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Establishment, Implementation and Improvement of Quality Management System

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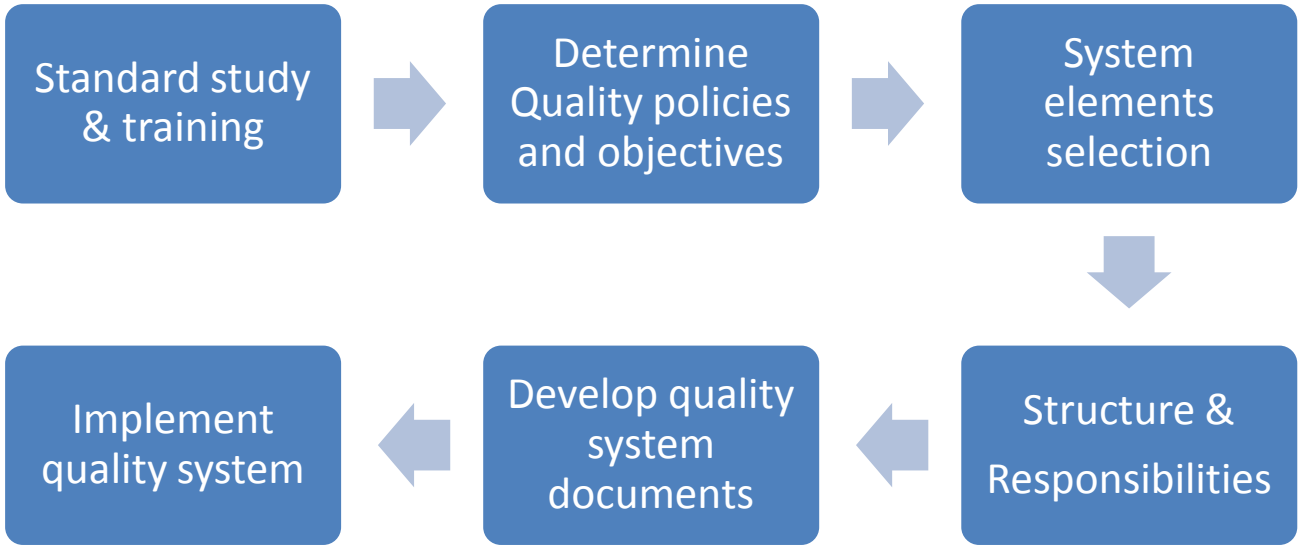
Management system

- *"The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test results. The system's documentation shall be communicate to, understood by, available to, and implemented by the appropriate personnel."*



Determine Quality policies and objectives

- Quality policies: Top management
- Quality objectives: measurable, challenge, achievable

Example:

Qualification rate of test report≥98%,
Customer satisfaction ≥98%

System elements selection

- The system elements selection
  - Meet the statutory and regulatory requirements
  - In accordance with Standards
  - Meet the costumer’s requirements
  - Suitable for testing activities (working scope, workload, personnel…)
  - Suitable for the capabilities and responsibilities of providing data and results

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Organization structure and responsibilities

- How to design the organization structure?
  - Span of Management
  - Scalar principle (report to whom? Supervision?)
  - Job description (who do what?)
  - Appropriate authorization
  - Right with responsibility

