

**ISO/IEC 17043- 2010
MANAGEMENT REQUIREMENTS**



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**ISO/IEC 17043 Requirements
5. Management Requirements**

- 5.1 Organization
- 5.2 Management System
- 5.3 Document Control
- 5.4 Contract Review
- 5.5 Subcontracting
- 5.6 Purchase of supplies and services
- 5.7 Service to Customers

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**ISO/IEC 17043 Requirements
5. Management Requirements (contd.)**

- 5.8 Complaints
- 5.9 Non conforming testing work
- 5.10 Improvement
- 5.11 Corrective action
- 5.12 Preventive Action
- 5.13 Control of Records
- 5.14 Internal Audit
- 5.15 Management review

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5.1 ORGANISATION



How the PT Provider is functioning in an organized manner

- Legal Identity of the PT Provider
- Meeting regulatory requirements (e.g) distribution of hazardous items
- Potential conflict of interest in the functioning of organization – PT activities & Testing PROCEDURE
- Availability of competent Managers – PT Coordinator, QM, TM and Statistician

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5.1 ORGANISATION



- Free from pressures on the personnel – Coordinator, QM, TM, technical & administrative staff & Statistician
- Protection of confidential information of customers & proprietary rights - PROCEDURE
- Avoid involvement in activities that would diminish in its competence, impartiality, judgment & operational integrity - PROCEDURE
- Organization Structure – Place of PT provider in the parent organization
- Organization Structure – Relationship between Quality management, Technical operations and Support services
- Specify responsibility, authority, inter relationships and required competence of personnel involved in PT activities

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5.1 ORGANISATION



- Awareness of Quality Policy and Objectives among all personnel and their roles in achieving the objectives
- Adequate supervision of technical staff including trainees by competent personnel
- Nomination of Technical Manager conversant with each discipline of testing/calibration... & provision of necessary resources to him – including technical expertise in testing, calibration ... and statistics
- Nomination of Quality Manager having direct access to highest level of management
- Substitute for Managers - PT Coordinator, QM & TM etc., in case of their absence
- Communications channel

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5.2 MANAGEMENT SYSTEM


Document & implement Management System

- Management system is **documented** as per ISO/IEC 17043:2010 standard?
- Quality Policy & Objectives are **documented**?
- Documents & policies are **communicated** to lab personnel?
- All concerned personnel have **understood** the documents & policies
- Documents are **available** for reference
- Policies & procedures are **implemented**

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5.2 MANAGEMENT SYSTEM


Documentation & implementation to include:

- PT item quality – Homogeneity & Stability
- Equipment calibration & method validation
- Assignment of Values by using appropriate Statistical procedures
- Evaluation of participant performance
- Distribution of PT items
- Storage & transport procedures
- Statistical treatment of PT results
- Reporting of PT results

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5.2 Management System


Document the Management system in different levels of documents

- Level – 1 : **Quality Manual**
- Level – 2 : **Quality Procedures**
- Level – 3 : **SOPs, Work Instructions**
- Level – 4 : **Records, Formats,, etc.,**

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5.2 Management System



- Documenting **Quality Policy & objectives** adequately
- Evidence of **commitment of Top management**
- Communication of the need to meet **customer, statutory & regulatory requirements**
- Structure of documentation
- Quality Manual to include **reference of Procedures**
- **Roles and responsibilities** of PT Coordinator, QM, TM and others
- **Integrity of management system** is maintained while making changes in Management System

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5.3 DOCUMENT CONTROL



Control of internal & external documents used by PT Provider

- Control all documents used by PT Provider – **Internal & external**
- Authorize personnel to **prepare & amend, review and approve** and **issue** Management System documents
- **Master List of Management System documents**– revision status and distribution

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5.3 DOCUMENT CONTROL



- **Controlled copies** of Quality Manual, Quality Procedures, SOPs are only used
- Management system documents being used are stamped as **“Controlled copy”**
- When documents are amended, obsolete pages or documents are removed and stamped as **“OBSOLETE”**
- **Comprehensive revision and updating** of all Management System documents periodically – **Bringing new issue**
- **Unique identification** of all Management System documents – Issue No, Revision status, Page number, Number of pages, Issuing authority

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5.3 DOCUMENT CONTROL



- **Revision/changes in documents** as per Document Control procedure
- **Identification of altered or new text** in documents – Highlighting or Italics
- Policy & procedure for **amendments by hand**
- Management System Documents kept in **Electronic media**

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5.4 REVIEW OF REQUESTS, TENDER & CONTRACTS



Understanding customer's requirements clearly & executing contract

PT Provider to ensure that

- ✓ **Requirements** (Test/calibration method, Equipments & PT items to be used) are defined & understood?
- ✓ **PTP** has **expertise** to meet the requirements?
- ✓ **PT Scheme** is technically appropriate?

