LECTURE 3

ELEMENTS OF MS ISO/IEC 17025 : 2005

MANAGEMENT REQUIREMENTS (CLAUSE 4)

ISO/IEC 17025

1. SCOPE
2. NORMATIVE REFERENCES
3. TERMS AND DEFINITIONS
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 the customer
4.8 Complaints
4.9 Control of non-conforming work
4.10 Improvement
4.11 Corrective action
4.12 Preventive action
4.13 Control of records
4.14 Internal audits
4.15 Management reviews

5. TECHNICAL REQUIREMENTS

5.1 General - factors contributing to correctness and reliability
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 the quality of test and calibration results
5.10 Reporting the results

1 Scope

1.1 This International Standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling.

It covers testing and calibration performed using;

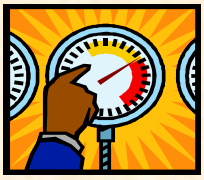
- standard methods,
- non-standard methods, and
- laboratory-developed methods.

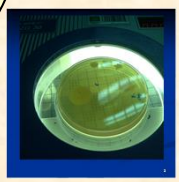
1 Scope

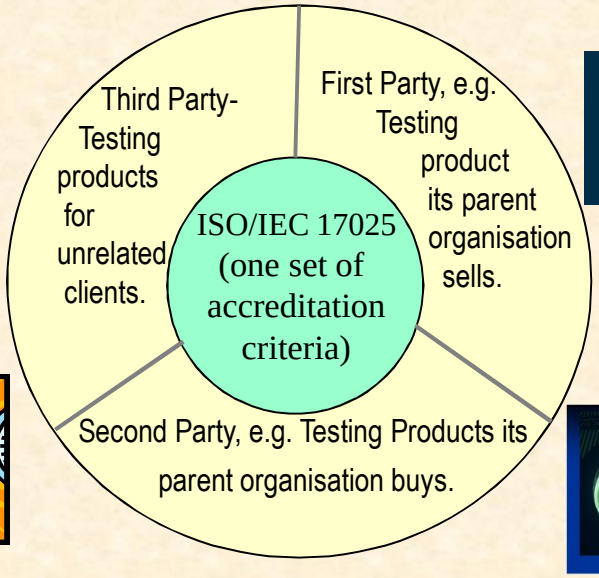
1.2 Standard applicable to all organisations performing tests and/or calibrations.

These include first-, second- and third-party laboratories and laboratories where testing and/or calibration forms part of inspection and product certification.

Types of Laboratory

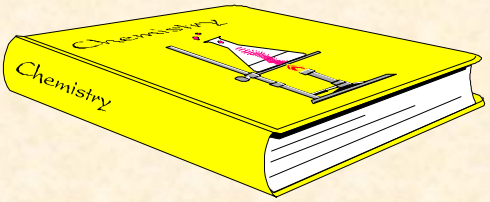






1 Scope

1.4 This standard is use by laboratories in developing their management system for quality, administrative and technical operations.



1 Scope

1.5 Compliance with regulatory and safety requirements on operation of laboratories is not covered by this International Standard

1.6 If testing and calibration laboratories comply with the requirements of this International Standard, they will operate a quality management system for their testing and calibration activities that also meets the principles of ISO 9001.

SIRIM TRAINING

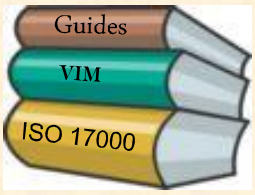
2. Normative References

(*Document that provides rules, guidelines, or characteristics for activities or their results).*

ISO/IEC 17000 Conformity Assessment - vocabulary and general principles.
VIM - International Vocabulary of basic and general terms in metrology.

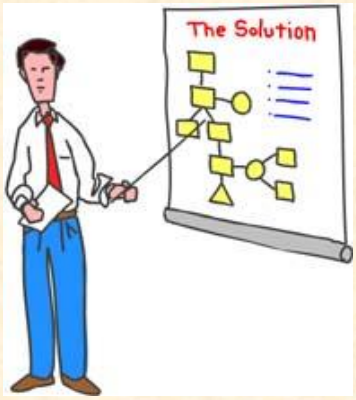
3. Terms and Definitions

ISO/IEC 17000 and VIM.



CLAUSE 4

MANAGEMENT REQUIREMENTS



4.1- ORGANISATION

4.1.1 Laboratory shall be a legal entity.

4.1.2 Laboratory is responsible to carry out its testing / calibration activities to meet this International Standard, needs of customer, regulatory authorities or organizations providing recognition.

4.1.3 Management system to cover all work (even if off-site).

4.1.4 Identify potential conflicts of interest if laboratory is part of an organisation performing activities other than testing and/or calibrations.

