SIRIM STS SDN BHD –
AWARENESS ON NEW TRANSITION ISO/IEC 17025:2017

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1. Introduction
2. Major changes
3. Implementation..

Part One

INTRODUCTION TO ISO 17025 REVISION

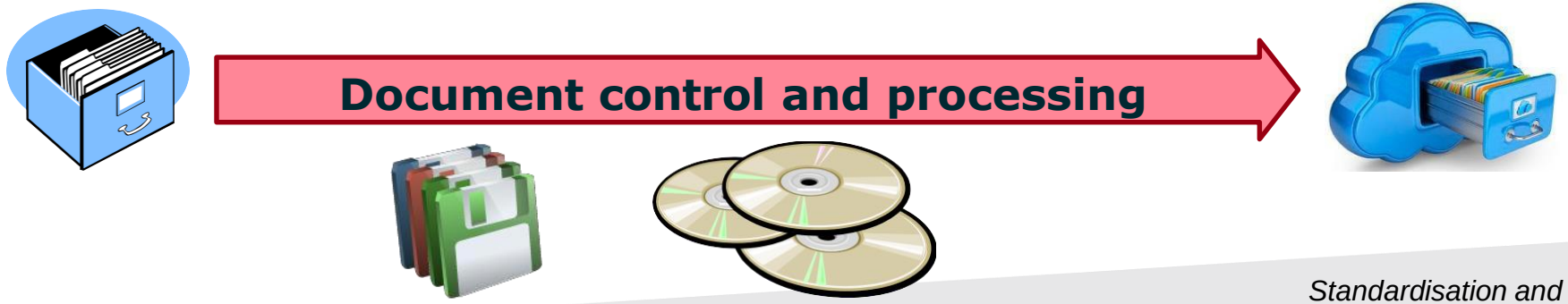
Standards' development work

- CASCO is the ISO committee that works on issues relating to conformity assessment
- CASCO develops policy and publishes standards related to conformity assessment
- It does not perform conformity assessment activities
- Membership in CASCO is open to full and correspondent members

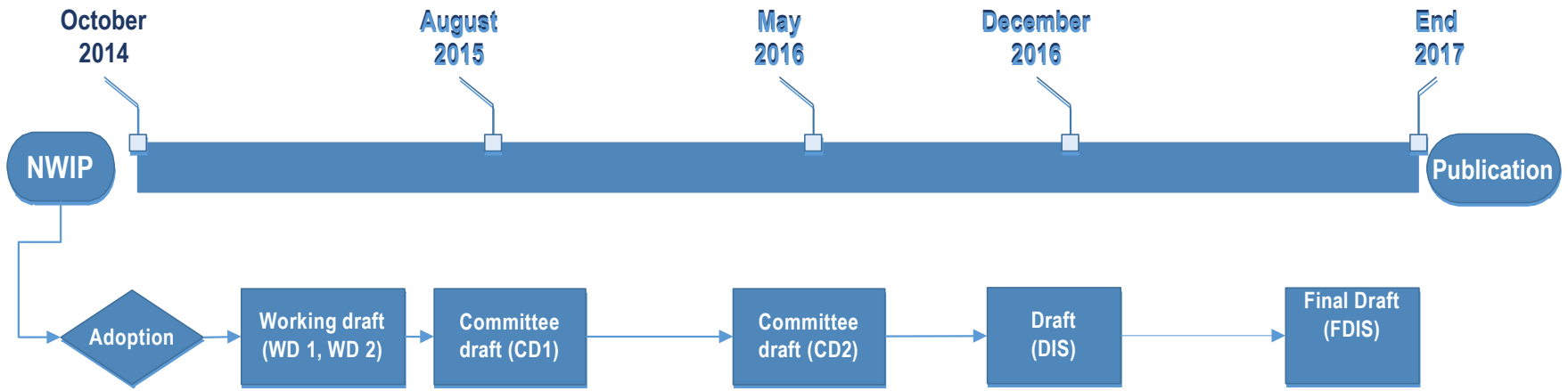
Standards for conformity assessment – The ISO CASCO Toolbox

ISO/IEC 17025 - Historical development

- Section 5 “Technical requirements” unchanged since 1999
- Have laboratories, testing and calibration laboratories changed??



