Training Program on

Analytical Techniques in Nutrition, Food Safety and Biosafety

September 01 –14, 2014

ICRISAT | Patancheru
Telangana | India

International Crops Research Institute
for the Semi-Arid Tropics

Sept 08, 2014

ISO/IEC 17025:2005
Cuts Through the Confusion

The updated standard will benefit users…
if they understand it.

Accreditation requirements of food testing laboratories

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Laboratory Quality Management System as per ISO 17025:2005

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Global Perspective of Laboratory Accreditation

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International standards and guides applicable to laboratories

ISO/IEC 17000:2004 – Conformity assessment – Vocabulary and general principles.

ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories.

ISO 15189:2012 – Medical laboratories – Particular requirements for quality and competence.

ISO/IEC Guide 43 – Proficiency testing by inter laboratory comparisons – Part I & II.

ISO/IEC 17011:2004 – General requirements for accreditation bodies accrediting conformity assessment bodies.

International Laboratory Accreditation Cooperation (ILAC)

ILAC started as a conference in 1977 with the aim of developing international cooperation for facilitating trade by promotion of the acceptance of accredited test and calibration results.

On 2nd November 2000, 36 laboratory accreditation bodies, full members of ILAC, from 28 countries, signed an arrangement in Washington DC, USA.

Roles of ILAC

1. To develop the principles and the practice of laboratory accreditation.
2. To harmonize procedures and criteria for accreditation.
3. To assist in the development of new programs.
4. To facilitate mutual recognition of members.
5. To improve international acceptability of test and calibration results.

ILAC Arrangement

It builds upon existing and developing regional arrangements established around the world. Recognized regional cooperation members are:

1. European Cooperation for Accreditation (EA)
2. Asia Pacific Laboratory Accreditation Cooperation (APLAC)
3. Inter-American Accreditation Cooperation (IAAC)
4. The African Accreditation Cooperation (AFRAC)

Reference: https://www.ilac.org

ILAC Arrangement Signatories

Currently there are 86 signatories to the ILAC Mutual Recognition Agreement (MRA) from all over the world.

Reference: https://www.ilac.org

APLAC

Asia Pacific Laboratory Accreditation Cooperation

APLAC

The Asia Pacific Laboratory Accreditation Cooperation was initiated in 1992 as a forum for laboratory accreditation bodies in the Asia Pacific region. Its primary aim was to establish, develop and expand a mutual recognition arrangement among accreditation bodies in the region.

Reference:

https://www.aplac.org/about.html

APLAC Signatories

NATA Australia - testing, calibration, inspection, RMP
SCC Canada - testing, calibration, ISO 15189
CALA Canada - testing (previously known as CAEAL)
QMP-LS Canada - ISO 15189
CNAS People's Republic of China - testing, calibration, inspection, ISO 15189, RMP
HKAS Hong Kong China - testing, calibration, ISO 15189, inspection, RMP, PTP
NABL India - testing, calibration, ISO 15189
NABCB India - inspection
KAN Indonesia - testing, calibration, inspection; ISO 15189
JAB Japan - testing, calibration, ISO 15189, inspection, RMP, PTP
IAJapan Japan - testing, calibration, RMP
VLAC Japan - testing
KOLAS Republic of Korea - testing, calibration
Standards Malaysia Malaysia - testing, calibration, ISO 15189
ema Mexico - testing, calibration, ISO 15189, inspection, PTP

Reference: https://www.aplac.org/about.html

APLAC Signatories

MNAS Mongolia - testing, calibration
IANZ New Zealand - testing, calibration, ISO 15189, inspection
PNAC Pakistan - testing, calibration
PNGLAS Papua New Guinea - testing
PAO Philippines - testing, calibration
AAC Analitica Russian Federation - testing; RMP
SAC Singapore - testing, calibration, ISO 15189, inspection, PTP
SLAB Sri Lanka - testing, ISO 15189, calibration
TAF Chinese Taipei - testing, calibration, ISO 15189, inspection, RMP, PTP
DMSc Thailand - testing, ISO 15189
DSS Thailand - testing
NSC-ONSC Thailand - testing, calibration, inspection (previously known as NSC-ONAC and TLAS)
A2LA USA - testing, calibration, inspection, RMP, ISO 15189, PTP
ANSI-ASQ National Accreditation Board doing business as ACLASS & FQS USA - testing, calibration, RMP, inspection, PTP
IAS USA - testing, calibration, inspection
A-S-B doing business as L-A-B USA - testing, calibration
NVLAP USA - testing, calibration
PJLA Inc. USA - testing, calibration, RMP
AIHA-LAP, LLC - testing

AFRAC

AFRICAN ACCREDITATION COOPERATION

AFRAC

AFRAC is established in the year 2010 with a mission to cooperate in building capacity in African accreditation with a goal of sustaining an internationally acceptable mutual recognition arrangement.

