ISO/IEC 17025: Potential Application In Food Composition Data Generation

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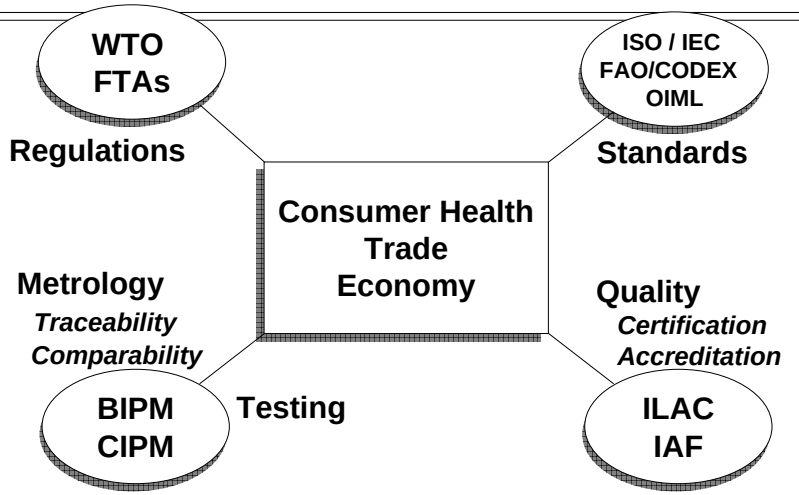
Global Imperatives Served by Responsible Organizations



 Source: C. Sanetra, 2005

Codex Alimentarius Commission

- **Created in 1963 by FAO and WHO**
- **To develop Food Standards, Guidelines,and related texts such as Codes of Practice under the Joint FAO/WHO Food Standards Programme**
- **Aimed at protecting health of the consumers, …**
  promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations ***Source: Codex Alimentarius Commission Website***

International Organization for Standardization (ISO)

- **Founded in 1947**
- **Composed of representatives from various national standards organizations**
- **To promulgate worldwide proprietary industrial and commercial standards that often become laws**

International Bureau of Weights an d Measures (BIPM)

- Created in 1875, after signing of the Metre Convention
- One of 3 international standards organizations established to maintain the International System of Units (SI) under the terms of the Metre Convention
- Thru Consultative Committees and own laboratory work

International Laboratory Accreditation (ILAC)

- Started as a Conference in 1977 by laboratory and inspection accreditation bodies
- To remove the technical barriers to trade
- By allowing people to make informed decision when selecting a laboratory, as it demonstrates competence, impartiality and capability

Codex Recommends Laboratory Quality Assurance

for Testing Laboratories in International Trade

- Use validated methods
- Use reference materials
- Use internal control systems
- Participate in Proficiency Testing
- Be accredited to ISO/IEC 17025

ISO/IEC 17025 Requires Laboratory Quality Assurance

- The difference between Good Analytical/Laboratory Practice and ISO/IEC 17025 is:
  the amount of DOCUMENTATION to be developed!
  to demonstrate that a laboratory…
  *operates a management system
  *is technically competent
  *is able to generate technically valid results

Source: LabCompliance Tutorial

Lack of Quality Assurance Means

- **What is not written**
  is not done.

- **What is not documented**
  is a rumor.

Laboratories Require Quality Assurance

- **Laboratory data are used for decision-making.**

- **It is easy to collect data.**
  It is difficult to collect correct data.
  It is even more difficult
  to convince others
  that your data are correct.

- **No data is better than bad data.**

ISO/IEC 17025:2005

- ***General requirements for the competence of testing and calibration laboratories***

- **A standard to:**
  - **develop and establish quality system in the laboratory**
  - **assess laboratory clients or third parties**

Source: LabCompliance Tutorial

Applications of ISO 17025

-To all organizations performing tests and/or calibrations

-To all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities

Source: Quality Network, UK, 2006

Benefits of ISO 17025

- Improved national and global reputation and image of the laboratory (international recognition)
- Assurance of validity and global comparability of test and/or calibration results (credibility)
- Access to more contacts for testing and/or calibration (markets)
- Continual improvement of data quality and laboratory effectiveness (confidence)
- Reduction of the no. of tests required in trading (reduced costs)

Source: LabCompliance Tutorial

5 Elements

1 Scope

2 Normative References

3 Terms and Definitions

4 Management Requirements

5 Technical Requirements

Elements 4 and 5 – actual accreditation requirements

Source: Quality Network, UK 2006

Requirements vis-a-vis Sample -to- Data Workflow

- Sample
- Sample Handling
- Testing
- Test Report
- Record Maintenance

Source: LabCompliance Tutorial

Requirements: Sample and Sample Handling

- Sampling Plan
- Sampling Documentation

- Sample Identification & Protection of Sample Integrity

Source: LabCompliance Tutorial

Requirements: Testing and Test Reports

- **Monitoring the Quality of the Test Results**
- **Test Conditions & Test Results with Estimated Uncertainty**

