



ISO/IEC 17025: 2017

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ISO/IEC 17025: 2017

- was prepared by the ISO Committee on Conformity Assessment (CASCO)
- 2nd ed. (ISO/IEC17025:2005) was cancelled and replaced
- Risks and opportunities need to be addressed.



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ISO/IEC 17025: 2017

- ประกาศ 29 November 2017
- Transition period : 3 years
- APLAC จัดอบรมให้ AB : 29 Nov. – 1 Dec. 2017





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Overview of Changes

- **Operate with 9001 Principles**
 - Leadership involvement
 - Process flow
 - PDCA & RBT
- **Address Risks & Opportunities**
 - Managed Risk > Risk Management
 - Policies & Procedures > Documented Information
- **Improve Continuously**
 - Increase effectiveness
 - Prevent negative events



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Structure

- 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 (informative)
Metrological traceability

Annex B (informative)
Management system

Bibliography




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High Level Structure

House	17025: 2017
<p>Building Code <small>ทั่วไป</small></p> <p>Foundation <small>ฐานราก/โครงสร้าง</small></p> <p>Frame & Systems <small>กรอบงาน</small></p> <p>Appliances</p> <p>Maintenance</p>	<p>General Structure</p> <p>Resources</p> <p>Processes</p> <p>Management System</p>





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High Level Structure

General Requirements
(Building Code)

Structural Requirements
(Foundation)



- 4.1 Impartiality ความเป็นกลาง/ยุติธรรม
- 4.2 Confidentiality รักษาความลับ
- 5.1 Legal entity (4.1)
- 5.2 Management (4.2)
- 5.3 Range of activities
- 5.4 Stakeholder responsibilities
- 5.5 Org. Relationships & Procedures
- 5.6 Authority & Resources
- 5.7 Competence

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High Level Structure




Resource Requirements (Systems)

- 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 & Services (4.6)

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High Level Structure

APLAC
Asia Pacific Laboratory Accreditation Cooperation



Process Requirements
(Appliances)

- 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 Validity of Results (QC) (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)

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High Level Structure




Management System
(Maintenance)

- 8.1 Options (A/B) – **NEW**
- 8.2 MS Documentation (4.2)
- 8.3 Control of MS Documentation (4.3)
- 8.4 Control of Records (4.13)
- 8.5 Risks & Opportunities – **NEW**
- 8.6 Improvements (4.10, 4.12)
- 8.7 Corrective Actions (4.11)
- 8.8 Internal Audits (4.14)
- 8.9 Management Reviews (4.15)

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1. Scope



- Competence
- Impartiality
- Consistency
- Applicability
- Conformity not compliance
- Stakeholder use







2. Normative References



- **ISO/IEC Guide 99 :**
International vocabulary of metrology
- **ISO/IEC 17000**
Conformity assessment –Vocabulary and
general principle







3. Terms & Definitions

- 3.1 Impartiality
- 3.2 Complaints
- 3.3 Interlaboratory comparison
- 3.4 Intralaboratory comparison
- 3.5 Proficiency Testing
- 3.6 **Laboratory**
- 3.7 **Decision Rule**
- 3.8 Verification
- 3.9 Validation





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laboratory

- body that performs one or more of the following activities:
 - Calibration
 - Testing
 - sampling, associated with subsequent calibration and testing





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Decision Rule



- Rule that describes how measurement uncertainty is accounted for when starting conformity with a specified requirement.





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- **shall** : requirement
- **should** : recommendation
- **may** : permission
- **can** : possibility or a capability



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4. General requirements

4.1 Impartiality : lab shall

4.1.1 Safeguard impartiality by

- Undertaken ผู้กมัด
- Structured
- managed

conflicts of interest
do not exist



17025:2005:
 4.1.4 organization
 4.1.5
 (b) influences;
 (d) policies/procedures;
 (e) organization;
 (f) interrelationship

4.1.2 Commit to impartiality



4.1.3 Responsible for the impartiality of lab activities

4.1.4 **Identify risks to its impartiality**

4.1.5 **how to eliminates/minimizes such risk**

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4.2 Confidentiality

2005



- 4.1.5 (c) protection of information
- 4.7.1 service to customer
- 5.4.7.2 (b) control of data

2017

- 4.2.1 information management
- 4.2.2 public release
- 4.2.3 external sources of information
- 4.2.4 external influences (committees, contractors, etc)



