

Update on the revision of ISO/IEC 17025

Discussion on the proposed changes

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SADCWater PT Evaluation Workshop 2016
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Overview

➤ Background

- Technical Barriers to Trade
- Accreditation

➤ ISO

- ISO 9001
- ISO CASCO

➤ ISO/IEC 17025:201X

- Timeline
- Structure and mandatory changes
- Aligned with ISO 9001
 - Philosophical
 - Section 8 – Management requirements
- Definitions clarified

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
- Unaccepted laboratory test data across national borders may create technical barriers to trade and leading to expensive re-testing

The Importance of Data

- It is generally agreed by the WTO that the biggest obstacle to trade is Non Tariff Technical Barriers (TBT's) i.e.
 - We need to develop a means of recognizing the technical infrastructure and output from one country in another country as being equivalent
- ISO/IEC 17025
 - Accreditation is the independent and formal recognition of competence to perform specific tests.
 - Accreditation body
 - Scope
 - Methods
 - Materials
 - Measurand / Analyte
 - Concentration range



Background - ISO



Directives ISO/CEI, Partie 2

- ISO (International Organization for Standardization)
 - The International Organization for Standardization is an international **standard-setting body** composed of representatives from various national standards organizations.
 - Started in 1946 when delegates from 25 countries met at the Institute of Civil Engineers in London and decided to create a new international organization **‘to facilitate the international coordination and unification of industrial standards’**.
 - Since then, over 21000 International Standards covering almost **all aspects of technology and manufacturing** have been published.
 - Currently has **members from 163 countries** and 3 368 technical bodies which take care of standard development.



Background - ISO

- ISO 9001: Quality management system
 - A standard that sets out the requirements for a quality management system.
 - It helps businesses and organizations to be more efficient and improve customer satisfaction.
 - This standard is based on a number of quality management principles:
 - Process approach
 - Strong customer focus
 - Decision making processes
 - Engagement of leadership and people
 - Relationship management
 - Continual improvement.
 - Does NOT define the actual quality of your product or service. The standard helps you achieve consistent results and continually improve your process.

Background - ISO

➤ ISO CASCO

- 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



Background

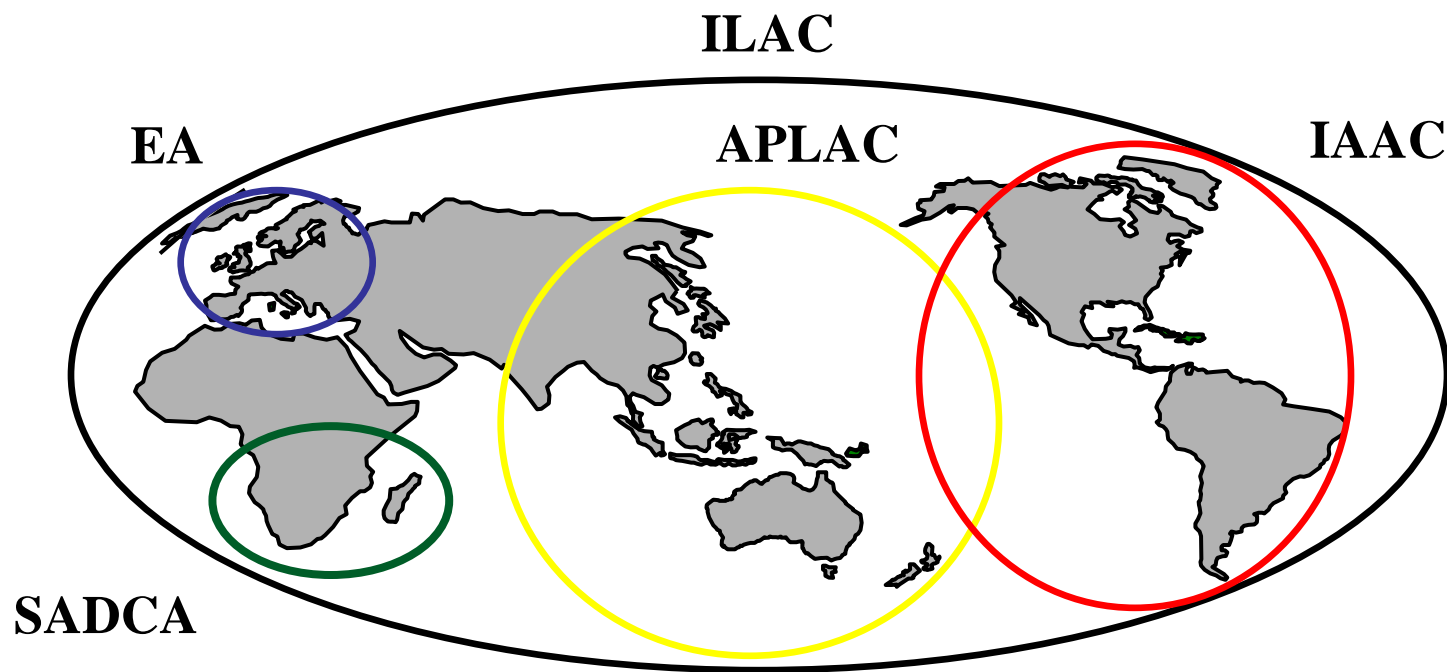
➤ ISO/IEC 17025

- Confirmation of the technical competency of a testing or calibration laboratory by an independent third party (accreditation body)

