FOOD SAFETY AND FOOD SECURITY

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VALIDATION

Part I

ACCREDITATION

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ISO/IEC 17025

A review of the new standard for laboratory accreditation

What is ISO/IEC 17025?

- ISO/IEC 17025 contains the criteria necessary for a laboratory to implement in order for it to perform its test work **competently**
- The criteria that a laboratory must comply with to be internationally acceptable is ISO/IEC 17025.

What is Accreditation?

Accreditation is the recognition that a Conformity Assessment Body (CAB) can produce "**accurate results**" within acceptable limits on a consistent and sustainable basis

or

produce "**competent results**" within acceptable limits on a consistent and sustainable basis

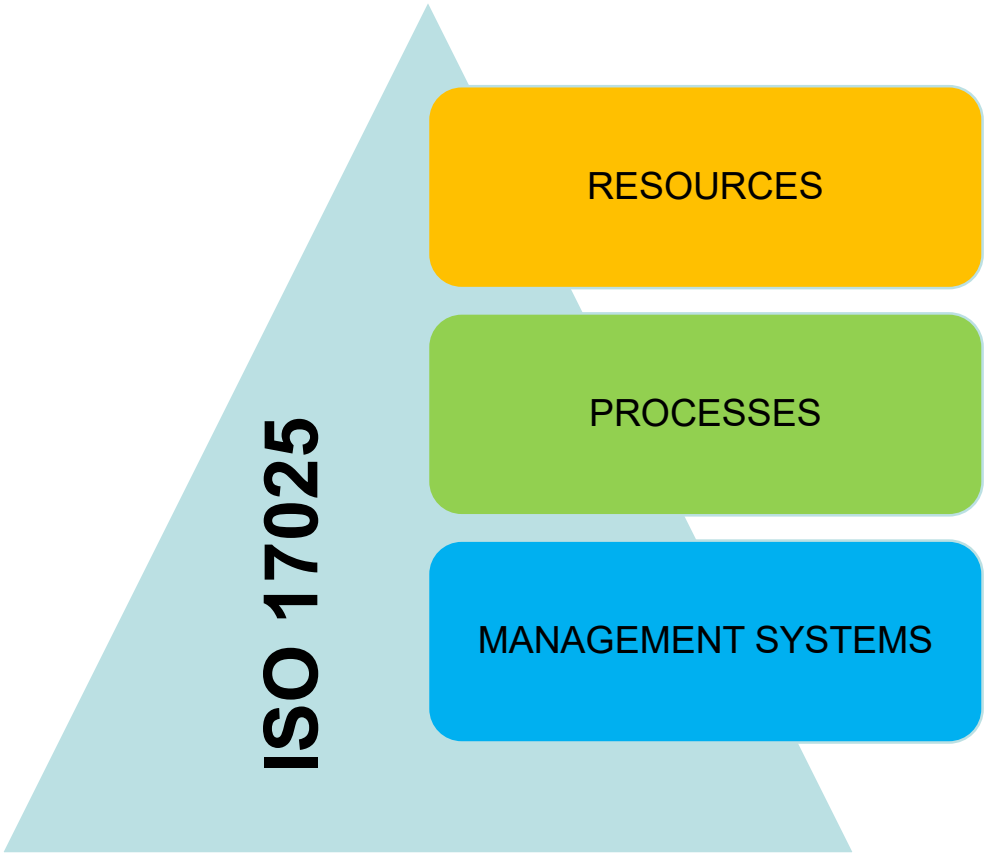
Laboratory Accreditation

Defined as a procedure by which an authoritative body* gives formal recognition that a *Conformity Assessment Body* fulfills specified requirements and is ***competent*** to carry out specific tasks.

Usually using ISO/IEC 17025

*(e.g. A2LA, NVLAP, NATA, UKAS, etc.)

ISO/IEC 17025 STRUCTURE



ISO/IEC 17025 STRUCTURE

RESOURCES

Personnel

Facility and Environmental Conditions

Equipment

Metrological traceability

External Provided Products and Services

ISO/IEC 17025 STRUCTURE

PROCESSES

- Review of requests, tenders and contracts
- **Selection, verification and validation of methods**
- **Validation of methods**
- Sampling
- Handling of tests or calibration items

ISO/IEC 17025

Selection, Verification and method Validation

ISO/IEC 17025:2017 Clause 7.2.1.1

"The laboratory shall **use appropriate methods** and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data".

ISO/IEC 17025

Selection, Verification and method Validation

Appropriate Methods

Dictionary meaning of appropriate….

- **Suitable** for the intended use
- **Proper** for the intended use
- **Fitting** for the intended use

ISO/IEC 17025

Selection, Verification and method Validation

How does the laboratory ensures that the method is **fit/proper/suitable** for purpose?

- Firstly, by understanding the **request (specified requirements)** from the customer
- Secondly, evaluating laboratory's **capability** and **resources**
- Thirdly, by **selecting, verifying** and **validating** method

ISO/IEC 17025

Selection, Verification and method Validation

- The laboratory shall ensure that it uses the latest **valid** version of a method..
- When the customer does not specify the method to be used, the laboratory shall select an **appropriate method** and inform the customer of the method chosen
- The laboratory shall **verify** that it can properly perform methods before introducing them by ensuring that it can achieve the required performance.
- When method development is required, this shall be a planned activity and shall be assigned to **competent personnel equipped with adequate resources**

ISO/IEC 17025

Selection, Verification and method Validation

- **The laboratory shall validate:**
  - non-standard methods,
  - laboratory-developed methods
  - standard methods used outside their intended scope or otherwise modified.

