

SADCMET WORKSHOP

KAMPALA

UGANDA

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**IN MEETING EVERY DAY CHALLENGES,
A LABORATORY MUST OFFER
PRODUCT / SERVICE THAT:**

meet customer needs

satisfy customer expectations

comply with specifications / standards, statutory

or other are competitively priced

are provided at a profit-yielding or budget

related cost




The laboratory should be organised that all factors, (technical, admin, etc.) affecting the “quality” of product / service, are always under **control**.



What is
“quality”
as far as
the laboratory
is concerned?





ISO/IEC 17025

A system for the competence of Testing and Calibration Laboratories



ISO 17025 & ACCREDITATION

TECHNOLOGY ORIENTATED

The basic requirements for a system where the laboratory has all the necessary self-regulating procedures, organisation and controls on all factors to demonstrate their competence to carry out tests to specified requirements (and provide evidence of this). So that it is possible to guarantee (give confidence) that the results produced fall within acceptable limits consistently.

COMPETENCE BASED

Competence concerning a laboratory

- Personnel
- Methods
- Equipment
- *Measurement traceability*
- *Environment*

- *There has to be criteria for this competence e.g. Standard Methods, known measurement relationship (standards, inter-comparisons).*

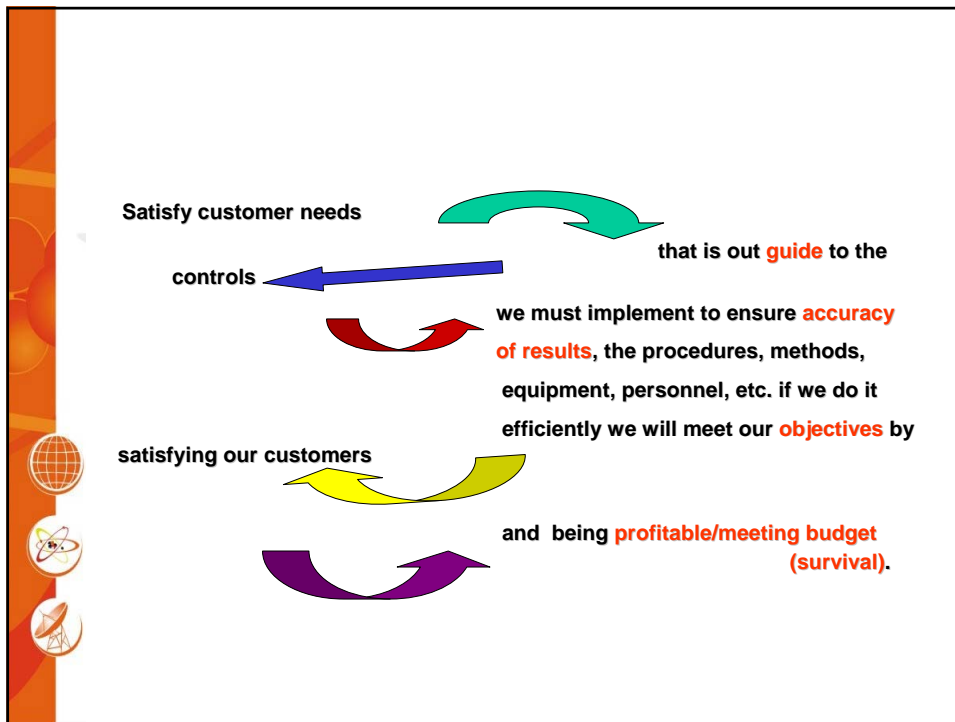


To achieve optimum **effectiveness and efficiency**, to protect laboratory interests and to satisfy customer expectations, a laboratory must develop and implement an **effective system**.

The system must be evaluated (assessed) periodically, to ensure its continued

adequacy.





QUALITY CONTROL

“The operational techniques and activities, that are used to fulfill requirements of quality.”

ISO 9000

QUALITY CONTROL

Is the method through which we measure actual performance, compare it with Standards and act on the difference.



QUALITY ASSURANCE

Is the activity of providing to all concerned the evidence needed to give confidence that the quality activity is being performed properly.



