

**ISO 17025:2007**

**LABORATORY MANAGEMENT SYSTEM**

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# **ISO 17025**

## **Interpretation of Standard Requirements**

# ISO 17025

- Management Requirements
- Technical Requirements

## **Contents of ISO / IEC 17025 : 2005**

- 1. Scope**
- 2. Normative References**
- 3. Terms and Definitions**
- 4. Management Requirements**
- 5. Technical Requirements**

## **1. SCOPE**

- ❖ Specifies requirements applicable to Testing / Calibration laboratories**
- ❖ Notes given in the standard are for guidance and do not contain requirements**
- ❖ Standard is meant for use by laboratories, Customers, accreditation bodies etc.**
- ❖ Compliance with the regulatory and safety requirements are not covered by the standard**
- ❖ Compliance with this standard ensures compliance with ISO 9001:2000**

## 2. NORMATIVE REFERENCES

- ♣ **ISO 9001 :2000 Quality Management System**
- ♣ **ISO / IEC Guide 2 : General terms and their definitions concerning standardization**
- ♣ **VIM: International Vocabulary of basic and general terms in metrology**

### **3. TERMS AND DEFINITIONS**

- ❖ Terms given in ISO/ IEC guide 2 and VIM are applicable**

## **4. MANAGEMENT REQUIREMENTS**

**4.1 Organization**

**4.2 Management System**

**4.3 Document control**

**4.4 Review of requests, tenders and contracts**

**4.5 Subcontracting of tests and calibrations**

**4.6 Purchasing services and supplies**

**4.7 Service to Customer**

**4.8 Complaints**

## **4. MANAGEMENT REQUIREMENTS –contd.**

**4.9 Control of non-conforming testing/ calibration**

**4.10 Improvement**

**4.11 Corrective actions**

**4.12 Preventive actions**

**4.13 Control of records**

**4.14 Internal audits**

**4.15 Management reviews**

## **4.1 ORGANIZATION**

- 4.1.1 Laboratory / organization shall be an entity that can be held legally responsible**
- 4.1.2 Laboratory to carry out activities to meet the requirements of this standard, Customers, regulatory authorities and organizations providing recognition**
- 4.1.3 Management system to cover permanent, temporary and mobile facilities**
- 4.1.4 If laboratory is part of an organization having different activities, responsibility of key personnel shall be defined**

#### **4.1.5 The laboratory shall have**

- a) Managerial and technical personnel**
- b) Policies and procedures to ensure personnel are free from undue pressures**
- c) Policies and procedures to ensure protection of Customer's confidential information**
- d) Policies and procedures to avoid involvement in any activities that would diminish confidence**
- e) Defined management structure**
- f) Defined authority and responsibility and inter-relationship of personnel**
- g) Adequate supervision of testing / calibration staff**
- h) Technical management**
- i) Appointment of Quality Manger**
- j) Deputies for key Management personnel**

## **4.2 Management System**

**4.2.1 Establish, maintain and implement Quality System appropriate to the scope of activities**

**4.2.2 Management System Policies and Objectives shall be defined in Quality Manual. Quality Policy shall be issued under the authority of chief executive and shall Contain**

- a) Commitment to good professional practices**
- b) Statement of laboratory's service**
- c) Objectives of Management System**
- d) Requirement that personnel concerned get familiarized with Management System**
- e) Commitment to comply with ISO/IEC 17025:2005**

- 4.2.3 Quality Manual shall include / refer to supporting procedures and outline structure of Management System**
- 4.2.4 Defined responsibility and authority of technical management and Quality Manager**

## **4.3 DOCUMENT CONTROL**

### **4.3.1 GENERAL**

**Procedure for Document Control, covering documents of internal and external origin**

### **4.3.2 DOCUMENT APPROVAL AND ISSUE**

**4.3.2.1 Approval of Documents by authorized personnel. Maintenance of Master List**

**4.3.2.2 The procedure shall ensure that**

- a) Availability of authorized appropriate documents**
- b) Periodic review and revision as needed**
- c) Removal of obsolete/ invalid documents**
- d) Suitable identification of obsolete document retained for knowledge/ legal purposes**

**4.3.2.3 Unique identification: date. Revision status, page number and number pages**

### **4.3.3 DOCUMENT CHANGES**

**4.3.3.1 Approval of changes by the same agency as original issue or authorized otherwise**

**4.3.3.2 Identification of changes either on the document or on attachments**

**4.3.3.3 If manual corrections are permitted define the same in the procedure**

**4.3.3.4 If documents are maintained on computer memory define the controls**

## 4.4 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

4.4.1 Establish and maintain documented procedure for review of requests, tenders and contracts for testing / calibration. The procedure shall cover

