

ISO/IEC 17043- 2010 TECHNICAL REQUIREMENTS – PART 2



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4.4.2 Preparation of proficiency test items

4.4.2.1 The PT provider shall establish and implement **PROCEDURES** to ensure that the proficiency test items are prepared in accordance with the plan described in 4.4.1

- Sufficient number of PT items must be prepared
- To replace any PT items lost or damaged during distribution
- Use as **TRAINING AIDS** for participants or as **REFERENCE MATERIAL**

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2

4.4.2 Preparation of proficiency test items

4.4.2.2 The PT provider shall establish and implement **PROCEDURES** to ensure appropriate acquisition, collection, handling, storage and, where required, disposal of all PT items

The PT Provider shall ensure that PT items are obtained in accordance with relevant regulatory and ethical requirements.

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3

4.4.2 Preparation of proficiency test items

4.4.2.3 PT items should match in terms of matrix, measurands and concentrations, as closely as practicable, to the type of items or materials encountered in routine testing or calibration

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.

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4

MATERIAL SELECTION for preparing PT items

When PT items are prepared from different constituents ensure that

- ❖ There is no adverse interaction between the constituents that may change the property values being determined
- ❖ Behaviour of the prepared PT items are similar to routinely tested samples (not less easily extractable, not loosely bonded)
- ❖ Property values of PT items not affected by containers of PT items – due to absorption or leaching

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5

ASSESSMENT OF MATERIALS used for preparation of PT items

- ❖ Which material is suitable ?
- ❖ Possible suppliers ?
- ❖ Origin of matrix ?
- ❖ Is the PT item homogeneous ?
- ❖ Is the PT item stable ?
- ❖ Which property values of interest ?

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6

4.4.5 ASSIGNED VALUE

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.

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

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7

4.4.5 ASSIGNED VALUE

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.

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8

4.4.5 ASSIGNED VALUE

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.

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9

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.

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10

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.

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11

4.6 OPERATION OF PT SCHEMES - 4.6.1 Instructions for participants

4.6.1.1 The proficiency testing provider shall give participants sufficient prior notice before sending proficiency test items, providing 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.

4.6.1.2 The proficiency testing provider shall give detailed documented instructions to all participants. Instructions to participants shall include the following:

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12

4.6 OPERATION OF PT SCHEMES -

4.6.1 Instructions for participants

The instruction 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 – **CENSORED RESULTS**);
- 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 testing scheme is limited to selected test methods, and the timing of the testing or measurement;

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13

4.6 OPERATION OF PT SCHEMES -

4.6.1 Instructions for participants

The instruction to participants shall include:

- c) detailed procedure for preparing or conditioning, or both preparing and conditioning, of the proficiency test items before conducting the tests or calibrations;
- d) any appropriate instructions on handling the proficiency test items, including any safety requirements;

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14

4.6 OPERATION OF PT SCHEMES -

4.6.1 Instructions for participants

The instruction to participants shall include:

- 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;
- f) specific and detailed instructions on the manner of recording and reporting test or 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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15

4.6 OPERATION OF PT SCHEMES -

4.6.1 Instructions for participants

The instruction to participants shall include:

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

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16

4.6.2 Proficiency test items handling and storage

4.6.2.1 The PT provider shall ensure that the PT items are appropriately identified and segregated and cannot become contaminated or degraded, from the time of preparation to their distribution to participants.

4.6.2.2 The PT provider shall provide secure storage areas or stock rooms, or both, which prevent damage or deterioration of any PT item between preparation and distribution. Appropriate procedures for authorizing despatch to, and receipt from, such areas shall be defined.

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17

4.6.2 Proficiency test items handling and storage

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

4.6.2.4 Where potentially hazardous PT items, chemicals and materials are used, facilities shall be available to ensure their safe handling, decontamination and disposal

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18

4.6.3 Packaging, labelling and distribution of PT items

4.6.3.1 The proficiency testing provider shall control **packaging and labelling processes** to the extent necessary to ensure conformity with relevant national, regional, or international **safety and transport requirements**.

NOTE: The proper distribution of proficiency test items can present severe problems for some types of material, e.g. those which require uninterrupted storage in cold conditions or which should not be exposed to X-rays, shock or vibration. Most types of chemical materials would benefit from airtight packaging to avoid contamination by atmospheric contaminants, e.g. fuel vapours or engine exhaust gases which can be encountered during transport

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19

4.6.3 Packaging, labelling and distribution of PT items

4.6.3.2 The proficiency testing provider shall specify **relevant environmental conditions** for the **transport** of proficiency test items. Where relevant, the proficiency testing provider shall monitor the pertinent environmental conditions of the proficiency test item during transport and assess the impact of environmental influences on the proficiency test item.

4.6.3.3 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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20

4.6.3 Packaging, labelling and distribution of PT items

4.6.3.4 The proficiency testing provider shall ensure that **labels are securely attached** to the packaging of individual proficiency test items and are designed to remain **legible and intact** throughout the proficiency testing round.

4.6.3.5 The proficiency testing provider shall follow a procedure to enable the **confirmation of delivery of the proficiency test items**.

3/17/2021
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21