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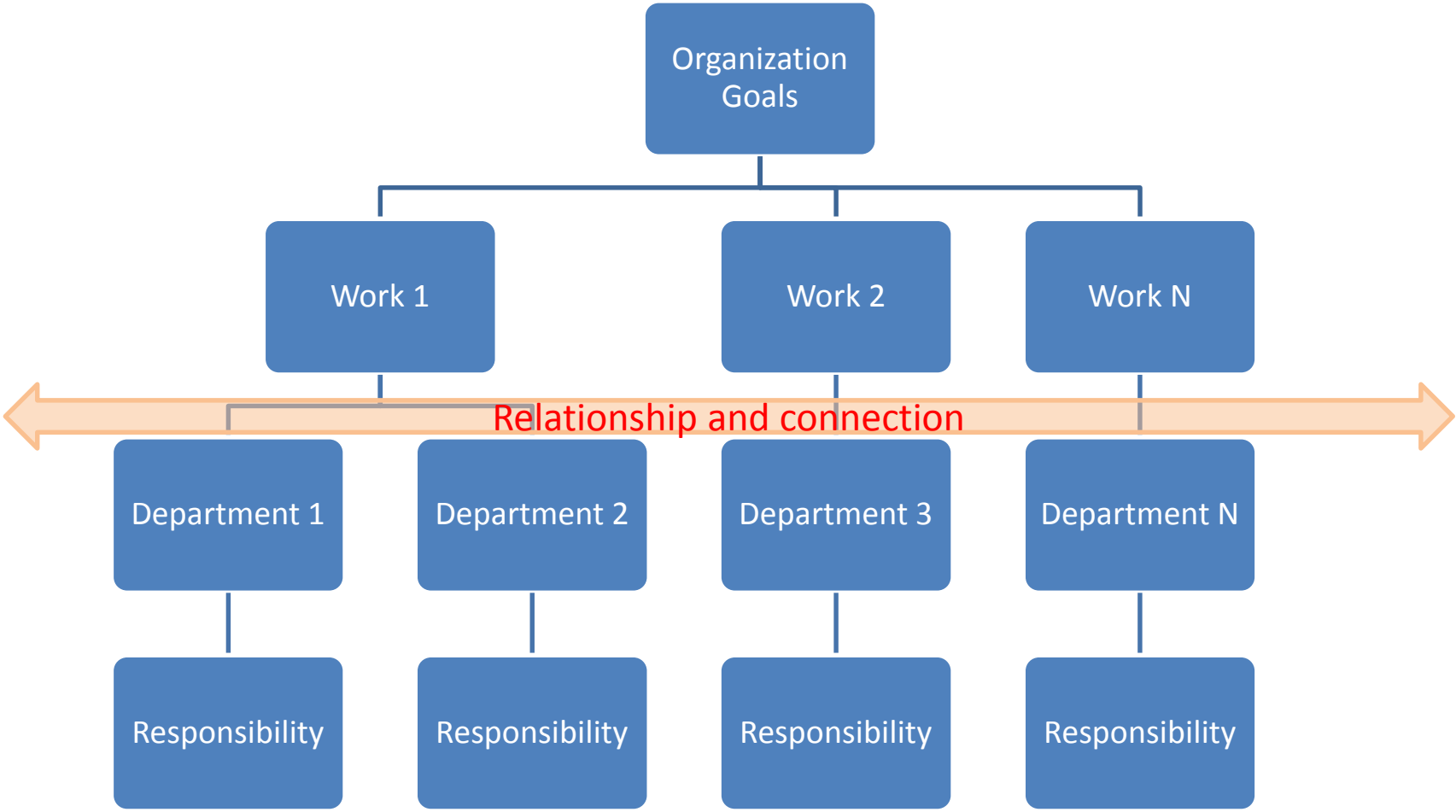
