Laboratory Management System
Understanding & implementation of ISO/IEC 17025:2005 in Calibration and Testing Laboratories
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_in Calibration and Testing Laboratories_
Overview

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, called “International Organization for Standardization”.
• ISO is a non-governmental organization established
  • in 1947 with head quarters in Geneva, Switzerland.
• IEC - International Electro technical Committee
• 17025 - is the number
Overview

Benefits of ISO 17025 Accreditation

• A systematic approach to control all its processes and well defined procedures and supporting documentation.

• Achieve international recognition of its technical competence, gain the confidence of customers and interested parties, as well as open doors to new market both locally and international.

• Greater quality awareness amongst employees and reduced defects, scraps, rework failures and service recovery.
  • Have a better corporate image in the eyes of regulators, customers, employees as well as the society at large.
  • Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.
Overview

Benefits of ISO 17025 Accreditation

• Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent.
• Control laboratory methods variation.
• Increase of confidence in Testing / Calibration data and personnel performing work.
• Validity and appropriateness of test methods.
• Traceability of measurements and calibrations to national standards.
• Suitability, calibration and maintenance of test equipment & Testing environment.
• Sampling, handling and transportation of test items, Quality assurance of test and calibration data. Potential increase in business due to enhanced customer confidence and satisfaction.
ISO/IEC 17025:2005 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/IEC17025:2005/NABL is not intended to be used as the basis for certification of laboratories.
Overview

Who should go for 17025 Accreditation?
ISO/IEC17025:2005 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/IEC17025:2005, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.
NATIONAL ACCREDITATION BOARD FOR TESTING AND CALIBRATION LABORATORIES (NABL)

- is an autonomous body
- registered under Societies Act in 1992
- under the aegis of Department of Science & Technology.
NABL – FUNCTIONING ROLE IN INDIA

- Grants accreditation in almost all areas of science, engineering and medical testing.

- The international standards followed are:
  ISO 15189:2007 (for Medical Testing),
  ISO/IEC 17025:2005 (for Testing, calibration) &
  ISO 17043:2010 (for PT providers) Proficiency Testing Provider
Background-ISO/IEC 17025

Development of ISO 9000 Series

- ISO 9000 series (1987)
- ISO 9000 series (1994)

Development of ISO/IEC 17025


1980 1990 2000 2010
Overview

General requirements for competence of testing and calibration laboratories.

ISO/IEC 17025 : 2005:
- covers several technical competency requirements that are not covered by ISO 9001:2000.
- Does not cover compliance with regulatory and safety requirements on the operation of the laboratory.
Structure of ISO/IEC 17025

1 Scope
2 Normative references
3 Terms and definitions
4 Management requirements
5 Technical requirements

Annexes

A: Cross-references to ISO 9001:2000

B: Guidelines for establishing specific requirements for laboratory competence.
4. MANAGEMENT REQUIREMENTS
4.1 Organization
4.2 Management system
4.3 Document control
4.4 Request, tender and contract review
4.5 Sub-contracting of tests and calibrations
4.6 Purchasing services and supplies
4.7 Service to the customer
4.8 Complaints
4.9 Control of nonconforming testing and/or calibration work
4.10 Improvement
4.11 Corrective action
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4.13 Records
4.14 Internal audits
4.15 Management reviews
5. TECHNICAL REQUIREMENTS

5.1 General
5.2 Personnel
5.3 Accommodation and environmental conditions
5.4 Test and calibration methods and method validation
5.5 Equipment
5.6 Measurement traceability
5.7 Sampling
5.8 Handling and transportation of test and calibration items
5.9 Assuring the quality of test and calibration results
5.10 Reporting the results.
Scope of ISO/IEC 17025

Covers General Requirements of Laboratory performing Testing and calibrations using -

• Standard methods,
• Non standard methods
• Laboratory-developed methods

Applicable to all organizations performing tests and/or calibrations,

These include, for example,

First-party, second party and third-party, and where testing and/or calibrations forms part of inspections and product verifications.
NABL, as an accreditation body, operates its own system as per ISO/IEC 17011.

NABL is signatory to APLAC / ILAC Mutual Recognition Arrangements (MRA) since 2000 after its first evaluation by APLAC.

