Update on the revision of ISO/IEC 17025

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Overview

- Background
  - ISO and Accreditation
- ISO/IEC 17025:2017
  - Timeline
  - Structure and mandatory changes
  - Other changes
    - Philosophical
    - Definitions
    - Resources
    - Processes
  - Section 8 – Management requirements
  - Annexes
- Summary

The Importance of Data

- Most traded products require proof that they fulfil
  - Technical specifications
  - Safety / health / environmental protection regulations
- Increasing technical requirements
  - The more open the market gets the more stringent the technical / quality requirements for the traded products.
  - Test results becomes of greater importance
- Regulators and customers must be able to rely on the results of tests conducted in laboratories in other countries, which requires valid test data produced by reliable laboratories

Background - ISO

- ISO (International Organization for Standardization)
  - The International Organization for Standardization is an international **standard-setting body** composed of representatives from various national standards organizations.
  - Publishing International Standards covering almost **all aspects of technology and manufacturing**.
- ISO 9001: Quality management system
  - A standard that sets out the requirements for a quality management system.
  - The standard helps you achieve consistent results and continually improve your process.

Directives ISO/CEI, Partie 2

Background - ISO

- ISO CASCO

  (Committee on Conformity Assessment)

  - CASCO is the ISO committee that works on issues relating to conformity assessment.
    - Conformity assessment, also known as compliance assessment is any activity to determine, directly or indirectly, that a process, product, or service meets relevant technical standards and fulfills relevant requirements
  - CASCO develops policy and publishes standards related to conformity assessment.

Background - ISO

- ISO CASCO
  - CASCO's policy work is carried out by three groups:
    - Chairman's Policy and Coordination Group (CPC): Coordinates the technical work of CASCO and assists in identifying strategic conformity assessment issues.
    - *Technical Interface Group (TIG): Liaises with other ISO technical committees (TCs) in order to ensure a consistent and harmonized approach to conformity assessment in those TCs.*
    - *Strategic Alliance and Regulatory Group (STAR): Forum for industry sectors and regulators to interact with CASCO.*

Background – ISO CASCO

- ISO 17000 - Series
  - ISO/IEC 17011:2004
    - Conformity assessment - General requirements for **accreditation bodies** accrediting conformity assessment bodies
  - ISO/IEC 17025:2005
    - General requirements for the competence of **testing and calibration laboratories**
  - ISO 17034:2016
    - General requirements for the competence of **reference material producers**
  - ISO/IEC 17043:2010
    - Conformity assessment - General requirements for **proficiency testing**

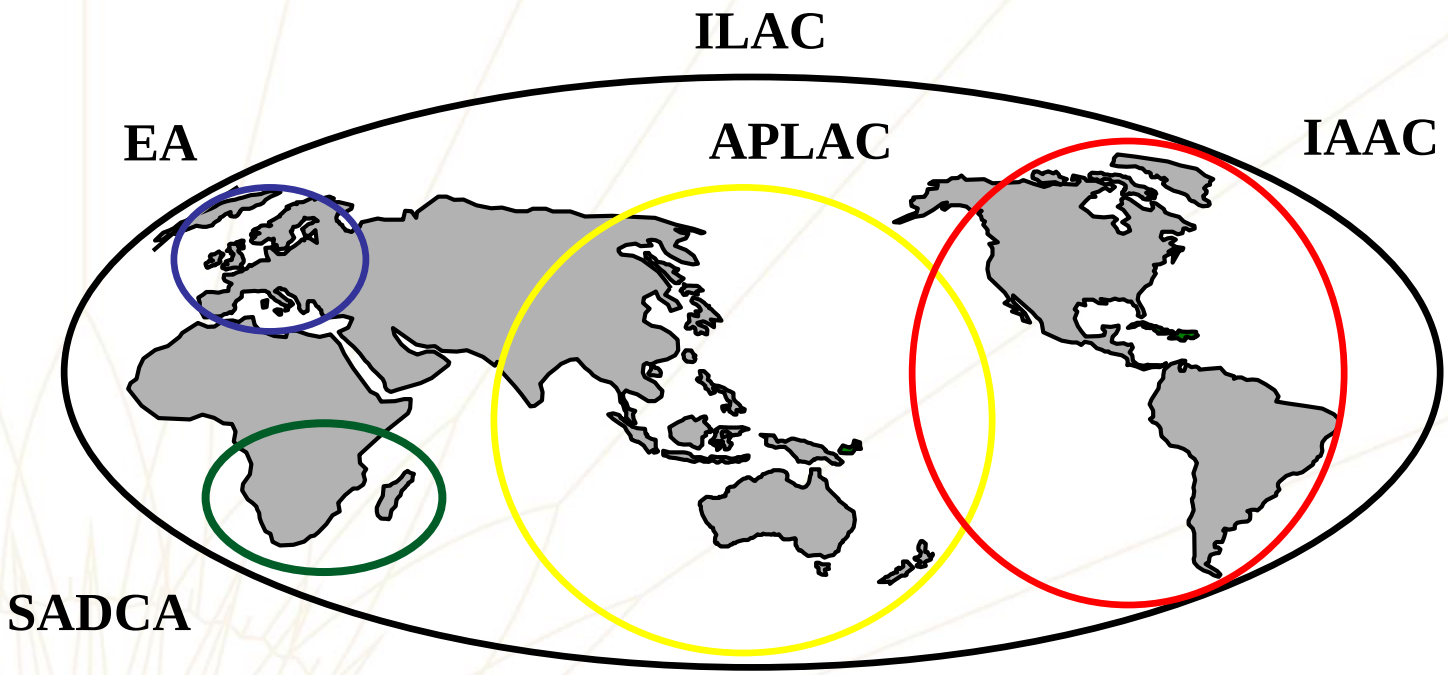
ISO CASCO

- ISO/IEC 17025
  - Confirmation of the technical competency of a testing or calibration laboratory by an independent third party (accreditation body)
    - Scope
      - Methods
      - Materials
      - Measurand / Analyte
      - Concentration range