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5. Structural requirements

5.1 a **Legal entity**, responsible (4.1.1)



5.2 **Management responsibility** : Specify responsibility authority and interrelationship of all personnel... (4.1.5 h)

5.3 **Range of activities** : define and document the range of laboratory activities (4.2.1)

5.4 Lab activities meet the **requirements of the Standard & stakeholders and** applied at all work locations (4.1.2, 4.1.3)



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5. Structural requirements

5.5 Define structure; specify responsibilities and authorities; document procedures for consistency
(4.1.5(e)(f), 4.2.1)

5.6 Personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties... : ➔ ไม่ระบุตำแหน่ง **QM** แต่ เน้นหน้าที่
(4.1.5(a)(i), 4.2.2(e), 4.2.3)

5.7 Laboratory management (แทน Top management)
shall...communicate, maintain integrity (4.2.7; 4.1.6, 4.2.4)

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6 Resource Requirements

2017		2005
Clause	Requirement	Clause
6.1	General	
6.2	Personnel	4.1.5(d)(g)(k), 4.2.1, 4.2.4, 4.3.1, 5.2, 5.4.3, 5.5.2
6.3	Facilities & Environment	4.1.3, 5.3.1, 5.3.2, 5.3.4, 5.4.7.2(c)

6 Resource Requirements



2017		2005
Clause	Requirement	Clause
6.4	Equipment	5.4.1, 5.4.7.2(a), 5.5, 5.6.1, 5.6.2.2.1, 5.6.3
6.5	Traceability	5.6

6.1 ยืนยันว่ามี resources:

คน เครื่องมือ
สิ่งอำนวยความสะดวก

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6.2 Personnel

6.2.1 impartiality : **internal/external**

6.2.2 shall **document** the competent : education, training, technical knowledge, skills and experience : มีเอกสารที่ระบุ **competence** ของแต่ละตำแหน่ง

6.2.3 **competence** to perform laboratory activities : ต้องมั่นใจ มีหลักฐาน



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6.2 Personnel

6.2.4 shall **communicate** to personnel their **duties, responsibilities and authorities**

สื่อสารให้ทุกคนเข้าใจ หน้าที่ ความรับผิดชอบ อำนาจ

6.2.5 have procedure and retain records...(สไลด์ถัดไป)

6.2.6 shall **authorize** personnel to perform specific laboratory

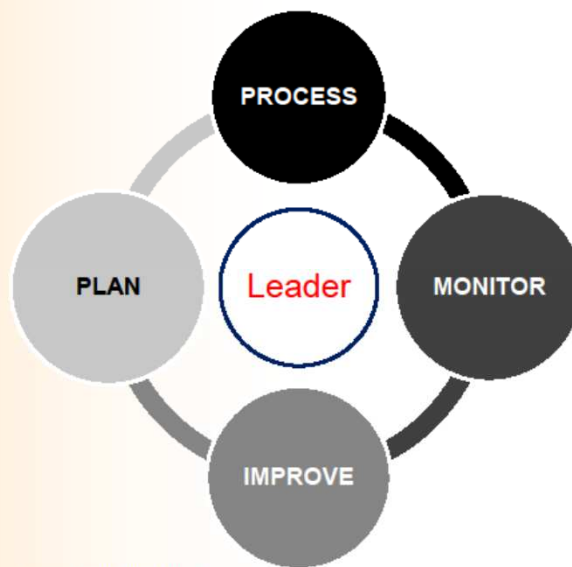


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6.2 PDCA of Personnel

6.2.5 Retain records for

- a. Competence Req.
- b. Selection
- c. Training
- d. Supervision
- e. Authorization
- f. Monitoring



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6.3 Facility and environmental condition

6.3.1 suitable, affect the validity of result (5.3.1)

6.3.2 shall be documented (5.3.1)

6.3.3 monitor, control, record (5.3.2)

6.3.4 measure periodically review : access, contamination, separation (5.3.2,5.3.3, 5.3.4)

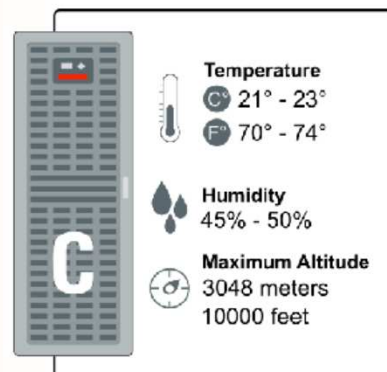
6.3.5 activity at site & external facility (5.3.1, 4.1.3)



