ISO/IEC 17025:2017

General requirements for the competence of testing and calibration laboratories

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กำหนดการอบรม

8.30.00-12.00น.	บทนำ/ขอบข่าย/เอกสารอ้างอิง
	คำศัพท์และคำจำกัดความ
	ข้อกำหนดทั่วไป
	ข้อกำหนดด้านโครงสร้าง
	ข้อกำหนดด้านทรัพยากร
13.00-16.30น.	ข้อกำหนดด้านกระบวนการ
	ข้อกำหนดด้านการบริหารงาน

Background of ISO/IEC 17025

ISO/IEC 17025-1999 1st edition(+ISO 9001/9002 :1994)

ISO/IEC 17025-2005 2 nd edition (+ISO 9001:2000)

ISO/IEC 17025-2017 3 rd edition (OptionA/OptionB)

ส่วนสำคัญที่ปรับเปลี่ยนเป็น ISO/IEC 17025:2017

1. โครงสร้างเอกสาร

สอดคล้องกับมาตรฐาน ISO17000 series

a)General:“ ความเป็นกลาง และรักษาความลับ ”

b)Structure: “รูปแบบองค์กร”

c)Resource: “ทรัพยากรที่ต้องมี”

d)Process: “สิ่งที่ต้องทำ”

e)Management: “สิ่งที่ต้องบริหารจัดการ”

ส่วนสำคัญที่ปรับเปลี่ยน ISO/IEC 17025:2017

2. Option A –ตามข้อกำหนด ISO/IEC 17025

   Option B –ตาม ISO 9001 และเพิ่มข้อกำหนดทางวิชาการของ ISO/IEC 17025

3. Risks and Opportunities

4. Decision Rules: statement of conformity

   False accept/ False reject

ISO/IEC 17025:2017

บทนำ(Introduction)

1. ขอบข่าย (Scope)

2. เอกสารอ้างอิง(Normative references)

3. คำศัพท์และคำจำกัดความ (Term and definitions)

4. ข้อกำหนดทั่วไป (General requirements)

5.ข้อกำหนดด้านโครงสร้าง (Structural requirements)

6.ข้อกำหนดด้านทรัพยากร (Resource requirements)

7. ข้อกำหนดด้านกระบวนการ (Process requirements)

8.ข้อกำหนดด้านการบริหารงาน(Management system requirements)

ภาคผนวก AnnexA: Metrological traceability

AnnexB : Management system options

7. เอกสารที่เกี่ยวข้อง (Bibliography)

Introduction

- Requirements for laboratories to generate valid results.
- In accordance with the principles of ISO 9001.

Option A/ Option B

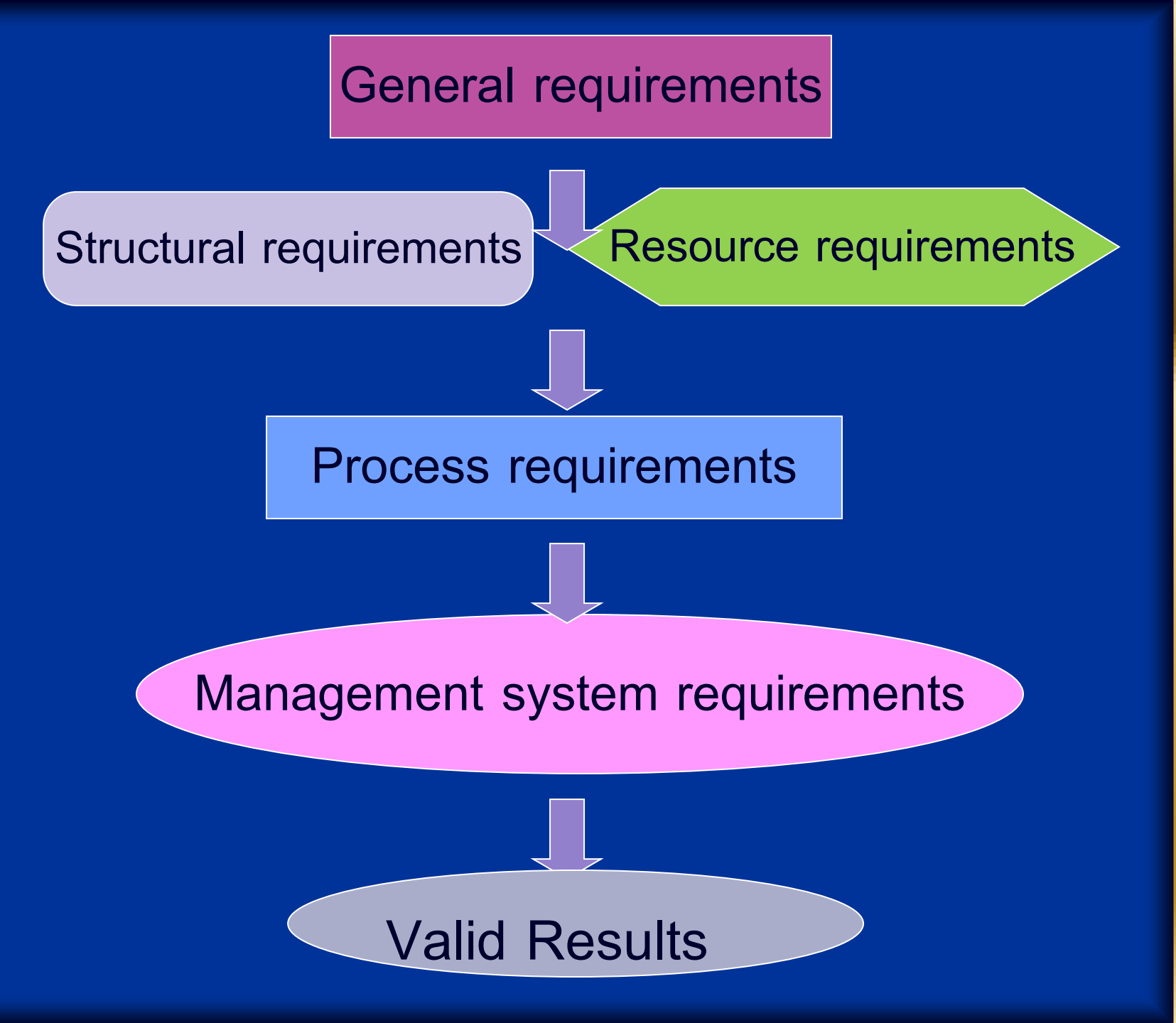
- Address risks and opportunities for increasing the effectiveness of the management system.

Risk&Opportunity

Decision Rule

1.Scope

- general requirements for the competence, impartiality and consistent operation of laboratories.
- applicable to all organizations performing laboratory activities, regardless of the number of personnel.
- confirming or recognizing the competence of laboratories.


