

## WHAT IS ISO 17025 or NABL?

ISO/IEC 17025 is the main standard used by testing & calibration laboratories. Originally known as ISO/IEC guide 25, ISO/IEC 17025 was initially issued by the international organization for the standardization in 1999. It was first published in 2001 & on 2005.

There are two main sections ISO/IEC 17025. Management requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory. Technical requirements address the competence of staff, methodology and test/calibration equipment. Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results.



Providing ISO 17025 consulting and Training services across the world.

## BENEFITS OF ISO 17025:2005

1. NATIONAL & INTERNATIONAL RECOGNITION
2. RECOGNIZES THE TECHNICAL COMPETENCE OF LABORATORY STAFF.
3. ASSURES THE CLIENT THAT RESULTS ARE TECHNICALLY VALID.
4. PROVIDES COMPARABILITY IN MEASUREMENTS
5. DECISION MAKERS CAN RELY ON TEST RESULTS
6. IMPROVES STAFF MOTIVATION
7. ENSURES BETTER SUPPORT IN THE EVENT OF LEGAL CHALLENGE.
8. TO ASSIST IN THE DEVELOPMENT OF NEW PROGRAMMES.
9. TO REDUCE TECHNICAL BARRIERS IN TRADE.
10. SAVES MONEY BY GETTING IT RIGHT FIRST TIME.



## What does Lakshy Management Consultant Pvt. Ltd. Offer in the field of ISO / IEC 17025 / NABL Accreditation ?

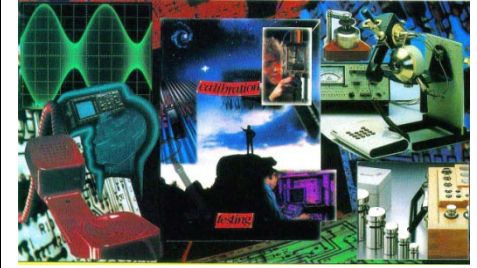
The laboratory quality management professionals at Lakshy, have considerable experience helping our clients to design and implement ISO 17025 laboratory accreditation programs / NABL Accreditation. In addition to planning, development, and implementation, we help our clients cooperatively work with ISO 17025 accreditation organizations such as the American Association for Laboratory Accreditation, National Quality Assurance, and National Accreditation Board for Laboratories - NABL.

Lakshy offers comprehensive services that will help you achieve your ISO 17025 quality goals. We can:

- Conduct an initial gap analysis
- Help you establish policies and objectives
- Identify documentation requirements
- Make assignments and prepare schedules
- Prepare documentation
- Coordinate document preparation, reviews, approvals, and production
- Manage implementation schedules, training, follow-up actions
- Help you select a Registrar that has experience in your industry
- Prepare status reports and monitor progress and achieve successful accreditation.

In addition to consulting (onsite and online), we provide following training

- "ISO 17025 Overview Training"
- "ISO 17025 for the Small Laboratory"
- "Developing Your Laboratory Quality System Documentation"
- "Internal Auditor training"
- "Estimation of Measurement Uncertainty"
- "ISO 17025 implementation training"



## GENERAL REUQUIREMENTS FOR THE ISO 17025

Quality system requires implementation of two sets of requirements/standards and activities.

The essential components are :

- Management requirements[ Clause 4]
- Technical requirements [Clause 5 ]

### MANAGEMENT REQUIREMENTS

- 4.1 Organization
- 4.2 QUALITY MANAGEMENT SYSTEM
- 4.3 DOCUMENT CONTROL
- 4.4 REVIEW OF CONTRACTS
- 4.5 SUBCONTRACTING OF TESTS AND CALIBERATION
- 4.6 PURCHASING SERVICES AND SUPPLIES
- 4.7 SERVICE TO THE CLIENT
- 4.8 COMPLAINTS
- 4.9 CONTROL OF NON-CONFORMING WORK
- 4.10 CORRECTIVE ACTION
- 4.11 PREVENTIVE ACTION
- 4.12 CONTROL OF QUALITY RECORDS
- 4.13 INTERNAL AUDITS

### TECHNICAL REQUIREMENTS

- 5.1 General
- 5.2 Personnel
- 5.3 Accommodation
- 5.4 Test methods and validation
- 5.5 Equipment
- 5.6 Measurement traceability
- 5.7 Sampling
- 5.8 Handling of test and calibration items
- 5.9 Assuring the quality of test and calibration Results
- 5.10 Reporting the results.

**Measurement of uncertainty** is a requirement of the ISO/IEC 17025 standard. When estimating the uncertainty of measurement , all uncertainty components which are of importance given situation shall be taken into account:

1. Reference stds. and reference materials with reported uncertainty in the calibration certificate.
2. Method employed .
3. Equipment used with reported uncertainty in the calibration certificate.
4. Environmental conditions.
5. Properties and condition of the item being tested/calibrated.