ISO/IEC 17025 – Timeline of Revision

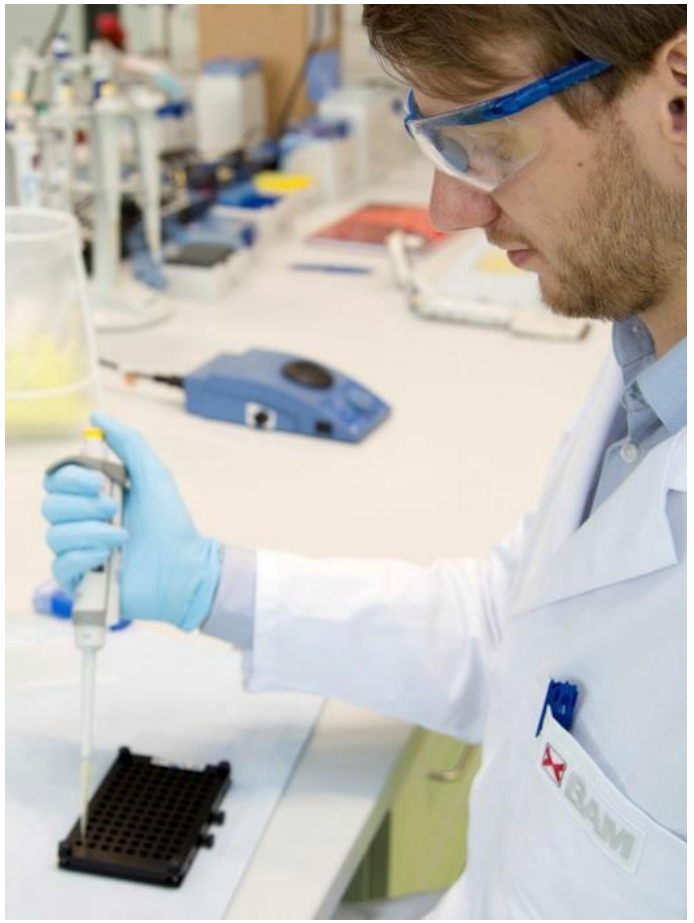


- Commenting on the 2nd Committee Draft completed internationally
- WG will prepare the publication of the DIS
- Publication of the DIS expected in Dec 2016/Jan 2017
- Total time of the revision: 36 months
- FDIS is basically optional, but probable

The old standard - Clauses in need for change

5.4	Test and calibration methods and method validation
5.5	Equipment (possibly)
5.6	Measurement traceability (Inclusion of the ILAC documents P9, P10 and P14)
5.7	Sampling
5.9	Assuring the quality of test and calibration results
5.10	Reporting the results

- ISO/IEC 17025:2005 was obsolete (structure and terminology)
- Revision of ISO 9001 (compatibility is important)
- Accreditors wanted an early revision



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Reminder of the principles

ISO/IEC 17025 is the international standard used to accredit the competence of testing and calibration laboratories worldwide.

Such competence is taken to be assured by the presence of certain features in the laboratory and its organisation:

1. Ability technically to get a valid result. This involves people, knowledge, equipment, supplies and process.

"getting it right"

2. A system to ensure impartiality, consistency, reliability

"once right……always right"

Applying the principles

These principles have applied to the various earlier versions of the Standard but were described in a more prescriptive way.

Now in the 2017 version, the laboratory is left to decide how to achieve any requirement, expressed more in the form of a required outcome. All based on anticipated/perceived risk and opportunity.

Examples:

"Job Descriptions" is now "staff shall be aware of their responsibilities"

"Quality Manual", "procedures" are now "necessary documented information".

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Other Changes

In rewriting the Standard ISO 17025 new revision are tried also to:

- **modernize it to remove references to paper; and**
- **ensure it catered for electronic data presentation, transmission, storage etc.; and**
- **be relatively future-proof.**

There are very few technical changes to the requirements to be met by the laboratories. Where changes have been made, Standard ISO 17025 have included elements from documents previously written to offer interpretation.
For example, in traceability and in decision rules.

In appearance, the biggest change is that of the structure of the document.Completely different!

Why Restructure 17025?

Experience with industry has shown a need for compatibility with ISO 9001 and related Standards.

