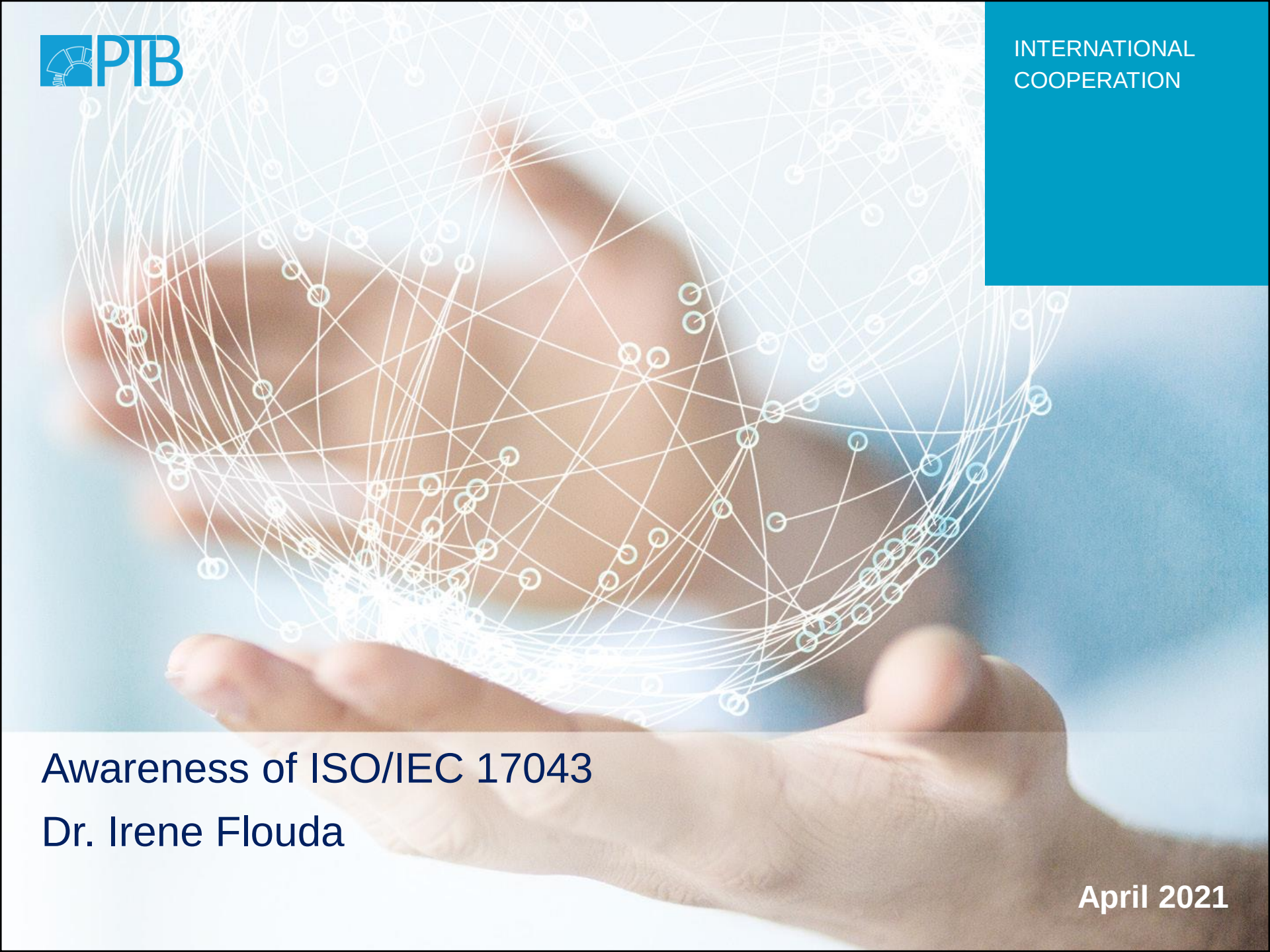


INTERNATIONAL COOPERATION

Awareness of ISO/IEC 17043

Dr. Irene Flouda

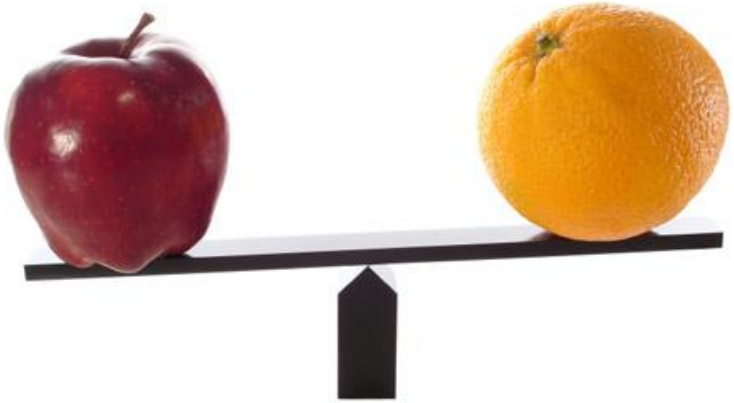
April 2021

Contents

- Introduction to ILCs and PTs
- Introduction to ISO/IEC 17043 (including Annex A)
- Management Requirements
- Technical Requirements
- Annex B
- Annex C

Introduction to ILCs and PTs

Interlaboratory comparison (ILC) -Definition



- **Interlaboratory comparison (ILC)** is the organization, performance and evaluation of calibrations/tests **on the same** or **similar calibration/test items** by **two or more laboratories** (*or inspection bodies**) in accordance with predetermined conditions

Why do we need Interlaboratory Comparisons?

a) **Evaluation** of the **performance** of laboratories for specific tests or measurements and monitoring laboratories' continuing performance;

b) **Identification of problems** in laboratories and initiation of actions for improvement which, for example, may be related to inadequate test or measurement procedures, effectiveness of staff training and supervision, or calibration of equipment;

c) Establishment of the **effectiveness and comparability** of test or measurement methods;

d) Provision of additional **confidence to participant**;

e) Identification of **interlaboratory differences**;

Why do we need Interlaboratory Comparisons?

f) **Education** of participating laboratories based on the outcomes of such comparisons;

g) **Validation of uncertainty claims**;

h) **Evaluation of the performance characteristics of a method** — often described as collaborative trials (method validation- standardization);

i) **Assignment of values to reference materials** and assessment of their suitability for use in specific test or measurement procedures; and

Why do we need Interlaboratory Comparisons?

j) **Support for statements of the equivalence of measurements of National Metrology Institutes** through “key comparisons” and supplementary comparisons conducted on behalf of the International Bureau of Weights and Measurement (BIPM) and associated regional metrology organizations.

Why do we need Interlaboratory Comparisons?

Interlaboratory comparison often consists of inter-comparison results of a laboratory and a reference (target) value of a reference laboratory which is the highest authority of a particular country for the measurement concerned

The goal of this ILC is to verify the competence of accredited or non-accredited laboratories, including verification of the reported measurement uncertainties, whenever possible

Proficiency Testing-Definition

- **Proficiency testing (PT)** is the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

Calibration or testing laboratory, inspection body

a) **Evaluation** of the **performance** of laboratories for specific tests or measurements and monitoring laboratories' continuing performance;

Proficiency test-What is it?

- An interlaboratory study in which the analysis or measurement results obtained by **different** persons, bodies and/or devices are **compared** to one another in an **anonymous** way.
- The PT offers an **independent** quality check on the measurements/analyses performed.

Terms and Definitions

- **Proficiency testing provider:**

  organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme

- **Proficiency test item:**

  sample, product, artefact, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing

Terms and Definitions

- **Proficiency testing round:**

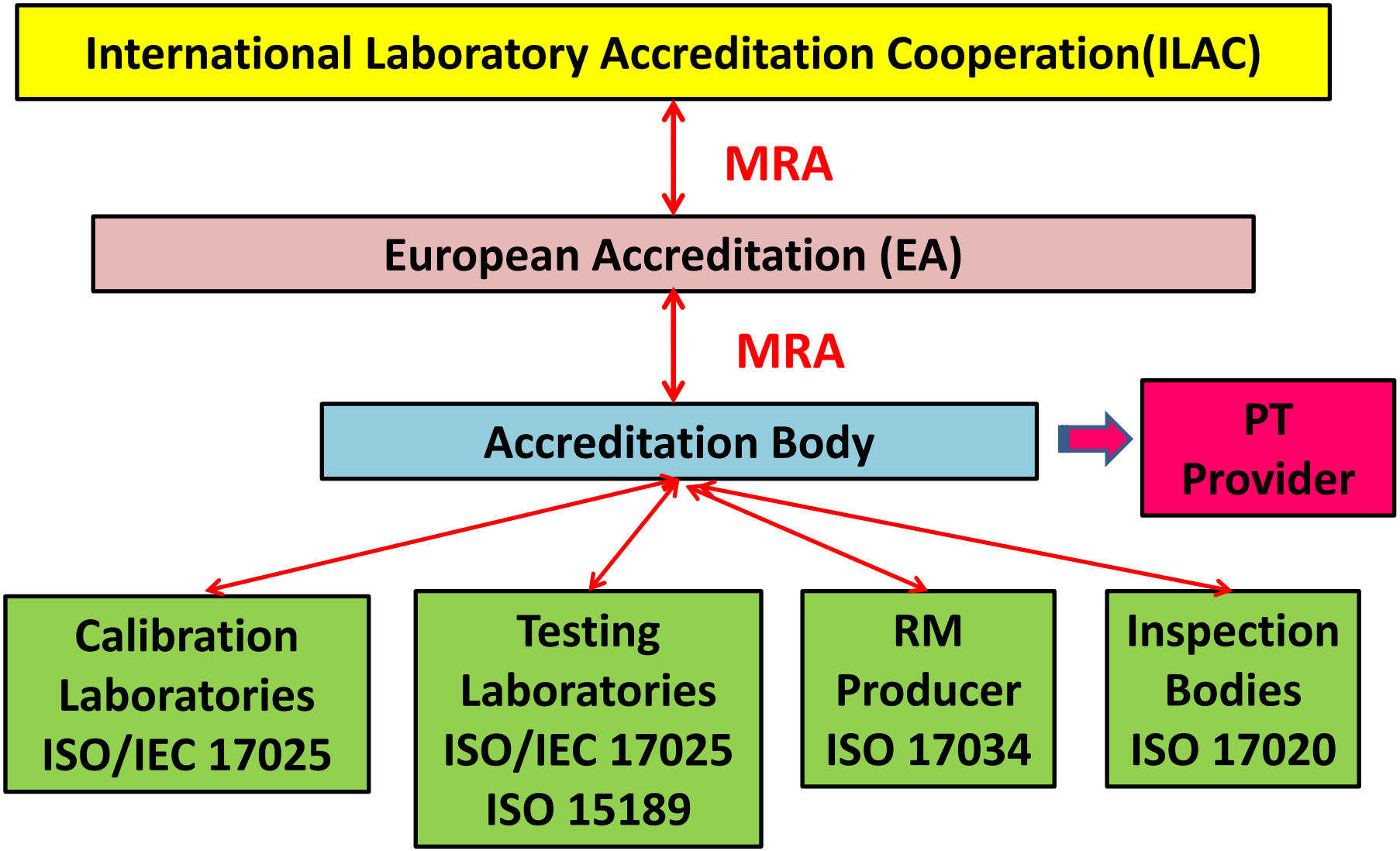
  single complete sequence of distribution of proficiency test items, and the evaluation and reporting of results to the participants

- **Proficiency testing scheme:**

  proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection

Benefits of ISO/IEC 17043:2010 Accreditation

- PT Providers receive an external “check” on their systems
- A credential for use for marketing / business expansion
- Laboratories receive assurance of technical competence of a PT provider
- Government/industry receive
  - ✓ assurance of technical competence in a PT provider
  - ✓ effective oversight of program that they rely on so that they can direct attention on other programs like regulations, permitting.


International Laboratory Accreditation Cooperation(ILAC)
MRA
European Accreditation (EA)
MRA
Accreditation Body
PT Provider
Calibration Laboratories ISO/IEC 17025
Testing Laboratories ISO/IEC 17025 ISO 15189
RM Producer ISO 17034
Inspection Bodies ISO 17020

Possible types of proficiency testing in accreditation

- a) Bilateral proficiency testing
- b) Proficiency testing schemes
- c) Interlaboratory comparisons designed primarily for other purposes: their results of, although gained originally for other purposes, may be used for the assessment of the laboratory's competence to carry out specific test methods, if the acceptability criteria are correctly and adequately defined

Measurement Audit /Bilateral proficiency testing

Laboratories receive a test item with accurately determined characteristics, which is to be tested in the context of an accreditation process.

The test item is given either by the assessor or provided by a third party.

When PTs are not available…

In specific sectors where no PTs are available, the laboratory should use alternative resources to prove its technical competence. These include (among others):

- The regular use of (certified) reference materials
- Comparison of results obtained by independent techniques
- Comparison of the results of 2 or more laboratories on their own initiative

PTB

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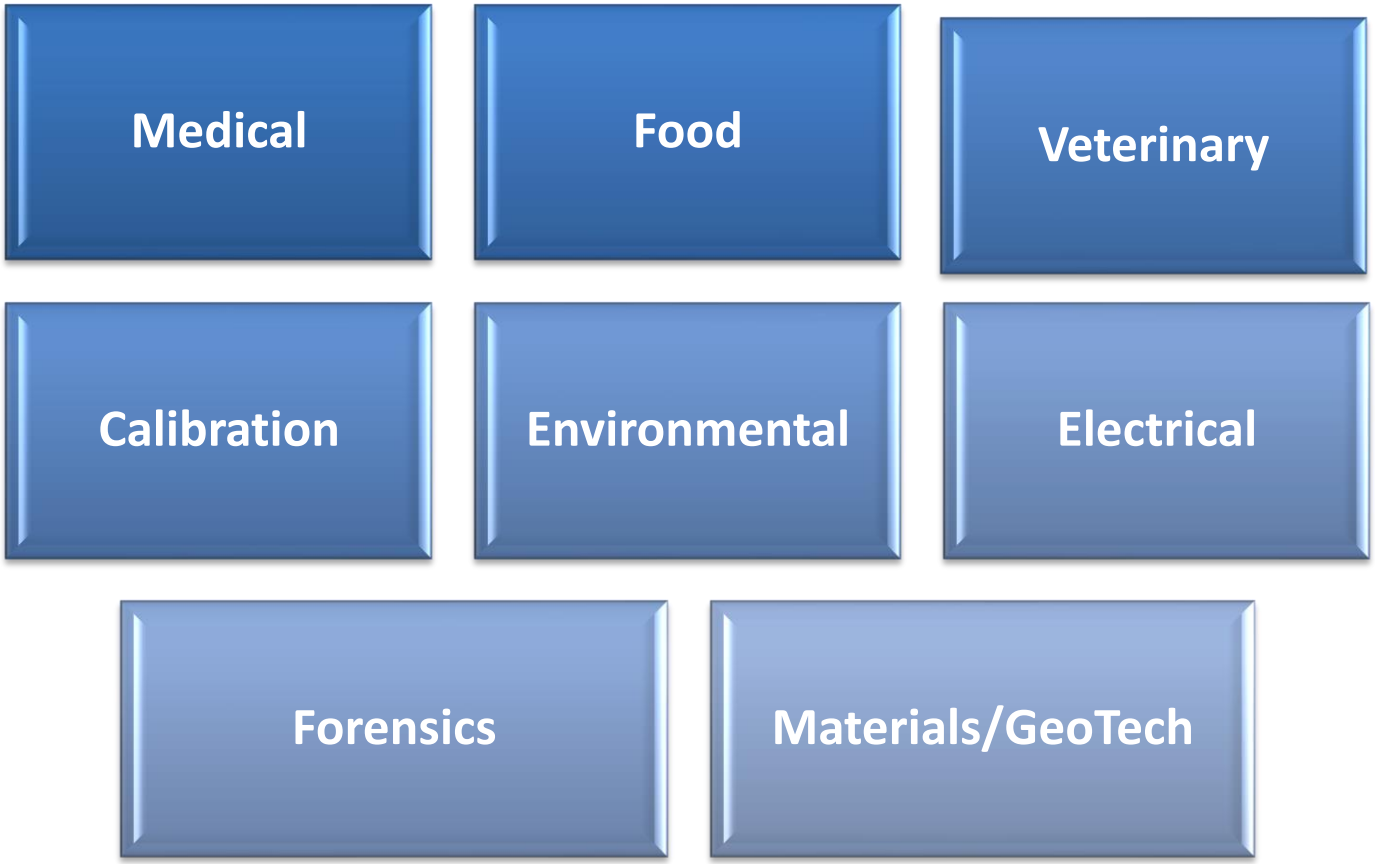
Introduction to ISO/IEC 17043 (including Annex A)

Intention of ISO/IEC 17043:2010 Conformity assessment — General requirements for proficiency testing

- For all types of lab based PT schemes
- Testing of conformity assessment activities
- Applicable to current and evolving areas

Why *General* Requirements"?

