Welcome to APFAN PT-2 Workshop

Implementing ISO/IEC 17025:2017 in Proficiency Testing (PT) Schemes and Reference Material (RM) Production

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Key notes

1. Results PT schemes : evaluation of a participant's performance

→ confidence in technical operation

ISO/IEC 17043

→ Laboratory checking homogeneity / stability/assign value

ISO/IEC 17025

Key notes

2. Technical competence of RM producer:

- ensure the quality and metrological traceability of RM/CRM

ISO/IEC 17034

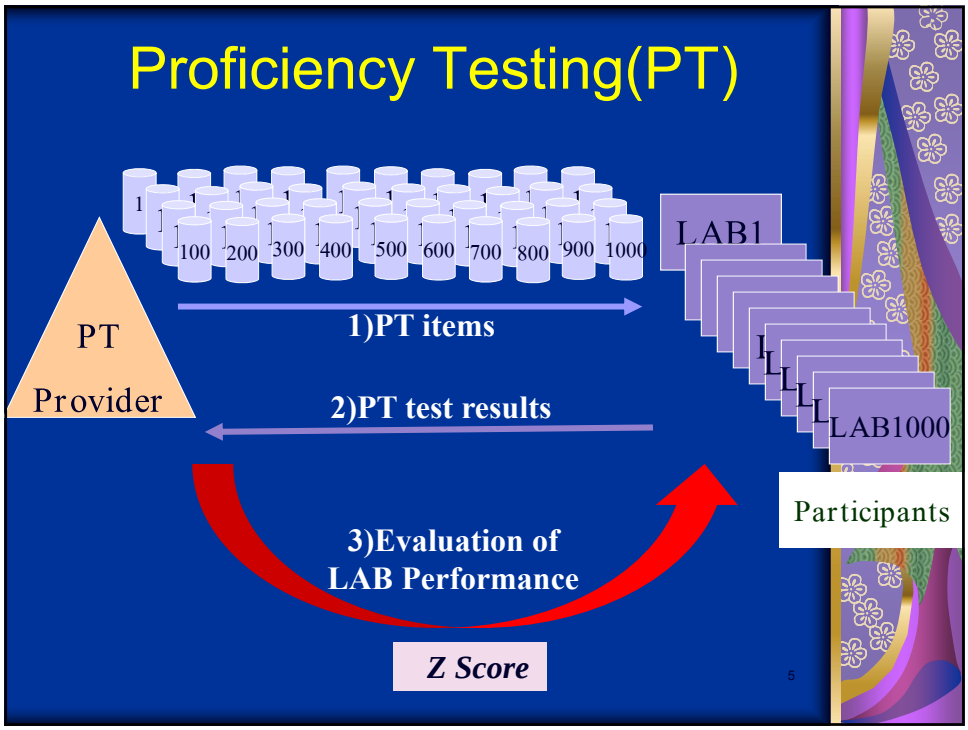
- Laboratory checking homogeneity / stability/characterization of RM