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6.3 Facilities & Environment

- Affects the validity of the results
- Documented Requirements
- Controls and Monitoring
- Measures periodically reviewed
- Sites & external facilities



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6.4 Equipment

- 6.4.1 required for the correct performance of laboratory activities **(5.5.1, 5.5.2)**
- 6.4.2 uses equipment outside laboratory permanent control **(5.5.1)**
- 6.4.3 shall have a procedure for handling, transport **(5.5.3, 5.5.6)**
- 6.4.4 verify, conforms to specified requirement **(5.5.2)**



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6.4 Equipment

6.4.5 capable of achieving the measurement accuracy / uncertainty **(5.5.2, 5.6.3.3)**

6.4.6 shall be calibrated when

- Affects the validity of reported result and/or
- Require to establish the metrological traceability

(5.6.1, 5.6.2.2.1, 5.6.3.1)

6.4.7 Calibration programme **(5.6.1, 5.5.2)**

6.4.8 identify the status of calibration **(5.5.8)**



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6.4 Equipment

6.4.9 overloading, mishandling, give questionable result (5.5.7)

6.4.10 intermediate check (5.5.10,5.6.3.2,5.6.3.3)

6.4.11 the reference material , correction factor (5.5.11)

6.4.12 prevent unintended adjustments (5.5.12)

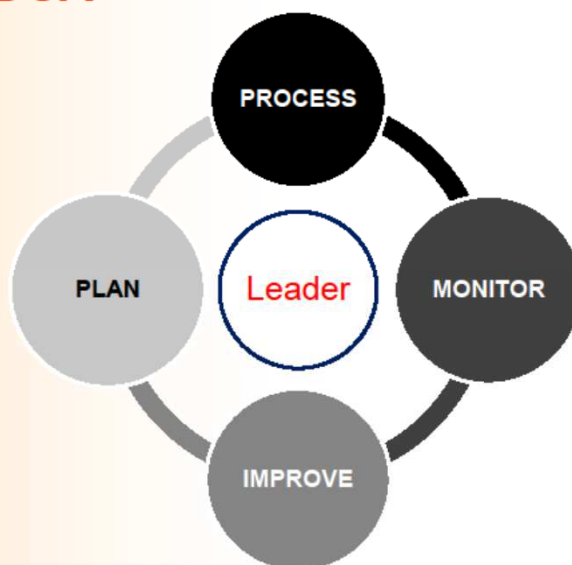
6.4.13 the recordsidentity of equipment, manufacturer's name, (5.5.5) เพิ่ม (f)documentation of RM



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6.4 Equipment – PDCA

- a. Calibrate
- b. Maintain
- c. Verify
- d. Validate
- e. Calibration Program
- f. Intermediate Checks





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6.5 Metrological traceability

6.5.1 establish and maintain metrological traceability

6.5.2 traceable to SI unit through....

- Calibration
- **new** Certified reference materials **by a competent producer**
- National or International standard

6.5.3 when metrological traceability to SI unit is not technically possible



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6.5 Traceability – SI Realization

- Unbroken Chain
- Measurement Uncertainty
- Appropriate Reference

The diagram illustrates the traceability chain for SI realization. It consists of three horizontal bars connected by a vertical line. The top bar is black and labeled 'Calibration' with a microscope icon. The middle bar is dark grey and labeled 'CRM' with a vial icon. The bottom bar is light grey and labeled 'Fundamental Constant' with a lamp icon.

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The bottom of the slide features two logos: 'ilac-MRA' on the left and 'LABORATORY ACCREDITATION BLA-DSS' on the right.

6.5 Traceability – non-SI Realization

- Certified Values of CRMs
- Reference Measurement Procedures
- Specified Methods
- Consensus Standards

CONDITIONS

- Results are
 - Described “clearly”
 - Accepted as “fit for use”
 - Ensured through suitable comparison

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6.6 Externally provided products and services

6.6.1 Externally provided products and services that affect lab activities (4.6.1, 4.6.2, 4.6.3)

NOTE :

- Products can include, for example,
 - measurement standards and equipment, auxiliary equipment, consumable materials and reference materials.
- Services can include, for example,
 - calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

....



