



ISO 17025: Everything Labs Need to Know

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ISO/IEC 17025 is a key compliance standard that testing and calibration laboratories around the world need to meet to demonstrate their competency and ability to generate reliable results.

Commonly shortened to ISO 17025, this standard requires labs to prioritize excellent quality practices and develop a reliable quality management system to demonstrate their competence.

Any organization that performs testing, sampling, or calibration and wants to demonstrate the reliability of its results needs to keep ISO 17025 in mind. In this guide, we'll explain the standard, show you how to meet it, and walk through how a LIMS can support compliance.

What is ISO 17025?

ISO 17025 is an internationally recognized standard that specifies requirements for the competence, impartiality, and consistent operation of laboratories. The latest standard was revised in 2017 and is officially known as

ISO/IEC 17025:2017. The revision included updates on IT (information technology), quality management system processes, and more emphasis on the responsibilities of senior management.

The standard is reviewed about every 5 years. The 2017 version was reviewed and reconfirmed in 2023.

This standard serves as a global benchmark for laboratories wishing to demonstrate their ability to produce reliable results, enhancing confidence in their work nationally and worldwide.

ISO 17025 can be broken down into five basic requirements:

- General requirements
- Structural requirements
- Resource requirements
- Process requirements
- Management requirements

We'll explore these in greater detail a bit later on to guide you through the best practices for each. It's worth noting that the management requirements align with

other ISO quality standards such as ISO 9001, however ISO 17025 places additional emphasis on the other parts.

Which Labs Should Consider ISO 17025

ISO 17025 applies to all laboratories engaged in testing, calibration, and sampling activities, regardless of their size, the industry they serve, or the complexity of the analyses they perform.

In short, if your lab measures something and wishes to demonstrate the reliability of those measurements then ISO 17025 applies.

Here are some specific examples of laboratories that need to comply with ISO 17025:

- **Testing laboratories:** These can include chemical, biological, microbiological, environmental, food, pharmaceutical, and materials testing labs. They perform a variety of tests across different materials and products to ensure safety, compliance, and quality.
- **Calibration laboratories:** Labs that provide calibration services for measurement instruments in fields such as temperature, pressure, electrical, dimensional, and optical

- need to comply. This ensures the accuracy and traceability of the measurement instruments they calibrate.
- **Government and regulatory laboratories:** Labs operated by government agencies or under their mandate, conducting tests and calibrations in the public interest, for regulatory compliance, public health, safety, and environmental monitoring.
- **Research and development laboratories:** Labs conducting R&D activities may also seek compliance if they provide testing and calibration services that require recognition for their technical competence and reliability of results.

Quality control laboratories: In industries like pharmaceuticals, manufacturing, and construction, quality control labs perform crucial tests on products and materials to ensure they meet specified standards and regulations.

Is ISO 17025 a Requirement for Labs?

Compliance with ISO 17025 is not mandatory for laboratories. Still, it is often a requirement for those wishing to demonstrate their technical competence and reliability to customers, regulatory authorities, and accreditation bodies.

Some businesses will not work with a lab that is not ISO 17025 certified.

If the accuracy (or inaccuracy) of your results can have serious consequences, you might turn this question around to whether you can afford to *not* be accredited.

Is ISO 17025 a Requirement for Labs?

If ISO 17025 is not required, why go through the effort to meet it? Aside from peace of mind, meeting ISO 17025 standards provides numerous benefits such as:

- A better reputation domestically and internationally
- Increased trust from potential and existing customers
- Likely eliminates any requirements from customers for independent 3rd party audits
- Reduced need for re-testing to verify results
- Reduced costs from putting in more efficient practices
- Time savings from task automation
- Demonstrated commitment to continuous improvement
- Centralizing key info and documents creates a single source of truth
- Proactive risk management to prevent double work and downtime

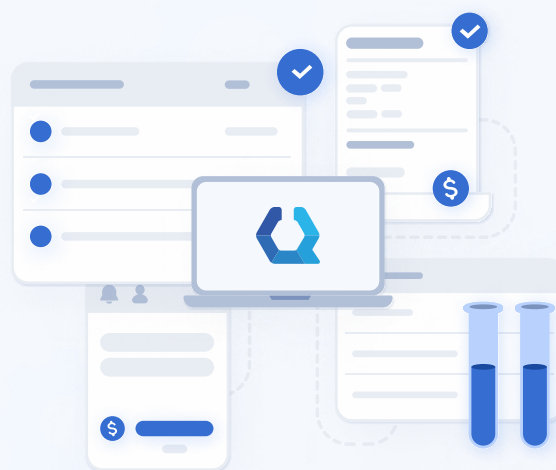
While ISO 17025 is not a requirement, it is often recommended to labs that hang their hat on reliable test results.

What Are the Requirements for Meeting ISO 17025?

The ISO/IEC 17025 standard is structured around five main categories of requirements:

- General requirements
- Structural requirements
- Resource requirements
- Process requirements
- Management requirements

Each category is designed to ensure that laboratories operate under a quality management system that enhances their ability to consistently produce valid results. Let's walk through these sections in depth.



General Requirements For ISO 17025

The general requirements for ISO/IEC 17025 include the following:

- **Impartiality:** Labs must be able to demonstrate that all work is completed with impartiality in mind.
- **Confidentiality:** Labs must demonstrate that customer information is kept confidential.

Structural Requirements For ISO 17025

The structural requirements for ISO/IEC 17025 include the following:

- **Management oversight:** There must be evidence of a person who has management responsibility for the laboratory
- **Legal setup:** The lab must be a legal entity or a part of a legal entity, which is responsible for its testing and calibration activities.
- **Documented procedures:** The lab must define a range of activities and document procedures.

Resource Requirements For ISO 17025

The resource requirements for ISO/IEC 17025 include the following:

- **Personnel:** The lab must document competence requirements such as the education and work experience of its staff. Records of their training and ongoing evaluations must be maintained as well.
- **Facilities:** The lab facilities and environmental conditions must be suitable for the activities being performed.
- **Equipment:** The lab must provide proof that all equipment is validated, calibrated, and checked before use.

Process Requirements For ISO 17025

The process requirements for ISO/IEC 17025 include the following:

- **Contract Review:** The lab must review all requests for tests and contracts.
- **Sampling:** This details the requirements for sampling and handling test items.
- **Technical Records:** Lab records must be maintained with sufficient information to produce an audit for an assessment cycle.
- **Ensuring the validity of results on an ongoing basis:** The lab must show that method validations and equipment are checked periodically.

- **Complaint handling:** The lab must have a procedure for handling complaints and non-conformances. By documenting and resolving non-conformances, the lab can identify opportunities for improvement.
- **Control of data:** The lab must have some sort of Laboratory Information Management System (LIMS). This system must be protected and in the event of a failure, backups are required to provide an audit trail.

Management Requirements For ISO 17025

The Management requirements for ISO/IEC 17025 include the following:

- **Document control:** Labs must establish and implement a system to maintain documents and the scope of their activities.
- **Risk management:** Labs must demonstrate their ability to identify, assess, and mitigate risks to procedures and operations.
- **Internal audits:** Labs must conduct regular internal audits to ensure they conform to the standards of ISO 17025.

How Does a LIMS Support ISO 17025

As you can see, measurement and document control are key pieces to meeting ISO 17025 standards. There is no better tool for labs to meet and maintain the rigorous standards of ISO 17025 than a LIMS.

A LIMS streamlines and automates laboratory processes, ensuring that data is accurately captured, processed, and stored, which in turn facilitates compliance with both the management and technical requirements of the standard.

A LIMS can support your lab in meeting ISO 17025 standards in the following ways:

- Improved data integrity and security
- Streamlined document control
- Support for validation and technical competence
- Ensuring traceability of measurements
- Managing quality control procedures
- Support for corrective and preventive actions
- Automated reporting

Improved Data Integrity And Security

A LIMS ensures that all data, from sample receipt to reporting results, is accurately captured and securely stored.

With features like audit trails, user access controls, and electronic signatures, a LIMS enhances data integrity and security, addressing the standard's requirements for control of records and information management.

Streamlined Document Control

Document control is a crucial management requirement under ISO/IEC 17025.

A LIMS simplifies the management of documents such as SOPs, calibration records, and quality manuals. It ensures that only the latest versions are accessible to personnel, thereby enhancing the lab's ability to manage its documentation efficiently and effectively.

Support For Method Validation And Technical Competence

A LIMS facilitates the validation of testing and calibration methods by maintaining detailed records of validation studies, including performance characteristics and approval status.

This supports the technical requirements

of the standard related to the use of validated methods and the laboratory's competence to perform these tests.

Ensuring Traceability of Measurements

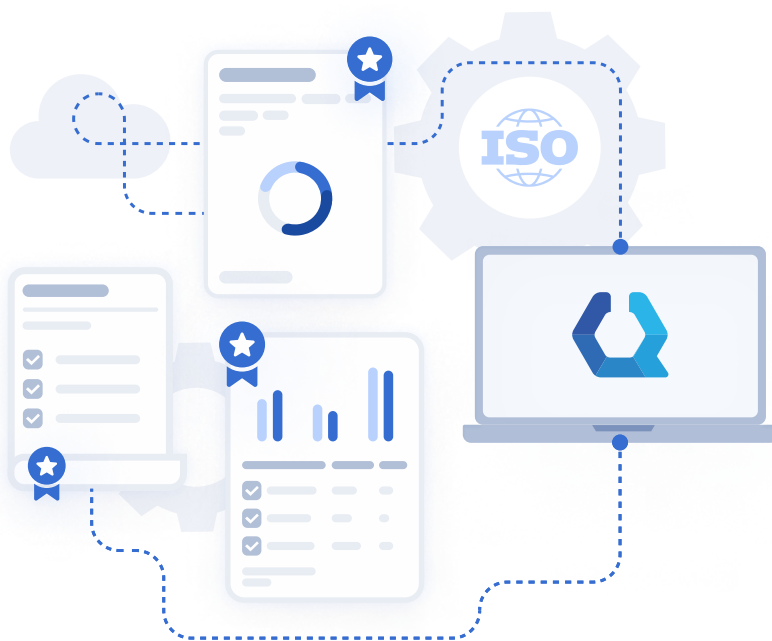
Recall that ISO/IEC 17025 emphasizes the traceability of measurements and calibrations to national or international standards. A LIMS can manage calibration schedules, record calibration data, and trace the measurement results back to the standards, thereby ensuring compliance with this requirement.



Managing Quality Control Procedures

To assure the quality of test and calibration results, a LIMS can automate the scheduling and recording of quality control activities, such as internal audits and proficiency testing. This helps laboratories to monitor their performance continuously and address any areas of concern promptly.

Not every LIMS has built-in quality control/quality assurance support, however, QBench LIMS has a native QMS that will provide you with everything you'll need along with its LIMS.



Automating Reporting And Customer Communication

A LIMS can generate accurate and detailed reports that comply with the reporting requirements of ISO 17025. It can also facilitate communication with customers by providing them with secure access to reports, test statuses, and other relevant information.

Support For Corrective And Preventive Actions

When nonconformities arise, ISO/IEC 17025 requires laboratories to take corrective and preventive actions. A LIMS can record incidents, track the investigation and resolution process, and document any actions taken to prevent recurrence, thus supporting continuous improvement.



Six Key Factors To Consider When Choosing A LIMS

It's no understatement to say that a LIMS can help your lab improve its efficiency and scale, so we understand this is a considered choice. When evaluating multiple platforms and their assorted features, it's easy to lose sight of what's best for your lab.

That's why we have grouped six keystone components of a LIMS that you should look for and use to evaluate the platforms you choose from:

1. Flexibility
2. Cloud vs. on-premises servers
3. APIs
4. User-friendliness
5. Workflow automation
6. Implementation timeline

Every lab is different, and will rank these based on their workflows. That is perfectly okay; there is no "right" or "wrong" way to combine these building blocks.

Lab managers who keep their processes, needs, and staff center stage when determining which LIMS is right for them will have the best experience choosing and implementing a LIMS.

Want to read more? Check out our free guide on [How to Choose the Best LIMS for Your Lab](#) and download the PDF.



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