➤ Accreditation body

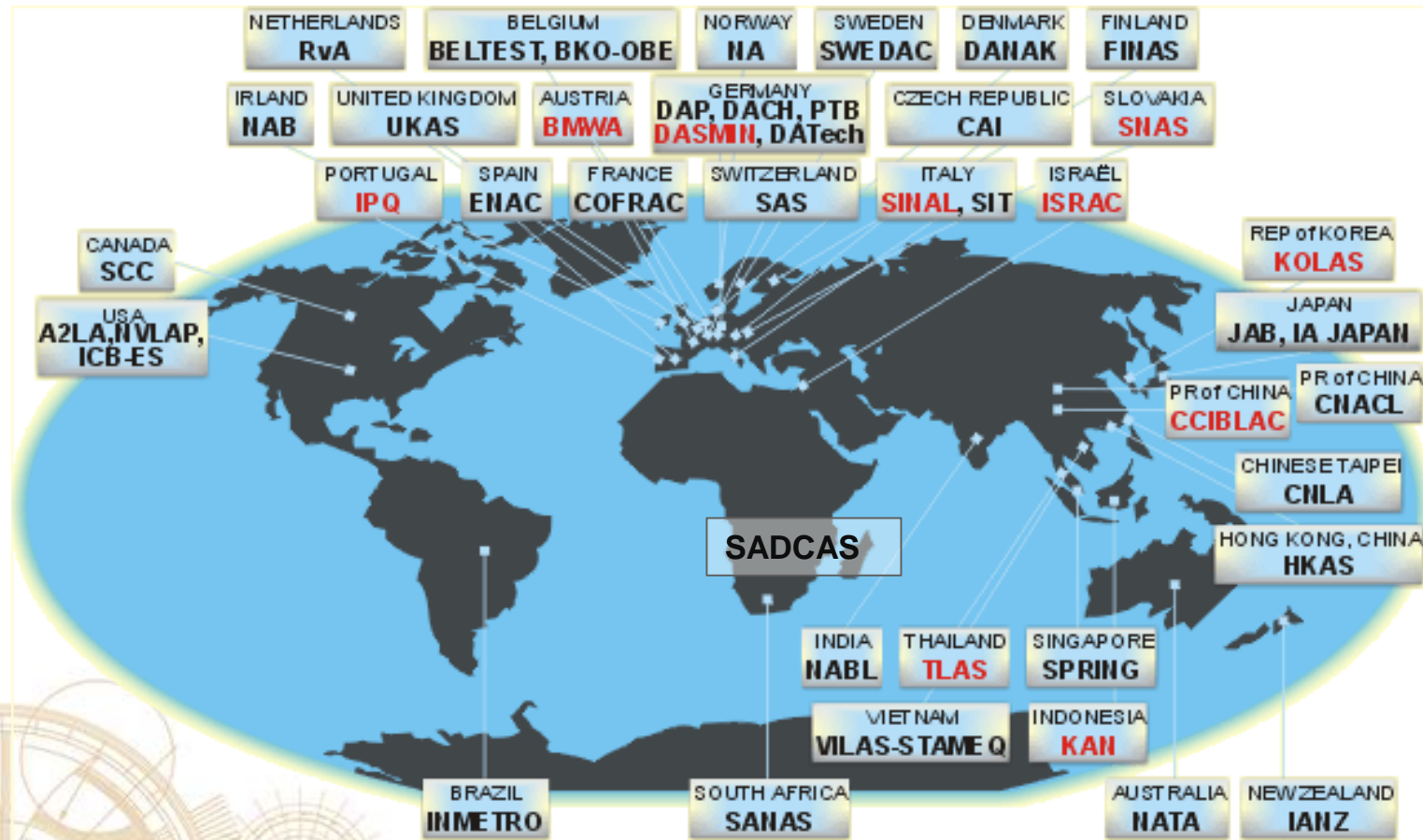
- Usually there are national regulations for one or several accreditation bodies in each country
- There is cooperation between accreditation bodies in international organisations
 - Worldwide: International Laboratory Accreditation Cooperation (ILAC)
 - Regional:
 - SADCA: Southern African Development 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



ILAC MRA: Mutual Recognition Arrangement

Peer Evaluation Process (ISO/IEC 17040)