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6.6 Externally provided products and services

6.6.2 have **procedure** and retain **record**

- Reviewing and approving
- Evaluation, selection, monitoring, re-evaluation

6.6.3 shall communication lab requirement to external providers for

- » Product and service
- » Acceptance criteria
- » Competence
- » activities



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6 Resource Requirements (cont.)



2017		2005
Clause	Requirement	Clause
6.6	External Services & Supplies	4.5, 4.6



"The Lighter Side Of The Cloud" Comic by David Fletcher © Cloudworks

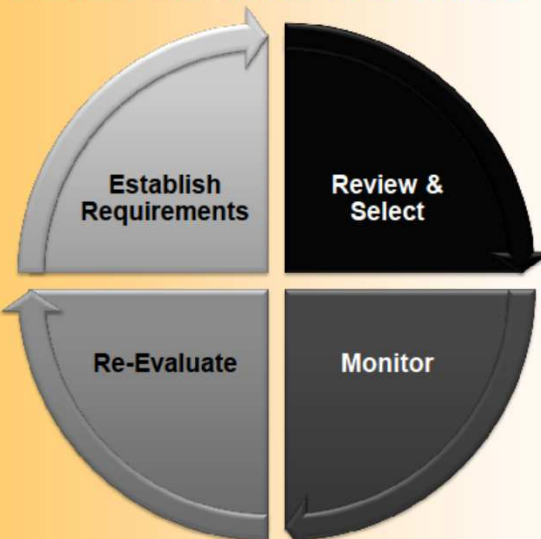
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6.6.2 External Services & Supplies





DISCUSSION QUESTION

Identify some of the risk monitors a laboratory might establish as part of its metrics . . .

What kind of evidence would you seek to identify if the laboratory is re-evaluating its vendors?

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7 Process Requirements





2017		2005
Clause	Requirement	Clause
7.1	Review of requests, tenders and contracts (including customer requirements around method selection and subcontracting)	4.4, 4.5.2, 5.4.2
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 measurement uncertainty	5.4.6
7.7	Ensuring the validity of results; use of reference materials	5.9, 5.6.3
7.8	Reporting of results; concept of reviewing results and authorizing them prior to the actual reporting; statements of conformity for calibration labs was moved to this section; amendments to records (reports)	5.10, 5.4.7.1, 5.6.2.1.1, 4.13

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2017		2005
Clause	Requirement	Clause
7.9	Complaints	4.8
7.10	Nonconforming work	4.9
7.11	Control of data and information management	4.13, 5.4.7





7.1 Review of requests, tenders and contracts

7.1.1 General ; (4.4.1)

- Have procedure for review of requests, tenders and contracts
- where external providers are used, **the requirement of 6.6** are applied
 - Externally provided laboratory activities
 - for unforeseen
 - does not have the resources or competence to perform the activities.



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7.1 Review of requests, tenders and contracts



7.1.2 shall inform customer when be inappropriate or out of date

7.1.3 - new When the customer requests a statement of **conformity to a specification or standard** (e.g. pass/fail, in-tolerance/out-of-tolerance)

- **Decision rule** shall be clearly defined
- **Decision rule** shall be communicated to, and agreed with, the customer (unless the decision rule is inherent in the requested specification or standard)





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7.2 Selection, verification and validation of methods

- In general, not many changes in the requirements themselves
- Section has been re-organized, mainly to differentiate between when the lab has to “**verify**” (7.2.1) that it can properly perform methods vs. when the lab has to “**validate**” (7.2.2) methods



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7.2 Selection, verification and validation of methods

7.2.1.4 The lab shall select an **appropriate method** and inform the customer of the method chosen. The lab can select:

- Methods published in international, regional or national standards
- Methods published by reputable technical organizations
- Methods published in relevant scientific texts or journals
- Methods specified by the manufacturer of the equipment
- Laboratory-developed methods
- Modified methods



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7.2 Selection, verification and validation of methods

7.2.1.5

- Regardless of the method selected, the lab has to **verify** that it can properly perform the methods before introducing them and retain records of verification
- If the method is **revised** by the issuing body, the lab has to **repeat the verification** to the extent necessary



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7.2 Selection, verification and validation of methods

7.2.2.1



Specifies the types of methods that need to be **validated** (and not just verified):

- Non-standard methods
- Laboratory-developed methods
- Standard methods used outside their intended scope or otherwise modified