General requirements
Structural requirements
Resource requirements
Process requirements
Management system requirements
Valid Results

2.Normative references

- ISO/IEC Guide 99 “International Vocabulary of metrology and associated Terms

(VIM, International vocabulary of basic and general terms in metrology, by BIPM)
The International Bureau of Weights and Measures
(French: Bureau international des poids et mesures, BIPM)

- ISO/IEC 17000, Conformity assessment - Vocabulary and general principles

3 Terms and definitions

- 3.1 impartiality
- 3.2 complaint
- 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

3 Terms and definitions

- 3.6
- “Laboratory:
- A body that performs one or more of the following activities:
- Calibration
- Testing
- Sampling, associated with subsequent
- calibration and testing”

3 Terms and definitions

- 3.7
- decision rule

  rule that describes how measurement uncertainty is accounted for when

  stating conformity with a specified requirement

- 4 General requirements
- 4.1 Impartiality

4.1.1 Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

4.1.2 The laboratory shall be committed to impartiality.

- 4 General requirements
- 4.1 Impartiality

4.1.3 The laboratory shall be responsible for and shall not compromise impartially

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis.

- 4 General requirements
- 4.1 Impartiality

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

- 4.2 Confidentiality
- 4.2.1 The laboratory shall be responsible for the management of all information.

  -place in the public

  -all information is considered proprietary information and shall be regarded as confidential.
- 4.2.2 unless prohibited by law, be notified of the information provided.

- **4.2 Confidentiality**

- **4.2.3 Information about the customer obtained from sources other than the customer shall be confidential between**

  -the customer and the laboratory.

  -the provider (source) and the laboratory.

- **4.2 Confidentiality**

- **4.2.4 Personnel, acting on the laboratory's behalf, shall keep confidential all information obtained, except as required by law.**

5 Structural requirements

- **5.1 The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.**

บริษัท

สถาบัน

สมาคม

กรม

5 Structural requirements

- 5.2 identify management
- 5.3 range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

Scope

ISO9000

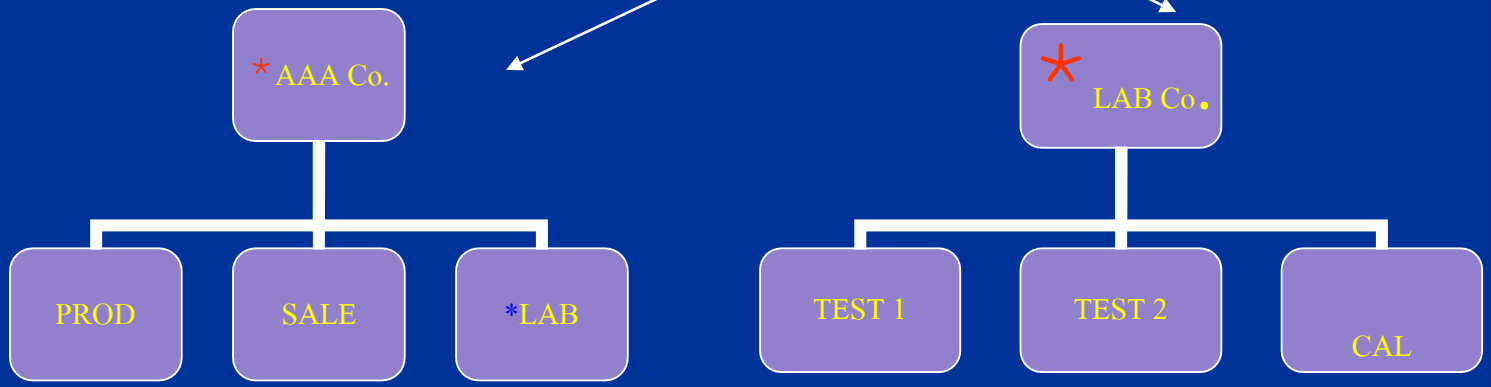
*Top management : person or group of people

who direct and controls an organization

at the highest level

***ISO9000:2000 company/institute**

*** ISO/IEC17000:2004 membership of / individual**



5 Structural requirements

- 5.4 meet the requirements of ISO/IEC17025, the laboratory’s customers, regulatory authorities and organizations providing recognition.

  @permanent facilities

  @ at sites away

  @temporary or mobile facilities/ customer's facility..

5 Structural requirements

- 5.5 a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services

5 Structural requirements

- 5.5 b) specify the responsibility, authority and interrelationship of all personnel

- 5.5 c) document its procedures to ensure the consistent application of its laboratory activities and the validity of the results.

5 Structural requirements

- 5.6 personnel have the authority and resources needed to carry out their duties, implementation, maintenance and improvement of the management system.

QM / TM

5 Structural requirements

- 5.7 laboratory management shall ensure
- -communication
- -integrity of the management system

Top Management

6 Resource requirements

- 6.1 General
- The laboratory shall have available the personnel, facilities, equipment, systems and support services.

6 Resource requirements

- 6.2 Personnel.
- 6.2.1internal or external personnel shall act impartially, be competent

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

6 Resource requirements

- 6.2.3 competent to perform laboratory activities and to evaluate the significance of deviations.
- 6.2.4 The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.

  (job description)

6 Resource requirements

- 6.2.5 procedure(s) and retain records
- 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.

6 Resource requirements

6.2.6 authorize personnel to:

- 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

- 6.3 Facilities and environmental conditions
- 6.3.1 facilities and environmental conditions suitable for the laboratory activities and not affect the validity of results.
- 6.3.2 requirements for facilities and environmental conditions shall be documented

6 Resource requirements

- 6.3.3 monitor, control and record environmental conditions

- 6.3.4 measures to control facilities shall be implemented, monitored and periodically reviewed
- a) access to and use of areas
- b) prevention of contamination,
- c) effective separation

6 Resource requirements

- 6.3.5 requirements at sites or facilities outside its permanent control

6 Resource requirements

- 6.4 Equipment
- 6.4.1 equipment required for the correct performance of laboratory activities
- 6.4.2 equipment outside its permanent control
- 6.4.3 procedure for handling, transport, storage, use and maintenance

6 Resource requirements

- 6.4 Equipment

6.4.4 verify that equipment conforms to specified requirements before being placed or returned into service.

6.4.5 equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required

6 Resource requirements

- 6.4 Equipment
- 6.4.6 measuring equipment shall be calibrated when:

  - affects the validity of the reported results
- - establish the metrological traceability

6 Resource requirements

- 6.4 Equipment
- 6.4.7 calibration programme
- 6.4.8 labelled and identify the status of calibration
- 6.4.9 defective or outside specified requirements, shall be taken out of service

6 Resource requirements

- 6.4 Equipment
- 6.4.10 intermediate checks
- 6.4.11 reference values or correction factors

6 Resource requirements

- 6.4 Equipment
- 6.4.12 prevent unintended adjustments of equipment

- 6.4.13 records shall be retained for equipment

  a) to h)

6 Resource requirements

- 6.5 Metrological traceability
- 6.5.1 documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.
- 6.5.2 traceable to the International System of Units (SI)

