

ISO/IEC 17043- 2010 TECHNICAL REQUIREMENTS – Part 3



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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.

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

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PT reports shall include :

- a) Name and contact details of **PT Provider**;
- b) Name and contact details of **PT Coordinator**;
- c) 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) **Date of issue** and status (e.g. preliminary, interim, or final) of the report;

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PT reports shall include :

- f) **Page numbers** and a clear indication of the end of the report;
- g) A statement of the extent to which **results are confidential**;
- h) **Report number** and clear identification of the PT 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**;

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PT reports shall include :

- j) **Participants' results**;
- k) **Statistical data and summaries**, including assigned values and range of acceptable results and graphical displays;
- l) **Procedures used to establish Assigned value**;
- m) Details of the **metrological traceability and measurement uncertainty** of assigned value;
- n) **Procedures used to establish the Standard Deviation for Proficiency Assessment**, or other criteria for evaluation;

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PT reports shall include :

- 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 PT Provider and technical advisers;
- q) Information about the **design and implementation** of the proficiency testing scheme;

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PT reports shall include :

- r) Procedures used to statistically analyze 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.

NOTE: For continuous proficiency testing schemes, it can be sufficient to have simpler reports, such that many of the elements in this clause could be excluded from routine reports, but included in proficiency testing scheme protocols or in periodic summary reports that are available to participants

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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.

NOTE: This allows for early investigation of possible error.

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

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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) Unique identification;
- b) Reference to the original report that it replaces or amends; and
- c) Statement concerning the reason for the amendment or re-issue.

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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 PT Scheme;
- b) Any **fees payable** for participation;
- c) Documented **eligibility criteria** for participation;
- d) **Confidentiality arrangements**; and
- e) Details of **how to apply**.

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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.

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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.

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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 purposes 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

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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.

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