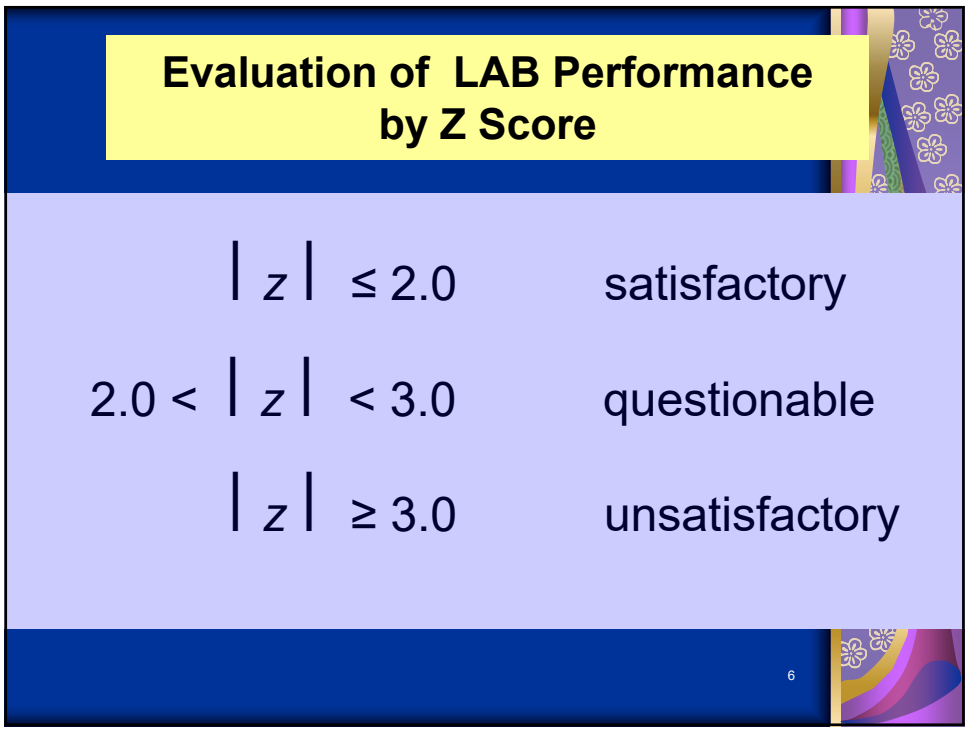
ISO/IEC 17025

Key notes

3. Laboratory complying with the relevant requirements of the ISO/IEC17025:2017

- Schemes of proficiency testing
- Types and quality of RM


Proficiency Testing(PT)
1
100
200
300
400
500
600
700
800
900
1000
LAB1
LAB1000
PT
Provider
1)PT items
2)PT test results
3)Evaluation of
LAB Performance
Z Score
Participants
5


Evaluation of LAB Performance
by Z Score
| z | ≤ 2.0 satisfactory
2.0 < | z | < 3.0 questionable
| z | ≥ 3.0 unsatisfactory
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Benefits of proficiency testing

a) evaluation of the performance of laboratories for specific tests and monitoring laboratories continuing performance.

b) education of participating laboratories based on the outcomes of such comparisons.

c) identification of problems in laboratories and initiation of actions for improvement e.g.
-inadequate test,
-effectiveness of staff training.

Benefits of proficiency testing

d) establishment of the effectiveness and comparability of test or measurement methods

e) provision of additional confidence to laboratory customers.

f) assignment of values to reference materials.

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Benefits of proficiency testing

g) support for "NMI key comparisons", comparisons conducted by BIPM(Bureau international des poids et mesures) and APMP(Asia Pacific MetrologyProgramme)

h) support for "ASEAN Reference Laboratory".

i) Requirement of laboratory accreditation.

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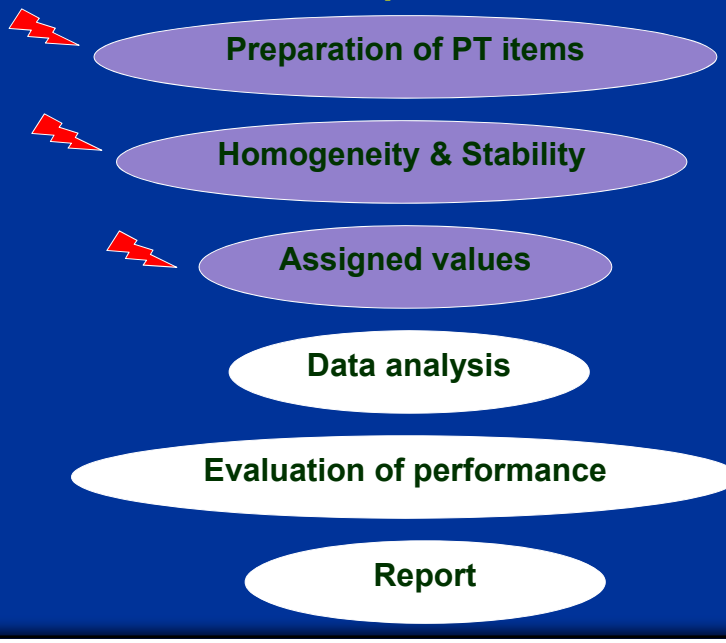
PT Operation