Requirements: Record Maintenance

- **Ensuring Record Integrity and Security**

Compliance across All Workflow Steps

- **Validation of analytical methods & procedures**
- **Equipment calibration, testing & maintenance**
- **Qualification of material**
- **Traceability**
- **Control of non-conforming testing**
- **Qualification of personnel**
- **Controlled environmental conditions**
- **Written procedures**

Compliance across the Laboratory

- **Documentation control**
- **Corrective and preventive actions**
- **Complaint handling**
- **Supplier & subcontractor management**
- **Non-conflicting organizational structure**
- **Internal audits**

Management Requirements

- Pertain to the operation and effectiveness of the quality management system within the laboratory
- Similar to ISO 9001

Source: LabCompliance Tutorial

Management Requirements

- Organization
- Quality system
- Document control
- Review of requests, tenders and contracts
- Subcontracting of tests and calibrations
- Purchasing services and supplies
- Service to clients
- Complaints
- Control of non-conforming testing and/or calibration work
- Corrective action
- Preventive action
- Control of records
- Internal audits
- Management reviews

Source: Quality Network, UK 2006

Management Requirements: Organization

- Defined roles and responsibilities of the laboratory, the management, and key personnel
- No conflicting interests (e.g. marketing) in structure
- Appointment of a Quality Manager
- No commercial/financial pressure on all personnel that may impact data quality

Source: LabCompliance Tutorial

Management Requirements: Management System

- Available Quality policies, standard procedures & work instructions
- Issued and communicated Quality Manual with policy statements
- Continually improved management system effectiveness

Source: LabCompliance Tutorial

Management Requirements: Document Control

- Authorized & controlled official documents
- Regularly reviewed & updated documents
- Same review process for changes

Source: LabCompliance Tutorial

Management Requirements: Purchasing Services/Supplies

- Selected and formally evaluated suppliers for quality
- Maintained records of the selection and evaluation process
- Verified quality of incoming material against predefined specifications

Source: LabCompliance Tutorial

Management Requirements: Control of Records

- Available procedures for identification, collection, indexing, storage, retrieval, & disposal of records
- Assured security, quality & integrity during record storage
- Available procedures for records protection
- Assured that original records are not overwritten by electronic system

 Source: LabCompliance Tutorial

Management Requirements: Internal Audit

- Available procedure and schedule for internal audits
- Yearly audit to cover all elements of the quality system
- Managed by Quality Manager
- Monitored effectiveness of audit follow-up activities, e.g. corrective and preventive actions

 Source: LabCompliance Tutorial

Technical Requirements

- **Address the competence of staff, sampling and testing methodology, equipment and the quality and reporting of test and calibration results**

Source: LabCompliance Tutorial

Technical Requirements

- Personnel, accommodation and environmental conditions
- Test and calibration methods and method validation
- Equipment
- Measurement traceability
- Sampling
- Handling of test and calibration items
- Assuring quality of test and calibration results
- Reporting the results

Source: Quality Network, UK 2006

Technical Requirements: Personnel

- Competent personnel, up to management level
- Appropriate education, experience or training
- Defined tasks, job description, and skills requirements
- Available and implemented training program
- Evaluated effectiveness of training
- Authorized personnel to operate specific types of instruments, issue test reports, interpret specific results, & train personnel

Source: LabCompliance Tutorial

Technical Requirements: Accommodation & Environment

- No adverse effect of environmental conditions on required quality of tests
- Monitored, controlled & recorded environmental conditions
- Separate areas for incompatible activities
- Limited access to test areas

Source: LabCompliance Tutorial

Technical Requirements: Test & Calibration Methods & Method Validation

- Clearly defined scope of methods & procedures
- Up-to-date instructions on use of methods & equipment
- Most recent & verified standard methods
- Fully validated literature methods
- Sample-relevant validation experiments
- Available MU estimation procedure
- Verified calculations/data evaluations

Source: LabCompliance Tutorial

DEFINITION

Method Validation

-Verification (provision of objective evidence that a given item fulfills specified requirements), where the specified requirements are adequate for an intended use

Source: JGCM 2008 (VIM3)

Method Validation

- Makes use of a set of tests that both:
  *test any assumptions on which the analytical method is based
  *establish/document the performance characteristics of a method thereby demonstrating whether the method is fit for a particular analytical purpose or not.