Definitions

**Testing** : Examination of a product design, product, service, process or plant and determination of their conformity with specific requirements or on the basis of professional judgment, general requirements.

**Calibration** : Calibration is set of operations which under specified conditions, establish the relationship between values indicated by measuring system and the corresponding known values of a measurand.

It is essentially comparison with higher standard which is traceable to national/international standard

**Management System** : Quality, Administrative and technical systems that governs the operations of a laboratory.

**Accreditation** : Assurance of Competency to perform operations.
Definitions

**Quality**- Good quality does not necessarily mean high quality. Instead it means a predictable degree of uniformity and dependability at low cost with a quality suited to the market (Deming)

Degree to which a set of inherent characteristics fulfils requirements (ISO 9001:2008)

**Quality Assurance**- “part of quality management focused on providing confidence that quality requirements will be fulfilled” (ISO 9001:2008)
4.1 Organization

Should be a legal identity

If Laboratory is part of a larger organization having activities other than calibration or testing, responsibilities of key laboratory personnel shall be defined in order to identify conflicts of interest.

Can be operated from Permanent facilities, at sites, or in associated temporary or mobile facilities.
4.1 Organization

Laboratory shall have

• Managerial and technical personnel with authority and resources
• Personnel free from pressures and influences.
• Policy & Procedure to Protect customer’s confidential information including results.
• Policy & Procedure to safeguard competence, impartially, operational integrity.
• Defined organization structure
• Adequate supervision
• Technical management – overall responsibility of technical operations.
• Quality manager-responsibility of implementation of management system.
4.2 Management system

• Establish and maintain a management system appropriate to the scope of its activities.
• Document its policies, system, programs procedures and instructions to the extent necessary to assure the quality of test / Calibration results.
• A Quality Policy statement and objectives shall be defined.
• Top management roles and responsibilities for meeting system requirements including commitment to good professional practices.
• Quality System Documentation : Quality manual, procedures, structure, roles and responsibility of technical management and Quality manager.
Purpose of implementation of Management Systems

The basic purpose of any calibration / Testing laboratory is to provide to its Customers, reliable results.

\[ R \pm U \]

Where,

- \( R \) is the reported value,
- \( U \) is the associated uncertainty at a specified confidence level.

Various requirements of management system as per clause 4 & 5 of ISO/IEC 17025 enable to achieve the above on an ongoing basis.
4.3 Document control

Establish and maintain Procedure to control all the documents (Externally/internally generated).

- Document approval and issue
- Document changes

Controls required are similar to ISO 9001

Additional requirements for Labs:
- Master list of documents (suggested)
- Document identification shall include
  - date of issue and/or revision identification
  - page numbering
  - the total number of pages or a mark to signify the end of the document,
  - issuing authority.
4.4 Review of requests, Tenders and Contracts

• Procedures for
  • Defining, documenting and understanding the testing requirements including test methods
  • Confirming that the Laboratory has the capability & resource to meet the requirements
  • Selection of Appropriate Test / Calibration method which is capable of meeting Customer’s requirement.

• Any difference between request or tender and contracts shall be resolved before start of work
• Records of review, including any significant changes shall be maintained
• Review should also cover any work that is sub-contracted
• Customer shall be informed of any deviation from contract
4.5 Subcontracting of tests & calibrations

- Laboratory can subcontract work because of
  - work load increase
  - temporary in-capability,
  - need for other expertise or
  - continuing basis through permanent arrangements

- Work can only be subcontracted to competent laboratory
- Customer has to be informed regarding subcontracting
- The laboratory shall always remain responsible for subcontractor’s work
4.6 Purchasing services & supplies

• Laboratory has to ensure that the quality of consumables such as reagents that are used for testing / calibration are of appropriate quality

• Laboratory can ensure the quality through
  – Inspection of the consumables
  – Other forms of verification
  – Evaluating suppliers of consumables (mandatory for critical consumables)

• The laboratory needs to maintain records of inspection, verification, purchase orders describing specifications and other quality requirements, and records of supplier evaluations
4.7 Service to the customer

• Laboratory shall be willing to co-operate with the customer in clarifying his request and in monitoring laboratory's performance in relation to work performed.