- a) Ensure that the requirements are adequately defined, documented and understood
- b) Laboratory has the capability and resources to meet the requirements
- c) Selection of appropriate test/ calibration method.  
Resolution of differences between contract and tender, if any

**4.4.2 Maintenance of records of review**

**4.4.3 Review also to cover sub-contracted work**

**4.4.4 Customer to be informed any deviation**

**4.4.5 Amendments to a contract shall also to be reviewed and communicated**

## **4.5 SUBCONTRACTING OF TESTS AND CALIBRATIONS**

**4.5.1 If laboratory sub-contracts the work, this shall be done on suitable subcontractors: satisfying the requirements of this standard**

**4.5.2 Information to Customer on such arrangement**

**4.5.3 Laboratory shall be responsible for subcontractor's work**

**4.5.4 Maintenance of register of subcontractors**

## **4.6 PURCHASING SERVICES AND SUPPLIES**

- 4.6.1 Procedure for selection and purchasing of services and supplies that affect quality of tests/ calibration**
- 4.6.2 Use of purchased materials only after inspection / verification**
- 4.6.3 Review and approval of purchase documents before release**
- 4.6.4 Evaluation of suppliers and maintenance of records ( for critical materials)**

## **4.7 SERVICE TO Customer**

**Laboratory shall afford Customer cooperation to clarify Customer's request and monitor performance of laboratory in relation to work performed and protect confidentiality of other Customers**

## 4.8 COMPLAINTS

- ❖ **Procedure for resolution of complaints from Customers and other parties**
- ❖ **Maintenance of Records of Complaints**

## **4.9 CONTROL OF NONCONFORMING TESTING/ CALIBRATION**

**4.9.1 Procedure for dealing with nonconforming testing/ calibration. The procedure shall ensure**

- a) Authority for management of nonconforming work to be defined**
- b) Evaluation of nonconforming work**
- c) Notification to Customer, if needed**
- d) Defined responsibility for resumption of work**

**4.9.2 In case of possibility of recurrence , initiation of suitable corrective action**

## 4.10 Improvement

The laboratory shall **continually improve** the effectiveness of its management system through the use of the **quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.**

## **4.11 CORRECTIVE ACTION**

**4.11.1 Procedure for implementing Corrective Action**

**4.11.2 Cause Analysis - Investigation of root cause**

**4.11.3 Selection and implementation of Corrective Action**

- **Selection and implementation of most suitable Corrective Action**
- **Document and implement any changes as result of Corrective Action**

**4.11.4 Monitoring of Corrective Action**

**4.11.5 Additional Audits, where needed**

## **4.12 PREVENTIVE ACTION**

**4.12.1 Identification and implementation of Preventive Actions**

**4.12.2 Procedure for Preventive Action shall include initiation and control**

## **4.13 CONTROL OF RECORDS**

### **4.13.1 GENERAL**

**4.13.1.1 Procedure for Quality and Technical Records (identification, collection, indexing, access filing, storage, maintenance and disposal )**

**4.13.1.2 Records shall be legible**

**4.13.1.3 Security of records**

**4.13.1.4 Procedure for protection and back-up**

## **4.13.2 TECHNICAL REPORTS**

**4.13.2.1 Records of original observations, derived data and personnel responsible for checking**

**4.13.2.2 Observations, data and conclusions shall be made when they are made**

**4.13.2.3 When mistakes occur the changes are entered after crossing the original observation; not by erasing**

## 4.14 INTERNAL AUDITS

### 4.14.1 Internal Audits as per predetermined schedule and procedure

\* All elements of Management System shall be covered

Quality Manager to ensure conducting audits

\* Audits by qualified and trained personnel, if possible independent of the area being audited

Cycle time for audits is usually 1 year

### 4.14.2 Timely corrective action and notification to Customer, if needed

### 4.14.3 Records of Internal Audits

### 4.14.4 Follow up audit to verify effectiveness of corrective actions

## **4.15 MANAGEMENT REVIEWS**

**4.15.1 Predetermined procedure and schedule for Management review. The review shall cover**

- ❖ Suitability of policies and procedures**
- ❖ Reports from Management and supervisors**
- ❖ Outcome of Internal Audits**
- ❖ Corrective and Preventive actions**
- ❖ Assessment by external agencies**
- ❖ Inter-laboratory comparisons/ proficiency testing**
- ❖ Changes in volume and type of work**
- ❖ Customer feedback / complaints**