Accreditation Body in country A
(ISO/IEC 17011)

Accreditation Body in country B
(ISO/IEC 17011)

Recognition

Laboratory in country A
(ISO/IEC 17025)

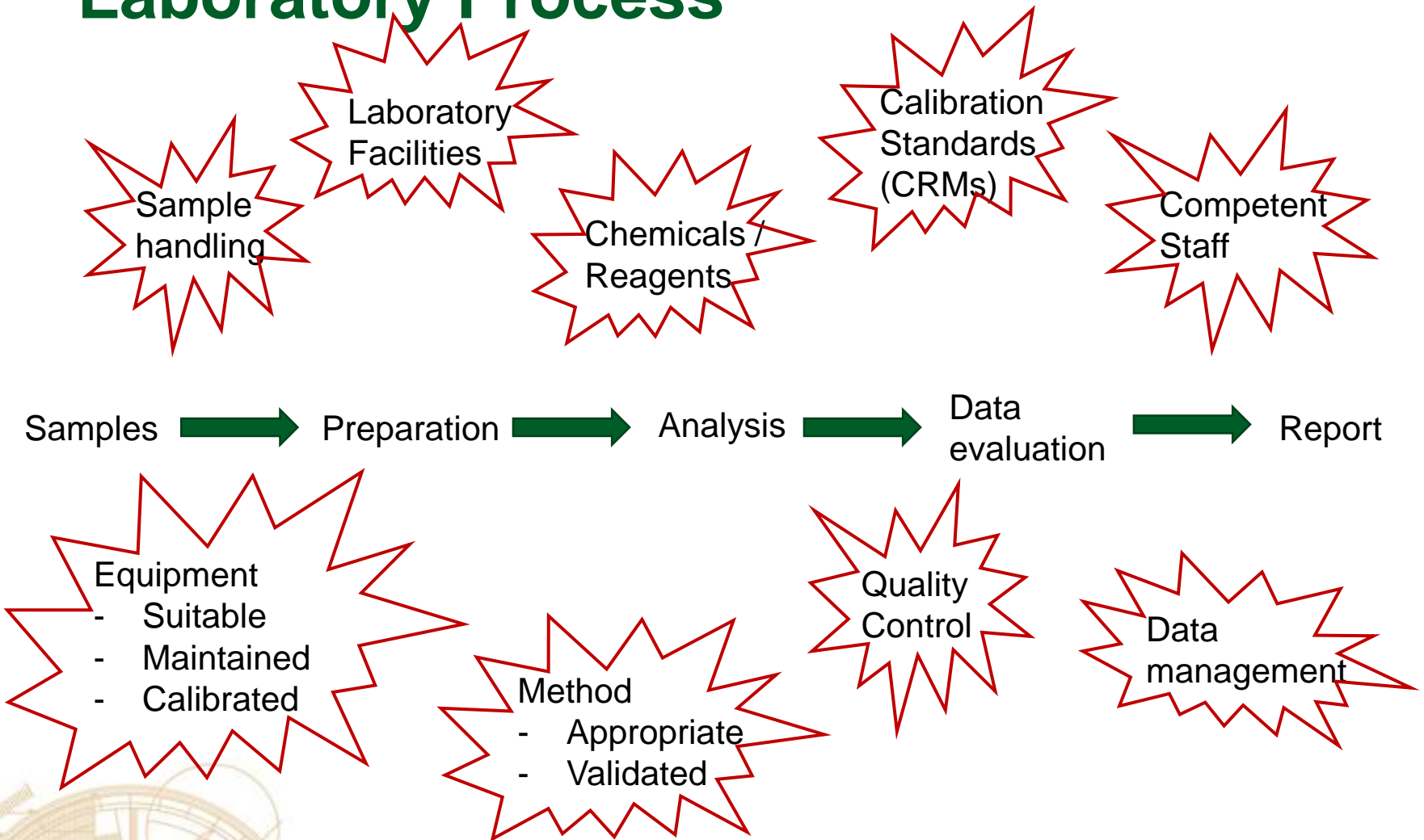
Laboratory in Country B
(ISO/IEC 17025)

