



PT1

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Accreditation of Providers of Proficiency Testing Schemes for Laboratory Testing

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CHANGES SINCE LAST EDITION

1 INTRODUCTION

- 1.1.1 The general requirements for accreditation are laid down in ISO/IEC Guide 43-1:1997 *Proficiency Testing by Interlaboratory comparisons – Part 1: Development and operation of proficiency testing schemes*. In addition the guidance document, ILAC–G13: 2000 *Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes* expands the interpretation of the requirements of ISO/IEC Guide 43. UKAS uses ILAC G13 as the basis for the assessment of Proficiency Testing Providers. ISO/IEC Guide 43 can apply to all types of proficiency testing; the requirements need to be interpreted according to the specific technical area being assessed.
- 1.1.2 This UKAS publication provides general guidance on the application of ISO/IEC Guide 43-1 and ILAC-G13 in the assessment of Proficiency Testing Scheme Providers. It has been produced by UKAS with the assistance of the UKAS Steering Group for Proficiency Testing Schemes. It provides amplification of those requirements in ILAC G13 that need interpretation when applied in assessing the providers of Proficiency Testing Schemes. It does not cover all of the requirements in that document, but Proficiency Testing Scheme Providers are reminded that they need to comply with all of the requirements ISO/IEC Guide 43-1 and ILAC-G13 to achieve accreditation status.

1.2 Definitions

- 1.2.1 **Provider** The organisation or company which undertakes the design and conduct of a proficiency testing scheme.
- 1.2.2 **Collaborator** An organisation or person that is contracted to undertake specific activities relating to the provision of the scheme for a proficiency testing scheme provider.
- 1.2.3 **Co-ordinator** An organisation or person with responsibility for co-ordinating all of the activities involved in the operation of a proficiency testing scheme.
- 1.2.4 **Proficiency Testing (PT) Scheme** A system to determine laboratory performance for particular fields of testing that is based on accepted prescribed methods
- 1.2.5 **Proficiency Testing (PT) Round** A single despatch or distribution of test materials to participants of a specified proficiency testing scheme.

2 MANAGEMENT SYSTEM REQUIREMENTS

2.2 Organisation & Management

Sub-Clause 2.2.2. (h)

Where PT Schemes are provided, within the same organisation as a laboratory testing operation and there is a common Quality Manager, the Quality Manager's responsibilities must be clearly defined and differentiated with respect to both the laboratory and PT activities (Testing & PT). This is particularly important if the testing laboratory is also a participant in the PT schemes provided.

2.3 Document Control

Sub-Clause 2.3.1

The Provider must ensure that document control procedures cover the following, where they are part of the scheme:

- Applicant packs
- Instructions to Participants
- Final reports
- Software

2.4 Request, Tender & Contract review

Sub-Clause 2.4

Contract review must be undertaken, and is particularly important where a client is:

- An organisation who wishes to have a PT Scheme created for some specific purpose
- A laboratory that wishes to participate in one or more rounds of an existing scheme

2.5 Use of Collaborators

Sub- Clause 2.5

Collaborators must be demonstrably competent to perform the specified tasks. It is the responsibility of the provider to assure themselves of the collaborator competence by either their own assessment, or the provision by the collaborators of some authorised verification of their work.

Records of assessment/ verification must be kept on file for each collaborator, for review as part of the accreditation assessment for the Provider.

The proficiency testing assessment may, but will not necessarily, involve a visit to a collaborators premises.

2.7 Client Feedback

Sub-Clause 2.7

Feedback records shall include both complaints and positive feedback responses from participants. Technical feedback highlighted by the participants shall be recorded, along with technical enquiries.

Feedback from overseas clients must also be collated and consideration given to collecting /receiving this information from any agents that may be involved in the chain of delivery for the PT round.

2.11 Records

Sub-Clause 2.11.3

Records of all technical data pertinent to each PT round must be retained. These should include:

- Instructions to participants
- Participants original results (raw data responses)
- Collated data for statistical analysis
- Final summary reports

2.12 Internal Audit

Sub-Clause 2.12

Providers shall carry out internal audits that cover all aspects of *ILAC-G13 and ISO/IEC Guide 43-1*, and must cover all activities within the scope. Internal auditors must be familiar with the requirements for Providers and where possible be independent from the activities being audited.