- **When changes are made to a validated method…., a new method validation shall be performed.**

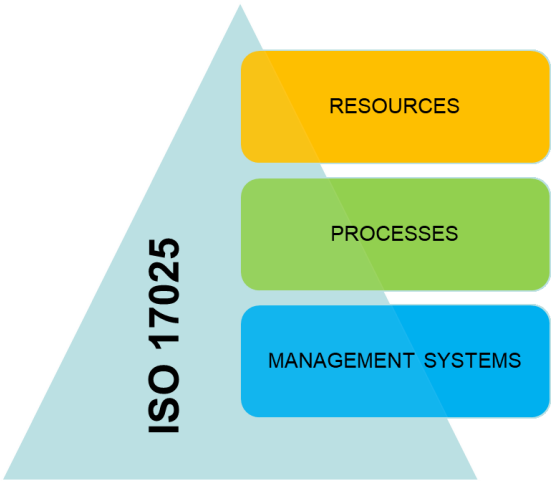
- The performance characteristics of validated methods as assessed for the intended use, **shall be relevant to the customers' needs and consistent with specified requirements**

ISO/IEC 17025

Valid results

For laboratories to produce valid results, the following need to be in place:

- Appropriate methods
- Competent personnel
- Suitable equipment
- Traceable measurements
- Supported by management system



Accreditation Ten Second Tutorial

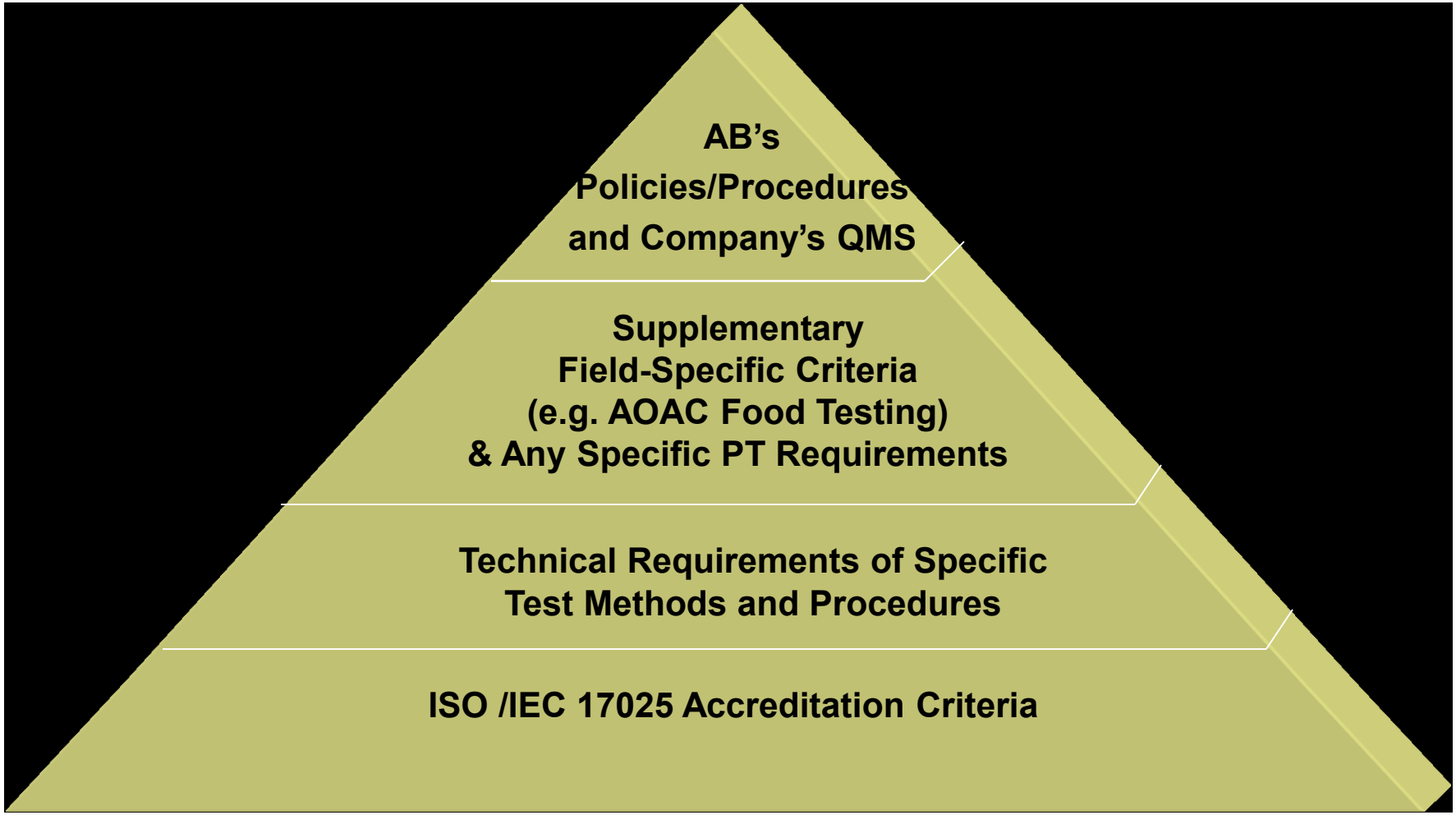
Do what you say you are doing

and be able to prove it!

