Food and Agriculture Organization of the United Nations

Raising confidence in quality measurements from soil laboratories in Sub-Saharan Africa

Dakar, 23-27 October

Quality Assurance - *Giving Confidence in Analytical Reliability*

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SoilFER

GLOSOLAN GLOBAL SOIL LABORATORY NETWORK

AFRILAB AFRICAN SOIL LABORATORY NETWORK

GLOBAL SOIL PARTNERSHIP

Quality management principles

Customer focus – to meet customer requirements
to exceed customer expectations

Leadership – to establish unity of purpose and direction

Engagement of people – competent, empowered staff enhance capability

Process approach – a coherent system achieves consistent and predictable results

Improvement – leads to successful organizations

Evidence-based decision making - produce desired results.

Relationship management – for sustained success

Objectives of the workshop

1. **Quality Management principles for Good Laboratory Practice**
2. **Examples for when a Quality Management system is essential – challenges faced in Africa.**
3. **Simple approach to making in-house Reference Materials and an example from Southern Africa**
4. **Data management – handling of data for judging data performance**
5. **How will an organisational and regional network of laboratories plan to improve their Quality Management**:
   (i) Exchange information between members
   (ii) Context for own setting.

Context

Many important decisions are based on the results of laboratory analysis.
Thus, it is important to have some indications on the quality of the results, i.e. client confidence/trust in your results to make a decision regulatory, commercial or scientific decision.

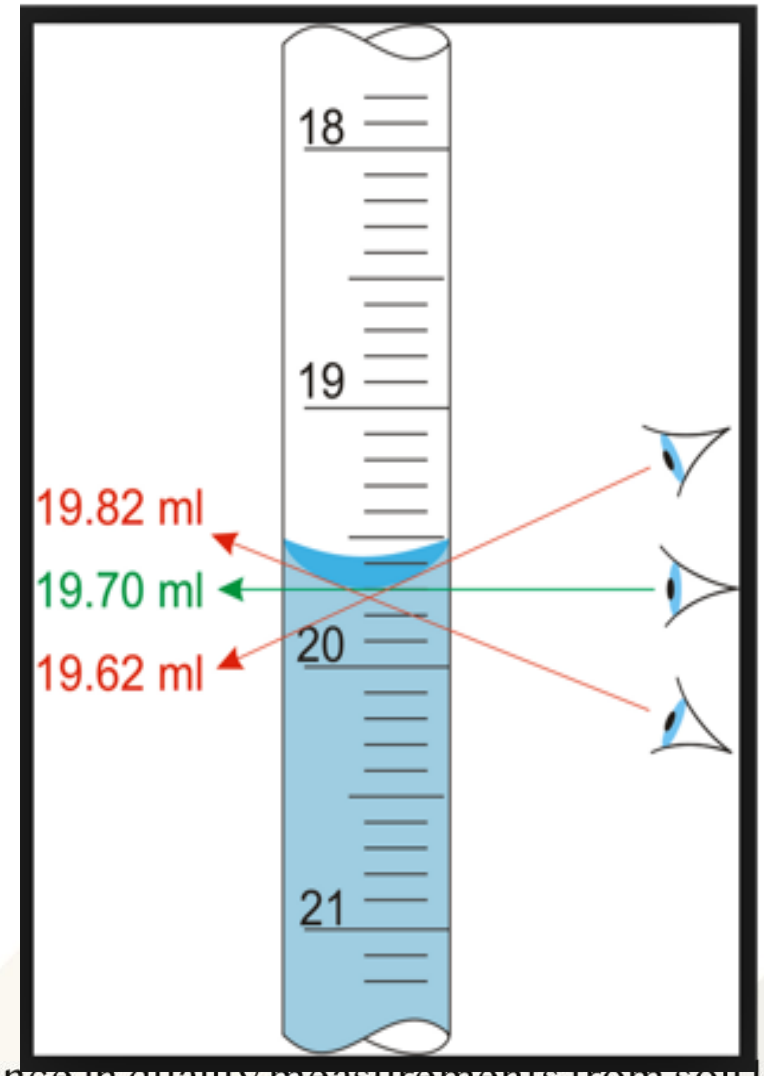
With globalisation, the lab managers are coming under an increasing pressure:
(i) to **demonstrate the quality of their results** and
(ii) to **demonstrate their results can be compared to results obtained by other laboratories or with the scientific literature.**