• Laboratory shall obtain customer feedback, use and analyze this feedback to improve management system and customer service.
4.8 Complaints

- Laboratory shall have Policy & Procedure for resolution of complaints received from customers and other parties.

- Record shall be maintained of all complaints, investigations, and corrective actions taken
4.9 **Control of non-conforming testing / calibration work.**

- The Laboratory needs to have procedures to deal with situations when any aspect of its work or test / calibration results do not confirm to its own procedure or with customer requirements.
- The procedure needs to:
  - Define who will be responsible to handle the non conforming work after it is detected.
  - Provide for an evaluation of significance of non-conforming work – criticality analysis.
  - Provide for immediate **Corrections** to deal with the situation.
  - Provide for Informing customer if necessary and recall any issued reports etc.
  - Evaluate need for **Corrective actions** if the non conformity is estimated to recur frequently.
Similar to ISO 9001, the Laboratory’s Quality System shall continually improve its effectiveness through the application of

- Quality Policy / Objective.
- Audit Results / Management Review
- Analysis of data, corrective / preventive actions
4.11 Corrective action

- The Laboratory needs to establish policy and procedure for implementing corrective action when non-conforming work has been identified or departure from policies and procedure in management systems or technical operation has been observed.

- The requirements for taking Corrective and Preventive actions are similar to ISO 9001. Steps include:
  - Root cause analysis
  - Identification and selection of potential corrective actions for elimination of problem and to prevent recurrence.
  - Documenting and implementing any change resulting from corrective action.
  - Monitoring of corrective actions.
  - Monitoring effectiveness.

- ISO 17025 recommends additional internal audits in case identification of any non-conformance or departures casts doubts on laboratories compliance with its own policies and procedure.
4.12 Preventive action

- Laboratory shall identify the improvements needed and the potential sources of non-conformance
- Develop action plans to reduce the likelihood of reoccurrence
- Application of controls to ensure that they are effective.
4.13 Control of records

- Establish and maintain Procedure to control records
- Controls required are similar to ISO 9001
- ISO 17025 additionally requires the following
  - Procedures to protect and back up electronically stored records and prevent unauthorized access
  - All records to be held securely and in confidence
4.13.2 Technical records

- Laboratory must retain the following technical information:
  - Records of original observations / derived data,
  - Calibration records
  - Staff records
  - Copy of each test / calibration reports issued
  - Uncertainty records
  - Records of persons who carried out the test
- All recording to be done immediately
- Errors / mistakes shall not be erased / replaced, but crossed out and new value entered by the side
Some Important records that need to be maintained during implementation of ISO /IEC 17025

Administrative and Quality System Records.
1) Document control Records.
3) Subcontracting Records.
4) Purchasing Records.
5) Customer feedback and analysis Records.
6) Complaint Records.
7) Non-conforming work Records.
8) Improvement records.
9) Corrective and preventive actions Record.
10) Internal Audit Records

Technical System Records.
1) Personnel Records.
2) Environmental Records.
3) Calibration/ Test observations / Raw Data/ int.check records.
4) Measurement Uncertainty Records.
5) Computer /Software related Records.
6) Equipment Records/Traceability Records
7) Sampling Records
8) Handling - receipt to dispatch- Records.
9) Quality Assurance Records.
10) Test reports/Calibration Certificates.
11) Retention Record for Documents /Samples
4.14 Internal audits

- Internal Audit shall be conducted on predetermined schedule to verify that its operations comply with requirements of its Management system and all elements of ISO 17025 requirements.
- Quality manager is responsible for internal audits.
- Audit shall be carried out by trained and qualified personnel independent of activity to be audited.
- When audit findings cast doubt on effectiveness of operations or on the correctness or validity of lab. results, laboratory shall take timely corrective action.
4.15 Management reviews

- Laboratory's **Top** Management shall periodically conduct a review of lab’s management system.
- Review Inputs are similar to ISO 9001, except the following additional inputs:
  - reports from managerial and supervisory personnel;
  - assessments by external bodies
  - the results of inter-laboratory comparisons or proficiency tests
  - changes in the volume and type of the work
  - quality control activities, resources and staff training.
- Findings from management reviews shall be recorded and actions taken in agreed timescale.
Technical Requirements
5.1 General