This needs to apply both ways round, i.e.:

- **A lab using 17025 needs to be considered as suitable as a 9001 contractor and should not need both.**
- **An organisation with 9001 should be able to add the technical requirements of 17025 to their existing system and be considered as an ISO 17025 lab.**

Management System Options

Option A – Using ISO 17025 directly, as before

Option B – Using ISO 9001 but ensuring that the MS meets the technical needs of 17025

The difference? Not a lot, as the new 17025 has largely been aligned with 9001 for requirements and terms

Accreditation Body (AB) assess that the system covers the 17025 requirements

The new structure

For a laboratory, in line with the other 17000 series standards:

Structure: "What it looks like"

Resource: "What it needs to have"

Process: "What it needs to do"

Some mandatory text (esp. Options A and B)

Headlines of Changes

Option to allow ISO 9001 Management System:

- needs to cover 17025 technical clauses

Risks and Opportunities to be considered:

- measures necessary in a given lab, therefore it is vary

Decision Rules; any sensible ones to be agreed:

- risks of false accept, etc
- reporting of decision rule used

Other Changes

Emphasis on Impartiality (measures) vs Independence (innate).

“Scoping” of Laboratory activities to be included in lab system to describe boundaries of covered activity.

2nd person for complaint handling (small labs).

Traceability possible from conformity certificates.

Glance through the Standard

Foreword

Introduction

1. Scope
2. Normative references
3. Terms and definitions
4. General requirements
5. Structural requirements
6. Resource requirements
7. Process requirements
8. Management requirements (with options)

Annex A (Traceability)

Annex B (Management System Options)

Bibliography

A first pass through the new Standard

Remember, there are very few technical changes, these are mainly more philosophical to modernise and introduce Risk and Opportunity.

The structure is similar to 17020 and 17065.

Many of the same clauses as in 2005, but could not express if they are Structural, Resource or Process?

A Revised Definition

Definition of Laboratory:

3.6 “Laboratory:

A body that performs one or more of the following activities:

Calibration;

Testing;

Sampling; associated with subsequent calibration and testing”

Another Definition

Definition of Decision Rule:

3.7 “rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement”

4.1 Impartiality

There are no references to independence.
Impartiality considerations shall be ongoing.

4.1.4
“the laboratory shall identify risks to its impartiality on an on-going basis……."

- Scoping

- 5.3 "The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this ISO 17025 document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis"

6.2 Personnel

No Job Descriptions specified.

"6.2.4 The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.

…but some procedures and records are mandatory.

6. Resource Requirements

6.2.5 "The laboratory shall have procedure(s) and retain records for:

a) determining the competence requirements;
b) selection of personnel;
c) training of personnel;
d) supervision of personnel;
e) authorization of personnel;
f) monitoring competence of personnel."

and some explicit authorisations are mandatory.

6. Resource Requirements

6.2.6 "The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

a) development, modification, verification and validation of methods;
b) analysis of results, including statements of conformity or opinions and interpretations;
c) report, review and authorization of results."

6. Resource Requirements

Traceability 6.5 has unchanged intention, but is clearer.
See also Annexe A.

Effectively allows “the three ways” but presumes competence for those sources complying with 17025 Calibration and 17034 CRM