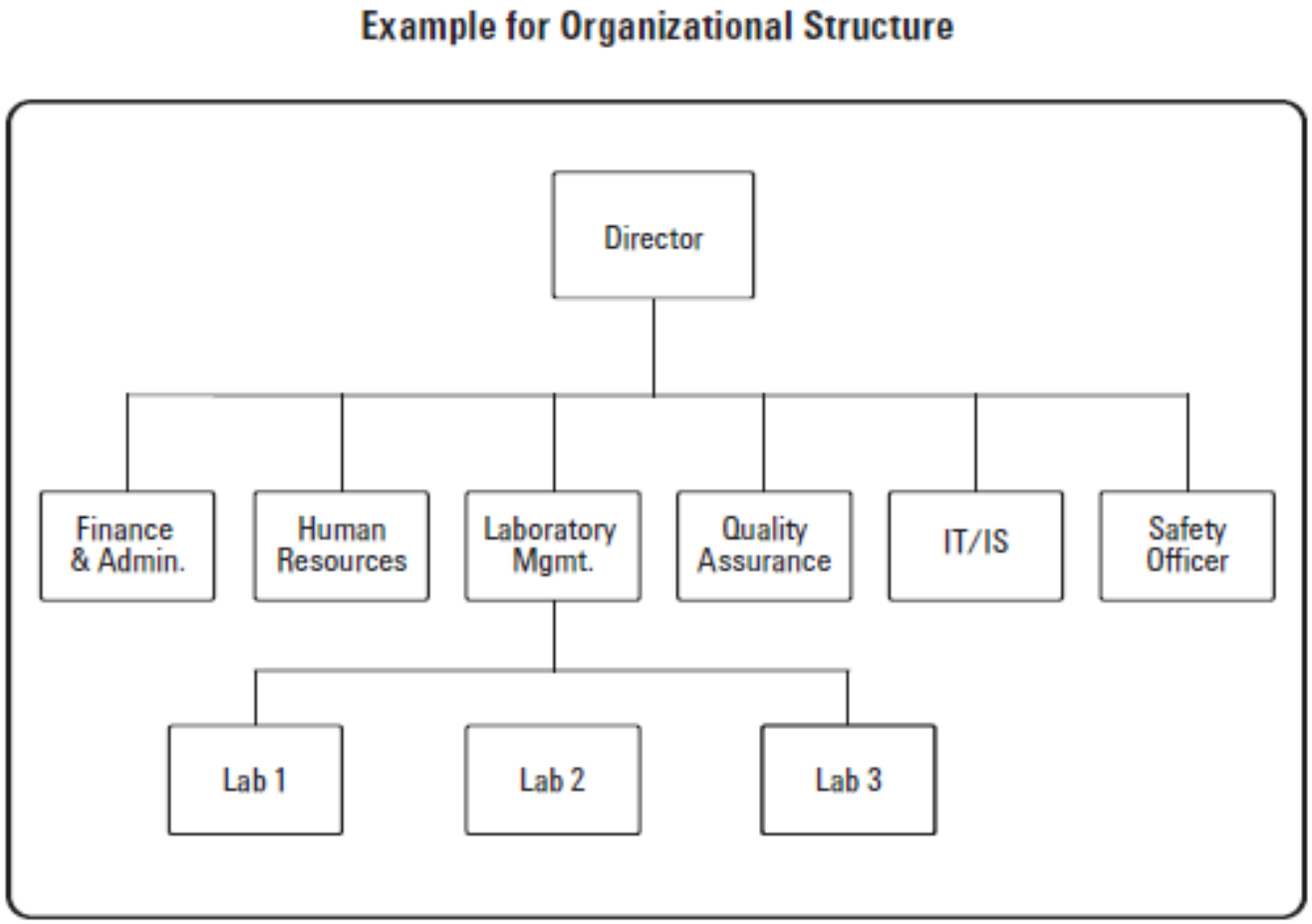
Organization structure and responsibilities