### INTERLABORATORY TEST PROGRAM/ PROFICIENCY TESTING & METHOD VALIDATION

It is the one of the powerful method of checking the validate of the test and / or calibration results.

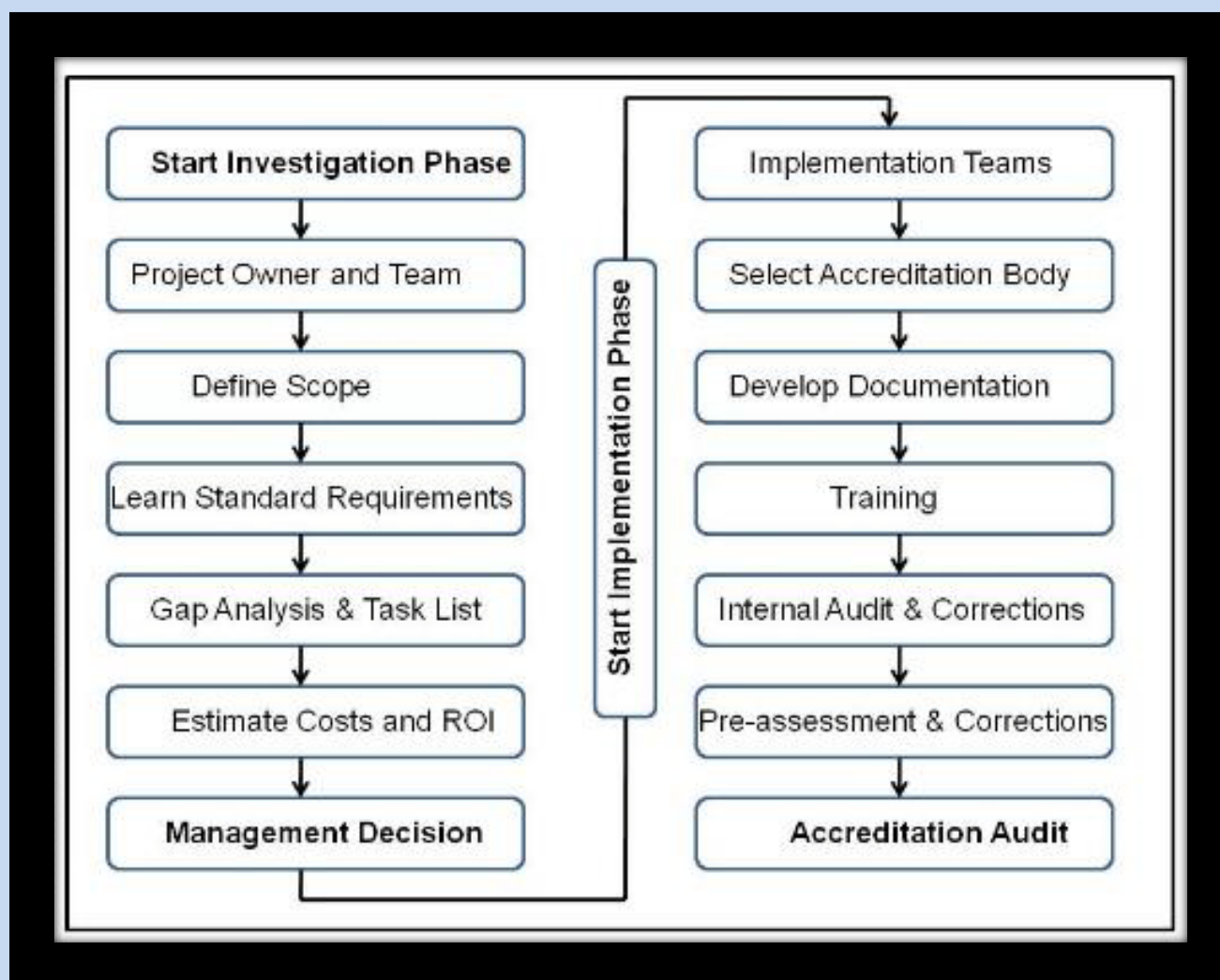
All NABL accredited testing and calibration laboratories are required to participate in proficiency testing programmes conducted by NABL or the nodule organizations appointed by NABL.

## Key steps towards accreditation are:

ISO/IEC 17025 accreditation should be well thought out and well prepared. It can be quite expensive but can also have big benefits. The balance between costs and benefits should be worked out and documented.