Test/Calibration
Results

Test /Calibration
Results

Recognition of
Equivalence

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

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

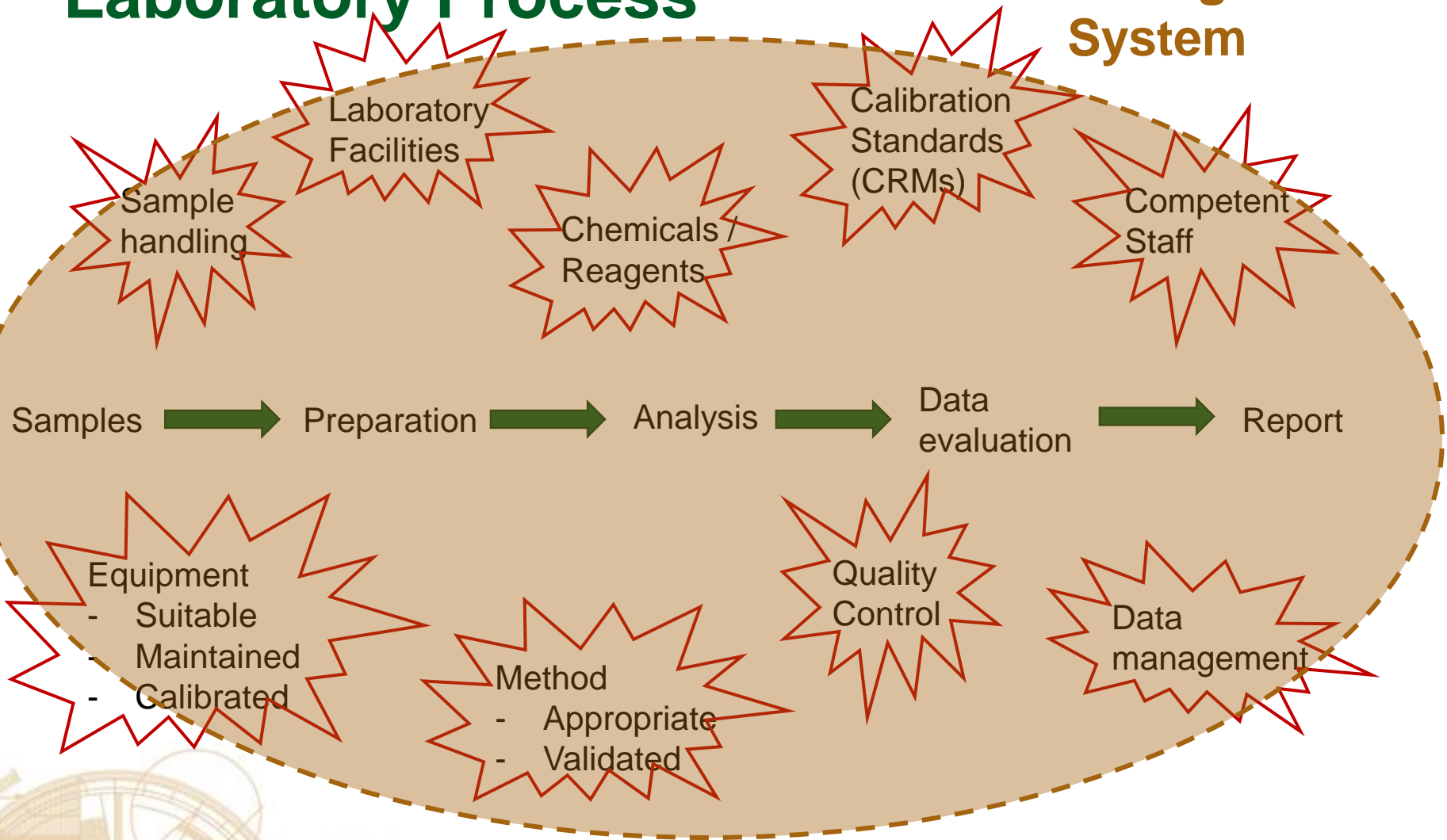
5.9 Assuring the quality of test and calibration results

5.10 Reporting the results

Bibliography

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

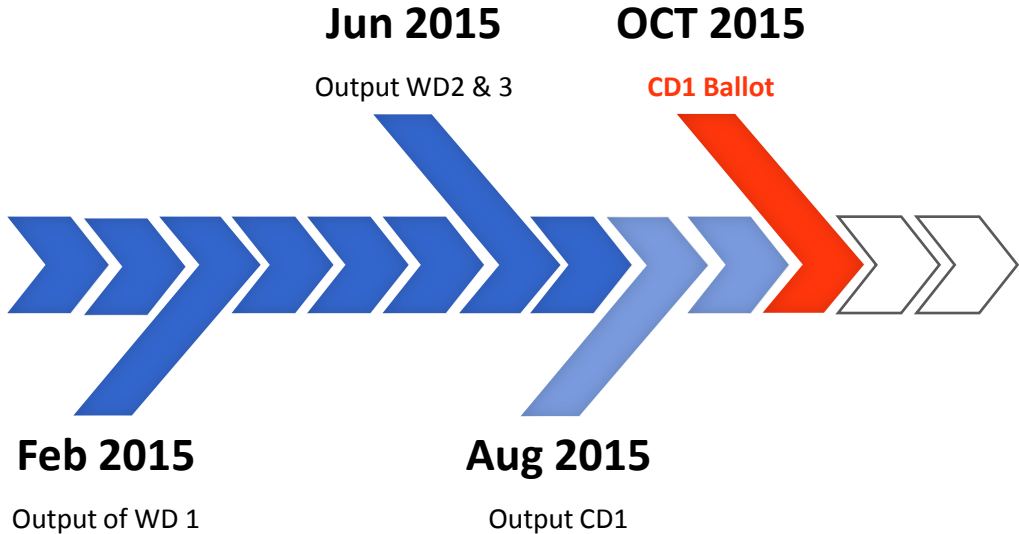
- 3 Conveners:
 - Warren Merkel (ANSI)
 - Steve Sidney (SABS)
 - Heribert Schorn (IEC)

