

INTRODUCTION TO ISO/IEC 17025:2017 ~ transition

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Module 1 - Introduction



PROGRAMME

| TIME | DAY 1 | DAY 2 |
|--------------------|--|--|
| 0900 – 1015 | <ul style="list-style-type: none"> • Introduction and course objective • Importance of QMS in the Lab • Accreditation Process • Exercise 1 | <ul style="list-style-type: none"> • Clause 6 – Resources requirements Continue • <i>Exercise 3</i> |
| 1015 – 1030 | Morning break | |
| 1030 – 1300 | <ul style="list-style-type: none"> • ISO/IEC 17025:2017 requirements • Clause 4 – General requirements | <ul style="list-style-type: none"> • Clause 7- Process requirement |
| 1300 – 1400 | Lunch break | |
| 1400 – 1530 | <ul style="list-style-type: none"> • ISO/IEC 17025:2017 requirements • Clause 5 – Structural requirements • <i>Exercise 2</i> | <ul style="list-style-type: none"> • Clause 7- Process requirement continue • <i>Exercise 4</i> |
| 1530 – 1545 | Afternoon Break | |
| 1545 – 1700 | <ul style="list-style-type: none"> • Clause 6 – Resources requirements | <ul style="list-style-type: none"> • Clause 8 management requirements <i>Exercise 5</i> • Q & A • Course Evaluation |

Course Objectives:

1. Describe the new requirements in ISO/IEC 17025:2017
2. Describe the changes to requirements in ISO/IEC 17025:2017
3. Detail requirements of ISO/IEC 17025

ISO (International Organization for Standardization)

- 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.
- has members from 163 countries and 3 368 technical bodies which take care of standard development.



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.