Three Critical Thoughts

- Does the laboratory “say” what they do?
  - **Are there written documents (policies, procedures, arrangements) that meet the requirements of ISO 17025?**
- Does the laboratory “do” what they say?
  - **Are they in compliance with their own quality system, test methods and ISO 17025?**
- Can they “prove” it with their records?
  - **Including everything from training records to standards preparation record to work books to client reports to audit reports and everything in between?**

Accreditation Requirements



Accreditation

One Test, Accepted Everywhere

Mutual Recognitions…

Mutual Recognition Between Accreditation Bodies

The Fundamental Purpose:

A conformity assessment body (testing lab) accredited by one partner has equivalent competence to carry out the same conformity assessment tasks as a conformity assessment body (testing lab) accredited by the other partner(s).

Primary Objective of Mutual Recognition

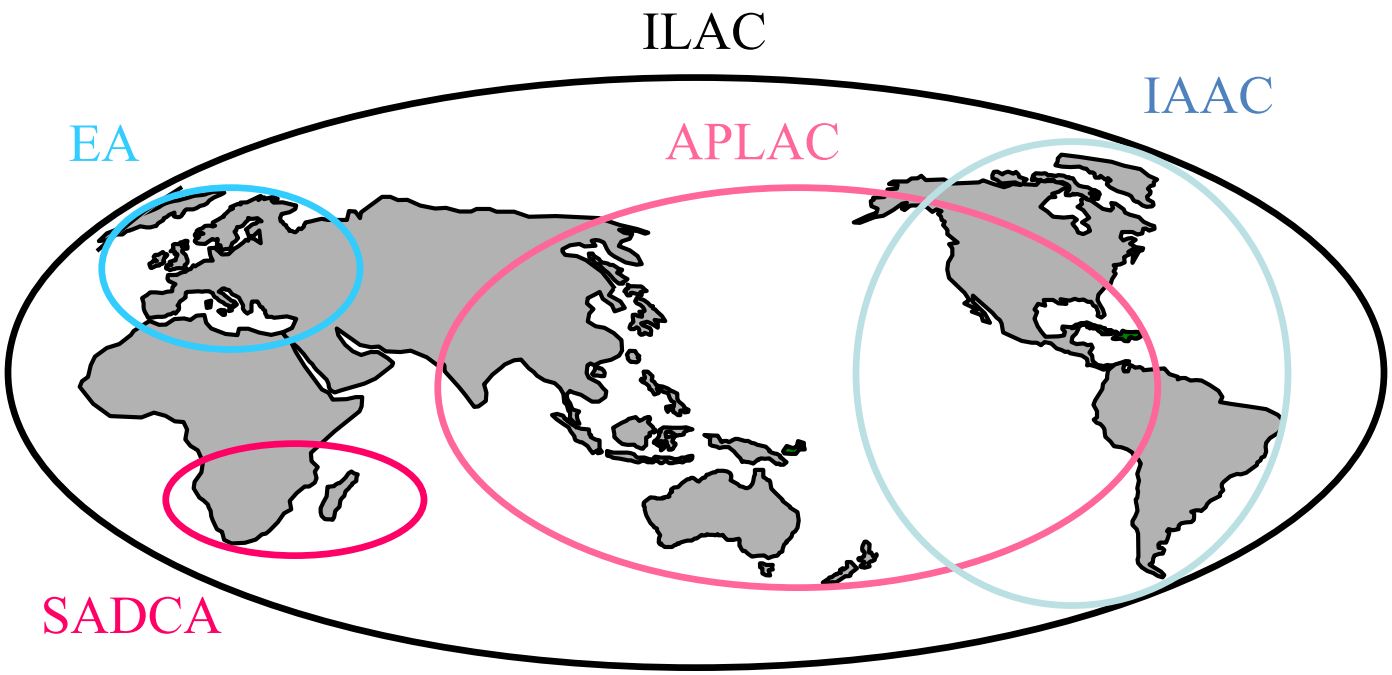
- Eliminate conformity assessment as a **Technical Barrier to Trade** *through*
- Recognition of **Competence** *between*
- **Accreditation Bodies.**

Recognized Accreditation Bodies

- - Operate to ISO/IEC 17011:2004 by:
  - Using ISO/IEC 17025 as minimum criteria for labs.
  - Undergoing periodic peer evaluations.

- - Are signatories to regional and international mutual recognition arrangements.