Organization structure



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Organization

- Define legally responsible
- The QMS must cover all activities for which accreditation is sought
- Organizational structure might cause a conflict of interest
- Sufficient authority and resources
- How do you define “undue pressure”? And where might it come from?

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Organization

- Protect client confidential information and proprietary rights?
- Activities would diminish confidence in competence, impartiality, judgment or integrity
- Define adequate supervision
- How would you identify whether the QA manager has sufficient authority
- Deputies for key personnel
- Management involvement in management system

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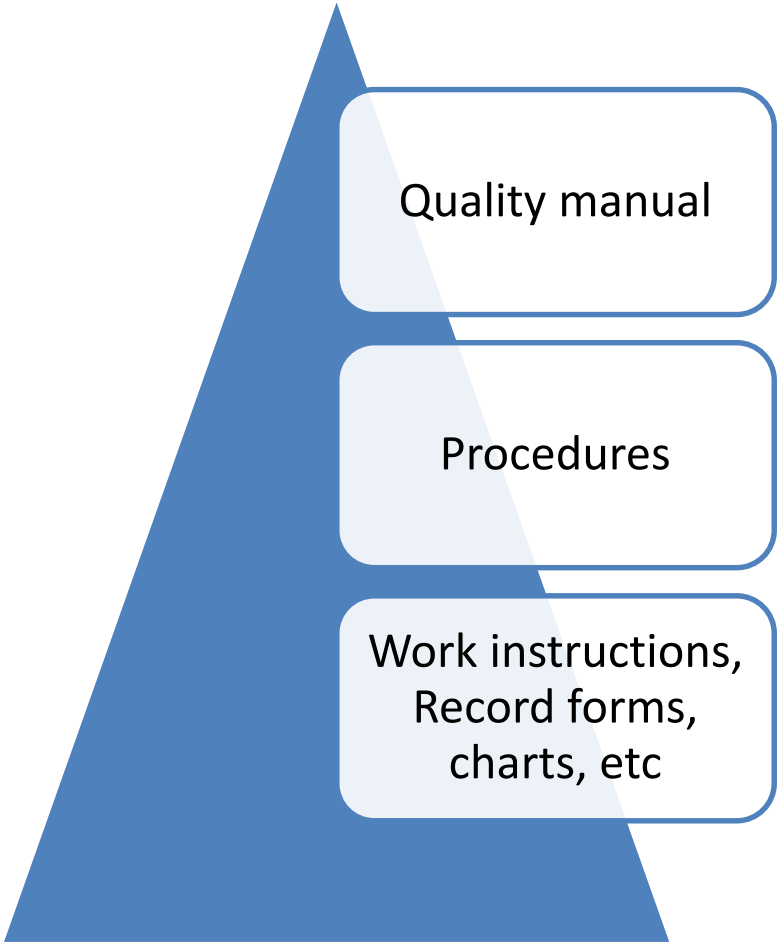
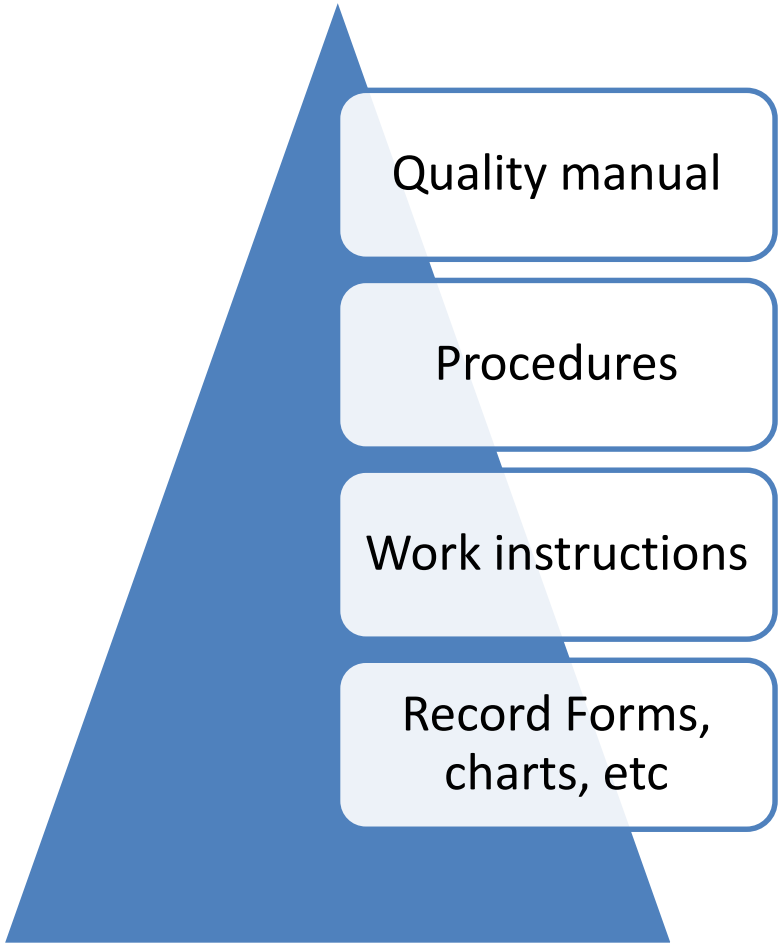
Key points

- An organizational structure, as well as responsibilities and tasks of both management and staff should be defined.
- The organizational structure should be such that departments having conflicting interests do not adversely influence the laboratory's work quality. Examples include commercial marketing or financing departments.
- A quality assurance manager should be appointed.
- All personnel should be free from any commercial or financial pressure that could adversely impact the quality of calibration and test results.