- Intended to be general so that they can be applied to ALL types of PT schemes:



Why *General* Requirements"?

- Specific technical requirements can then be added to these minimum general requirements for particular fields.
- A great example is the Requirements that are added to ISO/IEC 17043 for the Environmental Proficiency Testing Schemes.

Why *General* Requirements"?

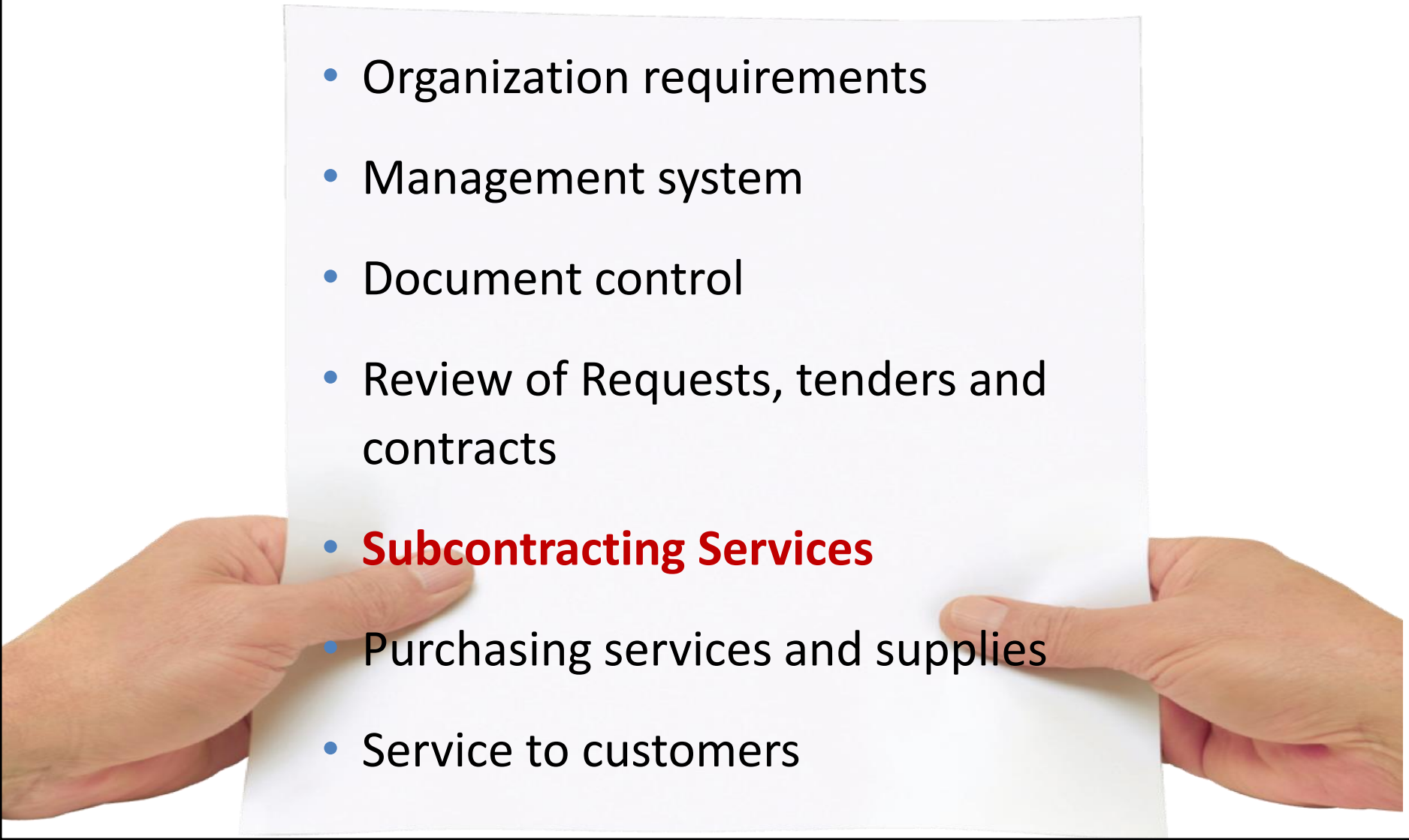
Specific technical requirements can then be added to these minimum general requirements for particular fields.

- A great example is the Requirements that are added to ISO/IEC 17043 for the Environmental Proficiency Testing Schemes.

ISO/IEC 17043 -Content

- Management System from ISO 17025:2005 (do you remember it?)
- Technical Requirements (including inspection bodies, sampling)
- Annex A on Types of Proficiency Testing (expands the description of PT for medical laboratories)
- Annex B on Statistical Methods (Reference ISO 13528 and IUPAC Harmonized Protocol)
- Annex C on use of PT data for accreditation or by different types of organizations, such as inspection bodies.

ISO/IEC 17043 – Organization and Management



- Organization requirements
- Management system
- Document control
- Review of Requests, tenders and contracts
- **Subcontracting Services**
- Purchasing services and supplies
- Service to customers

ISO/IEC 17043 – Organization and Management

- Complaints and appeals
- Control of non-conforming work
- Improvement
- Corrective actions
- Preventive actions
- Control of records
- Internal audits
- Management reviews

PT Laboratory Requirements

- Applies to PT-related testing/calibration
  - ✓ Verification of PT item composition
  - ✓ Homogeneity and Stability
  - ✓ Reference Values
- Lab (in-house or subcontractor) might be 17025 accredited for appropriate Scope
- If not accredited…should we assess?

Assessing PT Providers vs. Assessing Laboratories- Differences

- "Customer" is different
  - ✓ Participant laboratory is main customer
  - ✓ Also lab accreditor, regulator, client
- "Product" is different
  - ✓ PT results evaluation
  - ✓ PT scheme summary report
  - ✓ PT test item
- 17043 allows "Subcontractors"

PT Providers vs. Laboratories- Differences

- Processes are different
  - ✓ Scheme planning and design
  - ✓ Use of advisory experts
  - ✓ PT item production
  - ✓ PT item validation
  - ✓ Determination of Assigned Value
  - ✓ Determination of evaluation criteria
  - ✓ Data processing
  - ✓ Writing reports

General types of proficiency testing schemes (ISO/IEC 17043 Annex A)

Quantitative	• Results are numerical and reported on an interval or ratio scale (usually analysed statistically)
Qualitative	• Results are descriptive and reported on categorical or ordinal scale (identity of micro-organisms, or by identification of the presence of a specific measurand)
Interpretive	• “PT item” is information (test result-descriptive morphology statement, data set-determine a calibration line, case study)

Single occasion or continuous schemes

Types of PTs

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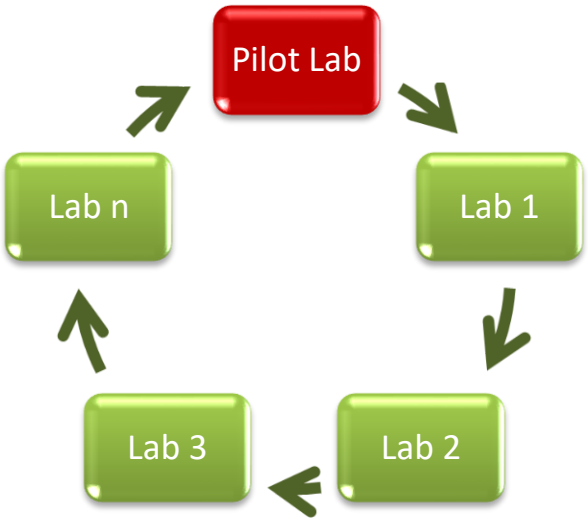
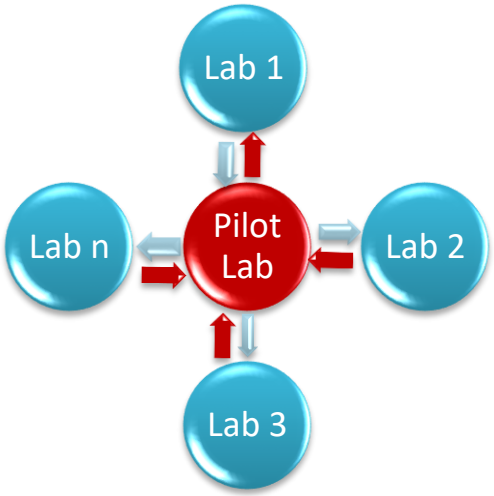
Ring type:



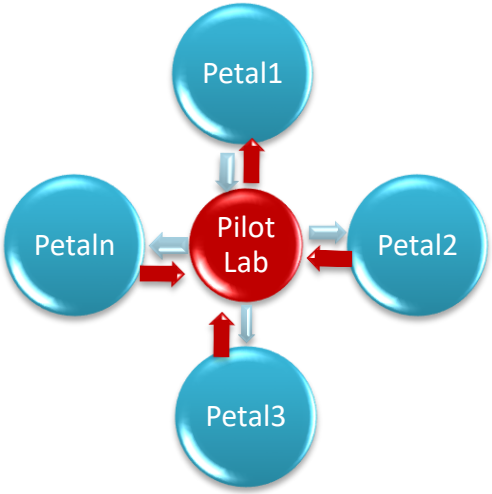
Sample circulates between laboratories-
Initial and final measurements are carried out by the pilot laboratory.

Star type:



Parallel distribution of samples-
Initial, intermediate and final measurements are carried out by the pilot laboratory.

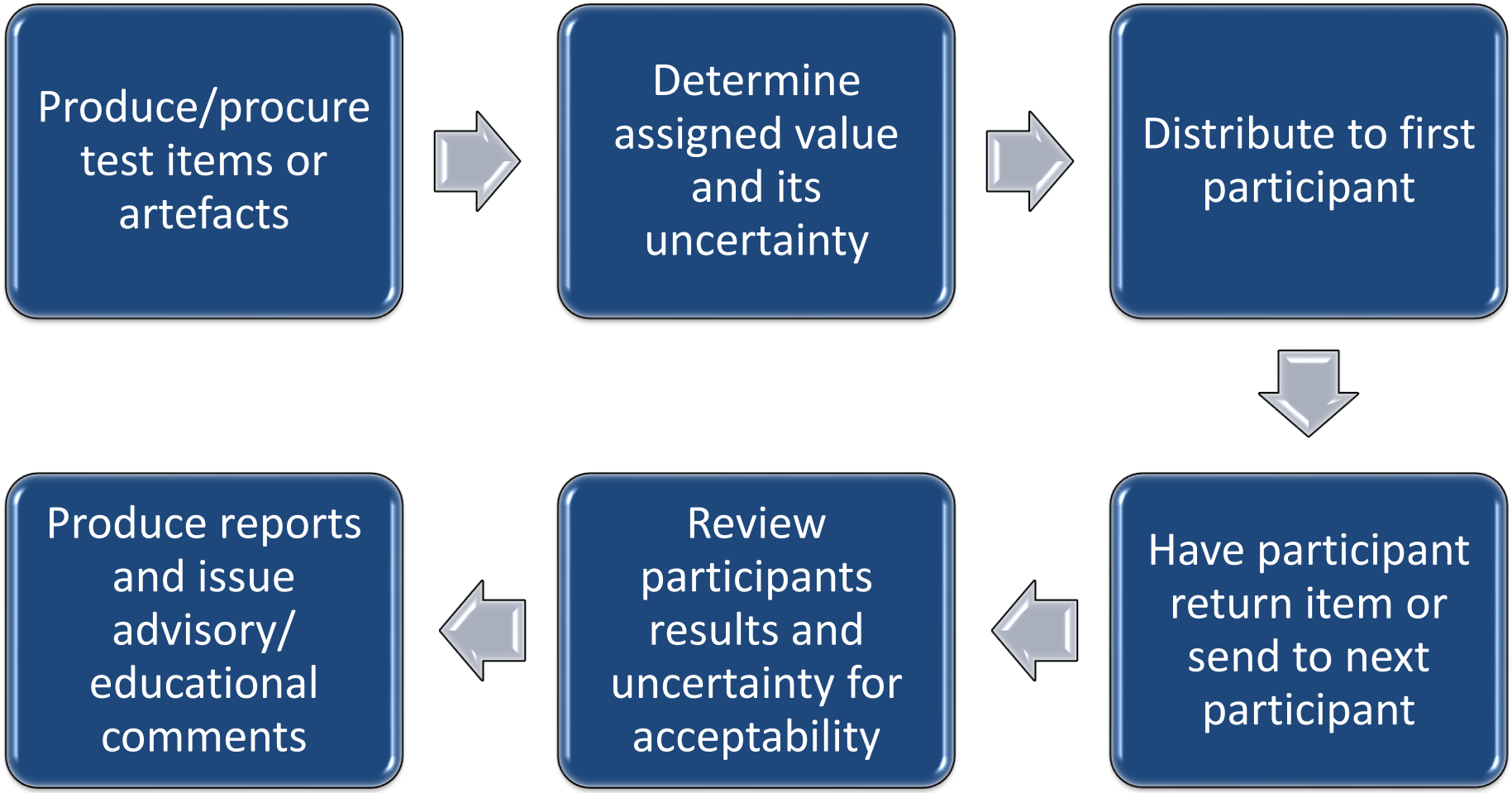
Split sample:



Initial, intermediate and final measurements are carried out by the pilot laboratory.