ISO/IEC 17043:2010

1. Scope
2. Normative references
3. Terms and definitions
4.Technical Requirement
4.1 General
4.2 Personnel: Competent for testing/equipment operation
4.3 Equipment, accommodation and environment
4.4 Design of proficiency testing schemes: Preparation of PT items/Homogeneity and stability/Assigned value
4.5 Choice of method of procedure
4.6 Operation of proficiency testing schemes
4.7 Data analysis and evaluation of proficiency testing scheme results

ISO/IEC 17043:2010

4.8 Reports
4.9 Communication with participants
4.10 Confidentiality
5 Management requirements
5.1 Organization: laboratory included(or not) in the quality system of PTP
5.2 Management system
5.3 Document control
5.4 Review of requests, tenders and contracts
5.5 Subcontracting services:technical competence
5.6 Purchasing services and supplies:verification of consumable material
5.7 Service to the customer
5.8 Complaints and appeals

ISO/IEC 17043: 2010

5.9 Control of nonconforming work
5.10 Improvement
5.11 Corrective actions
5.12 Preventive action
5.13 Control of records
5.14 Internal audits
5.15 Management reviews

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Key notes

2. Technical competence of RM producer:

- ensure the quality and metrological traceability of RM/CRM

ISO/IEC 17034

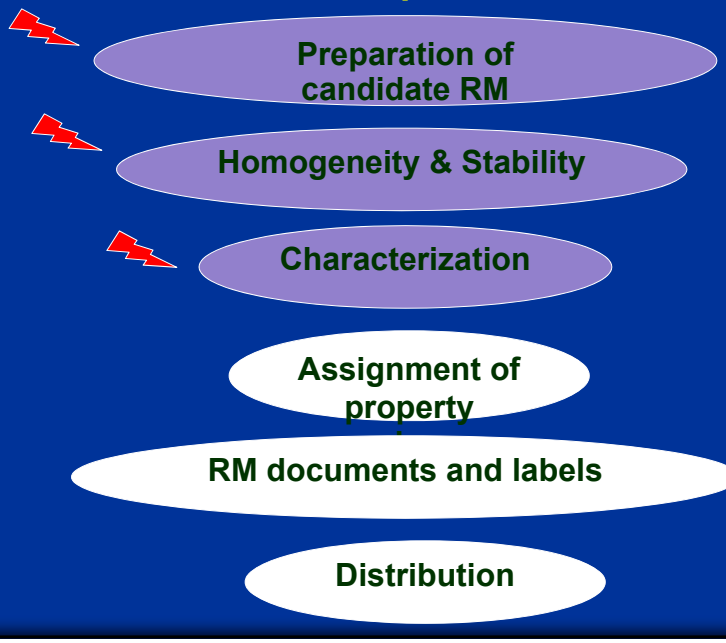
- Laboratory checking homogeneity / stability/characterization of RM

ISO/IEC 17025

Uses of Reference materials

a) calibration and verification of measuring equipment
b) validation of methods
c) training of staff
d) quality control
e) proficiency testing or inter-laboratory comparison
f) increasing of higher quality RM is from the demand of increased precision of measuring equipment and more accurate and reliable data

RMP Operation



ISO/IEC 17034: 2016

3.3 reference material RM
material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process
Note 1 to entry: Reference material is a generic term.
Note 2 to entry: Properties can be quantitative or qualitative, e.g. identity of substances or species.

