

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

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Course Schedule

28th Nov. 2012

- **What is Proficiency Testing**
- **Benefit of proficiency testing**
- **Benefit of proficiency testing accreditation**
- **Introduction, Scope, Normative references,**
- **Terms and Definitions related with ISO/IEC 17043: 2010**
- **Management requirements**
- **5.1 Organization**
- **5.2 Management system**
- **5.3 Document control**
- **5.4 Review of requests, tenders and contracts**
- **5.5 Subcontracting services**

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Course Schedule

29th Nov. 2012

- 5.6 Purchasing services and supplies
- 5.7 Service to the customer
- 5.8 Complaints and appeals
- 5.9 Control of nonconforming work
- 5.10 Improvement
- 5.11 Corrective actions
- 5.12 Preventive actions
- 5.13 Control of records
- 5.14 Internal audits
- 5.15 Management reviews
- Technical Requirement
- 4.1 General
- 4.2 Personnel
- 4.3 Equipment, accommodation and environment
- 4.4 Design of proficiency testing schemes
- 4.5 Choice of method of procedure

Course Schedule

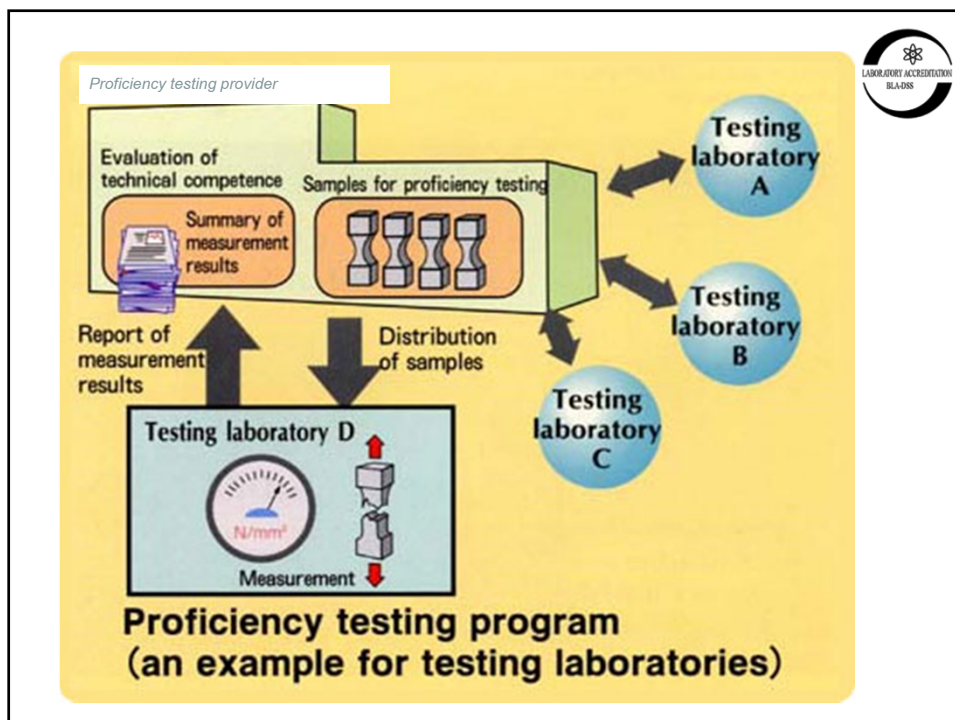
30th Nov. 2012

- 4.6 Operation of proficiency testing schemes
- 4.7 Data analysis and evaluation of proficiency testing scheme results
- 4.8 Reports
- 4.9 Communication with participants
- 4.10 Confidentiality
- Annex A
- Annex B
- Annex C
- Example of Proficiency Testing Provider (PTP)
- Process of Accreditation
- Discussion and Conclusion

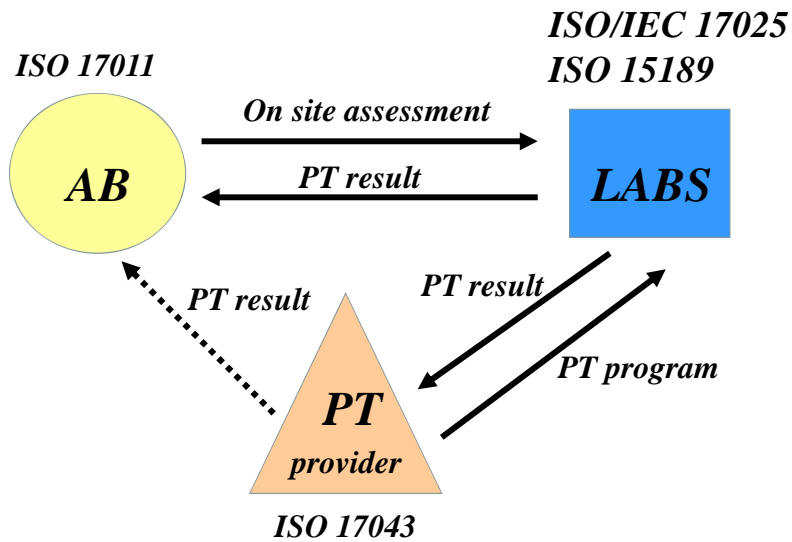
What is Proficiency Testing?

Proficiency Testing is the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

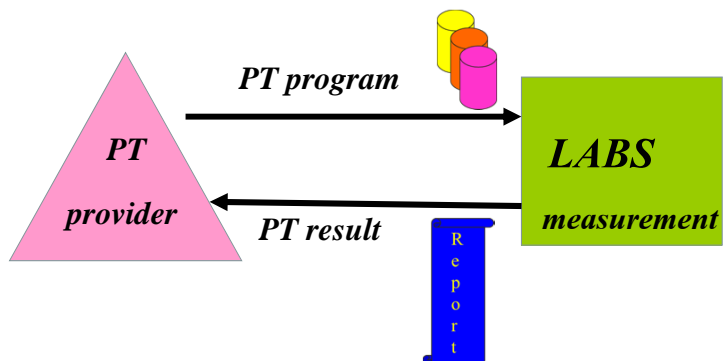
interlaboratory comparison organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions



**Relationship between Accreditation body,
PT provider and Laboratories**



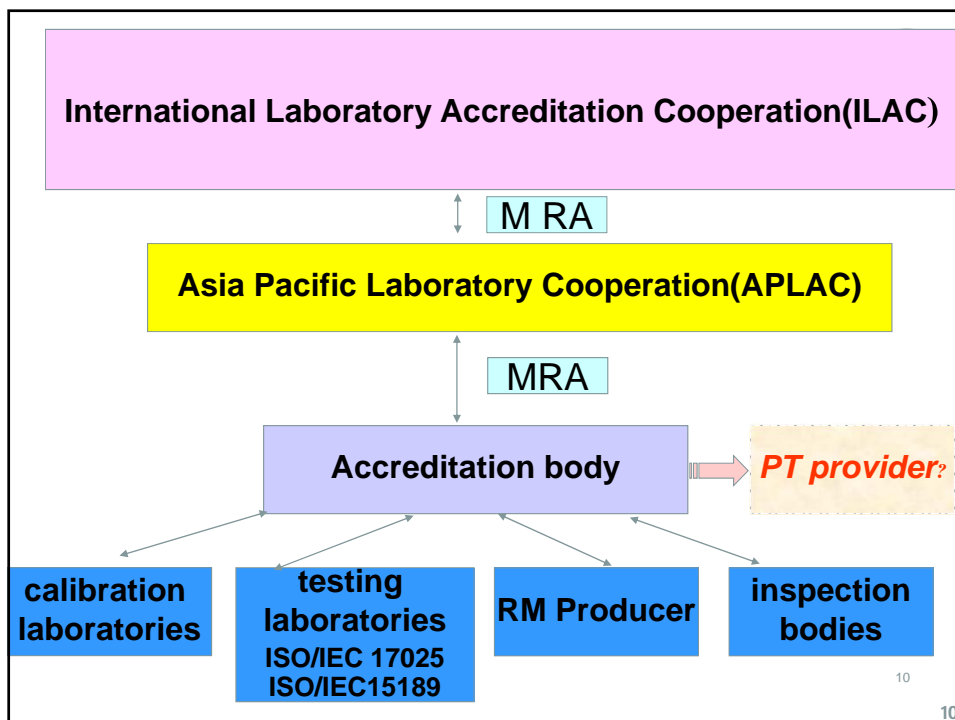
Proficiency Testing Program



Benefits of PT Provider Accreditation

Benefits of using an accredited PT Provider

1. international recognition
2. business success/ more accepted on overseas markets
3. international criteria applied
4. precision, reliability and confidence in the results are clearly demonstrated.
5. labs and ABs will be more confident to use the results of external proficiency testing schemes in the accreditation process.
6. other users of proficiency testing schemes may also have additional confidence if the schemes have been independently accredited.