4.1.5 The laboratory shall **have:**

a) Personnel with authority and resources (managerial and technical).

b) Free from commercial, financial and other pressures and influences.

c) Policies and procedures: client confidentiality.

d) Policies and procedures: involvement that diminish confidence.

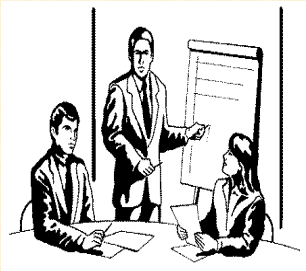
4.1.5 The laboratory shall **have:**

e) define organization and management structure.

f) responsibility, authority & interrelationships of personnel.

g) provision of adequate supervision, including trainees.

h) technical management.



4.1.5 The laboratory shall **have:**

i) quality manager.

j) appoint deputies for key managerial personnel (see note).

k) ensure that key personnel are aware of importance of objectives of management system.

Note: Individuals may have more than one function and it may be impractical to appoint deputies for every function.

4.1.6

Å Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

4.2 - MANAGEMENT SYSTEM

Clause 4.2.1

The laboratory shall

- Establish, implement and maintain a management system appropriate to the scope of its activities.
- Document its policies, systems, programmes, procedures, and instructions to ensure quality of test/calibration results.
- System documentation communicated, understood, available, and implemented by all personnel.

Clause 4.2.2

The Quality Policy of the Laboratory

A statement of the laboratory management's intentions with respect to the standard of service it will provide.

a) Management commitment to good professional practice.
b) Management statement of standard of service.
c) Purpose of quality management system.
d) Requirement that staff are familiar with and work to the quality management system.
e) Management commitment to ISO/IEC 17025 and to continually *improve the effectiveness of the management system.*

Clause 4.2.2

- Management system policies related to quality including quality policy statement shall be defined in a Quality Manual.
  Overall objectives shall be established and reviewed
  at management review meeting Quality policy statement shall be issued under the authority of top management.

Quality Policy - 'the overall intentions and direction of an organisation related to quality as formally expressed by top management.' (ISO 9000:2000)

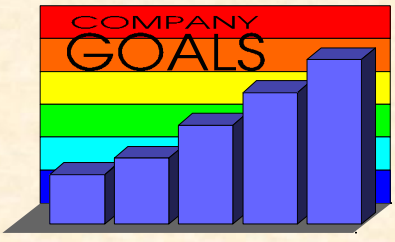
PURPOSE

POLICIES

GOALS

OBJECTIVES

ACTION PLAN



EXAMPLE OF QUALITY POLICY

We at ChemCal International understand that worldwide customer satisfaction can only be achieved through the consistency, quality, and effectiveness of both our products and our customer service . As a quality-minded organization, ChemCal International is committed to ensuring worldwide customer satisfaction by:

purpose → Å Posting only conservative product specifications based upon extensive uncertainty analyses;

good professional practice → Å Maintaining a laboratory environment and associated services consistent with the guidelines of ISO 17025;

Å Providing failure-free, error-free products tested and calibrated in accordance with ISO 17025, our quality documents, and customer requirements, and performed only by personnel fully trained to comply with the quality requirements, policies, and procedures of our quality system;

Å Standard of service, Å commitment to ISO17025, Å staff are informed

ÅTo continually improve the effectiveness of the management system. → Å continually improve

Å Meeting our product delivery and service turnaround expectations.

PRESIDENT

4.2.3 Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

4.2.4 Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

4.2.5 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system.

4.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance to this standard, shall be defined in the quality manual.

4.2.7 Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

THE ROLE OF THE QUALITY MANAGER

To ensure quality system is implemented and followed at all times such as:

- Åorganise audits,
- Åissue documents,
- Åapprove document change,
- Åensure document control is working properly,
- Åcoordinate proficiency tests or inter laboratory tests,
- Åplan calibration schedule.

4.3 - DOCUMENT CONTROL

4.3.1 Applies to ALL documents that forms part of the management system.

4.3.2 Document Approval And Issue

4.3.2.1 Reviewed and approved by authorised personnel prior to use.
Have a Master List or document control procedure.

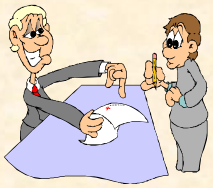
4.3.2.2 Document control procedure shall ensure:

- Appropriate documents are available at all locations essential for the effective functioning of the laboratory.
- Periodic review / revision to ensure continuing suitability and compliance.
- Removal of invalid documents or otherwise assured against unintended use.
- Obsolete documents that are retained - must have suitable markings.