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.**

Standards' development work

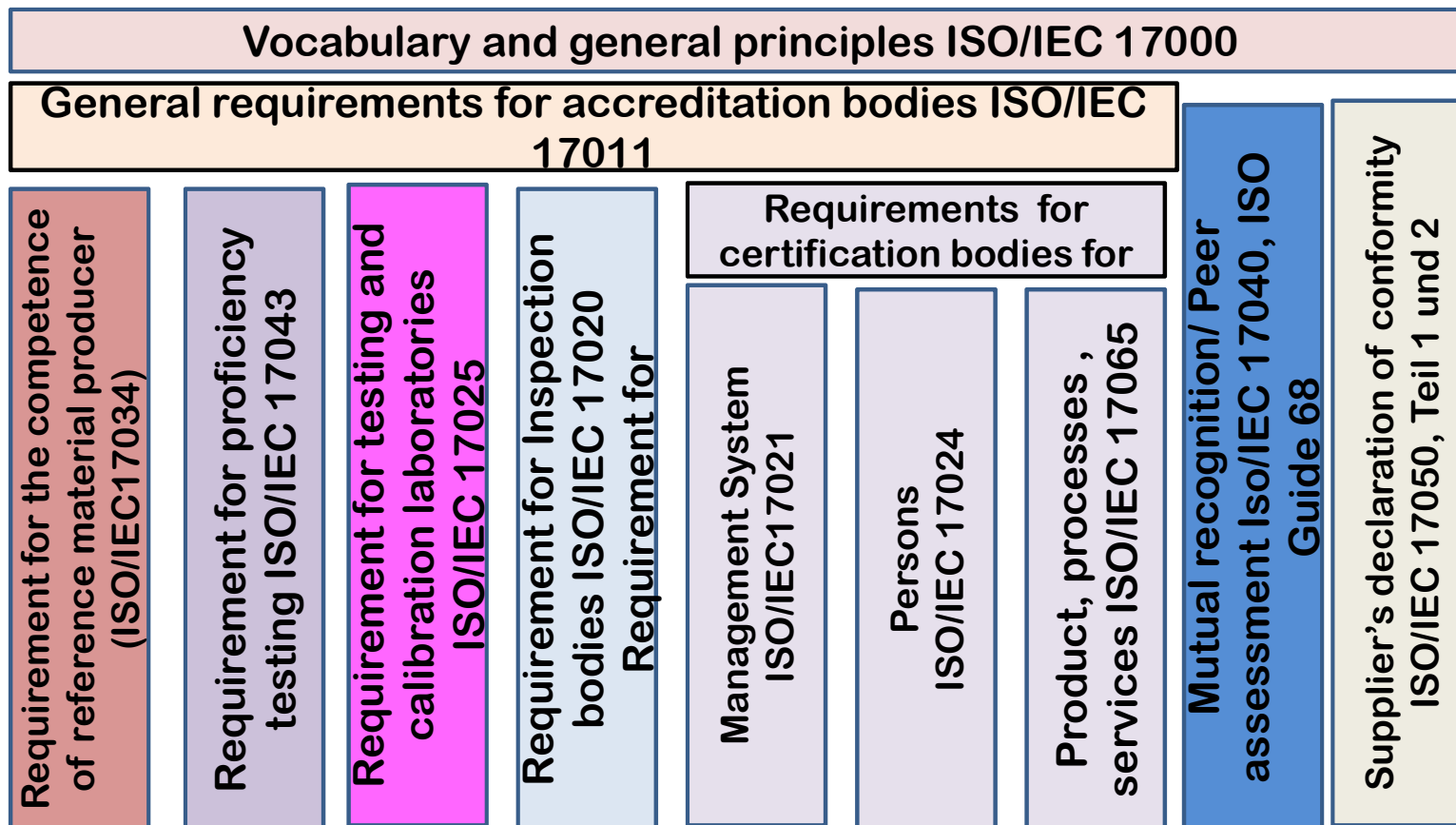


- CASCO is the ISO committee that works on issues relating to conformity assessment
- CASCO develops policy and publishes standards related to conformity assessment
- It does not perform conformity assessment activities
- Membership in CASCO is open to full and correspondent members

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.

Standards for conformity assessment - The ISO CASCO Toolbox



ACCREDITATION

“ Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment mark ”

...ISO/IEC 17011:2004

Accreditation body (AB) is the authoritative body that performs accreditation and the authority of an AB is generally derived from the government.

CERTIFICATION

- Procedure by which a third party (certification body) gives a written assurance that a product, process or service (of an organisation) conforms to specified requirements.

...ISO/IEC Guide 2:1996

- *Certification does not specifically evaluate technical competence.*
- *Certification is not appropriate for laboratories or inspection bodies.*

ACCREDITATION

Accreditation to ISO/IEC 17025 ...

- Assures the customer that the *procedures* are *technically valid*.
- Recognizes the *technical competence* of *laboratory staff*.
- Assures the customer that the *results* are *technically valid*.
- Endorses the *quality management system (QMS)*.