**4.15.2 Records of Management Review and follow up for actions**

# Technical Requirements

## **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 of test and calibration items**

**5.9 Assuring quality of test and calibration results**

**5.10 Reporting the results**

## **5.1 GENERAL**

**5.1.1 Factors affecting calibration / Test results**

**5.1.2 All these shall be taken into account while developing procedures, selection of equipment and training of personnel**

## **5.2 PERSONNEL**

- 5.2.1 Personnel performing specific tasks shall be qualified on the basis of education, training, experience and skills**
  - 5.2.2 Policy and procedure for identifying training needs and providing training**
  - 5.2.3 Ensure that contracted personnel work in accordance with laboratory's Management System**
  - 5.2.4 Maintenance of job description of technical, managerial and key personnel**
  - 5.2.5 Authorization for sampling, testing/ Calibration. Issue of certificates, interpretations/ opinions, operation of particular equipment**
- Maintenance of Records of qualifications, training and skills of personnel**

## **5.3 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS**

- 5.3.1 Technical requirements of accommodation and environmental conditions affecting testing/ calibration shall be documented and controlled**
- 5.3.2 Monitor, control and record environmental conditions**
- 5.3.3 Effective separation between neighboring areas**
- 5.3.4 Controlled access to testing/ calibration areas**
- 5.3.5 Good housekeeping**

## **5.4 TEST AND CALIBRATION METHODS AND METHOD VALIDATION**

### **5.4.1 GENERAL**

- **Use of appropriate methods for tests / calibration**
- **These include sampling, transport, storage, estimation of uncertainty etc.**
- **Availability of up to date instructions, standards, manuals and data at work places**

### **5.4.2 SELECTION OF METHODS**

- **Use of published methods/ procedures**
- **Use of validated laboratory developed methods**
- **Information to Customer when Customer suggested method is inappropriate**

### **5.4.3 LABORATORY DEVELOPED METHODS**

- ❖ Plan for development of test/ calibration methods**
- ❖ Assignment of activity to qualified personnel**
- ❖ Updating of plan as the development proceeds**

### **5.4.4 NON-STANDARD METHODS**

- ❖ Use of non-standard method is subject to agreement by Customer**
- ❖ Validation of such methods before use**

## **5.4.5 VALIDATION OF METHODS**

**5.4.5.1 Validation is the confirmation by examination and provision of objective evidence for suitability**

**5.4.5.2 Validation of non-standard, laboratory developed methods. Maintenance of records of validation**

**5.4.5.3 Range and accuracy obtainable from validation methods to suit Customer's needs**

## **5.4.6 ESTIMATION OF UNCERTAINTY OF MEASUREMENT**

**5.4.6.1 Procedure for estimation of uncertainty of measurement in all calibrations**

**5.4.6.2 Procedure for estimation of uncertainty of measurement in testing, to the extent possible using statistical methods**

**5.4.6.3 Consideration to all components in uncertainty estimation**

## **5.4.7 CONTROL OF DATA**

**5.4.7.1 Checks on calculations and data transfers**

**5.4.7.2 Suitable controls when data is acquired and processed through computers or automated equipment**

## **5.5 EQUIPMENT**

**5.5.1 Availability of necessary equipment**

**5.5.2 Equipment and software shall be suitable for achieving the required accuracy.**

**Establishment of calibration programme**

**5.5.3 Operation by authorized personnel using up to date instructions**

**5.5.4 Unique identification of each item of equipment**

**5.5.5 Maintenance of records of equipment**

**5.5.6 Procedures for safe handling, transport, storage, use and planned maintenance**

- 5.5.7 Removal from service subjected to overloading/ mishandling. Use of such equipment only after checking or calibration after repair**
- 5.5.8 Indication of calibration status on the equipment**
- 5.5.9 When an equipment goes outside the control of the laboratory, checking calibration validity before reuse**
- 5.5.10 Intermediate checks as per defined procedure**
- 5.5.11 Procedure to ensure application of correction factors where needed**
- 5.5.12 Safeguarding equipment against unintentional adjustments**

## **5.6 MEASUREMENT TRACEABILITY**

### **5.6.1 GENERAL**

- **Calibration of equipment before use**
- **A programme for calibration**

### **5.6.2 SPECIFIC REQUIREMENTS**

#### **5.6.2.1 Calibration**

##### **5.6.2.1.1 Calibrations traceable to International System of Units (SI Units)**

##### **5.6.2.1.2 Where there is no possibility of use of SI units, establishment of measurement traceability through**

- **Use of certified materials and specified methods**
- **Inter-laboratory comparisons**

