

ISO/IEC 17043- 2010 TECHNICAL REQUIREMENTS – PART 1



S.SUBRAMANIAN

Guides and standards related to Proficiency testing

- ✓ **ISO/IEC Guide 43-1:1997** Proficiency testing by interlaboratory comparisons — Part 1: Development and operation of proficiency testing schemes
- ✓ **ISO/IEC Guide 43-2:1997** Proficiency testing by interlaboratory comparisons - Part 2 Selection and use of proficiency testing schemes by laboratory accreditation bodies
- ✓ **ILAC-G13:2007** ILAC Guidelines for the Competence of Providers of Proficiency Testing Schemes
- ✓ **ISO/IEC 17043:2010 Conformity Assessment – General Requirements for Proficiency Testing**

3/17/2021

PT TRAINING
S.SUBRAMANIAN

2

Guides and standards related to Proficiency testing

- **ISO 13528:2005** Statistical Methods for use in Proficiency Testing by Interlaboratory comparisons
- **ISO 5725-1 to -6** Accuracy (trueness and precision) of measurement methods and results
- **IUPAC Technical Report 1/2006** The International Harmonized Protocol for the Proficiency Testing of Analytical Chemistry Laboratories
- **ISO 13528:2015 Statistical Methods for use in Proficiency Testing by Interlaboratory comparisons**

3/17/2021

PT TRAINING
S.SUBRAMANIAN

3

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

3/17/2021

PT TRAINING
S.SUBRAMANIAN

4

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

3/17/2021

PT TRAINING
S.SUBRAMANIAN

5

4.2 Personnel

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

4.2.2 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.

3/17/2021

PT TRAINING
S.SUBRAMANIAN

6

4.2 Personnel

4.2.3 The proficiency testing provider shall use personnel who are either employed by, or under contract to it. Where **contracted and additional technical** and key support personnel are used, the proficiency testing provider shall ensure that such personnel are **supervised** and **competent** and that they **work in accordance with the management system**

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

3/17/2021

PT TRAINING
S.SUBRAMANIAN

7

4.2 Personnel

4.2.4 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 !!!**

3/17/2021

PT TRAINING
S.SUBRAMANIAN

8

4.2 Personnel

4.2.5 The proficiency testing provider shall maintain **up-to-date records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience** of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which competence to perform their assigned tasks was assessed and confirmed.

3/17/2021

PT TRAINING
S.SUBRAMANIAN

9

4.2 Personnel

4.2.6 The proficiency testing provider shall formulate the **objectives with respect to the education, training, and skills** for each staff member involved with the operation of the proficiency testing scheme. The proficiency testing provider shall have a **policy and procedures** for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated needs of the proficiency testing provider.

NOTE : It is advisable to consider the need to retrain staff periodically. Staff training policies can take account of technological change, the need to demonstrate ongoing competence and aim at continual skills upgrading.

3/17/2021

PT TRAINING
S.SUBRAMANIAN

10

4.2 Personnel

4.2.7 The proficiency testing provider shall ensure that staff receive the necessary training to ensure competent performance of measurements, operation of equipment and any other activities which affect the quality of the proficiency testing scheme. **The effectiveness of training activities shall be evaluated.**

3/17/2021

PT TRAINING
S.SUBRAMANIAN

11

4.3 Equipment, accommodation and environment

4.3.1 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

3/17/2021

PT TRAINING
S.SUBRAMANIAN

12

4.3 Equipment, accommodation and environment

4.3.2 The proficiency testing provider shall ensure that the **environmental conditions** do not compromise the proficiency testing scheme or the required quality of operations. Particular care shall be taken when operations are undertaken at sites away from the proficiency testing provider's permanent facilities or are undertaken by subcontractors. The **technical requirements for accommodation and environmental conditions** that can affect the proficiency testing shall be documented

3/17/2021

PT TRAINING
S.SUBRAMANIAN

13

4.3 Equipment, accommodation and environment

4.3.3 Access to and use of areas affecting the quality of proficiency testing schemes shall be controlled. The proficiency testing provider shall determine the **extent of control** based on its particular circumstances.

3/17/2021

PT TRAINING
S.SUBRAMANIAN

14

4.3 Equipment, accommodation and environment

4.3.4 The proficiency testing provider shall **identify environmental conditions** that can **significantly influence the quality of the proficiency test items** and any **testing and calibration** carried out, including conditions that are required by relevant specifications and measurement procedures. The proficiency testing provider shall **control and monitor** these conditions, and shall **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.

NOTE: Conditions can include, for example, biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibrations levels, as appropriate to the technical activities concerned.

3/17/2021

PT TRAINING
S.SUBRAMANIAN

15

4.3 Equipment, accommodation and environment

4.3.5 There shall be **effective separation** between neighboring areas in which there are incompatible activities. **Action shall be taken to prevent cross-contamination.**

4.3.6 Proficiency testing providers shall ensure that **performance characteristics of laboratory methods and equipment** used to confirm the content, homogeneity and stability of proficiency testing items are appropriately **validated and maintained.**

3/17/2021

PT TRAINING
S.SUBRAMANIAN

16

4.4 Design of Proficiency Testing Schemes 4.4.1- PLANNING

4.4.1.1 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**

4.4.1.2 The proficiency testing provider **shall not subcontract the planning** of the proficiency testing scheme (see 5.5.2)

NOTE: The proficiency testing provider can utilize advice or assistance from any advisors, experts or steering group (see 4.4.1.4).

3/17/2021

PT TRAINING
S.SUBRAMANIAN

17

4.4 Design of Proficiency Testing Schemes 4.4.1- PLANNING

4.4.1.3 The proficiency testing provider shall **document a plan** before commencement of the proficiency testing scheme that addresses the **objectives, purpose and basic design** of the proficiency testing scheme, including the following information and, where appropriate, reasons for its selection or exclusion:

3/17/2021

PT TRAINING
S.SUBRAMANIAN

18

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;

3/17/2021

PT TRAINING
S.SUBRAMANIAN

19

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.

3/17/2021

PT TRAINING
S.SUBRAMANIAN

20

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]

3/17/2021

PT TRAINING
S.SUBRAMANIAN

21

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;

3/17/2021

PT TRAINING
S.SUBRAMANIAN

22

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;

3/17/2021

PT TRAINING
S.SUBRAMANIAN

23

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;

3/17/2021

PT TRAINING
S.SUBRAMANIAN

24

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 ****

3/17/2021

PT TRAINING
S.SUBRAMANIAN

25

4.4 Design of Proficiency Testing Schemes 4.4.1- PLANNING

4.4.1.4 The proficiency testing provider shall have access to the necessary technical expertise and experience in the relevant field of testing, calibration, sampling or inspection, as well as statistics. This may be achieved, if necessary, by establishing an advisory group (named as appropriate).

3/17/2021

PT TRAINING
S.SUBRAMANIAN

26

4.4 Design of Proficiency Testing Schemes 4.4.1- PLANNING –

4.4.1.5 Technical expertise shall be used, as appropriate, to determine matters such as the following:

- 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;

3/17/2021

PT TRAINING
S.SUBRAMANIAN

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.**

3/17/2021

PT TRAINING
S.SUBRAMANIAN

28