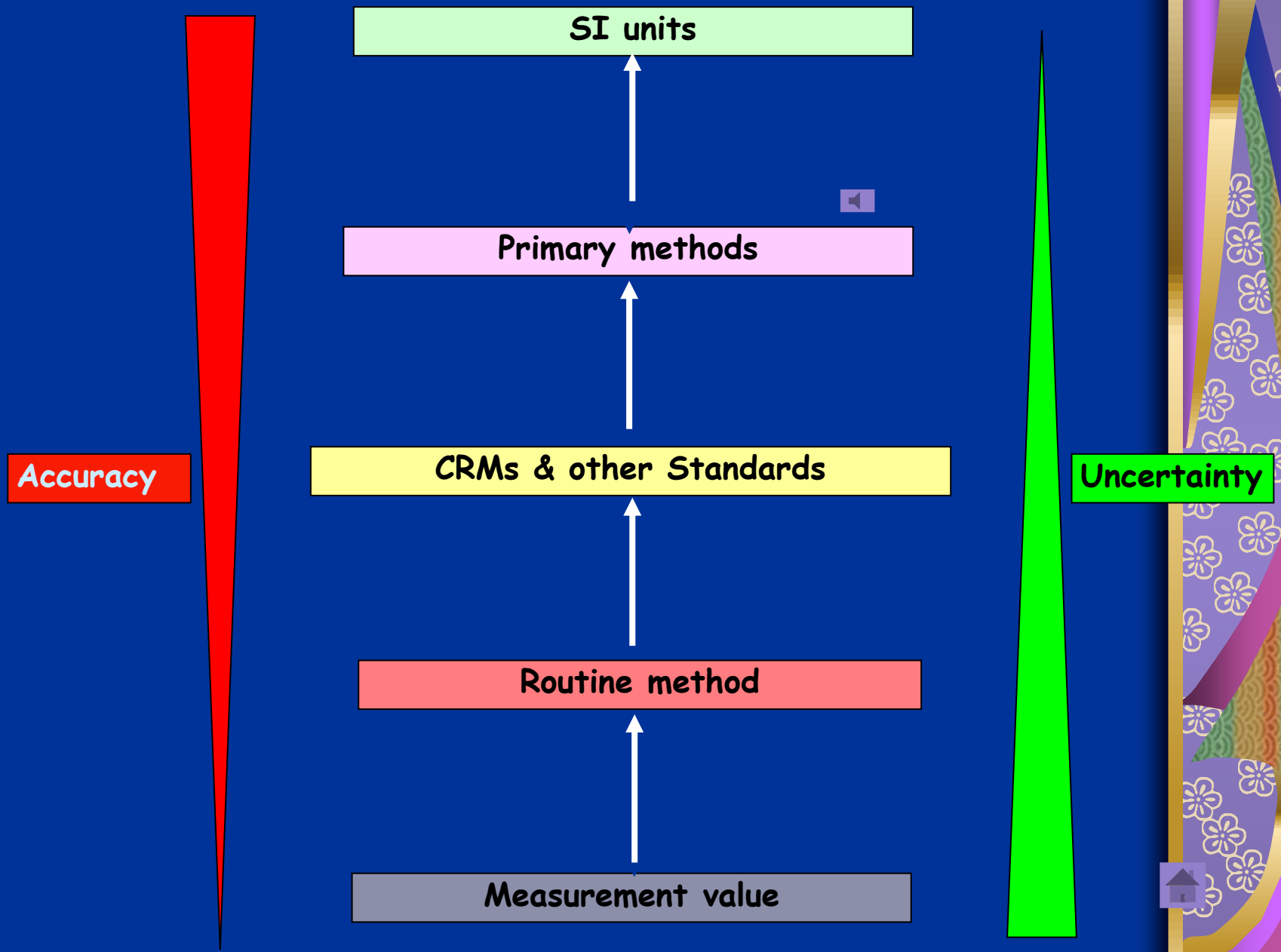
SI base unit

- **Kilogram (kg) → mass**
- **Meter (m) → length**
- **Second (s) → time**
- **Candela (cd) → luminous intensity temperature**
- **Ampere(A) → electric current**
- **Kelvin (K) → thermodynamic temperature**
- **Mole (mol) → amount of substance**

6 Resource requirements

- 6.5.3 when metrological traceability to the SI units is not technically possible
- a) certified reference materials provided by a competent producer;
- b) reference measurement procedures by suitable comparison.

- **AnnexA


SI units
Primary methods
CRMs & other Standards
Routine method
Measurement value
Accuracy
Uncertainty

6 Resource requirements

- 6.6 externally provided products and services

  6.6.1 suitable externally provided products and services

  6.6.2 procedure and record: requirement/evaluation/monitoring/ reevaluation

  6.6.3 communication of requirement

6 Resource requirements

- 6.6 Externally provided products and services

** products: standards/equipment/consumable materials/ reference materials.

** services:

calibration /sampling /testing /facility and equipment maintenance/

proficiency testing / assessment/ auditing.

7 Process requirements

- 7.1 Review of requests, tenders and contracts
- 7.1.1requirements are adequately defined, documented and understood;
- the capability and resources to meet the requirements
- appropriate methods or procedures are selected
- use external provider ?

7 Process requirements

- 7.1.2 inform the customer when the method requested by the customer is considered to be inappropriate or out of date

7 Process requirements

- 7.1.3 When the customer requests a statement of conformity 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 differences between the request shall be resolved
- 7.1.5 customer shall be informed of any deviation from the contract
- 7.1.6 contract is amended after work has commenced, the contract review shall be repeated
- 7.1.7 customer's request in monitoring the laboratory’s performance
- 7.1.8Records of reviews,

7 Process requirements

- 7.2 Selection, verification and validation of methods

- 7.2.1 Selection and verification of methods

  7.2.1.1 appropriate methods and procedures

  7.2..1.2 up to date available to personnel
- 7.2.1.3 latest valid version

7 Process requirements

- 7.2.1.4 select an appropriate method
- 7.2.1.5 verify method
- 7.2.1.6 periodic review shall be carried out
- 7.2.1.7 deviations from methods has been documented, technically justified, authorized, and accepted by the customer.

7 Process requirements

- 7.2.2 Validation of method
- 7.2.2.1validate non-standard methods, laboratory-developed methods and standard methods used outside the scope or modified

- 7.2.2.2 When changes are made to a validated method, a new method shall be performed.

