INTRODUCTION TO ISO/IEC 17025:2017 ~ transition

OVERVIEW OF CHANGES

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Module 2 – Overview of Changes

Main changes

1. the risk based thinking applied and has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;
2. greater flexibility in the requirements for processes, procedures, documented information and organizational responsibilities;
3. a definition of “laboratory” has been added

Major changes

1. Mandatory changes by CPC
2. Structure (CASCO)
3. 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/IEC 17025
4. Other changes
   - Philosophical
   - Definitions
   - Structural
   - Resources
   - Processes

The Basic Format

- **Similar to other new standards**
  e.g., ISO/IEC 17020 and ISO/IEC 17065.
- **Will be aligned to ISO 9001:2015 principles on resources and process.**
- **Follows the new ISO 9001 philosophy**
  - **Requires less documented procedures and policies**
  - **Focuses more on the outcomes of a process.**
    - **Example: no longer required to maintain a current job description (2005 – 5.2.4) but focuses on communicating to each person their duties, responsibilities and authorities (FDIS – 6.2.4)**

1. CPC* Mandatory changes

- Mandatory changes
  - Impartiality
    - General (4.1)
    - Resource (6.2)
  - Confidentiality
    - General (4.2)
  - Complaints
    - Process (7.9)
  - Management system (8)
    - Option A : ISO 17025:2005 clause4
    - 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

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**

Impartiality (4.1)

- Safeguard against lack of…
- Establish structure
- Mitigate pressures
- Identify & manage risks (on-going basis)

Confidentiality (4.2)

- Legally enforceable commitment
- Inform customer of if public exposure of information
- 3rd party communication requirement

Complaints (7.9)

- Documented process to receive, evaluate and make decisions
- Description of the handling process available to any interested party
- Acknowledge receipt, provide progress reports and the outcome

2. Structure

17025:2005	17025:2017
1 Scope	1 Scope
2 Normative References	2 Normative References
3 Terms & Definitions	3 Terms & Definitions
4 Management Requirements 5 Technical Requirements	4 General 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 option
Bibliography	Bibliography

2. Structure

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 PIC of management system 6.7 Communication and integrity
6. Resource Requirements	6.1 General 6.2 Personnel (5.2) 6.3 Facilities and environment condition (5.3) 6.4 Equipment (5.5) 6.5 Metrological traceability (5.6) 6.6 Externally provided products and services (4.6)

2 . Structure

7 Process Requirements	7.1 Review of RTC (4.4) 7.2 Selection, verification and validation of methods (5.4) 7.3 Sampling (5.7) 7.4 Handling of test or calibration items (5.8) 7.5 Technical records (4.13) 7.6 Evaluation of MU (5.4.6) 7.7 Ensuring the validity of results (Quality control (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 and information management (4.13)

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)**

3. Other changes - Philosophical changes

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

Risk management

- Requires the laboratory to plan and implement actions to address risks and opportunities.
  - Establishes a basis for:
    - increasing the effectiveness of the quality management system,
    - achieving improved results and
    - preventing negative effects.
- The laboratory is responsible for deciding which risks and opportunities need to be addressed

What Does this Mean for You?

Identify — What can happen, when, where why and how.

Assess — Determine existing controls, determine likelihood and consequences leading to estimate level of risk.

Evaluate — Compare against criteria, Identify and weigh options,

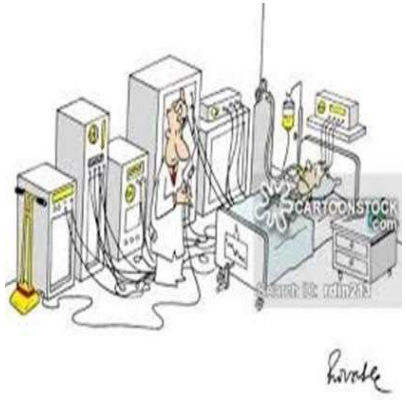
Control & Monitor — Decide on response and establish priorities. Mitigate by modify process, document outcomes