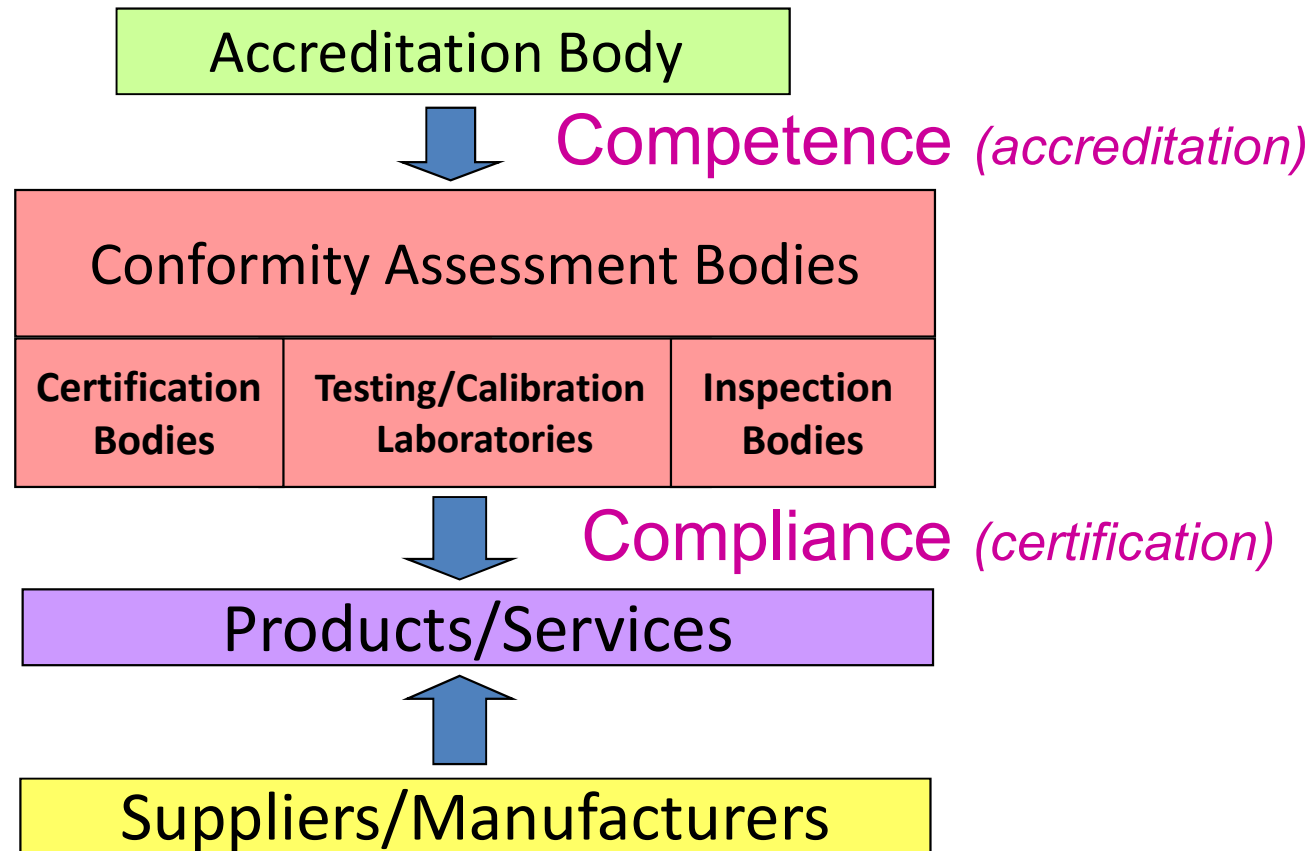
ACCREDITATION VS CERTIFICATION

CERTIFICATION = CONFORMITY

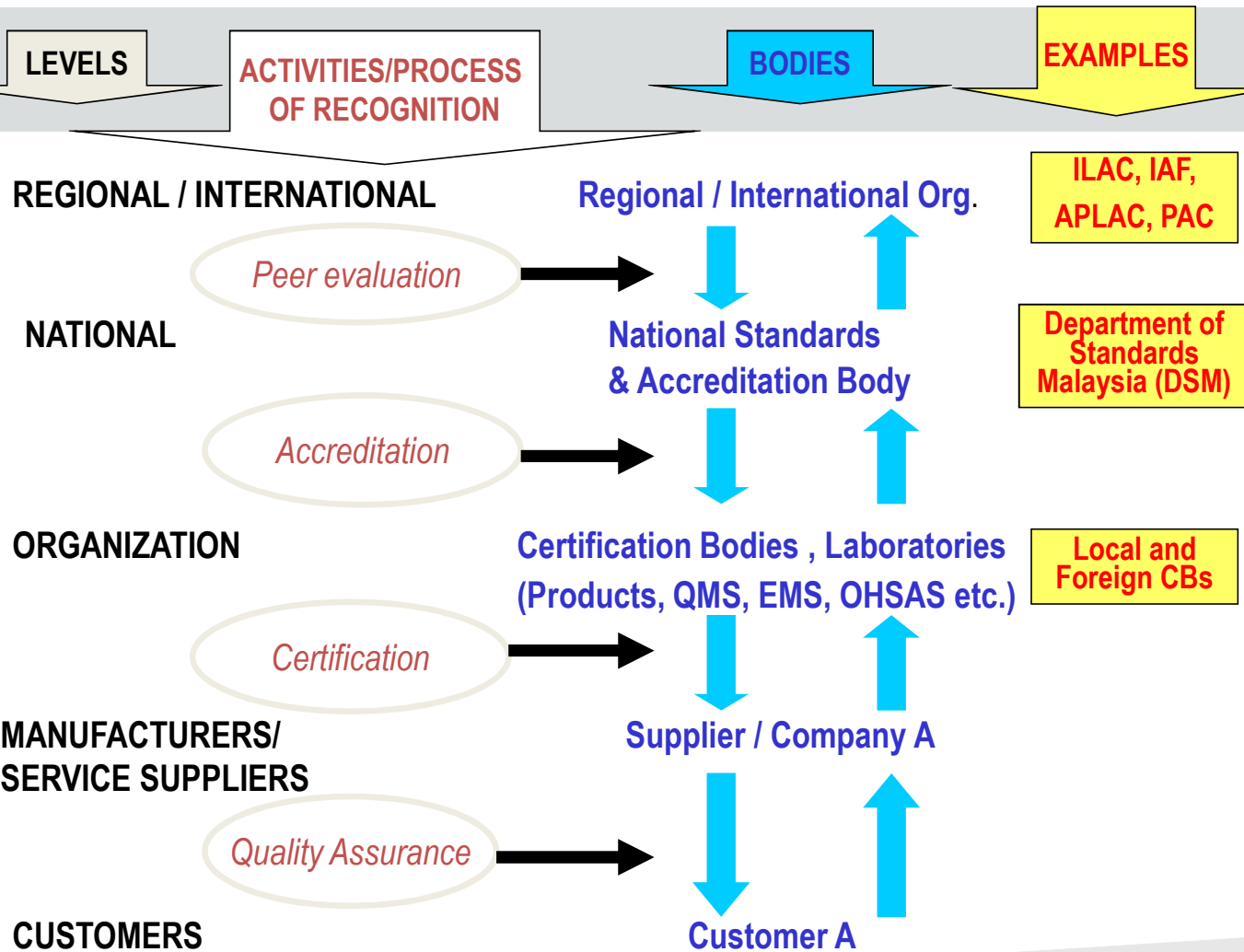
ACCREDITATION =



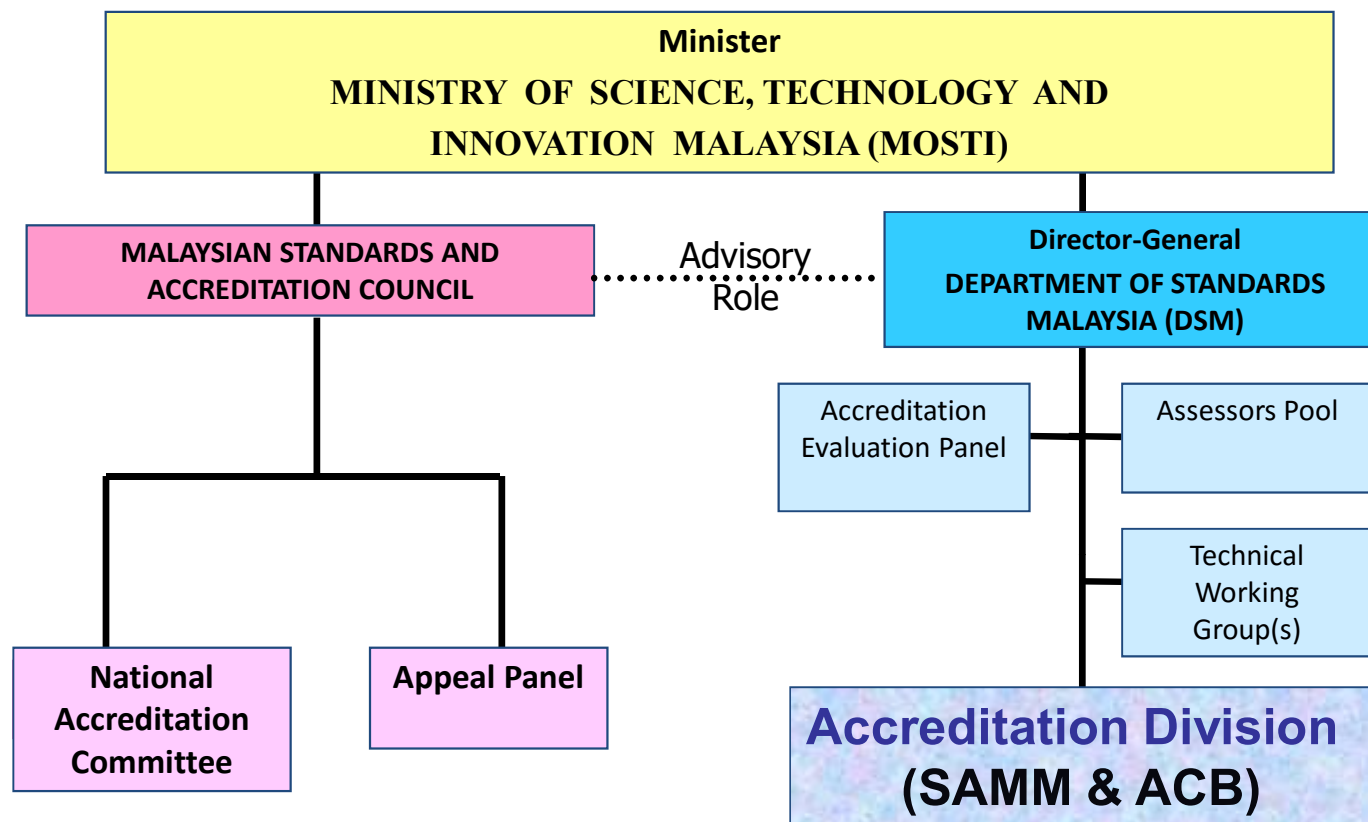
CONFORMITY ASSESSMENT



THE RECOGNITION PROCESS



MALAYSIAN STRUCTURE



Accreditation schemes



Skim Akreditasi Makmal Malaysia (SAMM) – Laboratory Accreditation Scheme of Malaysia

- Testing laboratories (non-medical)
- Calibration laboratories
- Medical testing laboratories



Accreditation of Certification Bodies (ACB) Scheme



Malaysia Inspection Bodies Accreditation Scheme (MIBAS)

MIBAS accreditation is opened to all types of inspection activities.



Standard+Training+Consultancy

Relationship between AB, CAB &
Suppliers/Manufacturer



International Organisation



Peer Evaluation -
Assess Compliance

Accreditation Body (AB)



Accreditation -
Assess Competence

Conformity Assessment Bodies (CABs)
Certification Bodies
Testing / Calibration Laboratories
Inspection Bodies