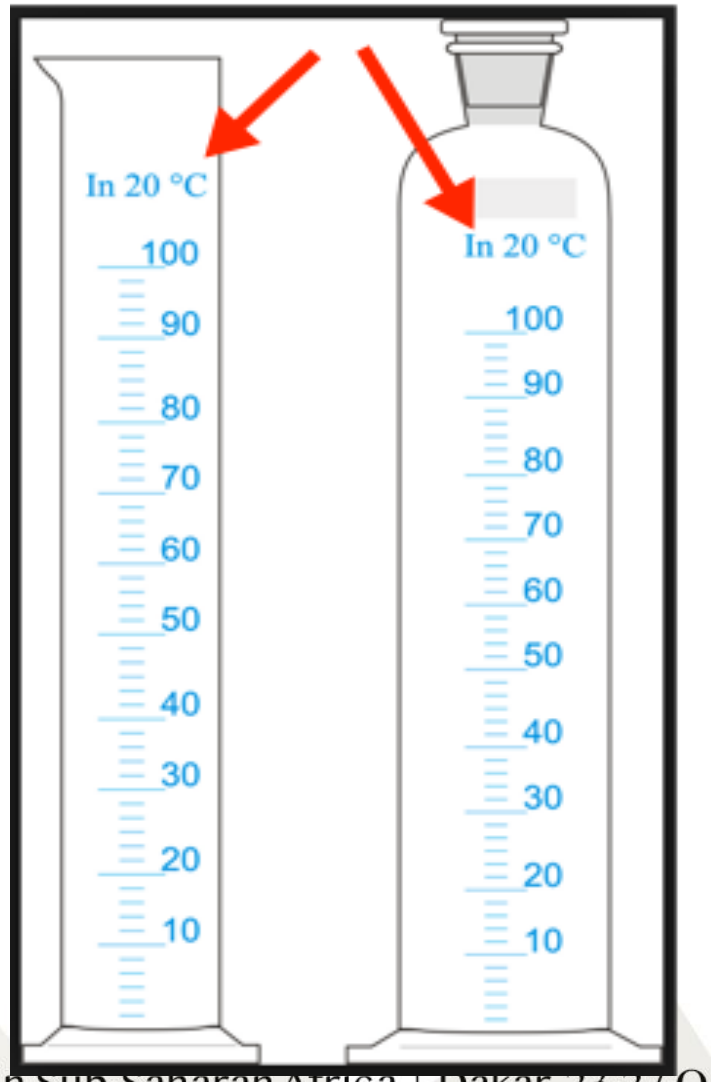
Common problems in the literature

- Lack of or unclear Aim and objectives to achieve that Aim.
- Lack of or no detail for quality assurance measures – lack of confidence in measurements, field collection strategy etc.
- Therefore, questioning of complex statistics, graphical representation and interpretation.
- **Decisions founded on data could be costly without appropriate evidence for traceability.**
- There maybe legal or financial implications for your data without traceability and evidence for quality measurements

Everybody can measure, but not everybody can do professional quality measures.

Factors e.g. operator / environment

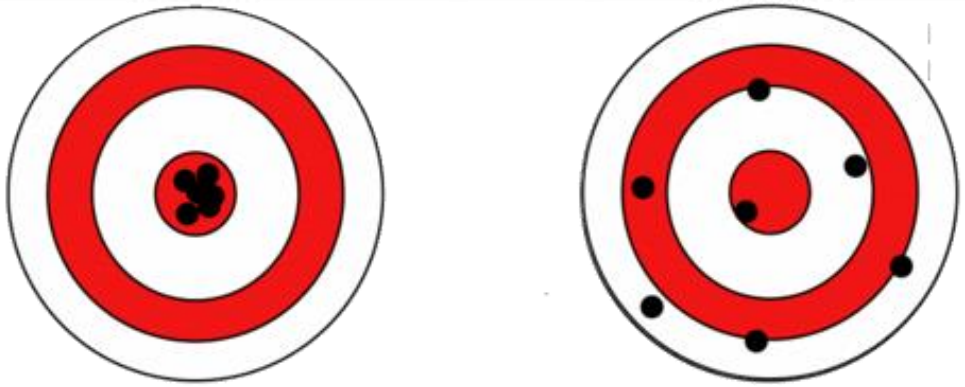




Precision: high low

Accuracy:

high



low

International Standards for Quality Management

- ISO 9001:2015 – generic management Standard
  - refers to an organization's structure for managing its activities
  - can be applied to any business enterprise, public administration, or government department
- ISO 17025:2017 – technical competency Standard
  - for laboratories - specifying the additional requirements for demonstrating technical competence

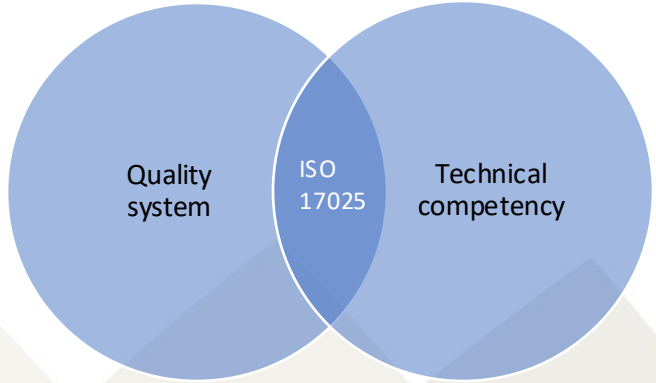
ISO/IEC 17025:2017

4. Management requirements

4.1. Organization
4.2. Management system
4.3. Document control
4.4. Review of requests, tenders, contracts
4.5. Subcontracting of tests
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 actions
4.12. Preventive actions
4.13. Control of quality records
4.14. Internal audits
4.15. Management review

5. Technical requirements

5.1. General
5.2. Personnel
5.3. Accommodation & environmental conditions
5.4. Test methods and validation
5.5. Equipment
5.6. Measurement traceability
5.7. Sampling
5.8. Handling of Test items
5.9. Assuring the quality of test results
5.10. Reporting the results