Validation shall be as extensive as necessary to meet the needs of the given application or field of application



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7.2 Selection, verification and validation of methods

7.2.2.2



- Changes to a validated method need to be assessed and if found to affect the original validation, a **new validation** needs to be performed

7.2.2.3



- **Performance characteristics** shall be relevant to **the customers' needs**

7.2.2.4

- **Retention of records** – validation procedure used, specification of the requirements, determination of the performance characteristics, results, a statement on the method validity



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7.2 Selection, verification and validation of methods

7.2.2.4

Records to be retained:

- Validation procedure used
- Specification of the requirements
- Determination of the performance characteristics
- Results obtained
- A statement on the validity of the method, detailing its fitness for the intended use



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7.3 Sampling

7.3.1 lab shall have a sampling plan and method when it carries out sampling

- Changed “**procedure**” to “**method**”
- Removal of redundancy – requirements on customer requests for deviations from sampling procedures is now covered under section **7.1.4**



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7.3 Sampling

7.3.2 The sampling method shall describe:

- The selection of samples or sites
- The sampling plan,
- Preparation and treatment of sample(s) from a substance, material or product
- CHANGE!** These requirements were “Notes” in the 2005 version
- NEW!** A “Note” that states “When received into the laboratory, further handling can be required as specified in 7.4” This implies that “sampling” is different from “sub-sampling”



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7.3 Sampling

7.3.3 The laboratory shall **retain records** of sampling data that forms part of the testing or calibration that is undertaken...

ADDED! Some records requirements... Date and time of sampling

- Data to identify and describe the sample (e.g., number, amount, name)
- Identification of the equipment used
- Transport conditions
- Deviations, additions to or exclusions from the sampling method and sampling plan



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7.4 Handling of Test or Calibration Items

7.4.1

- Requires that the laboratory **has procedures** for handling of test or calibration items, including provisions to protect the **integrity** of the test or calibration item and that the lab follow any handling instructions provided with the item



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7.4 Handling of Test or Calibration Items

7.4.2 System for the unambiguous identification of test and calibration items

- Added the word “unambiguous”

7.4.3 Deviations from specified conditions shall be recorded, asking the customer for further instructions and record the results of the consultation, and inclusion of a disclaimer

- Removed terms such as “abnormalities” and “normal”
- Added the requirement that if the customer wants the sample tested anyway, the lab needs to include a statement with the results



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7.4 Handling of Test or Calibration Items

7.4.4 When items need to be **stored or conditioned**, the conditions shall be maintained, monitored and recorded

- Again, redundancy has been removed – the requirement for the lab to **have procedures and appropriate facilities** for maintaining the integrity of the test or calibration item is captured in **Section 6.3 – Facilities and Environmental Conditions**





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7.5 Technical Records

- **REMOVED!** Any wording that implies paper records – e.g., “crossed out”, “not erased”, “signed”, etc..
- No substantive changes to requirements for retention of records, recording observations and data at the time they are made ไม่เปลี่ยนในสาระสำคัญ



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7.5 Technical Records

7.5.2

- The laboratory shall ensure that amendments to technical records **can be tracked** to previous versions or to original observations
- Original and amended data and files **shall be kept**, including the date of alteration, an indication of the altered aspects, and the personnel responsible for the alterations



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7.6 Evaluation of Measurement Uncertainty

7.6.1 General:



- Identify the contributions
- Evaluate significant contributors (**RISK**)
- Use appropriate methods

7.6.2 Calibration:

- Evaluate the MU for all calibrations





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7.6 Evaluation of Measurement Uncertainty

7.6.3 Testing

- shall **evaluate** MU (implies rigorous, calculated MU where possible)
- Where a rigorous MU cannot be calculated (e.g., qualitative tests), **estimate** the MU
 - Theoretical principles
 - Practical experience





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7.7 Ensuring the validity of results

ISO/IEC 17025:2005 – Section 5.9, 5.6.3

- **PROCEDURE**
- Separated **internal (7.7.1)** from **external (7.7.2)** activities
- Additional quality control tools:
 - Use of alternative instrumentation that has been calibrated
 - Functional check(s) of measuring and testing equipment
 - Review of reported results
 - Intra-laboratory comparisons (3.4)
 - Testing of blind samples



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7.7 Ensuring the validity of results

CHANGE!