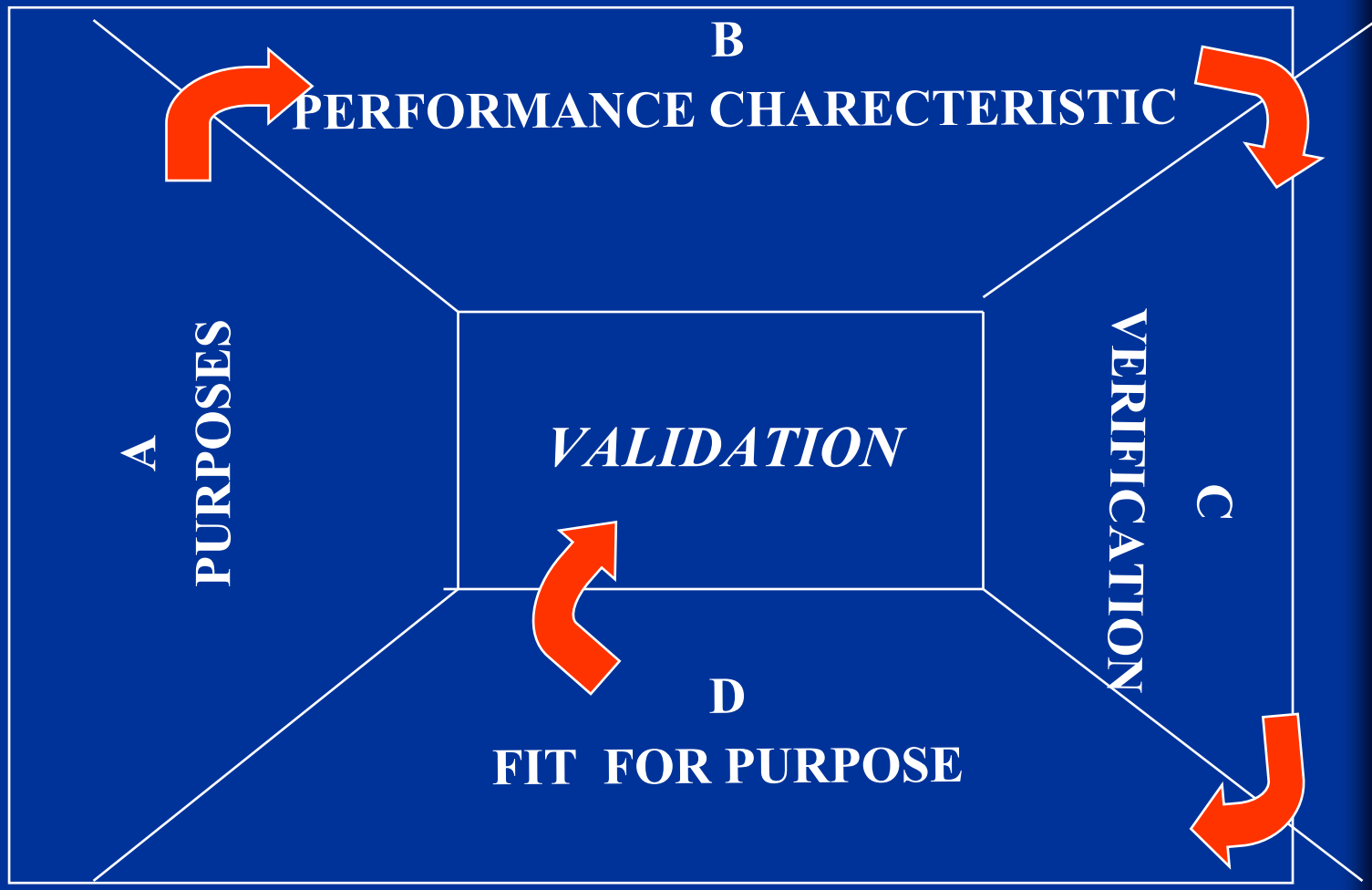
7 Process requirements

- 7.2.2 Validation of method
- 7.2.2.3 performance characteristics of validated methods for the intended use

Note:not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness.

4 STEPS FOR ISO/IEC 17025

Validation of Methods



7 Process requirements

- 7.2.2.4 retain the records
- a) validation procedure used
- b) specification of the requirement
- c) determination of the performance characteristics of the method
- d) results obtained
- e) a statement on the validity of the method, detailing its fitness for the intended use.

7 Process requirements

- 7.3 Sampling
- 7.3.1 sampling plan and method records of sampling data
- 7.3.2 sampling method :

  a) selection of samples or sites

  b) sampling plan

  c) preparation and treatment of sample
- 7.3.3 records of sampling data

  a) to h)

7 Process requirements

- 7.4 Handling of test or calibration items
- 7.4.1 procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items
- 7.4.2 identification of test or calibration items.

7 Process requirements

- 7.4.3 deviations from specified conditions shall be recorded.

- 7.4.4 items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

7 Process requirements

- 7.5 Technical records
- 7.5.1 contain the results, report and sufficient information

- 7.5.2 ensure that amendments to technical records can be tracked to previous versions or to original observations.

7.6 Evaluation of measurement uncertainty

- 7.6.1 identify the contributions to measurement uncertainty
- 7.6.2 calibrations: evaluate the measurement uncertainty for all calibrations.
- 7.6.3testing : evaluate measurement uncertainty where the test method precludes rigorous evaluation of measurement uncertainty

7.7 Ensuring the validity of results

- 7.7.1 procedure for monitoring the validity of results

a) use of reference materials or quality control materials

b) use of alternative instrumentation that has been calibrated to provide traceable results

c) functional check(s) of measuring and testing equipment

d) use of check or working standards with control charts

7.7 Ensuring the validity of results

- 7.7.1 procedure for monitoring the validity of results

e) intermediate checks on measuring equipment;

f) replicate tests

g) retesting of retained items

h) correlation of results for different characteristics of an item

7.7 Ensuring the validity of results

- 7.7.1 procedure for monitoring the validity of results

i) review of reported results

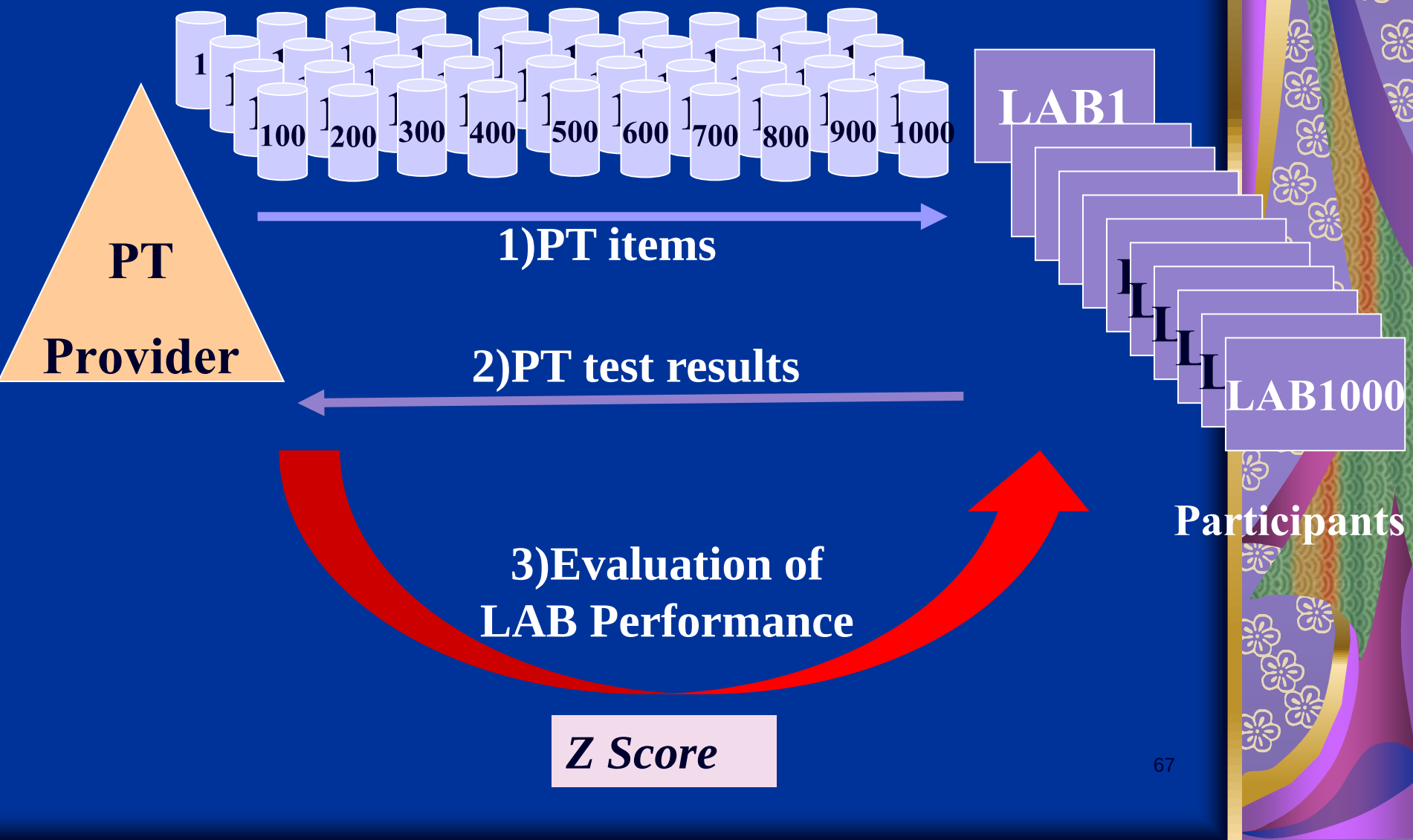
j) intralaboratory comparisons;

k) testing of blind sample(s).