Source: IUPAC 2002

Method Validation: Typical Performance Characteristics

- Applicabiity
- Selectivity
- Linearity/Calibration
- Trueness
- Precision
- Recovery
- Limit of quantitation
- Limit of detection
- Sensitivity
- Ruggedness

Source: IUPAC 2002

Technical Requirements: Equipment

- Conformant specifications relevant to the tests
- Identified and documented equipment and software
- Calibrated to establish meeting laboratory specification requirements
- Maintained/updated records
- Indicated calibration status on unit

Technical Requirements: Measurement Traceability

- Traceable (to SI units) equipment calibration
- Achieved traceability thru unbroken link
  - laboratory standard to secondary & primary or national standard (physical metrology). or
  - certified reference materials or consensus standards/methods (chemical metrology)

Source: LabCompliance Tutorial

DEFINITION

Metrological Traceability

- property of a measurement result whereby the result can be related to a reference through an unbroken chain of calibrations, each contributing to the measurement uncertainty

 Source: JCGM 2008 (VIM3)

DEFINITION

Measurement Uncertainty

- Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

Source: JCGM 2008 (VIM3)

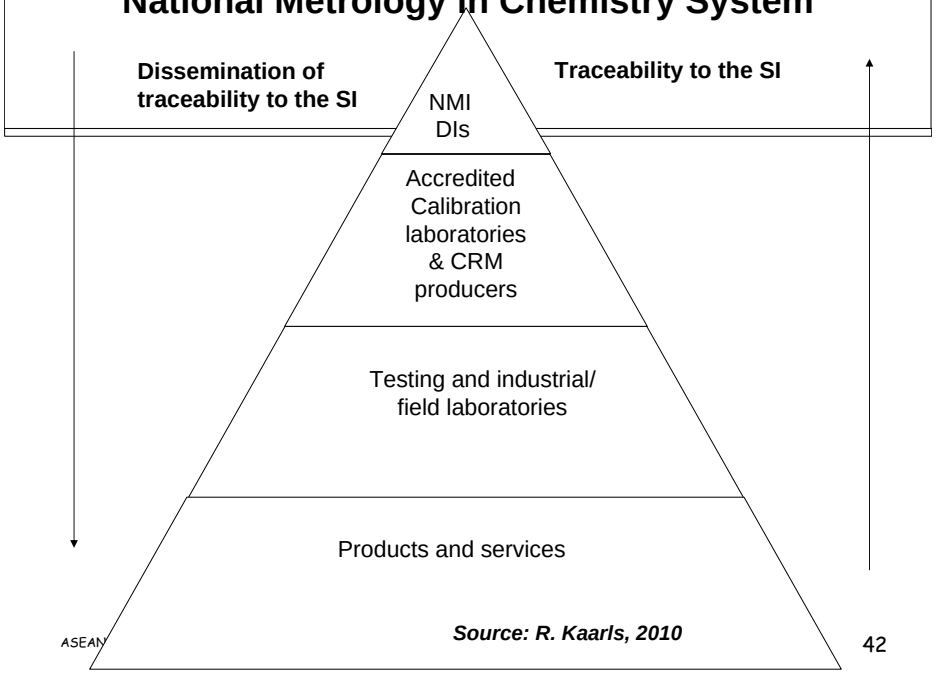
DEFINITION

Comparability

-of measurement results for quantities of a given kind that are traceable to the same reference

Source: JCGM 2008 (VIM3)

National Metrology in Chemistry System



Source: R. Kaarls, 2010

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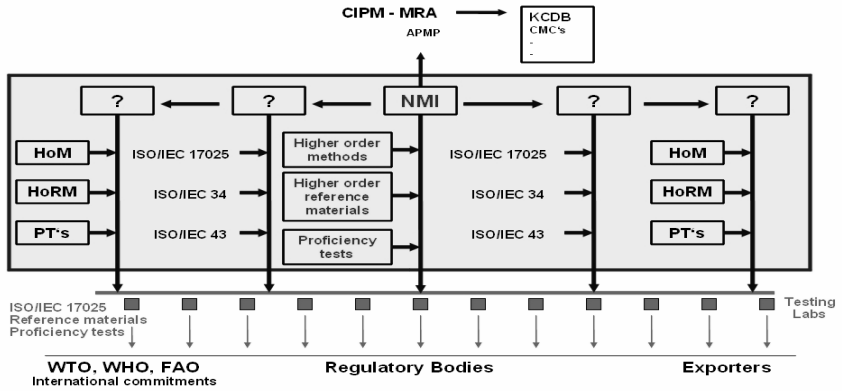