7.7.2 – Requirement for participation in

either or both



- Proficiency Testing (3.5) (PT) or
- Interlaboratory comparisons (3.3)

Note on ISO/IEC 17043

- PT providers that meet the requirements of ISO/IEC 17043 are considered competent






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7.7 Ensuring the validity of results

7.7.3 concept of analysing QC data to “control” and “improve” laboratory activities is additional

- Compliance  Control-based processes





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7.8 Reporting of results

ISO/IEC 17025:2005 – Section 5.10

- Re-organized General (7.8.1)
- Common requirements for reports (test, calibration or sampling) (7.8.2)
- Specific requirements for test reports (7.8.3)
- Specific requirements for calibration certificates (7.8.4)
- Specific requirements for reporting sampling (7.8.5)
- Reporting statements of conformity (7.8.6)
- Reporting opinions and interpretations (7.8.7)
- Amendments to reports (7.8.8)



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7.8 Reporting of results

7.8.1.1 - The results *shall be reviewed and authorized prior to release.* The results shall be provided accurately, clearly,...

- Reviewing and authorizing results prior to release is an important step in the process!

7.8.2.1 (o) - identification of the person(s) authorizing the report

- Removed the word “signature”



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7.8 Reporting of results

7.8.2.2 – NEW

- Lab shall be responsible for all information in the report, except when information is provided by the customer
- Data provided by the customer shall be clearly identified
- Disclaimer put on the report when the information is supplied by the customer and can affect the validity of the results
- When the sample is provided by the customer, it shall state in the report that the results apply to the sample “as received”
 - Is this different from *a statement to the effect that results relate only to the items tested, calibrated or samples (7.8.2.1 (l))*?



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7.8 Reporting of results – Sampling

7.8.5 (f)

“Where the laboratory is responsible for the sampling activity....reports shall include the following, where necessary for the interpretation of results:....f) information required to evaluate measurement uncertainty for subsequent testing or calibration”.





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7.8 Reporting of Results

7.8.6.1 – Decision Rules **NEW!**

- When a statement of **conformity to a specification or standard is provided**, the laboratory shall:
 - Document
 - Apply
- The statement of conformity has to be reported and clearly identifies:
 - To which results the statement of conformity applies;
 - Which specifications, standard or parts thereof are met or not met; and
 - The decision rule applied (unless it is inherent)
- Refer to **7.1.3**, regarding communication and agreement with the customer!





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7.8 Reporting of results

7.8.8 Amendments to reports

7.8.8.1 – change of information shall be clearly identified and, where appropriate, the reason for the change included in the report



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7.9 Complaints



Section 4.8 → Section 7.9

Observations:

- ISO heightened awareness
- **No** procedure or policy
- The requirements are not in the “Management Requirements” section





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7.9 Complaints


- 7.9.1 Documented process
- 7.9.2 – 7.9.4 Description
- 7.9.5 Acknowledge receipt
- 7.9.5 Provide updates
- 7.9.5 – 7.9.6 Report outcome
- 7.9.7 Conclusion



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7.10 Nonconforming Work



Section 4.9  Section 7.10

7.10.1 Procedure ensures

- Responsibilities
- Authorizations
- Risk Levels
- Actions





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7.11 Control of Data and Information management

- **Control of Records** Section 4.13 ➔ Section 7.11
- **calculations & transfers** 5.4.7.1 ➔ 7.11.6
- **computer systems** 5.4.7.2 ➔ 7.11.2

- Transition from “paper” to LIMS
- Note 2 – COTS = Validated





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8 Management system requirements

- **Option A** and **Option B** are intended to achieve the same result in the performance of the management system and compliance with Clauses 4 to 7
- **Annex B** (Informative) – provides some background and text



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8 Management system requirements



Option A:

As a minimum, the management system of the laboratory shall address the following....

