

ISO/IEC 17043- 2010 TECHNICAL REQUIREMENTS – PART 1



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ISO/IEC 17043 Requirements 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 schemes results
- 4.8 Reports
- 4.9 Communication with participants
- 4.10 Confidentiality

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4.1 General

- ☐ **Competence to conduct ILC's**
- ☐ **Access to expertise relating to the particular PT items**
- ☐ **PT Provider / Subcontractor to have Competence in the measurements of properties being determined**
- ☐ **Measurement: competence CAN BE demonstrated by ISO/IEC 17025 or ISO 15189 accreditation**
- ☐ **Production of PT items: competence demonstrated by ISO 17034**

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4.2 Personnel

- Have competent **Managers and technical personnel**
- Duties to be performed by these personnel with the necessary **authority, resources and competence**
- **Minimum levels of qualification and experience for key positions**
- The PT provider must ensure the **qualifications are met**

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4.2 Personnel

- **Employed by the PT provider or under contract.**
- Personnel **under contract** shall be competent, supervised and shall work in accordance with the management system.
- **Advisory or Steering Group on adhoc basis – O.K provided formal agreement or TERMS OF REFERENCE of Advisory group**

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4.2 Personnel

Authorize specific personnel to:

- ✓ Selection of PT items
- ✓ Plan PT Scheme !
- ✓ Perform particular type of sampling
- ✓ Operate specific equipment
- ✓ Conduct measurements – Homogeneity, Stability or Assigned values
- ✓ Prepare, handle & distribute PT items
- ✓ Operate data processing systems
- ✓ Conduct statistical analysis
- ✓ Evaluate performance of participants !!
- ✓ Give opinions & interpretations
- ✓ Authorize issue of PT reports !!!

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4.2 Personnel

- ✓ **Records** (authorizations, competence, qualifications, training, experience) of all **technical personnel** shall be **maintained** up-to-date and available.
- ✓ The **date** on which the competence for specific tasks was **assessed and confirmed** shall be included.
- ✓ PT provider must ensure that staff receive the necessary **training** for **all activities** that affect the quality of the PT schemes
- ✓ The **effectiveness of training** is to be **evaluated**.

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4.2 Personnel

- ✓ **PT provider** must **formulate training objectives** for each staff member
- ✓ **PT provider** must **identify training needs** and **provide it** (itself or through third parties)
- ✓ The **training program** must also take into account **anticipated needs**
- ✓ It is **advisable** to consider **periodic retraining of staff**.

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4.3 Equipment, accommodation and environment

PT shall ensure there is appropriate accommodation (facilities and equipment) for the operation of PT schemes. This includes:

- ❖ **Manufacturing**
- ❖ **Handling**
- ❖ **Calibration & testing**
- ❖ **Storage**
- ❖ **Despatch**
- ❖ **Data processing**
- ❖ **Communications**
- ❖ **Retrieval of materials**
- ❖ **Records**

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4.3 Equipment, accommodation and environment

- ❑ PT provider shall ensure that **environmental conditions** don't compromise the operation of PT schemes
- ❑ Particular care is to be taken when **operations are outside the permanent facility or done by subcontractors**
- ❑ **Access and use to areas affecting the quality of PT schemes shall be controlled**
- ❑ **The extent of the control depends on particular circumstances.**

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4.3 Equipment, accommodation and environment

- ❑ **Conditions that affect the operation of PT shall be identified and documented**
- ❑ Specific **attention** is to be made concerning the **storage of PT item and any testing** or calibration carried out
- ❑ The **conditions** are to be controlled, **monitored and recorded**
- ❑ **If the conditions may jeopardize the quality, the activity is to be stopped.**

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4.3 Equipment, accommodation and environment

- ❑ **Actions are taken to prevent cross-contamination (e.g. clear separation of activities)** [STORAGE OF PT ITEMS WITH OTHER CHEMICALS – NOT O.K.]
- ❑ PT Providers shall ensure that **EQUIPMENTS & the METHODS** used (for confirming content, homogeneity, and stability of PT items) are appropriately **validated**
- ❑ PT Providers shall ensure that the **equipments** used are appropriately **maintained**

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4.4 Design of Proficiency Testing Schemes

4.4.1- PLANNING

- ❑ The PT provider shall **identify and plan** the processes that directly affect the quality of PT schemes.
- ❑ The PT provider shall ensure that the **processes are carried out in accordance with prescribed procedures**
- ❑ **Planning cannot be subcontracted!**
- ❑ **Stakeholders, advisors, expert, steering groups** may however be involved in the planning.