7.7 Ensuring the validity of results

- 7.7.2 comparison with results of other laboratories
- a) participation in proficiency testing;
- b) participation in interlaboratory comparisons

Proficiency Testing(PT)



Evaluation of LAB Performance by Z Score

$|z| \leq 2.0$ satisfactory

$2.0 < |z| < 3.0$ questionable

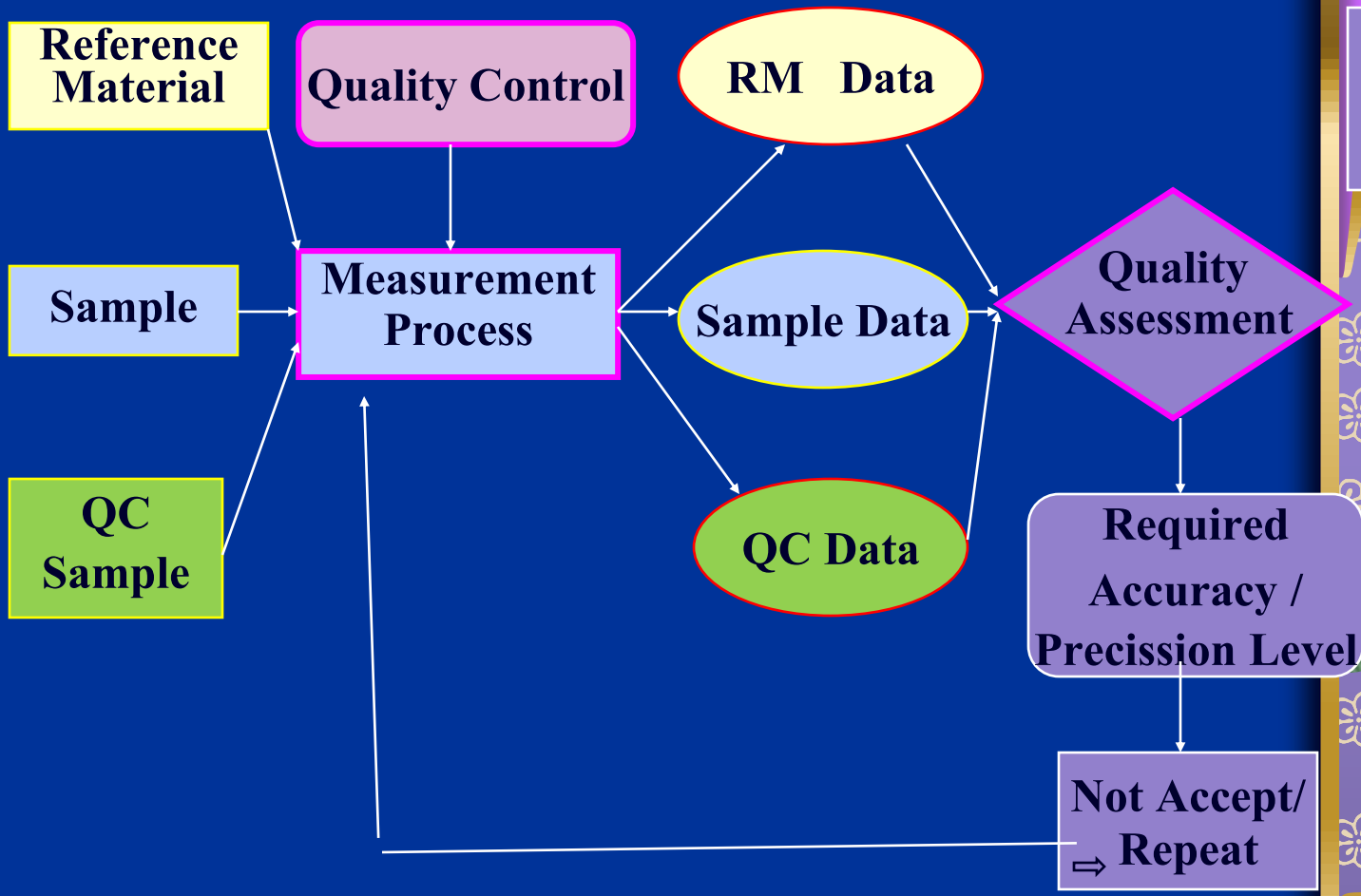
$|z| \geq 3.0$ unsatisfactory

7.7 Ensuring the validity of results

- 7.7.3 Data from monitoring activities shall be analysed, used to control and, if applicable, improve the laboratory's activities.

- If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

Quality Assurance of Measurement Process



7.8 Reporting of results

- 7.8.1.1 be reviewed and authorized prior to release.
- 7.8.1.2 accurately, clearly, unambiguously and objectively
- 7.8.1.3 may be reported in a simplified way but information that is not reported to the customer shall be readily available

7.8 Reporting of results

- 7.8.2 Common requirements
- 7.8.2.1 shall include at least :

a) title “Test Report

b) name and address of the laboratory

c) location of laboratory activities

d) unique identification

e) name and contact of customer

f) identification of the method used

g) description of the item;

h) date of receipt of the item

i)date of performance testing

7.8 Reporting of results

j)date of issue report

k)sampling plan and sampling method

l) a statement that the results relate only to the items tested

m)units of measurement

n)additions to, deviations, or exclusions from the method

o)person authorizing the report

p)identification external providers

- 7.8.2.2 laboratory shall be responsible for all the information

7.8 Reporting of results

- 7.8.3 Test reports

- 7.8.3.1 interpretation of test results
- a) information on specific test conditions
- b) where relevant, a statement of conformity with requirements or specifications

7.8 Reporting of results

- 7.8.3 test reports

c) measurement uncertainty

- relevant to the validity or application of the test results;
- customer's instruction so requires
- the measurement uncertaintyaffects conformity to a specification limit;

d) where appropriate, opinions and interpretations

e) additional information that may be required.

- 7.8.3.2 sampling activities(7.8.5)

7.8 Reporting of results

- 7.8.4 calibration certificates
- 7.8.4.1
- a) measurement uncertainty
- b) conditions
- c) metrologically traceable
- d) results before and after any adjustment or repair
- e) where relevant, a statement of conformity with requirements or specifications
- f) where appropriate,opinions and interpretations

- 7.8.4.2 sampling activity (7.8.5)
- 7.8.4.3 not contain the calibration interval

7.8 Reporting of results

7.8.5 Reporting sampling(7.8.2)

a) date of sampling;

b) unique identification of the item or material sampled (manufacturer, model or type of designation and serial numbers);

c) location of sampling, including any diagrams, sketches or photographs;

d) reference to the sampling plan and sampling method;

e) details of any environmental conditions;

f) information required to evaluate measurement uncertainty

7.8 Reporting of results

- 7.8.6 Reporting statements of conformity
- 7.8.6.1 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.