- management system documentation (see 8.2)
- control of management system documents (see 8.3)
- control of records (see 8.4)
- actions to address risks and opportunities (see 8.5)
- improvement (see 8.6)
- corrective action (see 8.7)
- internal audits (see 8.8)
- management reviews(see 8.9)





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Option A Requirements of ISO 9001 that are relevant to the scope of laboratory activities that are covered by the management system were incorporated into ISO/IEC 17025

- Therefore, laboratories that comply with Clauses 4 to 7 of ISO/IEC 17025:2017 and implement Option A will also operate generally in accordance with the principles of ISO 9001

• 11/





15/01/2018





A management system that: Meets the requirements of ISO 9001; and,

- **Is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7**
- Laboratories that implement Option B also operate in accordance with ISO 9001
- Compliance with ISO 9001 does not, in itself, demonstrate the competence of the laboratory to produce technically valid data and results





15/01/2018





8 Management requirements

- **Option B**
 - A laboratory that has **established and maintains** a management system, in accordance with the requirements of ISO 9001





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8.2 Management System Documentation

Section 4.2 → Section 8.2

- Removed prescriptive requirements:
 - quality policy,
 - quality manual, etc...)
- 8.2.1 & 8.2.2 – “document (v)” that address **competence**, **impartiality** and **consistent** operation which need to be acknowledged and implemented at all levels.



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8.2 Management System Documentation

8.2.3 – verbatim of 4.2.3 in 2005 version except for the removal of the term “**Top Management**”



8.2.4 – documents, records, etc., ... shall be: included in,

- referenced from, or
- linked to the management system

8.2.5 – similar to **4.2.1** in 2005 version





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8.3 Control of Management System Documents

Section 4.3 → Section 8.3

- LIMS focus from 7.11 Information Management
- No longer refer to hand-written amendments
- No “Master List”
- Less prescriptive ข้อกำหนด กฎเกณฑ์น้อยลง





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8.4 Control of Records

Section 4.13 → Section 8.4

- Additional requirements regarding technical records are in [7.5](#)





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8.5 Actions to Address Risks and Opportunities

- The laboratory shall: 8.5.1 consider the risks and opportunities...
- 8.5.2 plan actions to address these risks and opportunities, and
- plan how to integrate and implement and evaluate the effectiveness of these actions





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8.5 Actions to Address Risks and Opportunities

- QUESTION: What is the difference between a “risk” and an “opportunity?”
- 8.5.3 – Actions shall be proportional to the potential impact on the validity of the laboratory results



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Risk-based Approach (RBT)