(Juran definition)

ISO/IEC 17025 Clause 4.1 Organisation

Legally responsible

Satisfy the needs of the customer,

Regulatory authorities

&

Organisations providing recognition.

Manage conflicts of interest



ISO/IEC 17025 Clause 4.1 Organisation

4.1.5a) the system to suit the lab.

4.1.5b-j)

Pressures, Confidentiality,

Structures (authority, responsibility,
interrelationships).

Technical Management, “QA manager,”

Deputies



ISO/IEC 17025 Clause 4.2 Management System

4.2.1.

Documented System



5 cups cake flour
2½ handfuls oil
Salt
Add boiling water
Knead
Roll and cook



ISO/IEC 17025 Clause 4.2 Management System

4.2.2.

***Policy, Objectives
& Commitment***



POLICY

1. A plan of action adopted or pursued by an individual, government, business, etc.
2. Wisdom, prudence, shrewdness or sagacity.
3. Scot (often p1.) the improved grounds surrounding a country house.



OBJECTIVES

Object of ones endeavors, goal, aim.

QUALITY POLICY

Overall intentions and directions of an organisation to quality. As formally Expressed by Top Management.

ISO 9000



QUALITY IMPROVEMENT

Actions taken throughout the organisation, to increase the effectiveness and efficiency of activities and processes to provide added benefits to both the organisation and its customers.

ISO 9000



Management Policy Statement

As the technical manager of TT&S laboratory I commit myself and my staff to the implementation of the criteria of ISO 17025 and the Accreditation Body requirements. The implementation of these requirements will be the basis for attaining the goals and objectives set by management.

The main goals of the laboratory are to meet client requirements, which include the provision of timeous and accurate results, and to meet the business objectives of the Laboratory.

This will be done by performing our work in the most effective, efficient and profitable way which will be reflected in the laboratory procedures and methods covering the various activities within the laboratory.

I therefore require all personnel to read, understand and implement the policy of this laboratory so that all our efforts can be directed towards good laboratory Practice, achieving our goals and identifying improvements. This will enable us to service our clients in a professional and efficient manner whilst remaining competitive.

Signed
Technical Manager

ISO/IEC 17025 Clause 4.3 Document Control

Approval & Issue

Appropriate Documents available at necessary locations.

Periodic Review

Control of obsolete documents

Document changes



**ISO/IEC 17025 Clause 4.4 Review of requests
tenders and contracts**

Policies & Procedures

*Methods adequately defined and
documented*

Capability & resources

*Reviews for internal customers
(also refer 5.10.1)*

Records of reviews & significant changes



**Subcontracting occurs when an individual
or in many cases a business signs a
contract to perform part or all of the
obligations of another's contract**



**ISO/IEC 17025 Clause 4.5 Subcontracting,
4.6 Purchasing**

Subcontracting

When, to whom (choice) & register.

Purchasing

Policies & Procedures

Checks (incoming), to whom (choice) & register.



**ISO/IEC 17025 Clause 4.7 Service to the
Customer.**

Willing to cooperate with the Customer.

Shall seek feedback from it's Customers



ISO/IEC 17025 Clauses

4.8 Complaints.

4.9 Control of non-con Testing

4.11 Corrective Action

4.12 Preventive Action



4.10 Improvement



ISO/IEC 17025 Clause 4.13 Records.

Procedures.

**Collection, Filing, Indexing, Identification,
Access, Storage, Maintenance, Disposal.
Retention time.**



Technical records.

Audit trail.



ISO/IEC 17025 Clause 4.14 Internal Audits.

Procedures.

Schedule

System & Technical elements

Trained and qualified personnel



ISO/IEC 17025 Clause 4.15 Management Reviews.

Procedures.

Schedule

Back to policy and objectives



**FORMULATE MEASURABLE
OBJECTIVES IN TERMS OF:**

- **RESULTS - (WHAT must be achieved)**
- **CRITERIA / STANDARDS (HOW?)**
- **TIME - (WHEN?)**
- **RESPONSIBILITY - (BY WHOM?)**