- The Laboratory must identify factors, which determine the correctness and reliability of test and calibration results and factors that contribute to uncertainty of measurement.
- These factors must be accounted
  - in developing test/calibration methods,
  - during training and qualification of personnel, and
  - in selection and calibration of equipment it uses.
Major Sources of Uncertainties

I – Instrument (5.5)
1 – Instrumental Error Acceptance Norm.
2 – Uncertainty of calibration
3 – Instrumental Resolution
4 – Repeatability (Type A)

W – Work piece (5.7, 5.8)
1 – Non-homogeneity of test material
2 – Instrumental Resolution
   (When instrument is under calibration)

P – Person (5.2) / Procedure (5.4)
1 – Repeatability (Type A)
(Skill of operator for positioning and measuring pressure etc.)

S – Standard (5.5 & 5.6)
1 – Un-compensated Dev. from nominal value.
2 – Uncertainty of calibration.
3 – Non-homogeneity (Type A).

E – Environmental Factors (5.3)
Temperature control limits
   Temperature variation.
   Humidity.
   Cleanliness (Type A).
   Vibration (Type A).
5.2 Personnel

- A laboratory can use personnel either employed or under contract.
- However, it must ensure that personnel are competent to perform their respective task.
- The laboratory is required to formulate goals with respect to education, training, and skills of personnel.
- The laboratory must have procedures for trainings. The effectiveness of the training actions taken shall be evaluated.
- Job descriptions are required to be maintained for all laboratory persons.
- A formal system of authorization of personnel is required for specific tasks such as performing tests, issue of reports, giving opinions & interpretations.
5.3 Accommodation and environmental conditions.

- The laboratory needs to ensure that facilities and environmental conditions do not adversely affect tests or calibrations.
- Particular care is necessary for sampling and testing / calibration at off-site locations
- Some tests / calibrations require specified environmental conditions. The laboratory must monitor that these conditions are met and not proceed if the conditions are not met.
- In some types of tests, effective separation of Test / calibration area may be required
- Access to areas affecting quality should be controlled.
- The laboratory should install measures for good house keeping
5.4 Test and calibration methods and method validations

- The laboratory should normally carry out tests or calibrations using ‘Standard methods’. These are methods published in national / International standards, reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment.
- Methods cover sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty.
- Laboratory can also use self developed methods for its own use.
- Non-standard method, can be used for performing tests / calibrations for customers but these need to be approved by him.
- Laboratory developed methods and non standard methods require validation.
- Validation can be carried out through calibration with reference materials, inter-lab comparisons, systematic evaluation of influencing factors.
5.5 Equipment

- Laboratory shall be furnished with all items for sampling, measurement, and test equipment required for correct performance for test/calibration.
- Equipment
  - shall be capable of achieving the accuracy required
  - shall comply with specification relevant to tests / or calibrations concerned.
  - shall be calibrated.
- Laboratory must allow use of equipment to authorized persons only.
- The operating instrumentation shall be available.
- There should be unique identification of each item of equipment.
- The Equipment History record must include
  - Identification
  - Manufacturer’s name, type identification, sr. No. Etc.
  - Dates, results and copies of report and certificates of calibration, adjustment,
  - Acceptance criteria, and due date of next calibration.
  - Maintenance plan, date of maintenance.
  - Details of any damage, malfunctioning or repairs.
Other requirements with respect to equipment are:

• A procedure for safe handling / transportation / storage /use and planned maintenance to prevent deterioration.
• Removing from service, those equipments, which give, suspected results or have been mishandled
• Examining the impact of defects and Non-conforming test/ calibration on previous results
• Identification of the Calibration status through labeling of equipment
• Intermediate checks to maintain confidence in the calibration status.
• Safeguarding from adjustments which would invalidate the tests and/or calibration results.
5.6 Measurement traceability

• All equipment used for tests / calibrations, having an effect on validity of results shall be calibrated.
• Laboratory should have established program and procedures for calibration Program for calibration shall be designed to ensure that measurements are traceable to the international system of units (SI) by reference to national measurement standards
• Calibration services from laboratories that can demonstrate competence, measurement capability and traceability.
• When traceability is not possible, other methods permitted:
  – Use of certified reference material provided by competent supplier & specified methods.
  – Use of specified methods and/or consensus standards
• Reference standards shall be calibrated, made traceable to SI units,
• Reference material should be traceable to SI units or certified reference material
• Intermediate checks for maintaining confidence in calibration status of reference
5.7 Sampling