ISO/IEC 17034: 2016

3.2 certified reference material CRM
reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

ISO/IEC 17034: 2016

3.4 certified value
value, assigned to a property of a reference material that is accompanied by an uncertainty statement and a statement of metrological traceability, identified as such in the reference material certificate
[SOURCE: ISO Guide 30:2015, 2.2.3]

ISO/IEC 17034: 2016

1 Scope
2 Normative references:ISO/IEC 17025
3 Terms and definitions
4 General Requirements
5 Structural requirements
6 Resource requirements
6.1 Personnel :Competent for testing/ equipment operation
6.2 Subcontracting :accredited?
6.3 Provision of equipment services and supplies: calibrated or verified
6.4 Facilities and environmental conditions : controled /monitored/ recorded

ISO/IEC 17034: 2016

7 Technical and production requirements
7.1 General requirements
7.2 Production planning
7.3 Production control
7.4 Material handling and storage
7.5 Material processing
7.6 Measurement procedures
7.7 Measuring equipment
7.8 Data integrity and evaluation
7.9 Metrological traceability of certified values

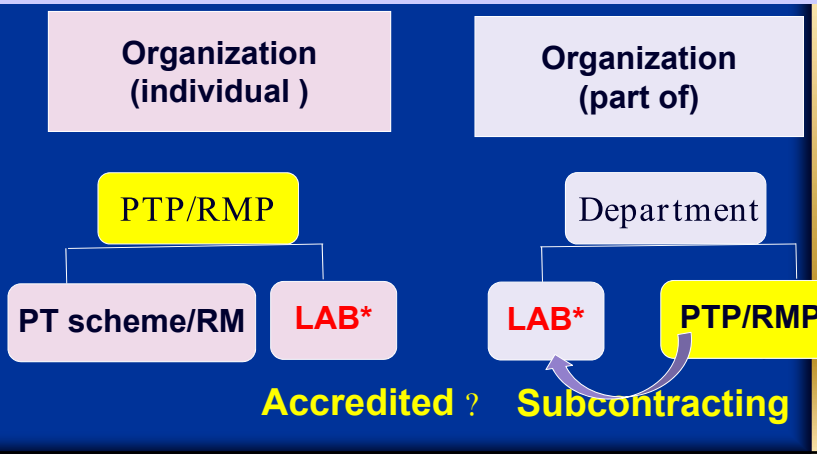
ISO/IEC 17034: 2016

7.10 Assessment of homogeneity
7.11 Assessment of stability
7.12 Characterization
7.13 Assignment of property values
and their uncertainties
7.14 RM documents and labels
7.15 Distribution service
7.16 Control of quality and technical records
7.17 Management of non-conforming work
7.18 Complaints
8 Management system requirements

Organization

PT Provider/RM Producer: legally identifiable

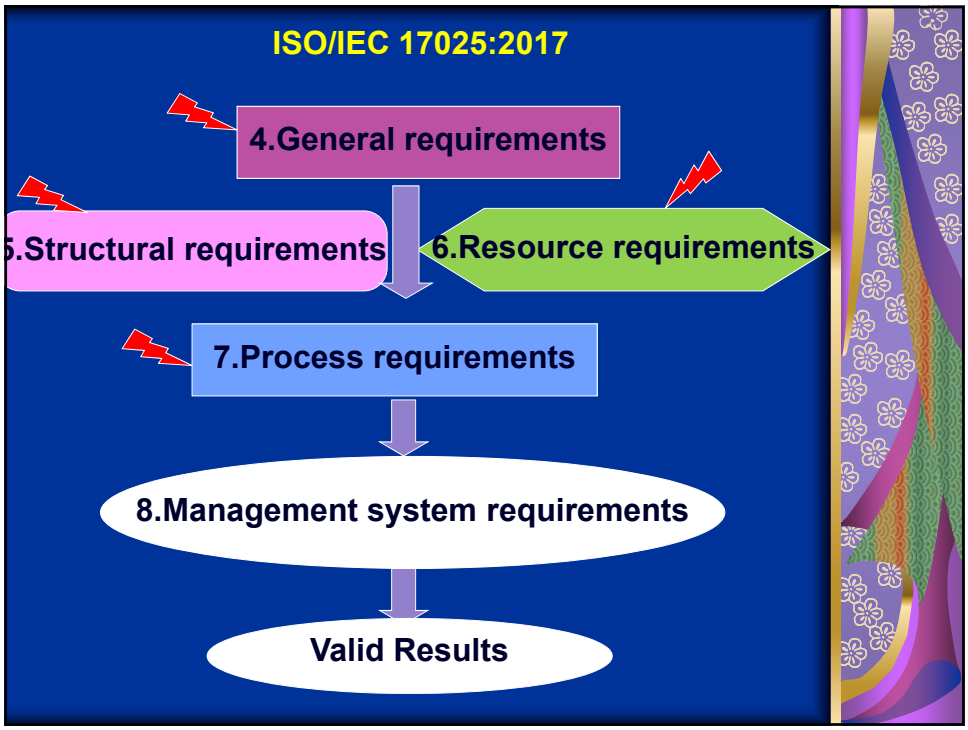
PTP/RMP, or the organization of which it is part, shall be an entity that is legally identifiable and accountable.