- This review is particularly important when a customer requests a PT Scheme to be created for a specific purpose or for a different level or frequency of participation
- Simplified approach when the PT Scheme is fully described in a catalogue or other notice, and the participant is enrolling for a routine shipment

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5.4 REVIEW OF REQUESTS, TENDER & CONTRACTS



- Maintain **records of review** with customers, including any changes in the PT Scheme
- Review to cover **all aspects of customer's request** including any work subcontracted by PT Provider
- Any **change in design or operation of PT scheme** as given in protocol – Inform participants and other **customers**
- Any **amendment in request or contract** after the commencement of PT Scheme – repeat review process and inform the amendments to all affected personnel

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5.5 SUBCONTRACTING SERVICES



Performing some of the tasks of the PT Provider by some other organization

- ☐ To demonstrate that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of ISO/IEC 17043:2010 and other appropriate standards
- ☐ Do not subcontract
 - a) Planning of the PT Scheme (4.4.1.2),
 - b) Evaluation of performance (4.7.2.1)
 - c) Authorization of the final report (4.8.1)

NOTE: This does not preclude the PT Provider utilizing advice or assistance from any advisors, experts or steering group

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5.5 SUBCONTRACTING SERVICES



- ☐ Inform the participants, in advance and in writing, of services that are, or may be, subcontracted

NOTE: This notification can be in the form of a statement in the PT Scheme documentation, such as : "Various aspects of the proficiency testing scheme can from time to time be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and the PT Provider is responsible for this work."

- ☐ PT Provider shall be responsible to the participants & other customers for the subcontractor's work – exception if regulatory authority specifies subcontractor
- ☐ Maintain a register of all subcontractors used in the operation of PT Schemes, including the scope of subcontracting and a record of the competence assessment against relevant parts of ISO/IEC 17043:2010 and other appropriate standards for the work in question

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5.6 PURCHASING SERVICES AND SUPPLIES



Select proper suppliers and service providers and verify the items ordered prior to use

- List of approved suppliers including supplier of PT items & service providers
- Procedures for purchase, reception and storage of reagents, PT items, reference materials and other critical consumables relevant for the PT Schemes
- Inspection of PT items & other items ordered & verification of critical consumables done before using them and their records
- Purchase orders are reviewed for technical contents
- Evaluation of suppliers & service providers – periodically

NOTE: Some PT Providers may be required to implement their purchasing procedures in accordance with policies defined by their parent company or a host organization.

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5.7 SERVICE TO THE CUSTOMER



Steps for enhancement of customer satisfaction and customer base

- Co-operation for any **clarification** and monitoring of work by **participants & other customers**
- Maintain **confidentiality** of information provided by all **customers and participants**
- Communicate **delays** in the PT Scheme
- Obtain positive & negative **feedback**, from **customers (may be AB or Regulatory Body also) participants and Advisory Group**. Analyze it and take action to improve management system

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5.8.COMPLAINTS & APPEALS

Investigate and take proper corrective action in case of complaints from participants, customers or other parties

- Register **verbal** & written complaints and appeals
- **Investigate** and find out root-cause
- Respond to the customer **at the earliest**
- **Maintain records** of complaints & appeals

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5.9 CONTROL OF NON-CONFORMING WORK



Exercise appropriate control while encountering non-conforming work

- Non conforming work **identified through** – **complaints from participants**, management review, internal or external audits, quality control, **preparations of PT items, homogeneity & stability tests, data analysis, instructions to participants**, and materials handling and storage
- Evaluate **significance of non-conforming work**
- **Decision** on the need for immediate action and timescale
- **Decision** about **acceptability of nonconforming work**

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5.9 CONTROL OF NON-CONFORMING WORK

Exercise appropriate control while encountering non-conforming work

- Halt work in case of on going PT Scheme till investigation is over
- Withhold report – if not issued to the participants and/or Customer
- Inform participants and customer
- Recall or disregard the non conforming PT item / report – if already sent
- Responsibility for authorization of the resumption of work
- Take appropriate Corrective Action such that the problem does not recur

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5.10 IMPROVEMENT

Continually improve the effectiveness of management system implemented

- Ensure continued compliance with ISO/IEC 17043:2010
- Review achievement of objectives
- Review adequacy of the Objectives
- Review the type and number of NCs in the Internal audits and NABL assessments