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Introduction

1 Scope

2 Normative references

3 Terms and definitions

4 Technical Requirements

4.1 General

4.2 Personnel

4.3 Equipment, accommodation and environment

4.4 Design of proficiency testing schemes

4.5 Choice of method or procedure

4.6 Operation of proficiency testing schemes

4.7 Data analysis and evaluation of proficiency testing scheme results

4.8 Reports

4.9 Communication with participants

4.10 Confidentiality

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5 Management requirements

5.1 Organization

5.2 Management system

5.3 Document control

5.4 Review of requests, tenders and contracts

5.5 Subcontracting services

5.6 Purchasing services and supplies

5.7 Service to the customer

5.8 Complaints and appeals

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5.11 Corrective actions
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Annex A Types of proficiency testing schemes
Annex B Statistical methods for proficiency testing
Annex C Selection and use of proficiency testing
Bibliography

Coverage

***•Intended to apply to traditional PT
(inter laboratory comparisons) for testing and
calibration laboratories and inspection bodies***

***1 st ed. ISO/IEC 17043 cancels and
Replaces ISO/IEC Guide 43-1:1997
and ISO/IEC Guide 43-2:1997***

Title
<p>Conformity assessment – General requirements for proficiency testing</p> <p>(ILAC G13: Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes)</p> <p>(Guide 43: Proficiency testing by interlaboratory Comparisons - Development and operation of proficiency testing schemes)</p>

Title
<p>Conformity assessment –requirements for proficiency testing</p> <p>PT is “conformity assessment activity”, so PT providers are CABs per ISO 17011</p> <p>Title does not say “providers”</p>

Introduction

Interlaboratory comparisons:

Purposes :

- 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 eg.
 - inadequate test or measurement procedures,**
 - effectiveness of staff training and supervision,**
 - calibration of equipment.****

Introduction

- c) establishment of the effectiveness and comparability of test or measurement methods.**
- d) provision of additional confidence to laboratory customers.**
- e) identification of interlaboratory differences;**

Introduction

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 (collaborative trials).*

Introduction

i) assignment of values to reference materials

j) support for NMI “key comparisons”, comparisons conducted by BIPM, and regional metrology Organizations e.g. APMP..

Scope

This International Standard specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes.

Scope

These requirements are intended to be general for all types of proficiency testing schemes, and they can be used as a basis for specific technical requirements for particular fields of application.

Normative references

**ISO/IEC 17000:2004, Conformity assessment-
Vocabulary and general principles**

**ISO/IEC Guide 99:2007, International vocabulary
of metrology—Basic and general
concepts and associated terms (VIM)**

Informative References

- ISO/IEC 17011**
- ISO/IEC 17025**
- ISO 15189**
- ISO Guide 34**
- ISO/IEC Guide 98 (GUM)**

Terms & Definitions

assigned value

value attributed to a particular property of a proficiency test item

coordinator

one or more individuals with responsibility for organizing and managing all of the activities involved in the operation of a proficiency testing scheme

customer

organization or individual for which a proficiency testing scheme is provided through a contractual Arrangement

Terms & Definitions

interlaboratory comparison

organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

outlier

observation in a set of data that appears to be inconsistent with the remainder of that set

NOTE An outlier can originate from a different population or be the result of an incorrect recording or other gross error.

participant

laboratory, organization or individual that receives proficiency test items and submits results for review by the proficiency testing provider

NOTE In some cases, the participant can be an inspection body.

Terms & Definitions

proficiency testing
evaluation of participant performance against pre-established criteria by means of interlaboratory Comparisons

NOTE 1

a) quantitative scheme

where the objective is to quantify one or more measurands of the proficiency test item;

b) qualitative scheme

where the objective is to identify or describe one or more characteristics of the proficiency test item;

Terms & Definitions

c) sequential scheme

where one or more proficiency test items are distributed sequentially for testing or measurement and returned to the proficiency testing provider at intervals;

d) simultaneous scheme

where proficiency test items are distributed for concurrent testing or measurement within a defined time period;

e) single occasion exercise

where proficiency test items are provided on a single occasion;

Terms & Definitions

f) continuous scheme

where proficiency test items are provided at regular intervals;

g) sampling

where samples are taken for subsequent analysis;

h) data transformation and interpretation

where sets of data or other information are furnished and the information is processed to provide an interpretation (or other outcome).

NOTE 2 : proficiency testing in the medical area use the term “External Quality Assessment (EQA)”

Terms & Definitions

proficiency test item

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

proficiency testing provider

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

proficiency testing round

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

Terms & Definitions

proficiency testing scheme

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

robust statistical method

statistical method insensitive to small departures from underlying assumptions surrounding an underlying probabilistic model

standard deviation for proficiency assessment

measure of dispersion used in the evaluation of results of proficiency testing, based on the available information

Terms & Definitions

subcontractor

organization or individual engaged by the proficiency testing provider to perform activities “collaborators.”

measurement uncertainty

non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

Terms & Definitions

metrological traceability

property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

JCGM 200:2008 International vocabulary of metrology

Basic and general concepts and associated terms (3rd ed.VIM)

Definition [ISO/IEC Guide 99:2007

“International vocabulary of metrology and associated Terms(VIM)”

Terms & Definitions

“NOTE 1 reference” can be a definition of a measurement unit through its practical realization, or a measurement procedure

NOTE 2 Metrological traceability requires an established calibration hierarchy

NOTE 3 Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy,

NOTE 4 For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrologically traceable and the calibration hierarchy involved

Terms & Definitions

NOTE 5 measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

NOTE 6 A comparison between two measurement standards may be viewed as a calibration

NOTE 7 The ILAC metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard

NOTE 8 The abbreviated term “traceability” is sometimes used to mean “metrological traceability”

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Management Requirements

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5.1 Organization

5.1.1 PT Provider legally identifiable

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

5.1.2 PT Provider requirements

- it is the responsibility of the PT Provider to:
 - carry its proficiency testing operations in such a way to meet the requirements of this International Standard
 - satisfy the needs of:
 - the participants
 - regulatory authorities and
 - organizations providing recognition

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5.1 Organization

5.1.3 Management system at facilities

- the management system shall:
 - cover work carried out in the provider's permanent facilities
 - at sites away from its permanent facilities, and
 - in associated temporary facilities

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5.1 Organization

5.1.4 Key personnel conflict of interest

- the PT provider is part of an organization performing other activities, then the PT Provider shall:
 - identify the responsibilities of key personnel in the organization that:
 - an have involvement in or
 - could have influence on the proficiency test activities,
 - in order to identify potential conflicts of interest
 - where potential conflicts of interest are identified, procedures shall be:
 - put in place to ensure that all activities of the proficiency testing provider are
 - conducted with impartiality

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5.1 Organization

5.1.5 Personnel requirements

- the PT Provider shall:
 - a) have managerial and technical personnel who, irrespective of other
 - responsibilities, have:
 - the authority and resources needed to carry out their duties,
 - including the implementation, maintenance and improvement of the management system, and
 - to identify the occurrence of departures from the management system or from the procedures for providing proficiency testing schemes, and
 - to initiate actions to prevent or minimize such departures

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5.1 Organization

- **b) have arrangements to ensure that its management and personnel are free from**
- **commercial financial and other pressures that**
- **any undue internal or external commercial, may adversely affect the quality of their work**
- **c) have policies and procedures to ensure:**
 - **the protection of its participants' confidential information and proprietary rights, including**
 - **procedures for their protection during electronic storage and transmission**

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5.1 Organization

- d) have policies and procedures to avoid:**
 - diminish its involvement in any activities that might**
 - confidence in competence, impartiality, judgement or**
 - operational integrity**
- e) define the organization and management structure,**
 - **its place in any parent organization, and personnel who**
 - manage, perform or verify work affecting the quality of the**
 - the relationships between quality management, technical**
 - operations and support service**

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5.1 Organization

- **f) specify the responsibility, authority, interrelationships and required competence of all personnel who manage, perform or verify work affecting the quality of the operation of proficiency testing schemes**
- **g) ensure that the personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the system**
- **management**
- **h) provide adequate supervision of technical staff, including trainees, by persons familiar with procedures for each activity**

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5.1 Organization

- i) **have technical management which has overall for the technical responsibility operations**
 - the provision of the resources needed to ensure the required quality of proficiency testing schemes,**
 - including access to the necessary technical expertise and experience in the relevant field of testing, calibration or inspection, as well as statistics, as indicated in 4.4.1.4**

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5.1 Organization

j) appoint a member of staff as quality manager (named as appropriate) who, irrespective of other duties and responsibilities, shall have:

