

What is ISO 17025:2005 or NABL?

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# Lakshy Management Consultant Pvt. Ltd



## *ISO 17025-2005 NABL*

### *Awareness, Implementation & Accreditation Methodology*

E-Mail : [info@lakshy.com](mailto:info@lakshy.com)

Web : [www.lakshy.com](http://www.lakshy.com)



# ***What is ISO 17025:2005 or NABL?***



- ISO/IEC 17025:2005 / NABL specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

# ***Scope of ISO 17025***

- It is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.

# ***Application of ISO 17025***

- ISO/IEC 17025:2005 / NABL is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. ISO/IEC 17025:2005 / NABL is not intended to be used as the basis for certification of laboratories.

# ***Who should go for ISO 17025 ?***

- ISO/IEC 17025:2005 /NABL is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by ISO/IEC 17025:2005 / NABL, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

# ***Requirements of ISO 17025***

- 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
  - Management requirements
  - Technical requirements
- As is the case with other ISO standards, sections 1, 2 and 3 are for guidance only, and not auditable.

# 10 Step Approach to ISO 17025 Accreditation

- Awareness Training
- Quality Policy & Objectives Finalization
- Gap Analysis
- Documentation / Process Design
- Documentation / Process Implementation
- Internal Audit
- Management Review Meeting
- Shadow Audit
- Corrective – Preventive Actions
- Final Certification Audit



# Step 1: Awareness Training

## Deliverables:-

### Organization wide awareness about Quality and ISO 17025.

- Separate training sessions for top management, middle management and junior level management.
- Creates a motivating environment throughout the organization for ISO 17025 implementation.

# Step 2:- Quality Policy & Objectives

## Deliverables:-

**Development of Quality Policy & Quality Objectives for the organization considering vision, mission and goal .**

- Work shop with top management on development of quality policy.
- Work shop with top management and middle level functional management on development of quality objectives.

# Step 3:- Gap Analysis

## Deliverables:-

**Identification of degree of compliance of existing system with requirements of ISO 17025:2008 standard.**

- Understanding of all the operations of the organization.
- Development of process map for the activities of the organization.
- Comparing existing operations with requirements of ISO 17025:2005 standard.

# Step 4:- Documentation / Process Design

## Deliverables:-

**Documentation of the entire process as per requirements of ISO 17025:2008 Quality Management System.**

- Quality Manual
- Functional Procedures
- Work Instructions
- System Procedures
- Formats

**Work-shop on design and development of documents as per ISO 17025 requirements**

# ***Step 5:- Documentation / Process Implementation***

## **Deliverables:-**

**Processes / Documents developed in the last module implemented across the organization covering all the departments and activities.**

- Work–shop on process / document implementation as per ISO 17025 requirements.
- Departmental / Individual assistance in implementing the new processes / documents.

# Step 6:- Internal Audit

## Deliverables:-

**A robust internal audit system for the organization.**

- Internal Audit Training & Examination (Optional).
- Successful employees / we carry out internal audit of the organization covering all the departments and operations.
- Suggest corrective and preventive actions for improvements in each of the audited departments.

# Step 7:- Management Review Meeting

## Deliverables:-

**A formal system of top management reviewing various business critical aspects of the organization.**

Review the following:-

- Quality Policy & Objectives
- Results of internal audit
- Results of supplier evaluation
- Results of customer complaints
- Results of customer feed-back etc.

**....and develop action plan**

# Step 8:- Shadow Audit

## Deliverables:-

**A formal Pre Certification audit conducted to assess effectiveness of ISO implementation in the organization.**

- A replica of final certification audit.
- Finds degree of compliance with ISO 17025 standard.
- Gives an idea to the employees about the conduct of the final certification audit.

# Step 9:- Corrective – Preventive Actions

## Deliverables:-

### Organization ready for final accreditation audit.

- On the basis of shadow audit conducted in the last step, all the non-conformities will be assigned corrective and preventive actions.
- A check will ensure that all the NCs are closed and the organization is ready for the final certification audit.

# Step 10:- Final Certification Audit

## Deliverables:-

**Organization awarded ISO 17025:2005 accreditation .**

- Upon completion of various stages of accreditation audit, the audit, your organization will be awarded ISO 17025:2005 accreditation.

# WHAT IS ISO ?

- ISO –Greek word “isos” means “equal”
- pronunciation “eye-soh”
- ISO is a worldwide federation of national standards from more than 140 countries.
- ISO is a non-governmental organization established in 1947 with head quarters in Geneva, Switzerland.

ISO 17025 Implementation Steps

# ***Need More Information.....?***



**Lakshy Management Consultant Pvt. Ltd.**

232, Sai Chambers, Sector 11, CBD Belapur,  
Navi Mumbai 400 614, India

Phone: +91 22 32995241

24 Hour Customer Care: +91 9821780035

Email: [info@lakshy.com](mailto:info@lakshy.com)

Web: [www.lakshy.com](http://www.lakshy.com)