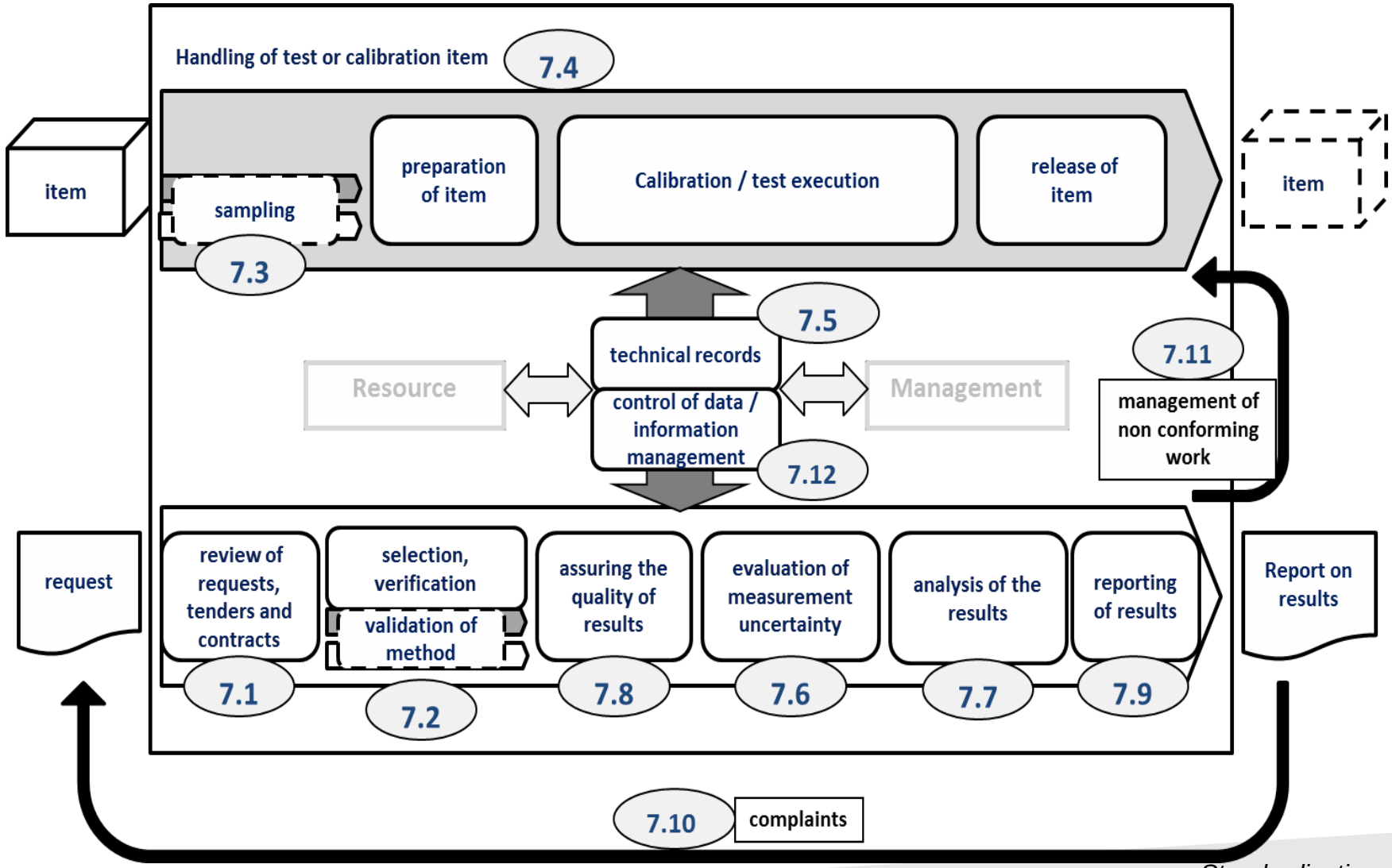
6. Resource Requirements

There are no significant changes about subcontractors and external supplies, but the wording is quite different

"6.6 Externally provided products and services"

A requirement to inform and agree with the client is when laboratory activity is conducted by an external body is elsewhere, in 7.1.1 c)

The Process Approach



7. Process Requirements

- Review of Requests (Contract Review) largely unchanged. The lab may have to divulge the identity of an external supplier

- “7.1.1c) c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval

7. Process Requirements

- The clause on Decision Rules (Pass/Fail Criteria) is much clearer now and obviates the need for ILAC to specify a method as in ILAC G8.

- There are clearly choices to make and agree with clients, so suggestions and examples will be useful in new guidance documents

7. Process Requirements

- 7.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in- tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.

7. Process Requirements

- 7.1.4 Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.

7. Process Requirements

- 7.7.2 The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:

a) participation in proficiency testing;

b) participation in interlaboratory comparisons

- other than proficiency testing.

7. Process Requirements

- Three pages of reporting requirements in the new Standard, split into Common, Testing, Calibration and Sampling, but….

- 7.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.

- and when sampling is involved….