Test & calibrate sample/
specimen - Certify companies

Products / Services

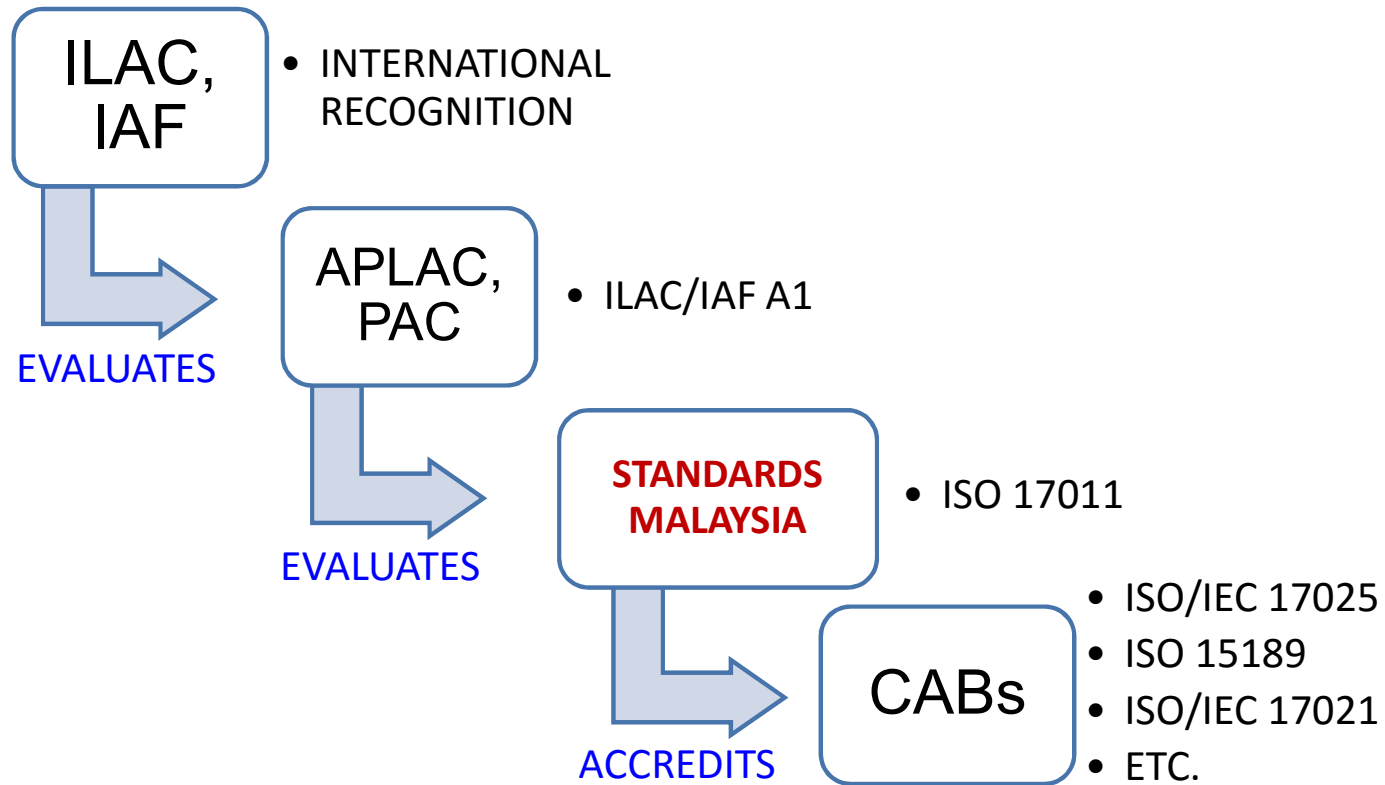


Suppliers / Manufacturers

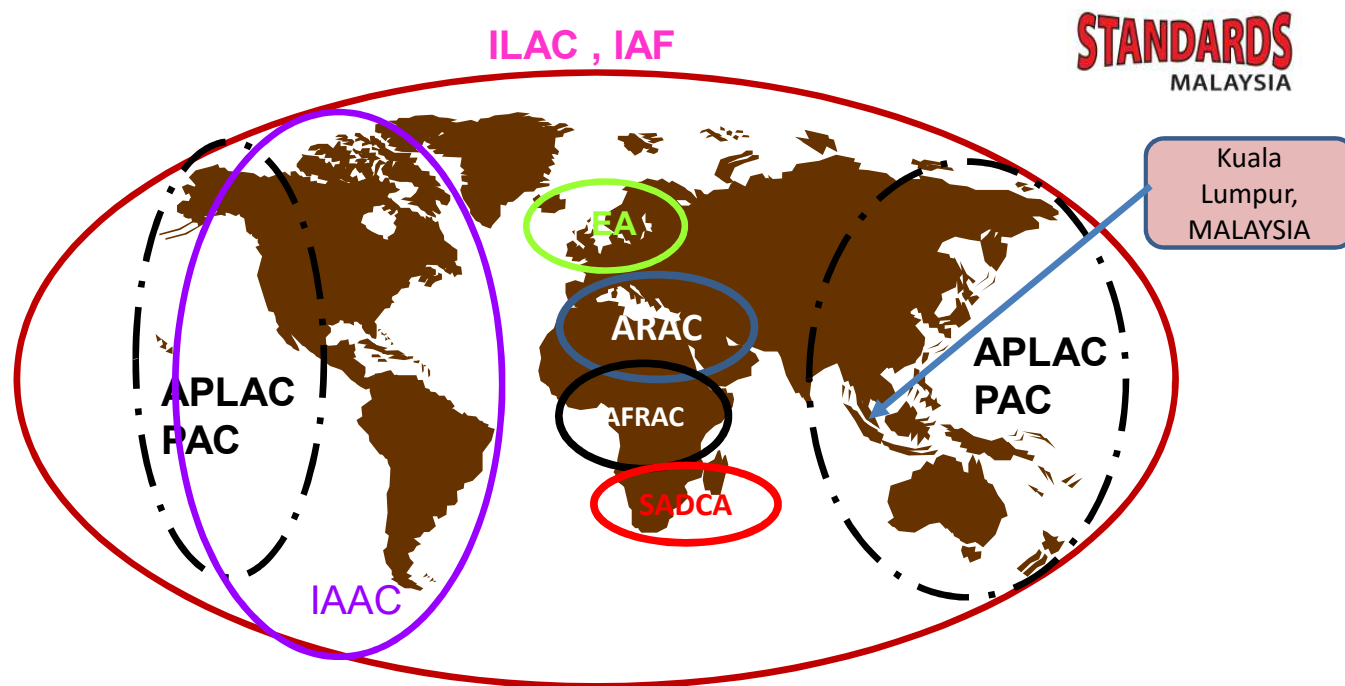


Standardisation and Competency Assured