Background

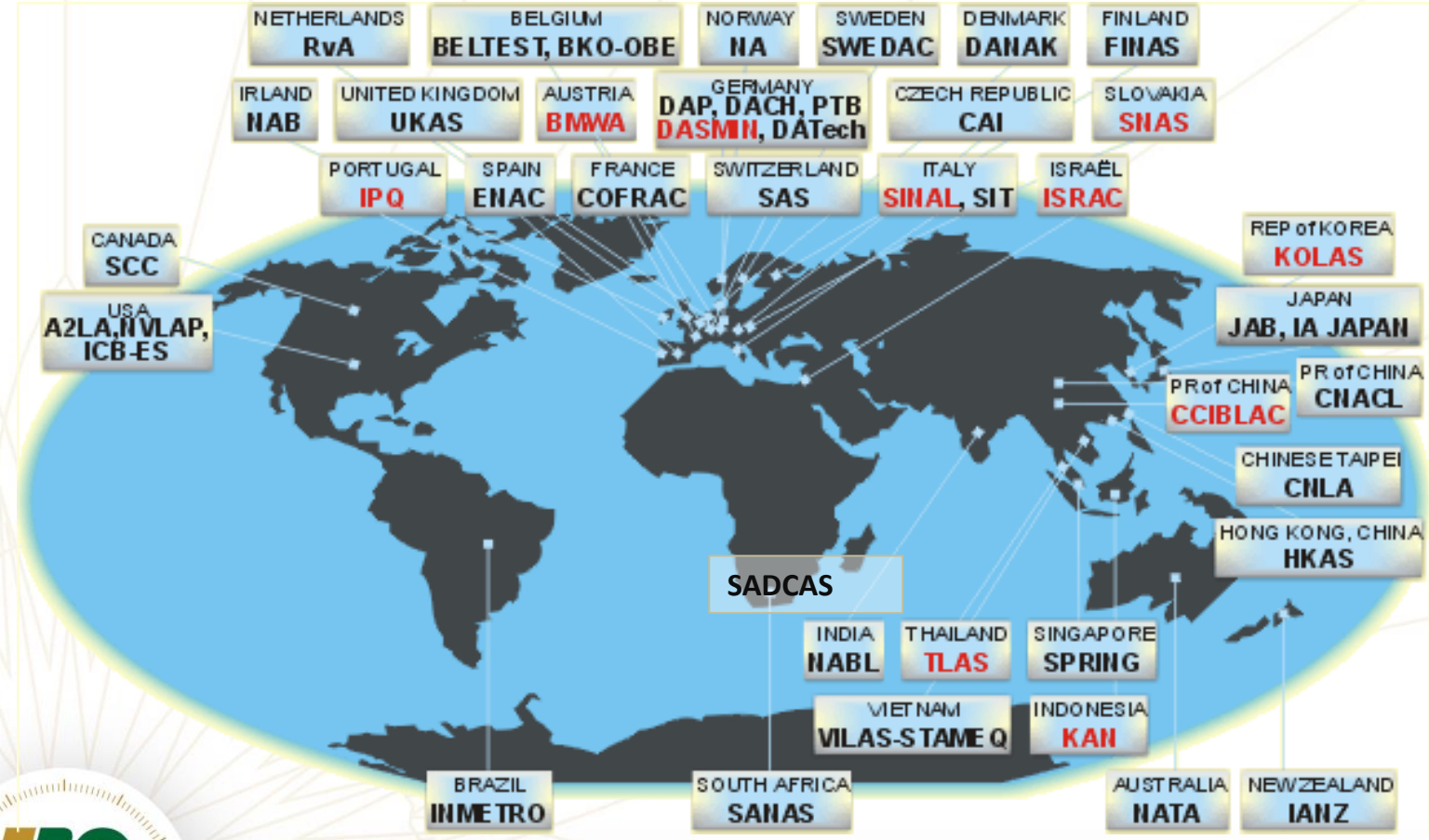
- Accreditation body
  - There is cooperation between accreditation bodies in international organisations
    - Worldwide: International Laboratory Accreditation Cooperation (**ILAC**)
    - Regional:
      - **SADCA**: Southern African Development Community Cooperation in Accreditation
      - **APLAC**: Asia Pacific Laboratory Accreditation Cooperation Inc.
      - **EA**: European co-operation for Accreditation
      - **IAAC**: Inter American Accreditation Cooperation

Mutual Recognition Arrangements



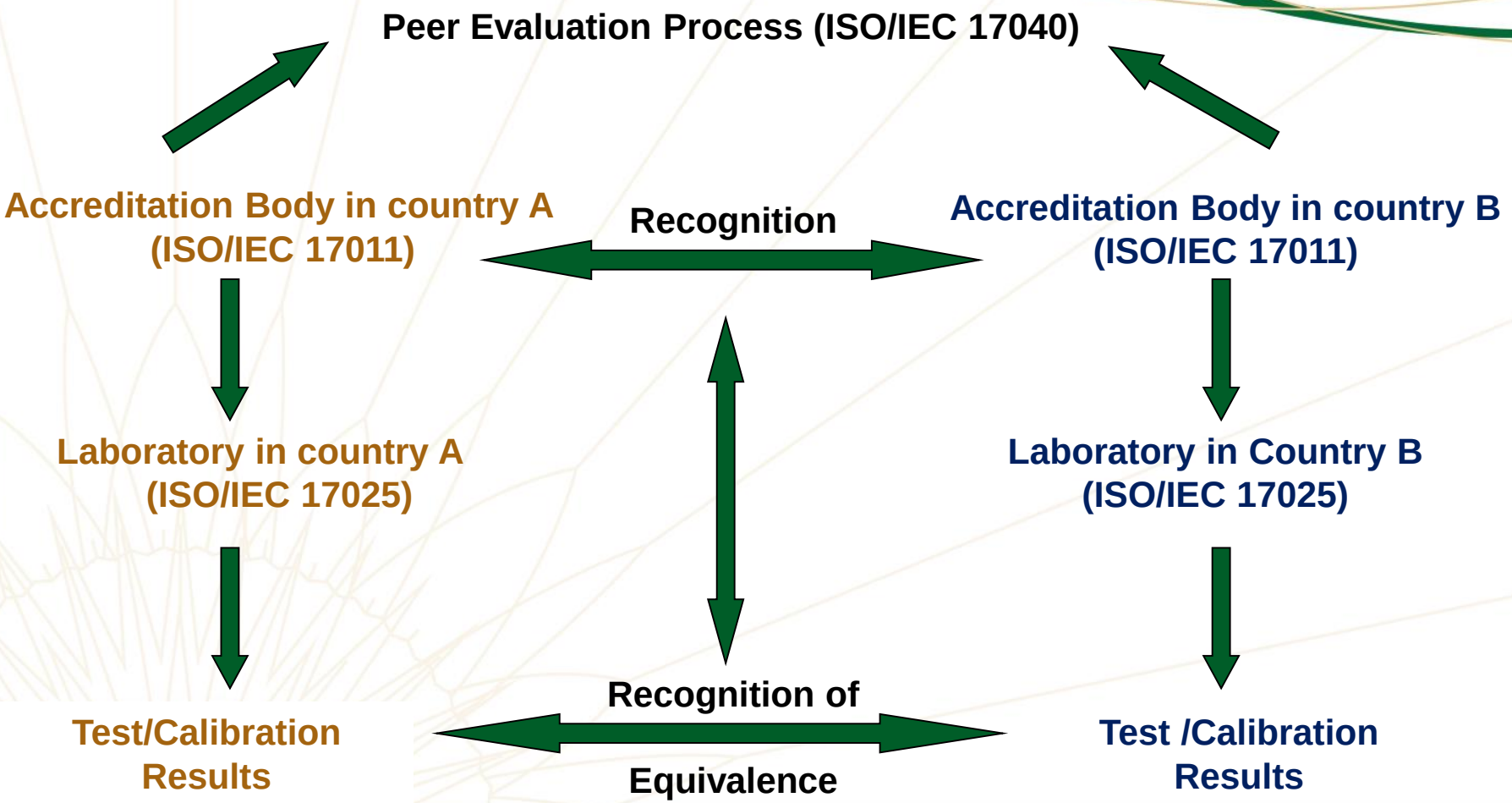
- ILAC: International Laboratory Accreditation Cooperation
  - SADCA: Southern African Development Community Cooperation in Accreditation
  - EA: European co-operation for Accreditation
  - APLAC: Asia Pacific Laboratory Accreditation Cooperation
  - IAAC: Inter-American Accreditation Cooperation