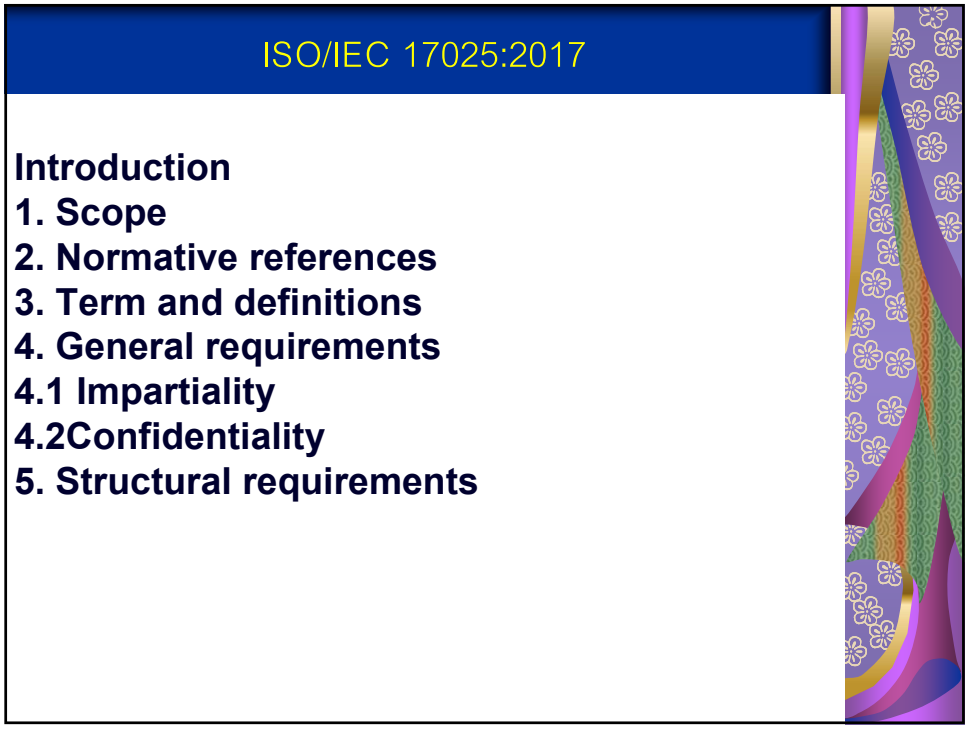


Laboratory: ISO/IEC 17025:2017

1. Technically ability to get a valid result: people, knowledge, equipment, supplies and process.

2. A system to ensure impartiality, consistency, confidentiality and reliability.


ISO/IEC 17025:2017
4.General requirements
5.Structural requirements
6.Resource requirements
7.Process requirements
8.Management system requirements
Valid Results


ISO/IEC 17025:2017
Introduction
1. Scope
2. Normative references
3. Term and definitions
4. General requirements
4.1 Impartiality
4.2Confidentiality
5. Structural requirements