Types of proficiency testing schemes (ISO/IEC 17043 Annex A)

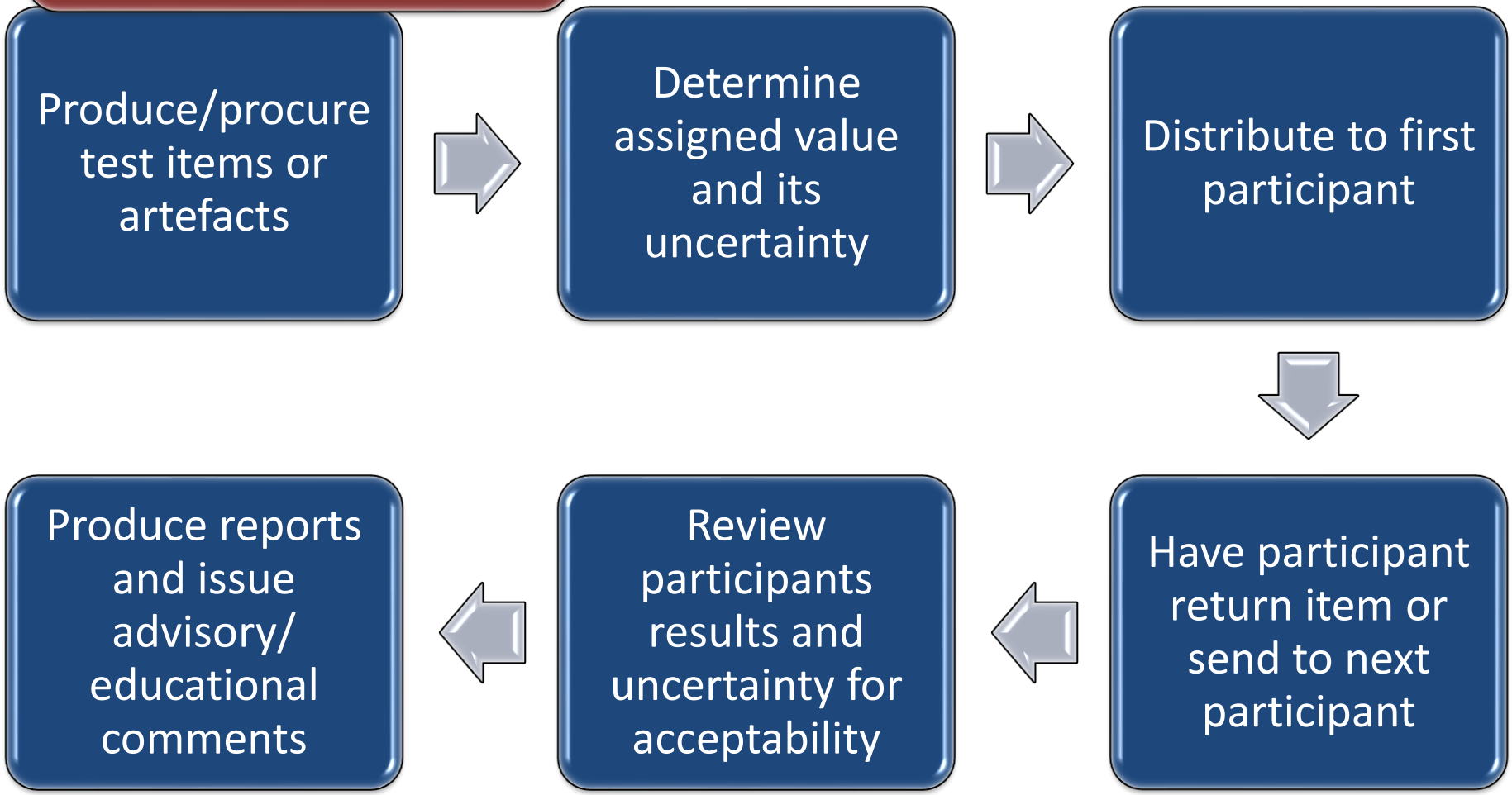
- **Sequential participation schemes**



sting schemes (ISO/IEC 17043 Annex A)

on schemes

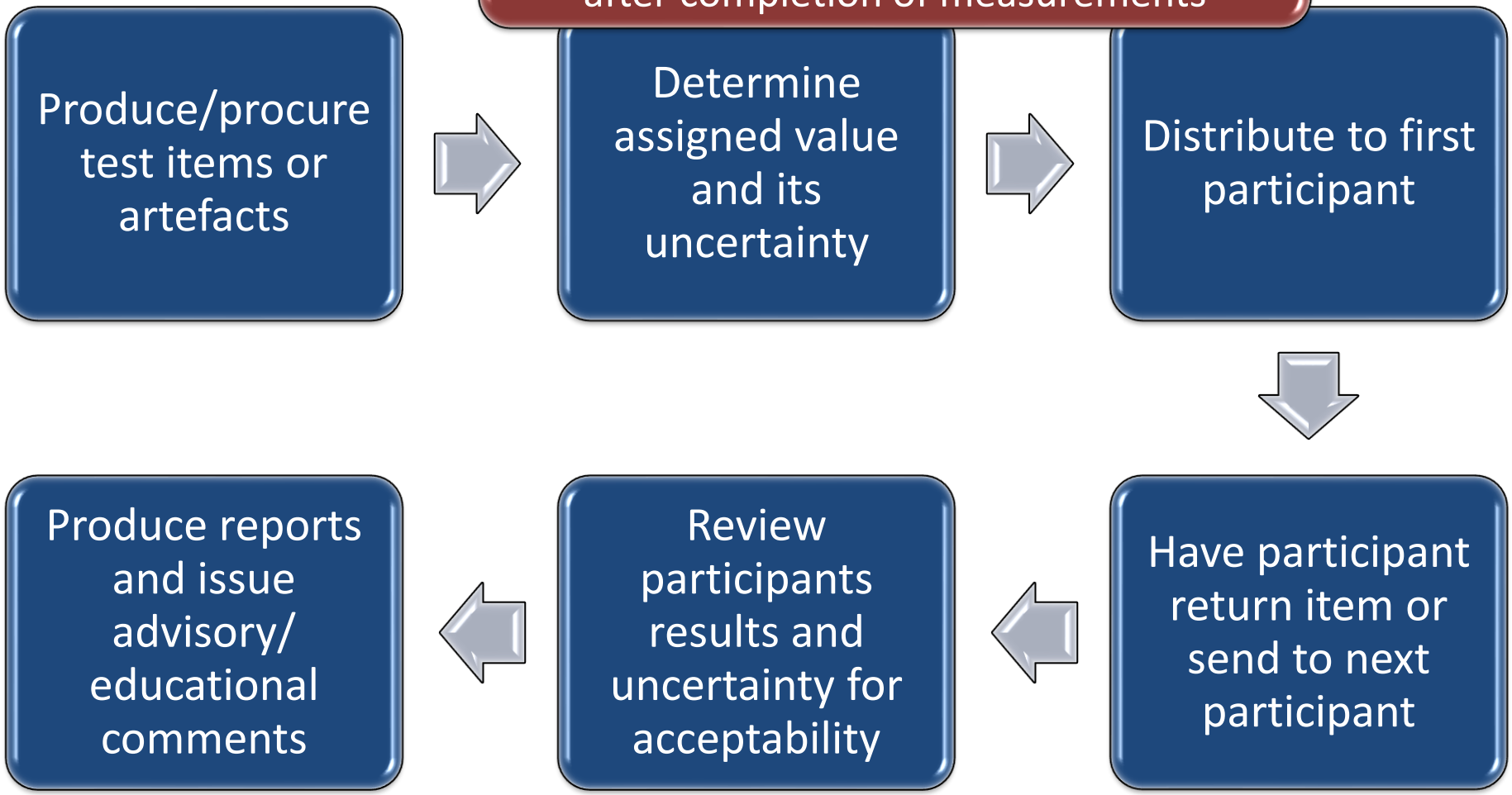
Measurement reference standards, or, in medical programmes, histology slides with confirmed diagnoses



Types of proficiency … nnex A)

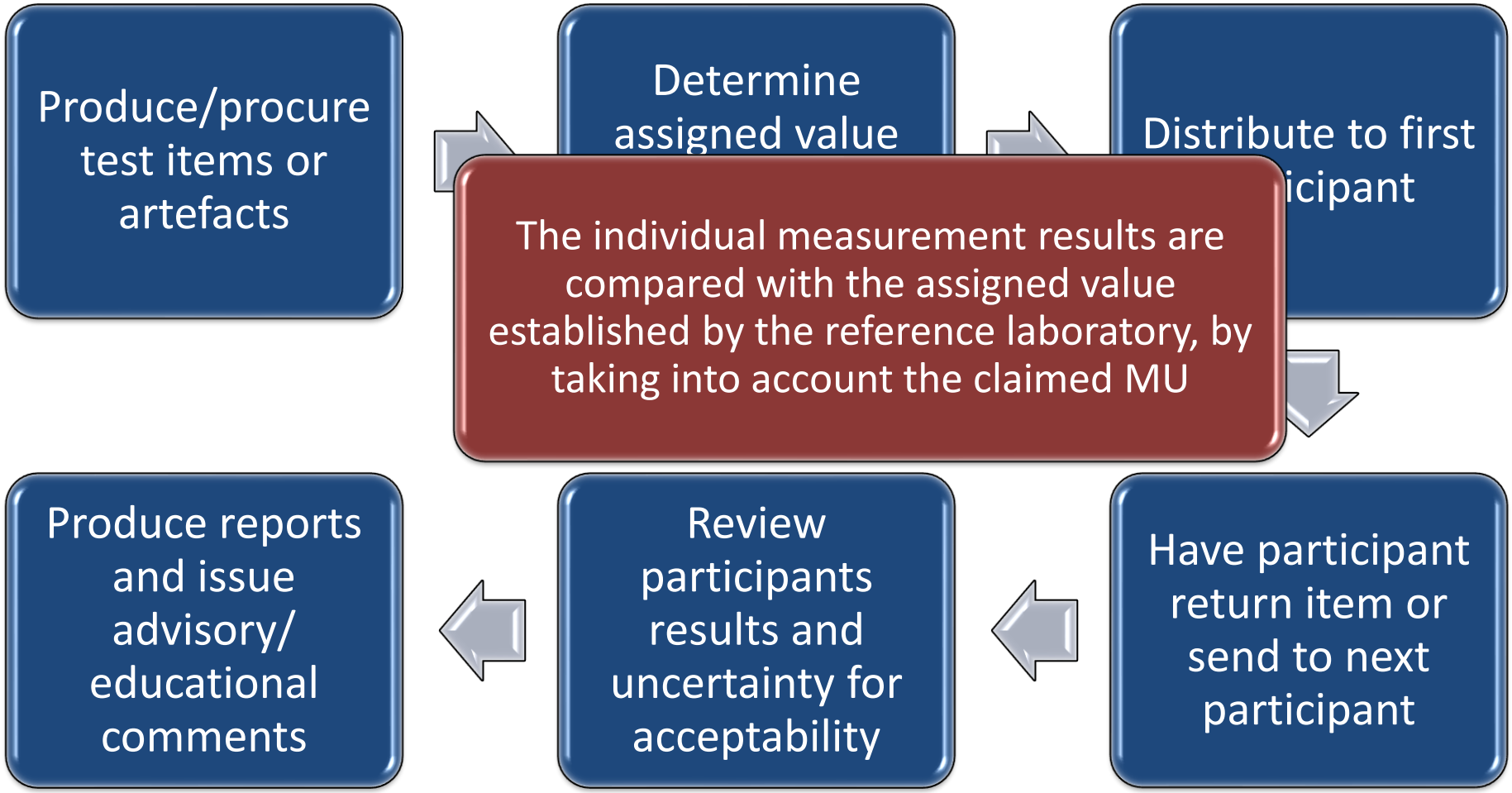
- **Sequential partici…**

A reference laboratory that is capable of providing a metrologically traceable assigned value with sufficiently small measurement uncertainty and reliability for the proficiency test item- Consensus, after completion of measurements



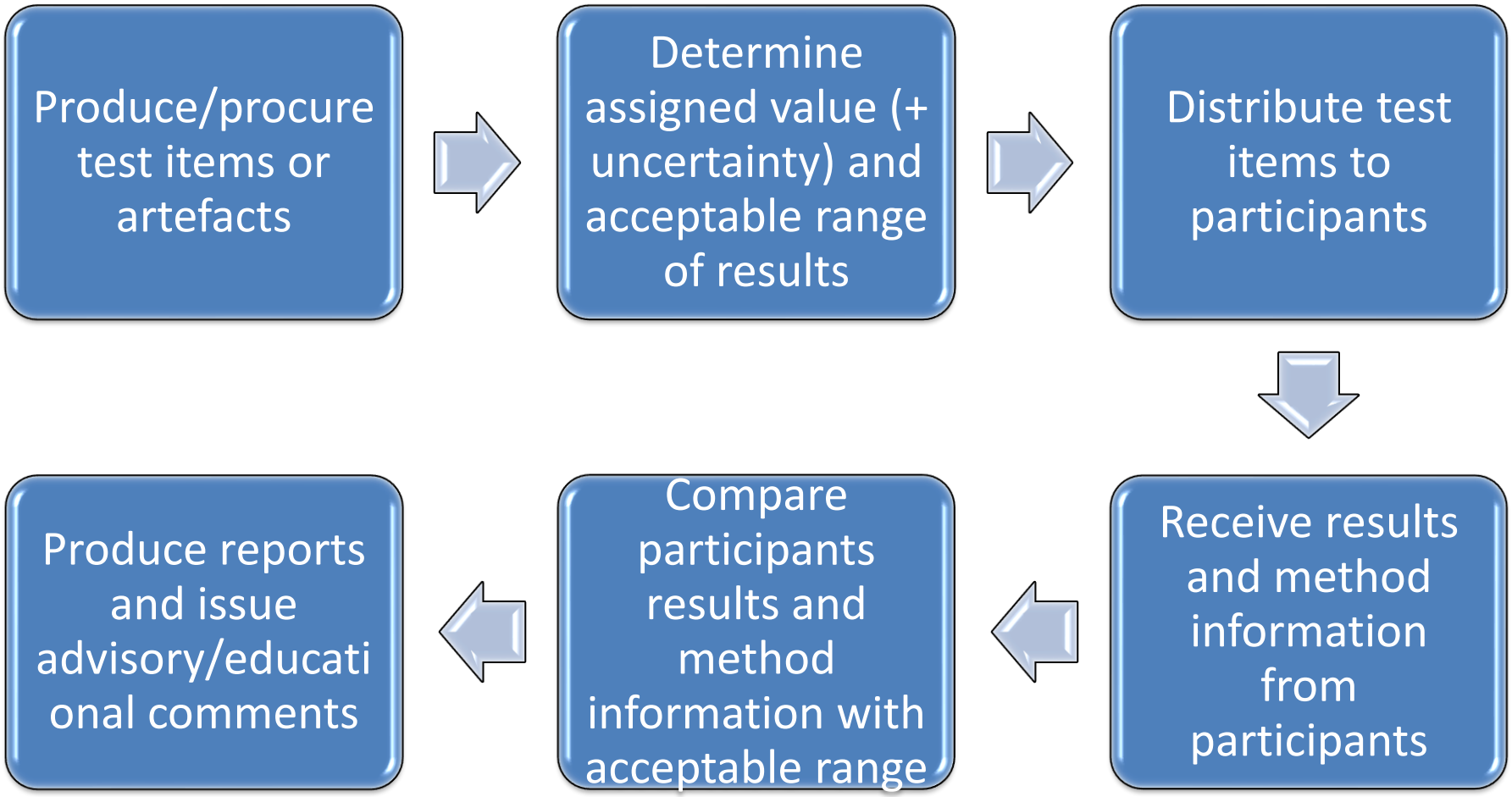
Types of proficiency testing schemes (ISO/IEC 17043 Annex A)

- **Sequential participation schemes**



Types of proficiency testing schemes (ISO/IEC 17043 Annex A)

- **Simultaneous participation schemes (split-level, split-sample, partial process)**



sting schemes (ISO/IEC 17043 Annex A)

ation schemes (split-level, split-sample,

Randomly selected sub-samples from a source of material (food, body fluids, agricultural products, water, soils, minerals …), CRMs