Regional Accreditation Co-Operations



EA European co-operation for Accreditation

SADCA Southern African Accreditation Cooperation

IAAC Inter-American Accreditation Cooperation

APLAC Asia Pacific Laboratory Accreditation Cooperation

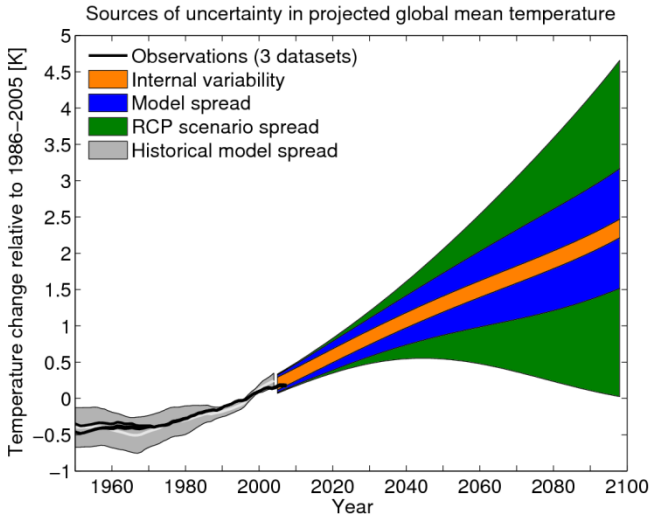
ILAC International Laboratory Accreditation Cooperation (www.ilac.org)

What is necessary to obtain accreditation?

- - Develop, implement, and review all policies, procedures and the quality manual with staff assistance.

- - Proficiency Testing data needed for:
  - Each major testing sub-discipline.
  - As many analytes/methods as possible.

- - Estimates of Measurement Uncertainty:
  - Develop procedures and identify contributing factors.
  - Train personnel to perform calculations.

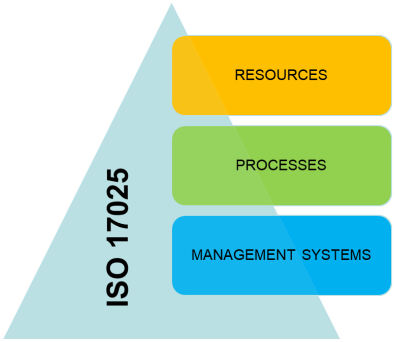


- - Traceability of Calibrations:
  - Through an unbroken chain of comparisons, each step having stated uncertainties.
  - Demonstrable competence performing calibration.

Accredited Laboratories: Documented Technical Competence

- A laboratory accredited by a reputable accreditation body:
  - Has achieved a prescribed level of technical competence to perform specific activities.
  - Is capable of producing data that are accurate, traceable and reproducible.
- Using an accredited laboratory:
  - Increases confidence in data.
  - Reduces uncertainties associated with decisions.
  - Increases public confidence because accreditation is a recognizable mark of approval.
  - Eliminates redundant reviews and improves efficiency of the assessment process (may reduce costs).

Overall Benefits of Accredita



- - Corrective and preventive actions, method approval plans, and management review attach timelines to improvement processes ensuring completion.
- - Issues with methods, personnel, and equipment are identified and resolved more quickly.
- - System is continually maturing and improving.
- - Customer satisfaction is improved.
- - Specialized, customer quality requirements are met.
- - Business opportunities may increase.

Benefits: Continuous Improvement Requirements

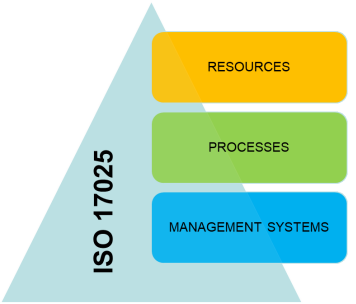
- - Corrective actions are issued for:
  - Problem data uncovered in the recheck process.
  - Processes not followed as written.
  - Sample traceability issues.
  - QC or PT problems.
  - Customer complaints.
  - Audit non-conformances.

- Preventive actions are issued when a potential problem is noted. They are usually more complex and a longer term fix is needed.

- Both CA and PA are tracked. A timeline is assigned requiring completion and verification of effectiveness.

- - CA and PA tracking allows for trending of issues and “encouragement” to complete on time.

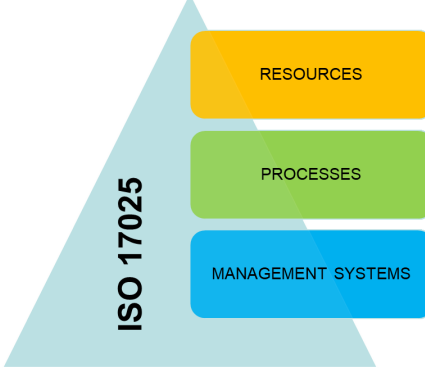
Benefits: Continuous Improveme Requirements



- - Management Review is a periodic meeting of members of management and supervisory staff. It allows for a broad review of the quality system including:

- Trending of corrective actions and non-conforming testing.
- Customer complaints.
- QC and proficiency results.
- Supplier performance.
- Supervisory reports on resources and work flow.

Benefits: Technical Requirem



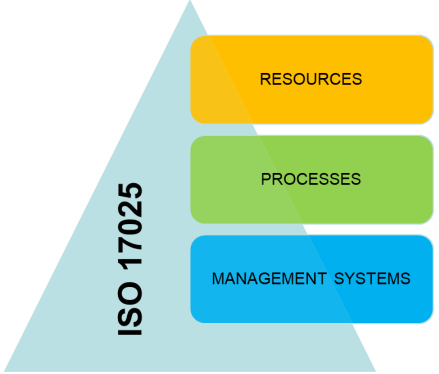
- - Personnel / Training:

  - Training plans are required for all new personnel, changes in position or changes in responsibilities and are assessed regularly.

  - Training records include analytical data when appropriate.

    Example: Training summary spreadsheets showing current training status and total number trained per method allows for resource planning.