International Multilateral Agreement Between Accreditation Bodies

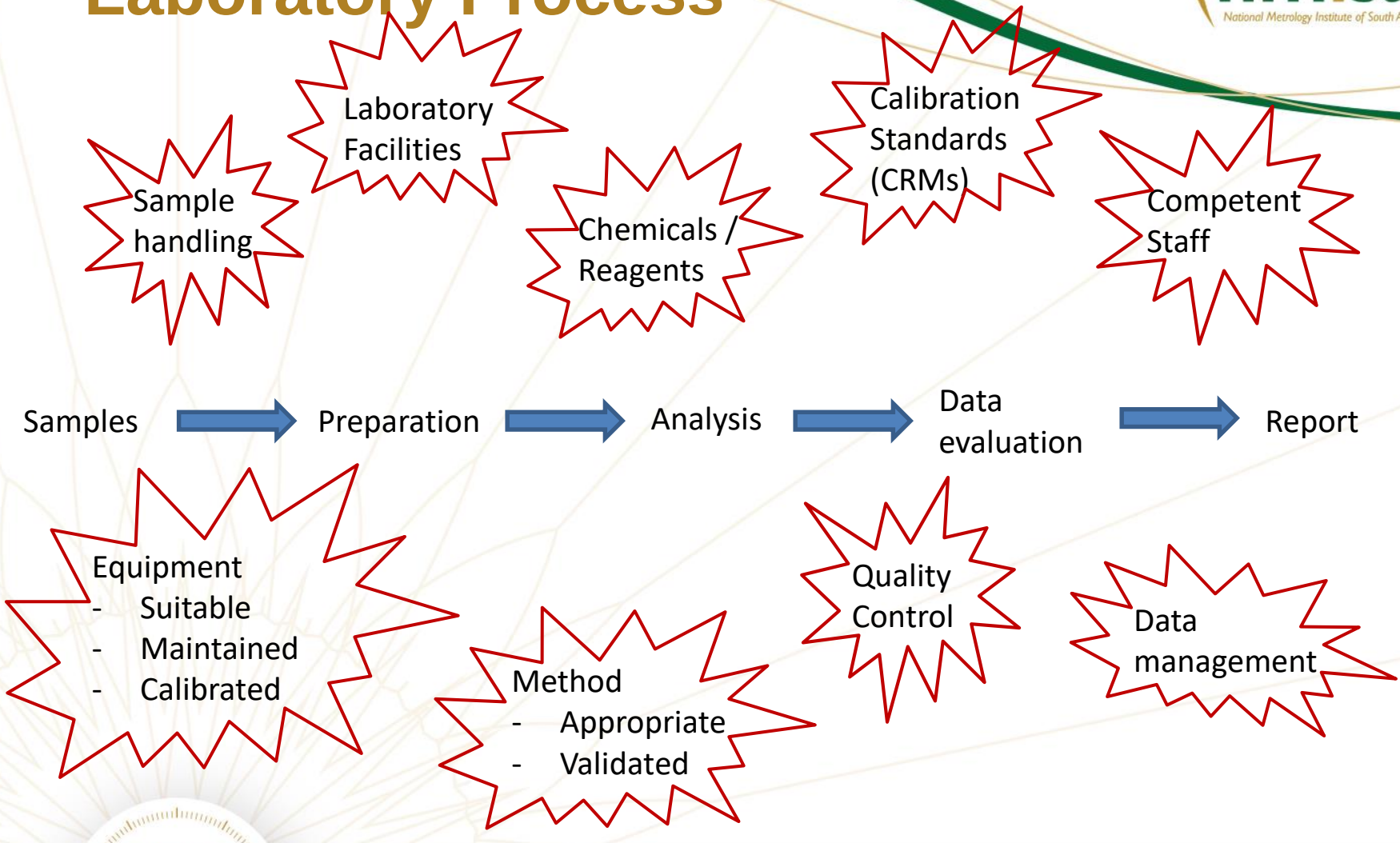


In: Wenclawiak, Koch, Hadjicostas (eds.) Quality Assurance in Analytical Chemistry – Training and Teaching