- 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; and**

k) appoint deputies for key managerial personnel

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5.2 Management system

5.2.1 Scope of management system

the PT Provider shall:

establish, implement and maintain a management system appropriate to its scope of activities,

- including the type, range and volume of proficiency testing that it provides**

5.2.2 Management system policies and procedures

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5.2 Management system

5.2.2 Management system policies and procedures

the PT Provider shall:

- define and document its policies, programmes, procedures and instructions to the quality all of proficiency testing extent necessary to assure the of aspects the system's documentation shall be:
- communicated to
- understood by
- available to, and
- implemented by the appropriate personnel

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5.2 Management system

5.2.3 Quality manual and quality policy statement requirements

the Provider's management system policies related to quality, including a quality policy statement, shall be:

- defined in a quality manual (named as appropriate)

the overall objectives shall be:

- established and reviewed during management review

the quality policy statement shall be:

- issued under the authority of top management

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5.2 Management system

it shall include:

least the following:

- a) the management's commitment to the quality of its proficiency testing 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; and
- e) the management's commitment to:
 - comply with this International Standard
 - continually improve the effectiveness of the management system

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5.2 Management system

5.2.4 Management commitment to management system

- top management shall:
- provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness

5.2.5 Management communicate customer & regulatory requirements

top management shall:

- communicate to the organization the importance of meeting customer requirements, as well as statutory and regulatory requirements

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5.2 Management system

5.2.6 Quality manual and supporting procedures

- the quality manual shall:
 - include or make reference to the supporting procedures, including technical procedures
- outline the structure

5.2.7 Technical and Quality Manager roles and responsibilities

- the quality manual shall define:
 - the roles and responsibilities of technical management and the quality manager
 - their responsibility for ensuring compliance with this International Standard

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5.2 Management system

5.2.8 Management ensure integrity of management system

- top management shall ensure:
 - that the integrity of the management system is maintained when changes to the management system are planned and implemented

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5.3 Document control

5.3.1 General

5.3.1 General document control

the PT Provider shall:

- establish and maintain procedures to control all documents that form part of its management system (internally generated, or from external sources), such as:
 - regulations, standards, other normative documents
- proficiency testing scheme protocols
- test or calibration methods, or both test and calibration methods, as well as drawings, software specifications, instructions and manuals

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5.3 Document control

5.3.2 Document approval and issue

5.3.2.1 Master list

all documents issued as part of the management system shall be:

- reviewed and approved for use by authorized personnel prior to issue

a master list or equivalent document control procedure shall:

- shall be established
- identifying the current revision status and distribution of documents in the management system
- be readily available in order to prevent the use of invalid or obsolete documents or both

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5.3 Document control

5.3.2.2 Procedures adopted

- procedures adopted shall also ensure that:
- a) authorized editions of appropriate documents are available at all locations where activities essential to the effective operation of proficiency testing schemes are performed
- b) documents are periodically reviewed and updated, as necessary, to ensure continuing suitability and compliance with applicable requirements
- c) invalid or obsolete documents are promptly removed from all points of issue or use otherwise assured against unintended use; use, or and
- d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked

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5.3 Document control

5.3.2.3 Unique identification of QS documents

management system documents generated by the PT Provider shall be:

- uniquely identified

such identification shall include:

the date of issue or revision identification, or both

- page numbering
- the total number of pages or a mark to signify the end of a document
- the issuing authority/authorities

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5.3 Document control

5.3.3 Document changes

5.3.3.1 Document changes reviewed and approved

changes to documents shall be:

- reviewed and approved by the same function that performed the original review and approval
- unless specifically designated otherwise

the designated personnel shall:

- have access to pertinent background information upon which to base their review and approval

5.3.3.2 Altered or new text identification

the altered or new text where practicable shall be:

- identified in the document or the appropriate attachments

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5.3 Document control

5.3.3.3 Handwritten amendments

- if the PT provider's document control system allows for the amendment of documents by hand, pending re-issue of the documents:
 - the procedures and authorities for such amendments shall be defined
 - amendments shall be:
 - clearly marked, initialed and dated
 - a revised document shall be:
 - issued as soon as practicable

5.3.3.4 Computerized amendments

procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled

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5.4 Review of requests, tenders and contracts

5.4.1 Policies and procedures

the PT Provider shall:

- establish and maintain policies and procedures for the review of requests, tenders and contracts
- these reviews shall ensure that:
 - a) the requirements including those for test and calibration methods measuring methods, equipment and proficiency test items to be used, are adequately defined, documented and understood
 - b) the proficiency testing provider has the capability and resources to meet the requirements; and
 - c) the proficiency testing scheme is technically appropriate

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5.4 Review of requests, tenders and contracts

5.4.2 Records shall be maintained of

- such reviews, including any changes
- pertinent discussions with a customer relating to the customer's requirements, or the results of the work during the period of execution of the contract, or both

5.4.3 Review includes subcontracted work

the review shall:

cover all aspects of the request

including any work that is subcontracted by the PT provider

5.4.4 Notification of contract or design deviation

5.4.5 Contract amendments and communication

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5.5 Subcontracting services

5.5.1 Subcontractor competency

when a testing provider subcontracts work, proficiency the PT Provider shall

- demonstrate that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of this International Standard and other appropriate standards

5.5.2 No subcontracting of planning, evaluation, final report authorization

5.5.3 Participants informed

- inform participants, in advance and in writing, of services that are, or may be subcontracted

5.5.4 PT Provider responsible for subcontract work

5.5.5 Maintain records of subcontractors and competency

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5.6 Purchasing services & supplies

5.6.1 Policy & procedures for selection and purchase

- the PT Provider shall have a policy and procedure(s) for:
 - the selection of services and supplies that it uses and
 - that affect the quality of its proficiency testing schemes
- procedures shall exist for:
 - the purchase, reception and storage of:
 - reagents
 - proficiency test items
 - materials reference and
 - other consumable materials relevant for the proficiency testing schemes

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5.6 Purchasing services & supplies

- **5.6.2 Inspected and verification of purchases**
- **the PT Provider shall ensure that:**
 - **purchased supplies, equipment and consumable materials that affect the quality of proficiency testing schemes are not used until they have been inspected**
 - **or otherwise verified as complying with specifications or requirements**
- **5.6.3 Purchasing documents information**
- **purchasing documents for items affecting the quality of proficiency testing schemes shall:**
 - **contain data describing the services and supplies ordered**
 - **be reviewed and approved for technical content prior to release**

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5.6 Purchasing services & supplies

- **5.6.4 Evaluation and listing of suppliers**
- **evaluate suppliers of critical supplies and services which affect the quality of proficiency testing schemes**
- **maintain records of these evaluations, and list those suppliers that are approved**

5.7 Service to customer

- **5.7.1 Cooperation with participants and customers**
- ***be willing to cooperate with participants and other customers in clarifying customers' requests and monitoring the PT provider's performance in relation to the work performed***
- ***provided that the PT provider assures confidentiality to its participants***
- **5.7.2 Feedback used to improve management system**
- ***seek feedback, both positive and negative, from its customers***
- ***used and analysed for improvement***

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5.8 Complaints and appeals

- have a policy and follow a procedure for
- the resolution of complaints and appeals received from participants, customers or other parties
- records shall be maintained

5.9 Control of nonconforming work

5.9.1 Policies and procedures for nonconforming work shall have a policy and procedure:

- be implemented when any aspect of its activities does not conform to its own procedures or the agreed requirements of its customers

5.9.2 Corrective actions promptly followed

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5.10 Improvement

- **5.10 Continual improvement of management system**
- **continually improve the effectiveness of its management system**

5.11 Corrective actions

5.11.1 Policies and procedures for corrective actions

5.11.2 Cause analysis: Root cause analysis

5.11.3 Selection and implementation of corrective actions

5.11.4 Monitoring of corrective actions

5.11.5 Additional audits

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5.12 Preventive actions

- 5.12.1 Action identification
- 5.12.2 Initiation of effective actions and controls

5.13 Control of records

5.13.1 General

- 5.13.1.1 Procedures for control of records
- 5.13.1.2 Record integrity and retrievable
- 5.13.1.3 Security and confidentiality
- 5.13.1.4 Protection of electronic records

5.13.2 Technical records

- 5.13.2.1 Retain records of all technical data
- 5.13.2.2 Recording and identification of information
- 5.13.2.3 Corrections of record

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5.14 Internal audits

- 5.14.1 Requirements for regular internal audits

the internal audit programme shall:

- address all elements of the management system
- including the technical procedures and
- proficiency test item preparation storage and distribution
- reporting activities for the operation of a proficiency testing scheme

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5.14 Internal audits

it is the responsibility of the quality manager to:

- plan and organize audits as required the schedule and requested by management

internal audits shall be:

- carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited
- 5.14.2 Implementation of corrective actions
- 5.14.3 Recording audit findings and corrective actions
- 5.14.4 Follow up audit verification

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5.15 Management reviews

- 5.15.1 Objectives and contents of meeting
- periodically conduct a review of the PT provider's management system and proficiency testing activities

shall take account of:

- a) the suitability of policies and procedures
- b) reports from management and supervisory personnel
- c) the outcome of recent internal audits
- d) corrective and preventive actions

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5.15 Management reviews

- e) assessments by external bodies
- f) changes in the volume and type of work
- g) customer, advisory group or participant feedback
- h) complaints and appeals
- i) recommendations for improvement; and
- j) other relevant factors, such as resources and staff training
- 5.15.2 Implementation of actions recorded and within agreed time scale

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4 Technical Requirements



- 4.1 General
- 4.2 Personnel
- 4.3 Equipment, accommodation and environment
- 4.4 Design of proficiency testing schemes
- 4.5 Choice of method or procedure
- 4.6 Operation of proficiency testing schemes
- 4.7 Data analysis and evaluation of proficiency testing scheme results
- 4.8 Reports
- 4.9 Communication with participants
- 4.10 Confidentiality

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4 Technical Requirements

4.1 General

PT provider's undertaking the development and operation of proficiency testing schemes shall have:

- *competence to conduct interlaboratory comparisons*
- *access to expertise with particular type of proficiency testing items*

PT provider's (or their subcontractors) shall also have:

- *competence in measurement of the properties being determine*

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4.2 Personnel

4.2.1 Authority, resources and demonstrated competency

“The proficiency testing provider shall have managerial and technical personnel with the necessary authority, resources and technical competence required to perform their duties.”

the PT provider shall have managerial and technical personnel with necessary:

- authority
- resources
- technical competency to perform duties

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4.2 Personnel

4.2.2 Qualifications and experience of key positions

“The proficiency testing provider’s management shall define the minimum levels of qualification and experience necessary for the key positions within its organization and ensure those qualifications are met.”

the PT provider’s management shall define:

- the minimum levels of qualification
 - experience necessary for the key positions within its organization
- ensure those qualifications are met*

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4.2 Personnel

4.2.3 Employees supervision and competency

the PT provider shall use personnel who are:

- *employed by it*
- *under contract to it*

where contracted additional technical and key support personnel are used, the PT provider shall ensure that such personnel are:

- *supervised*
- *competent*
- *working in accordance with the management system*

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4.2 Personnel

4.2.3 Employees supervision and competency

“Note: Where technical experts are used on an ad-hoc basis or as part of an advisory or steering group (see 4.4.1.4),

The existence of formal agreements through, for example, group terms of reference or other means, can be considered to satisfy this requirement.”

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4.2 Personnel

4.2.4 Authorized personnel duties

the PT provider shall authorize specific personnel to:

- a) select appropriate proficiency test items*
- b) proficiency testing schemes*
- plan c) perform particular types of sampling*
- d) operate specific equipment*

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4.2 Personnel

4.2.4 Authorized personnel duties

the PT provider shall authorize specific personnel to:

- e) conduct measurements to determine stability and homogeneity, as well as 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) Analysis conduct statistical*
- i) evaluate the performance of proficiency testing participants*
- j) give opinions and interpretations; and*
- k) authorize the issue of proficiency testing reports*

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4.2 Personnel

4.2.5 Records of all technical personnel and their competency

the PT provider shall maintain, for all technical personnel, including contracted personnel up to date .

personnel, up-to-records of relevant:

- *authorization(s)*
- *competence*
- *educational and professional qualifications*
- *training, skills and experience*

this information shall:

- *be readily available*
- *include the date on which competence to perform their assigned tasks was:*
- *assessed and*
- *confirmed*

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4.2 Personnel

4.2.6 Training objectives and policy & procedures for training program

the PT provider shall:

- *formulate the objectives with respect to the education, training, and skills*
 - *for each staff member involved with the operation of the scheme*
- proficiency testing the PT provider shall have a policy and procedures for:*
- *identifying training needs*
 - *providing training of personnel*

the training programme shall be:

- *relevant to the present and anticipated needs of the PT provider*

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4.2 Personnel

4.2.7 Training program and evaluation

the PT Provider shall ensure:

- *staff receive the necessary training to ensure competency in:*
 - *performance of measurements*
 - *operation of equipment*
 - *any other activities which affect the quality of the proficiency testing scheme*
- effectiveness of training activities shall be evaluated*

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4.3 Equipment, accommodation and environment

4.3.1 Appropriate facilities and equipment

the PT Provider shall ensure appropriate accommodation for the operation of the proficiency testing scheme

including facilities and equipment for:

- *proficiency testing item*
- *manufacturing, handling, calibration, testing, storage and despatch*
- *data processing*
- *communications*
- *retrieval of materials and records*

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4.3 Equipment, accommodation and environment

4.3.2 Environmental conditions not compromise operations

the PT Provider shall ensure that the environmental conditions do not:

- compromise the proficiency testing scheme*
- the required quality of operation*

particular care shall be taken when:

- operations are undertaken at sites away from the PT provider's permanent facilities*

- operations are undertaken by subcontractors*

the technical requirements shall be documented

- for accommodation & environmental conditions that can affect the proficiency testing*

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4.3 Equipment, accommodation and environment

4.3.3 Access control

access to and use of areas shall:

- controlled if it affects quality of proficiency testing*

be the the PT Provider shall determine:

- the extent of control based on its particular circumstances*

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4.3 Equipment, accommodation and environment

4.3.4 Facility control monitoring and stoppage of testing

the PT Provider shall:

- identify environmental conditions that can significantly influence*
- the quality of the proficiency test items*
- any testing and calibration carried out*
- those required by relevant specifications and measurement procedures*
- control and monitor these conditions*
- record all relevant monitoring activities*

relevant proficiency testing activities shall be stopped when:

- the environmental conditions jeopardize the quality or the operations of the proficiency testing scheme*

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4.3 Equipment, accommodation and environment

4.3.5 Incompatible activities

effective separation between neighbouring areas

- in which there are incompatible activities*

action shall be taken to prevent cross-contamination

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4.3 Equipment, accommodation and environment

4.3.6 Performance characteristics validated and maintained

the PT Provider shall ensure that performance characteristics of laboratory methods and equipment:

- *used to confirm:*
- *content,*
- *homogeneity and*
- *stability of proficiency testing items*
- *are appropriately:*
- *validated and*
- *maintained*

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4.4 Design of proficiency schemes

4.4.1 Planning

4.4.1.1 Identify & plan processes to prescribed procedures

the PT Provider shall:

- *identify and plan those processes which directly affect the quality of the proficiency testing scheme*
- *ensure that they are carried out in accordance with prescribed procedures*

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4.4 Design of proficiency schemes

4.4.1.2 Planning cannot be subcontracted

the PT Provider shall not:

- subcontract the planning of the proficiency testing scheme (see 5.5.2)

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4.4 Design of proficiency schemes

4.4.1.3 Plan objectives, purpose and design of PT scheme

the PT Provider shall:

- document a plan before commencement of the proficiency testing scheme

that plan has to address

- the objectives,
- purpose and
- basic design of the proficiency testing scheme

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4.4 Design of proficiency schemes

4.4.1.3 Plan objectives, purpose and design of PT scheme

the plan has to include the following information and where appropriate reasons and, appropriate, for its selection or exclusion:

- a) the name and address of the proficiency testing provider*
- b) the name, address and affiliation of the coordinator and other personnel involved in the design and operation of the proficiency testing scheme*

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4.4 Design of proficiency schemes

the plan has to include:

- c) the activities to be subcontracted and
 - the names and addresses of subcontractors involved in the operation of the proficiency testing scheme**
- d) criteria to be met for participation*
- e) the number and type of expected participants in the proficiency testing scheme*
- f) selection of the measurand or characteristic of interest,
 - including information on what the participants are to identify, measure, or test for in the specific proficiency testing round**

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4.4 Design of proficiency schemes

g) a description of the range of values or characteristics, or both, to be expected for the proficiency test items

h) the potential major sources of errors involved in the area of proficiency testing offered

i) requirements for

- the production,*
- quality control,*
- storage and distribution of proficiency test items*

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4.4 Design of proficiency schemes

j) reasonable precautions to prevent collusion between participants or falsification of results, and

- procedures to be employed if collusion or falsification of results is suspected*

k) a description of the information which is to be supplied to participants and

- the time schedule for the various phases of the proficiency testing scheme*

l) for continuous proficiency testing schemes,

- the frequency or dates upon which proficiency test items are to be distributed to participants,*
- the deadlines for the return of results by participants and,*
- appropriate the dates on which testing or measurement is to be where appropriate, carried out by participants*

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4.4 Design of proficiency schemes

- m) any information on methods or procedures which participants need to use to prepare the test material and perform the tests or measurements*
- n) procedures for the test or measurement methods to be used for the homogeneity and stability testing of proficiency test items and,
 - where applicable, to determine their biological viability*
- o) preparation of any standardized reporting formats to be used by participants*
- p) a detailed description of the statistical analysis to be used*

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4.4 Design of proficiency schemes

- q) the origin, metrological traceability and measurement uncertainty of any assigned values*
- r) criteria for the evaluation of performance of participants*
- s) a description of
 - the data
 - interim reports or
 - information to be returned to participants*

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4.4 Design of proficiency schemes

- t) a description of the extent to which participant and results,
 - the conclusions that will be based on the outcome of the proficiency testing scheme,
 - are to be made public; and
- u) actions to be taken in the case of lost or damaged proficiency test items.”