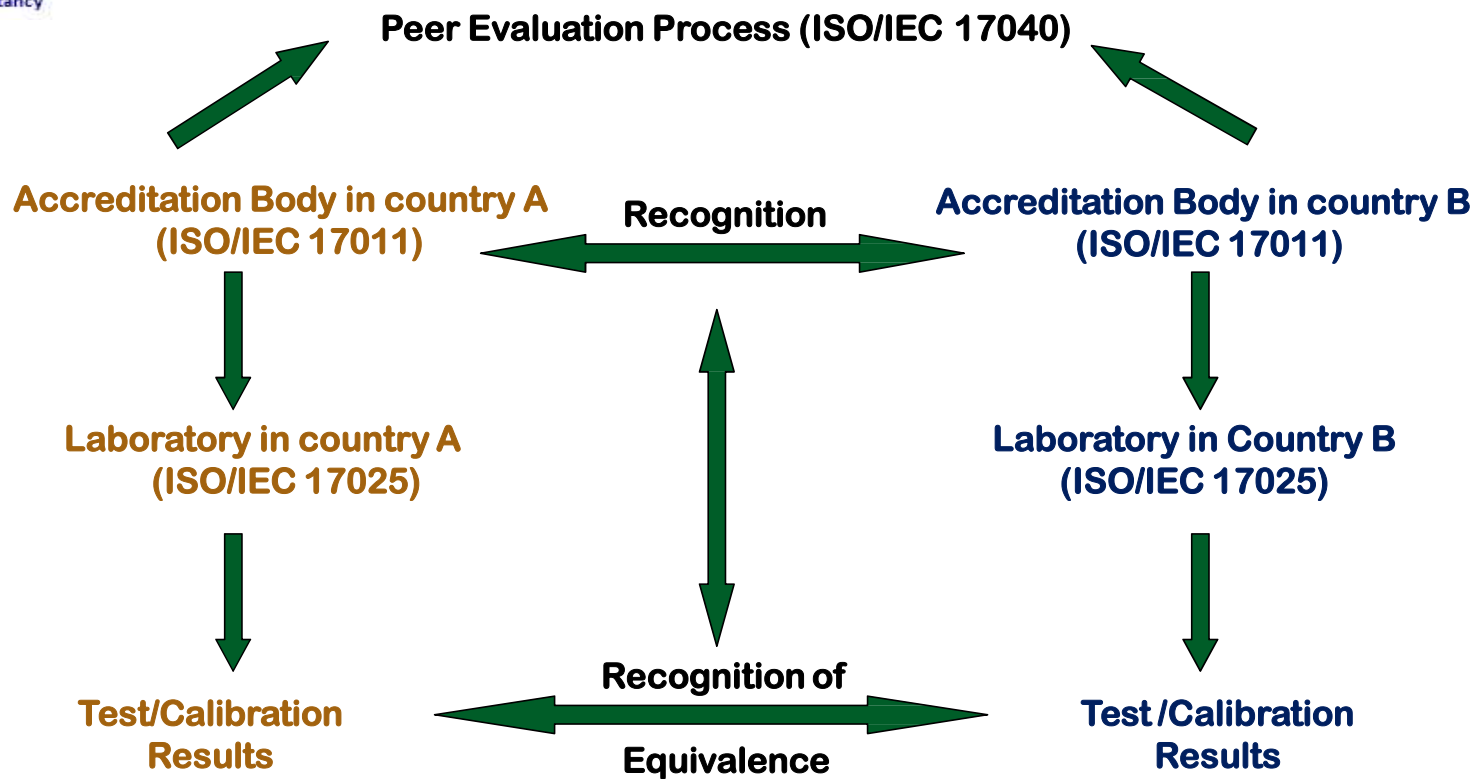
PEER EVALUATION



INTERNATIONAL MUTUAL RECOGNITION



ILAC MRA: Mutual Recognition Arrangement

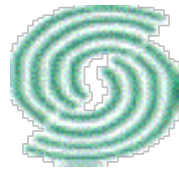


The following are the signatories of the APLAC MRA:

1. National Association of Testing Authorities (NATA), Australia



2. Standards Council of Canada (SCC), Canada



3. China National Accreditation Board for Laboratories (CNAL), People's Republic of China



4. Hong Kong Accreditation Service, Hong Kong, China



5. National Accreditation Board for Testing and Calibration Laboratories (NABL), **India**



6. Komite Akreditasi Nasional (KAN), **Indonesia**



The following are the signatories of the APLAC MRA:

7. The Japan Accreditation Board for Conformity Assessment (JAB), **Japan**



10. Korea Laboratory Accreditation Scheme (KOLAS), Republic of Korea



8. International Accreditation Japan (IAJapan), **Japan**



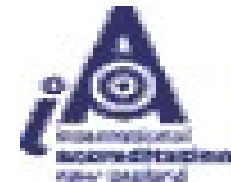
11. Department of Standards Malaysia (DSM), **Malaysia**



9. Voluntary EMC Laboratory Accreditation Center Inc. (VLAC), **Japan**



12. International Accreditation New Zealand (IANZ), New Zealand





Standard+Training+Consultancy

The following are the signatories of the APLAC MRA:

13. Singapore Accreditation Council
(SAC-SINGLAS), **Singapore**



17. American Association for
Laboratory Accreditation
(A2LA), **USA**



14. Chinese National laboratory
Accreditation (CNLA), **Chinese
Taipei**



18. International Accreditation
Service Inc, **USA**



15. TLAS, Office of the National
Accreditation Council, Thai
Industrial Standards Institute,
Thailand



19. National Voluntary
Laboratory Accreditation
Program (NVLAP), **USA**



16. Department of Medical
Sciences, **Thailand**



20. Vietnam Laboratory
Accreditation Scheme
(VILAS), **Vietnam**



Standardisation and Competency Assured

Specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.



Laboratory Process

Sample
handling

Laboratory
Facilities

Chemicals /
Reagents

Calibration
Standards (CRMs)