ILAC MRA:
Mutual Recognition Arrangement



Laboratory Process



ISO 17025 Structure

17025:2005

1 Scope
2 Normative References
3 Terms & Definitions

4 Management Requirements
5 Technical Requirements

Annex A – 9001 Cross References

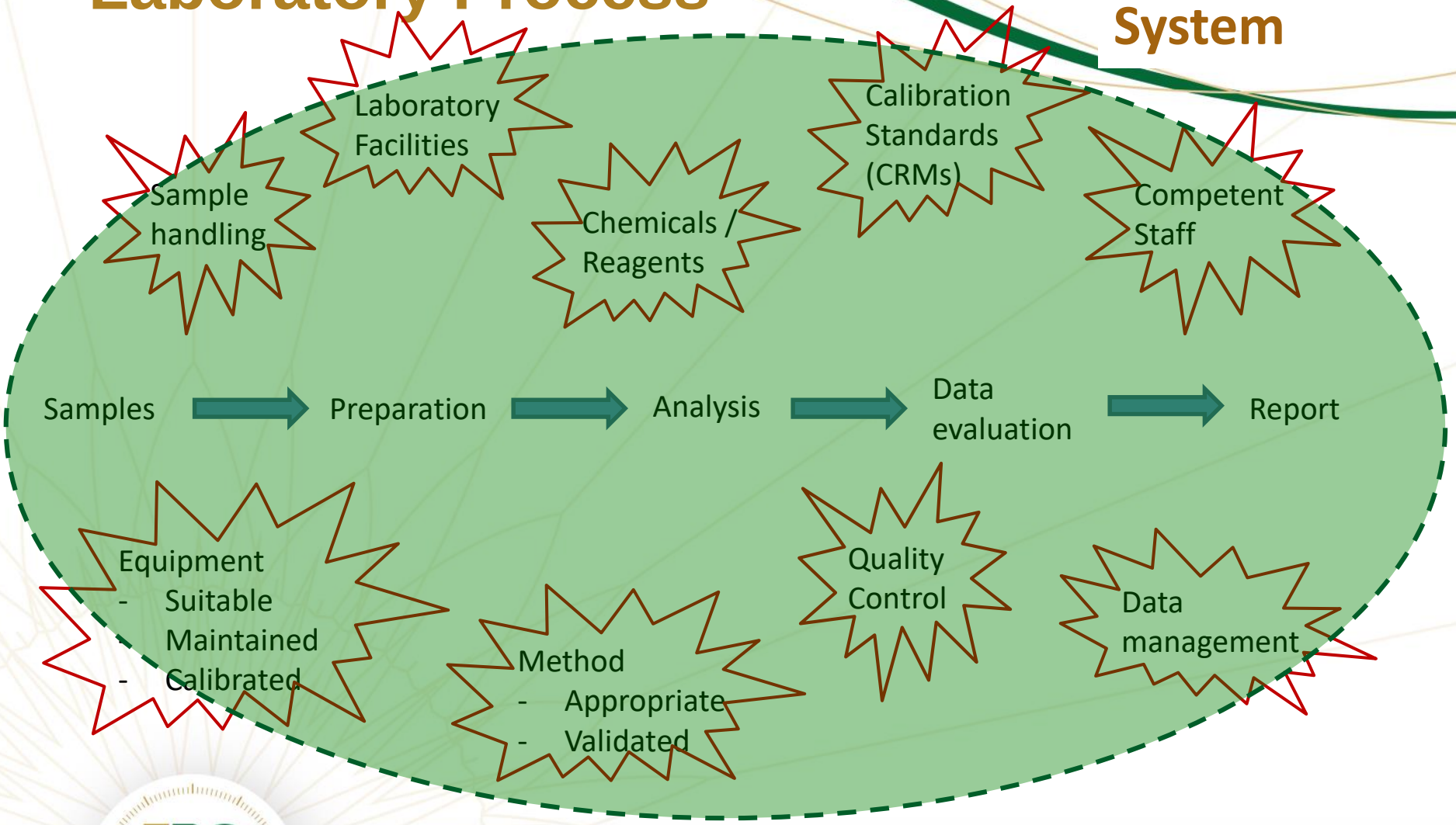
Annex B – Guidelines for Applications

Bibliography

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

Laboratory Process

Management System



ISO 17025 Structure

17025:2005

1 Scope
2 Normative References
3 Terms & Definitions

4 Management Requirements
5 Technical Requirements

Annex A – 9001 Cross References

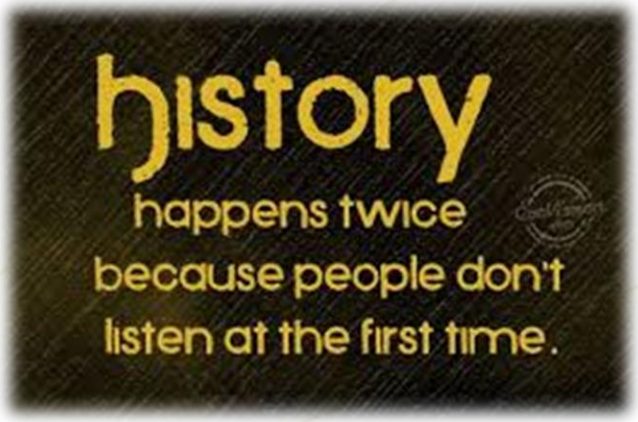
Annex B – Guidelines for Applications

Bibliography

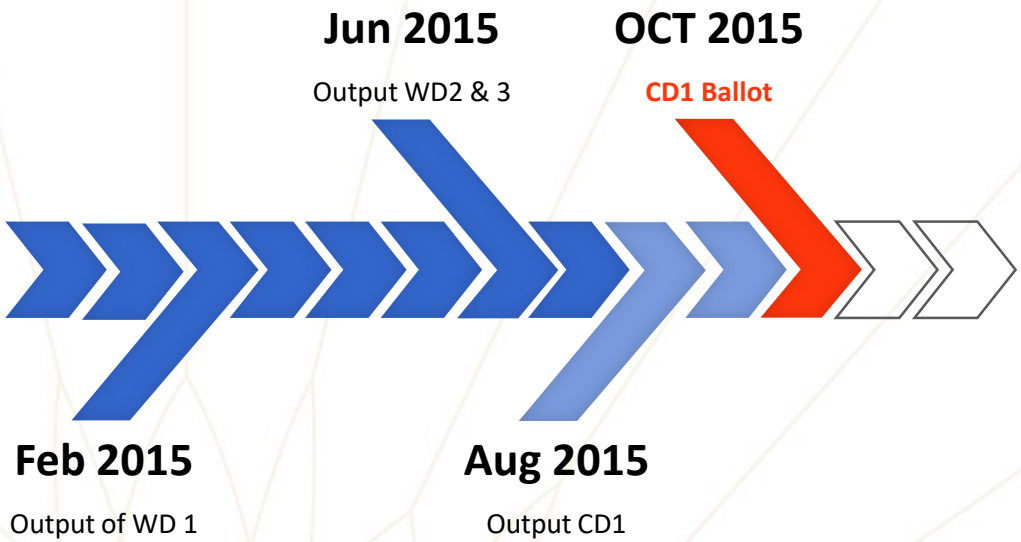
- 4.1 Organization
- 4.2 Management System
- 4.3 Document Control
- 4.4 Review of requests, tenders and contracts
- 4.5 Subcontracting of tests and calibrations
- 4.6 Purchasing supplies
- 4.7 Service to the customer
- 4.8 Complaints
- 4.9 Control of non-conforming testing and/or calibration work
- 4.10 Improvement
- 4.11 Corrective action
- 4.12 Preventative action
- 4.13 Control of records
- 4.14 Internal Audits
- 4.15 Management reviews