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4.4 Design of proficiency schemes

- 4.4.1.4 Technical expertise and advisory group
- the PT Provider shall have:
- access to the necessary technical expertise
 - experience in the relevant field of testing, calibration, sampling or inspection
 - experience in statistics
- may be achieved, if necessary, by establishing an advisory group:
- named as appropriate

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4.4 Design of proficiency schemes

4.4.1.5 Technical expertise used for

Technical expertise shall be used as appropriate:

to determine matters such as the following:

- a) *planning requirements as listed in 4.4.1.3*
- b) *identification and resolution of any difficulties expected in*
 - *the preparation and maintenance of homogeneous proficiency test items, or*
 - *the provision of a stable assigned value for a proficiency test item*
- c) *preparation of detailed instructions for participants*
- d) *Comments on*
 - *any technical difficulties or*
 - *other remarks raised by participants in previous proficiency testing rounds*
- e) *provision of advice in evaluating the performance of participants*

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4.4 Design of proficiency schemes

- f) *comments on the results and performance of participants*
- g) *provision of advice for participants*
- h) *responding to feedback from participants*
- i) *planning or participating in technical meetings with participants*

4.4.2 Preparation of proficiency test items

4.4.2.1 establish and implement procedures in accordance with the plan

4.4.2.2 procedures to ensure appropriate acquisition, collection, preparation, handling, storage and, where required, disposal of all proficiency test items

4.4 Design of proficiency schemes

4.4.2.3 Proficiency test items should match in terms of matrix, measurands and concentrations

4.4.2.4 require participants to prepare or manipulate, or both prepare and manipulate, the proficiency test item and submit it to the proficiency testing provider, the proficiency testing provider shall issue instructions for preparation, packaging and transport of the proficiency test item.

4.5 Choice of method or procedure

4.5.1 Participants shall normally be expected to use the test method, calibration or measurement procedure of their choice,

4.5.2 Use a method of their choice,

- a) have a policy and follow a procedure regarding comparison of results obtained by different test or measurement methods;*
- b) be aware of which different test or measurement methods for any measurand are technically equivalent,*



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4.4 DESIGN OF PROFICIENCY TESTING SCHEME

- 4.4.2 Preparation of proficiency test items
- 4.4.3 Homogeneity and stability
- 4.4.4 Statistical design
- 4.4.5 Assigned values



4.4.2 Preparation of proficiency test items

4.4.2.1

The proficiency testing provider shall establish and implement procedures to ensure that proficiency test items are prepared in accordance with the plan described in 4.4.1.

Note...

4.4.2 Preparation of proficiency test items



4.4.2.1

Note...

It is advisable that the proficiency testing provider give due consideration to the preparation of sufficient numbers of proficiency test items, in order to allow for the need to replace any such proficiency test items lost or damaged during distribution, or intended to be provided for use after the results of the proficiency testing scheme have been evaluated. Such uses can include training aids for participants or use as a reference material.

4.4.2 Preparation of proficiency test items



4.4.2.2

The proficiency testing provider shall establish and implement procedures to ensure appropriate acquisition, collection, preparation, handling, storage and, where required, disposal of all proficiency test items. The procedures shall ensure that materials used to manufacture proficiency test items are obtained in accordance with relevant regulatory and ethical requirements.

4.4.2 Preparation of proficiency test items



4.4.2.3

Proficiency test items should match in terms of matrix, measurands and concentrations, as closely as practicable, the type of items or materials encountered in routine testing or calibration.

4.4.2 Preparation of proficiency test items



4.4.2.4

In proficiency testing schemes that require participants to prepare or manipulate, or both prepare and manipulate, the proficiency test item and submit it to the proficiency testing provider, the proficiency testing provider shall issue instructions for preparation, packaging and transport of the proficiency test item.

4.4.2 Preparation of proficiency test items



4.4.2.4

In proficiency testing schemes that require participants to prepare or manipulate, or both prepare and manipulate, the proficiency test item and submit it to the proficiency testing provider, the proficiency testing provider shall issue instructions for preparation, packaging and transport of the proficiency test item.

4.4.3 Homogeneity and stability



4.4.3.1

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.

Note...

4.4.3 Homogeneity and stability



4.4.3.1

Note 1 The requirements in this subclause are intended to ensure that every participant receives comparable proficiency test items, and that these proficiency test items remain stable throughout the proficiency testing. Careful planning, manufacture and shipping are necessary to achieve this, and testing is usually needed to confirm it.

Note 2 In some cases, it is not feasible for proficiency test items to be subjected to homogeneity and stability testing. Such cases would include, for example, when limited material is available to prepare proficiency testing items.

Note 3 In some cases, materials that are not sufficiently homogeneous or stable are the best available; in such cases, they can still be useful as proficiency test items, provided that the uncertainties of the assigned values or the evaluation of results take due account of this (see B.3.1.3..)

Note 4 Considerations for homogeneity and stability are further discussed in ISO Guide 34, ISO Guide 35 and ISO 13528

4.4.3 Homogeneity and stability



4.4.3.2

The procedures for the assessment of homogeneity and stability shall be documented and conducted, where applicable, in accordance with appropriate statistical designs. Where possible, the proficiency testing provider shall use a statistically random selection of a representative number of proficiency test items from the whole batch of test material in order to assess the homogeneity of the material.

4.4.3 Homogeneity and stability



4.4.3.3

The assessment of homogeneity shall normally be performed after the proficiency test items have been packaged in the final form and before distribution to participants unless, for example, stability studies indicate that they should be stored in bulk form.

Note 1 Homogeneity can be demonstrated prior to packaging where no influence of packaging is reasonably expected.

Note 2 On some occasions, homogeneity testing cannot be carried out prior to distribution for practical, technical or logistical reasons.

4.4.3 Homogeneity and stability



4.4.3.4

Proficiency test items shall be demonstrated to be sufficiently stable to ensure that they will not undergo any significant change throughout the conduct of the proficiency testing, including storage and transport conditions. When this is not possible, the stability shall be quantified and considered as an additional component of the measurement uncertainty associated with the assigned value of the proficiency test item, and/or taken into account in the evaluation criteria.

4.4.3 Homogeneity and stability



4.4.3.5

When proficiency test items from previous rounds are retained for future use, the property values to be determined in the proficiency testing scheme shall be confirmed by the proficiency testing provider prior to distribution.

4.4.3 Homogeneity and stability



4.4.3.6

In circumstances where homogeneity and stability testing is not feasible, the proficiency testing provider shall demonstrate that the procedures used to collect, produce, package and distribute the proficiency test items are sufficient for the purpose of the proficiency testing.

4.4.4 Statistical design



4.4.4.1

Statistical designs shall be developed to **meet the objectives of the scheme**, based on the nature of the data (quantitative or qualitative, including ordinal and categorical), statistical assumptions, the nature of errors, and the expected number of results (see B.3.2.2).

Note..

4.4.4 Statistical design



4.4.4.1

Note 1 Statistical design covers the process of planning, collection, analysis and reporting of the proficiency testing scheme data. Statistical designs are often based on stated objectives for the proficiency testing scheme, such as detection of certain types of errors with specified power or determination of assigned values with specified measurement uncertainty.

Note 2 Data analysis methods could vary from the very simple (e.g. descriptive statistics) to the complex, using statistical models with probabilistic assumptions or combinations of results for different proficiency test items.

Note 3 In cases where the proficiency testing scheme design is mandated by a specification given by, for example, a customer, regulatory authority or accreditation body, the statistical design and data analysis

Note 4 In the absence of reliable information needed to produce a statistical design, a preliminary interlaboratory comparison can be used.

4.4.4 Statistical design



4.4.4.2

The proficiency testing provider shall document the statistical design and data analysis methods to be used **to identify the assigned value and evaluate participant results**, and shall provide a description of the reasons for their selection and assumptions upon which they are based. The proficiency testing provider shall be able to demonstrate that **statistical assumptions are reasonable** and that statistical analyses are carried out in accordance with prescribed procedures.