Benefits: Technical Requirem

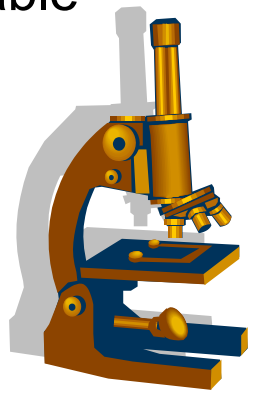


- - Equipment:

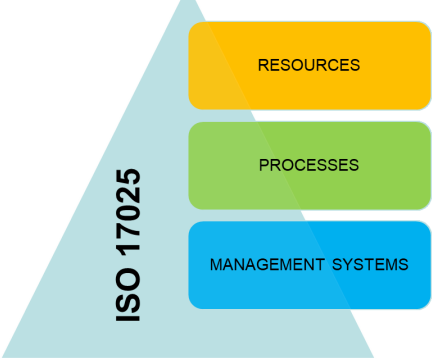
  - A defined system helps ensure that all equipment is maintained and calibrated as required.

- - Measurement Traceability:

  - Calibrations are required to be traceable to standard reference materials, whenever possible.
  - Calibrations must be performed by services with comparable quality standards, whenever possible.



PT and Accreditation



- - To achieve initial accreditation a laboratory must be able to demonstrate successful participation in at least one PT event.

- - A laboratory must develop a plan to demonstrate how they will cover the test methods/technologies on their scope of accreditation over a 4-year period.

- - This PT plan must include commercially available and relevant PT such as PT offered by ASTM.

PT and Accreditation

- - Proficiency testing results must be submitted to the competent authority within 30 days of receipt of the final report.
- - Corrective action must be taken for any outlying results.
- - Unacceptable PT results may result in an adverse accreditation action such as suspension of that test from the scope until the lab can dem acceptable performance.

Benefits of Proficiency Testing

- - Laboratory Improvement:
  - Discover sources of error.
  - Systematic errors.
  - Precision (inconsistency).
  - Internal method comparison.
  - Effectiveness of changes.
  - Common understanding of method differe
  - Discovery of method sensitivities.
  - Demonstration of effectiveness of changes
  - To methods.
  - To instructions.

- - Education:
  - Interpretive information.
  - New or rare analytes and matrices.
  - Peer communication.

Prevention is Better than cure!

'*It costs less to prevent a problem than it does to correct it*'

A formal quality system in the laboratory should prevent mistakes by means of:

- quality assurance measures
- quality control of the analytical results
- thorough documentation of the system
- efficient maintenance of records
- regular audits of all aspects of the system

QA and QC systems

Quality Control:

planned activities designed to provide a quality product.

Quality Assurance:

planned activities designed to ensure that the quality control activities are being properly implemented.

(As defined by the Association of Official Analytical Chemists)

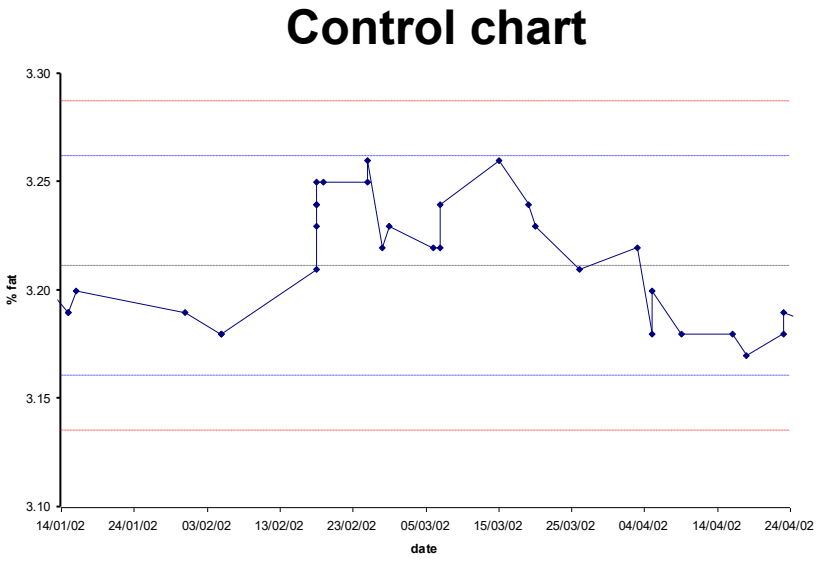
QA Systems

Quality Assurance measures apply to the laboratory analytical work overall, which includes;

- **identifying the person having the overall responsibility for quality**
- **having laboratory equipment calibrated to recognised standards**
- **using reference materials**
- **joining proficiency testing schemes with other laboratories doing similar tests**