2.13 Management review

Sub-Clause 2.13

The management review must cover all aspects of *ILAC-G13 and ISO/IEC Guide 43-1*. Where a Provider is part of a larger organisation it may be most appropriate to hold a separate Management Review to cover the specific PT activities.

3 TECHNICAL REQUIREMENTS

3.1 Management, Staffing & Training

Sub-clause 3.1.1

Where a Provider involved in making measurements (e.g. testing/calibration), has accreditation for ISO/IEC 17025, for those measurements, this would normally be sufficient evidence for demonstration of competence.

Sub-clause 3.1.6

Where objective measures have been used to demonstrate staff competence, records of this shall be kept.

3.2 Collaborators

Sub-clause 3.2.4

Where collaborators are used, the evidence to demonstrate their competence should include where appropriate:

- details of their methods used
- results / reports of audits carried out by the provider on the collaborator
- accreditation / certification schedules of the collaborator

and in addition the provider shall maintain:

- a register of all collaborators used
- record of dialogue/meetings/arrangements/contracts as appropriate

3.3 Organisation & Design Logistics

Sub-clause 3.3.1.1

For existing schemes, i.e. those that have been in place and operational prior to assessment, it is not expected that a full plan would be documented. However for any schemes developed after assessment this requirement will apply.

It is possible that providers could undertake the planning exercise for existing schemes in retrospect, and hence formally review the way a scheme has been devised and implemented.

Sub-clause 3.3.1.3

The Provider should keep on file details of the competence held by members of the technical group. These records may include, for example:

- CV's
- Letters of nomination
- Current status in the technical field

Records of the technical group activities and any meetings it holds must be kept and should include

- Terms of reference
- Attendance records for meetings
- Minutes of meetings

3.3.2 Preparation of Test Items

Sub-clause 3.3.2.1

The procedures for planning the overall process must be sufficiently detailed to describe the operations involved.

3.3.3 Homogeneity

Sub-clause 3.3.3.1

The number of samples randomly selected from a batch of test materials must be justifiable in relation to the total volume/numbers of those test materials produced.

Sub-clause 3.3.3.2

Where homogeneity testing is undertaken at any time other than post packaging of the final form, the reasons for this departure must be justified and recorded

3.5 Conduct of Proficiency Testing Schemes

Sub-clause 3.5.1

All instructions to participants must be included in the document control system of the provider.

Packing, Labelling & Distribution

Sub-clause 3.5.3.1

Where Providers are issuing PT rounds to overseas participants, the packaging and process of distribution must demonstrate compliance with international safety & transport requirements.

Providers should have on file the current details of such international regulations for the countries of their overseas participants. These documents must be included into the provider's document control system.

3.6 Data analysis

Sub-clause 3.6.1.3

Where computer software is utilised this must be validated according to a documented procedure prior to being brought into use. Commercially available packages are generally accepted as pre-validated, but configured laboratory-bespoke software must be validated, and records kept of this validation. In addition, periodic checks on the continuing suitability of the software used may be appropriate.

Sub-clause 3.6.1.4

Data transfer checks must be in place to ensure correct data entry. These checks shall be recorded.

The Provider must undertake an appropriate level of data transfer checks. These must be sufficient to give confidence in the accuracy of the data.

3.7 Communication with participants

Sub-clause 3.7.1

The scheme protocol may often be used to define the operation of the scheme and as such is an important document for review. The protocol should include:

- scope of the scheme
- participant fees
- frequency of distributions
- statistical evaluations used for results analysis
- contact names / addresses of providers

Sub clause 3.7.2

Where changes to a scheme are planned a Provider may communicate these changes at the annual membership renewal of a participant. However, where changes are to be implemented sooner, and may affect current PT rounds, the details of that change must be communicated prior to the change being implemented.

Sub-clause 3.7.4

Evidence to demonstrate that participants are encouraged to provide feedback to providers on schemes could include:

- use of questionnaires
- user-group meetings

3.8 Confidentiality

Confidentiality of participants is often achieved by the use of “participant codes”, which may be different for each PT round.

3.9 Collusion

Control of collusion may be achieved by ensuring that

- PT round results are not issued until all participant responses have been received
- Not all participants receive exactly the same samples
- Maintaining participant anonymity