7.8 Reporting of results

- 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.

7.8 Reporting of results

- **7.8.6.2 statement clearly identifies:**
- a) to which results the statement of conformity applies;
- b) which specifications, standards or parts thereof are met or not met;
- c) the decision rule applied (unless it is inherent in the requested specification or standard).

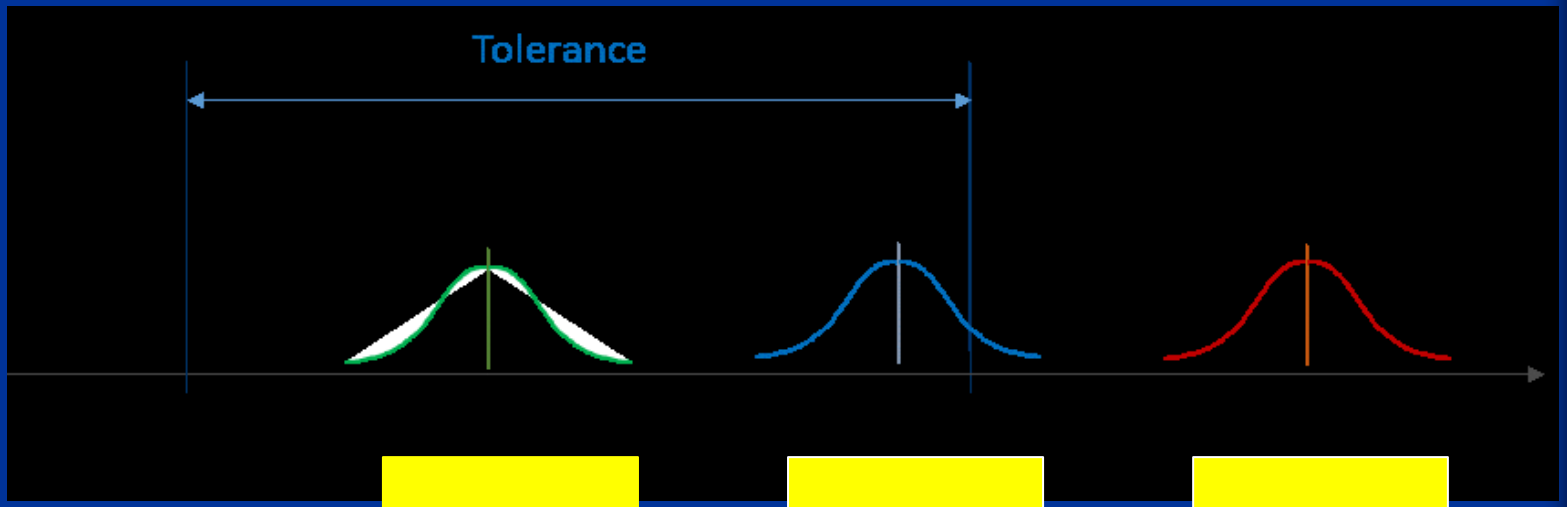
1. ISO/IEC Guide 98-4. (JCGM)
2. The JCGM 106:2012 “Evaluation of Measurement Data- the Role of

measurement uncertainty in conformance assessment”

in compliance assessment” in 2007

3. ILAC G-8:03/2009 “Guidelines on the reporting of compliance to specification”
4. The Eurachem/CITAC Guide “Use of uncertainty information
5. Eurolab Technical Report No.1/2017-

Decision rules applied to conformity assessment



Case A **Case B** **Case C**

case A: in conformity

case C: out of conformity

case B: undefined situation ⇨ Decision rule

7.8 Reporting of results

- ### 7.8.7 Reporting opinions and interpretations

7.8.7.1 When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement.

7.8 Reporting of results

- ### 7.8.7 Reporting opinions and interpretations

7.8.7.2 The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

7.8 Reporting of results

- 7.8.7 Reporting opinions and interpretations

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.

7.8 Reporting of results

- ### 7.8.8Amendments to reports

7.8.8.1 When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

7.8 Reporting of results

- 7.8.8Amendments to reports

7.8.8.2 Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement “Amendment to Report, serial number... [or as otherwise identified]”, or an equivalent form of wording.

7.8 Reporting of results

- 7.8.8Amendments to reports

7.8.8.3 When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

7.9 Complaints

Definition

3.2 complaint

expression of dissatisfaction by any person or organization to a *laboratory*

relating to the activities or results of that laboratory, where a response is expected

7.9 Complaints

- 7.9.1 documented process to receive, evaluate and make decisions on complaints.

- 7.9.2 handling process for complaints shall be available to any interested party on request laboratory shall be responsible for all decisions at all levels of the handling process for complaints

7.9 Complaints

- 7.9.3 The process for handling complaints shall include at least

a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it

b) tracking and recording

c) any appropriate action is taken.

7.9 Complaints

- 7.9.4 The laboratory shall be responsible for gathering and verifying all necessary information to validate the complaint.
- 7.9.5 The laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9 Complaints

- 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.
- 7.9.7 the laboratory shall give formal notice of the end of the complaint handling to the complainant.

7.10 Nonconforming work

- **any aspect of laboratory activities or results of the work do not conform to laboratory procedures or the agreed requirements of the customer**
- **7.10.1**

a) responsibilities and authorities for the management of nonconforming work are defined;

7.10 Nonconforming work

b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;

c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

7.10 Nonconforming work

d) a decision is taken on the acceptability of the nonconforming work;

e) where necessary, the customer is notified and work is recalled;

f) the responsibility for authorizing the resumption of work is defined.

7.10.2 retain records of nonconforming work and actions

7.10 Nonconforming work

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.

7.11 Control of data and information management

- 7.11.1 access to the data and information needed to perform laboratory activities.
- 7.11.2 laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated by the laboratory before introduction

7.11 Control of data and information management

- 7.11.3 The laboratory information management system(s) shall:
- a) be protected from unauthorized access;
- b) be safeguarded against tampering and loss;

7.11 Control of data and information management

c) be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

d) be maintained in a manner that ensures the integrity of the data and information;

e) include recording system failures and the appropriate immediate and corrective actions.

7.11 Control of data and information management

- 7.11.4 When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

7.11 Control of data and information management

- 7.11.5 The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.
- 7.11.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.

8 Management system requirements

- 8.1 laboratory shall implement a management system in accordance with
- Option A : address the requirements clauses 8.2-8.9
- Option B: requirements of ISO 9001, and fulfilment of clauses 4 to 7 and intent of clause 8.2 to 8.9.

8 Management system requirements

- **8.2 Management system documentation**

  8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.

8 Management system requirements

- **8.2 Management system documentation**

  8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.

8 Management system requirements

- 8.2 Management system documentation

  8.2.3 Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

8 Management system requirements

- 8.2 Management system documentation

  8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.