4.4.4 Statistical design



4.4.4.3 In designing a statistical analysis, the proficiency testing provider shall give careful consideration to the following:

- a) the accuracy (trueness and precision) as well as the measurement uncertainty required or expected for each measurand or characteristic in the proficiency testing;
- b) the minimum number of participants in the proficiency testing scheme needed to meet the objectives of the statistical design; in cases where there is an insufficient number of participants to meet these objectives or to produce statistically meaningful analysis of results, the proficiency testing provider shall document, and provide to participants, details of the alternative approaches used to assess participant performance;

4.4.4 Statistical design



4.4.4.3

- c) the relevance of significant figures to the reported result, including the number of decimal places;
- d) the number of proficiency test items to be tested or measured and the number of repeat tests, calibrations or measurements to be conducted on each proficiency test item or for each determination;
- e) the procedures used to establish the standard deviation for proficiency assessment or other evaluation criteria;

4.4.4 Statistical design



4.4.4.3

- f) procedures to be used to identify or handle outliers, or both;
- g) where relevant, the procedures for the evaluation of values excluded from statistical analysis; and
- h) where appropriate, the objectives to be met for the design and the frequency of proficiency testing rounds.

4.4.5 Assigned values



4.4.5.1

The proficiency testing provider shall document the procedure for determining the assigned values for the measurands or characteristics in a particular proficiency testing scheme. This procedure shall take into account the metrological traceability and measurement uncertainty required to demonstrate that the proficiency testing scheme is fit for its purpose.

Note Metrological traceability is not always possible or appropriate.

4.4.5 Assigned values



4.4.5.2

Proficiency testing schemes in the area of calibration shall have assigned values with metrological traceability, including measurement uncertainty.

4.4.5 Assigned values



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.

Note The required metrological traceability chain can differ depending on the type of proficiency test item, the measurand or characteristic, and the availability of traceable calibrations and reference materials.

4.4.5 Assigned values



4.4.5.4

When a **consensus value** is used as the assigned value (see Annex B), the proficiency testing provider shall document **the reason** for that selection and **shall estimate the uncertainty of the assigned value** as described in the plan for the proficiency testing scheme.

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.

4.4.5 Assigned values



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.

Note The required metrological traceability chain can differ depending on the type of proficiency test item, the measurand or characteristic, and the availability of traceable calibrations and reference materials.

4.5 Choice of method or procedure



4.5.1

Participants shall normally be expected to use the test method, calibration or measurement procedure of their choice, which should be consistent with **their routine procedures**. The proficiency testing provider may instruct participants to use a **specified method** in accordance with the design of the proficiency testing scheme.

4.5 Choice of method or procedure



4.5.2

Where participants are permitted to use a method of their choice, the proficiency testing provider shall:

- a) have a policy and follow a procedure regarding comparison of results obtained by **different test or measurement methods**;
- b) 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 Technical Requirements(cont.)



- 4.6 Operation of proficiency testing schemes
- 4.7 Data analysis and evaluation of proficiency testing scheme results
- 4.8 Reports
- 4.9 Communication with participants
- 4.10 Confidentiality

1

4.6 Operation of proficiency schemes

- 4.6.1 Instructions to participants
 - 4.6.1.1 Prior notice of despatch or arrival
- the PT Provider shall
- give participants sufficient prior notice before sending proficiency test items
 - provide the date on which the proficiency test items are likely to arrive or to be despatched
 - unless the design of the proficiency testing scheme makes it inappropriate to do so

2

4.6 Operation of proficiency schemes

4.6.1.2 Detailed documented instructions

instructions to participants shall include:

- a) the necessity to treat proficiency test items in the same manner as the majority of routinely tested samples

(unless there are particular requirements of the proficiency testing scheme which require departure from this principle)

3

4.6 Operation of proficiency schemes

- b) details of factors which could influence the testing or calibration of the proficiency test items, e.g.

- the nature of the proficiency test items,
- conditions of storage,
- whether the proficiency scheme is limited to the selected test methods, and the timing of the testing or measurement

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4.6 Operation of proficiency schemes

c) detailed procedure for preparing or conditioning, or both preparing an items before conducting the tests or calibrations

d) any appropriate instructions on handling the proficiency test items, including any safety requirements

e) any specific environmental conditions for the participant to conduct tests or calibrations, or both, and, if relevant, any requirement for the participants to report relevant environmental conditions during the time of the measurement

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4.6 Operation of proficiency schemes

f) specific and detailed instructions on the manner of recording and test or reporting measurement results and associated uncertainties

if the instructions include reporting of the uncertainty of the reported result or measurement, this shall include the coverage factor and, whenever practicable, the coverage probability

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4.6 Operation of proficiency schemes

- g) the latest date for the provider to receive the proficiency testing or Measurement results for analysis
- h) on the contact details of the proficiency testing provider for enquiries; and
- i) instructions on return of the proficiency test items, when applicable

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4.6 Operation of proficiency schemes

4.6.2.1 Test items identified and segregated

- that proficiency test items are appropriately identified and segregated
- items cannot become contaminated or degraded, from the time of preparation to their distribution to participants

4.6.2.2 Procedures for storage, dispatch and receipt

- provide secure storage areas or stock rooms, or both
 - prevent damage or deterioration of any proficiency test item
- between preparation distribution and appropriate procedures for authorizing despatch to, and receipt from, such areas shall be defined

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4.6 Operation of proficiency schemes

4.6.2.3 Periodic assessment of chemicals and materials

the condition of stored or stocked proficiency test items, chemicals and materials shall be, when appropriate assessed at specified intervals during their storage life in order to detect possible deterioration

4.6.2.4 Facilities for potentially hazardous test items

facilities, where potentially hazardous proficiency test items, chemicals and materials are used, shall be available to ensure their safe handling, decontamination and disposal

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4.6 Operation of proficiency schemes

4.6.3.1 Processes for control of packaging and labelling

control packaging and labelling processes to the extent necessary to ensure conformity with relevant national, regional, or international safety and transport requirements

4.6.3.2 Specific transportation requirements and monitoring

- specify relevant environmental conditions for the transport of proficiency test items
- where relevant, monitor the pertinent environmental conditions of the proficiency test item during transport and assess the impact of environmental influences on the proficiency test item

10

4.6 Operation of proficiency schemes

4.6.3.3 Specific transport instructions between participants

in proficiency testing schemes where:

- participants are required to transport the proficiency test items to other participants
- documented instructions for this transport shall be supplied

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4.6 Operation of proficiency schemes

4.6.3.4 Security and integrity of labels

- that labels are securely attached to the packaging of individual proficiency test items
- labels are designed to remain legible and intact throughout the proficiency testing round

4.6.3.5 Procedure for confirmation of delivery

- follow a procedure to enable the confirmation of delivery of the proficiency test items

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4.7 Data analysis and evaluation of proficiency testing scheme results

4.7.1 Data analysis and records

4.7.2 Evaluation of performance

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4.7 Data analysis and evaluation of proficiency testing scheme results

4.7.1 Data analysis and records

4.7.2 Evaluation of performance

4.8 Reports

4.9 Communication with participants

4.10 Confidentiality



4.7 Data analysis and evaluation of proficiency testing scheme results

4.7.1 Data analysis and records

4.7.1.1

All data processing equipment and software shall be validated in accordance with procedures before being brought into use. Computer system maintenance shall include a back-up process and system recovery plan. The results of such maintenance and operational checks shall be recorded.



4.7 Data analysis and evaluation of proficiency testing scheme results

4.7.1.2

Results received from participants shall be recorded and analysed by appropriate methods. Procedures shall be established and implemented to check the validity of data entry, data transfer, statistical analysis, and reporting.

4.7.1.3

Data analysis shall generate summary statistics and performance statistics, and associated information consistent with the statistical design of the proficiency testing scheme.

4.7 Data analysis and evaluation of proficiency testing scheme results



4.7.1.4

The influence of outliers on summary statistics shall be minimized by the use of **robust statistical methods** or appropriate tests to detect statistical outliers.

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.**

4.7 Data analysis and evaluation of proficiency testing scheme results



4.7.1.6

The proficiency testing provider shall have documented criteria and procedures to identify and manage proficiency test items that have been distributed and are subsequently found to be unsuitable for performance evaluation, e.g. because of inhomogeneity, instability, damage or contamination.

4.7 Data analysis and evaluation of proficiency testing scheme results



4.7.2 Evaluation of performance

4.7.2.1

- The proficiency testing provider shall use valid methods of evaluation which meet the purpose of the proficiency testing scheme. The methods shall be documented and include a description of the basis for the evaluation. The evaluation of performance shall not be subcontracted (see 5.5.2).