ISO/IEC 17025:2017

6 Resource reements

6.1 General

6.2 Personnel

6.3 Facilities and environmental conditions

6.4 Equipment

6.5 Metrological traceability

6.6 Externally provided products and services

ISO/IEC 17025:2017

7.1 Review of requests, tenders and contracts

7.2 Selection, verification and validation of methods

7.3 Sampling

7.4 Handling of test or calibration items

7.5 Technical records

7.6 Evaluation of measurement uncertainty

7.7 Ensuring the validity of results

7.8 Reporting of results

ISO/IEC 17025:2017

7.9 Complaints

7.10 Nonconforming work

7.11 Control of data and information management

8 Management system requirements

6 Resource requirements

6.2 Personnel.

- **internal or external personnel shall act impartially,**
- **be competent**

*****on the job training**

- **education, qualification, training, technical knowledge, skills and experience.**

6 Resource requirements

- Personnel duties, responsibilities and authorities.
- ***job description
- retain records

6 Resource requirements

authorize personnel to

- a) verification and validation of methods;
- b) analysis of PT item/ RM candidate

6 Resource requirements

- 6.3 Facilities and environmental conditions
- *** conditions

monitor, control and record

6 Resource requirements

- 6.4 Equipment
- correct performance

verify that equipment conforms to specified requirements

***fit to measurement accuracy and/or measurement uncertainty required

6 Resource requirements

- 6.4 Equipment
- ***equipment shall be calibrated when:

  - affects the validity of the reported results

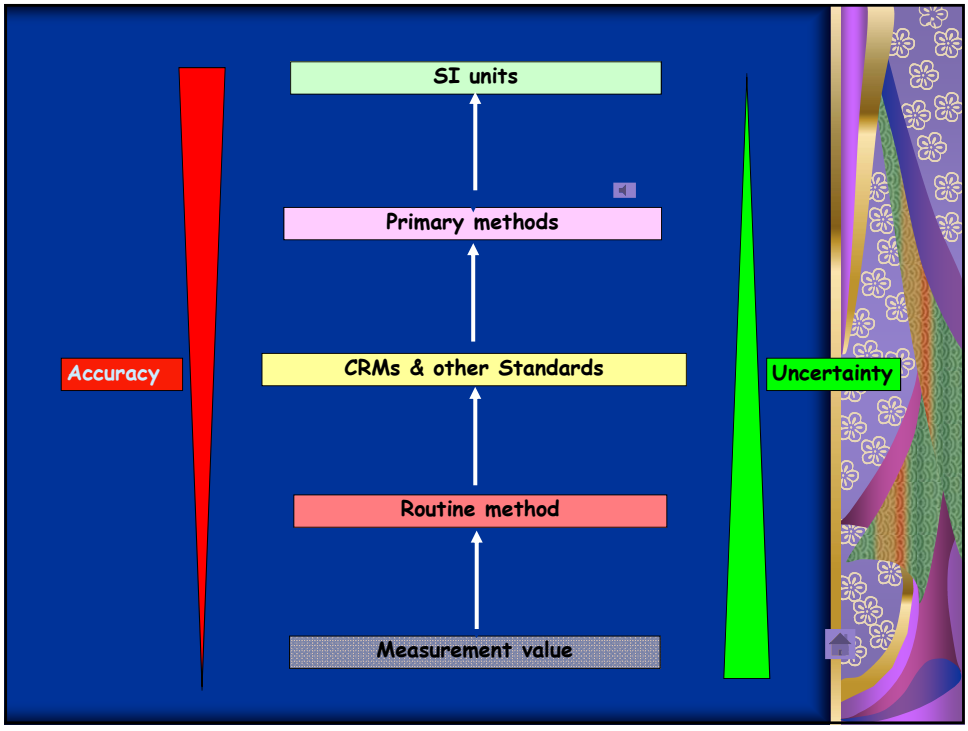
***- establish the metrological traceability

6 Resource requirements

- 6.4 Equipment
- calibration programme
- labelled and identify the status of calibration
- ***intermediate checks
- reference values or correction factors
- records shall be retained for equipment

