SafetyCulture

A Quick Guide to Understanding ISO 17025

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What is the ISO 17025 Standard?

ISO/IEC 17025:2017 is the international standard created by the International Organization for Standardization (ISO) together with the International Electrotechnical Commission (IEC). It is comprised of various requirements and guidelines used by laboratory customers, regulation boards, accreditation authorities, and organizations to verify, recognize, and ensure the competency, impartiality, and consistent operation of laboratories in their testing and calibration processes.

The ISO/IEC 17025:2017 serves as a Quality Management System (QMS) for laboratories to improve their process of facilitating more accurate diagnostics, efficient treatment, and reduced errors in the laboratory process. This coincides with the ultimate goal in laboratory medicine which is to improve an organization's overall QMS toward ensuring patient safety.

What is the Importance of ISO 17025?

Across industries, it's highly encouraged to create a QMS that best fits the needs of an organization. This is to help improve the quality and efficiency of laboratory safety practices, processes, and systems.

The standard's current version which is the ISO 17025:2017 is key to establishing guidelines and protocols that are aligned with Good Laboratory Practices (GLP). Ultimately, maintaining compliance with ISO 17025 standards can lead to creating replicable testing and calibration processes, thus eliminating the need for retesting.

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What are the Requirements for ISO 17025?

It's important for organizations to be aware of the various ISO 17025 requirements so that they can establish the necessary compliance protocols across the board. For starters, there have been notable changes introduced in the 2017 version from its previous 2005 version. Some of these include the following:

- The Management Requirements and Technical Requirements clauses previously included in the 2005 version were replaced with the clauses for General Requirements and Structural Requirements.
- Clauses 6 to 8 detailing the Resource, Process, and Management System Requirements were added.

With these, it's worth mentioning that the 2017 version now specifies the general requirements needed to guide laboratories in their operations, especially when it comes to ensuring their competence and impartiality.

The ISO 17025 standard is comprised of the following clauses and elements:

1 Scope	**2** Normative References	**3** Terms and Definitions	**4** General Requirements
5 Structural Requirements	**6** Resource Requirements	**7** Process Requirements	**8** Management System Requirements

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1. **Scope** – Discusses the objective of the standard, who can use it, and what ISO 17025 is for
2. **Normative References** – Highlights brief details on how certain guides and standards are referenced in ISO 17025
3. **Terms and Definitions** – Defines the terminology used in the standard
4. **General Requirements** – Covers the two main requirements of the standard which are:
   - Impartiality (laboratories won't let any commercial, financial, or other pressuring factors manipulate, compromise, or alter the quality of the testing results)
   - Confidentiality (laboratories are required to ensure that the results and other key information are kept private)
5. **Structural Requirement**s – Outlines a laboratory's basic organizational structure and components, its processes, and its adherence to an efficient management system
6. **Resource Requirements** – Contains the 6 clauses that specify the necessary components a laboratory must have:
   - General
   - Personnel
   - Facilities and environmental conditions
   - Equipment
   - Metrological traceability
   - Externally provided products and services
7. **Process Requirements** – Details the 11 key processes on how to improve and implement the efficiency of the standard's requirements:
   - Review of requests, tenders, and contracts
   - Selection, verification, and validation of methods
   - Sampling
   - Handling of test or calibration items
   - Technical records
   - Evaluation of measurement uncertainty
   - Ensuring the validity of results
   - Reporting of results
   - Complaints
   - Nonconforming work
   - Control of data and information management
8. **Management System Requirements** – Emphasizes the two options available for organizations complying with the standard, the differences between the two, and the various activities involved in this section:
   - Options
     - Option A – Applies to laboratories that have separate QMS from any other management system
     - Option B – Applies to laboratories that are part of larger organizations or if they have their own established management systems aligned with ISO 9001:2015
   - Management system documentation
   - Control of management system documents
   - Control of records
   - Actions to address risks and opportunities
   - Improvement
   - Corrective actions
   - Internal audits
   - Management reviews

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5 Practical Steps to Prepare for ISO 17025 Certification

To ensure that a laboratory is prepared for ISO 17025:2017 certification, a coordinated effort within the organization is required. Here are 5 steps to follow in preparation for third-party certification:

1. **Be familiar with the ISO 17025:2017 standard**; if the organization chooses option B for the standard's management system requirement, be sure to review the ISO 9001 standard as well.
2. **Conduct internal audits** to determine gaps and discover areas for improvement.
3. **Analyze the audit results** and use the information collected to train employees and align processes with the standard.
4. **Ensure that the audit results, changes in the processes**, and laboratory and employee competencies **are well documented**.
5. **Contact a recognized third party auditor** and apply for ISO 17025 certification.