4.7 Data analysis and evaluation of proficiency testing scheme results



4.7.2.2

Where appropriate for the purpose of the proficiency testing scheme, the proficiency testing provider 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;

4.7 Data analysis and evaluation of proficiency testing scheme results



- c) variation between methods or procedures;
- d) possible sources of error (with reference to outliers) and suggestions for improving performance;
- e) advice and educational feedback to participants as part of the continual improvement procedures of participants;
- f) situations where unusual factors make evaluation of results and commentary on performance impossible;
- g) any other suggestions, recommendations or general comments; and
- h) conclusions.

Note It can be useful to provide individual summary sheets for participants periodically during or after completion of a particular proficiency testing scheme. These can include updated summaries of performance for individual participants over successive proficiency testing rounds of a continuous proficiency testing scheme. Such summaries can be further analysed and trends highlighted, if required.

4.8 Reports



4.8.1

Proficiency test reports shall be clear and comprehensive and include data covering the results of all participants, together with an indication of the performance of individual participants. The authorization of the final report shall not be subcontracted (see 5.5.2).

Note Where all original data cannot be reported to participants, a summary of the results, e.g. in tabulated or graphical form, can be supplied.

4.8 Reports



4.8.2

Reports shall include the following, unless it is not applicable or the proficiency testing provider has valid reasons for not doing so:

4.8 Reports



4.8.2

- a) the name and contact details for the proficiency testing provider;
- b) the name and contact details for the coordinator;
- c) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the report;
- d) an indication of which activities are subcontracted by the proficiency testing provider;
- e) the date of issue and status (e.g. preliminary, interim, or final) of the report;
- f) page numbers and a clear indication of the end of the report;
- g) a statement of the extent to which results are confidential;

4.8 Reports



4.8.2

- h) the report number and clear identification of the proficiency testing scheme;
- i) a clear description of the proficiency test items used, including necessary details of the proficiency test item's preparation and homogeneity and stability assessment;
- j) the participants' results;
- k) statistical data and summaries, including assigned values and range of acceptable results and graphical displays;
- l) procedures used to establish any assigned value;
- m) details of the metrological traceability and measurement uncertainty of any assigned value;
- n) procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation;

4.8 Reports



4.8.2

- o) assigned values and summary statistics for test methods/procedures used by each group of participants (if different methods are used by different groups of participants);
- p) comments on participants' performance by the proficiency testing provider and technical advisers;
- q) information about the design and implementation of the proficiency testing scheme;
- r) procedures used to statistically analyse the data;
- s) advice on the interpretation of the statistical analysis; and
- t) comments or recommendations, based on the outcomes of the proficiency testing round.

4.8 Reports



4.8.3

Reports shall be made available to participants within planned timescales. In sequential proficiency testing schemes, e.g. where the turn-around time may be very long, and in schemes involving perishable materials, preliminary or anticipated results may be provided before final results are disclosed.

4.8.4

The proficiency testing provider shall have a policy for the use of reports by individuals and organizations.

4.8 Reports



4.8.5

When it is necessary to issue a new or amended report for a proficiency testing scheme, this shall include the following:

- a) a unique identification;
- b) a reference to the original report that it replaces or amends; and
- c) a statement concerning the reason for the amendment or re-issue.

4.9 Communication with participants



4.9.1

The proficiency testing provider shall make detailed information available about the proficiency testing scheme. This shall include:

- a) relevant details of the scope of the proficiency testing scheme;
- b) any fees for participation;
- c) documented eligibility criteria for participation;
- d) confidentiality arrangements; and
- e) details of how to apply.

4.9 Communication with participants



4.9.2

Participants shall be advised promptly by the proficiency testing provider of any changes in proficiency testing scheme design or operation.

4.9.3

There shall be documented procedures for enabling participants to appeal against the evaluation of their performance in a proficiency testing scheme. The availability of this process shall be communicated to proficiency testing scheme participants.

4.9 Communication with participants



4.9.4

Relevant records of communications with participants shall be maintained and retained, as appropriate.

4.9.5

If the proficiency testing provider issues statements of participation or performance, they shall contain sufficient information to not be misleading.

4.10 Confidentiality



4.10.1

The identity of participants in a proficiency testing scheme shall be confidential and known only to persons involved in the operation of the proficiency testing scheme, unless the participant waives confidentiality.

4.10.2

All information supplied by a participant to the proficiency testing provider shall be treated as confidential.

Note Participants can elect to waive confidentiality within the proficiency testing scheme for the purpose of discussion and mutual assistance, e.g. to improve performance. Confidentiality can also be waived by the participant for regulatory or recognition purposes. In most instances, the proficiency testing results can be provided to the relevant authority by the participants themselves.

4.10 Confidentiality



4.10.3

When an interested party requires the proficiency testing results to be directly provided by the proficiency testing provider, the participants shall be made aware of the arrangement in advance of participation.

4.10.4

In exceptional circumstances, when a regulatory authority requires proficiency testing results to be directly provided to the authority by the proficiency testing provider, the affected participants shall be notified of this action in writing.

Annex A(informative)

Types of proficiency testing schemes

A.1 General

*Three basic types of laboratory examinations:
quantitative, qualitative and interpretive.*

A.2 Sequential participation schemes

A.3 Simultaneous participation schemes

A.3.1 General, randomly selected sub-samples distributed simultaneously to participants

A.3.2 Split-level designs

A.3.3 Split-sample testing schemes

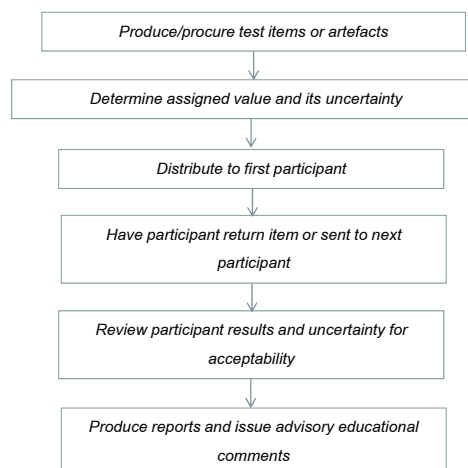
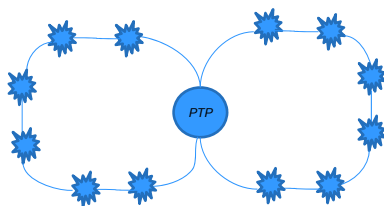
A.3.4 Partial-process schemes

Types of proficiency testing schemes (Annex A)



1. Sequential participation schemes
2. Simultaneous participation schemes
3. Split-level designs
4. Split-sample testing schemes
5. Partial-process schemes
6. External quality assessment (EQA) programmes

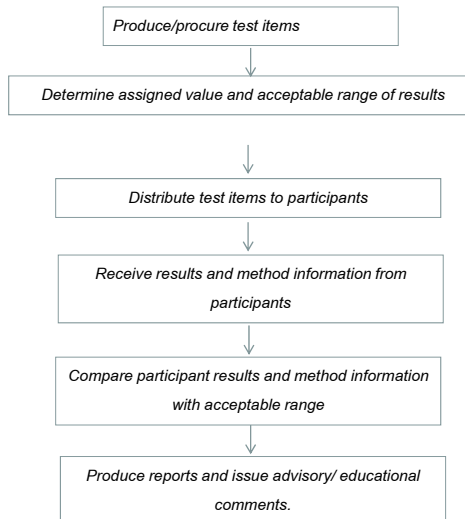
Sequential participation schemes (Model 1)



Simultaneous participation scheme (Model 2)



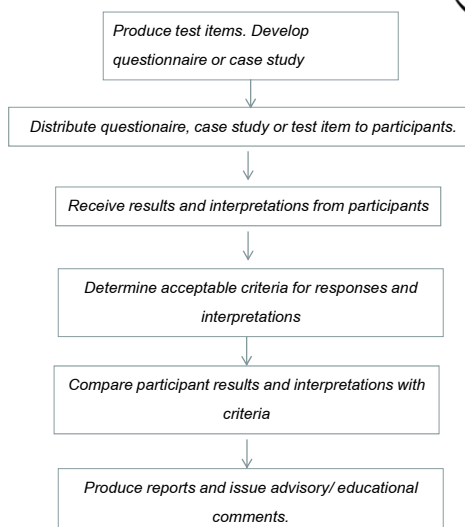
Usually involve randomly selected sub-samples from a source of material being distributed simultaneously to participants for concurrent testing.