Develop quality system documents





Develop quality system documents

- Quality management system documents (any forms) include:
  - Quality policies and objectives
  - Quality manual
  - Procedures
  - Work instructions
  - Forms
  - Quality plan
  - Specifications
  - External documents
  - Records

Any forms – hard copy, electronic version, photographs, etc.

Develop quality system documents

- The general structure of Quality Manual
  - Title
  - Contents
  - Commitment (Release)
  - Preface (laboratory introduction)
  - Description of scope, deletion, rationality
  - Referenced standards
  - Definition (if necessary)
  - Organization structure, responsibility and authority
  - Elements description of quality management documents
  - Structure description of quality management documents
  - The interaction description of processes of the quality management
  - Annex

Develop quality system documents

- Procedures required
  - Protection of its customers' confidential information (4.1.5.c)
  - Avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity (4.1.5.d)
  - Control all documents (4.3.1)
  - Describe how changes in documents maintained in computerized systems are made and controlled (4.3.3.4)
  - Review of requests, tenders and contracts (4.4.1)

Develop quality system documents

- Procedures required (cont.)
  - Selection and purchasing of services and supplies (4.6.1)
  - Resolution of complaints received from customers, or other parties (4.8)
  - Control of nonconforming testing (4.9.1)
  - Designate appropriate authorities for implementing corrective action (4.11.1)
  - Preventive actions (4.12.2)
  - Control of record (4.13.1.1)
  - Internal audits (4.14.1)
  - Management review (4.15.1)

Develop quality system documents

- Procedures required
  - Identify training needs and providing training of personnel (5.2.2)
  - Housekeeping in the laboratory when necessary (5.3.5)
  - Test method and method validation (5.4.1)
  - New test methods and method validation (5.4.4 note)
  - Estimation of uncertainty of measurement (5.4.6.1, 5.4.6.2)
  - Data protection (5.4.7.2.b)
  - Safe handling, transport, storage, use and planned maintenance of measuring equipment (5.5.6)

Develop quality system documents

- Procedures required
  - Calibration of equipments (5.6.1)
  - Calibration of reference standards (5.6.3.1)
  - Additional procedures for testing outside of permanent sites as necessary (5.3.1, 5.5.6 note, 5.6.3.4 note)
  - Intermediate checks (5.5.10, 5.6.3.3)
  - Safety handling, transport, storage and use of reference standards and reference materials (5.6.3.4)
  - Sampling (5.7.1)
  - Handling of testing items (5.8.1)

Develop quality system documents

- Procedures include:
  - Purpose and scope
  - What?
  - Who?
  - When?
  - Where?
  - How?
  - What materials, equipments, documents?
  - How to control the activities and record?

Develop quality system documents

- Work instruction: detailed descriptions of how to implement and record
  - Testing method and additional documents
  - Operation instruction of the equipments
  - Preparation and handling of samples
  - Intermediate checks method
  - ……

Develop quality system documents

- The purpose of Procedures and Work instructions
  - Define the activities, responsibilities, workflow, and method
  - Easy to implement in the laboratory
  - Easy to train the new staff
  - Easy to track the problems and eliminate unnecessary differences of doing the same thing in different ways

Clear In Practically	Easy to use Reach a consensus

Develop quality system documents

- Record: Clarify the results obtained or provide evidence of the completed activities
  - Record is a special document. The record form is controlled by the document control. When the record form is filled in data or info, it becomes a record.
  - Quality record & technical record
  - Record requires sufficient information, and clearly written, easy to access, and has a keeping period.
  - Original record shall be recorded when testing.
  - If there is any error in the record, it can be changed, and shall not be rubbed off.
  - There should avoid any missing or changing of the original record for the electronic copy.