- 7.8.3.2 Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5

- …with a similar clause for calibration

7. Process Requirements

- On Sampling (Only?) Reports

- 7.8.5 f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

7. Process Requirements

- Complaints
- Note that there is a detailed section on complaint handling and a complaint is defined as:

- 3.2 Complaint
- expression of dissatisfaction by any person or organization to a laboratory (3.6), relating to the activities or results of that laboratory, where a response is expected

7. Process Requirements

- Complaints
- Now lab need a 2nd person to handle a complaint

- 7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.
- NOTE This can be performed by external
- personnel.

- 8.1 Options All labs:
- 8.1.1 General
- The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results.

8. Management System Requirements

- 8.1 Options
- 8.1.1 General
- “In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B”
- Option A Using Section 8 in the Standard Option B Using ISO 9001

- 8.1.2 Option A
- Section 8 in the Standard
- A list of minimum features, mainly as before in 2005, with useful detail. Note that it now includes....

- — actions to address risks and opportunities

8. Management System Requirements

- Option B using ISO 9001
- “8.1.3 Option B
- A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.”

17025 vs 9001: …why having 17025?

From Annexe B

"Conformity of the management system within which the laboratory operates to the requirements of *ISO 9001 does not of itself demonstrate the competence of the laboratory* to produce technically valid data and results. This is accomplished through compliance with clauses 4 to 7 of ISO/IEC 17025."

Part Two

The main changes

1. Risk and Opportunity

A look at Risk and Opportunity

From the Foreword:

—the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;

—there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities;

Risk and Opportunity

From the Introduction:

This document requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects.
The laboratory is responsible for deciding which risks and opportunities need to be addressed

Risk and Opportunity

There is mention of risk throughout the Standard and the section on Impartiality as an example:

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel…..

Risk and Opportunity

And..

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk

This type of consideration applies to most lab features and to everything it does.

Risk based approach - The General Case

A risk based approach to management system implementation is one in which the breadth and depth of the implementation of particular clauses is varied to best suit the perceived risk involved for the particular laboratory

Less Prescriptive More Consideration

ISO 17025:2005

- Lab shall have policies and procedures to ensure protection of confidential information… including electronic storage and transmission of results

ISO 17025:2017

- The lab shall ensure the protection of confidential information…. including electronic storage and transmission of results

The relaxation of prescription makes it essential for each lab to consider the risk for each clause:

1. **To discuss and agree what measures are required**
2. **To implement that in a known and controlled way for consistency**
3. **To keep under review**

Risk for a given clause

- **How likely that a given area of compliance might lead to problems, ie non-compliance with the Standard**

Taking into account, the circumstances of the body, like:

- **Technical nature of the work**
- **Cultural setting**
- **Ownership**
- **Customer base**
- **Geographics and Environment**
- **Employees**

Impartiality and Risk

❖ The requirement for impartiality is a good **example** of where the risk and measures necessary do vary greatly between laboratories.

- **A privately owned independent lab, with many customers, where the owner has no other activities or ownerships is unlikely to need extensive measures to protect impartiality.**
- **Consider alternatively:**
  - **A lab with only one customer**
  - **A lab where the owner owns some customers**
  - **A lab of a manufacturer also taking on third party work**
  - **A lab with minimum wage-staff in a culture known for corruption**
  - **A lab where its ownership is complex and keeps changing as does that of related bodies**

A Technical Example

- **6.4.10** When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.

- **The complexity of this varies according to risk. A gauge block used as a reference may need little by way of intermediate checks but a sensitive electronic item exhibiting drift may need frequent checks, plotting and calculation from comparisons resulting in a drifting reference value being derived.**

- **All according to risk; similarly with calibration intervals**

This philosophy is not new!

- **It has always been a requirement to take appropriate steps but a tendency to compare activities in dissimilar risk laboratories lead to some difficulties. Accreditation Bodies were criticised for "requiring" activities in some labs but not in others.**

- **Now it is quite clear that the extent of activity to comply with a particular clause will vary and it is the responsibility of the lab to achieve this appropriately.**

- **Clause 8.5 of the new 17025 describes the purpose……..**

The purpose

- **8.5.1** The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:
- a) give assurance that the management system can achieve its intended results;
- b) enhance opportunities to achieve the purpose and objectives of the laboratory;
- c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities; and
- d) achieve improvement.

The laboratory shall….