I DENTIFY
A NALYZE
E VALUATE
T REAT

I Always Eat 'Taters

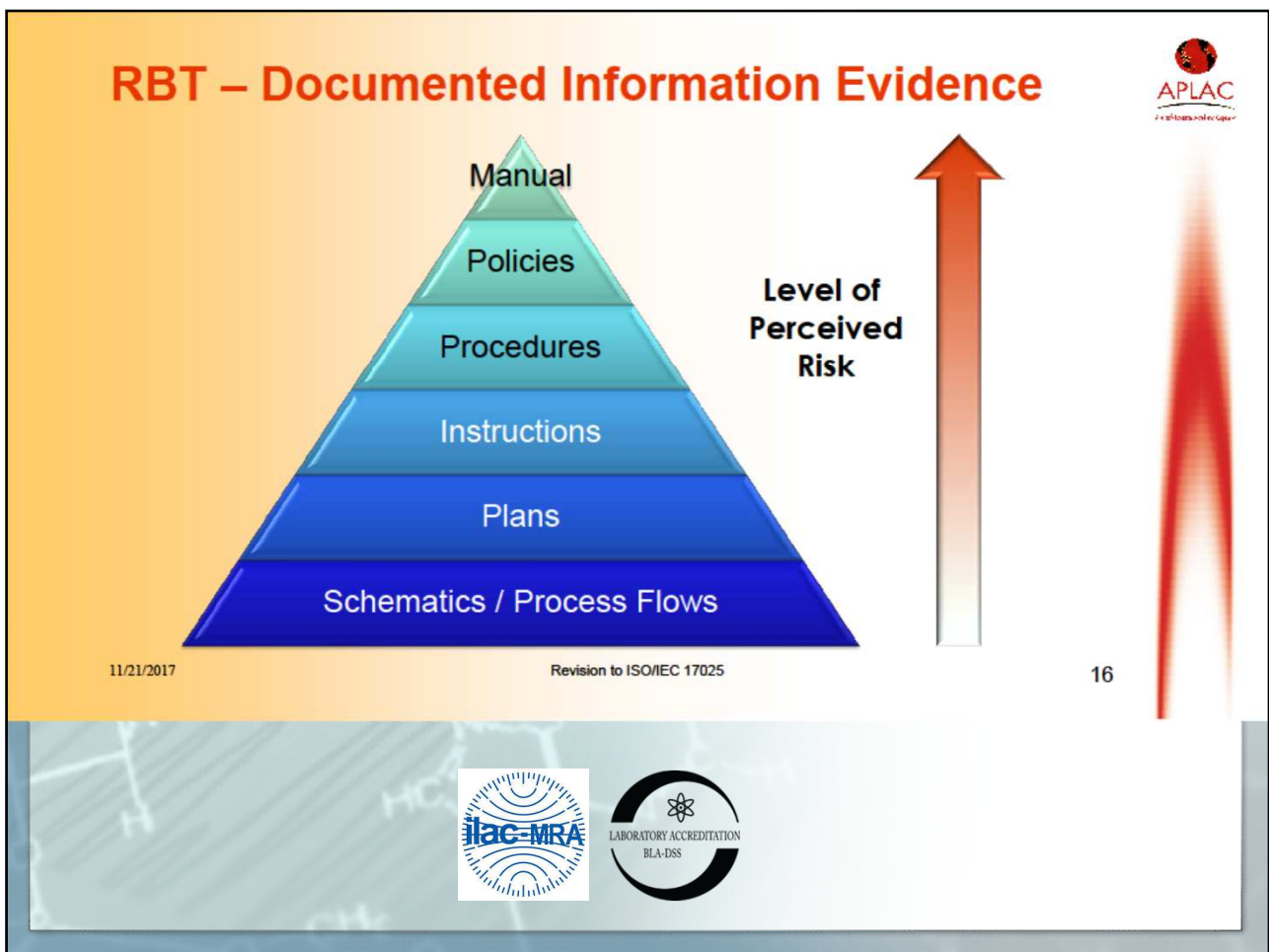
RIDM

CRM

APLAC
Association of Professional Laboratories Accreditation Council

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RBT – Records Evidence



- Non-Technical Records
 - Organizational Structure (4.1.1, 5.5)
 - Competencies, Responsibilities and Authorizations (5.5, 6.2)
 - Environmental (6.3)
 - Equipment, Traceability & Handling (6.4, 6.5, 7.4)
 - Vendors (6.6)
 - Customer discussions (7.1, 7.2)
 - Complaints (7.9)
 - Nonconforming Work (7.10)
 - Objectives (8.2)
 - Improvements (8.6)
 - Corrective Actions (8.7)
 - Internal Audits (8.8)
 - Management Review (8.9)

11/21/2017

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RBT – Records Evidence

- Technical Records (7.5)
 - Verification & validation of methods (7.2)
 - Sampling (7.3)
 - Evaluation of Measurement Uncertainty (7.6)
 - Assuring the Quality of Results (7.7)
 - Reporting (7.8)
 - Nonconforming Work (7.10)

11/21/2017

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8.6 Improvement



Section 4.10 → Section 8.6

8.6.1

- Identify and select opportunities
- Implement any necessary actions





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8.6 Improvement

8.6.2

- Seek feedback (positive and negative)
- Analyse feedback and use it for improvement



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8.7 Corrective Action

Section 4.11 → Section 8.7

8.7.1 (b) determining the causes

- determine if similar non-conformities exist
- And, if necessary:
 - (e) update risks and opportunities determined during planning
 - (f) make changes to the management system

8.7.2 Corrective actions appropriate to levels of NCW



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8.8 Internal Audits

Section 4.14 ➔ Section 8.8



2005	2017
Procedure	Audit Programme
Predetermined schedule	Planned Intervals
Quality Manager (responsibilities)	Authorized & Competent Person (6.2)
Timely Corrective Action	Without undue delay
Compliance with Standard and Management System requirements	+ effectively implemented and maintained
	<p>NEW: Results of previous audits</p> <p>NEW: Ensure results of audits are reported to relevant management</p>

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8.8 Internal Audits

- 8.8.2 (b) – “*define the audit criteria and scope...*”
- Notification of customers in writing appears to be deleted – **but** refer to 7.10.1 (e)
 - Similar redundancy removed for recording corrective actions
- 2005 clause 4.14.1 “*wherever resources permit, independent of the activity to be audited.*”





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8.9 Management Reviews

Section 4.15 → Section 8.9

- Re-organized the requirements into:
 - 8.9.1 – Planned intervals and objectives
 - 8.9.2 – Inputs
 - 8.9.3 – Outputs



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Thank you for your attention!