Management Requirements

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Management system

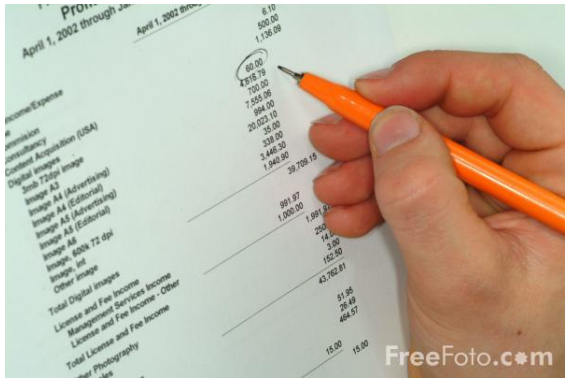
- Establish, implement and maintain documentation of policies and procedures - review
- Management commitment to stated standard of service and to improve
- Staff to familiarize themselves with and implement the policy
- Define roles of Quality and Technical Management

Document control

- Establish procedures for review and approval
- Approval and issue
  - Availability at point of use
  - Periodic review
  - Version control (archiving)
  - Unique identification
- Change review and approval
  - Traceability
  - Hand written or computerized

Review of requests, tenders and contracts

- Define, document and understand all requirements
- Ensure capability and resources
- Select appropriate test method
- Resolve differences before staring work
- Record checks and changes
  - communications with the client
- Include subcontracting
- Communicate deviation



Subcontracting of tests and calibrations

- Competent subcontractor
- Advise customer
- Responsibility for subcontractor
- Keep a register

Purchasing services and supplies

- Policy & procedure – purchase, reception, storage
- Inspection for compliance
- Specify services and supplies
- Evaluate suppliers and keep a record

Service to the customer

- Cooperate to clarify request
  - Access to witness
- Confidentiality
- Communication
  - throughout the work
- Seek feedback
  - Analyse for improvement

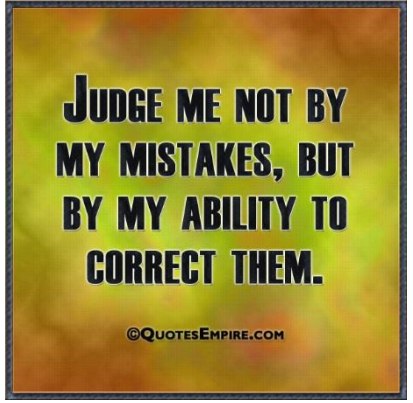
Complaints

- Policy and procedure for handling complaints
- Keep records of complaints, investigations and actions

Control of non-conforming work

- Policy and procedure for investigation when any aspect does not conform
  - Results of Audits or other observations
  - QC failures
- Responsibility for who does what
- Evaluation
- Corrective and Preventative Actions
- Notification or recall?
- Authorize resumption

Corrective actions



- Continually improve the effectiveness of the management system
  - Quality policy and objectives
  - Audit results
  - Corrective and Preventative Actions
  - Management review

Preventive actions

- Identify needed improvements
- Potential sources of non-conformities
- Improvement opportunities
- Ensure effectiveness

Control of quality records

- Identification, collection, indexing, access, filing, storage, maintenance and disposal
- Readily retrievable suitable environment
- Secure and in confidence
- Protect and back up electronic records