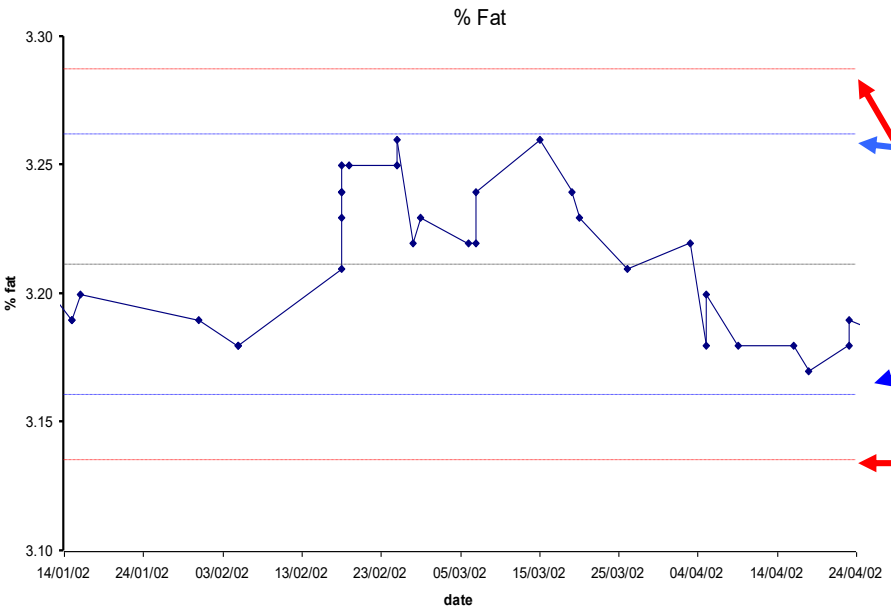
QC systems

Quality control measures apply to each analytical test in the laboratory by use of:



- reagent blanks;
- verified standard solutions;
- check samples (from both within the lab and from outside);
- blind samples
- replicate analyses;
- and control charts

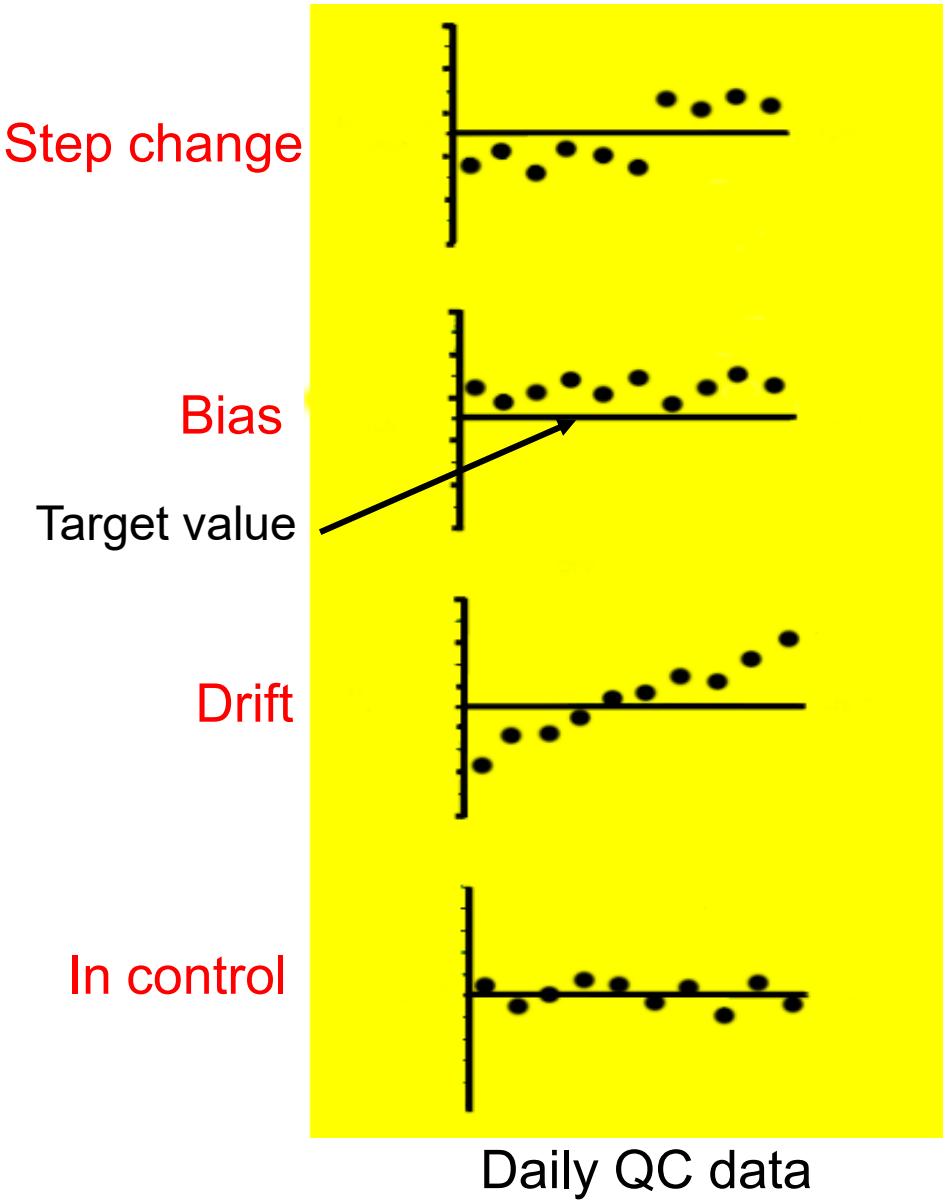
Quality systems - control charts



A control chart is a means of ensuring that the method remains in 'control' - continues to perform in accordance with expectations. This usually means that results from analysing standards fall within **± 2 standard deviations of the accepted value** (within the blue lines on the chart). Any results appearing outside the red lines **(± 3 standard deviations**) indicate that the method is not longer in control and requires investigation.