- **8.5.2** The laboratory shall plan:
- a) actions to address these risks and opportunities;
- b) how to:
  - integrate and implement the actions into its management system;
  - evaluate the effectiveness of these actions.
- **8.5.3** Actions taken to address risks and opportunities shall be proportionate to the potential impact on the validity of laboratory results.

Making risk and opportunity consideration happen

- **Ensure a culture in which risk and opportunity can be safely considered openly and honestly**
- **Provide a mechanism for all staff (whose activities can affect the output of the lab) to consider this, discuss and bring forward any ideas**
- **Agenda item on departmental meetings and reviews.**
- **Major item on Management System Review agenda**
- **Expected of all staff by their managers/top management**

Why is this a good thing?

- **Gives opportunity to be a better lab!**
- **Can reduce risk (or share it)**
- **Can provide opportunity to save effort or money**
- **Can encourage development, new techniques, quicker or easier calibrations, lower prices, higher profit, happier customers, better reputation**
- **Not all labs are the same so they should not all have the same features in their management systems**

What is not required

- **There is no expectation of adherence to Risk Management formal standards like ISO 31000 although these may make useful reading in setting up enhancements in a 17025 laboratory environment**

- **It is more expected that the features will be inherent in the normal operation of the laboratory using 17025 with the enhancements appearing in several places in the management system**

Part Two

The main changes

2. Management System Options

Management System Option A

Annex B.2;

"Option A (see 8.1.2) lists the minimum requirements for implementation of a management system in a laboratory. Care has been taken to incorporate all those requirements of ISO 9001 that are relevant to the scope of laboratory activities that are covered by the management system. **Laboratories that comply with Clauses 4 to 7 and implement Option A of Clause 8 will therefore also operate generally in accordance with the principles of ISO 9001.**"

Management System Option B

Annex B.3;

"Option B (see 8.1.3) allows laboratories to establish and maintain a management system in accordance with the requirements of ISO 9001, in a manner that supports and demonstrates the consistent fulfilment of Clauses 4 to 7. **Laboratories that implement Option B of Clause 8 will therefore also operate in accordance with ISO 9001.** "

The important clauses – Clauses 4 to 6

4 General requirements

1. Impartiality
2. Confidentiality

5 Structural requirements

6 Resource requirements

1. General
2. Personnel
3. Laboratory facilities and environmental conditions
4. Equipment
5. Metrological traceability
6. Externally provided products and services

The Important Clauses - Clause 7

7 Process requirements

1. Review of requests, tenders and contracts
2. Selection, verification and validation of methods
3. Sampling
4. Handling of test or calibration items
5. Technical records
6. Evaluation of measurement uncertainty
7. Assuring the quality of results
8. Reporting of results
9. Complaints
10. Management of nonconforming work
11. Control of data – Information management

Clause 8 offers the choice

This contains the management system requirements to be met by laboratories:

Using 17025 directly – Option A

Using 9001 – Option B

On assessment/audit(s) this might often appear as:
Lead Assessor for Clause 8
Technical Assessor for Clause 6-7
..but it is not quite as simple as that, with Clause 4-5 covered by either or both. It may be that the assessment/audit split is not by clause.

Part Two

The main changes

3. Decision Rules

Decision Rules

This is not new. Previously, in Reporting:

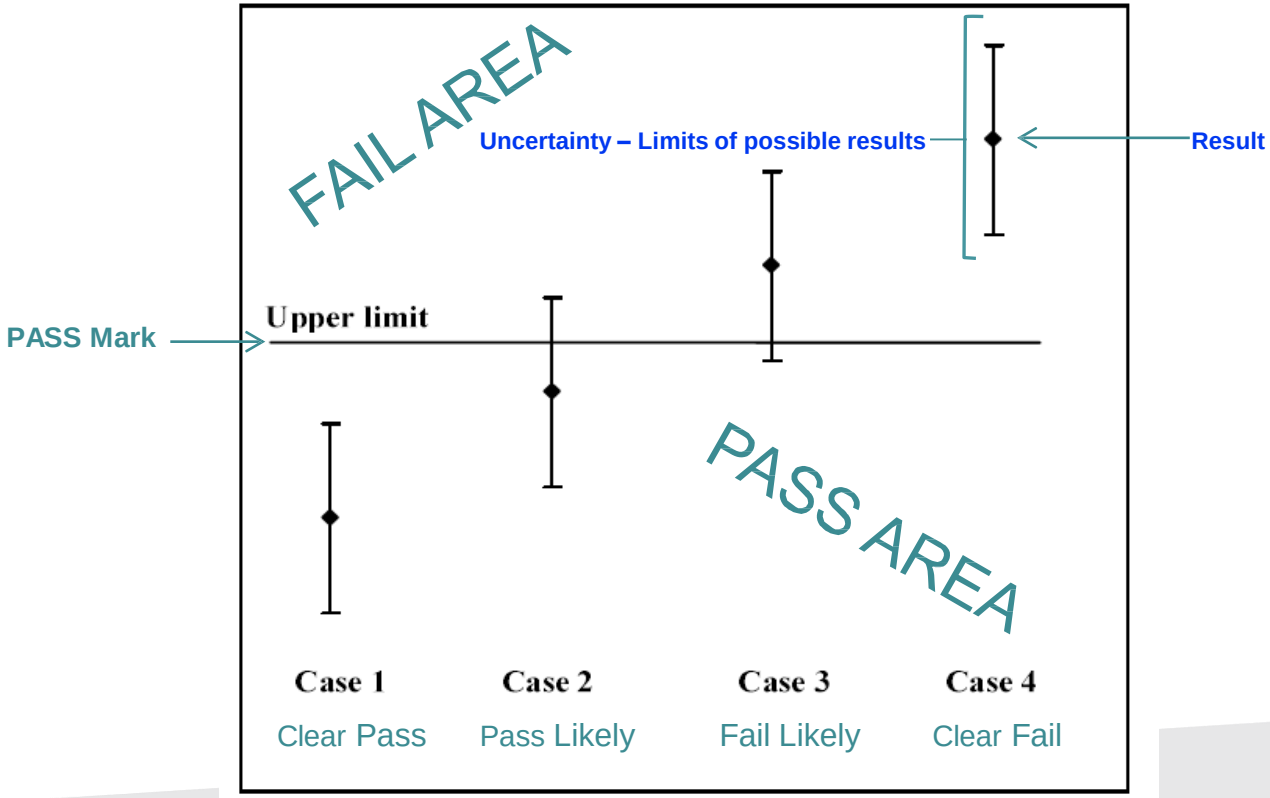
5.10.3.1 b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;

5.10.4.2 When statements of compliance are made, the uncertainty of measurement shall be taken into account.

There are many ways of doing this and potential for lack of comparability between labs.

Decision Rules (Pass/Fail Criteria)

Previously, 17025 simply stated that a statement of compliance (pass/fail) takes uncertainties into account. This was augmented by ILAC G8 suggesting that the so called ILAC model was used



Decision Rules

Specify the “decision rule” used…

7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule.

NOTE: Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

Decision Rule Choices

Taking risk level into account:

- ILAC model (default ?)
- Simple pass/fail ?
- In specification
- In legislation
- Industry expectation
- Client required
- Others, including specified risk ie % PFA

Part 3: The Transition Plan

(To those Laboratory affected)

Accreditation Body Transition Plan Summary

First, all labs will complete a readiness report assessment; a sort of gap analysis.

Sep 2017	**Development of Gap Analysis methods**
Jan 2018	**Published Standard**
Jan 2018	**Awareness Training of Staff and Related Auditors**
Mar 2018	**New Standard applications accepted**
Jan 2019	**Until then both or either assessment Jan 2019**
	From then new standard only assessed
Jun 2020	**Transition completed**
Dec 2020	**Old standard no longer valid**

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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

CONCLUSION…

- *No significant technical changes but a new philosophy.*

- *Previously 17025 requirements managed the risks, now the lab manages the risks.*

Changes in summary…

1999/2005 Standard Managed Risk	2017 Risk and Opportunity Managed
x Quality Manual	✓ Documented Info
x Policies	✓ Processes
x Procedures	✓ Decision Rules
x Job Descriptions	
x Top Mgmt	
x QM, TM	

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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.

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Key points for Transition

- All labs will be transitioned
- Labs will complete readiness gap analysis doc, first
- All labs to be transitioned by June 2020.
- 17025:2005 accreditations invalid from Dec 2020

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THANK YOU

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