6 Resource requirements

- **6.5 Metrological traceability**
- documented unbroken chain of calibrations, **each contributing** to the measurement uncertainty, linking them to an appropriate reference.
- **Pt scheme:** Metrological traceability is not always possible or appropriate.
- **CRM : metrological traceability shall be established**



6 Resource requirements

6.6 Externally provided service (subcontracting

PTP shall not subcontract:

a) planning of the proficiency test scheme

b) evaluation of performance

c) authorization of the final report

- Evaluate and register competent subcontractors

6 Resource requirements

6.6 Externally provided service (subcontracting)

RMP shall not subcontract:

- production planning;
- election of subcontractors;
- assignment of property values and their uncertainties;
- authorization of property values and their uncertainties;
- authorization of documents.

6 Resource requirements

- **6.6 Externally provided service (subcontracting)**
  -evaluation and approved
- a) scope of testing:accredted?
- b) competence, qualification of personnel/ PT participation result

7 Process requirements

- **7.1 Review of requests, tenders and contracts**
- **the capability and resources**
- ***appropriate methods or procedures are selected**

7 Process requirements

7.2 ***Selection, verification and validation of methods

- select an appropriate method: latest version standard method
- Verify method
- Validate method
- periodically review

7 Process requirements

- 7.4 Handling of test or calibration items
- procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items
- Integrity of test item
- identification of test or calibration items:confidential/collusion?

7 Process requirements

- 7.5 Technical records
- results and sufficient information for measurement result and associated measurement uncertainty
- original observations.

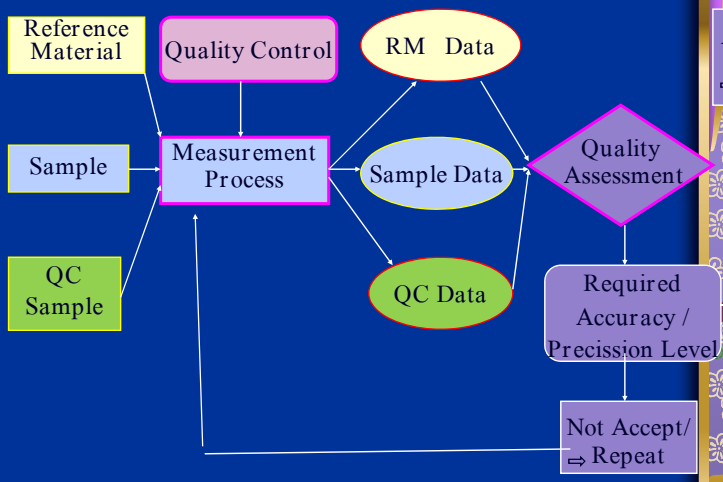
7.6 Evaluation of measurement uncertainty

- testing : evaluate measurement uncertainty
- **PTP:** calibration shall have assigned values with metrological traceability, including measurement uncertainty.
- **PTP: testing ??**
- **RMP:** shall take due account of technical information on test methods and equipment, including reported uncertainty information,

7.7 Ensuring the validity of results

- 7.7.1 procedure for monitoring the validity of results
- ***use of reference materials or quality control materials
- use of check or working standards with control charts
- replicate tests
- ***participation in proficiency testing(other PTP)
- participation in interlaboratory comparisons

Quality Assurance of Measurement Process



7.8 Reporting of results

accurately, clearly, unambiguously and objectively

shall include at least :

- title "Test Report
- name and address of the laboratory
- location of laboratory activities
- unique identification
- name of customer
- identification of the method used
- description of the item;
- date of receipt of the item
- date of performance testing

7.8 Reporting of results

- date of issue report
- units of measurement
- additions to, deviations, or exclusions from the method
- person authorizing the report
- Identification external providers

APFAN PT-2 Workshop
Food Analysis Workshop: Proficiency Testing and Reference Materials Development

Food and Nutrition Research Institute, ProficiencyTesting Laboratory,

Philippines

USCDC Vietnam

19th - 21st June 2019, Bangkok, THAILAND