Reference:

http://www.intra-afrac.com/index.php

Accreditation bodies under AFRAC

Accreditation Body	Website
Egyptian Accreditation Council (EGAC)	www.egac.gov.eg
Ethiopia National Accreditation Office (ENAO)	www.enao-eth.org
Kenya Accreditation Service (KENAS)	www.kenyaaccreditation.org
Libya National Centre for Standardisation and Metrology (LNCSM)	www.lncsm.org.ly
Mauritius Accreditation Service (MAURITAS)	www.mauritas.org
Southern African Development Community Accreditation Service (SADCAS)	www.sadcas.org
South African National Accreditation System (SANAS)	www.sanas.co.za
Tunisia Accreditation Council (TUNAC)	tunac@tunac.tn

Other African bodies that participate in AFRAC include

Body	Website
Common Market for Eastern and Southern Africa (COMESA) Secretariat	www.comesa.int
East African Community (EAC) Secretariat	www.eac.int
Economic Community of West African States (ECOWAS) Secretariat	www.ecowas.int
New Partnership for Africa's Development (NEPAD)	www.nepad.org
Southern African Development Community (SADC) Secretariat	www.sadc.int
Système Ouest Africain D'Accreditation (SOAC)	www.uemoa.int

Accreditation co-operations that participate in AFRAC include

Accreditation co-operation	Website
APLAC	www.aplac.org
EA	www.european-accreditation.org
IAAC	www.iaac.org.mx
SADCA	www.sadca.org

Functions of Regional cooperation members

1. To assist and support the establishment of national accreditation bodies.

2. To foster collaboration amongst member states having national accreditation bodies.

3. To create and maintain a system for the recognition of accreditation bodies in member states within the framework of and consistent with international requirements.

4. To coordinate, cooperate, and liaise with regional and international organizations concerned with accreditation.

… contd

5. To represent their region in all matters of accreditation within the international fora.

6. To harmonize accreditation practices within the region in compliance with international requirements.

7. To develop and manage training and technical assistance programs for transferring expertise and technical information, sharing of information and activities identified to assist new or developing accreditation programs, among present and potential members.

Quality Management Systems for Testing Laboratories

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What is Quality?

1. Good quality does not necessarily mean “High quality”. Instead it means, a predictable degree of uniformity and dependability at an economical price with a quality suited to the market.

2. Quality is “fitness for purpose”

3. Product meeting customer requirements at an economical price.

4. ISO 9000:2000 – Degree to which a set of inherent characteristics fulfills requirements.

Quality Management System (QMS)

1. ISO 9000:2000 – It is a management system to direct and control an organization with regard to quality.

2. It comprises all the manuals, procedures, reference standards, other documents and records that:

   Identify the customer requirements.

   Control operations and activities.

   Record all relevant information.

   Deliver the product or service as per customer requirement.

Quality Assurance

• ISO 9000:2000 – Part of the quality management system focused on providing confidence that quality requirements will be fulfilled.

It includes all activities associated with the attainment of quality.

Quality Control

• ISO 9000:2000 – Part of quality management focused on fulfilling quality requirements.

It includes operational activities aimed at monitoring the quality of products and services throughout the testing process, and at identifying unsatisfactory performance

Quality Improvement

• ISO 9000:2000 – Part of management system focused on increasing the ability to fulfill quality requirements.

Benefits include:

✓Improved staff morale.

✓Improved client satisfaction.

✓Better business.

ISO 17025

Interpretation of ISO/IEC 17025:2005 standard

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- Management Requirements (clauses 4.x)
- Technical Requirements (clauses 5.x)

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Management requirements of ISO/IEC 17025:2005 standard

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What is ISO/IEC 17025 ?

It is an international standard used by testing and calibration laboratories in developing their quality, administrative, and technical systems that govern their operations.

Reference to ISO 9001

1. Testing and calibration laboratories complying with ISO/IEC 17025 standard will also meet the principles of ISO 9001:2008.
2. Certification against ISO 9001:2008 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results.
3. ISO/IEC 17025 covers technical competence requirements that are not covered by ISO 9001:2008.

In the following slides **(P)** Indicates a Mandatory Procedure

Organization (Clause 4.1)

1. Legally responsible.
2. Meet the needs of customer, ISO/IEC 17025:2005, regulatory authorities, statutory requirements etc.
3. Defined authority and responsibility.
4. Avoiding potential conflict of interest when an organization is part of a larger organization.
5. Employees to be free from commercial, financial pressures and influences.
6. Adequate managerial and technical personnel.