8 Management system requirements

- **8.2 Management system documentation**

  8.2.5 All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 Control of management system documents

8.3.1 The laboratory shall control the documents (internal and external)

8.3.2 ensure that

a) approved prior to issue

b) periodically reviewed

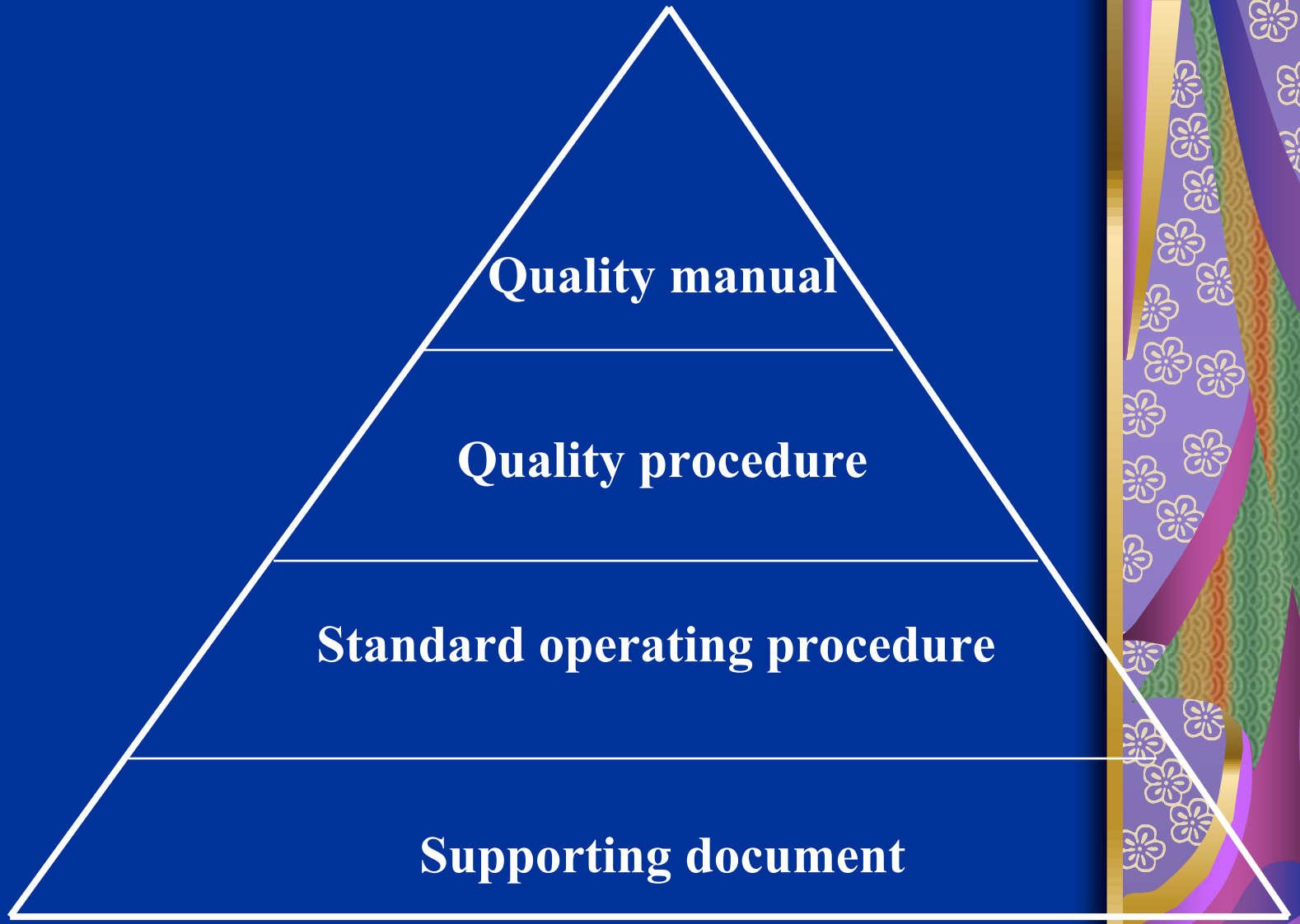
c) current revision are identified

d) available at points of use

e) uniquely identified

f) unintended use of obsolete documents

Documentation



8.4 Control of records

- 8.4.1establish and retain legible records:
- 8.4.2 identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of laboratory records

8.5 Actions to address risks and opportunities

- **8.5.1 consider the risks and opportunities associated with the laboratory activities**

a) management system achieves its intended results;

b) achieve the purpose and objectives of the laboratory;

c) prevent, or reduce, undesired impacts

d) achieve improvement.

8.5 Actions to address risks and opportunities

- **8.5.2 The laboratory shall plan:**
- a) actions to address these risks and opportunities;
- b) how to:

- integrate and implement these actions into its management system;

- evaluate the effectiveness of these actions.

8.5 Actions to address risks and opportunities

- 8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

8.5 Actions to address risks and opportunities

- **ISO/TR31000 Risk management – Guideline
- ISO/TR31004 Risk management – Guideline for the implementation of ISO3100

8.5 Actions to address risks and opportunities

Practical approaches in risk

- risk identification process, we have to decide whether to deal
- proactively with a significant risk which has the likelihood that it will occur (typically,these will have at least moderate probability and impact).

8.5 Actions to address risks and opportunities

- All assessment of risk depends on determining risk probability it will occur and risk severity on its impact if it occurs. Mathematically, it is calculated as:
- Risk Index (RI) estimation = Frequency (F) x Severity (S)
- where F can be scaled for example, from 1 to 5, and S, from 1 to 5