Develop quality system documents

- Record in the laboratory includes
  - Records of Reviews of requests, tenders and contracts (4.4.2)
  - A register of all subcontractors and keep records of the evidence of compliance of their work with the standards (4.5.4)
  - Records of conformity check activities taken for purchasing services and supplies, records of supplier evaluations and list of approved suppliers (4.6.4)
  - The complaints from customers and other investigations, and corrective actions (4.8)
  - Internal audit report, corrective action taken and follow-up audit activities to verify the implementation and effectiveness of the corrective actions (4.14)
  - Management review report and record of corrective action taken (4.15)

Develop quality system documents

- Record in the laboratory includes
  - Records of authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical staff (5.2.5)
  - Monitoring and control records of environmental conditions (5.3.2)
  - Method validation records (5.4.5.2)
  - Records of each item of equipment and its software significant to the tests(5.5.5)
  - Record the status of the sample upon receipt (5.8.3)

Develop quality system documents

- Form: A document used to record the data required by the quality management system
- Form includes:
  - Title
  - Identification number
  - Revision status and date
  - The form should be referenced or attached to the Quality Manual, the Procedures and/or Work instructions

Develop quality system documents

- External documents: relevant documents from the outside of the laboratory
  - In the quality management system document, it should specify which are the external documents and to be controlled
  - External documents could be laws, regulations, standards, specifications, manuals, the pattern provided by the customer, etc
  - It needs to track the external documents to ensure use the latest valid version or appropriate version.

Develop quality system documents

- The Quality Manual is generally written by one person. Verify the compliance in accordance with the standards.
- Procedures and work instructions may written by different people.

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Implement quality system

1. • Appointment a Quality Manager
2. • Document Propaganda
3. • Trial run (the period is determined by the laboratory, normally at least 3 months)
4. • Internal audit and management review

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Implement quality system

- **Internal audit**: evaluate the compliance and effectiveness of the quality management system; implement correction actions and improvements to the nonconformity in order to make sure the effective running of the quality management system

ISO/IEC 17025
Quality manual
Laws, regulations

	1	2	3	4	5	6	7	8	9	10	11	12
4												
4.1		△										
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Implement quality system

	1	2	3	4	5	6	7	8	9	10	11	12
5												
5.1		△								△		
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Additional audit as necessary

△Planned ▲implemented ○Developed the corrective actions plan □adopted corrective actions ●Verified the corrective actions

Implement quality system

- **Management reviews**: ensure the continuing suitability and effectiveness of the laboratory's management system
  - The suitability of policies and procedures
  - Reports from managerial and supervisory personnel
  - The outcome of recent internal audits
  - Corrective and preventive actions
  - Assessments by external bodies
  - The results of IC or PT
  - Changes in the volume and types of work
  - Customer feedback
  - Complaints
  - Recommendations for improvement
  - Other relevant actors, such as quality control activities, resources and staff training

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Quality system

- How would you know if a system is established, implemented and maintained? What is appropriate?
- How would you identify whether the system is communicated and understood? Available?
- Do we need to see a quality manual?
- What about a Quality Policy & objectives? Their content? Management involvement & approval
- What are supporting procedures?
- Responsibility of technical and Quality manager in manual

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Key points

- There should be policies, standard procedures and work instructions to ensure the quality of test results.
- There should be a quality manual with policy statements that are issued and communicated by top-level management.
- The effectiveness of the management system should be continually improved.

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The Climate Technology Centre and Network (CTCN) fosters technology transfer and deployment at the request of developing countries through three core services: technical assistance, capacity building and scaling up international collaboration. The Centre is the operational arm of the UNFCCC Technology Mechanism, it is hosted and managed by the United Nations Environment and the United Nations Industrial Development Organization (UNIDO), and supported by more than 300 network partners around the world.

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