Organization (Clause 4.1)

7. Policies and procedures for customer confidentiality.

8. Defined organizational structure.

9. Competence, impartiality, judgment and integrity.

10. Technical management with overall responsibility for technical operations and quality manager, with direct access to top management, having responsibility towards quality operations.

11. Deputies to key personnel.

12. Ensure communication.

Management System (Clause 4.2)

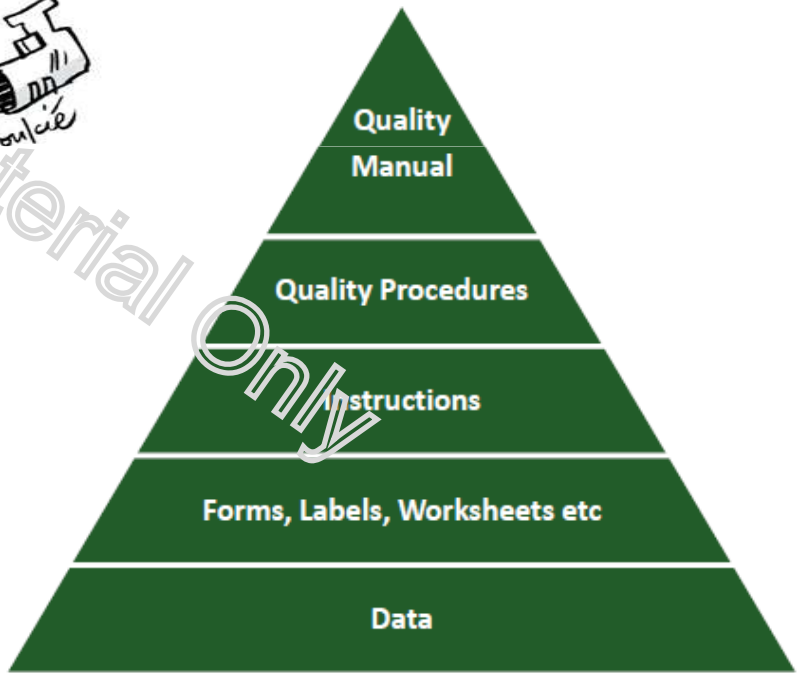
1. Establish, Implement, and Maintain a QMS.

2. Document policies, procedures etc.

3. QMS documentation is:
   i) Communicated to,
   ii) Understood by,
   iii) Available to and
   iv) Implemented by laboratory personnel.

Contd.,

Documentation Structure



The Quality Manual Contd.,

As per ISO 10013, it is a document stating the quality policy and describing the quality system of an organization.

Quality System Procedure

As per ISO 8402:1994 – "a specified way to perform an activity".

Management System

1. Evidence of commitment for continual improvement.
2. Communicate to the organization the importance of meeting customer as well as statutory and regulatory requirements.
3. Reference of procedures in the quality manual.
4. Roles and responsibilities of top management, at a minimum.
5. Maintain integrity of the QMS.

Document Control (Clause 4.3)

Procedure(P) to control:

✓External Documents
✓Internal Documents

- ☞ **Review and approval by authorized personnel prior to use.**
- ☞ **Master list**
- ☞ **Goal of procedure:**
  - i. Availability
  - ii. Periodic review and revision
  - iii. Removal of obsolete documents
  - iv. Identification of retained obsolete documents

Contd.,

- **Unique identification**
  - i. Dates
  - ii. Revision identification
  - iii. Total number of pages or mark to signify end of document
  - iv. Authority for issue

- **Document changes**
  - i. Reason(s) for amendments
  - ii. Defined authority
  - iii. Identification of altered or new text
  - iv. Hand corrections
  - v. Amendment in computerized systems

Review of Requests, Tenders, and Contracts (Clause 4.4)

1. The laboratory must have a formal procedure(P) for the planned and systematic evaluation of its capability to undertake each request to provide a testing or calibration service.

2. The procedure shall also apply to undertaking or accepting a significant increase in the volume of testing work currently being performed.

Contd.,

Reviewed Items:

i. Clarify customer needs.

ii. Laboratory resources.

iii. Staff skills and knowledge.

iv. Agreement on cost and TAT.

v. Delivery of results and means of delivery.

vi. Impact of new work on existing work.

vii. Any sub-contracting required?

viii. Final contract agreed in writing.

ix. Records of review.

x. Client to be informed of any deviations.

xi. Amendments in contract after commencement of work.

Subcontracting of Tests and Calibrations (Clause 4.5)

1. Reasons for sub-contracting
2. Approval from client, preferably in writing, when the laboratory intends to subcontract.
3. Ensure subcontractor's compliance with ISO/IEC 17025:2005.
4. Laboratory's responsibility to subcontractor's work.
5. Maintain register of all subcontracting work.