➤ 73 Members

➤ 18 Liaisons

➤ 8 Observers

Timeline

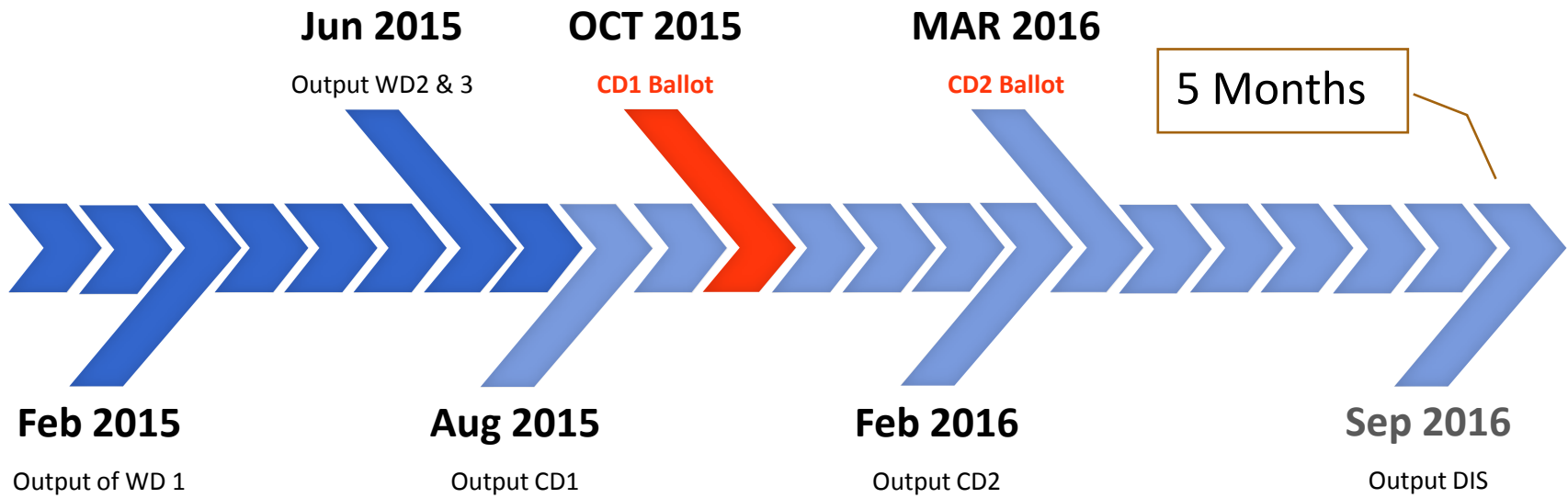


-  20 Preparatory
-  30 Committee
-  40 Inquiry
-  50 Approval
-  Transition Event