Is ISO 17025 Mandatory?

While ISO 17025 isn't required, there are numerous benefits to gaining an accreditation or certification. Following internationally recognized standards allows organizations to become at par with what's considered competent and trusted in the industry. Hence, this helps significantly increase the public's level of confidence and the trust of peers in the laboratories' work.

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What are the Benefits of ISO 17025 Accreditation?

Even if the standards and requirements are released by the ISO and the IEC, third-party enforcement agencies are in charge of implementing and monitoring compliance. They conduct audits on how an organization's QMS when it comes to laboratory testing and calibration aligns with industry standards set out in the ISO 17025 standard.

Why Get an ISO 17025 Certification

Proactive culture of safety

Optimized quality management

Established credibility

Improved customer confidence

Gaining an ISO 17025 certification merits an organization the following benefits:

- Proactive culture of safety
- Optimized quality management
- Established credibility
- Improved customer confidence

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FAQs About ISO 17025

What is the Difference Between ISO 17025 and ISO 9001?

ISO 17025 and ISO 9001 are both quality management systems. But what sets them apart is the scope and the requirements. The requirements for ISO 17025 are specific to testing and calibration laboratories only. Meanwhile, ISO 9001 applies to organizations in all industries.
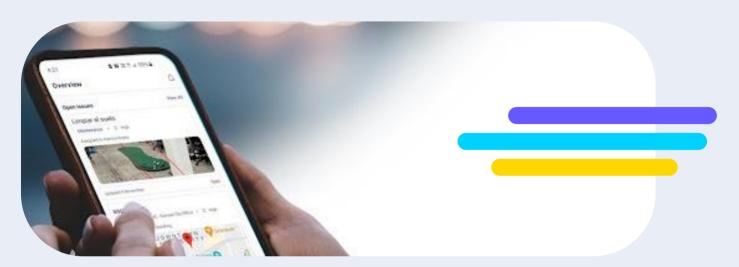
What is ISO 17025 training?

Making sure that your workers, managers, and leaders are well-informed and skilled in laboratory safety and quality practices is key to building a sustainable system of industry-standard processes. Provide ample training programs so that ISO 17025 compliance measures can be improved, strictly enforced, and maintained. Along the way, encourage employees to always practice putting consumer safety and legal obligations in mind and at the heart of what they do.

What is an ISO 17025 Checklist?

An ISO 17025:2017 checklist is a tool used by laboratory managers or metrologists to determine if a laboratory meets the required competencies for testing and calibration set by the ISO 17025:2017 standard. It contains the 5 main sections of the standard's requirements: general, structural, resource, process, and management system requirements.

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Ensuring ISO 17025 Compliance with a Digital Tool

iAuditor by SafetyCulture is a powerful, mobile-first operations platform used in digital audits and overall compliance monitoring to help organizations standardize laboratory practices, maintain quality systems, and ensure compliance with the ISO 17025 standard.

Beyond using an ISO 17025 checklist, auditors, laboratory supervisors, and leadership teams can maximize iAuditor's features by doing the following:

- Download or customize this ISO 17025:2017 checklist from our Public Library to help you ensure every requirement is accounted for and nothing is overlooked.
- Conduct regular internal audits by setting up inspection schedules to monitor all processes involved in maintaining ISO 17025 compliance.
- Capture compliance issues during audits and inspections so that the teams and employees responsible can create corrective actions in a timely manner.
- Streamline reporting and recordkeeping protocols so that everything is documented and ready for presentation during the third-party audit.
- Benchmark performance and determine areas for improvement to ensure continued compliance using analytics.
- Organize and store process documentation in iAuditor's secure cloud storage for easier and efficient retrieval once needed during audits.
- Keep Persons-in-Charge (PICs), leaders, workers, ad other stakeholders in the loop of all safe and quality laboratory processes and updates via Heads Up.

Find out how to transform your workplace with iAuditor. Book a demo