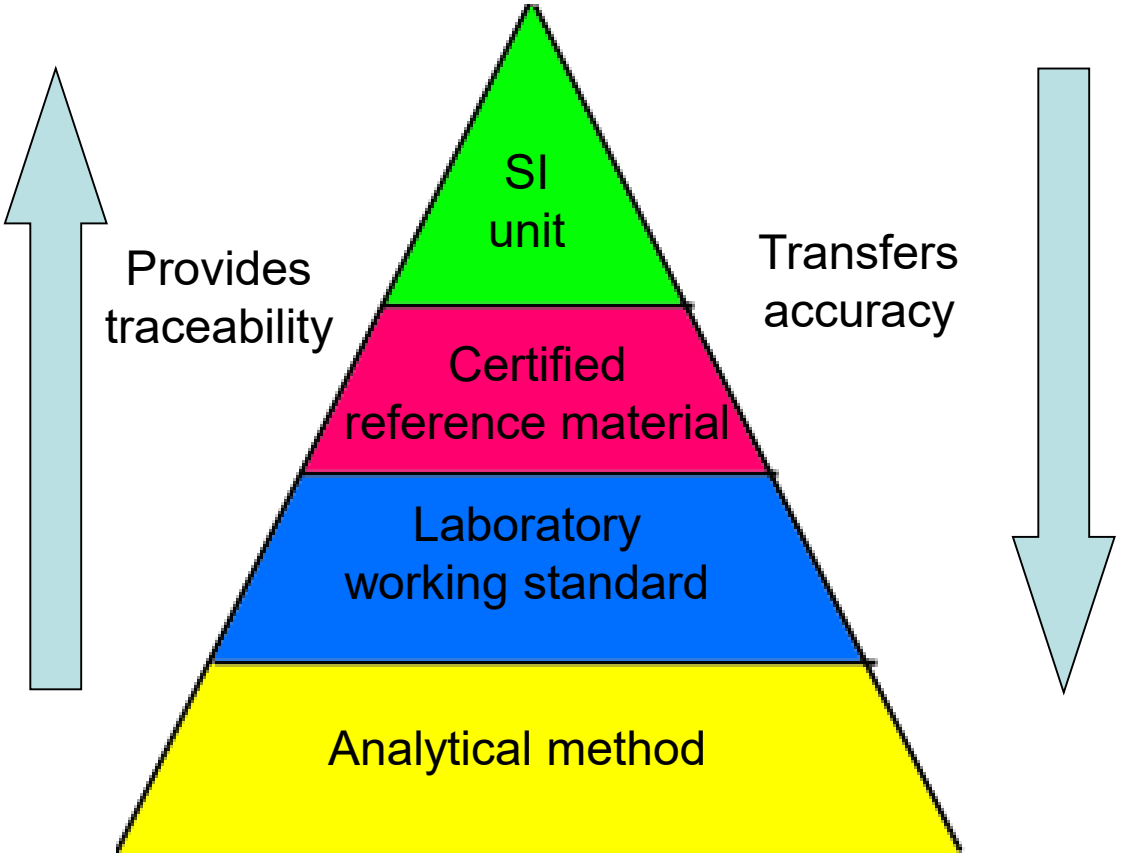
Use of QC Samples

Regular analysis of a single control sample will identify a system in or out of control conditions