Purchasing Services and Supplies (Clause 4.6)

Policy and procedure(P) for selection and purchasing of services and supplies that affect the quality of tests and calibrations.

Service to the customer (Clause 4.7)

1. Cooperate with clients or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.

2. Laboratory to ensure confidentiality of other clients.

3. Seek feedback and analyze the same for improvement.

Complaints (Clause 4.8)

1. Policy and procedure(P) for resolution of complaints.

2. Records of complaints, including all investigations and corrective actions maintained.

Control of Non-conforming testing and/or calibration (Clause 4.9)

Policy and procedure(P) for non-conformance shall include:

i. Responsibilities and authorities are defined and defined actions are taken.

ii. Evaluation of significance.

iii. Remedial actions.

iv. Recall of non-conforming work released to the clients.

v. Responsibility for halting and resumption of work.

Identification of nonconformity:

- QC procedures
- Calibration results
- External assessments
- Internal audits
- Management review
- Customer complaint / feedback

Records of nonconforming work:

- Date and time nonconformity was detected.
- Nature of nonconforming work.
- Quantity of nonconforming work.
- Significance of nonconforming work in terms of potential consequences.
- Authority for disposition decision.

Improvement (Clause 4.10)

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

i. Quality policy

ii. Quality objectives

iii. Audit results

iv. Data analysis

v. Corrective and preventive actions

vi. Management review

Corrective Action (Clause 4.11)

1. Action taken to eliminate or correct the cause of a detected nonconformity.
2. Is taken to prevent recurrence of nonconformity.
3. It focuses on fixing problems that already exists.
4. Must be implemented when departures from acceptable practices are identified.
5. Policy, procedures, and designated authorities for implementing corrective actions.
6. Perform root cause analysis; Identify and implement appropriate corrective action; Monitor its effectiveness; If ineffective repeat the cycle.
7. Additional audits may be necessary for monitoring effectiveness.

Preventive Action (Clause 4.12)

1. A procedure(P) should exist describing the process to be followed.
2. Action taken to eliminate the cause of potential nonconformity.
3. Is taken to prevent the occurrence of a nonconformity.
4. Controls should be established for monitoring effectiveness.
5. Effective tool for improvement.

Control of Records (Clause 4.13)

1. ISO 9000:2000 states that a record is a document stating results achieved or providing evidence of activities performed.
2. Should be a procedure(P) for identification, collection, indexing, access, storage, maintenance, disposal of quality and technical records.

Contd.,

3. Legible, readily retrievable, stored in a suitable environment.
4. Secured and confidential.
5. Protection and back-up of computer records.
6. Retention time to be established.
7. Retain original observations, derived data etc to establish an audit trail.
8. Enough information to allow repeat of test under identical conditions.
9. Identification of personnel involved.
10. Mistakes crossed out, corrections entered alongside, signed and dated (preferably enter time also) by the person making corrections. No over writing and use of whiteners.
11. Similar actions for computer records.

Internal Audits (Clause 4.14)

1. A procedure(P) shall exist.
2. At predetermined schedules.
3. Comply with requirements of management system and ISO/IEC 17025:2005.
4. Cover all elements of management system.
5. By trained, independent and qualified personnel.

Contd.,

Audit report shall at a minimum contain:

i. Name of auditor
ii. Date of audit
iii. Area(s) audited
iv. Details of aspects examined including sample number, equipments with identification etc.
v. Nonconformance observed, if any.
vi. Signatures of auditor and auditee.
vii. Agreed corrective action and time period for its implementation.
viii. Signature of quality manager confirming that corrective action has been satisfactorily completed.

NOTE: Normally, it is not required to classify the nonconformance as major or minor during internal audit.

Management Review (Clause 4.15)

1. Predetermined schedule and procedure(P).
2. Top management responsibility.
3. Suitability and effectiveness.
4. Changes for improvements.
5. Quality manager is responsible to prepare agenda and communicate to all personnel who are to attend.
6. Quality manager is also responsible for initiating as well as ensuring that the actions decided during management review meeting gets implemented within a appropriate and agreed time frame.

Contd.,

Inputs:

i. Suitability of policies and procedures.
ii. Reports from supervisory and management personnel.
iii. Outcome of recent internal audits.
iv. Assessments by external bodies.
v. Corrective and preventive actions.
vi. ILC and PT performance.
vii. Internal QC results.
viii. Changes in volume and type of work.
ix. Client feedback.
x. Complaints and nonconformance work.
xi. Recommendations for improvements.

