

The International Standard ISO/IEC 17025:2005

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The International Standard **ISO/IEC 17025:2005** "General requirements for the competence of testing and calibration laboratories," is a standard published by:

ISO: *International Organization for Standardization, and*

IEC: *International Electrotechnical Commission.*

These are international standardization bodies, prestigious and highly recognized worldwide.

ISO/IEC 17025:2005 has its origins in the Guide ISO/IEC 25 "General requirements for the competence of calibration and testing laboratories" and the standard EN 45001 "General Criteria for the Operation of Testing Laboratories", and the first version became effective in 1999.

In some countries or regions ISO/IEC 17025 adopted different nomenclatures (including year of publication), such as:

- + NMX-EC-17025-IMNC: 2006 (Mexico).
- + UNE-EN ISO/IEC 17025:2005 (Spain).
- + IRAM 301:2005 (Argentina).
- + NTC-ISO/IEC 17025:2005 (Colombia).
- + NCh-ISO 17025Of2005 (Chile).
- + Etc.



ISO/IEC 17025 emerged as a reference guide for those laboratories which perform testing or calibration activities and seek to demonstrate that:

- **They operate an effective quality management system, which is continuously improving.** The laboratory

implements a quality system in order to manage and use its administrative and technical documentation.

- **They are technically competent.** Technical competence of personnel is demonstrated, including facilities and environmental conditions, validated methods, equipment and reliable standards traceable to the units of the International System of Units (SI).
- **They are capable of reporting reliable testing or calibration results.** The laboratory implements programs for quality assurance of results, to generate technically valid results.

ISO/IEC 17025 applies to any kind of calibration or testing laboratory, regardless of size or activity, and is comprised of a series of requirements grouped into 25 sections. The first 15 sections correspond to the requirements for management (administrative) and are characterized by their great similarity with ISO 9001 standard. The remaining sections have a merely technical approach and contain requirements that the laboratory must meet to demonstrate their technical competence and ensure the validity of their results.

ISO / IEC 17025 has been adopted as a reference guide of accreditation bodies to assess the conformity of testing and calibration laboratories, and it is used worldwide for accreditation purposes.

The accreditation body is responsible for assessing the conformity of compliance with the requirements of **ISO/IEC 17025**, and witnesses the laboratory's competence to perform specific tasks of the testing or calibration in order to declare the accreditation.

Standard ISO/IEC 17025:2005	
Management requirements	Technical requirements
4.1 Organization 4.2 Management system 4.3 Document control 4.4 Review of requests, tenders and contracts 4.5 Subcontracting of tests and calibrations 4.6 Purchasing services and supplies 4.7 Service to the customer 4.8 Complaints 4.9 Control of nonconforming testing and/or calibration work 4.10 Improvement 4.11 Corrective action 4.12 Preventive action 4.13 Control of records 4.14 Internal audits 4.15 Management reviews	5.1 General 5.2 Personnel 5.3 Accommodation and environmental conditions 5.4 Test and calibration methods and method validation 5.5 Equipment 5.6 Measurement traceability 5.7 Sampling 5.8 Handling of testing and calibration items 5.9 Assuring the quality of test and calibration results 5.10 Reporting the results

A testing or calibration laboratory seeking accreditation under the International Standard **ISO/IEC 17025**, or its equivalent national or regional standard, must satisfy and show evidence of compliance with the requirements contained in the 25 sections of the table above.

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These requirements include the preparation and implementation of:

- ✓ A quality manual.
- ✓ Managerial and technical policies, including a quality policy.
- ✓ Managerial and technical procedures.

Guide for implementing a quality system
ISO/IEC17025



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And the generation of objective evidence of their implementation:

- ✓ Managerial and technical records.

The **Guide M-17025** is a tool that leads the user through the process of implementing the quality system ISO/IEC 17025 in their laboratory with minimal training, in a simple, orderly, reliable, compact way and in the shortest time possible.

[Ref]: ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories".