

ISO 17025 Standard – An Overview

A Strategic Growth Tool for Laboratories



Lakshy Management Consultant Pvt. Ltd.

Web: www.lakshy.com

Email: info@lakshy.com

What is ISO 17025:2005 Standard ?

ISO/IEC 17025:2005 is the standard published by ISO for use by laboratories in developing their management system for quality, administrative and technical operations.

Scope of ISO 17025:2005 Standard:

- **ISO/IEC 17025:2005 is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities.**
- **Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories.**

When was ISO 17025:2005 Published ?

This standard was published in the year 2005 and is a joint effort of ISO (International Organization for Standardization) & IEC (International Electrotechnical Commission)

ISO 17025:2005 accreditation means that.....

- **The laboratory has a basic quality system in place.**
- **The lab facility has adequate equipment to perform its testing or calibration tasks.**
- **The lab facility has adequate laboratory personnel with the competence to perform the calibration and testing.**
- **In addition accreditation to ISO 17025:2005 require proficiency testing amongst the laboratories.**

Contents of the ISO 17025:2005 standard

The standard is divided into five major sections, as follows:

- General requirements for the competence of testing and calibration laboratories
- Normative references
- Terms and definitions
- Clause No. 4: Management requirements
- Clause No: 5: Technical requirements

Contents of the ISO 17025:2005 standard

- **Clause No. 4 of the standard is about establishing an quality management system in the laboratory. This section is inspired from the standard ISO 9001:2000 to a certain extent.**
- **Clause No. 5 of the standard talks specifically about the functional aspect of the laboratory.**

Clause No. 5 – Technical Requirements contains.....

The following are specifically covered in clause no. 5 – technical requirements.

- **Test & calibration methods & method of validation.**
- **Equipment & its maintenance**
- **Measurement traceability**
- **Sampling**
- **Handling of test and calibration items**
- **Assuring the quality of test and calibration results**
- **Reporting the results**

A final note:

- **If your company is not already ISO 9001 compliant (or, better yet, certified), implementing ISO 17025 at the same time as ISO 9001 should seriously be considered.**
- **ISO 9001:2000 provides an excellent, process-based foundation for 17025.**
- **While ISO 9001 can take care of the management and functional aspect of the organization, ISO 17025 can take care of the technical excellence required by the laboratory.**