Figure 4

 Source: H. Bion, 2010

DEFINITION

Primary Method

-reference measurement procedure used to obtain a measurement result without relation to a measurement standard for a quantity of the same kind

 Source: JCGM 2008 (VIM3)

Traceability to Potential Primary Methods

- **Gravimetry**
- **Titrimetry**
- **Coulometry**
- **Calorimetry (differential scanning)**
- **Cavity ring down spectrometry**
- **Isotope dilution mass spectrometry**
- **Instrumental neutron activation analysis**

Becomes primary: Only when…

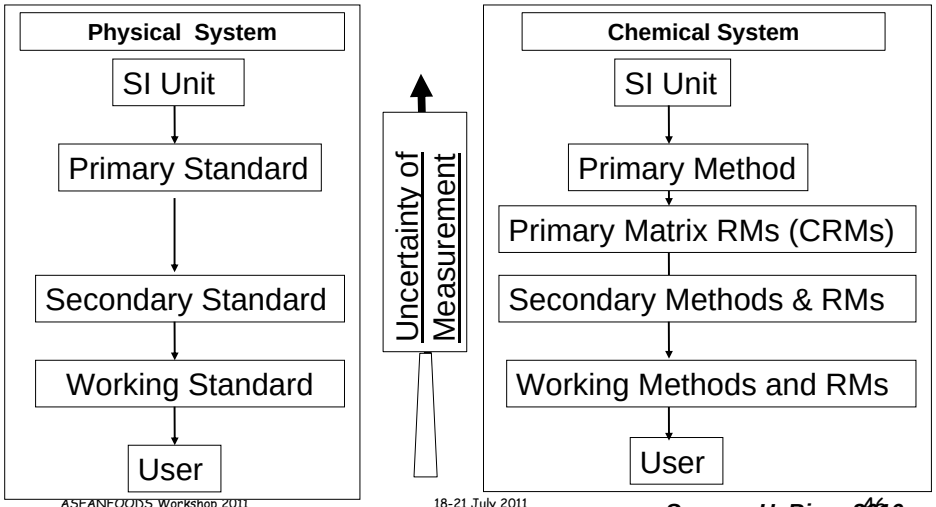
-procedure is completely understood/precisely followed

-staff is competent/experienced

to carry out measurement/analysis process

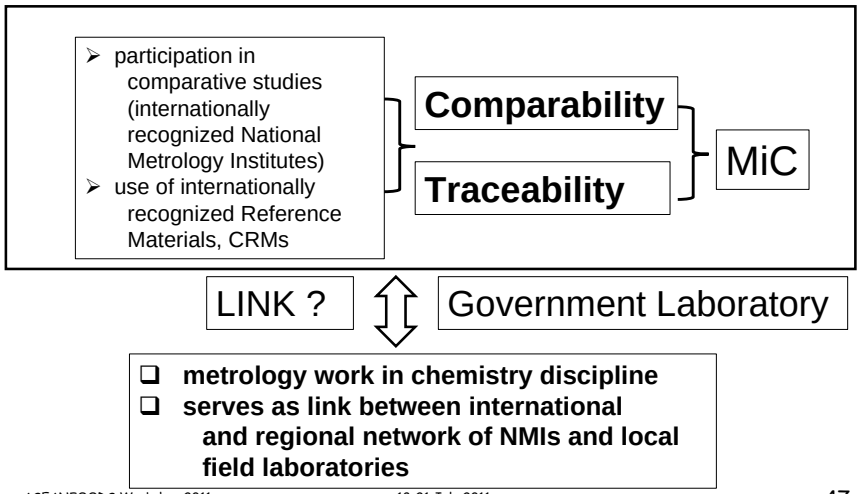
Source: R. Kaarls , 2010

Traceability System for Physical and Chemical Standards



Source: H. Bion, 2010

Two Essential Elements to Establish Global Mutual Recognition of Chemical Measurements



Source: H. Bion, 2010

Traceability to Identified References

Purity analysis (100 - % impurities)

Impurity analysis: MU, less critical

- Calibration solutions

- Calibrators, pure compounds

- Certified Reference Materials (CRMs)

*** matrix CRMs**

*** Recovery factor**

*** Method validation**

Source: R. Kaarls , 2010

DEFINITION

Reference Material

- material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties

Source: JCGM 200:2008 (VIM3)

Producers: Certified Reference Materials

- Foreign traceable CRMs from NMIs – available
  - -NIST (USA)
  - -NMIJ (Japan)
  - -KRISS (Korea)
  - -NIM (China)
  - -NMIA (Australia)
  - -IRMM (EU, Belgium)
  - -LGC (UK)
  - -PTB(Germany)

Conditions for Traceability Claims

- Only by own primary realization or from another recognized NMI/DI
- Not from a non-NMI/DI
- Not from CRMs delivered by non-NMIs/DIs, unless purity analysis is done by NMI/DI and CRM quality conforms with fit-for-purpose requirement
- Not by result in a comparison or PT scheme

Source: R. Kaarls , 2010

Technical Requirements: Sampling

- Documented sampling plan & procedure
- Statistical method-based sampling plan
- Completely described sampling procedure (selection & withdrawal of representative sample)
- Recorded sampling location & procedure, sampler, etc.