Working group 44 – CD1

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

Timeline



Translation

DEC 2016

DIS Ballot

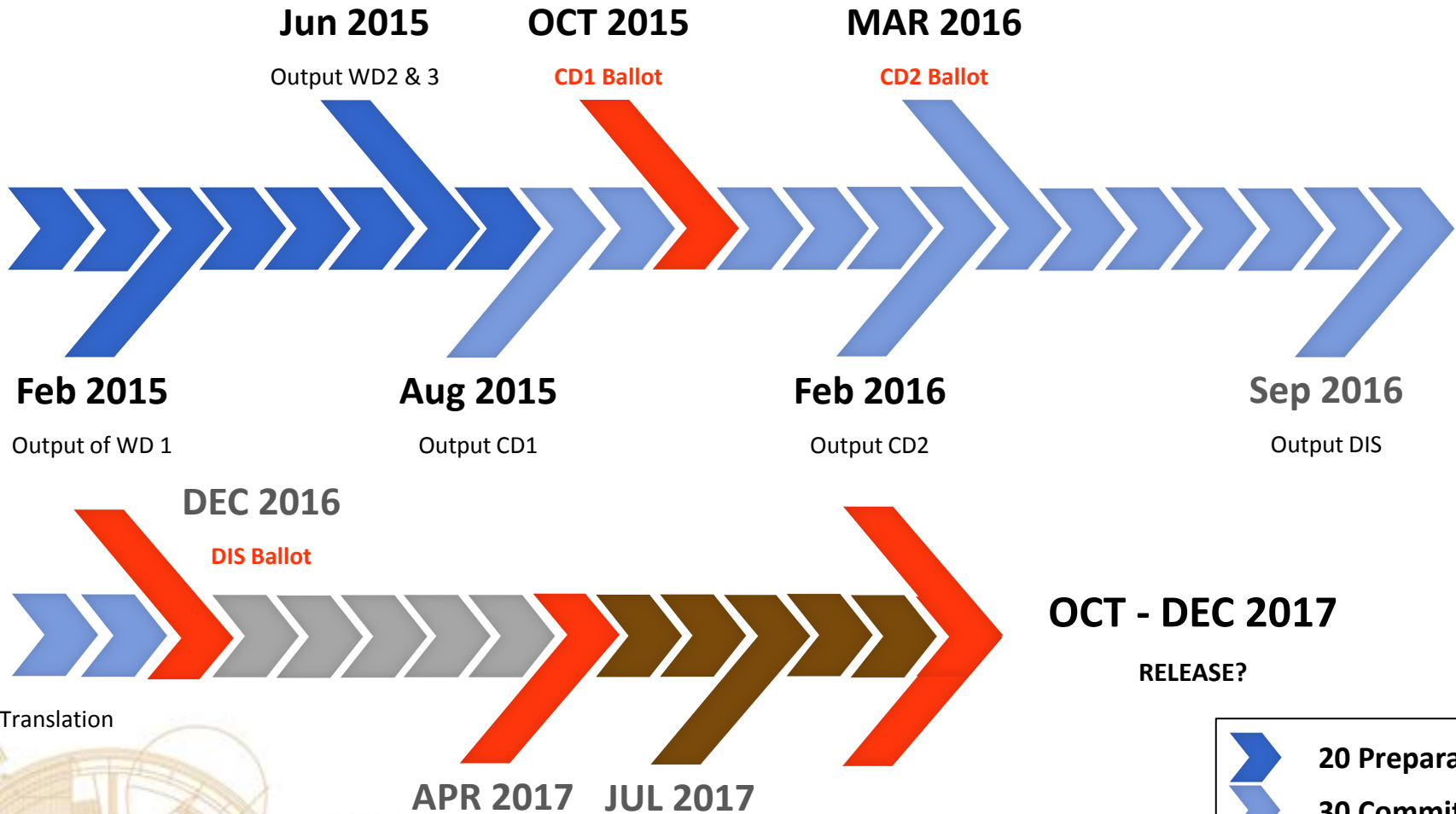
-  20 Preparatory
-  30 Committee
-  40 Inquiry
-  50 Approval
-  Transition Event

5/10/2016

Working group 44 – CD2

- CD2 Ballot Results – 2300 comments
 - 89 members cast a vote:
 - Yes - 35 members
 - Yes, with comments - 46 members
 - No - 3 members (Chile, Germany and Japan)
 - Abstain - 5 members

Timeline



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

5/10/2016

Overview of major changes

- Mandatory changes by CPC
- Structure (CASCO)
- Quality requirements fully aligned with ISO 9001
 - Option A:
ISO 17025:2005 Clause 4 management requirements
 - Option B:
Companies who are registered/certified to ISO 9001 are exempted from implementing another management system to conform to ISO 17025
- Other changes
 - Philosophical
 - Definitions
 - Structural
 - Resources
 - Processes

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

5/10/2016

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

17025:201X

- 1 Scope
- 2 Normative references
- 3 Terms and definitions

- 4 General requirements
- 5 Structural requirements
- 6 Resource requirements
- 7 Process requirements
- 8 Management requirements

- Annex A – Metrological traceability
- Annex B – Management system
- 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 Responsible for activities
- 5.4 Defined range of activities
- 5.5 Authority and resource availability
- 5.6 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 External products and services (4.6)
- 6.6 Metrological traceability (5.6)

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 Analysis of results (NEW) (5.10.4.2)
- 7.8 Quality control (5.9)
- 7.9 Reporting of results (5.10)
- 7.10 Complaints (4.8)
- 7.11 Nonconforming work (4.9)
- 7.12 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 – 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)

Philosophical changes

➤ ISO 9001 Principles

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

Philosophical changes

➤ Vocabulary:

- “shall” – Requirement
- “should” – Recommendation
- “may” – Permission
- “can” – Possibility / Capability