Revision of ISO/IEC 17025

- ISO/IEC 17025 - History
  - ISO Guide 25
  - ISO/IEC 17025:1999
  - ISO/IEC 17025:2005
  - *ISO/IEC 17025:2017?*
- Working group 44
  - 3 Conveners: ANSI, SABS, IEC
  - 73 Members
  - 18 Liaisons
  - 8 Observers



Timeline


Jun 2015
Output WD2 & 3
OCT 2015
CD1 Ballot
Feb 2015
Output of WD 1
Aug 2015
Output CD1


20 Preparatory
30 Committee
40 Inquiry
50 Approval
Transition Event

Working group 44 – CD1

- CD1 Ballot Results – 2606 comments
  - Yes – 22
  - Yes with comments – 44
  - No – 10
    - CAN, CHL, DEU, FIN, IRL, JAP, NPL, THA, SWE, USA
  - Abstain – 10

Timeline

Jun 2015
Output WD2 & 3

OCT 2015
CD1 Ballot

MAR 2016
CD2 Ballot

Feb 2015
Output of WD 1

Aug 2015
Output CD1

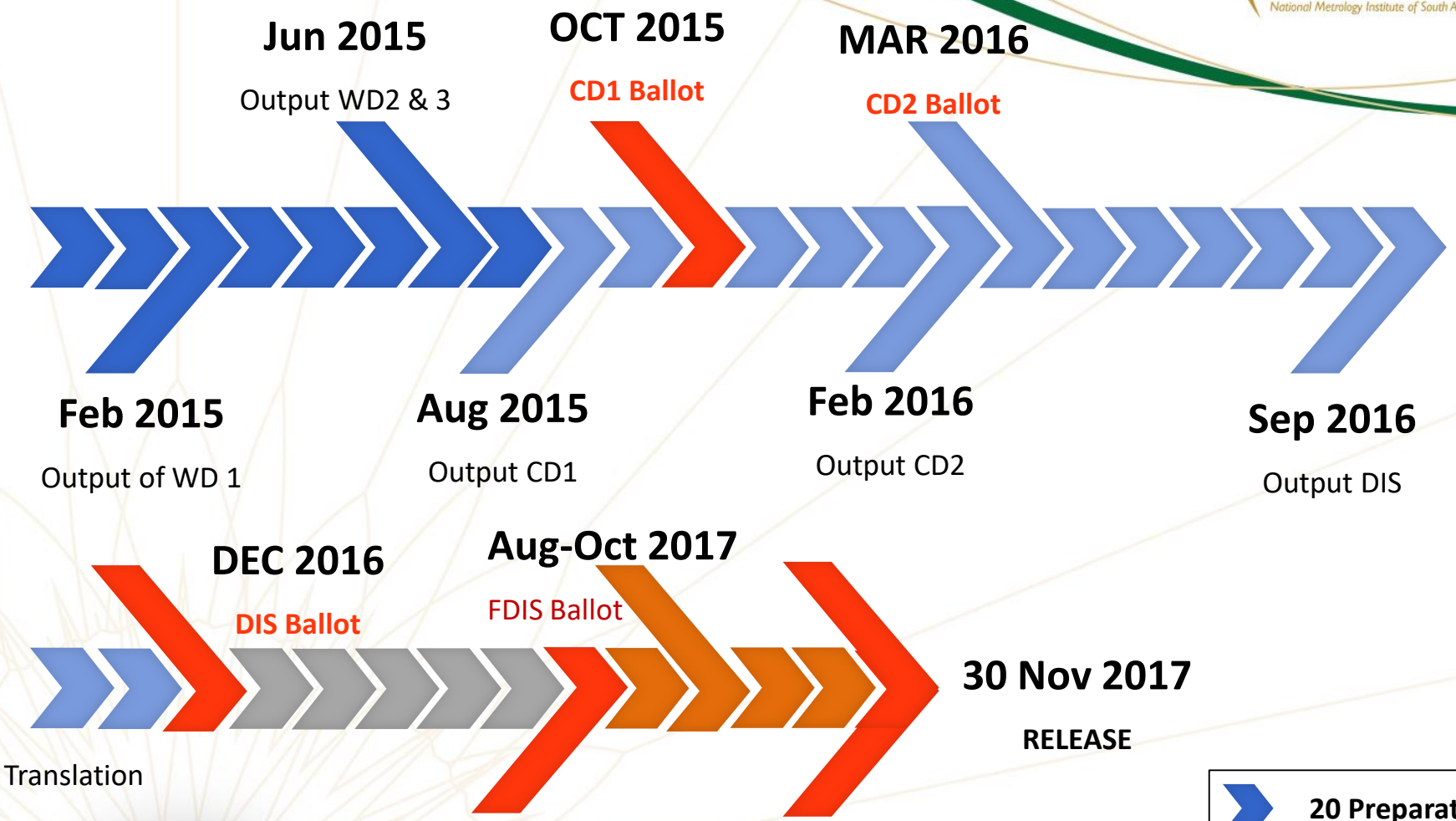
Feb 2016
Output CD2

- 20 Preparatory
- 30 Committee
- 40 Inquiry
- 50 Approval
- Transition Event

Working group 44 – CD2

- CD2 Ballot Results – 2300 comments
  - Yes - 35 members
  - Yes, with comments - 46 members
  - No - 3 members
    - Chile, Germany and Japan
  - Abstain - 5 members