Documents Control Procedure

Obsolete Documents

4.3 - DOCUMENT CONTROL



4.3.2.3 Quality system documents must have unique identification ï *for internally generated*

Åname of document
Ådate of issue and/or revision identification
Åpage number
Åtotal number of pages or mark to signify ñendò
Åissuing authority(ies) ï *may be in the index*
Åindication that they are controlled and not just a copy

4.3.3 Document changes

4.3.3.1 Changes to documents shall be reviewed and approved by the same function that perform the original review unless specifically designated otherwise.

4.3.3.2 Where practicable, the altered or new text shall be identified in the document or appropriate attachments.

4.3.3.3 Defined allowances for amendment by handô Åmarked, initialed, dated.

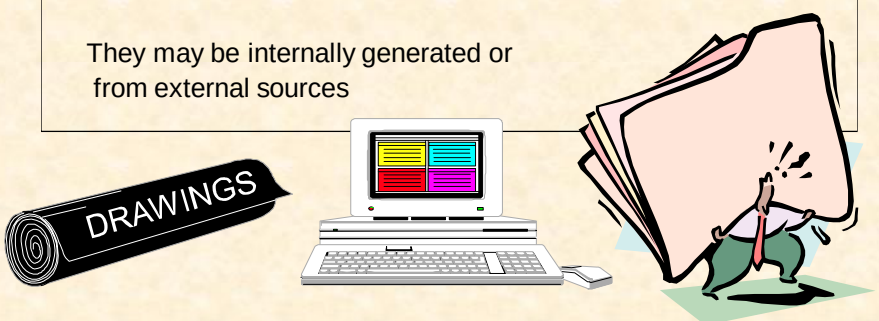
4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

Documents include:

Information or instructions, policy statements, text books, procedures, specifications, calibration tables, biological reference intervals, charts, posters, notices, memoranda, software, drawings, plans, regulations, standards which form part of the quality system.

They may be on various media including hard copy, electronic, digital, analogue or photographic

They may be internally generated or from external sources



4.4 - Review of requests, tenders and contracts

Contract review serves to establish that the laboratory has the necessary personnel, equipment, methods, expertise and other resources to perform the testing work in question.

- **Subcontract of work.**
- **Records of reviews must be maintained.**
- **Clients must be informed of deviations from contracts.**
- **If contracts are amended, another review is needed.**

4.5 - Subcontracting of tests and calibrations

4.5.1 Competent subcontractors used.
- competent: e.g. comply with *this* standard for the work in question.

4.5.2 Advise and gain approval of the customer, when appropriate (preferably in writing).

4.5.3 Laboratory is responsible for contractors work, except when specified by client or regulatory authority.

4.5.4 Maintain register of all sub contractors used and evidence of compliance to this standard for the work in question.

4.6 - Purchasing services and supplies

The quality of the testing services provided by a laboratory is critically dependent on the quality of the consumable supplies and services it uses.

Requirement for Purchase Product

4.6.1 Documented policies and procedures for the purchase selection, reception and storage of:
- ◆external services
- ◆ consumable supplies

Acceptance/rejection criteria needed.

4.6.2 Quality of purchased services and supplies must be inspected or verified before use.

4.6.3 Purchasing documents contain information on purchases (product & supplies) and technical content reviewed and approved.

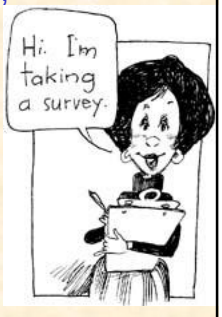
4.6.4 Evaluation of suppliers and approved list: records must be kept.

4.7 - Service to the customer

4.7.1 Labs shall be willing to cooperate with customersô requests to monitor lab performance in relation to the work performed, provided that the lab ensures confidentiality to other customers.

Å Reasonable access to relevant areas of the lab for witnessing tests, good communication, seek feedback.

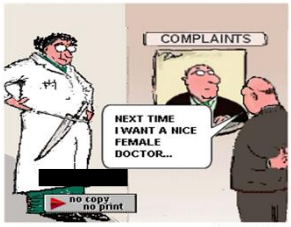
4.7.2 Laboratories shall seek feedback from its customers. The feedback shall be used for improvement of QMS.



4.8 - Complaints

In spite of all efforts to ensure provision of quality testing service, not all customers will be satisfied. Things can go wrong in the laboratory and correction and corrective action will be necessary.

Laboratories need a policy and documented procedures for the resolution of complaints.
Records shall be maintained of complaints, investigations and corrective actions taken.



4.9 - Control of non-conforming testing / calibration work

Non-conforming work such as mistakes in test results or reports may be identified through QC results, staff observations or complaints.