➤ Notes

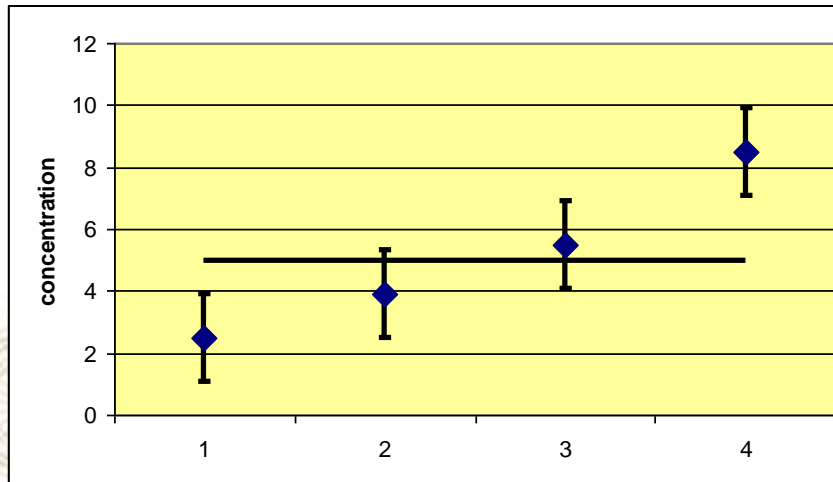
- If the NOTE did not provide value it was removed otherwise it was moved to a requirement

Changes – Definitions

- 3.8 working standard (**new**) ISO/TR 16015:2003, 3.4.2
 - also called check standard,
 - only used in 7.8.1d
- 3.9 laboratory (**new**)
 - body that performs one or more of the following activities:
 - calibration
 - testing
 - sampling, associated with subsequent calibration and testing

Changes – Definitions

- 3.10 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"
 - 7.7: Documenting decision rules for the analysis of results
 - 7.9.5: Reporting statements of conformity



5/10/2016

Changes – Resources

- Personnel (6.2)
 - Define and document competency requirements

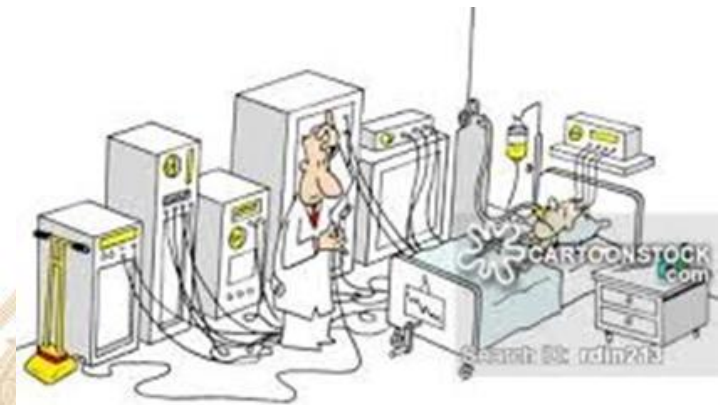


**We have highly educated and
extremely reliable personnel**

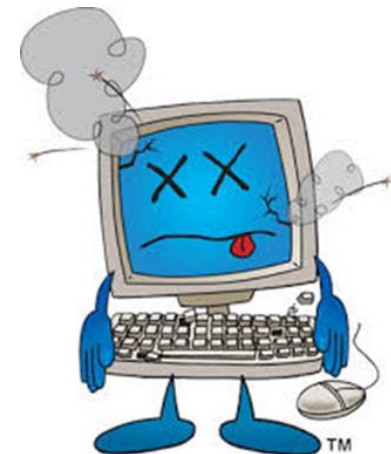
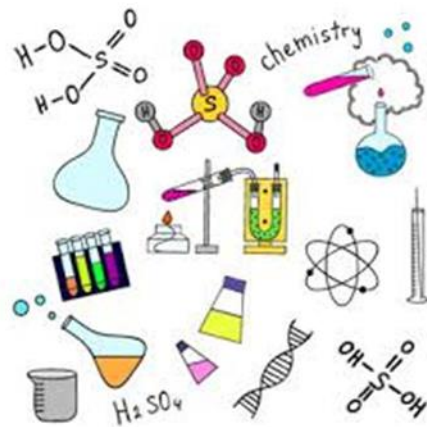
Changes – Resources