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4.4 Design of Proficiency Testing Schemes

4.4.1- PLANNING

- ❑ **A documented plan must be made before the PT Scheme starts**
- ❑ The **objectives, the purpose and the basic design** are included in the plan
- ❑ A lot of **specific information** is to be included in the plan
- ❑ **If any information is not included, the PT provider must justify why**

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4.4 Design of Proficiency Testing Schemes

4.4.1- PLANNING

Information to be included in plan:

- a) Name and address of the **PT Provider**;
- b) Name, address and affiliation of **Coordinator and other personnel** involved in the design & operation of the PT Scheme;
- c) **Activities to be subcontracted** and the names and addresses of subcontractors involved in the operation of the PT Scheme;

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4.4 Design of Proficiency Testing Schemes 4.4.1- PLANNING

Information to be included in plan:

- d) **Criteria to be met for participation;**
- e) **Number and type of expected participants in the proficiency testing scheme;**
- f) **Selection of the measurand(s) or characteristic(s) of interest, including information on what the participants are to identify, measure, or test for in the PT;**
- g) **Description of the range of values or characteristics, or both, to be expected for the PT items.**

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4.4 Design of Proficiency Testing Schemes 4.4.1- PLANNING

Information to be included in plan:

- h) **Potential major sources of errors involved in the area of PT offered;**
- i) **Requirements for the production, quality control, storage & distribution of PT items;**
- 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; [REFER NABL 181]**

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4.4 Design of Proficiency Testing Schemes 4.4.1- PLANNING

Information to be included in plan:

- k) **Description of the information which is to be supplied to participants & time schedule for the various phases of PT Scheme;**
- l) **For continuous proficiency testing schemes, the frequency or dates upon which PT items are to be distributed to participants, the deadlines for the return of results by the participants and, where appropriate, the dates on which testing or measurement is to be carried out by participants;**

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4.4 Design of Proficiency Testing Schemes

4.4.1- PLANNING

Information to be included in plan:

- m) 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 PT items** and, where applicable, to determine their **biological viability**;
- o) Preparation of any **standardized reporting formats** to be used by participants;

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4.4 Design of Proficiency Testing Schemes

4.4.1- PLANNING

Information to be included in plan:

- p) Detailed description of the **statistical analysis to be used**;
- q) The **origin, metrological traceability and measurement uncertainty** of any **assigned values**;
- r) **Criteria for the evaluation** of performance of participants;
- s) Description of the **data, interim reports or information to be returned to participants**;

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4.4 Design of Proficiency Testing Schemes

4.4.1- PLANNING

Information to be included in plan:

- t) Description of the **extent to which participant results, and conclusions** that will be based on outcome of the PT scheme, are to be **made public**;
- u) Actions to be taken in the case of **lost or damaged PT items**. –
**** Typical example of a PT Plan ****

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4.4 Design of Proficiency Testing Schemes 4.4.1- PLANNING

- ☐ PT Provider shall have **access to the necessary expertise in testing, calibration, sampling, inspection and STATISTICS.**
- ☐ The PT Provider can have **in-house expertise** or alternatively, through an **Advisory group.**

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4.4 Design of Proficiency Testing Schemes 4.4.1- PLANNING –

USE OF ADVISORY GROUP

Expertise is needed for specific matters, such as:

- a) **Planning requirements ;**
- b) **Identification & resolution of any difficulties** expected in the **preparation & maintenance of homogeneous PT items**, or in the provision of a **stable assigned value** for PT item;
- c) **Preparation of detailed instructions** for use by **participants;**
- d) **Comments on any technical difficulties** or other remarks **raised by participants** in previous proficiency testing rounds;

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4.4 Design of Proficiency Testing Schemes 4.4.1- PLANNING

Expertise is needed for specific matters, such as:

- e) **Provision of advice in evaluating the performance of participants;**
- f) **Comments on the results and performance of participants – as a whole and, groups of participants or individual participants;**
- g) **Provision of advice for participants (within limits of confidentiality), individually or within the report;**
- h) **Responding to feedback** from participants;
- i) **Planning or participating in technical meetings with participants.**

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