Produce/procure test items or artefacts

Determine assigned value (+ uncertainty) and acceptable range of results

Distribute test items to participants

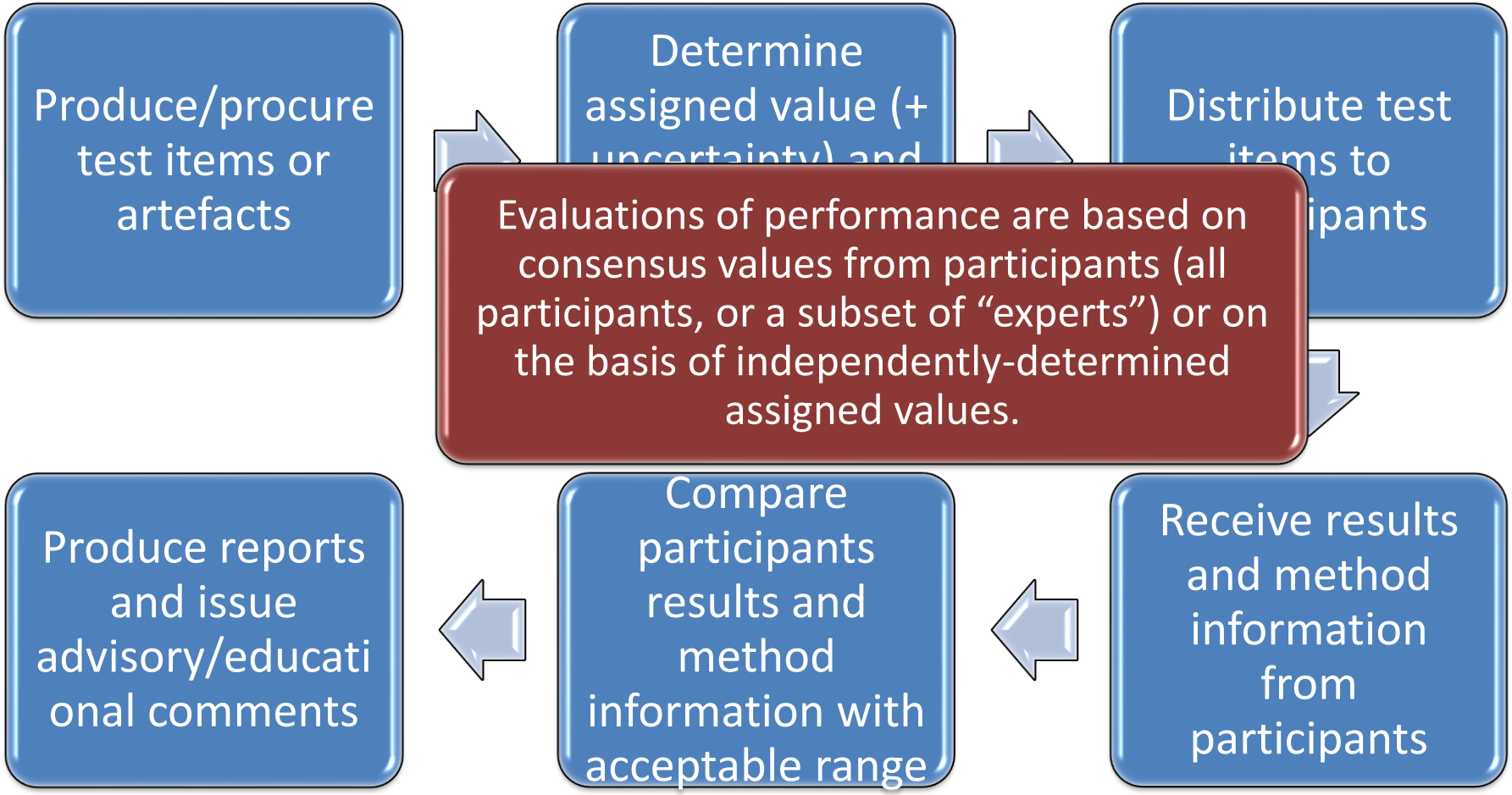
Receive results and method information from participants

Compare participants results and method information with acceptable range

Produce reports and issue advisory/educational comments

Types of proficiency testing schemes (ISO/IEC 17043 Annex A)

- **Simultaneous participation schemes (split-level, split-sample, partial process)**



Types of proficiency testing schemes

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- Simultaneous participation schemes (split-level, split-sample, partial process)

Split Level

- Similar (but not identical) levels of measurand are included in two separate PT items
- Estimate the participant's precision at a specific level of a measurand

Split Sample

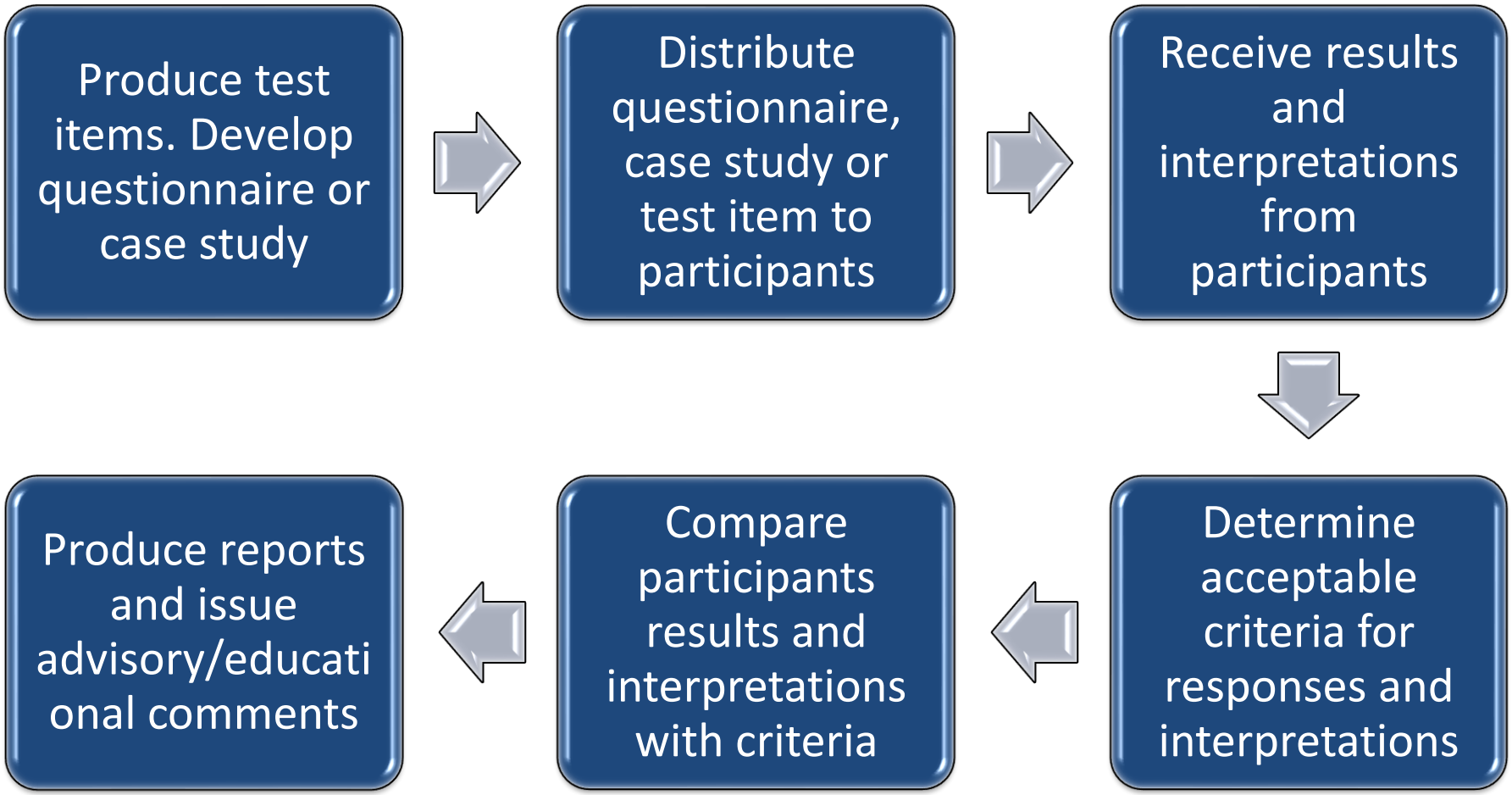
- Samples of a product or a material are divided into two or more parts, with each participant testing one part of the sample
- Identifying poor accuracy, consistent bias, effectiveness of corrective actions

Partial Process Schemes

- Evaluation of participants' abilities to perform parts of the overall testing or measurement process
- Transform and report a given set of data, make interpretations, prepare samples or specimens in accordance with a specification.

Types of proficiency testing schemes (ISO/IEC 17043 Annex A)

- Simultaneous participation schemes- **Interpretive**



Types of proficiency testing schemes (ISO/IEC 17043 Annex A)

- Calibration (usually): Sequential participation schemes
  - ✓ circulation of proficiency testing item (transfer standard) among participants
- Variants: successive circulation or in the form of a petal
  - ✓ use of a reference laboratory (pilot) providing a metrologically traceable assigned value, sufficiently small measurement uncertainty and reliability

Types	Proficiency testing	Validation of Method	Materials Certification
Assessing	Laboratory performance	Analytical methods performance	Reference quantity values
Number of labs	Not specified	8 and more (min.5)	Not specified
Experience of labs	Various	Only experienced	Only experienced
Analytical method	Various	Strictly specified	Various
Influence of lab competence	Significant	Low	Low
Traceability	Not required	Required	Extremely important
Target quantity	X, σ, z	r, R	X→μ
Standards	ISO 17043:2010	ISO 5725-2	ISO Guide 35:2006 ISO 17034:2016

PTB

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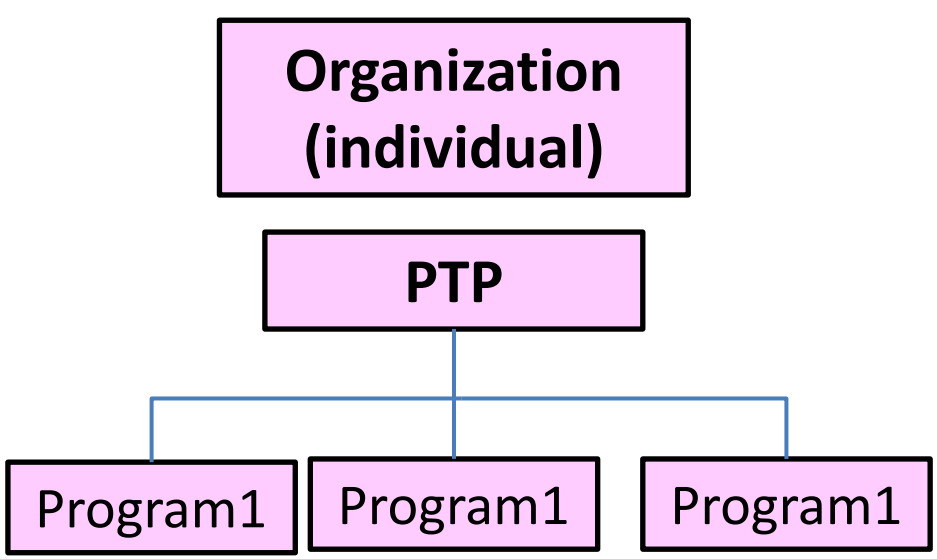
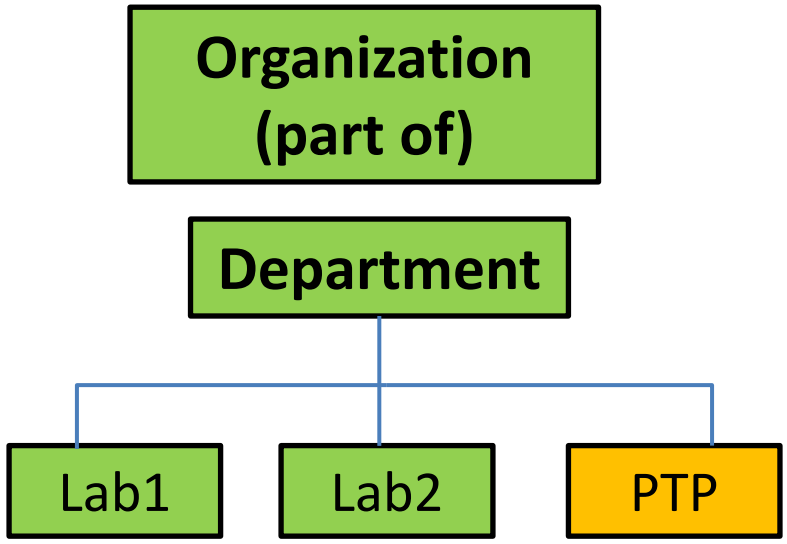
ISO/IEC 17043: Management Requirements

Management System Highlights

Organization (5.1):

- 5.1.1 PT Provider legally identifiable
- PT provider, or the organization of which it is part, shall be an entity that is legally identifiable and accountable.





ISO 17043 Management system requirements

5.1 Organization	5.8 Complaints and appeals
5.2 Management system	5.9 Non-conforming activities
5.3 Document control	5.10 Improvement
5.4 Review of requests, tenders and contracts	5.11 Corrective action
5.5 Subcontracting services	5.12 Preventive action
5.6 Purchasing services & supplies	5.13 Control of Records
	5.14 Internal Audits
5.7 Service to customer	5.15 Management reviews

Management System Highlights

Organization (5.1):

- Entity that is legally identifiable and accountable
- Work carried out in the PTP's permanent facilities, at sites away from its permanent facilities, and in associated temporary facilities
- Impartiality issues
- Confidentiality issues
- Define organization and management structure

Management System Highlights

Organization (5.1):

- Specify the responsibility, authority, interrelationships and required competence of all personnel involved in PT schemes
- Supervision of technical staff
- Technical management that has overall responsibility for the technical operations and the provision of the needed resources
- Named positions: Quality Manager, Coordinator (although, in other clauses

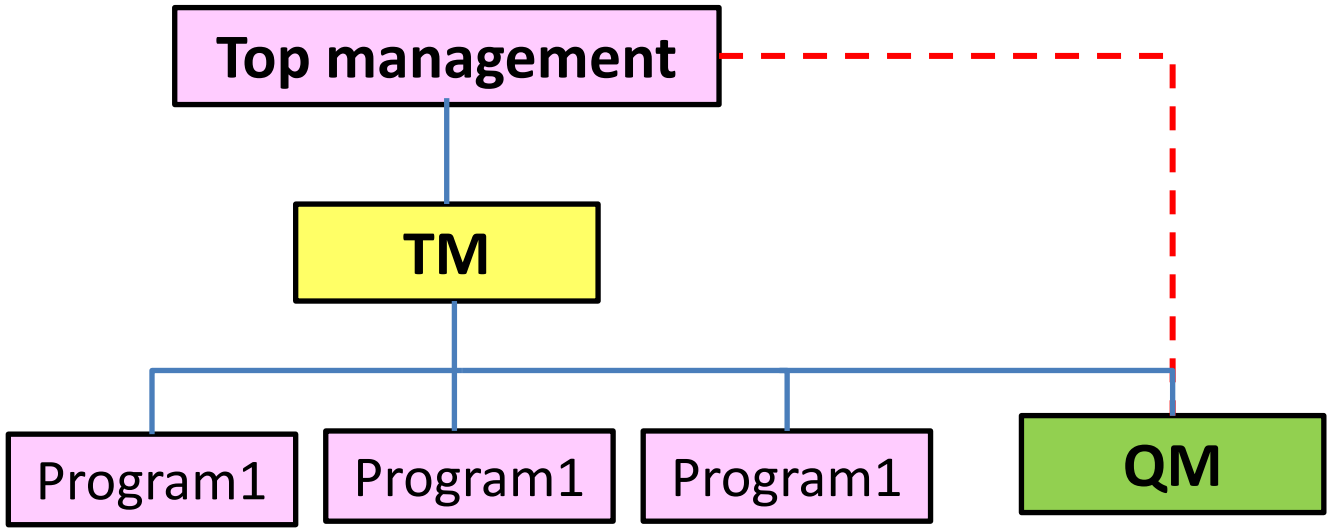
Management System Highlights

- **Organization (5.1)**
- 5.1.2 PT operation shall meet ISO/IEC 17043 requirements and satisfy the needs of:
  - ✓ Participants: LAB
  - ✓ regulatory authorities: RB
  - ✓ organizations providing recognition: AB

Management System Highlights

Organization (5.1)

- 5.1.4 identify responsibility of key personnel and potential conflict of interest.
- 5.1.5 define the organization and management structure:
  - ✓technical management and quality manager.



Management System Highlights

Organization (5.1)

Quality Manager

- defined responsibility and authority for ensuring that **the management system is implemented and followed** at all times
- **direct access to the highest level of management** at which decisions are taken on the proficiency testing provider's policies or resources

Technical Management-Coordinator

- overall **responsibility for the technical operations and the provision of the resources needed**
- **access to the necessary technical expertise and experience** in the relevant field of testing, calibration or inspection, as well as statistics

Management System Highlights

Management System (5.2):

- Specific requirements for Quality Policy Statement (5.2.3) and Quality Manual
- Evidence of commitment by the top management on the scope, implementation and continual improvement of the MS
- Effective communication
- Roles and responsibilities of technical management and quality manager to be defined in the quality manual
- Top management to ensure integrity of the MS in case of changes

Management System Highlights

Management System (5.2)

- 5.2.1 establish, implement and maintain management system.
- 5.2.2 define and document policies, programes, procedures and instructions to the quality of all proficiency testing.
- 5.2.3 Top management : issue quality policy statement.
- 5.2.4 Top management: implement the management system and continual improvement.