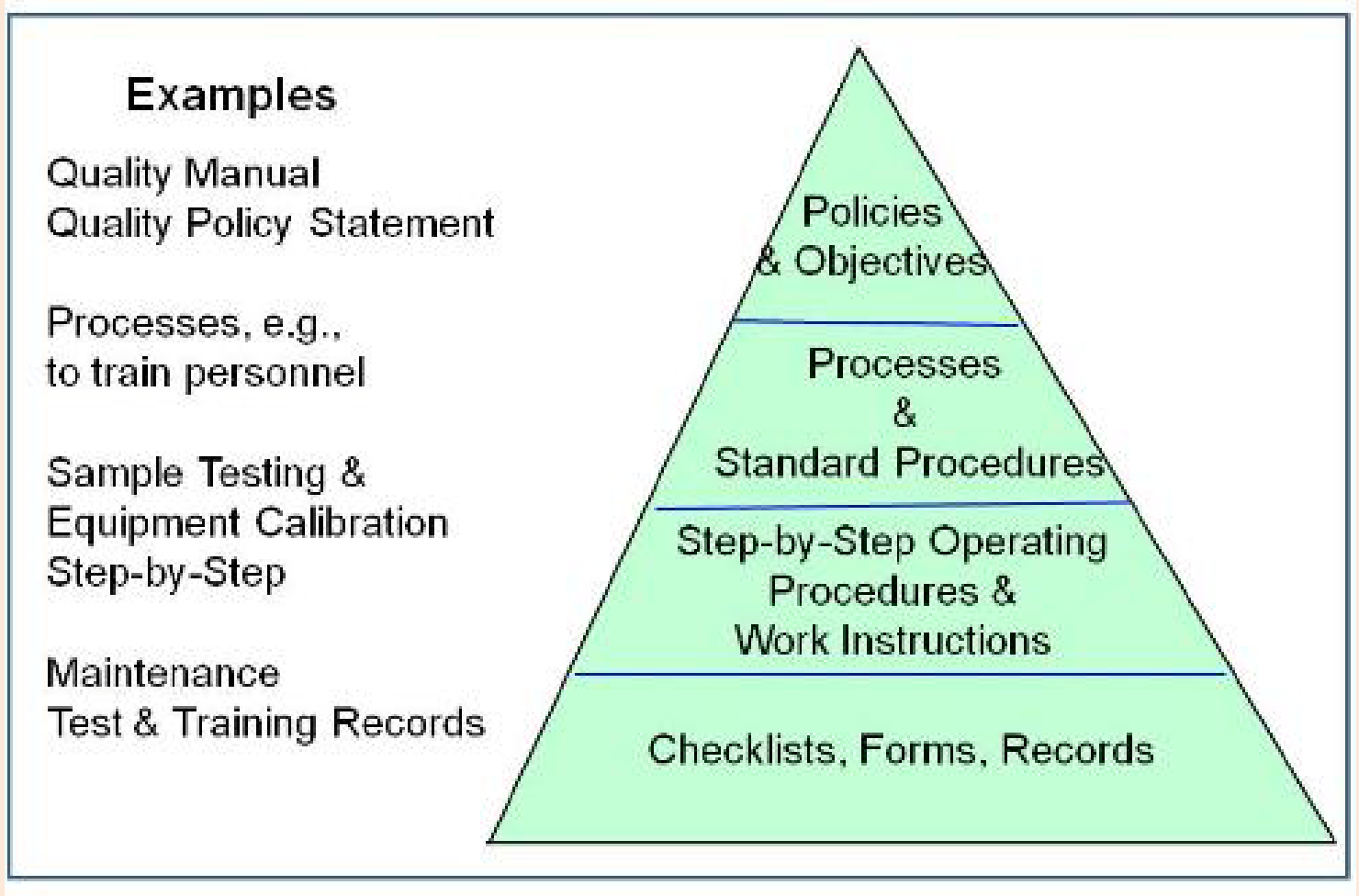
Going for ISO/IEC 17025 will impact the entire laboratory and supporting services such as human resources, documentation and finance departments. Therefore, while the decision to initiate and fund the project will be made by management, all affected departments should be involved in the process.

The entire process is divided into two phases: Investigation phase and implementation phase. In the investigation phase information is collected to decide if going for accreditation makes business sense. Once the decision is made the laboratory develops and implements documentation in preparation for the accreditation assessment.



## Documentation

ISO/IEC requires different types of documentation as illustrated in the documentation pyramid below.



- ❖ A policy documents the laboratory intent and goal of the laboratory to conform with ISO /IEC requirements.
- ❖ Quality manual describes the approaches to achieve quality data. It includes quality policy.
- ❖ A process describes how various quality requirements can be achieved.
- ❖ Standard operating procedures or working procedures are step by step instructions on how to exactly perform a specific task .
- ❖ Records are generated on day by day basis.
- ❖ All records should be well controlled.

With a team of highly qualified consultants and trainers having vast industrial experience, we partner organizations across the world to implement and achieve ISO / IEC 17025 / NABL Accreditation.

Our consulting approach is highly professional, time bound and effective resulting in ease of implementation and adds value to the business processes of the client organization.

Contact us at [info@lakshy.com](mailto:info@lakshy.com) to get your organization ISO / IEC 17025 / NABL Accredited.