## **5.6.3 REFERENCE STANDARDS AND MATERIALS**

### **5.6.3.1 Reference Standards**

- **Programme for calibration of reference Standards**
- **Use only for calibrations**
- **Calibration before after adjustments, if any**

### **5.6.3.2 Reference Materials**

- **Reference Materials traceable to SI units, wherever possible**

### **5.6.3.3 Intermediate Checks**

- **Intermediate checks as per defined procedures and schedules**

### **5.6.3.4 Transport and Storage**

- **Procedures for safe handling of reference materials, reference standards**

## **5.7 SAMPLING**

**5.7.1 Sampling Plan / procedure for sampling where needed. This shall be based on appropriate statistical techniques, where possible**

**5.7.2 Where Customer wants deviation to the procedure**

**necessary details shall be included in all documents related to testing/ calibration**

**5.7.3 Procedures for recording relevant data on sampling carried out**

## **5.8 HANDLING OF TEST AND CALIBRATION ITEMS**

- 5.8.1 Procedure for transportation, receipt, handling, protection, storage, retention and disposal of items received for testing/ calibration**
- 5.8.2 A system/ procedure for identification of test/ calibration items**
- 5.8.3 Recording abnormalities of items, if any and consultation with the Customer for necessary further instructions/ action**
- 5.8.4 Procedure for avoiding deterioration during handling, storage and preparation**

## **5.9 ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS**

- **Use of quality control procedures for monitoring the validity of test/ calibrations**
- **Monitoring may include, but not limited to**
  - a) **Use of certified materials**
  - b) **Participation in inter-laboratory comparisons/ proficiency testing**
  - c) **Replicate testing**
  - d) **Re-testing / re-calibration of retained items**
  - e) **Correlation of results for different characteristics**

## 5.10 REPORTING THE RESULTS

### 5.10.1 GENERAL

- ❖ Reporting the results clearly and objectively in a Test / Calibration Report form
- ❖ In case of internal Customer or special agreement with Customer the results may be reported in a simplified way; however complete information (listed in 5.10.2 – 5.10.4) shall be maintained by the laboratory

## **5.10.2 TEST AND CALIBRATION CERTIFICATES**

- **Test Report/ Calibration Certificate shall contain**
  - a) **Title (Test Report/ Calibration Certificate)**
  - b) **Name & address of the laboratory**
  - c) **Unique identification (like serial number)**
  - d) **Name & address of the Customer**
  - e) **Identification of Test Method**
  - f) **Condition & identification of Test/ Calibration item**
  - g) **Date of receipt & date of test/ calibration**
  - h) **Reference to sampling plan, if any**
  - i) **Test/ calibration results**
  - j) **Name & designation of persons authorizing report**
  - k) **A statement to the effect that the results relate to only the items tested/ calibrated**

## **5.10.3 TEST REPORTS**

**5.10.3.1 In addition to the above (5.10.2) Test Reports shall contain**

- a) Deviations from Test Procedures & environmental conditions, if applicable**
- b) Statement of compliance / non-compliance, if relevant**
- c) Statement of estimated uncertainty**
- d) Opinions/ interpretations, if applicable**
- e) Additional information required by Customer**

**5.10.3.2 Where sampling is applicable details of date, method, environmental conditions etc. shall be included**

## **5.10.4 CALIBRATION CERTIFICATE**

**5.10.4.1 In addition to the details given in 5.10.2**

**Calibration Certificates shall include**

- a) Environmental conditions, if applicable**
- b) Uncertainty of measurement**
- c) Evidence measurement traceability**

**5.10.4.2 Statement of compliance shall include**

**which parameters of specification are met /  
not met**

**5.10.4.3 Any adjustments/ repairs carried out shall  
be reported**

**5.10.4.4 No recommendation on calibration interval**

### **5.10.5 OPINIONS AND INTERPRETATIONS**

- Document the basis of giving opinions/ interpretations
- Clear marking of the same in the reports

### **5.10.6 TESTING/ CALIBRATION RESULTS FROM SUBCONTRACTORS**

- Clear identification of results from subcontractor

### **5.10.7 ELECTRONIC TRANSMISSION OF RESULTS**

- Necessary controls to protect confidentiality while transmitting results by electronic media like fax, telephone etc

## **5.10.8 FORMAT OF REPORTS/ CERTIFICATES**

- **Suitable format for test/ calibration report/ certificate to avoid misunderstanding**

## **5.10.9 AMENDMENTS TO TEST REPORTS AND CALIBRATION CERTIFICATES**

- **Material amendments to test/ calibration reports through a further report, giving reference to earlier report**
- **Amendments shall meet this international standard**