Management System Highlights

Quality Policy Statement (5.2.3)

a) the management's commitment to the quality of its PT services to participants and other customers;

b) the management's statement of the standard of service;

c) the purpose of the management system related to quality;

d) a requirement that all personnel concerned with the proficiency testing activities familiarize themselves with the quality documentation and implement the policies and procedures in their work;

e) the management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system.

Management System Highlights (5.2)

- 5.2.5 **Top management:** communicate to the organization the importance of meeting customer requirements and regulatory requirements.
- 5.2.6 Structure of the documentation used in management system
- 5.2.7 Define roles and responsibilities of technical management and quality manager.
- 5.2.8 **Top management**: ensure the integrity of the management system is maintained when changes to the management system.

Management System Highlights

Document Control (5.3):

Establish and maintain procedures to control all documents (internal or external):

- Regulations
- Standards
- Other normative documents
- Proficiency testing scheme protocols
- Test and/or calibration methods
- Drawings
- **Software specifications**
- Instructions and manuals

Management System Highlights

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Document Control (5.3):

Special reference to changes and their control made to documents maintained in computerized systems

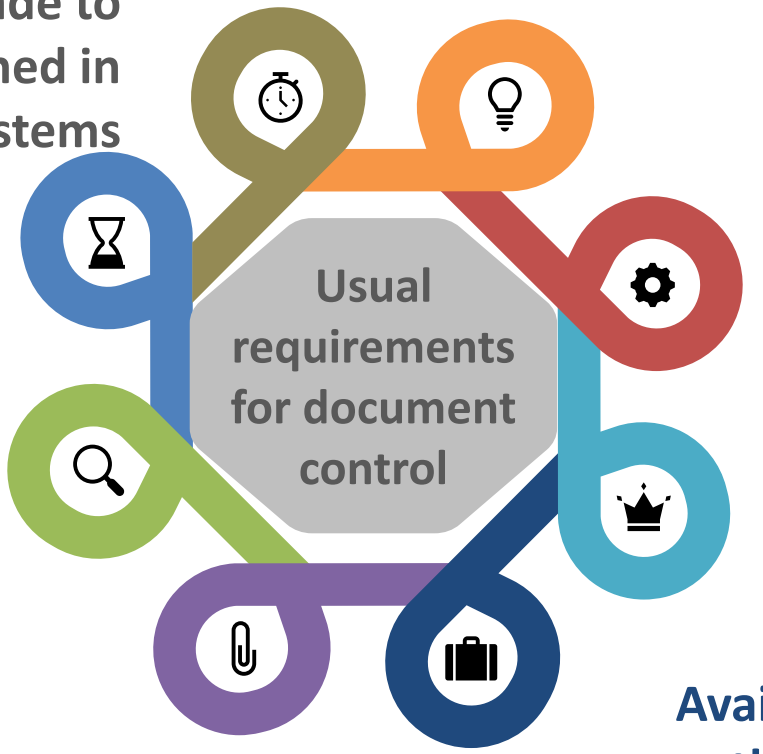
Approval and review before issue

Provisions for changes to documents

Periodic review and update

Unique identification of all generated documents

Master list needed



Removal of obsolete documents

Availability of authorized editions at all necessary locations

Management System Highlights

Document Control (5.3):

- Specific requirements for Quality Policy Statement (5.2.3) and Quality Manual
- Evidence of commitment by the top management on the scope, implementation and continual improvement of the MS
- Effective communication
- Roles and responsibilities of technical management and quality manager to be defined in the quality manual
- Top management to ensure integrity of the MS in case of changes

5.4 Review of requests, tenders, contracts

- Review all contracts, tenders and requests
  - ✓ New schemes, additions to current scheme
  - ✓ Assure Provider has capability
  - ✓ Technically appropriate for participants
- Review includes work by subcontractors
- Inform participants of changes

5.4 Review of requests, tenders, contracts

- Review all contracts, tenders and requests
  - ✓ New sche
  - ✓ Assure Pro
  - ✓ Technically appropriate for participants
- Review includes work by subcontractors
- Inform participants of changes

5.4.3 The review shall cover all aspects of the request, including any work that is subcontracted by the proficiency testing provider.

5.4.4 The participants and other customers, as appropriate, shall be informed of any deviation in the contract or agreed proficiency testing scheme design.

5.5 Subcontracted services

PTP is responsible for any subcontracted work and shall be able to demonstrate the subcontractors' experience and technical competence.

Subcontracting of planning, evaluation of laboratory performance and authorization of reports is prohibited

5.5 Subcontracted services

- Assure competence of subcontractors
- Notify participants, in advance and in writing, of subcontracted services
- PTP accepts responsibility for subcontracted work
- Maintain register of all subcontractors and competence assessments

5.5 Subcontracted services

Tasks that can be subcontracted:

- Manufacture of Proficiency Testing items
  - If not fully verified by PT provider
- Reference results for assigned value
- Tests for homogeneity and stability
- Handling and shipping (not courier)
- Data entry
- Statistical analysis

Purchasing services and supplies (5.6)

- Policy and procedures for selection of critical services and supplies.
- Procedures for purchase, reception & storage of reagents, PT items, reference materials.
- Inspection before use.
- Evaluation of suppliers (records + list of approved suppliers)

Service to the Customer (5.7)

Many types of customers – need to service all	Actively solicit feedback
• Participant laboratories • Accreditation bodies/regulators • Laboratory customers	• No need for customer satisfaction survey • Request for comment on response form is adequate

5.8 Complaints

- PTP shall resolve of complaints and appeals and maintain records.

5.9 Nonconforming work

- Policy and procedures for non-conformities to PTP's own procedures or the agreed requirements of its customers
- Includes undiscovered inhomogeneity, instability, incorrect statistical analysis and reports

5.9 Nonconforming work

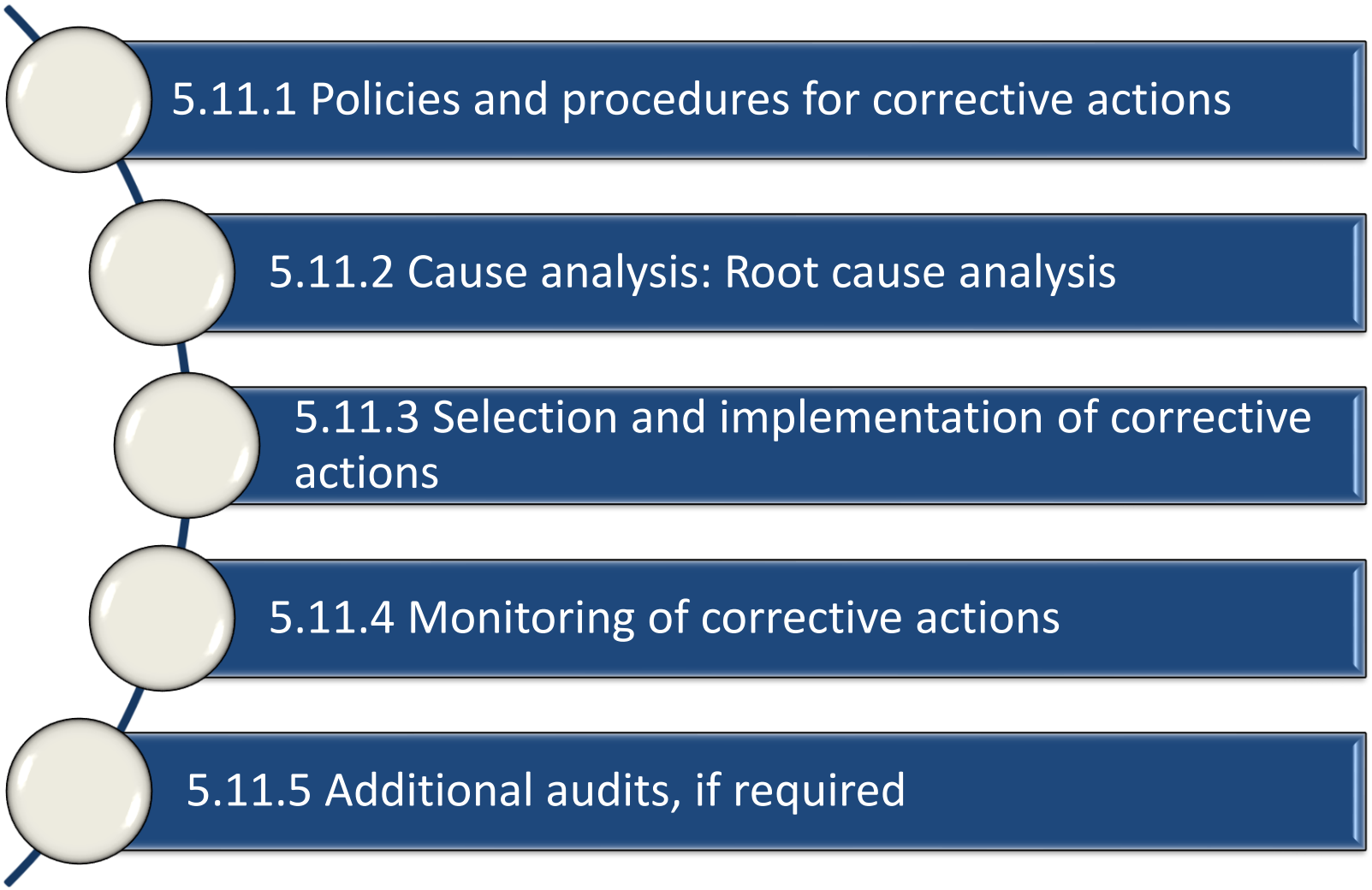
- 5.9.1 PTP shall implement on NC work:
  - ✓ a)designate responsibilities for the NC work
  - ✓ b) evaluate of the significance of the NC work
  - ✓ c) action is taken immediately

  - ✓ d) customers are informed and the PT test items or reports already sent to participants are recalled or disregarded
- 5.9.2 Corrective actions shall be promptly followed.

5.10 Improvement

The PTP shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

5.11 Corrective actions



5.12 Preventive actions

Identification of areas of improvement, potential sources of NCs

Development, implementation and monitoring of action plans for improvement and/or preventive actions, aiming to reduce NCs and take advantage of opportunities

5.13 Records

- Procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of records.
- Need for protection and back-up
- May have retention times specified by regulation (+accreditation body)

Technical records:

- Include collected data, results of homogeneity & stability testing, and all reports.
- Data entry, checking and calculations: Identification of the specific task + person responsible
- Requirements for mistakes and alterations

5.14 Internal Audits

- Responsibility of QM
- **Advise** to carry it out annually

5.15 Management Reviews

- Conduct them according to a pre-determined schedule
- **Advise** to carry it out annually
- Topics in 5.15.1

PTB

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ISO/IEC 17043: Technical Requirements

ISO 17043 technical requirements

4.1 General	4.6 Operation of PT Schemes
4.2 Personnel	4.7 Data Analysis & Evaluation of PT Results
4.3 Equipment, accommodation & environment	4.8 Reports
4.4 Design of PT schemes	4.9 Communication
4.5 Choice of method or procedure	4.10 Confidentiality

General (4.1)

- Provider must have experience with ILC and the particular type of tests items
- Provider or subcontractor must have competence to make necessary measurements (e.g., homogeneity)
  - ✓ This may not be possible in new areas
  - ✓ ISO/IEC 17025 or ISO 15189 can be used to demonstrate competence in testing

Personnel (4.2)

The PTP shall have managerial and technical personnel with:

- **Authority**
- **Resources**
- **Technical competence** required to perform their duties

Personnel (4.2)

- Define minimum levels of competence needed by key personnel
- Ensure technical management has necessary competence and experience
- Ensure sufficient staff and experience
- Assure staff receives sufficient training, as needed (policy and procedures for training identification). Objectively assess competence
- Maintain records for authorization(s), competence, educational and professional qualifications, training, skills and experience (+ respective dates

Personnel (4.2)

- List of authorizations:

a) select appropriate test items;
b) plan PT schemes;
c) perform particular types of sampling;
d) operate specific equipment;
e) conduct measurements to determine stability and homogeneity, assigned values and associated uncertainties of the measurands of the proficiency test item;
f) prepare, handle and distribute proficiency test items;
g) operate the data processing system;
h) conduct statistical analysis;
i) evaluate the performance of proficiency testing participants;
j) give opinions and interpretations; and
k) authorize the issue of proficiency testing reports.

Equipment, accommodation and environment (4.3)

Appropriate facilities and equipment for:

- Manufacturing, handling, calibration, testing, storage and dispatch, data processing, data communications, record keeping.
- Control access to areas affecting the quality of PT schemes. Appropriate separation of facilities to prevent contamination/ Safe decontamination and disposal of potentially toxic or hazardous materials.
- Control and monitor conditions- record all relevant monitoring activities. PT activities stopped when conditions are outside prescribed specifications

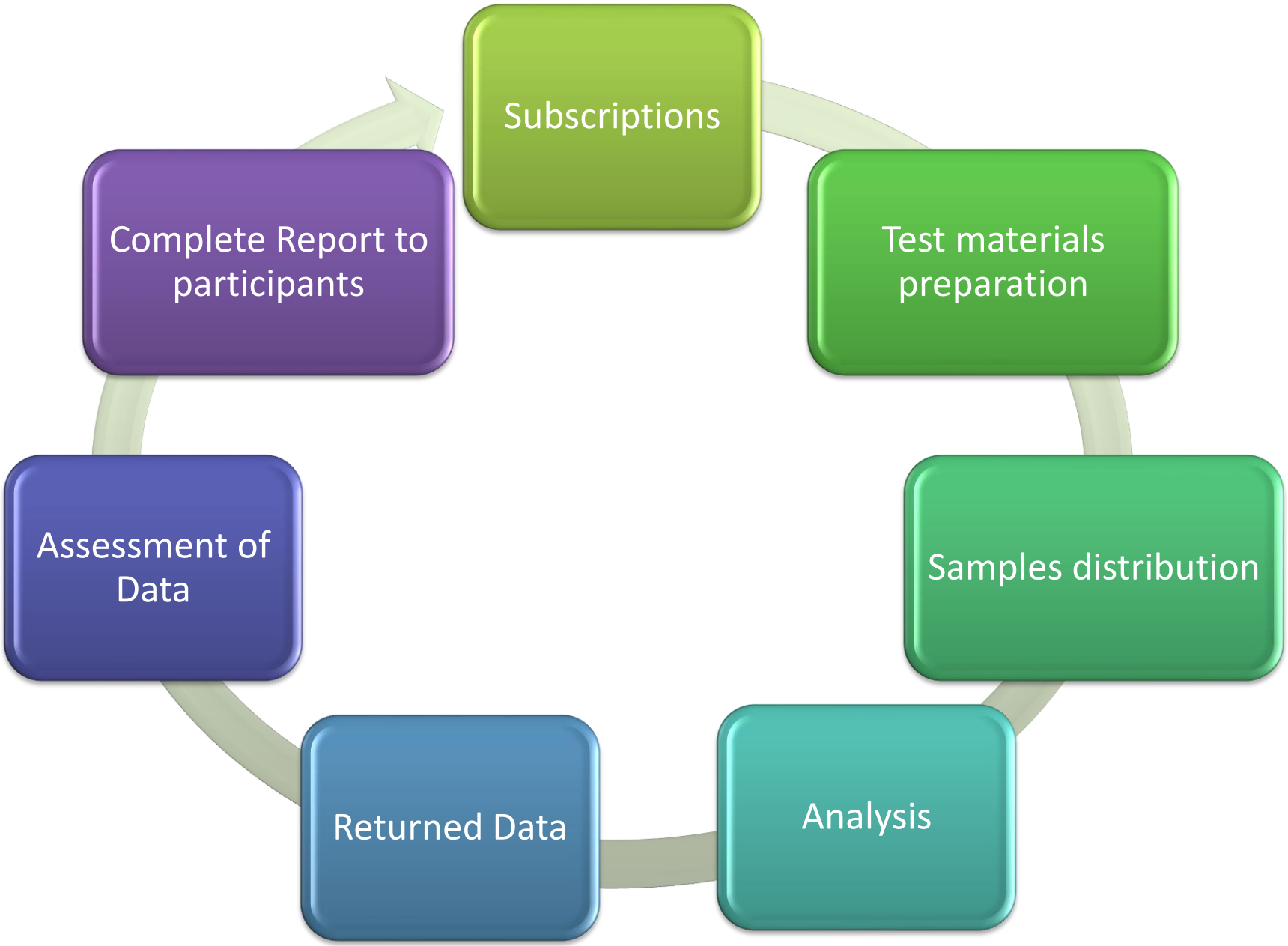
Eq

Biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibrations levels, as appropriate to the technical activities concerned.