3. Other changes - 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

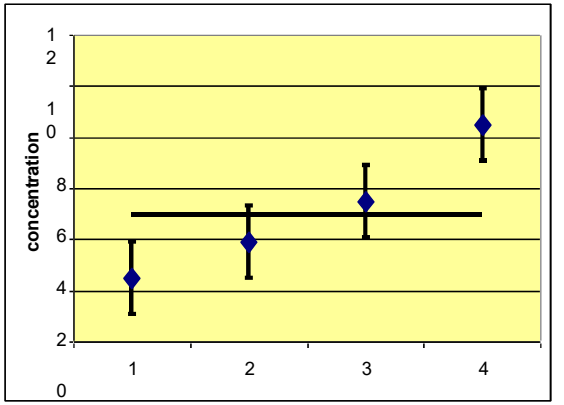
3. Other changes - Definitions

- 3.6 laboratory (new)
  - body that performs one or more of the following activities:
    - testing
    - calibration
    - sampling, associated with subsequent testing and calibration



3.7 decision rule (new)

- Documented rule that describes how measurement uncertainty will be accounted for when stating conformity with specified requirement
  - ISO Guide 98/4, 3.3.12: Modified, added "in statements of compliance"
  - 7.1.3 : Documenting decision rules for the analysis of results
  - 7.8.6: Reporting statements of conformity

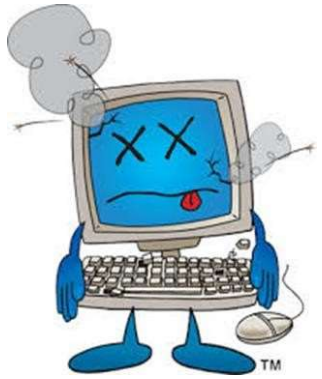


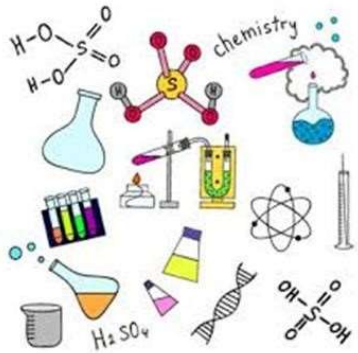
- **Personnel (6.2)**
  - **Define and document competency requirements**