Technical Requirements of ISO/IEC 17025:2005 Standard

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General (Clause 5.1)

Factors determining the correctness and reliability of results:

i. Personnel

ii. Accommodation and environmental conditions

iii. Equipment

iv. Measurement traceability

v. Sampling

vi. Handing

Personnel (Clause 5.2)

Qualifications

- **Competence of personnel to**
  i. Perform tests / calibrations
  ii. Operate equipments
  iii. Performing specific tasks

- **Supervision of trainees**

- **The "people" requirement of accreditation**
  i. Number required for workload
  ii. Qualifications and experience
  iii. Responsibilities and authority
  iv. Job descriptions
  v. Performance criteria and performance appraisal
  vi. Training needs identification and records

Contd.,

Planning a training program

i. Identify and agree on needs
ii. Set training objectives
iii. Select training methods
iv. Ensure qualified trainers
v. Implement training
vi. Training records
vii. Review effectiveness
viii. Provide periodic refresher training

Job descriptions: Must be defined at least for managerial, technical and key support staff. Items to be included, at a minimum:

i. Job title
ii. Person to report to
iii. Responsibilities and authorities
iv. Authorized signatory status

Contd.,

Authorized personnel

i. Authorization of specific personnel to perform specific tasks such as sampling, analysis, issuing reports, give opinions and interpretations etc.
ii. Laboratory to maintain a record of all authorized personnel.

Role of Technical Manager

i. Selection, approval, and commissioning of test methods.
ii. Management and training of staff.
iii. Evaluation and sign-off of staff competency.
iv. Management of equipments and facilities.
v. Responsibility for technical validity of results.
vi. Liaison with quality manager

Role of Quality Manager

i. Design and implementation of quality program.
ii. Authority to stop work when non-conformances are detected.
iii. Coordinating with accreditation bodies.
iv. Responsible to implement decisions taken during management review meeting.
v. Responsible to address and close non-conformances arising from audits.

Contd.,

AB Approved Signatories

Approved signatory status is granted to those staff members of a laboratory who are sufficiently qualified and experienced and who have been assessed by AB to be fully competent in technical and quality management aspects of the laboratory.

Criteria for granting of "Approved signatory" status:

i. Relevant qualifications and experience.
ii. Close involvement in day-to-day operations.
iii. Familiarity with test procedures.
iv. Ability to make critical evaluations of results.
v. Knowledge of QMS.
vi. Knowledge of and commitment to AB and their criteria and ISO/IEC 17025:2005 standard.

Contd.,

Information relevant to approved signatories:

i. Approved signatory status is not transferable from one laboratory to another.

ii. Approved signatory status can only be granted following a personal assessment of competence.

iii. The laboratory must have at least one approved signatory to retain it accreditation.

iv. AB must be informed of any changes in the authorized signatory status.

Accommodation and Environmental Conditions (Clause 5.3)

Accommodation considerations are:

i. Design and construction materials

ii. Space including storage

iii. Services and facilities

iv. Access, safety and security

v. Area for administrative duties

vi. Physical separation between areas of incompatible activities

Contd.,

Laboratory environment considerations are:

- Temperature and Humidity
- Dust, biological sterility, chemical cleanliness
- Ventilation and fume extraction
- Noise levels, acoustics and ergonomics
- Vibration and radiation
- Cross contamination prevention
- Power supply and electromagnetic compatibility
- Lighting

Proper storage space is needed for:

- Samples (current and retained)
- Working materials and consumables
- Laboratory documentation
- Hazardous substances
- Staff belongings
- Clerical material and equipment

Test and Calibration methods and Method Validation (Clause 5.4)

Methods and procedures to be available for activities such as:

i. Sampling
ii. Handling
iii. Transporting
iv. Storing
v. Preparing
vi. Analyzing
vii. Reporting

Deviations to be technically justified, authorized, and accepted by client

Method Selection

Contd.,

Select methods that,

i. Meet the needs of the client
ii. Are appropriate
iii. Published (preferably) by a standard writing institution such as AOAC, CODEX, ASTM, ISO, US FDA, US EPA, FAO etc.

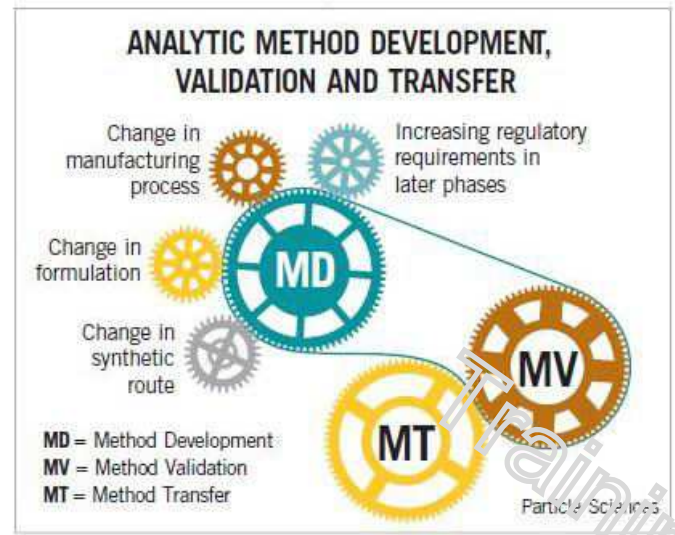
When customer does not specify a test method, inform the customer of method chosen, and select methods that are either:

i. Published standards methods
ii. Published by reputed technical organizations or professional bodies.
iii. Prescribed by regulatory bodies.
iv. Industry accepted methods.
v. Published in reputed journals.
vi. Validated methods adopted by the laboratory.
vii. Validated laboratory developed methods

When non-standard methods are used, ensure that,

i. Customer approval has been obtained.
ii. Specifications of customer requirements are met.
iii. Purpose is identified.
iv. Method is validated prior to use.

Contd.,

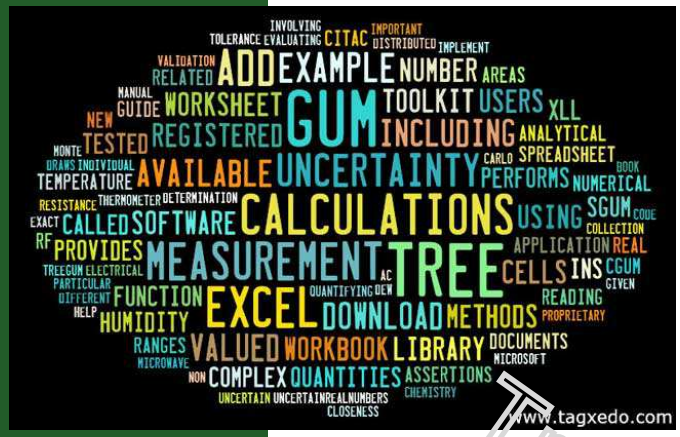


Method validation:

- It is confirmation by examination and the provision of the objective evidence that the particular requirements for specific intended use are fulfilled.
- All non standard methods and standard methods outside their scope must be validated.

During method validation maintain and check for:

- ☞Procedure used
- ☞Records of validation
- ☞Selectivity
- ☞Uncertainty of results
- ☞Range, Repeatability and Reproducibility
- ☞Robustness
- ☞Precision and Accuracy
- ☞LOD and LOQ



Contd.,

Measurement Uncertainty (P)

ISO definition: A parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

I. Calibration laboratories and testing laboratories doing calibrations must formally estimate uncertainty for all calibrations.

II. Testing laboratories must estimate uncertainty but with less rigor than calibration laboratories. They must make a “reasonable estimation” and “attempt to identify all components of uncertainty”.

Eurachem

A FOCUS FOR ANALYTICAL CHEMISTRY IN EUROPE

Contd.,

i. Eurachem approach is one of the most common approaches to estimating uncertainty.

ii. Estimate and add up all components of uncertainty … sampling, sample preparation, calibration standards, purity of reference materials and reagents, instrument measurement, temperature and humidity effects, analyst effects, balance effect etc.

Eurachem guide for uncertainty measurement in analytical chemistry can be downloaded from:

http://www.eurachem.org/images/stories/Guides/pdf/QUAM2012_P1.pdf

Contd.,

Control of data

i. Calculations and data transfers must be checked in a systematic manner.

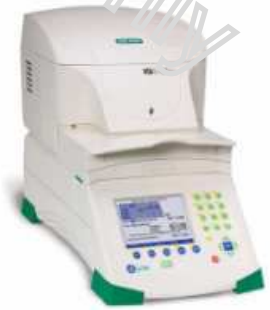
ii. Computers and other automated equipments including user developed software must be validated prior to use.

iii. Data protection procedures shall address integrity and confidentiality, storage, transmission, and processing.

Equipment (Clause 5.5)

Equipment requirements:

i. Sufficient and appropriate
ii. Proper environmental conditions
iii. Commissioning and verification (IQ, OQ, PQ)
iv. Maintenance schedules
v. Control and repair procedures
vi. Records of all equipments



Contd.,

Equipment records:

i. Unique identification of the equipment

ii. Manufacturer details and instructions

iii. Checks to verify compliance

iv. Maintenance records

v. History and usage records

vi. Service records

vii. Procedures (P) for intermediate calibration checks, safe handling, transport, storage, use, and planned maintenance.

Measurement Traceability (Clause 5.6)

- All equipments have significant effect on the accuracy and reliability of results.
- Must be calibrated prior to putting into use.
- Established program and procedure (P) for calibration of equipments.