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5.10 IMPROVEMENT

- Effectiveness of C.A taken on Complaints, non conforming work, NCs encountered
- Prepare a preventive action plan
- Obtain feedback and analyze
- Evaluate suppliers and service providers
- Evaluate of supplies and services availed
- Comprehensive annual management review

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5.11 CORRECTIVE ACTION

Take appropriate corrective action after conducting root cause analysis, for following deficiencies

→ Investigate **root-cause** of the deficiency covering–

Customer requirements
PT items & their specifications
Methods & Procedures
Staff skill & training
Consumable supplies
Preparation of PT items
Homogeneity & Stability tests
Statistical design
Instructions to participants
Material Handling & Storage

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5.11 CORRECTIVE ACTION

→ Identify **potential corrective action**

→ **Implement** corrective action by designated authorities

→ **Monitor the effectiveness of corrective action**

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5.12 PREVENTIVE ACTION

Plan a proactive action for dealing with a problem before it happens and identify improvement opportunities

→ Obtain **feedback** from participants / customers & Advisory Group

→ **Verify** the characteristics of PT items periodically

→ Develop **preventive action plans**, implement and monitor – (e.g) Preventing occurrence of the same NCs in other sections

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5.13 CONTROL OF RECORDS



Maintenance of all records generated

- **Quality records:** Internal & external audit reports, Management review minutes, Complaints, Appeals, Feedback, C.A & P.A
- **Technical Records:** Personnel & training, environment control, Method validation, Planning of PT Schemes, Results of Homogeneity & Stability testing, Instructions to participants, Participants' original response, Results of participants, Collated data for statistical analysis, Assignment of Values to PT items, PT Scheme reports, Communication with participants and customers

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5.13 CONTROL OF RECORDS



- **Procedure** for maintaining and storage of quality and technical records
- **Easy Retrieval, Protection & Retention period** of records
- **Confidentiality & Security** of records
- **Procedures for protection and control of electronic records**

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5.13 CONTROL OF RECORDS



- **Data entry, checking and calculations** shall be recorded at the time they are made and shall be identifiable to the specific task and to the personnel responsible
- **Access of records** by authorised personnel only (electronic & hard copy)
- **Backup** of electronic records
- When **mistakes occur** in technical records and alterations are made – **identify the change and date of alteration, avoid loss of original data, identify the person making alteration**

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5.14 INTERNAL AUDITS

Verify the extent of implementation of the Quality Management System

THREE TYPES AUDIT

- First party audit – **Self** (Internal audit)
- Second party audit – **Audit by customers**
- Third party audit – **Neutral** (Accreditation Body)



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5.14 INTERNAL AUDITS

- **Planning** & organizing periodical internal audits by Quality Manager
- Auditing by **trained personnel** not responsible for audited area (**preferable**)
- Inform the **schedule** in advance to Auditee & Internal Auditors
- Ensure that **all the departments of the PT provider and subcontractors** are covered – including Quality Manager, PT Coordinator, PT item preparation, storage and distribution, Statistical Evaluation, as well as reporting activities for the operation of a PT Scheme



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5.14 INTERNAL AUDITS

- Ensure that **all the elements of ISO/IEC 17043:2010** are covered
- **Maintain records** of activity audited, audit findings and corrective actions
- **NCs raised are to be closed** after verifying the C.A taken
- Closing of the NCs within **reasonable period of time**



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5.15 MANAGEMENT REVIEW

Review the effectiveness of implementation of Management System

- Conduct **periodical** management review as per predetermined schedule & procedure with an **AGENDA**
- Ensure **all the key personnel** of the PT Provider including PT Coordinator, Quality Manager, Technical Manager and other key personnel involved in PT activities attend the management review
- Prepare the **minutes of the review** – incorporate the decisions, responsibility for taking action & target date

NOTE: Where the PT Provider is part of a larger organization ((say) Testing Lab, it can be appropriate to hold a separate review meeting to cover proficiency testing activities

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5.15 MANAGEMENT REVIEW - AGENDA

- (i) Suitability of policies and procedures
- (ii) Reports of Technical Manager and other supervisory personnel
- (iii) Outcome of internal audits
- (iv) Corrective and preventing actions
- (v) Assessment by the accreditation body
- (vi) Change in volume & type of work

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5.15 MANAGEMENT REVIEW - AGENDA

- (vii) **Feedback** obtained from customers, participants and /or Advisory Group
- (viii) **Complaints** and appeals
- (ix) **Recommendations** for improvement
- (x) **Training needs** of personnel
- (xi) **Review of the objectives** set within the management system
- (xii) **Achievement of objectives**

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Thanks for your attendance



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