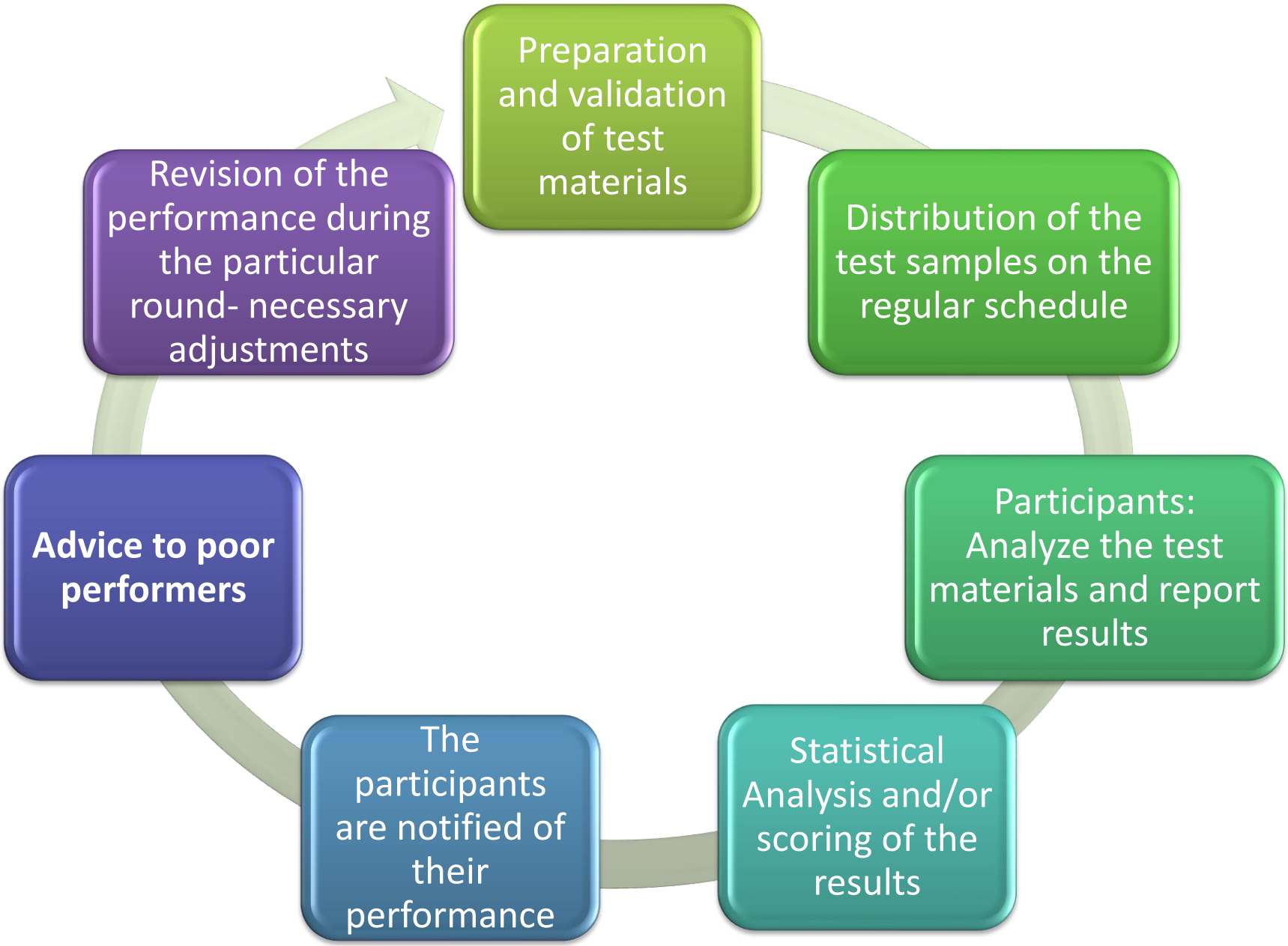
Appropriate facilities and equipment for:

- Manufacturing, handling, calibration, testing, storage and dispatch, data processing, data communications, record keeping.
- Control access to areas affecting the quality of PT schemes. Appropriate separation of facilities to prevent contamination/ Safe decontamination and disposal of potentially toxic or hazardous materials.
- Control and monitor conditions- record all relevant monitoring activities. PT activities stopped when conditions are outside prescribed specifications

Framework of PT Scheme



PT scheme- How it works



4.4 Design of PT Scheme

- 4.4.1 Planning
- 4.4.2 Preparation of PT items
- 4.4.3 Homogeneity and stability
- 4.4.4 Statistical design
- 4.4.5 Assigned values

4.4.1 Planning and Design of PT Scheme

Planning is not subcontracted!

- Shall identify and plan all processes that affect the quality of the scheme (objectives, purpose and basic design)
- Assure plan is carried out according to the defined procedures (4.4.1.3 a to u)
  - ✓ Types of labs to participate
  - ✓ Number of participants
  - ✓ Source and nature of test items
  - ✓ Outline the statistical analysis
  - ✓ Basis of performance evaluation

4.4.1 Planning and Design of PT Scheme

- Initial Questions
  - ✓ What laboratories to include?
  - ✓ What items to test / measure?
  - ✓ How many laboratories?

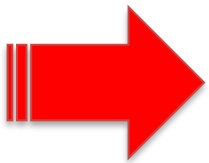
- Cost considerations
  - ✓ Cost to produce and ship materials?
  - ✓ Cost for laboratories to participate?
  - ✓ Who will pay?

4.4.1 Planning and Design of PT Scheme

- Number of laboratories
  - ✓ sometimes few, sometimes many
  - ✓ use appropriate statistics

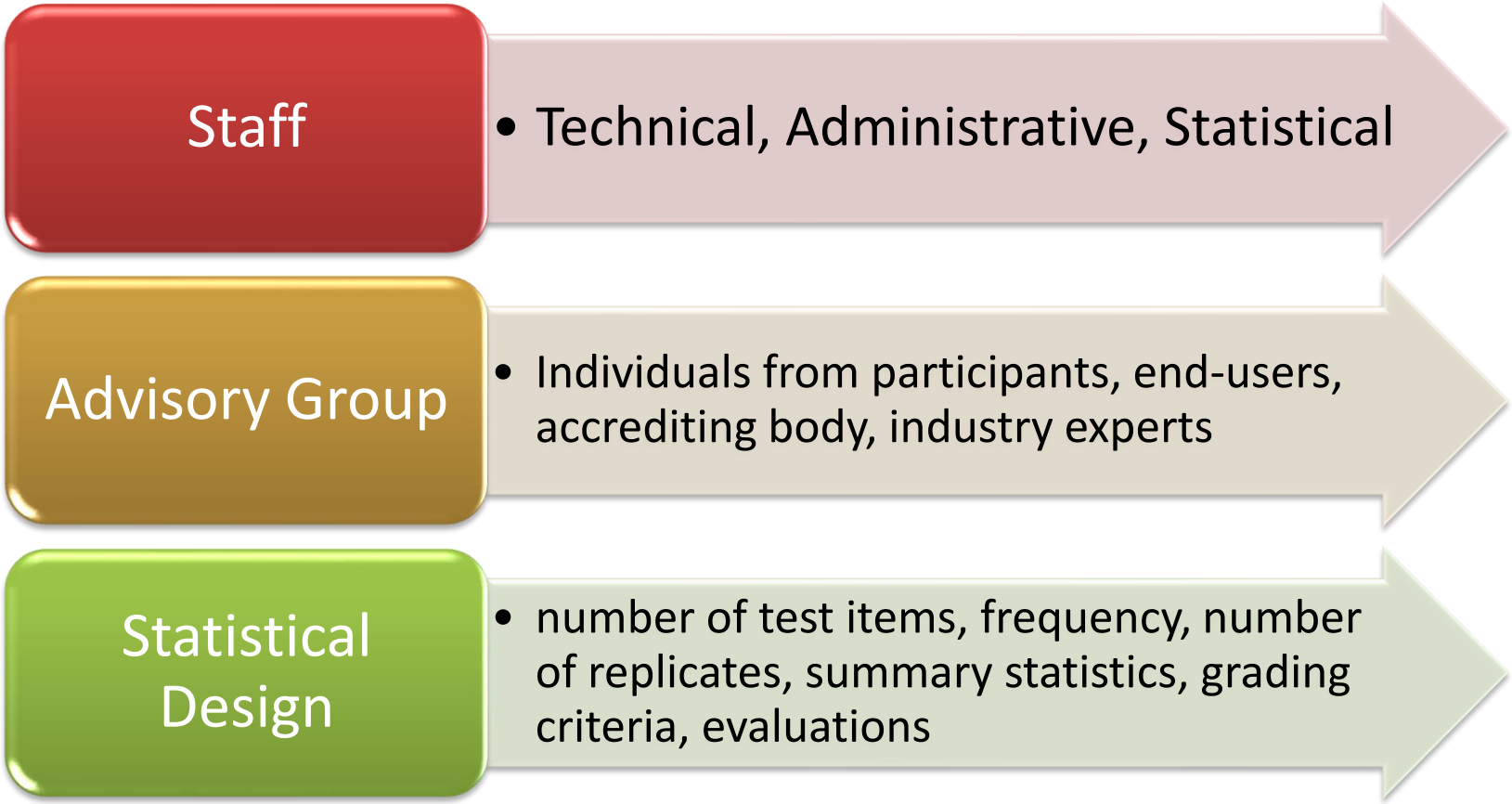
ISO 5725-1
EA-4/21

- Number of samples
  - ✓ Positive / Negative (or identification)?
  - ✓ Measuring Range to cover
  - ✓ Important decision points
  - ✓ Have as many samples as possible



Cost!!!

4.4.1 Planning and Design of PT Scheme Resources:



4.4.1 Planning and Design of PT Scheme

- The provider **shall** ensure access to technical expertise and detailed experience (including statistics), perhaps with **advisory group** (4.4.1.4)

4.4.1 Planning and Design of PT Scheme

Advisory group (or any other technical expertise). Advise on (4.4.1.5) :

- The planning of PT
- the choice of the types of test materials
- the frequency of the rounds
- the scoring system and statistical procedures (including those used in homogeneity testing)
- the advice that can be offered to the participants
- specific and general problems arising during the operation of the scheme

4.4.1 Planning and Design of PT Scheme

Advisory group (or any other technical expertise). Advise on (4.4.1.5) :(cont'd)

- the instructions sent to participants
- the participants' format for reporting results
- the contents of the reports sent to participants
- other means of communicating with the participants
- comments from participants or end-users relating to the operation of the scheme
- the level of confidentiality appropriate to the scheme

4.4.2 Preparation of PT Items

Establish and implement procedures to ensure appropriate acquisition, collection, preparation, handling, storage and, where required, disposal of all PT items.

PT items should match in terms of matrix, measurands and concentrations, the type of items in their customers routine testing.

Appropriate instructions to participants for preparation, packaging and transport, in case they have to prepare and/or manipulate PT items.

4.4.2 Preparation of PT Items

- Positive / Negative tests
  - ✓ Use appropriate mix of pos/neg samples
  - ✓ Usually more positives
  - ✓ Use many different types of “positive”
    - (e.g, different organisms or alloy types)
  - ✓ Do as many as you can!

Design of PT Scheme- Test Item Management

- Homogeneous Test Items-Assure items are “sufficiently” homogeneous
  - ✓ ISO 13528: assure that inhomogeneity does not impact evaluation of performance
  - ✓ Inhomogeneous material allowed, if accounted for
- Assure items are “sufficiently” stable, with no significant change throughout the conduct of the test

4.4.3 Homogeneity and Stability

ISO 17043 put more emphasis and definition onto homogeneity and stability

– “Criteria for suitable homogeneity and stability shall be established and shall be based on the effect that inhomogeneity and instability will have on the evaluation of the participants' performance” (4.4.3.1)

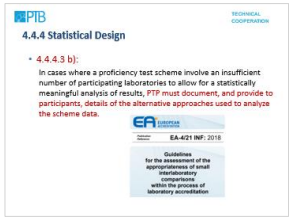
– Requires that they are tested as applicable

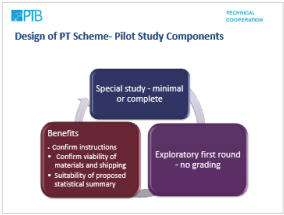
4.4.3 Homogeneity and Stability

- Documented procedure, according to appropriate statistical design.
- Statistically random selection of a representative number of PT items (when possible).
- Performed after the PT items have been packaged in the final form and before distribution to participants
- Stable PT items to ensure that they will not undergo any significant change during PT, and during storage and transport (sequential designs)
- If not feasible, PTP shall ensure sufficient procedures for collecting, producing, packaging and distributing.

4.4.4 Statistical Design

- Statistical model and analysis techniques must be documented, with reasons for selection.
- Considerations (shall)- 4.4.4.3:
  - ✓ Trueness and precision required for test
  - ✓ Minimum number of participants
  - ✓ Replicate measurements on each sample
  - ✓ Method of determining assigned value
  - ✓ Procedure to accommodate outliers
  - ✓ Homogeneity and stability
- Conduct pilot scheme if necessary



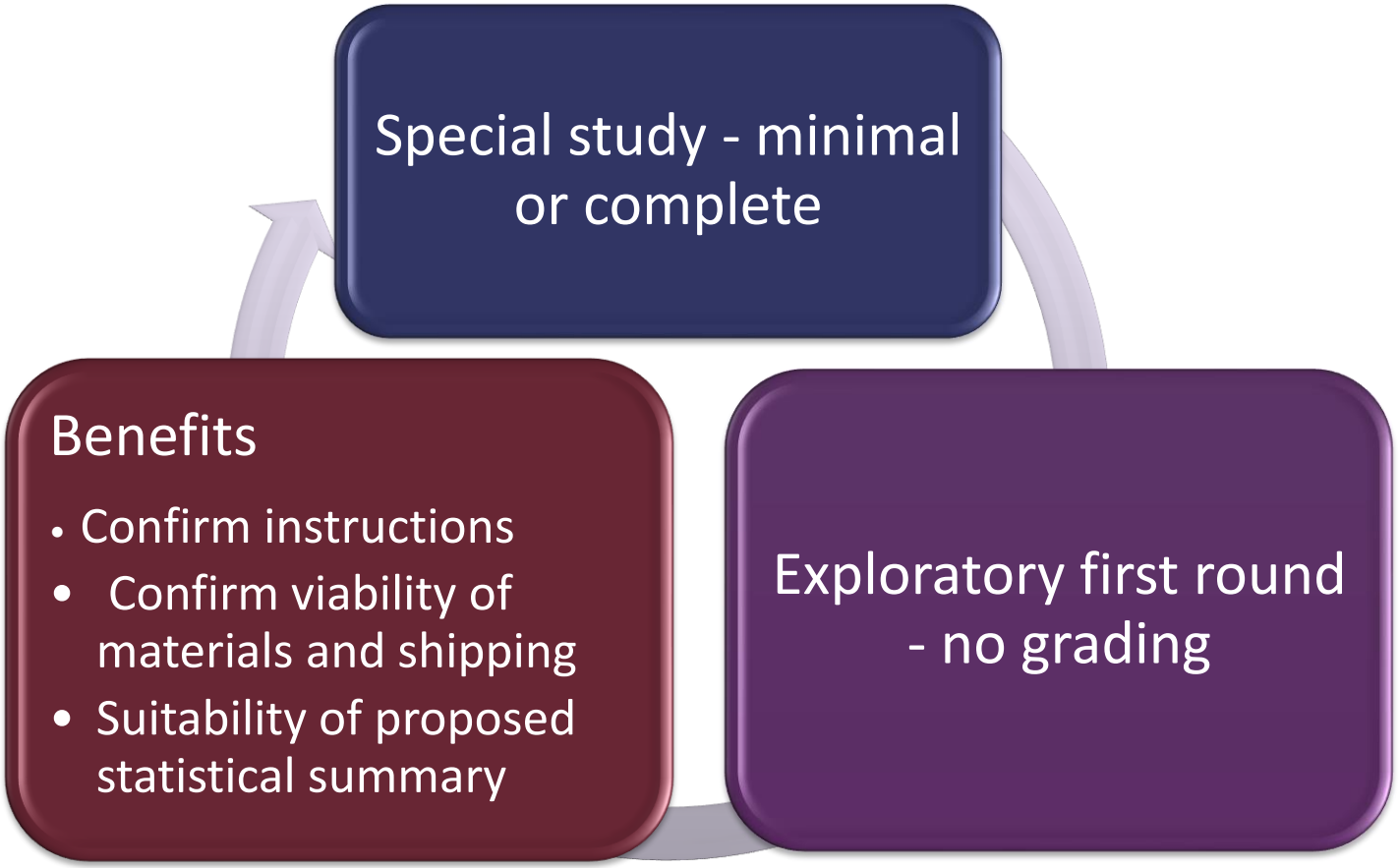


4.4.4 Statistical Design

- 4.4.4.3 b):

  In cases where a proficiency test scheme involve an insufficient number of participating laboratories to allow for a statistically meaningful analysis of results, PTP must document, and provide to participants, details of the alternative approaches used to analyze the scheme data.