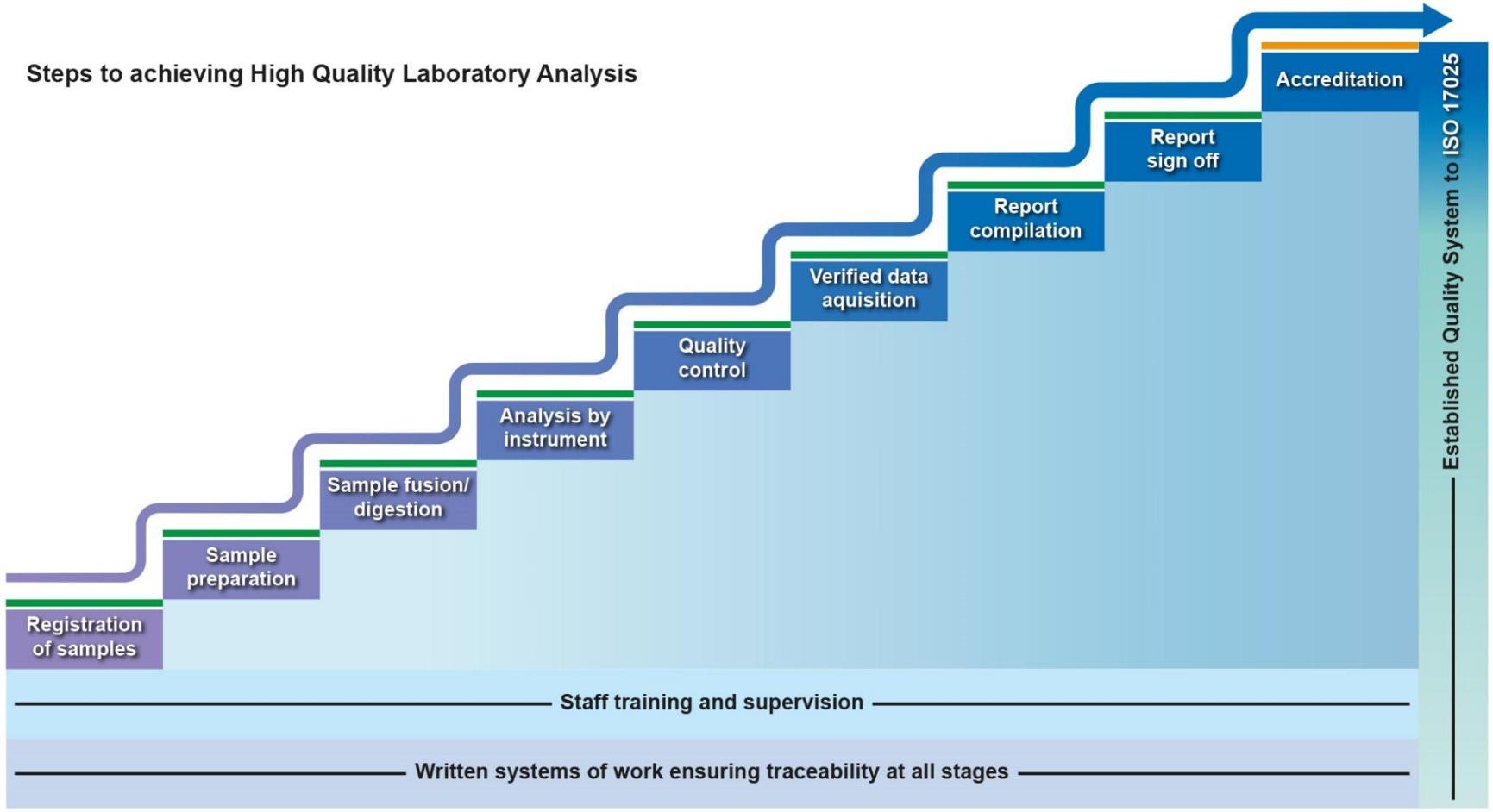
Internal audits

- Predetermined schedule and procedure
- Verify operations continue to comply
- Address all elements of Standard
- Carried out by trained and qualified personnel
  - Independent of activity
- Timely response
- Notify clients if results have been affected
- Implementation and effectiveness of Corrective Actions

Management review

- Review of management system and testing ~~by top management~~
  - Suitability
  - Internal and external audits
  - Corrective and Preventative Actions
  - Interlaboratory comparisons and Quality Control
  - Changes in work load
  - Customer feedback
- Recommendations for improvement
- Actions carried out in a timely manner

Technical requirements



Personnel

- Competence – operation, evaluation, reporting
- Qualification – training, education, experience
- Training goals and training needs
- Employed – supervised and competent
- Job descriptions for key staff
- Authorization
  - Training records

Accommodation and environmental conditions

- Ensure environmental conditions do not invalidate
- Monitor and control:

  sterility, dust, electromagnetics, radiation, humidity, electricity, lighting, temperature, sound, vibration, etc.
- Effective separation for incompatibles
- Laboratory access
- Housekeeping

Test methods and validation 1

- Select appropriate methods – inform client
  - Client preference – define, suitability
- Plan a method for – revise
- Qualified operator
- Non-standard methods by agreement
- Document method

Method description - SOPs

- Appropriate identification and specified scope
- Parameters and ranges
- Equipment (performance requirements)
- Reference standards and reference materials
- Environmental conditions - stabilization
- Labelling, checks on samples, instrument checks, how to record results, safety measures
- Approval criteria
- Recording and presenting of data
- Uncertainty

Test methods and validation 2

- Validation
  - Confirmation by examination
  - Provision of objective evidence
  - Range and accuracy…

- Estimate uncertainty of measurement
  - identify components – performance, scope, experience
- Control of data – making checks
  - document computer programs

Method performance

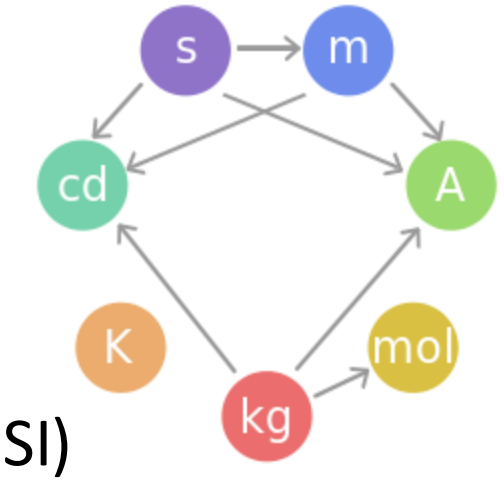
- Sampling, handling and transportation
- Calibration using traceable standards
- Comparison of data with other methods/results
- **Interlaboratory comparisons – PT schemes**
- Systematic assessment of factors influencing results
- Theoretical understanding and practical experience

range	accuracy	detection limit
selectivity	linearity	repeatability
reproducibility	robustness	matrix sensitivity

Equipment

- Furnish with all required items for work
- Capable of required accuracy before use
- Checked and calibrated
  - Identify calibration status/out of use
- Use by authorized personnel
- Operating and maintenance instructions readily available
- Equipment records and unique identification
- Safe handling, storage, use and maintenance