Calibration traceability

I. For calibration laboratories, the program of calibration of equipments shall be designed and operated so as to ensure that calibrations and measurements made by the lab are traceable to the International system of units (SI units).

II. When traceability can not be made to SI units, traceability should be made to CRMs provided by a competent supplier to give reliable physical or chemical characterization of the material.

Contd.,

Reference standards and reference materials

Reference standards:

i. Program and procedure (P) of calibration.
ii. Traceable to SI units by a competent body.
iii. Used for calibration only.
iv. Calibration of reference standards before and after any adjustment.

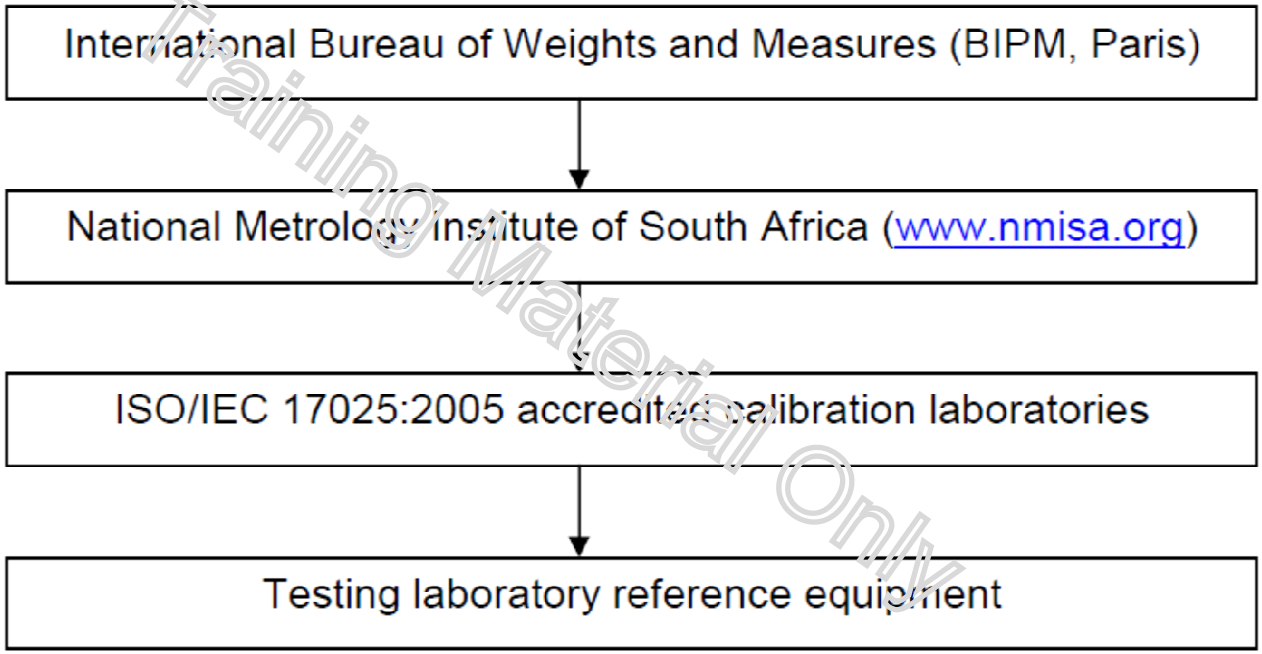
Reference materials shall be traceable to SI units or CRMs.

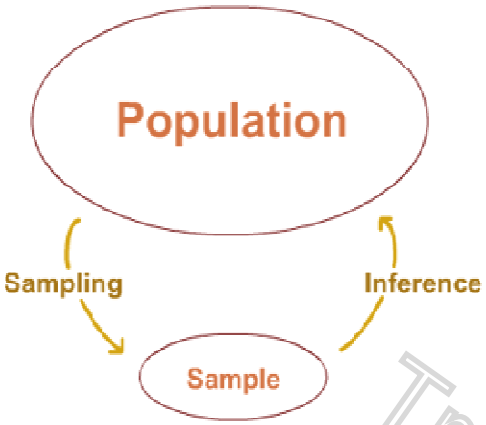
Intermediate checks:

i. Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out.
ii. The laboratory shall have procedures (P) for safe handling, transport, storage, and use of reference standards and reference materials.

Contd.,

Example path for traceability of measurement





Sampling (Clause 5.7)

i. Sampling plan and procedure (P) – based on appropriate statistical methods.

ii. Deviations to be documented in all appropriate documents.

iii. Sampling records shall indicate complete details.

iv. If the laboratory is not responsible for sampling or has no assurance that the samples truly represent the bulk of the product to be assessed, it must include an appropriate note in the reports.