Timeline


Jun 2015
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Feb 2015
Output of WD 1
Aug 2015
Output CD1
Feb 2016
Output CD2
Sep 2016
Output DIS
DEC 2016
DIS Ballot
Aug-Oct 2017
FDIS Ballot
30 Nov 2017
RELEASE
Translation
JUL 2017
WG Meet
20 Preparatory
30 Committee
40 Inquiry
50 Approval
Transition Event

Overview of major changes

- Mandatory changes by CPC
- Structure (CASCO)
- Other changes
  - Philosophical
  - Definitions
  - Structural
  - Resources
  - Processes
- Quality requirements fully aligned with ISO 9001
  - Option A: ISO 17025:2005 Clause 4 management requirements
  - Option B: ISO 9001

CPC* Changes

- Proc/33 Mandatory changes
  - Impartiality
    - General (4.1)
    - Resource (6.2)
  - Confidentiality
    - General (4.2)
  - Complaints
    - Process (7.10)
  - Management system (8)
    - Option A : ISO 17025:2005 clause 4
    - Option B : Inclusion of ISO 9001 registered/certified bodies

Directives ISO/CEI, Partie 2

QS-CAS-PROC/33

November 2014

*ISO/CASCO Chairman's Policy and Coordination Group

CPC* Mandatory changes
ISO/CASCO document structure

Informative preliminary	Title page Table of contents Foreword Introduction (including relationship to other standards
Normative General	Title Scope Normative references
Normative Technical	Terms and definitions Requirements Structural requirements Resource requirements (including human resources) Process requirements (including operational functions) Management system requirements Normative annexes
Informative supplementary	Any further explanations that are not part of the normative process Informative annexes Bibliography Indexes

* ISO/CASCO Chairman's Policy and Coordination Group

Structure

17025:2005	17025:2017
1 Scope	1 Scope
2 Normative References	2 Normative references
3 Terms & Definitions	3 Terms and definitions
4 Management Requirements	4 General requirements
5 Technical Requirements	5 Structural requirements
	6 Resource requirements
	7 Process requirements
	8 Management requirements
Annex A – 9001 Cross References	Annex A – Metrological traceability
Annex B – Guidelines for Applications	Annex B – Management system
Bibliography	Bibliography

This doesn't mean you have to change your Quality Manual!

Structure
17025:201X

4 General Requirements

- 4.1 Impartiality
- 4.2 Confidentiality

5 Structural Requirements

- 5.1 Legal entity (4.1)
- 5.2 Management (4.2)
- 5.3 Defined range of activities
- 5.4 Responsible for activities
- 5.5 Management structure, authority and procedures
- 5.6 Personnel and resource availability
- 5.7 Communication and integrity

6 Resource Requirements

- 6.1 General
- 6.2 Personnel (5.2)
- 6.3 Laboratory environment (5.3)
- 6.4 Equipment (5.5)
- 6.5 Metrological traceability (5.6)
- 6.6 External products and services (4.6)

Structure

17025:201X

7 Process Requirements

- **7.1 Review of RTC (4.4)**
- **7.2 Selection of methods (5.4)**
- **7.3 Sampling (5.7)**
- **7.4 Handling of customer items (5.8)**
- **7.5 Technical records (4.13)**
- **7.6 Evaluation of MU (5.4.6)**
- **7.7 Assuring validity of results (5.9)**
- **7.8 Reporting of results (5.10)**
- **7.9 Complaints (4.8)**
- **7.10 Nonconforming work (4.9)**
- **7.11 Control of data (4.13)**

Structure

17025:201X

8 Management Requirements

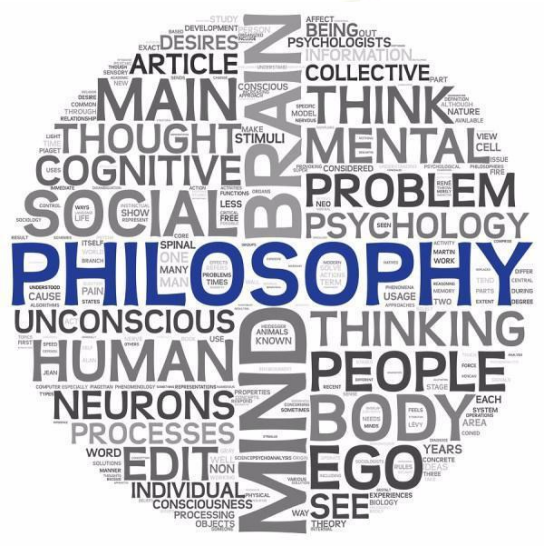
8.1 Options (A & B)
8.2 Option A – Management system documentation (4.2)
8.3 Option A – Control of documents (4.3)
8.4 Option A – Control of records (4.13)
8.5 Option A – Risks and opportunities (4.10)
8.6 Option A – Improvement (4.10, 4.12)
8.7 Option A – Corrective action (4.11)
8.8 Option A – Internal audits (4.14)
8.9 Option A – Management reviews (4.15)

Annex A – Metrological traceability

Annex B – Management system options

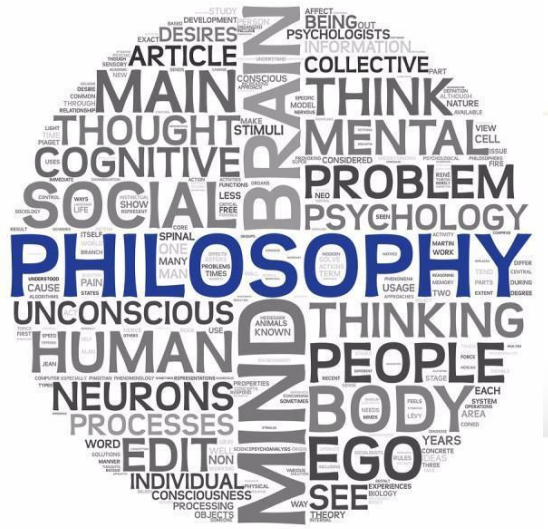
Philosophical changes

- ISO 9001 Principles
  - Risk management (ISO 9001)
  - Process management vs. Policies and procedures
  - “Fit for Use/Purpose”
  - Impartiality / Confidentiality



Philosophical changes

- Vocabulary:
  - “shall” – Requirement
  - “should” – Recommendation
  - “may” – Permission
  - “can” – Possibility / Capability
- Notes
  - If the NOTE did not provide value it was removed otherwise it was moved to a requirement