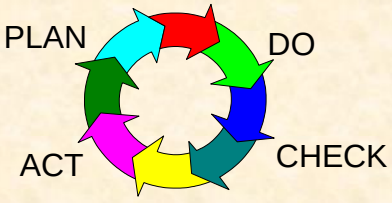
- designate responsibility and authority for the management of non-conforming work.
- take actions when non-conforming work is defined.
- review and investigate all non-conformances.
- take and record remedial action.
- recall/correct non-conforming results and notify customers.
- enter corrective action procedure if recurrence possible.

4.10 - Improvement

The laboratory shall continually improve the effectiveness of its management system through the use of the:

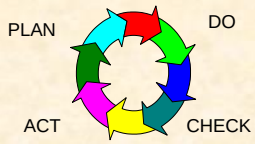
- quality policy.
- quality objectives.
- audit results.
- analysis of data.
- corrective and preventive actions.
- management review.

4.11 - Corrective Action



- Problems Identified -
  complaints, audits, incidents, staff identify improvements, non-conformance.
- Causes analysis -
  materials, equipment, accommodation, procedures, people.
- Selection and Implementation of Corrective Actions.
- Monitor results ï
  to ensure they have been effective.
- Additional Audits -
  Where there is doubt over compliance with the quality system, appropriate areas must be audited. Results of corrective actions must be submitted for management review.
- Close out.

4.12 - Preventive Action



Preventive action involves the PROACTIVE identification of potential weaknesses and the correction of these BEFORE problems develop.

- identify potential non-conformities and needed improvement ï review systematically all operations, brainstorm and flowchart the actual procedure, identify differences in operations, identify hazards, identify improvements.
- if preventive action is required, action plans shall be developed, implemented, monitored to reduce likelihood of occurrence of non-conformance and to take advantage of the opportunities for improvement.

4.13 - Control of Records

QUALITY AND TECHNICAL RECORDS

4.13.1 Record control procedure
- Identified
- Stored
- Protected
- Disposition

Record Control Procedure

4.13.1.2 Records shall be
- Legible
- Readily retrievable
- Maintained in a suitable environment
- Define retention time

4.13 - Control of Records

4.13.1.3 All records shall be held secure and in confidence.

4.13.1.4 May be on electronic data - procedures to protect and have back up records.

Examples of Quality Records:

4.13 - Control of Records

4.13.2.1 TECHNICAL RECORDS

The Laboratory shall retain records of:

- original observations.
- derived data.
- sufficient information to establish an audit trail.
- calibration records.
- staff record.
- test report / calibration certificate.

Retained records of each test or calibration shall contain sufficient information (if possible) to:

1. Identify factors affecting the uncertainty.
2. Enable the test or calibration to be repeated using original conditions.

4.13 - Control of Records

4.13.2.2 Recording - observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

4.13.2.3 Correction of Records

- Original records is not obscured
- Equivalent measures must be taken for records stored electronically

4.14 - Internal Audits

An internal audit program needs to be established to determine whether laboratory quality management system including testing and calibration activities are effectively implemented and maintained.

- procedure established
- predetermined schedule or requested by management
- Quality Manager to plan and organize
- timely corrective action for non-conformance
- audit activity, findings and corrective actions to be recorded
- follow-up activities shall verify and record implementation and effectiveness of corrective action

MANAGEMENT REVIEW

(Are we doing the right things?)

Formal meeting of senior management conducted at least annually to review suitability and effectiveness of quality system and testing/calibration activities in achieving established objectives.

Effectiveness - measure of the extent to which planned activities are realized and planned results achieved. *ISO 9000:2005*

4.15 - Management Reviews

4.15.1 The review shall at least take into account of:

- the suitability of policies and procedures
- reports from managerial and supervisory personnel
- the outcomes of recent internal audit
- corrective and preventive actions
- assessments by external bodies
- results of inter-laboratory comparisons or proficiency tests
- changes in volume and type of work
- customer feedback
- complaints
- recommendations for improvement
- other relevant factors, such as quality control activities, resources and staff training

IMPORTANT!!!

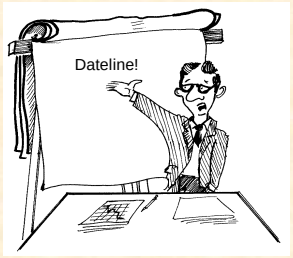
Note 1 : A typical period for conducting MR is once every 12 months.

Note 2 : Results should feed the laboratory planning system and should include the goals, objectives and action plans for coming year.

Note 3 : A management review includes considerations of related subjects at regular meetings.

4.15 - Management Reviews

4.15.2 Findings from management reviews and the actions that arises from them shall be recorded.
The management shall ensure that those actions are carried out with an appropriate and agreed timescale.



End of session 3: Management requirement

Thank you very much