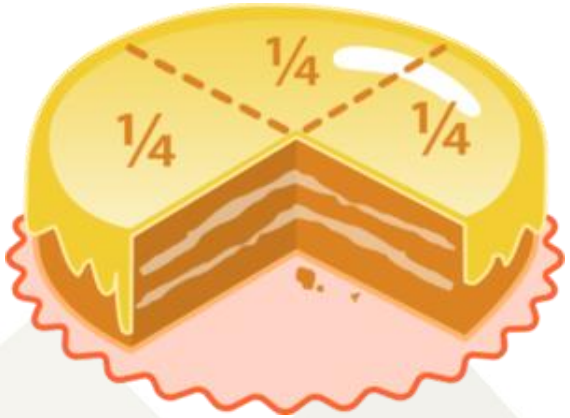
Measurement traceability

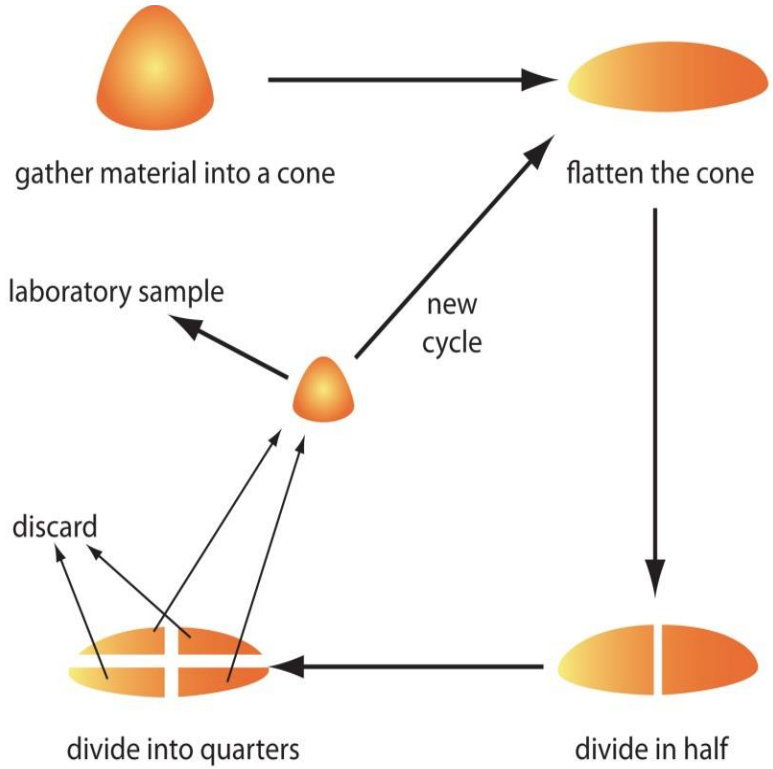


- Calibrate all equipment before use
  - following set procedure
- Traceable to International System of Units (SI)
  - reference to a primary standard
- Calibration standards
- Certified Reference Materials (CRM)
- Intermediate checks to maintain confidence in the calibration
- Handling, storage - prevent contamination/deterioration

Sampling

- Sampling plan to address controlling factors
  - Based on appropriate statistical methods
- Record client requested deviations for reporting
- Procedures for recording sampling data