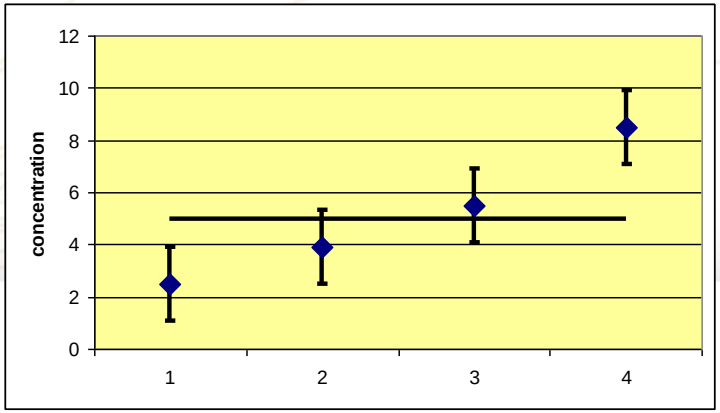


Changes – Definitions

- 3.6 laboratory (new)
  - Body that performs one or more of the following activities:
    - Calibration
    - Testing
    - Sampling, associated with subsequent calibration and testing

Changes – Definitions

- 3.7 decision rule (new)
  - Documented rule that describes how measurement uncertainty will be accounted for in statements of compliance with regard to accepting or rejecting an item, given a specified requirement and the result of a measurement
    - ISO Guide 98/4, 3.3.12: Modified, added "in statements of compliance"
    - 7.8: Documenting decision rules for the analysis of results
    - 7.8.6: Reporting statements of conformity



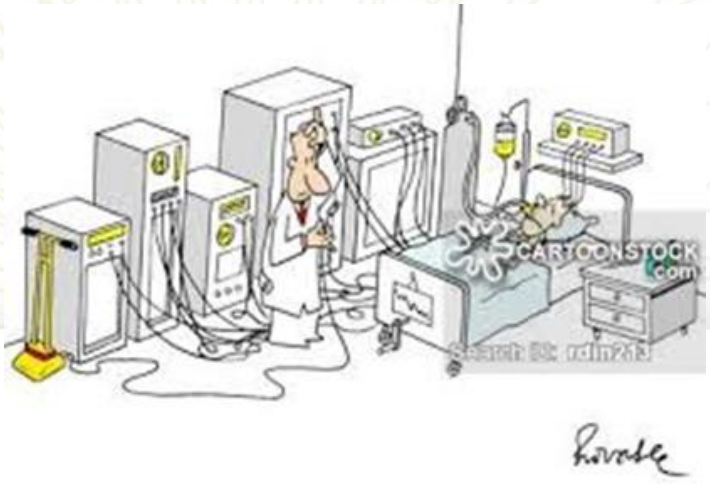
Changes – Resources

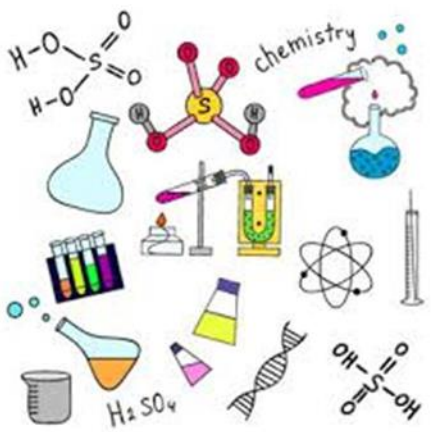
- Personnel (6.2)
  - Impartiality
  - Define and document competency requirements
  - Duties and responsibilities
  - Records
  - Authorisations

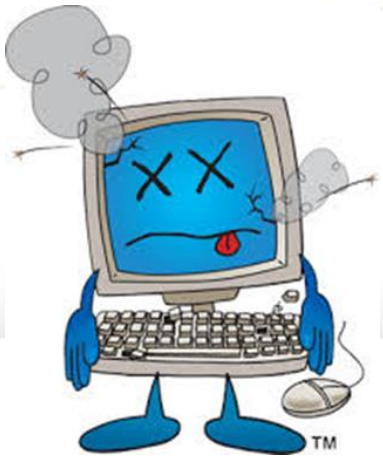
We have highly educated and extremely reliable personnel

Changes – Resources

- Equipment (6.4)
  - Clearer definition – anything affecting the measurement results
    - "Equipment shall include software, measurement standards, reference materials, reagents and consumables or auxiliary apparatus or combination thereof …"
  - Reference materials clarified