Design of PT Scheme- Pilot Study Components



4.4.5 Assigned Values

- **Shalls:**

- Procedure for determining the assigned values for the measurands or characteristics in a particular PT scheme
- Calibrations: metrological traceability + uncertainty
- In areas other than calibrations: metrological traceability + measurement uncertainty required to demonstrate that the PT is fit for its purpose
- Requirements for when using consensus values: Justification, estimation of uncertainty

4.4.5 A

- **Shal**

4.4.5.3 For proficiency testing schemes in areas other than calibration, the relevance, needs and feasibility for metrological traceability and associated measurement uncertainty of the assigned value shall be determined by taking into account specified requirements of participants or other interested parties, or by the design of the proficiency testing scheme.

- Procedure for determining the assigned values for the measurands or characteristics in a particular PT scheme
- Calibrations: metrological traceability + uncertainty
- In areas other than calibrations: metrological traceability + measurement uncertainty required to demonstrate that the PT is fit for its purpose
- Requirements for when using consensus values: Justification, estimation of uncertainty

4.4.5 Assigned Values

- 4.4.5.5 The proficiency testing provider **shall** have a policy regarding the disclosure of assigned values.
- The policy **shall** ensure that participants cannot gain advantage from early disclosure.

4.5 Choice of Method or Procedure

- Requirements for provisions for participants in using methods/procedures of their choice.
- Special methods may be required by PTP
- PTP shall have procedures to address use of participants different methodologies
- PTP must request details of method used, to allow analysis and comment

4.5 Choice of Method or Procedure

4.5.2 Where participants are permitted to use a method of their choice, the PTP **shall**:

- have a policy and follow a procedure for comparison of results obtained by different test or measurement methods.
- be aware of which different test or measurement methods for any measurand are technically equivalent, and take steps to assess participants' results using these methods accordingly

4.5 Choice of Method or Procedure

- Does not require grading separately by method
  - ✓ Have a policy and procedure on what to do *(deliberate and justifiable)*

- STRONG requirements for competence of PTP
  - ✓ Must understand all test methods that can be used, and evaluate performance accordingly
  - ✓ Can be used to encourage method agreement
  - ✓ Can be specified by regulation

4.6 Operation of PT Scheme

- 4.6.1 Instructions to participants
- 4.6.2 PT items handling and storage
- 4.6.3 Packaging, labelling and distribution of PT items

4.6.1 Instructions to Participants

- Storage and preparation of test items
- Dates for analysis, especially last date
- Test method and report units
- Recording results
- Influential factors and hazards
- Treatment of PT samples - lab issues
- Contact information

4.6.1 Instructions to Participants

- Participants must know when PT will be conducted
- Specific instructions on storage, reporting units, significant figures, end date for receipt of results
- Participant required to treat PT as usual samples

- No disclosure of assigned values until done (may give ranges, as appropriate)
- Give preliminary results, where appropriate

4.6.2 Sample Handling

- Appropriate identification of PT items
- Avoid contamination during preparation and storage, by segregation of materials
- Avoid damage or deterioration by proper packaging and storage
- Secure storage areas, authorized dispatch
- Assess materials periodically to detect deterioration

4.6.3 Packaging and Shipping

- Allow delivery without damage or deterioration
- Specify relevant environmental conditions for transportation (monitor them, if needed)
- Conform with appropriate packaging and labeling regulations (e.g., Customs)
  - ✓ Consider sample integrity
  - ✓ Safety hazards
  - ✓ May require detailed handling instructions to participants on subsequent shipping of items
  - ✓ Contact information

4.6.3 Packaging and Shipping

- Assure labels are securely attached and remain legible

- **4.6.3.5** Have a procedure to confirm delivery of PT items.
  - ✓ Allow statement such as an advance notice to notify PT provider if shipment does not arrive before a specified date.

4.7 Data Analysis and Evaluation of Results

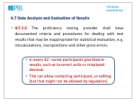
- PT Provider shall have provisions in place for validation of data processing equipment & software and back up process for computer systems (results shall be recorded).
- Participant results shall be recorded and analyzed by appropriate methods.
- Procedures for checking the validity of data entry, data transfer, statistical analysis and reporting
- Appropriate summary statistics
- Description of the basis for the evaluation of participants results

4.7 Data Analysis – Statistical Analysis

- Control influence of extreme results
  - ✓ Outlier removal
  - ✓ Robust methods (preferred)

A characteristic describing a model's, te
to effectively perform while its variables or assumptions are altered. A robust concept can operate without failure under a variety of conditions.

- Procedures to dealing with results that cannot be evaluated (gross errors)



- Procedures and criteria to detect PT items (data sets) that cannot be evaluated (because of inhomogeneity, instability, damage or contamination)

4.7 Data Analysis and Evaluation of Results

- Decide readiness for graded PT

Technical Advisory Committee	Pilot programs	Determine criteria for performance (consider number of laboratories)	Implement grading

4.7 Data Analysis and Evaluation of Results

- **4.7.1.5** The proficiency testing provider shall have documented criteria and procedures for dealing with test results that may be inappropriate for statistical evaluation, e.g. miscalculations, transpositions and other gross errors.

- In every ILC –some participants give bizarre results, such as incorrect units or misplaced decimal.
- This can allow contacting participant, or editing (but that might not be allowed by regulation)

4.7 Data Analysis and Evaluation of Results- Basis for evaluation

The evaluation of performance shall not be subcontracted

(ISO 13528): Three different general approaches for evaluation:
Performance evaluated by comparison:

- a) with externally derived criteria
- b) with other participants
- c) with claimed measurement uncertainty

Might have a mix of consensus statistics and reference criteria

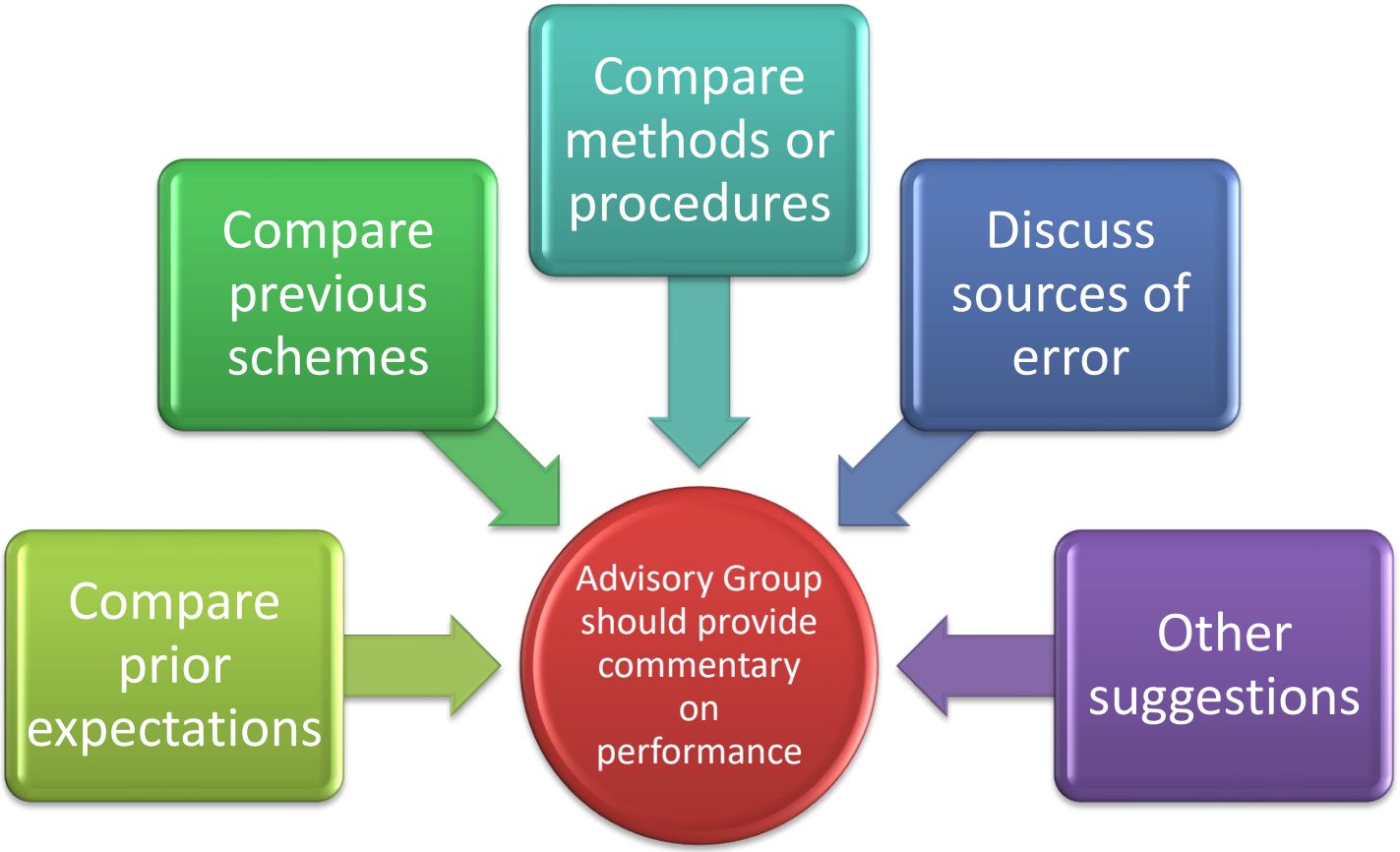
- Mean or reference value
- Participants Standard Deviation or experts criteria

4.7 Data Analysis and Evaluation of Results- Basis for evaluation

- **4.7.2.2** Where appropriate for the purpose of the PT scheme, the PTP shall provide expert commentary on the performance of participants with regard to the following:
  - ✓ a) overall performance against prior expectations, taking measurement uncertainties into account
  - ✓ b) variation within and between participants, and comparisons with any previous proficiency testing rounds, similar proficiency testing schemes, or published precision data
  - ✓ c) variation between methods or procedures

4.7 Data Analysis and Evaluation of Results

- Procedure for appropriate evaluation, including the basis of evaluation



4.8 Reports

The authorization of the final report shall not be subcontracted

- Concise, understandable, informative
- **Timely** - (for error detection)
- Participants should be able to reproduce performance scores and evaluations

- Participants should see the distribution of scores from other participants and other methods.

4.8 Reports

4.8.2: Detailed report content

Report should be “stand-alone” document, but for routine programs, some items can be available in other areas.

Minimum: have labs reported results, assigned value (+ traceability & uncertainty), performance statistic, acceptable range for all measurands, comments/recommendations

4.8 Reports

Include information on individual and group performance, including distribution of results from all participants

- Can be in summarized form

Reports available within specified timetables

- Interim reports may be needed, if scheme takes long time to complete

PTP shall have a policy for use of reports by individuals or organizations

4.9 Communications with Participants

PT Provider shall make information available on the scope and fees of the PT scheme, eligibility criteria

Instructions for participants on how to appeal (apply for review) results

Participation information confidential unless they consent

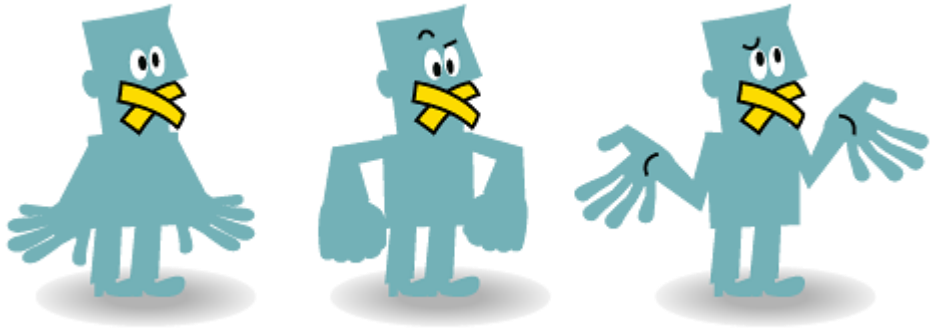
Appropriate information for prospective participants on details of program

Advise participants (in writing) of changes

Records of all communications

4.10 Confidentiality

- Identity of participants shall be protected, known to minimum number of people, involved in PT.
- All information and communication is confidential.
  - ✓ Confidentiality can be waived for purposes of discussion and mutual assistance.
- If an interested party (i.e. AB) gets data from PTP, participants shall be informed before they participate.
- If regulator gets PT data from PTP, participants shall be informed in writing.