Handling of Test and Calibration Items (Clause 5.8)

- Procedure (P) for
  - i. Transportation
  - ii. Receipt
  - iii. Handling
  - iv. Protection
  - v. Storage
  - vi. Retention
  - vii. Disposal

- Identify test / calibration items and sub-samples throughout.
- Record abnormalities of items and consult client for advice.
- Prevent damage / deterioration during storage and handling – monitor and records environmental conditions.

Assuring Quality of Test and Calibration Results (Clause 5.9)

Procedure (P) for monitoring results validity.

Monitoring includes:

i. Use of CRMs and reference materials.
ii. Replicate and retesting
iii. PT and ILC
iv. Correlation with other parameters

Reporting the Results (Clause 5.10)

Test report should be:

i. Accurate
ii. Clear
iii. Unambiguous
iv. In accordance with client requirements

At a minimum, reports should include:

i. Title
ii. Name and address of the laboratory
iii. Location where tests are carried out, if applicable
iv. Report ID on each page
v. Name and address of the client
vi. Brief description of the sample, including dates of sampling, receipt, and analyses.

Contd.,

vii. Reference to sampling plan and procedures
viii. Proper sample identification
ix. Results with units
x. Name, designation, and signature of the signing authority
xi. Deviations

- *Opinions and interpretations*

  The laboratory shall document the basis upon which opinions and interpretations have been made, when applicable.

- *Subcontractor results*
- *Electronic transmission of results*
- *Report format*
- *Amended report*

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Acknowledgements

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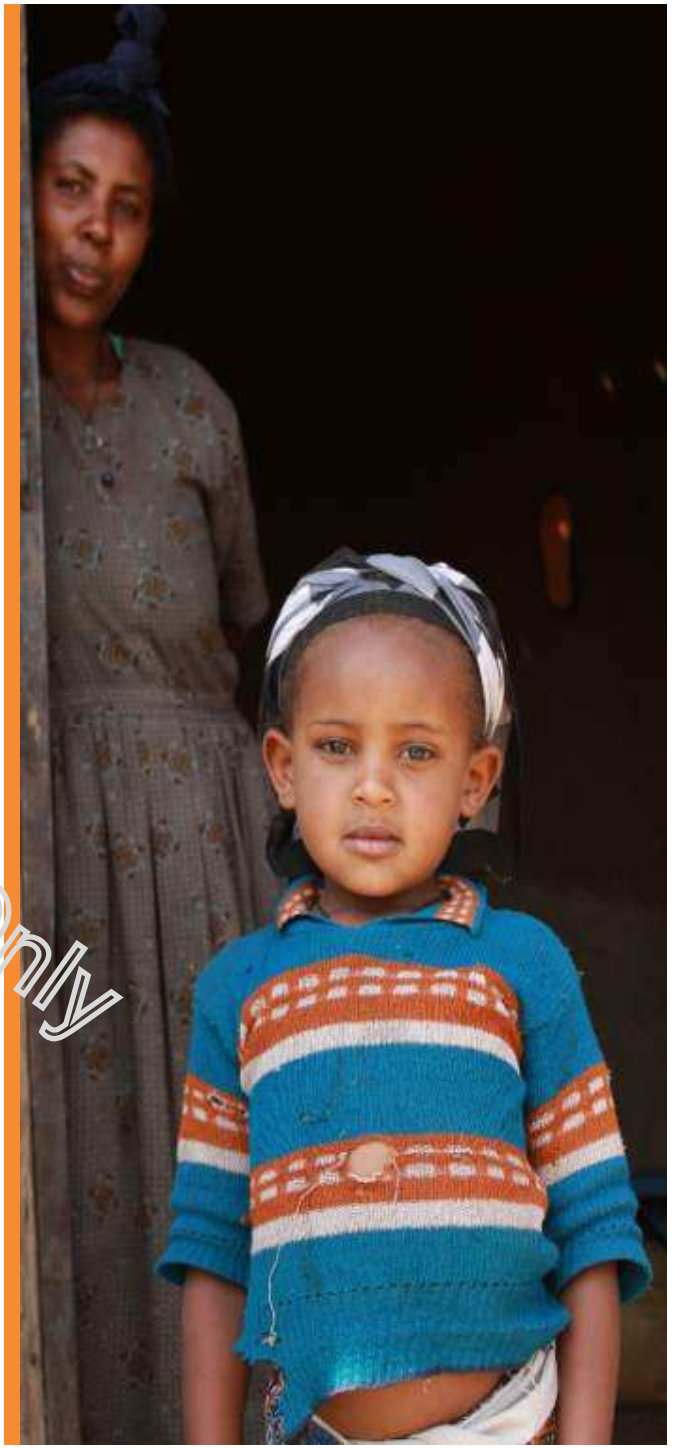
Thank you!



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