (3)	Maximum Consultancy Support (4)
Develop TCLMS (5 days)	500£	1000£	2500£
Implement TCLMS (5 days)	500£	1000£	2500£
Maintain TCLMS (2 x 3 years)	600£	600£	3000£
Accreditation Year 1	5000£	5000£	5000£
Year 2	2000£	2000£	2000£
Year 3	2000£	2000£	2000£
Total 3-year cost	£10,600	£11,600	£17,000
Typical duration to Accreditation	11 months	5 months	4 months

Notes:

1. The accreditation cycle is three years, and the Accreditation Body contract is always for a 3-year period.
2. No outside help. The project leader would need [ISO 17025 Lead Auditor Training](#). Avoid this option unless your experience is sufficient to ensure an effective laboratory management system from the outset.

3. Four days of [consultancy](#) support is included here. Priced at £ 500 p.d., consultancy costs range from £300 to £700 per day. Satisfactory references must be obtained for previous ISO 17025 projects.
4. Maintenance here includes two days annually for internal auditing and Management Review support.



Who Issues ISO 17025 Accreditation Certificates?

The ISO develops International Standards, such as ISO 9001 and ISO 14001, but is not involved in their certification or accreditation. ISO does not issue certificates, so a **company or organization cannot be certified by ISO**. External organizations perform this.

ISO 17025 accreditation certificates are issued by [Accreditation Bodies](#) (and not by [Certification Bodies \(CABs\)](#)) and are based on a comprehensive 2-stage audit (itself based on the [auditing standard, ISO 19011](#)). The Accreditation Body gathers and documents objective evidence of compliance with ISO 17025 accreditation requirements, focusing on laboratory methods. After a suitable review within the Accreditation Body, an Accreditation Certificate is issued, as is permission to use logos to publicize the fact.

For more, visit [UKAS, the National Accreditation Body for the United Kingdom](#).



Can I choose which Accreditation Body to use?

While there is currently a choice of three Accreditation Bodies in the USA, the answer is no in practice elsewhere. In Europe, the national accreditation bodies operate an effective cabal, with these bodies refusing to accept work from organizations based outside their national territory.

There are such things as maverick accreditation bodies. While not illegal, their accreditation certificates are worthless. The trustworthy National Accreditation Boards have their own international organization, the [International Laboratory Accreditation Cooperation \(ILAC\)](#), which oversees an ongoing program of witnessed self-assessment of ILAC Members of each others' activities. ILAC is closely associated with the International Accreditation Forum (IAF), which oversees certification to other ISO management system standards.

A Certificate from an accredited test or calibration laboratory will carry three logos. #1 the Laboratories own logo and #2 the Accreditation Boards logo and #3 the ILAC logo. If you present a Report or Certificate to a customer or potential customer that does not carry all three logos, expect to be challenged. Without a plausible explanation, you can expect your approach to be rejected.

Can I check the ISO 17025 Accreditation Status of an organization?

Yes. Go to the website of the relevant (usually national) Accreditation Body and search for the name of the test or calibration laboratory. There you will find details of the Laboratory and the scope of its accreditation, that is, a list of the test methods for which they hold accreditation.



Does ISO 17025 Accreditation cover all Test Laboratory services?

No. And some offer reports with a variety of logos. Check these carefully. Remember that those reviewing tender documents are unlikely to be inexperienced. They will recognize a poor Accreditation Certificate instantly. And your offer will go directly into the rubbish bin with the hard work you've expended to develop Laboratory or calibration services you are proud of will be totally wasted when an ISO Auditor finds such a bogus Certificate.



Does ISO 17025 Accreditation cover all Calibration Laboratory services?

See the previous answer. Some Calibration Laboratories still offer ISO 9001 Certification and claim that it is an ISO 17025 equivalent. This statement is untrue. ISO 9001 has no equivalent to the detailed sampling, testing, and reporting requirements of ISO 17025. You should [seek out laboratories accredited to ISO 17025 wherever possible](#).



What are the Option A and Option B choices regarding Management System requirements?

This choice of management system options in ISO 17025 is unique to this Standard. The easiest way to understand the choices is to quote from the Standard itself.

8.1 Options

8.1.1 General

The Laboratory shall establish, document, implement and maintain a management system that can support and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the Laboratory shall implement a management system in accordance with Option A or Option B.

8.1.2 Option A

As a minimum, the management system of the Laboratory shall address the following:

- Management system documentation (see 8.2).
- Control of management system documents (see 8.3).
- Control of records (see 8.4).
- Actions to address risks and opportunities (see 8.5).
- Improvement (see 8.6).
- Corrective action (see 8.7).
- Internal audits (see 8.8).
- Management reviews (see 8.9).

8.1.3 Option B

A laboratory that has established and maintains a management system in accordance with the requirements of ISO 9001 and that can support and demonstrating the consistent fulfillment of the requirements of Clauses 4 to 7 also fulfills at least the intent of the management system requirements specified in 8.2 to 8.9.

All organizations certified to ISO 9001 will, almost without exception, choose Option B.



Do Internal Auditors need training?

Again, training here is not mandatory. However, [effective internal audits](#) are essential to doing a professional job in maintaining your TCLMS and avoiding nasty surprises at your next Accreditation Body audit. Also, if you don't train them, your auditors won't have any of the [skills necessary](#) to 'harvest' those improvement suggestions from the people in your organization who actually do the work.

For more, visit the [ISO 17025 Internal Auditor Course](#). At this link, you find a complete selection of ISO 17025 Courses.



Got a question we haven't answered?

We'd love to hear it and, if possible, answer it for you. Just use our Support Ticket System. You'll find a Knowledge Base there that might have an immediate answer for you. Otherwise, fill in a Ticket.

For more, visit [deGRANDSON Support Ticket](#).