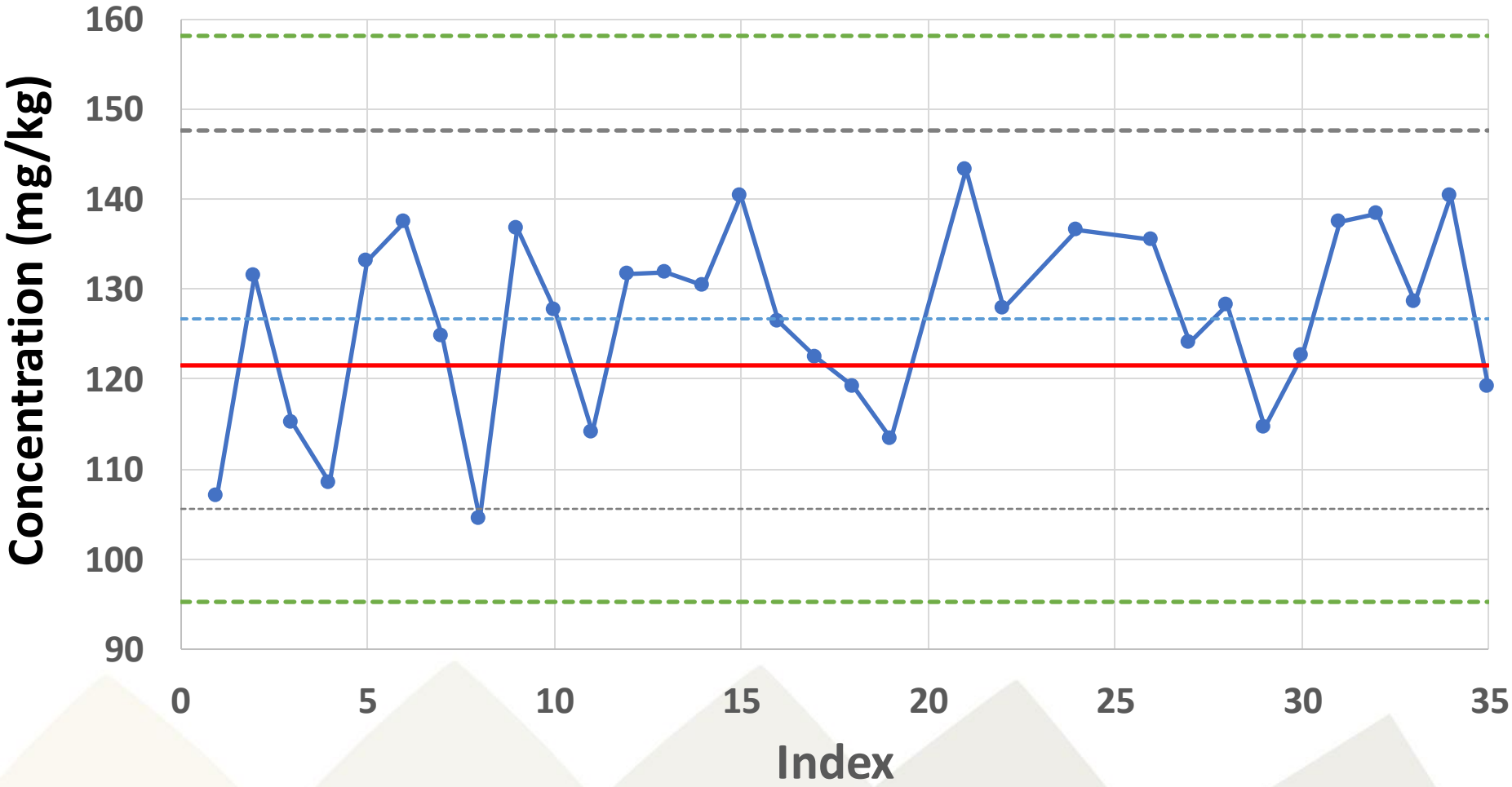
Handling of test items

- Procedures for transportation, receipt, handling, protection, storage, retention, disposal
  - Protect sample integrity
- System for sample identification – avoid confusion
- Record state on receipt – seek further information
- Facilities to avoid deterioration, loss or damage
- Maintain, monitor and record conditions

Assuring the quality of test results

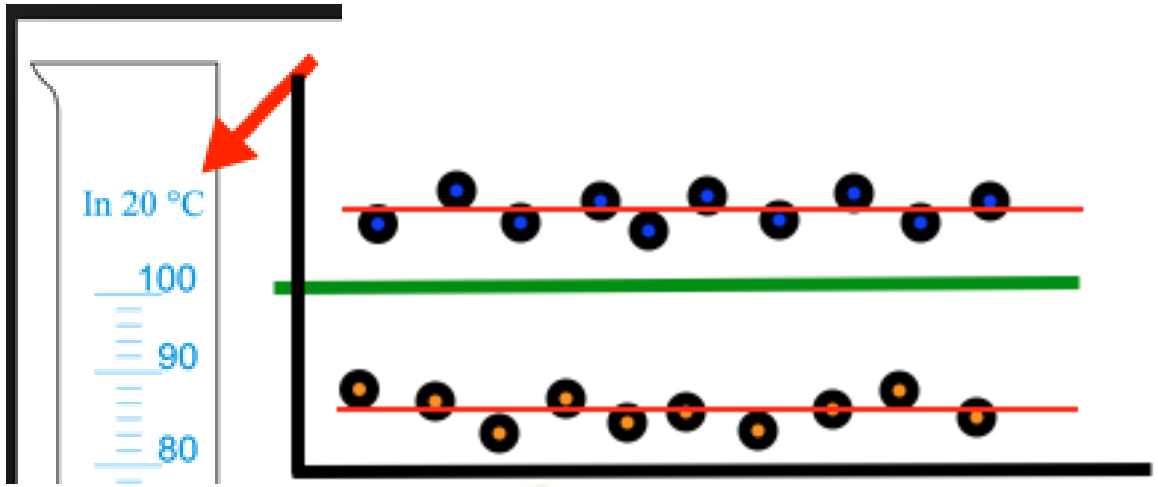
- Quality Control (QC) procedures
- Record results - to view trends
- Statistical evaluation of QC data
- Plan and review monitoring of QC data
  - CRMs, secondary standards
  - Proficiency Testing schemes - EPTIS
  - Replicates and repeats
- Predefined acceptance criteria
  - Shewhart chart – Westgard rules
- Planned action to correct and prevent

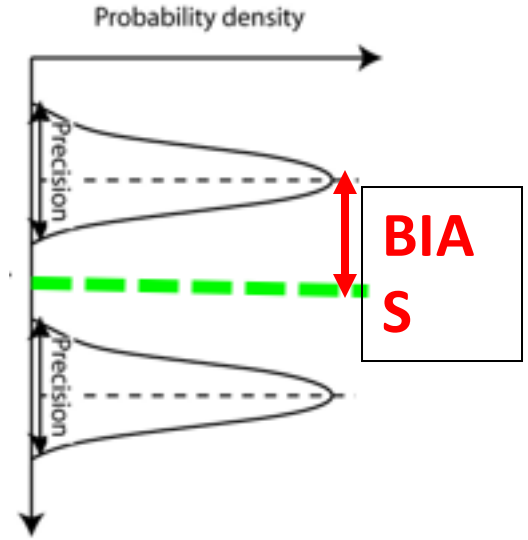
Shewhart QC chart



Analytical errors can be of 2 categories:

2. Systematic or ‘predictable’, regular deviation from the "true" value.





Data management

- Ongoing records for Quality control samples
- Requires discipline to collate QC/RM data for each batch
- Monitor within and between batch variation

- Knowledge of MS Excel – formulae, charts?