ISO/IEC 17043: Annex B

Annex B on Data Analysis

General concepts and references

- ISO 13528
- IUPAC Harmonized Protocol
- ISO Guide 35

Topics referenced

- Demonstration of homogeneity and stability
- Determination of assigned value
- Robust statistical techniques
- Performance statistics
- Evaluation of performance

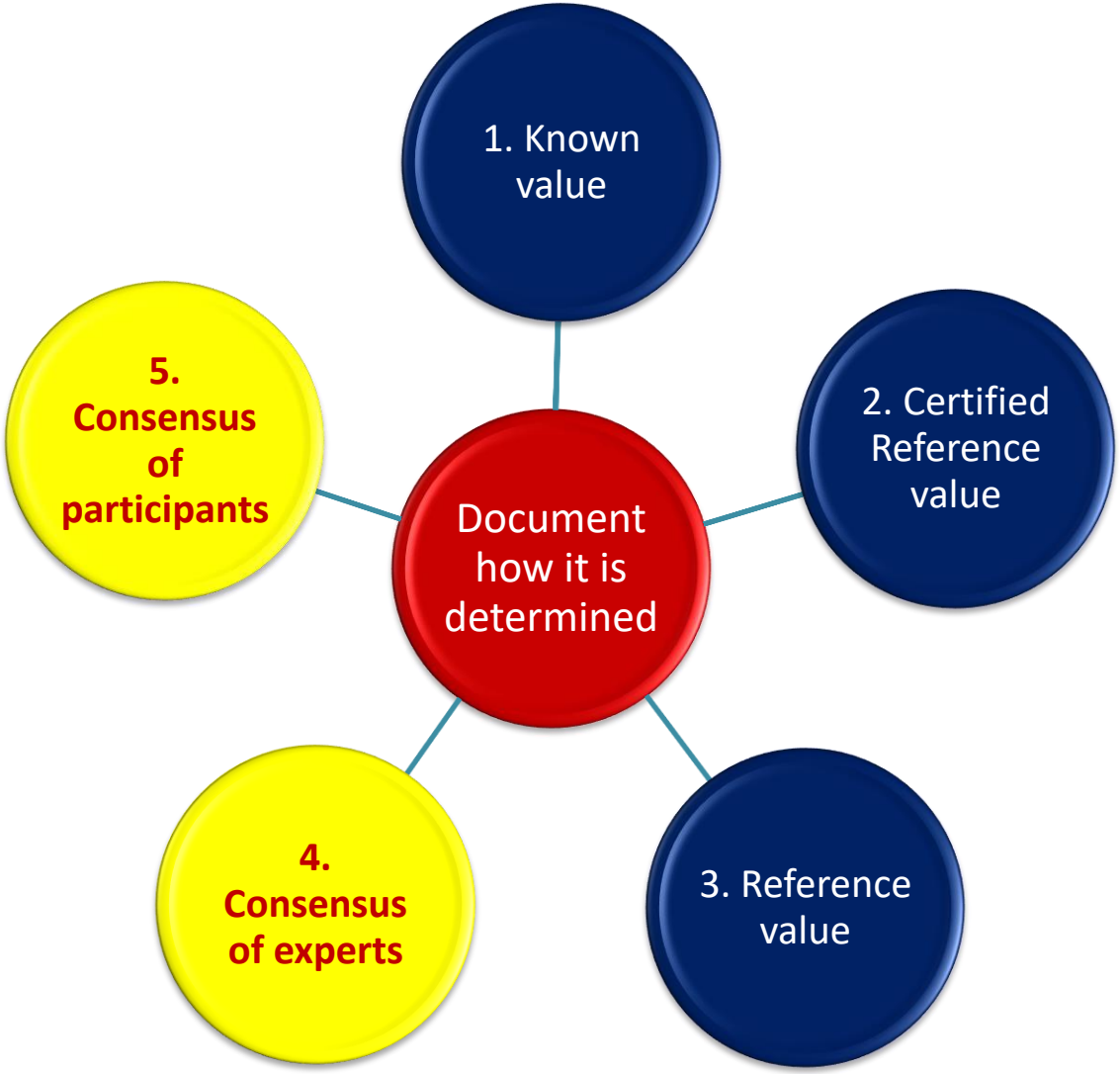
Determination of assigned value and its uncertainty

A measure of the quality of the design of a PT is how well it can distinguish between reliable and unreliable measurements.

The width of the grey zone between reliable and unreliable measurements as judged by the PT can be thought of as the uncertainty of the PT.

To minimize the uncertainty of the proficiency test it is necessary to have a reference value that is reliable and has a low uncertainty.

Determination of assigned value and its uncertainty



Determination of assigned value and its uncertainty

1. Known values- by formulation (i.e., e.g. manufacture or dilution);

Accepted reference value- Assigned value: A value that serves as an agreed-upon reference for comparison. Various procedures available, listed below in an order of increasing uncertainty:

2. the certified reference value(s) for a CRM or standard used as a test material;
3. reference values – as determined by analysis, measurement or comparison of the PT item alongside a RM or standard, traceable to a national or international standard;
4. consensus values from expert laboratories, with demonstrable competence, using validated and of high accuracy methods;
5. consensus values from participants (that is, a value derived directly from reported results)

Determination of assigned value and its uncertainty

- The consensus is not theoretically the best option for the assigned value but is usually the only practicable value.
- The consensus is not necessary identical with the “true” value. PTPs have to be alert to this possibility.

Mean	Robust mean	Median
• Easy to calculate but affected by outliers and asymmetry.	• Fairly easy to calculate, handles outliers, but affected by asymmetry	• Easy to calculate, more robust for asymmetric distributions, but larger standard error that robust mean

Determination of assigned value and its uncertainty

If consensus, control outliers by statistically valid techniques (§B.2.5)

- Results exhibiting obvious blunders should be removed from data and treated separately
- Minimize their influence by statistical methods/ robust statistics
- Results removed as outliers should still be evaluated within the PT scheme

Other considerations

- Establish trueness of assigned values
- Use acceptability criteria in terms of uncertainty

Standard Uncertainty of Assigned Value

Formulation: estimated by combination of uncertainties using the approach described in the GUM.

Certified reference values : derived from the information on uncertainty provided on the certificate for the CRM.

Reference values: derived from the test results of the chosen laboratory, and the uncertainties of the certified reference values of the CRM.

Consensus values from expert laboratories:

$$u_x = \frac{1{,}25}{p} \times \sqrt{\sum_{i=1}^{p} u_i^2}$$

u_i = the standard uncertainty from the expert laboratory

p = number of expert laboratories

Uncertainty of Assigned Value

Consensus value from participants:

$$u_x = \frac{1{,}25 \times s^*}{\sqrt{p}}$$

s^* = robust standard deviation of the participants results.

p = number of participants

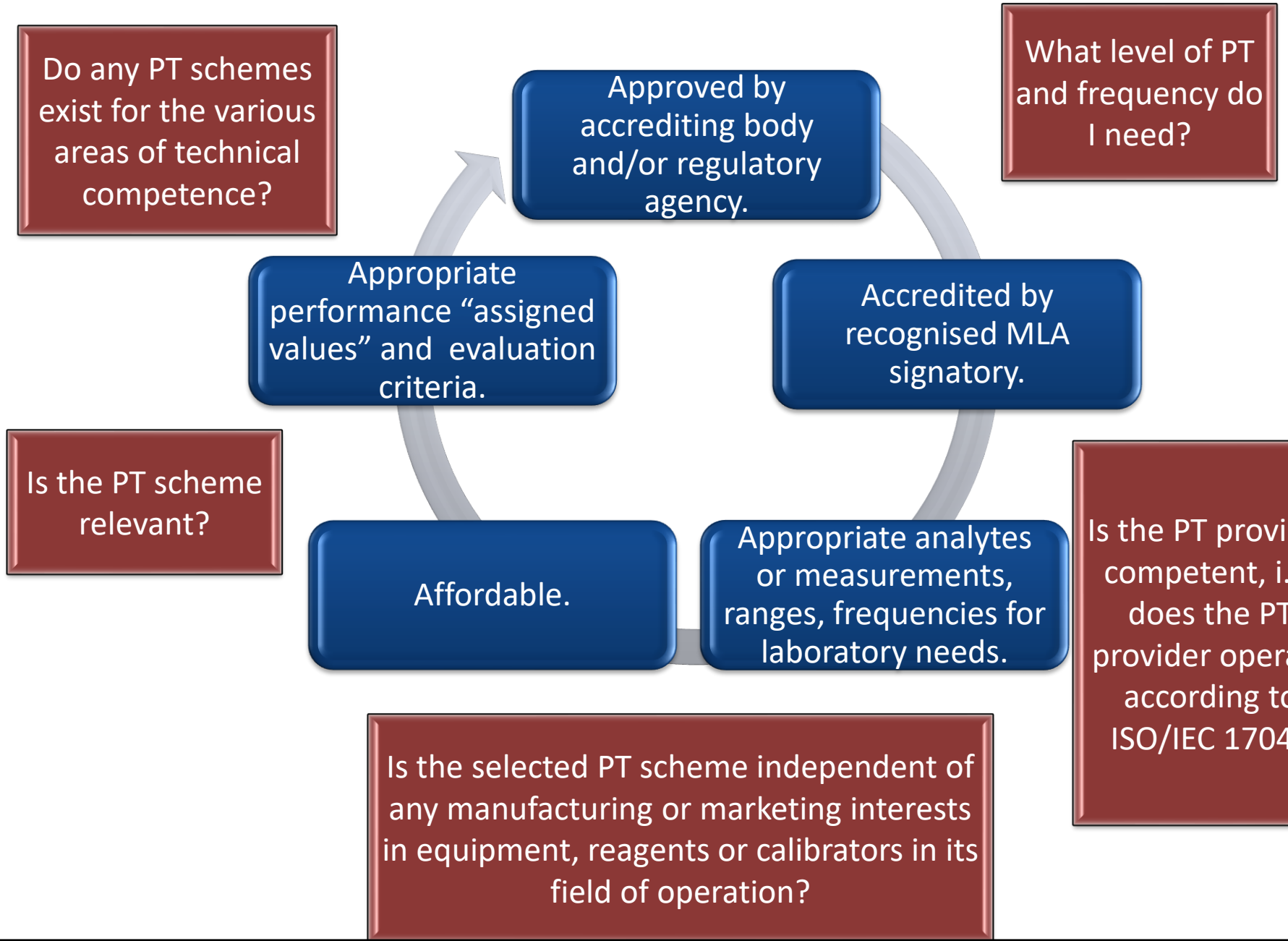
Limitations

a) there may be no real consensus amongst the participants;

b) the consensus may be biased by the general use of faulty methodology and this bias will not be reflected in the standard uncertainty of the assigned value calculated as described above.

Annex C: Selection and use of proficiency testing

C.2-Selection of PT schemes



C.4 Use of proficiency testing by participants

C.4.1 Participants should draw their own conclusions about their performance from an evaluation of the organization and design of the proficiency testing scheme. Reviews should consider the relation between the proficiency testing scheme and the needs of the participant's customers. The information that should be taken into consideration includes:

C.4 Use of proficiency testing by participants

a) the origin and character of proficiency test items;

b) the test and measurement methods used and, where possible, the assigned values for particular test or measurement methods;

c) the organization of the proficiency testing scheme (e.g. the statistical design, the number of replicates, the measurands, the manner of execution);

d) the criteria used by the proficiency testing provider to evaluate the participants' performance;

e) any relevant regulatory, accreditation or other requirements.

C.4 Use of proficiency testing by participants

C.4.2 Participants should maintain their own records of performance in proficiency testing, including the outcomes of investigations of any unsatisfactory results and any subsequent corrective or preventive actions.

PT Provider Responsibilities

- Assure competence and quality
- Comply with accrediting requirements
- Cooperate with stakeholders on program design
- Establish open communication policy
- Document all procedures and complaints
- Maintain confidentiality

Laboratory Responsibilities

- Choose competent PT provider/Select suitable PT schemes
- Follow instructions from PT provider and accrediting body.
- Use routine methods, avoid collusion.
- Act on unsatisfactory results.
- Use data for self-improvement.
- Retain results and document actions.
- Participate in PT scheme improvement

Accreditation Body Responsibilities

- Assist design of appropriate scheme.
- Establish policies for participation in PTs.
- Establish policies for use of PT data.
- Maintain oversight of approved PT schemes using experienced personnel.
- Train assessors on proper use of PTs.

Accreditation Body/Assessors Responsibilities

- Collect and provide information about appropriate PTs (i.e. EPTIS)
- Promote the benefits of participation in PTs and how performance is used to help the competence of labs.
- Support the organization of PTs, whenever possible and useful in the most cost-effective manner.
- Judge the appropriateness of PTs in which the lab participates, which will be taken into account in accreditation.

AB-Competence of assessors

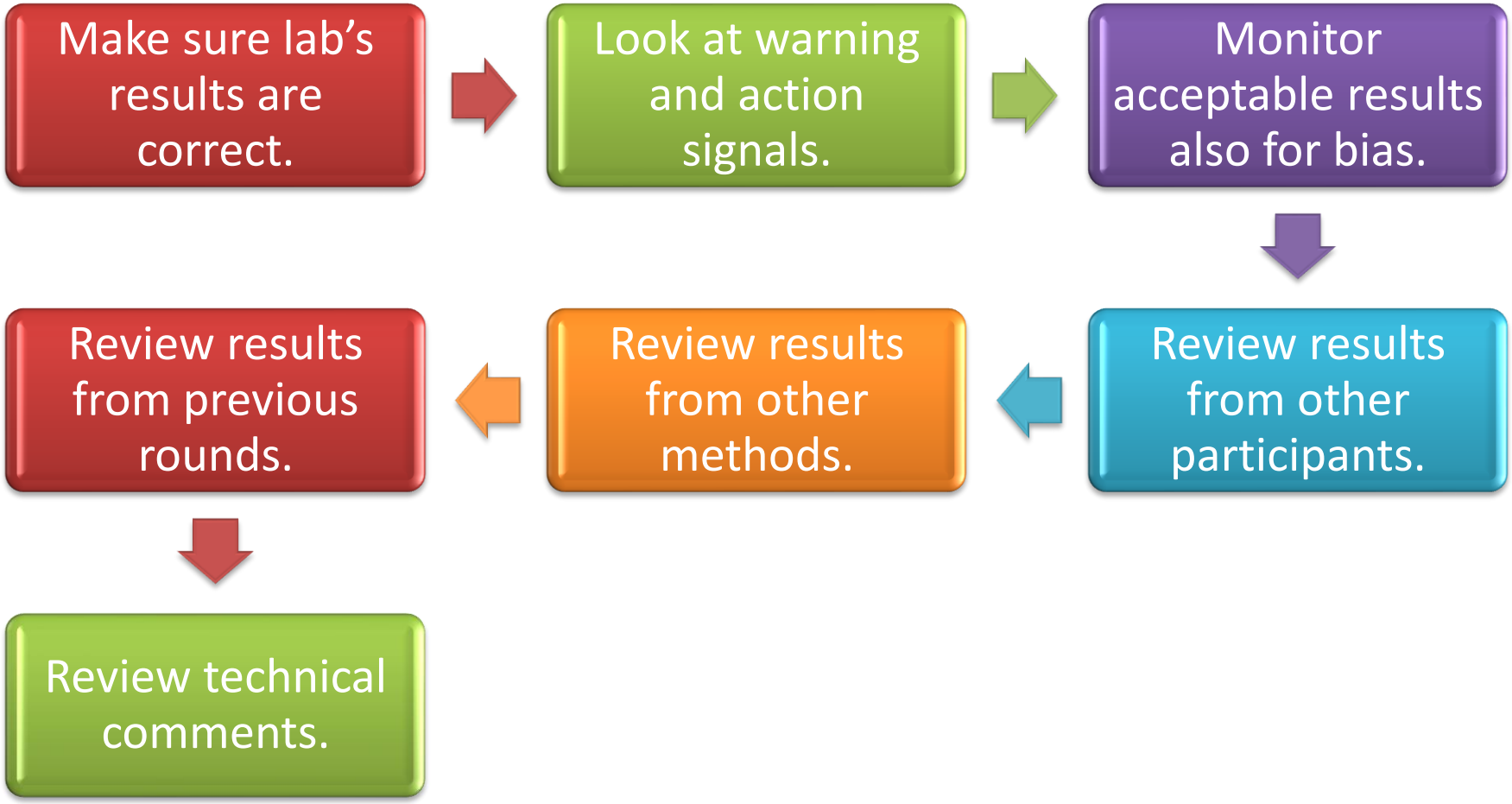
- Demonstrable competence in interpretation of the assigned value and acceptability criteria in all types of PTs in order to afford a critical evaluation of quantitative and qualitative results of laboratories
- Have relevant knowledge about standards and guidelines on the organisation, performance and evaluation of interlaboratory comparisons, as e. g. ISO/IEC 17043, ISO 13528, ISO 5725 B1.1-6
- Have competence in the use of different types of PTs for accreditation purposes appropriate to the work of the laboratory being assessed and in basic principles for proficiency testing.

Evaluation of a PT scheme (Laboratory's responsibility)

- Competence of the proficiency testing organizer, if not accredited (ISO 17043)- Evaluation by the laboratory:
  - the analysis of the testing/calibration data and the subsequent determination of laboratory testing performance
  - the establishment of the reference values and the relevant uncertainties from testing/calibration laboratories, able to demonstrate the traceability of their measurements to National or International Standards, in accordance with ISO/IEC 17025 requirements.

The AB has to assess all the aforementioned collected information!

Participants-Interpreting results



Thank you for your attention!