- The laboratory should have sampling plans & procedure for sampling when it is responsible for carrying out sampling.
- The sampling process shall address the factors to be controlled to ensure the validity of test and calibration results.
- Related data and operations related to sampling that forms a part of testing and calibration should be recorded properly.
5.8 Handling of test / calibration items

- The laboratory should have a procedure for transportation / handling / storage / disposal of test / calibration items.
- In case any abnormalities / departures from normal functioning or normal conditions are observed these shall be recorded.
- There should be a Procedure for avoiding deterioration, loss or damage to Test / calibration item while it is in the custody of the laboratory.
5.9 Assuring the quality of test and calibration results

- The laboratory must have an internal quality control procedure for monitoring the validity of calibrations undertaken.
- Results data shall be recorded in such a way that trends are detectable: where practicable statistical techniques shall be applied.
- Monitoring methods used:
  - Internal quality control using secondary reference materials
  - Participation in inter-laboratory comparison or proficiency testing programme
  - Replicate testing
  - Retesting of returned items
  - Correlation of item using different characteristics of the item
5.10 Reporting of results

- Test report / calibration certificate should be reporting the results accurately and clearly.
- The report must contain
  - Title of the report
  - Name and address of laboratory,
  - Report I.D. on each page
  - Name and address of client
  - Identification of method used,
  - Unique item identification, description and condition
  - Dates of item receipt, test or calibration conducted
  - Sampling plan and procedures used,
  - The test or calibration results
  - Identification of person(s) authorizing the test report or calibration certificate
  - Details of environmental conditions during test / calibration
  - Uncertainty in case of calibration reports
5.10 Reporting of results

- Opinions and interpretations can be given but shall document the basis up on which the opinions and interpretations have made.
- Results of test performed by subcontractor shall be clearly identified.
- Electronic transmission of results can be done but requirements of this standard shall be met.
- The format for report and certificate shall be designed to accommodate each type of test and calibration.
- Amendment to the test and calibration certificate
  - Can be issued as a supplement to test / calibration report
  - Complete issue shall be uniquely identified and shall contain reference to the original that it replaces.
Major role of Quality Manager

- Implementation, maintenance of Management system complying to ISO/IEC 17025.
- Maintenance of Impartiality, integrity, confidentiality and customer’s proprietary rights in lab operations.
- Ensure control for all documents internally generated as well as externally generated.
- Review of customer requests, tenders & Contracts.
- Evaluation, selection of Suppliers.
- Effective resolution of Customer complaints.
- Organizing Internal audit as per scheduled plan.
- Initiating corrective actions against every non-compliance identified in external and internal audit and maintenance of all management system records.
Major role of technical Manager

- Selection, documentation and approval of test/ calibration methods
- Periodic updation of B.M.C. values for test / calibration activities, as and when changed.
- Ensure Traceability of all the lab equipment and reference standards and their fitness for subsequent use.
- Management and training of staff
- Evaluate and ensure staff competency
- Design and implementation of the QC program
- Stopping work when QC criteria are violated
- Attention to matters relating to impartiality and confidentiality.
- Ensure technical validity of the results
- Liaison with the quality manager in matters of common concern, affecting testing or calibration.
Major role of Authorized Signatory

• The testing laboratory is obligated to fulfil the requirements of ISO/IEC 17025 and to have approved authorized signatory who bears the full responsibility for proper execution of the test or calibration and correctness of the data in the test report/ Calibration Certificates.

• Lab has to have at least one approved authorized signatory for each specific discipline.
• Authorized signatories should Carry out regular measures to assure the quality of test results are maintained.
Major role of Authorized Signatory

• The authorized signatory should be qualified, experienced in the relevant discipline as per the specific criteria demonstrating skill for the Job assigned i.e. testing or calibration. E.g. NABL 102 - Specific Criteria for Biological Testing Laboratories NABL 103-Specific Guidelines for Chemical Testing Laboratories NABL 114-Guidelines for Food Testing Laboratories documents given by NABL and must posses the
Questions..?
Thank you for your kind attention