- Frequency

Rare =1 Not expected to occur

Remote =2 Not likely to occur

Occasional =3 Possible or know to occur

Frequent= 4 Common occurrence

Almost certain =5 Continual of repeated occurrence

- Severity

Negligible =1 Not likely to cause any impact

Minor= 2 No significant impact

Moderate= 3 Having very slight impact

Major= 4 Having considerable impact

Catastrophic =5 Having significant impact

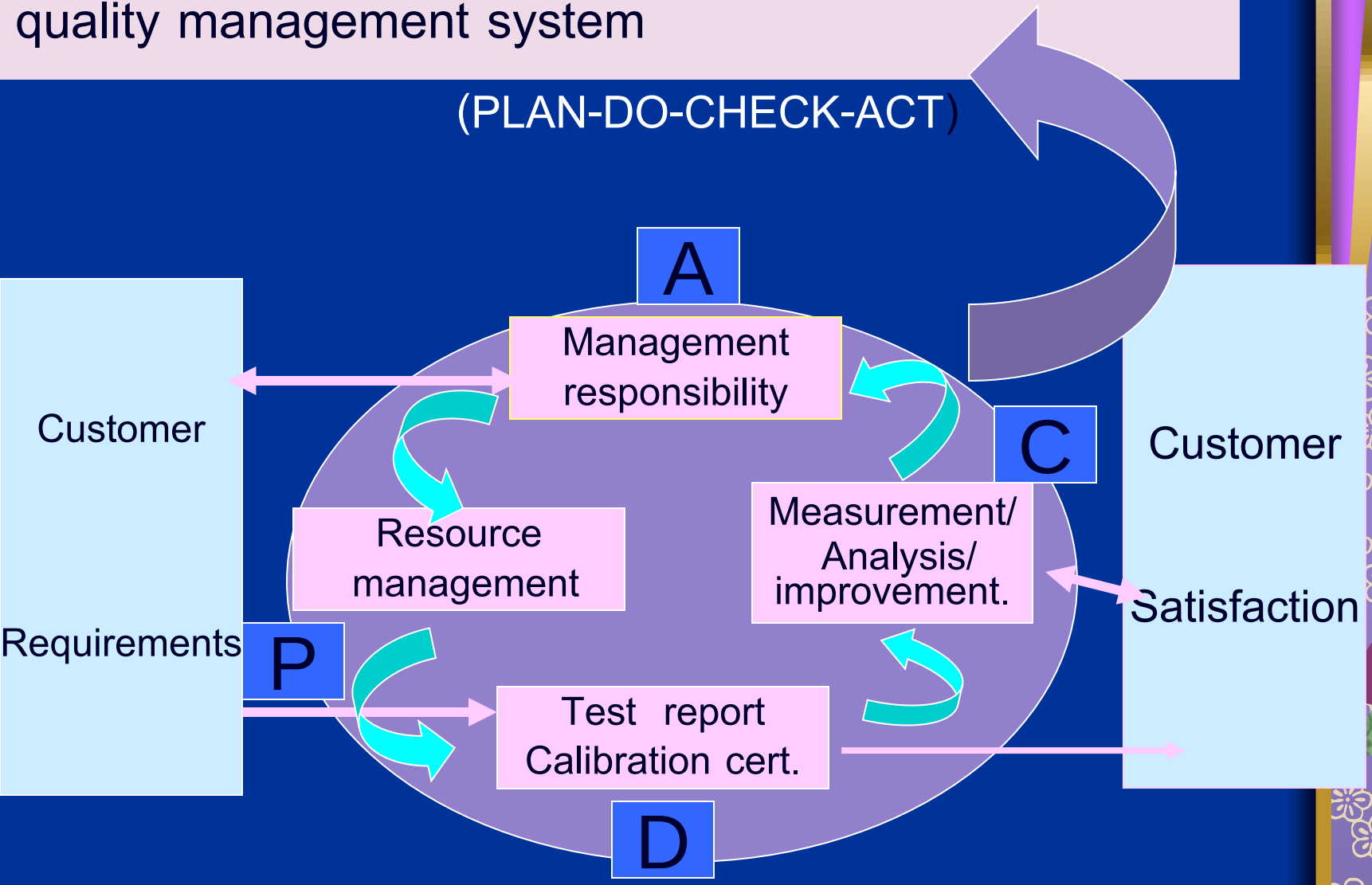
Risk index

Frequency / Severity	1	2	3	4	5
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15
4	4	8	12	16	20
5	5	10	15	20	25

8.6 Improvement

- 8.6.1 identify and select opportunities for improvement and implement any necessary actions
- 8.6.2 seek feedback, both positive and negative, from its customers and used to improve the management system

Continual improvement of the quality management system



8.7 Corrective actions

- 8.7.1 nonconformity occurs:

a) react to the nonconformity

b) evaluate the need for action to eliminate the cause

c) implement any action needed

d) review the effectiveness

e) update risks and opportunities;

f) make changes to the management system, if necessary.

8.7 Corrective actions

- 8.7.2 Corrective actions shall be appropriate to the effects
- 8.7.3 The laboratory shall retain records
- a) the nature of the nonconformities, cause(s) and any subsequent actions taken;
- b) the results of any corrective action.

8.8 Internal audits

- 8.8.1 The laboratory shall conduct internal audits at planned intervals
- 8.8.2 The laboratory shall

a) plan, establish, implement and maintain an audit programme

b) define the audit criteria and scope

c) audits are reported

d) implement appropriate correction and corrective actions

e) retain records

NOTE: ISO 19011 provides guidance for internal audits.

ผู้ตรวจติดตาม

- มีคุณสมบัติเหมาะสม
- ได้รับการอบรม
- เป็นอิสระจากงานที่ตรวจ

- **8.9 Management reviews**
- **8.9.1 The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.**

- **8.9.2 The inputs to management review shall be recorded**

a) changes in internal and external issues

b) fulfilment of objectives

c) suitability of policies and procedures

d) status of actions from previous management reviews

e) outcome of recent internal audits

f) corrective actions

- **8.9.2 The inputs to management review shall be recorded**

g) assessments by external bodies;

h) changes in the volume and type of the work

i) customer and personnel feedback

j) complaints

k) effectiveness of any implemented improvements

- **8.9.2 The inputs to management review shall be recorded**

l) adequacy of resources

m) results of risk identification

n) outcomes of the assurance of the validity of results

o) other relevant factors

- 8.9.3 The outputs from the management review shall record all decisions and actions related to at least:
- a) the effectiveness of the management system
- b) improvement of the laboratory activities
- c) provision of required resources
- d) any need for change.

- **Annex A(informative)**

Metrological traceability

A.1 General:

comparability of measurement results both nationally and internationally.

A.2 Establishing metrological traceability

A.3 Demonstrating metrological traceability

Annex A(informative)

Metrological traceability

A.2 Establishing metrological traceability

A.2.1 Metrological traceability is established by considering, and then ensuring, the following:

a) the specification of the measurand (quantity to be measured);

b) a documented unbroken chain of calibrations going back to stated and appropriate references (appropriate references include national or international standards, and intrinsic standards);

Annex A(informative)

Metrological traceability

A.2 Establishing metrological traceability

A.2.2 The systematic measurement error (sometimes called “bias”) of the calibrated equipment is taken into account to disseminate metrological traceability to measurement results in the laboratory. There are several mechanisms available to take into account the systematic measurement errors in the dissemination of measurement metrological traceability.

Annex A(informative)

Metrological traceability

A.2 Establishing metrological traceability

A.2.3 Measurement standards that have reported information from a competent laboratory that includes only a statement of conformity to a specification (omitting the measurement results and associated uncertainties) are sometimes used to disseminate metrological traceability. This approach, in which the specification limits are imported as the source of uncertainty, is dependent upon:

Annex A(informative)

Metrological traceability

A.3 Demonstrating metrological traceability

A.3.1 Laboratories are responsible for establishing metrological traceability in accordance with this document.

-Calibration results from laboratories

-Certified values of certified reference materials from reference material producers conforming to ISO 17034

-Internationally accepted paths

Annex A(informative)
Metrological traceability

A.3 Demonstrating metrological traceability

a) Calibration and measurement capabilities provided by national metrology institutes and designated institutes that have been subject to suitable peer-review processes. Such peer-review is conducted under the CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement). Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database) which details the range and measurement uncertainty for each listed service.

Annex A(informative)
Metrological traceability

A.3 Demonstrating metrological traceability

b) Calibration and measurement capabilities that have been accredited by an accreditation body subject to the ILAC (International Laboratory Accreditation Cooperation) Arrangement or to Regional Arrangements recognized by ILAC have demonstrated metrological traceability. Scopes of accredited laboratories are publicly available from their respective accreditation bodies.

Annex A(informative) Metrological traceability

A.3 Demonstrating metrological traceability

A.3.2 The Joint BIPM, OIML (International Organization of Legal Metrology), ILAC and ISO Declaration on Metrological Traceability provides specific guidance when there is a need to demonstrate international acceptability of the metrological traceability chain.

- Annex B(informative)

1.Laboratories that comply with Clause 4 to 7 and Option A of Clause 8 will therefore also operate generally with the principles of ISO 9001

2. laboratory with ISO 9001, and Clause 4 to 7 also fulfils requirements specified in 8.2 to 8.9

- Bibliography