ISO 17025:2007

LABORATORY MANAGEMENT SYSTEM

ISO / IEC 17025 : 2005

ISO 17025

Interpretation of Standard Requirements

ISO / IEC 17025 : 2005

ISO 17025

- Management Requirements
- Technical Requirements

Contents of ISO / IEC 17025 : 2005

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

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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

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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

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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

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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

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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