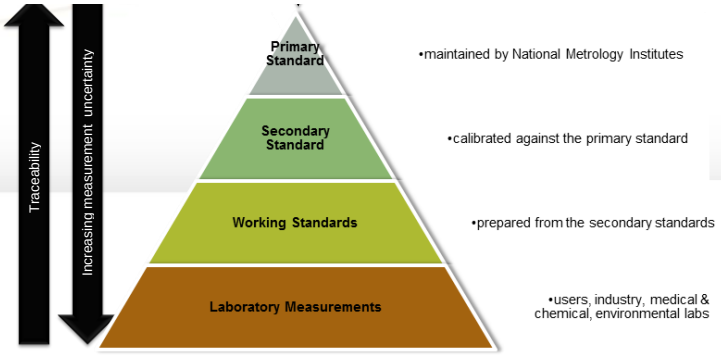




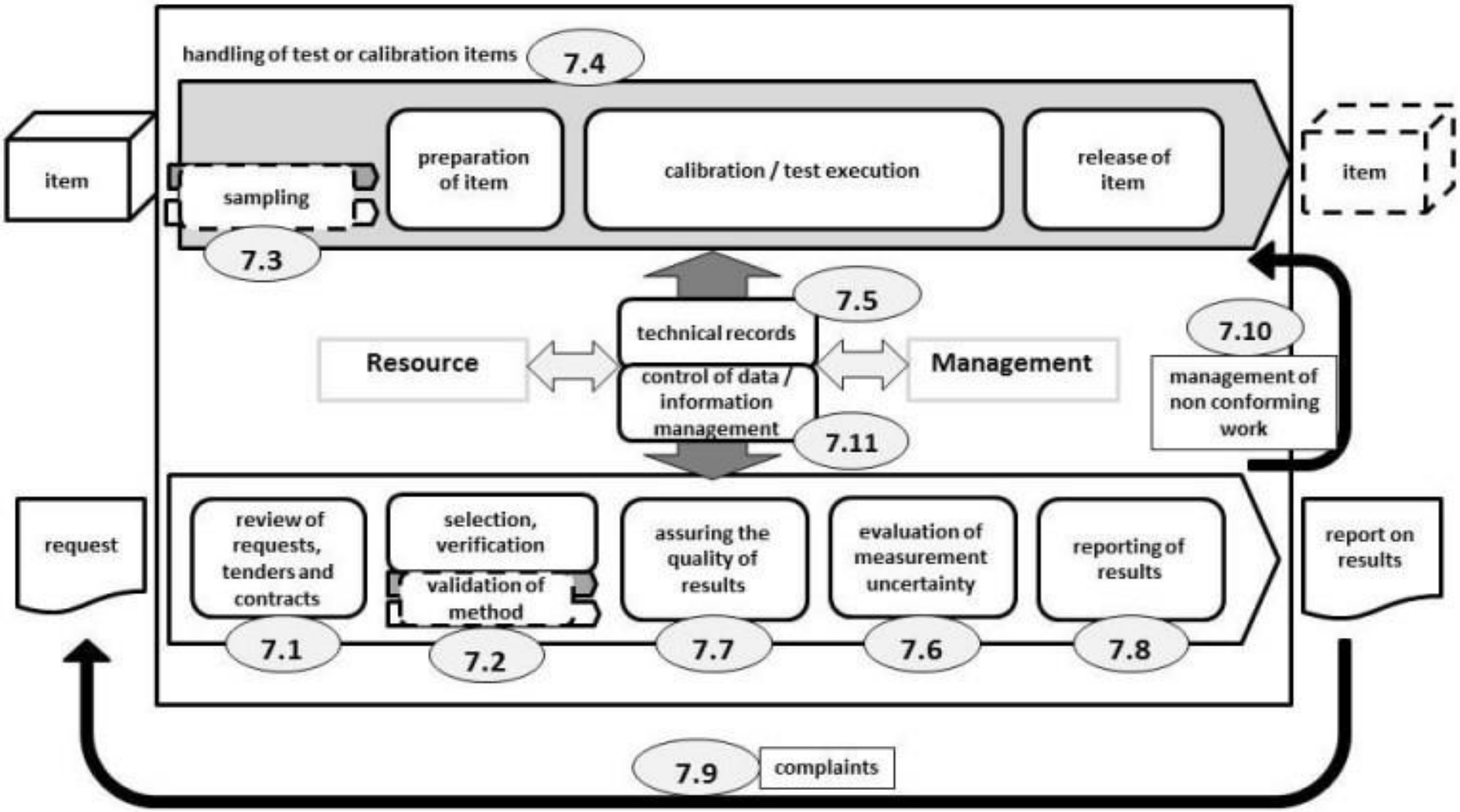


Changes – Resources

- Metrological traceability (6.5)
  - Clarified and moved much of 2005 content to Annex A
  - Role and requirements of certified values of certified reference materials (CRMs) clarified
- Externally provided products and services (6.6)
  - Adopted and modified (ISO 9001:2015 content)
  - Include calibration and testing services



7. Process requirements



Changes – Processes

- Review of Requests, Tenders and Contracts (7.1)
  - Clarification of requirements and conditions for external providers of laboratory activities
- Selection, verification and validation of methods (7.2)
  - Clarification of general use of terminology
- Evaluation of MU (7.3)
  - All contributions of significance, including sampling
  - Calibration also performed in testing laboratories
  - Different approaches

Changes – Processes

- Assuring the validity of results (7.7)
  - Equal weighting between external and internal processes
    - **Internal processes:**
      - Reference / Quality control materials
      - Alternative traceable instruments
      - Control charts with check / working standards
      - Intermediate instrument checks
      - Replicate tests / calibrations
      - Intra-laboratory testing
      - Blind tests
    - **External processes:**
      - Proficiency testing
      - Inter-laboratory testing

Changes – Processes

- Reporting the results (7.8)
  - Common requirements (7.8.2)
    - Date of performance of the test
    - Date of issuance of the report
  - Specific requirements
    - Test,
    - Calibration,
    - Reporting sampling
  - Measurement uncertainty
    - Same unit or relative units (%) (7.8.4.1)

Changes – Processes

- Reporting the results (7.8)
  - Statements of Conformity (7.8.6.1) – identified to a
    - Specific result, and
    - Clause of the specification (7.8.6.2)
    - Documented decision rules
    - Definition (3.7)
    - Decision rules and contracts (7.1.3)
    - Reference (ISO/IEC Guide 98-4 and JCGM 106)
  - Amendments (7.8.8)
    - Changes shall be clearly identified

Section 8
Management Requirements

Section 8 – Management Requirements

Section 8 covers management requirements and while the practical measures required are almost unchanged it is structurally very different

- Introduction of Options A and B
- Mostly “Mandatory Text”
- Acknowledges use of ISO 9001 as a basis to use for conformity to ISO 17025

Changes – Management

- Option A (Clauses 8.2 to 8.9)
  - Option A is to use ISO 17025 alone and directly to demonstrate a management system capable of supporting the technical requirements of the standard
  - No major changes in requirements
  - Addressing risks and opportunities (8.5)
    - Introduction of KPIs to the standard
  - Improvement (8.6) – removed Preventive action (redundant)

Option A
(ISO 17025 directly)

As a minimum the management system of the laboratory shall address the following:

- management system documentation
- control of management system documents
- control of records
- actions to address risks and opportunities
- improvement
- corrective action
- internal audits
- management review

Option B (ISO 9001)

Option B is to use an ISO 9001 management system as a basis for conformity with ISO 17025 provided that it addresses the technical requirements of the standard

- Allows for a single system based on ISO 9001
- Requires ISO 17025 (clauses 4 to 7) requirements to be addressed

Annexes

- Annex A – Metrological traceability
  - Establishing metrological traceability
    - Systematic measurement error
    - Statements of conformity
  - Demonstrating metrological traceability
- Annex B – Management system options
  - Option A
  - Option B

Summary

- Structure and mandatory changes
- Quality requirements strive to implement the principles of ISO 9001
- Technical requirements: clarification and documentation
- Management requirements
  - Option A
  - Option B
- 3 years timeframe to implement

Acknowledgements

Dr. Angelique Botha

Thank You