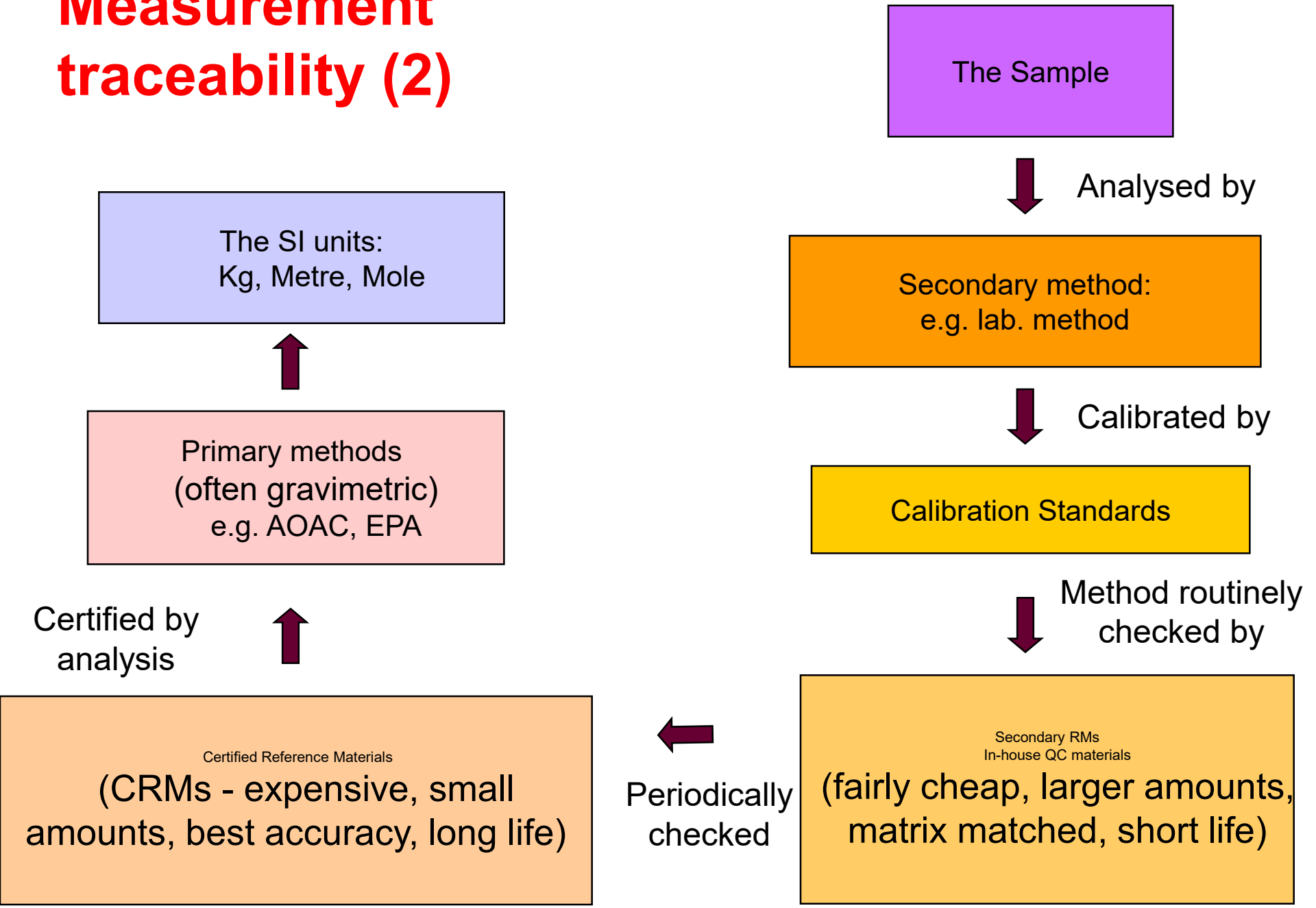


Measurement traceability

In an absolute sense, the ‘true’ value can be defined only as being that value directly traceable to the base system of measurement (SI) or their derivatives - ie: to national or international standards via **an unbroken chain of comparisons**



Measurement traceability (2)



Reference materials & check samples

INTERNAL QC SAMPLES

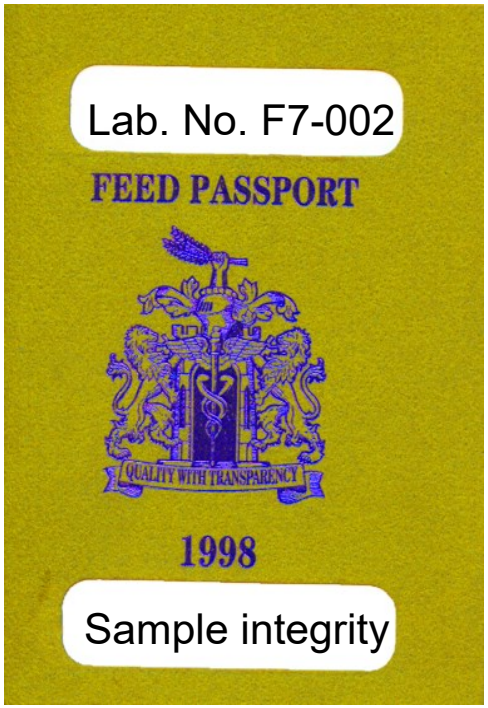
Internal QC samples are prepared and quantity values of target components are checked against CRMs

CERTIFIED REFERENCE MATERIALS (CRMs)

SAMPLES SUPPLIED FOR PROFICIENCY TESTING

An accredited laboratory has to prove its performance by routinely analysing samples supplied by an independent laboratory

Keeping track of the samples



- **Sample registration gives each sample a unique lab number.**
- **The sample register records all the information about the sample.**
- **Just like a sample's passport, you should not confuse any sample with any other.**
- **The history of the sample should be traceable throughout.**

Samples recorded on receipt

Quality Manual

A quality manual defines the quality system under which the laboratory operates

Laboratory Quality System Quality Manual Amiable Laboratory	Admin 1.5.1. Page 1 of 1 Issue No.
Title of Section **Title Page**	Issue Date Issued by

QUALITY MANUAL

for

Amiable Laboratory
Benevolent Department
Well-intentioned Organisation
Usual Location

This Manual is issued under the authority of

Issue Date	
Issue No.	3
Copy No.	
Holder	

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A Person
Head of Laboratory

Quality Manual - contents (1)

Laboratory Quality System - Quality manual Amiable Laboratory Benevolent Department Well-intentioned Organisation	Admin 1.5.1. Index Page 1 of 2 Issue No. 3 Copy No.
Title of Section Index of Contents	Issue Date Issued by

Quality Manual - contents (2)

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	4.1	Purpose
	4.2	Responsibility
	4.3	Implementation
5		EQUIPMENT
	5.1	Calibration and Testing Equipment
	5.2	Operation and Maintenance of Equipment
	5.3	Equipment Records
6		MEASUREMENT TRACEABILITY AND CALIBRATION
	6.1	Policy
	6.2	Uncertainty of Measurement
	6.3	Calibration
7		METHODS AND PROCEDURES FOR TESTS
	7.1	Policy and Scope
	7.3	Documentation of Methods and Procedures
	7.4	Integrity of Data
	7.5	Uncertainty of Results

Quality Manual - contents (3)