- QC software can be expensive

- Possible to make QC charts in MS Excel
  - plug-in for MS Excel called SPCC – see BGS report

Reporting the results

- Accurate, clear, unambiguous, objective
- Specified contents of test report
- Basis for opinions and interpretations
- Results from subcontractors identified
- Format to minimize misuse or misunderstanding
- Allow for amendments or supplementary reports with independent reference

Test reports

- Report title
- Laboratory address
- Unique identification
- Customer details
- Method identification
- Description of items tested
- Date of receipt and of test
- Sampling details
- Test results
- Name, function and signature of authorizer

Where necessary for the interpretation of results:

- Deviations
- Compliance, uncertainty, opinions/interpretations
- Sampling procedure, location and date

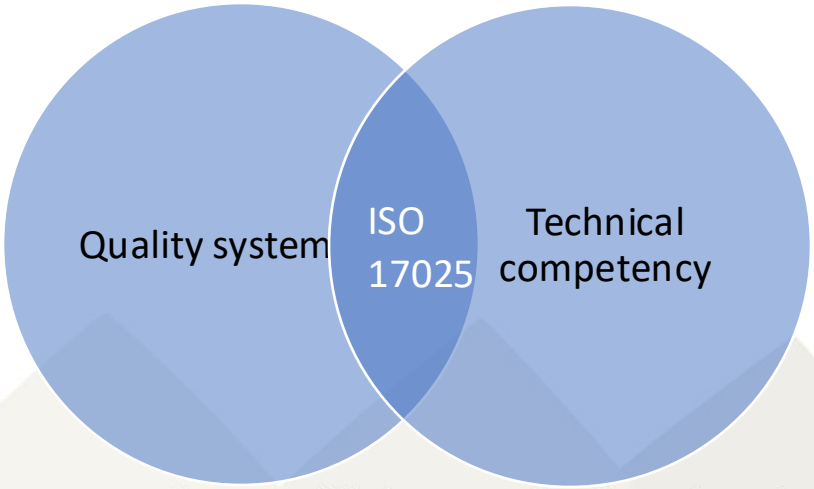
ISO 17025 provides

General requirements for the competence of laboratories to demonstrate that they:

operate a quality system,

are technically competent

are able to generate technically valid results



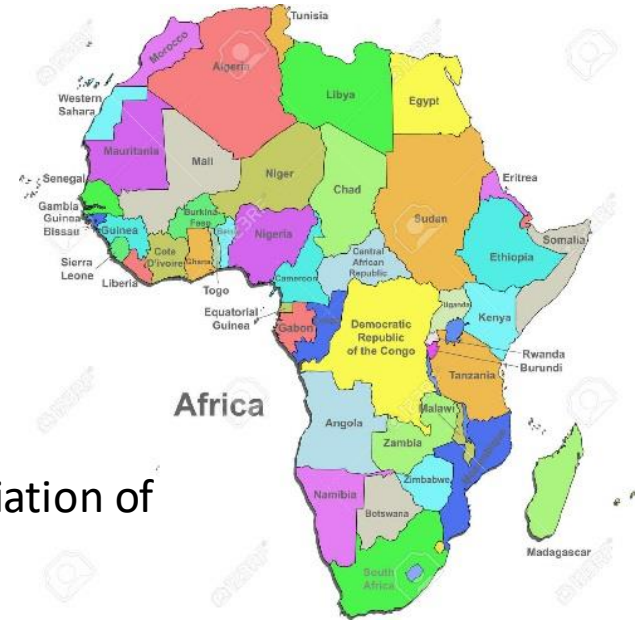
Benefits of accreditation

1. Increased prestige on a national and international level.
2. Customers can trust valid and documented results.
3. Proven traceability to National Standards.
4. Well organized, customer-oriented laboratory operation.
5. Recognition of professional and technical staff ability.
6. Assurance that equipment is suitable for measurements, properly maintained and frequently checked.
7. Proven and documented uncertainty budget.

Accreditation process

- Document a quality management system; a man requirement for laboratory accreditation.
- Establish quality management procedures for how the system is maintained.
- Implement the quality management system in the laboratory.
- Apply for accreditation.
- Establish (over several months) the records that will be reviewed at an accreditation audit.
- Assessment by an accreditation body that is certified to perform laboratory accreditation (ILAC).