➤ 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**

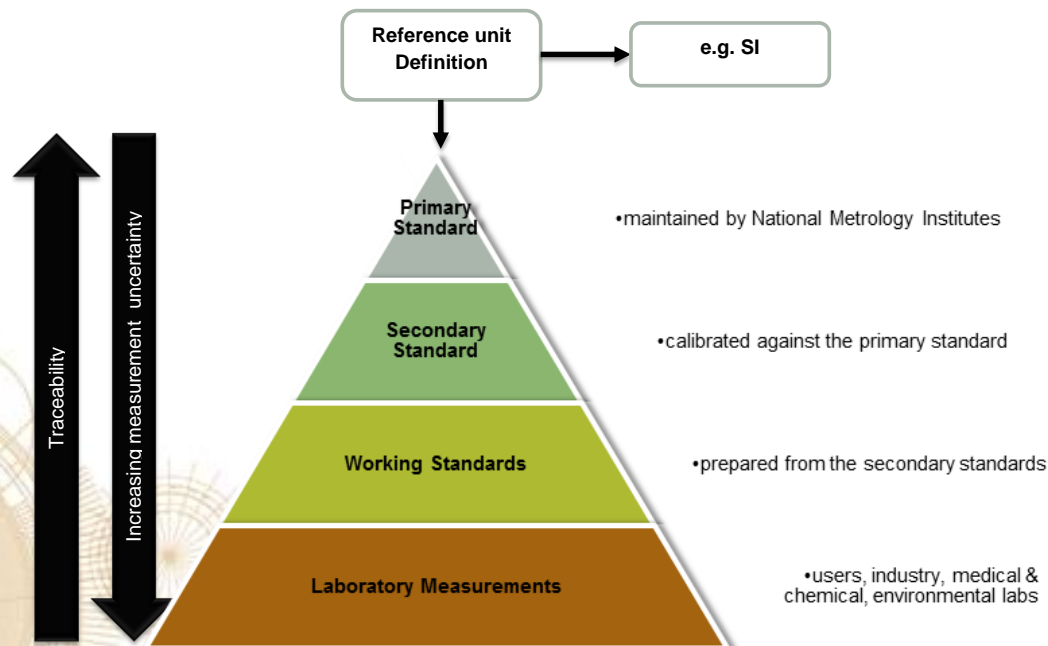


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Changes – Resources

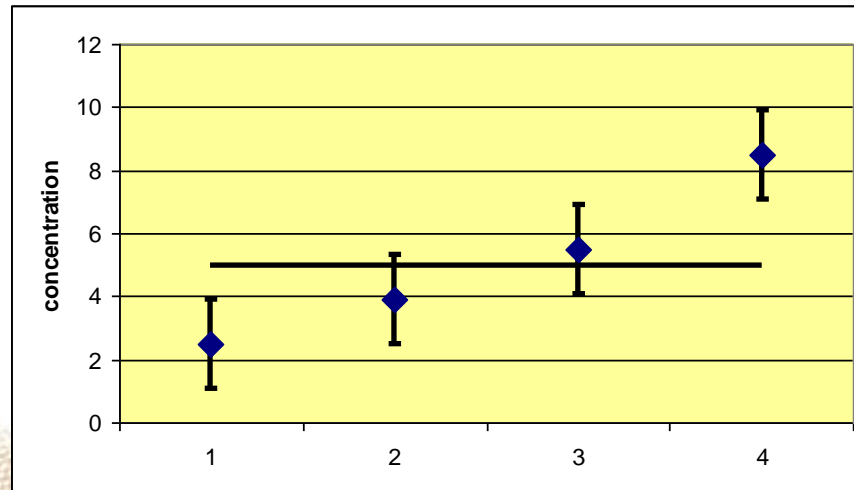
- Externally provided products and services (6.5)
 - Adopted and modified ISO 9001:2015 content
 - Include calibration and testing services
- Metrological traceability (6.6)
 - Clarified and moved much of 2005 content to Annex A



5/10/2016

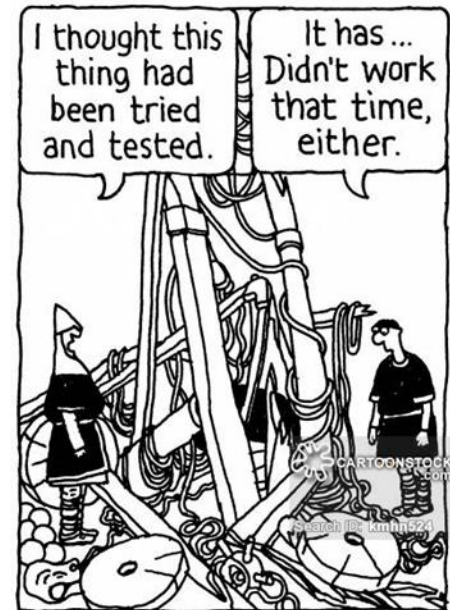
Changes – Processes

- Analysis of results (7.7)
 - Documented decision rules
 - Definition (3.10)
 - Decision rules and contracts (7.1.1.3)
 - Reference (ISO/IEC Guide 98-4 and JCGM 106)



Changes – Processes

- Quality Assurance (7.8)
 - 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 (7.9)
 - Common requirements (7.9.2)
 - Date of performance of the test
 - Date of issuance of the report
 - Measurement uncertainty
 - Same unit or relative units (%) (7.9.4.1)
 - Statements of Conformity (7.9.5.1) – identified to a
 - Specific result, and
 - Clause of the specification (7.9.5.1)
 - Amendments (7.9.6)
 - 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



Summary

- Structure and mandatory changes
- Quality requirements fully aligned with ISO 9001
- Results analysis and reporting: clarification and documentation
- Management requirements
 - Option A
 - Option B
- 3 years timeframe to comply



Thank You