Interpretive scheme (Model 3)



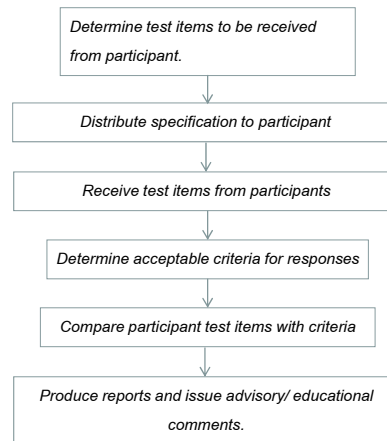
In interpretive tests, the “proficiency testing item” is a test result (e.g. a descriptive morphology statement), a set of data (e.g. to determine a calibration line) or other set of information (e.g. a case study), concerning an interpretative feature of the participant’s competence.



Sample review scheme (Model 4)



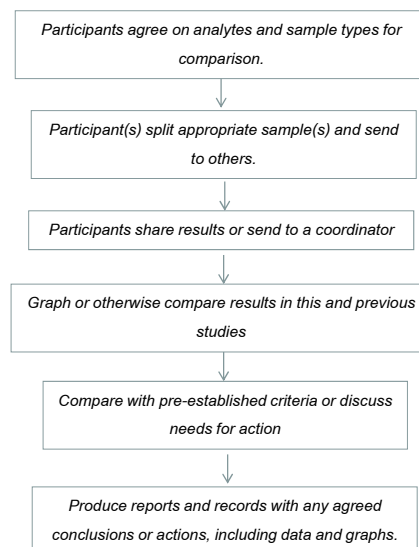
In “sample review” scheme, participants may be required to provide the “proficiency test items” to the EQA provider. This may take the form of a processed specimen or sample (e.g. stained slide or fixed tissue), laboratory data (e.g. test results, laboratory reports or quality assurance/ control records) or documentation (e.g. procedures or method verification criteria).



Split sample scheme (Model 5)



One special type of proficiency testing design that is often used by participants’ customers and some regulatory bodies is the “split-sample” design.



Annex A(informative)

Types of proficiency testing schemes

A.4 External quality assessment (EQA) programmes

- complete path of workflow of the laboratory, and not just the testing processes.*
- continuous schemes that include long term follow-up of laboratory performance.*
- education to participants and promote quality improvement*
- advisory and educational comments*

Annex B(informative)

Statistical methods for proficiency testing

B.1 General:Proficiency test results can appear in many forms, spanning a wide range of data types and underlying statistical distributions

B.2 Determination of the assigned value and its uncertainty

B.3 Calculation of performance statistics

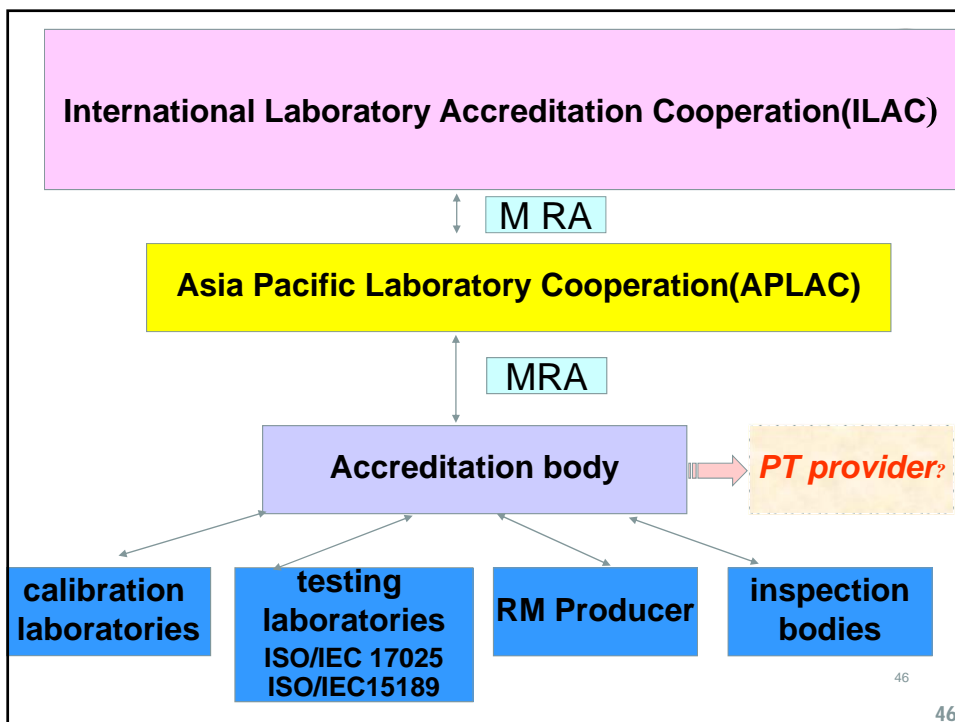
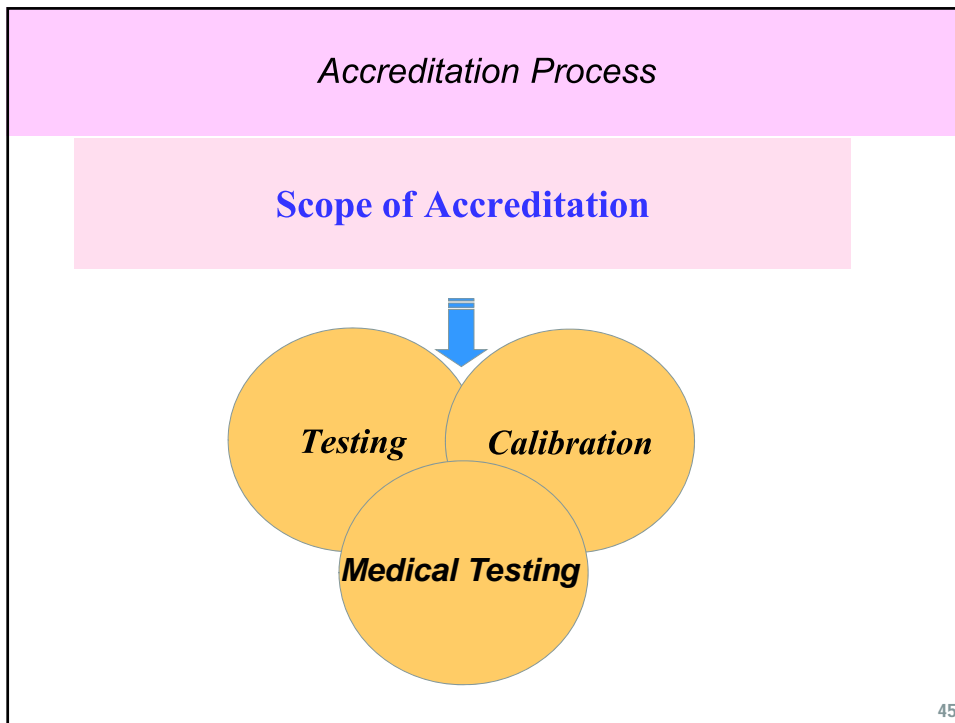
B.3.1 Performance for quantitative results

B.3.2 Performance for qualitative and semi-quantitative results

B.3.3 Combined performance scores

<i>Annex B(informative)</i> <i>Statistical methods for proficiency testing</i>
<i>B.4 Evaluation of performance</i>
<i>B.4.1 Initial performance</i>
<i>B.4.2 Monitoring performance over time</i>
<i>B.5 Demonstration of proficiency test item homogeneity and stability</i>

<i>Annex C(informative)</i> <i>Selection and use of proficiency testing</i>
<i>C.1 General</i>
<i>Selection and use of proficiency testing schemes by participants and other interested parties.</i>
<i>Promote the harmonized use of proficiency testing schemes by interested parties</i>
<i>C.2 Selection of proficiency testing schemes</i>
<i>C.3 Policies on participation in proficiency testing schemes</i>
<i>C.4 Use of proficiency testing by participants</i>
<i>C.5 Use of results by interested parties</i>
<i>C.6 Use of proficiency testing by regulatory bodies</i>



Accreditation process

- **Lead Assessor**
 - key contact person
 - document review
 - assessment preparation
 - manages assessment process
 - responsible for findings
- **Technical Assessor**
 - provides technical and
 - Statistical support

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Accreditation process



- **Application**
Application form/Quality Manual/Quality procedure/Work Instruction/final report of PT Scheme
- **Documentation review**
- **pre-assessment visit is an option**
- **On-site assessment: witnessing**
 1. sample preparation
 2. packaging, labelling and distribution
 3. competent testing lab : homogeneity and stability
- **Clearance of Nonconformities: 3 months**
- **Suggest the scope of accreditation**

Accreditation process



- **Accreditation decision**
 1. **Technical sub Committee**
 2. **Laboratory Accreditation Committee**
 3. **Granting of Accreditation**
 4. **Surveillance once every year**
 4. **Reassessment every 3 years**

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