Accreditation Bodies



International Laboratory Accreditation Cooperation (ILAC)

Regional cooperation bodies:

African Accreditation Cooperation (AFRAC)
Phone: +27 12 740 8420
Email: nonhlanhlah@sanas.co.za
Website: http://www.intra-afrac.com

Southern African Development Community in Accreditation Secretariat - South Africa (SADCA)
Phone: +27 12 740 8420
Email: nonhlanhlah@sanas.co.za
Website: http://www.sadca.org

Stakeholder:

National Laboratories Association of Zimbabwe (NLAZ)

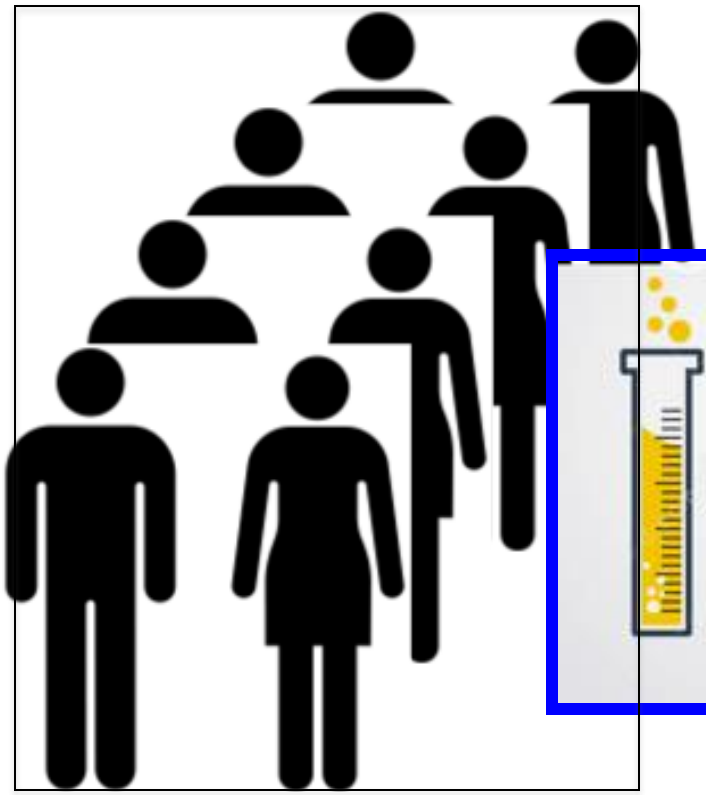
Phone: +263 4 753 800/2
Fax: +263 4 749 181
Email: nlaz@mweb.co.zw
Website: http://www.nlaz.co.zw

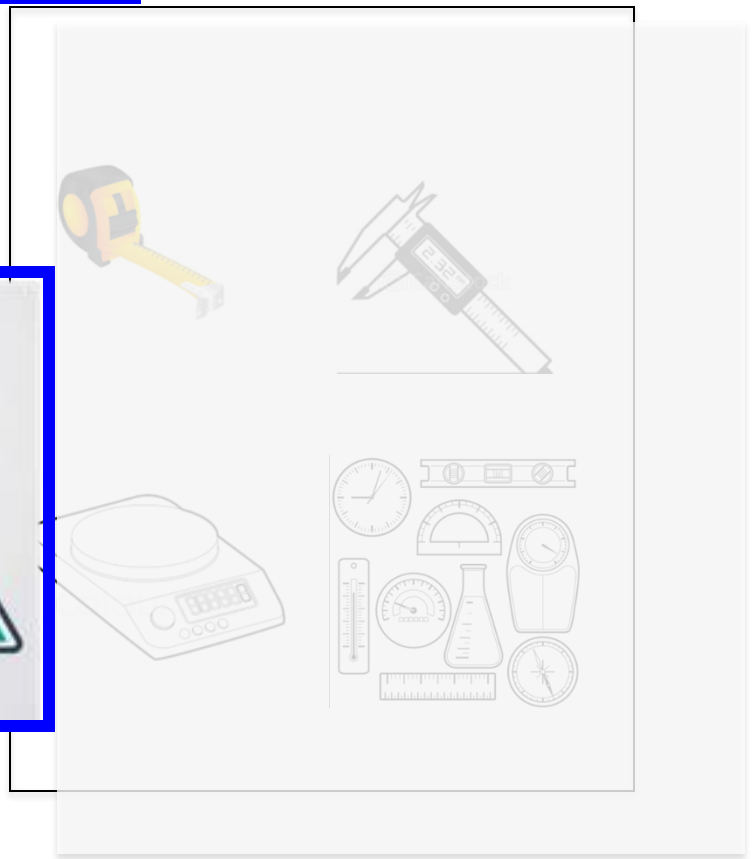
Quality Management

- You do not need accreditation for good quality management – accreditation is expensive to set-up and to maintain.
- However, the principles can be applied anywhere.
- Not funding dependent – a Quality Assurance system requires lab staff and management to take responsibility and support the process.
- Where resources are limited, networks can assist – peer review.

ANALYSIS:

People + chemical reactions + Instruments





Staff but also… students

every body must work the same way…. how? SOP !

Quality Management-summary

- Documented SOPs, clearly defined responsibilities and checks on data

  → promote reproducibility

  → promote safe working practices

  → provide confidence in data outputs

Traceability from arrival of sample to reporting of data

Evaluate and monitor

What can you do?

- Networks exist to facilitate quality management e.g. GLOSOLAN
- Reference Materials could be made in-house
- Inter-laboratory comparisons could be with colleagues at other local institutions or even ask a lab with a quality management system help your lab
- Take part in Proficiency Testing schemes – particularly when they are free! (Glosolan) - **Every lab can improve**.
- Devise a plan to remedy data problems – DO NOT IGNORE- ask for help.
- Hopefully we will see better confidence in measured data in the literature and potential for income generation kept within developing countries
- Resources kept in-country with improved confidence in data for Applied Geochemistry

Food and Agriculture Organization of the United Nations

AFRILAB PT 2023

DETAILS IN HERE

5 soils for ……. Determinands

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