Source: LabCompliance Tutorial

Technical Requirements: Handling Test & Calibration Items

- Uniquely identified tests and calibration items
- Documented procedures for sample transportation, receipt, handling, protection, storage, retention, and/or disposal
- Available procedures to prevent sample deterioration and cross-contamination during storage & transport

Source: LabCompliance Tutorial

Technical Requirements: Assuring Quality of Tests/Calibration Results

- Monitored validity of test results, on an on-going basis, thru regular quality control samples or participation in proficiency testing programs
- Planned, justified, documented & reviewed type & frequency of tests
- Regular use of quality control checks, e.g. use of certified reference materials
- Replicating tests or calibrations on test reports using the same or different methods
- Retesting or recalibration of retained items

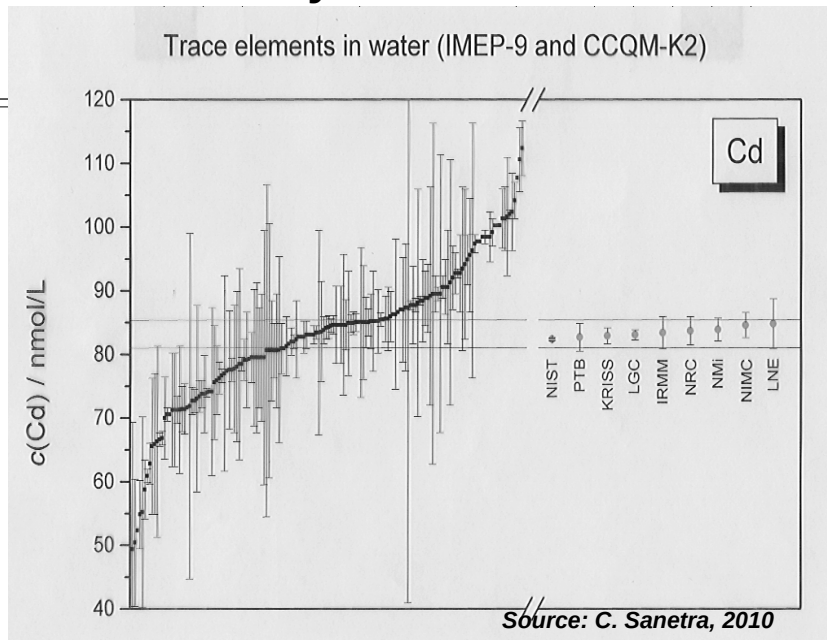
Source: LabCompliance Tutorial

DEFINITION

Proficiency Testing

-evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons

Proficiency of NMIs vs. Others



Source: C. Sanetra, 2010

Technical Requirements: Reporting of Results

- Name & address of the laboratory
- Unique identification of the test report or calibration certificate, e.g. serial no.
- Name and address of the customer
- Identification of the method
- Description & identification of the item(s) tested or calibrated
- Reference to the sampling plan and procedures used by the laboratory
- Test or calibration results with the units of measurement
- Name(s), function(s), and signature(s) of persons(s) authorizing the test report or calibration certificate
- A statement on estimated measurement uncertainty (for test report, where applicable)
- Documentation for opinions & interpretations, clearly marked as such

Source: LabCompliance Tutorial

Minimum Investments for Laboratory Quality Assurance in Food Composition Data Generation

- appropriately qualified staff
- properly controlled environment & calibrated equipment/apparatus, & correct reagents/chemicals
- validated measurement procedures
- appropriate/traceable reference standards*
- appropriate/periodic check standards & control charts (internal QC)
- appropriate/periodic/regular proficiency testing

Postcripts 1

- Metrology is fast evolving:
  - -vocabulary/analytical terminology (VIM3)
  - -MU estimation to include sampling
  - -delivery of traceability from CRMs by NMIs/DIs
- PTs reveal most measurement errors not related to traceability

Postcript 2

- **Personal Safety**

  in the laboratory

  is included

  in ISO/IEC 17025

Thank You!