We have highly educated and extremely reliable personnel

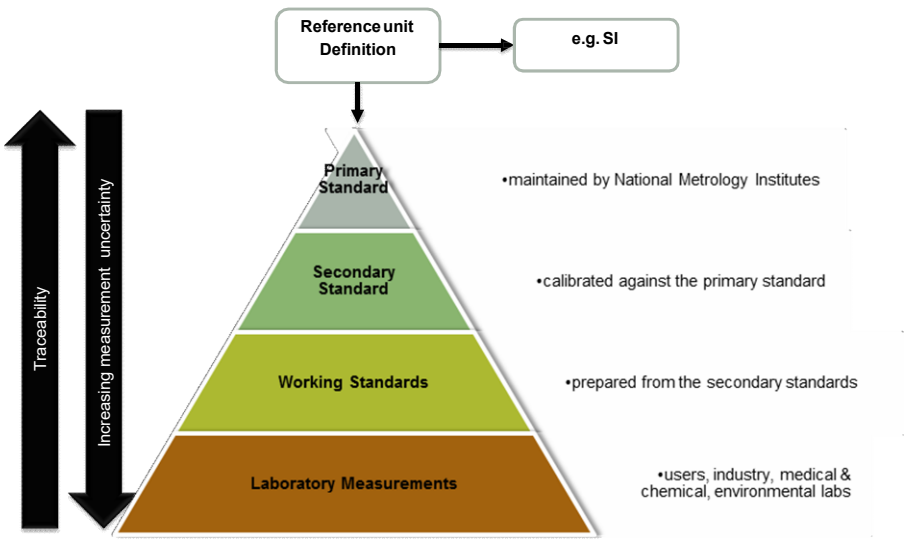
3. Other changes - Resources

- 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



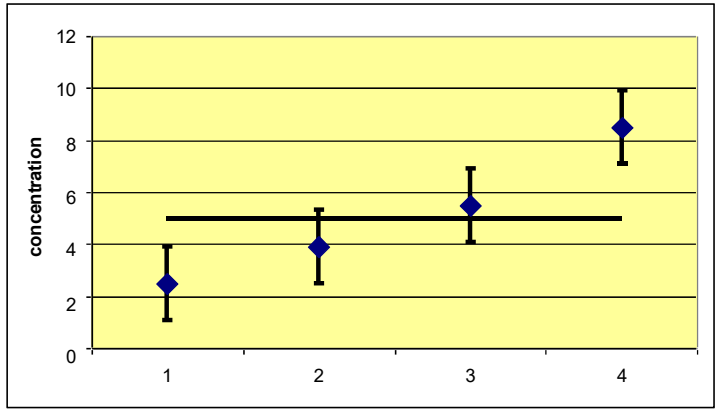


3. Other changes - Resources



- 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

- Reporting of results (7.8)
  - Documented decision rules
  - Decision rules and contracts (7.1.3)
  - Reference (ISO/IEC Guide 98-4 and JCGM 106)



3. Other changes - Processes

- Ensuring the validity of result /Quality Assurance (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

3. Other changes - Processes

- Reporting the results (7.8)
  - Common requirements (7.8.2)
    - Date of performance of the test (7.8.2.1i)
    - Date of issuance of the report (7.8.2.1j)
  - Measurement uncertainty
    - Same unit or relative units (%) (7.8.4.1)
  - Statements of Conformity (7.8.6.1) – identified to a
    - Specific result, and
    - Clause of the specification (7.8.6.2)
  - Amendments (7.8.8)
    - Changes shall be clearly identified

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 17025directly)

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

Summary of the deadlines

Date	Item	Remark
1 January 2018	All new applications submitted after 1 January 2018 will be assessed using ISO/IEC 17025:2017	Applicable to new applicants
	Accredited laboratories may request in writing for assessment transitioning to ISO/IEC 17025:2017	All accredited laboratories
1 July 2018	All existing applicants and accredited laboratories to submit Transition Plan to Standards Malaysia	All existing applicants and accredited laboratories
January 2019	Existing applicants (before 1 January 2018) and accredited laboratories shall be assessed to ISO/IEC 17025:2017	All existing applicants and accredited laboratories
30 November 2020	End of transition period	All laboratories

Documented information (laboratory document) based on ISO/IEC 17025:2017

a) Company profile and information about the laboratory including legal entity and its activities;

b) Structure/Organisation chart;

c) Policies and objectives;

d) Identified management personnel who is responsible for the laboratory's activities (name and responsibility);

e) Risk assessment analysis/report;

f) Internal audit report; and

g) Management review minutes.

TRANSITION PLAN BY LABORATORY FOR ISO/IEC 17025:2017

The laboratory shall submit this Transition Plan to Standards Malaysia by 1 July 2018.

The laboratory shall submit this Transition Plan to Standards Malaysia by **1 July 2018.**

Laboratory Name:		
SAMM No:		
Proposed date of transition: (preferably during schedule assessment)		
Processes:		**Planned Date (DD MM YYYY)**
1.	Gap analysis	
2.	Documentation updated to meet ISO/IEC 17025:2017 requirements	
3.	Implementation of the revised management system	
4.	Internal audit conducted based on ISO/IEC 17025:2017	
5.	Management review conducted based on ISO/IEC 17025:2017	
6.	Others (Please specify)	

Prepared by laboratory's authorised personnel (however named)

Name: ..... Signature: .....

Date: .....

Step for the transition…

1) Conduct a gap analysis between your current quality system and the requirements in the revised standard.
2) Decide on your timeline. Make sure the timeline fits with your reassessment schedule.
3) Update your documentation. This includes updates to existing policies and procedures as required, plus the addition of any new policies and procedures.
4) Create a training plan and a communication plan
5) Implement the new and revised policies and procedures.

Exercise 2

Refer to the note and standard, please find the answer.

Duration: 15 minutes