Competent
Staff

Samples → Preparation → Analysis → Data
evaluation → Report

Equipment
- Suitable
- Maintained
- Calibrated

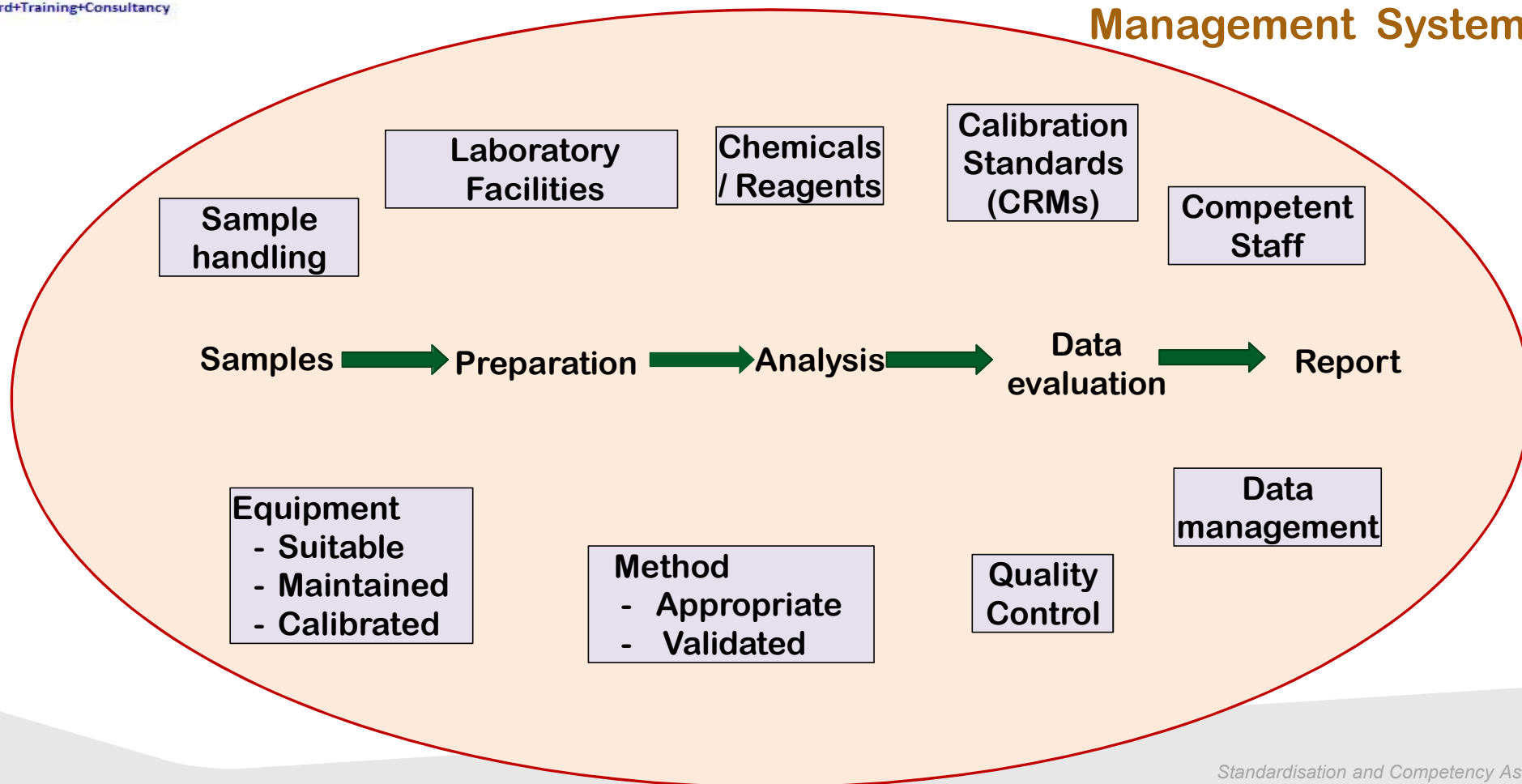
Method
- Appropriate
- Validated

Quality
Control

Data
management

Laboratory Process

Management System



ISO 17025 Structure

17025: 2005 to 2017

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

1. **General**
2. **Personnel**
3. **Accommodation and environmental conditions**
4. **Test and calibration methods and method validation**
5. **Equipment**
6. **Measurement Traceability**
7. **Sampling**
8. **Handling of test and calibration items**
9. **Assuring the quality of test and calibration results**
10. **Reporting the results**

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**

17025: 2005 to 2017

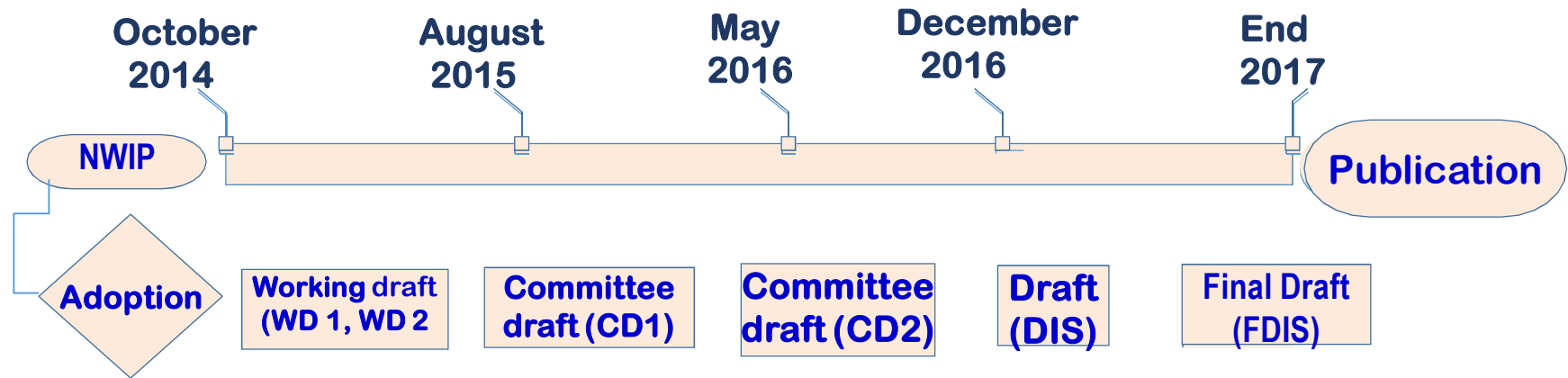
- 1. Organization**
- 2. Management System**
- 3. Document Control**
- 4. Review of requests, tenders and contracts**
- 5. Subcontracting of tests and calibrations**
- 6. Purchasing supplies**
- 7. Service to the customer**
- 8. Complaints**
- 9. Control of non-conforming testing and/or calibration work**
- 10. Improvement**
- 11. Corrective action**
- 12. Preventative action**
- 13. Control of records**
- 14. Internal Audits**
- 15. Management reviews**

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
- **NWIP – New Work Item Proposal**